VERSION HISTORY

Formal Deliverable 6 – User-Centered Design (UCD) Process Document, will be updated to reflect changes that incorporate the Centers for Disease Control and Prevention and Prevention’s review and feedback, as well as any new requirements or changes to the business environment in which the project exists. The following table will track changes and updates to the document.

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1 INTRODUCTION

1.1 Project Overview

CNI Advantage, LLC (CNIADV) is conducting the Immunization-centric Electronic Health Record (EHR) Certification Process Development Project (referred to as both “the Project” and “Phase 3”) for the Centers for Disease Control and Prevention (CDC), National Center for Immunization and Respiratory Diseases (NCIRD).

This Project builds upon the work and deliverables completed during the Immunization-Centric EHR Certification Process Pilot Project (Phase 2) and EHR Certification Process Project (Phase 1). The Project will advance the integration of immunization-related capabilities within EHRs and other clinical software by supporting the publication, widespread dissemination, and implementation of immunization-related requirements, guidance, and test scripts developed during Phases 1 and 2.

By the end of Phase 3, and as reviewed and agreed upon by CDC on November 12, 2015, CNIADV seeks to achieve the following goals and desired outcomes:

1. Widespread awareness of the availability of immunization-related software requirements and related guidance and testing tools;
2. Operating a subcontracted independent body that is:
   a. Publishing immunization-related requirements for clinical software;
   b. Making testing tools publicly available;
   c. Developing additional methods for independently validating inclusion of requirements within software; and
   d. Gaining ongoing input from users related to their implementation of requirements and test methods, in order to facilitate improvement.
3. Clinical software companies are reviewing the requirements and using the testing tools.

CNIADV will achieve these goals and desired outcomes by conducting the following four activities, as shared with CDC on November 12, 2015:

1. Conduct a formal process to identify, select, and contract with an independent body that will carry out implementation activities to advance the integration of immunization-related capabilities within EHRs.
2. Collaborate with the subcontracted independent body to:
   a. Independently publish and widely disseminate immunization-related requirements, guidance, and test scripts for clinical software;
   b. Engage clinical software developers in using requirements, guidance, and test scripts to integrate immunization-related capabilities within their software;
   c. Develop and implement methods for gaining input from users as they implement and use the requirements, guidance, and test scripts; and
   d. Develop and implement a process for independently validating and communicating inclusion of immunization-related capabilities within clinical software.
3. Conduct evaluation of the immunization-related clinical software program.
4. Successfully and fully transfer knowledge and assets to an independent body upon completion of Phase 3.

This deliverable is based on the Usability Option, an added work component requested by CDC to provide guidance to software developers for evaluating usability for selected workflows. As seen in Exhibit 1, the work for the Usability Option is organized into six tasks, each of which includes a deliverable.

**Exhibit 1: Phase 3 Usability Option Project Deliverables**

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<th>Task</th>
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<th>Date</th>
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<td>03/28/2016</td>
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<td>3</td>
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<td>4</td>
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<tr>
<td>5</td>
<td>Learning from Mock Summative Test</td>
<td>8/19/2016</td>
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CNIADV developed several deliverables and work products during Phases 1 and 2 to support the implementation of a program to advance the integration of immunization-related capabilities within EHRs and other clinical software. Key outcomes of Phases 1 2 include the following, as outlined in Exhibit 2.

**Exhibit 2: Phase 1 and 2 Deliverables and Work Products**

<table>
<thead>
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<th>Phase 1 and 2 Outcomes</th>
<th>Description</th>
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<tr>
<td>1. Immunization-related requirements for EHRs and other clinical software</td>
<td>Forty-seven immunization-related software requirements, described within the context of eight general user workflows, which were informed by:</td>
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<td>• Interviews with more than 60 individuals representing clinicians and other immunization providers, IIS’, EHR and other clinical software developers, certification and testing bodies, and others in a position to provide incentives for adoption of such capabilities;</td>
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<td>• An online survey of stakeholders, including clinicians, EHR developers, and the IIS community;</td>
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<td>• Review by subject matter experts during two working sessions;</td>
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<td>• Review for inclusion in a subset of commercial EHR products conducted through a clinical software assessment; and</td>
</tr>
<tr>
<td></td>
<td>• Pilot testing with a subset of commercial EHR vendors.</td>
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<tr>
<td>2. Immunization-related software requirement guidance</td>
<td>Guidance for software developers and users regarding technical and operational aspects of implementing the immunization-related software requirements, which were informed by subject matter experts.</td>
</tr>
<tr>
<td>3. Immunization-related test scripts</td>
<td>Test scripts that support validation of inclusion of immunization-related requirements within software, informed by:</td>
</tr>
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<td></td>
<td>• Review by subject matter experts; and</td>
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<tr>
<td>Phase 1 and 2 Outcomes</td>
<td>Description</td>
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<td>• Pilot-testing with a subset of commercial EHR vendors.</td>
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4. **Usability priorities, guidance, design primer, and user-centered design model documentation**
   • Usability priorities identified through an open-ended question included in the online survey of clinicians, clinical software developers, and IIS'; and
   • Usability guidance, a user-centered design primer, and user-centered design model documentation for two immunization-related workflows (forecasting and data quality for documentation), developed by usability experts.

5. **Online survey results**
   Results of an online survey of clinicians and other immunization providers, EHR and other clinical software developers, and the IIS community regarding:
   • For each of the 47 immunization-related requirements:
     - Perceived impact on health or health care;
     - Readiness to implement the requirement; and
     - Assessment of whether the requirement was important enough to warrant voluntary testing and validation.
   • Feedback on the types of immunization-related functionalities that should be tested for usability; and
   • Stakeholder-specific assessments of value.

6. **Governance recommendations**
   • An overview of the primary functions required to implement an immunization-related program;
   • Approaches for carrying out such functions;
   • Principles and general considerations for governance; and
   • Organizational options and the advantages and disadvantages of each.

7. **Communications Plan**
   A Communications Plan, targeted for audiences that include clinicians and other immunization providers, EHR and other software developers, IIS', and others in a position to provide incentives for adoption of immunization-related capabilities. Contents of the Communications Plan include:
   • Goals and objectives of a communications strategy;
   • Analysis of the target audience;
   • Key issues for the target audience;
   • Perceptions of value;
   • Key messages that resonate; and
   • Strategies for communicating with the target audience.

8. **Implementation Plan**
   Implementation plan, including the following:
   • Implementation strategy and approach;
   • Key factors informing strategy and approach;
   • Incentives to drive adoption of immunization-related capabilities;
   • Primary operational activities, governance, key attributes, and critical success factors to support the following key functions:
     - Gaining consensus on capabilities or requirements;
     - Developing and supporting use of testing methods; and
     - Independently validating and communicating results.
   • Alternative roles for CDC based on appropriate government role and precedence; and
   • Available project deliverables to support implementation.
2 APPLICATION OF UCD METHODS TO IMMUNIZATION WORKFLOWS

CNIADV’s usability team includes human factors specialists and designers. The team performed a user-centered design (UCD) process on prototype EHR applications to address immunization functionality. The team performed UCD activities that included creating user interface designs from business workflow requirements and functional prototypes based on immunization content.

Phase II, Formal Deliverable 10a, Attachment C: UCD Primer, provides the background for optimizing usability with a UCD process. The deliverable also outlines the UCD process for this immunization project. As illustrated in Exhibit 3, NCIRD agreed to proceed with two workflows for the project: Immunization Reconciliation and Immunization Inventory Management, identified on December 3, 2015.

The CNIADV usability team conducted a series of UCD activities for each workflow. These activities included 1) discovery and definition activities, and 2) three rounds of usability testing with actual end users provided by the vendors who participated in the project. Each workflow had similar UCD activities.

Exhibit 3. User-Centered Design (UCD) Process for Immunizations Project

2.1 Project Definition and Selection of Workflows

This deliverable highlights each UCD activity. It includes references to documents created throughout the project that detail each activity. This deliverable also provides a discussion of the learnings for each workflow.

The first steps in the UCD demonstration pilot included the following:

- Define project scope and select workflows;
- Identify and obtain vendor participation; and
- Review work from prior phases of immunization project.

Below we present the highlights of these first steps. Details can be found in the Phase 3 deliverable titled, User-Centered Design (UCD) Use Case and UCD Discover and Definition Formal Deliverable.

2.1.1 Define Project Scope and Select Workflows

The CNIADV team reviewed the following sources to determine the most challenging issues related to immunization:

- Information gleaned from interviews with a wide range of stakeholders in Phase 1 of the project. (Phase 1: FD1: Interview Summary);
- Stakeholder input during in-person meetings held in June 2014 and September 2014 as part of Phase 1 of the project;
- Discussions with usability experts and review of usability literature, including specific publications regarding usability-related safety issues for pediatrics in Phase 2 of the project;
- Observations from demonstrations of twelve vendor products with high market share to determine immunization-related function and identify aspects important to usability in Phase 2. (See Phase 2: FD-4- EHR Clinical Software Assessment); and
- Review of findings with subject matter experts (physicians, the IIS community, usability experts, CDC NCIRD) to select the most challenging issues to address within the scope of the project in Phase 2 and in the current phase of the project.

For Phase 3, CNIADV and NCIRD considered options for usability evaluation and determined the following two topics would add the most benefit to EHR vendors and implementers at this time (December 3, 2015 – Attachments A and B):

1. **Immunization Reconciliation:** The goal of a typical immunization reconciliation workflow is to derive a single reconciled list of immunization data that accurately reflect the patient’s immunization history from two or more sources of immunization information. The most essential high-level tasks involved in this workflow are 1) determining the need for a reconciliation process, 2) importing multiple sources of immunization data into the system, and 3) reconciling that data.
   
   a. The scope of our UCD process will focus on the third task – reconciling the data. Reconciling data requires the user to engage in a comparison of multiple sources of immunization information and decide what information to include and what to exclude.
   
   b. User groups identified as engaging in immunization reconciliation workflows in clinical practice settings include physicians, mid-level practitioners (advanced practice nurses and physician assistants), and nurses with authority to make changes to patient immunization records. The scope of our UCD process will only focus on members of the physician and mid-level user group since these are the most common users identified.

2. **Inventory Management:** The goals of inventory management processes are 1) to maintain accurate tracking of local inventory for public and private vaccine stock and 2)
to assure adequate stock is available in the provider setting (order, stock / restock) from guarantee programs such as the Vaccines for Children (VFC) program or private sources.

a. The scope of our UCD process will inform how EHRs can enable the following activities:
   i. Coordinate the inventory requirements with those of the ExIS system;¹
   ii. Provide guidance for managing guarantee program and private stock; and
   iii. Inform how the EHR can enable providers to easily order appropriate vaccines for a given patient (e.g., based on eligibility) from on-hand inventory, document administered vaccines, and automatically decrement inventory when documented.

b. The target user group for the Inventory Management UCD process includes nurses or other staff members assigned to enter and update inventory data and order, manage, and track inventory.

2.1.2 Environmental Context

The CNIADV team identified relevant environmental contexts from the Phase 1 literature, stakeholder interviews and requirement analysis, and also from the Phase 2 clinical software assessment and expert panel review. The team identified environments to inform the system design throughout the UCD process. Typical environments in which users engage in immunization reconciliation tasks include:

- Traditional ambulatory pediatric or family practices;
- Patient-centered homes.

These environments are often fast-paced and include a heavy patient load. Such environments impose frequent interruption and distraction for users.

2.1.3 Selection of Workflows Based on Risk Assessment

The two workflows chosen offer the opportunity to improve efficiency. For immunization reconciliation, accurate knowledge of each patient’s then current immunization status takes time and must be completed with each patient during each visit. Providers increasingly perform bidirectional information exchange with IIS. They must evaluate these data in context of information known to the practice and successfully determine the next vaccine to provide and its timing.

The inventory management workflow also impacts providers’ time. Providers also must complete the inventory management activities with each patient visit. Moreover, in order to qualify for future shipments from vaccine guarantee programs, providers also must report

---

¹ The Centers for Disease Control and Prevention Vaccine Tracking system (VTrckS) ExIS (External Information System) interface is a means for guarantee program awardees to process vaccine requests by uploading data from their Immunization Information System (IIS) to VTrckS. ExIS systems allow providers to manually enter vaccine inventory receipt and usage online. Information is available at: http://www.cdc.gov/vaccines/programs/vtrcks/topics/exis.html.
inventory information in the ExIS system to the respective IIS. Therefore, providers must manage accurate information both for guarantee program and for private vaccine stock inventory reporting to support their clinical practices. For these reasons, these two workflows are ideally suited to usability evaluation.

### 2.1.4 Identify and Obtain Vendor Participation

The CNIADV team contacted vendors regarding their willingness to participate in the usability efforts. The CNIADV team conducted kickoff meetings with participating vendors during which we summarized basic activities and vendor participation requirements. Exhibit 4 lists the activities vendors completed as part of demonstration UCD processes.

#### Exhibit 4. Basic UCD Activities with Vendor Participation

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<thead>
<tr>
<th>Activity</th>
<th>Purpose and Description</th>
<th>Attendees</th>
<th>Estimated Level of Effort from Vendor</th>
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| Kickoff Meeting                 | The Kickoff meeting allowed the CNIADV team to describe the project, present the basic usability activities in which the vendor will participate, and describe the need for the vendor to recruit product end users for the usability testing.                                                                                                                                                                                                                                           | • CNIADV Lead  
• CNIADV usability team member(s)  
• Vendor representative responsible for coordinating the vendor team's involvement in the project | 1 hour                                                                                                                                     |
| Prototype Review                | During the Prototype Review meeting, we shared the current status of prototype(s) to be used for usability testing and to obtain feedback from each vendor’s team.                                                                                                                                                                                                                                                                   | • CNIADV usability team member(s)  
• Vendor team members (as determined by the vendor)                                                                                                                                             | 1 – 2 hours                                                               |
| Participant Recruiting          | Each vendor was asked to provide contact information for up to five end users in each of two user groups:  
• Physicians and mid-level practitioners with authority to make changes to patient immunization records; and  
• Nurses or other staff members assigned to enter, update inventory data and nurse or other staff member assigned to order, manage, and track inventory.  
Vendors scheduled their end users across three (3) rounds of testing.  
Slots were filled on a first come basis.                                                                                                                                                                                                                                  | • CNIADV usability team member assigned to scheduling test sessions  
• Vendor representative responsible for coordinating contact with the vendor’s end users                                                                                                                                                                                                                               | Time for by the vendor to identify and recruit end users will be variable, but will not cause project delays due to the number of vendors expected to participate. |
| Round 1 Formative Usability Test Sessions | During Round 1 Formative Testing, we conducted moderated individual 30-minute sessions with end users. During these sessions, we showed end users a low-fidelity prototype and interviewed                                                                                                                                                                                                 | • CNIADV usability team moderator  
• CNIADV usability team data logger  
• Other CNIADV team                                                                                                                                                                                                                                                          | • Each end user participant = 30 minutes  
• Each vendor team member                                                                                               |
<table>
<thead>
<tr>
<th>Activity</th>
<th>Purpose and Description</th>
<th>Attendees</th>
<th>Estimated Level of Effort from Vendor</th>
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</thead>
</table>
|          | them about the information needs to support each workflow. Findings were used to inform the next design iteration of the prototype(s). Vendor team members observed sessions where their end users participated in the test. (Note: no vendor observed a session where another vendor’s end user participated). | members (optional)  
- Vendor team members (as determined by the vendor) | = 30 minutes per session attended |
| Round 2  | During Round 2 Formative Testing we conducted moderated 30-minute sessions with individual end users. During these sessions, we asked end users to use an interactive low-fidelity prototype to perform tasks that are part of each workflow. Findings were used to inform the next design iteration of the prototype(s). Vendor team members observed sessions where their end users participated in the test. (Note: no vendor observed a session where another vendor’s end user participated). | CNIADV usability team moderator  
- CNIADV usability team data logger  
- Other CNIADV team members (optional)  
- Vendor team members (as determined by the vendor) | Each end user participant = 30 minutes  
Each vendor team member = 30 minutes per session attended |
| “Mock” Summative Usability Test Sessions | During Round 3 “Mock” Summative Testing, we conducted moderated 30-minute sessions with individual end users. During these sessions, we asked end users to use an interactive low-fidelity prototype to perform tasks that are part of each workflow. Findings were used to prepare a Mock Summative Test Report. Vendor team members observed sessions where their end users participated in the test. (Note: no vendor observed a session where another vendor’s end user participated). | CNIADV usability team moderator  
- CNIADV usability team data logger  
- Other CNIADV team members (optional)  
- Vendor team members (as determined by the vendor) | Each end user participant = 30 minutes  
Each vendor team member = 30 minutes per session attended |
| Findings Review Meeting | During the Findings Review meeting, we will review the overall usability project and activities with the vendor. A separate meeting will be held with each participating vendor. | CNIADV usability team member(s)  
Other CNIADV team members (optional)  
Vendor team members (as determined by the vendor) | 1.5 hours |
<table>
<thead>
<tr>
<th>Activity</th>
<th>Purpose and Description</th>
<th>Attendees</th>
<th>Estimated Level of Effort from Vendor</th>
</tr>
</thead>
</table>
| Communications as Needed       | We communicated regularly with participants and vendors to schedule meetings, request end user contact information, and provide updates or request additional assistance related to scheduling end user participants in testing sessions | • CNIADV usability team member assigned to scheduling test sessions  
• Vendor representative responsible for coordinating the vendor team’s involvement in the project | As needed                              |

### 2.1.5 Review Work Products from Prior Phases of Immunization Project

CNIADV usability team members reviewed work products from prior project phases. This review:

- provided immunization-centric business workflow requirements;
- identified the range of functional abilities currently in use by providers for managing immunizations for patients today; and
- revealed existing product characteristics of the user interface and screen flows that might impact usability.

Using what was learned from the prior project phases, and drawing from previous within-context observations and interview knowledge, we recognized the need to include UCD activities that focus on “two bins of usability” (Ratwani, Fairbanks, Hettinger, and Benda, 2015). The first bin, **User Interface Design**, addresses displays and controls, screen design, clicks & drags, colors, and navigation. The second bin, **Cognitive Task Support**, focuses on workflow design, data visualization, support of cognitive work, and functionality.

Once the team selected the workflows, we completed the following initial UCD activities for each included immunization workflow:

- Discovery and definition:
  - Identify the end users;
  - Task analysis;
  - Task mapping;
  - Risk assessment; and
  - Additional discovery activities.

To complete the UCD process, we completed the following activities:

1. Create an iterative formative design with stakeholder and user feedback;
2. Conduct a “mock” summative usability test with the final prototype; and
3. Describe and report the methods and findings.

In order to present the UCD process and activity learnings, we organized the remaining parts of this document with a section for each workflow: Section 3 – Immunization Reconciliation and Section 4 – Immunization Inventory Management. For each workflow, we describe the UCD process and the learnings that impacted design decisions and changes to the prototype EHR.
applications to address immunization functionality. In addition, we discuss learnings related to each workflow that may interest developers and EHR companies.

## 3 IMMUNIZATION RECONCILIATION WORKFLOW

### 3.1 Discovery and Definition of Immunization Reconciliation Workflow User Requirements

This section describes the discovery and definition activities conducted to help define user requirements for the immunization reconciliation workflow. The CNIADV usability team completed the following activities in order to discover and define the users, user environments, user workflows, user tasks, and user information needs to inform immunization reconciliation design concepts:

- Understand end users;
- Task analysis;
- Task mapping;
- Risk assessment; and
- Additional discovery activities.

#### 3.1.1 Understand End User(s) of Immunization Reconciliation Workflow

We identified users by examining relevant literature, consulting with subject matter experts, and reviewing our experience with previous UCD immunization activities. We identified two user groups that engage in immunization reconciliation workflows:

1. Physicians and mid-level practitioners (i.e., advanced practice nurses and physician assistants) with authority to make changes to patient immunization records; and
2. Nurses with authority to make changes to patient immunization records.

The scope of our UCD process only focuses on members of the physician and mid-level user group, since these are the most common users.

#### 3.1.2 Task Analysis Activities for the Immunization Reconciliation Workflow

A task analysis is a breakdown of the tasks and subtasks required to successfully operate a system. A cognitive task analysis is appropriate for situations where there are large mental demands on the user. The CNIADV team conducted a cognitive task analysis on the immunization reconciliation workflow. The purpose of the analysis was to determine the tasks and subtasks a user must perform to complete the task, as well as to identify the mental demands of those tasks – especially those requiring high cognitive functioning, such as perception, memory, information processing, and decision making.

The task analysis informed the early design concepts, such as prioritizing and laying out information on a display. Exhibit 5 illustrates the documentation of a cognitive task analysis. The complete analysis can be found in the Phase 3 deliverable titled, User-Centered Design (UCD) Description of Initial Designs of Initial Prototype for Workflow 1 and Workflow 2 Formal Deliverable 2.
3.1.3 Task Mapping Activities for Immunization Reconciliation Workflow

A task map is a diagram showing the tasks and subtasks users might perform in a given system workflow. Exhibit 6 presents the task map CNIADV created for the immunization reconciliation workflow. The three major sub-workflows include: 1) determine a reconciliation is needed, 2) import other immunization information, and 3) reconcile. The task map further provides the sub-steps within each of the sub-workflows.
The task map helped the CNIADV team understand the detailed steps in a user’s progression through the immunization reconciliation workflow. For example, the task map visually displayed the mental steps a user might complete in order to reconcile two immunization histories. This allowed the team to develop an early design concept to include in prototypes for testing and eliciting end user feedback. The task map also helped the team develop the tasks to include in formative and summative usability tests.

### 3.1.4 Risk Assessment of the Immunization Reconciliation Workflow

Risk analysis identifies use errors and user interface design issues. It also classifies the severity of an error based on its potential consequence. User errors that cause subtask failures, or that are known industry risk issues, are considered more severe than noncritical system usability issues related to efficiency.

The CNIADV team performed continuous analysis to assess risk associated with the user interface throughout the UCD process. For each sub-workflow in the reconciliation process, the team assessed risks due to cognitive demand (e.g., long term memory and selective attestation), sensory / perceptual demands (e.g., correctly see, hear, and/or feeling system feedback), and response demands (e.g., use of fine motor skills, such as moving and clicking the mouse, etc.). In addition, the team used an analytical approach to identify potential usage errors that might impact patient safety.
The findings from the initial risk analysis can be found in the Phase 3 deliverable titled, User-Centered Design (UCD) Description of Initial Designs of Initial Prototype for Workflow 1 and Workflow 2 Formal Deliverable 2.

3.1.5 Additional Discovery Activities for Immunization Reconciliation Workflow

As part of the discovery and definition activities, the CNIADV team performed additional reviews and analyses to better understand issues and guidance related to immunization reconciliation. These activities included review of:


The results of this analysis aided in defining an early immunization reconciliation design concept. Previous work by Markowitz, Powsner, & Shneiderman, B. (2013) addresses cognitive demands of medication reconciliation. The medication reconciliation prototype provided in Belden, Plaisant and Johnson (2014 – http://inspiredehrs.org) provided the basis for the team’s initial immunization reconciliation concept.

3.1.6 Initial Design Concepts for Immunization Reconciliation Workflow

UCD discovery and definition activities resulted in the immunization reconciliation user interface requirements presented in this section. Note that not all requirements were addressed during the UCD demonstration project:

1. The system should include an Import/Receive function for receiving an immunization report from IIS;

2. The search function for local immunization data should include the following search criteria:
   a. Full name;
   b. Address;
   c. Phone Number;
   d. Age;
   e. Gender;
   f. Birth order (if applicable); and
   g. Other demographic information (especially distinguishing information).

3. The system should provide list(s) of vaccines including vaccines currently documented in the EHR and vaccines from multiple external sources:
   a. We investigated vertical vs. horizontal list. Teams might identify other layouts;
b. Clear indication of which lists are from the EHR and which are from the public registry (or other sources);
c. Clear indication of data elements and the associated data values between lists that are shared, unique;

4. The system should provide clear way(s) of marking vaccines to keep on record, clear off record (reject), or assign to someone for further investigation (e.g., I don’t have enough information to know what to do with this vaccine). The system should also provide methods of marking multiple items at once (e.g. keep or reject entire column, etc.) to improve performance of experienced users;
   a. The system should provide clear indication of items that are marked to keep, reject, or need attention through terminology, color, and/or symbols;
   b. The systems should provide consistent undo method for mistakes (e.g. a “clear all” for an entire list, etc.)

5. The system should provide a global restart/clear (similar to the Twinlist “start over” feature presented in the top of the browser demonstration in reference 3) to allow the user to return to the original display:
   http://www.cs.umd.edu/hcil/sharp/twinlist/dev/indev/ipad/index.html?case=__DATASET_APPENDECTOMY__&version=__VERSION_FULL__&animate=__AUTO_ANIMATE_ON__) Exhibit 8 shows a screen shot of the Twinlist model that includes “intake” and “hospital” medication lists in a side-by-side comparison. In the top banner Twinlist provides action buttons; “start over?” is one of those options. The “Twinlist” model is an interactive presentation available at:
   http://www.cs.umd.edu/hcil/sharp/twinlist/dev/indev/ipad/index.html?case=__DATASET_APPENDECTOMY__&version=__VERSION_FULL__&animate=__AUTO_ANIMATE_ON__.3; and

6. The system should allow the user to adjust the animation speed, including turning off animation entirely.
7. Vaccine details should include:
   a. Vaccine name(s);
   b. Lot number;
   c. Manufacturer;
   d. Expiration date; and
   e. Similar to the previously referenced Twinlist model, some details can be located directly near the items while other details can be displayed at the bottom.

8. The function to incorporate reconciled data into the vaccine administration record should include:
   a. A “finish” button;
   b. An onscreen and/or printable confirmation of history reconciliation;
   c. An onscreen or other type of report confirming that any reconciled differences have been sent to appropriate IIS’.

9. There should be a function to add/edit a new vaccine that was not found in either list. This should be similar to the add and edit functions in the Twinlist model.

10. Advanced Options for List Customization should have a filter with the following functions:
    a. Ability to filter by vaccine detail level;
    b. List presentation (e.g. Twinlist model, simple two column list, etc.)
c. “Group by” feature which changes listing order to group by specific detail (similar to grouping by diagnosis in the Twinlist model)

11. Help
   a. Provide help documentation that is succinct in order to scaffold novice users and provide quick learning of basic features

The CNIADV usability team reviewed the information from the discovery and definition phase and the user requirements to produce an initial design concept. Exhibit 7 provides a representative screen shot of the initial design concept. Additional screens were included in a prototype to support usability test tasks from immunization reconciliation.

Exhibit 8. Representative Screen Shot of Initial Immunization Reconciliation Design Concept

![Patient Banner]

3.1.7 Obtain Input from Subject Matter Experts on Early Immunization Reconciliation Workflow Concepts

The next step in the UCD process was to conduct a web-based interview with a clinical member of the CNIADV team acting in the role of a subject matter expert. This interview demonstrated how to plan and execute stakeholder interviews and helped identify information needs and priorities for refining early immunization reconciliation prototypes used in the first formative testing round. The subject matter expert provided opinions and answered questions related to vocabulary, functionality, experience with other products, and what information is needed and when (e.g., persistent on the screen, on mouse over, 1-click away, etc.). This information helped us make decisions related to what immunizations should be included/excluded in a reconciled immunization list.
3.2 Conduct Vaccine Immunization Reconciliation Workflow Formative Usability Test (Round 1)

This section describes the first round of formative usability testing in the UCD process (Round 1). Details can be found in the Phase 3 deliverable titled, Formal Deliverable 3A Round 1 Formative Usability Test – Immunization Reconciliation Findings and Planned Prototype Changes.

3.2.1 Objectives

The objectives of the first round of formative usability testing included:

- To understand user needs, issues, and opinions related to early design concepts for vaccine immunization reconciliation;
- To further define information needs and priorities that support decision making related to the reconciliation of vaccines from external sources; and
- To use the findings to update design concepts and prototypes in support of a second round of formative testing.

3.2.2 Methods

We recruited four end user participants. Each participant was familiar with immunization or medication reconciliation procedures at their respective practices.

We used remote usability testing to conduct the interactive sessions. During the session, the participant sat at his/her computer, while the usability test team members sat at their computers. The participant viewed and interacted with the prototype application via WebEx, and the usability team members were able to observe these interactions in real time. Each session lasted 30 minutes.

In addition to collecting background information about each end user participant, the CNIADV usability team used a talk-aloud protocol and collected the following information related to the prototype wireframes:

- Participant impressions and reactions to concepts;
- Participant feedback, opinions, and preferences;
- Participant expressed needs for information display and priority; and
- Usability issues observed by the CNIADV team.

We did not collect quantifiable measures (e.g., task times, number of clicks, etc.) for this formative test.

3.2.3 Findings

The CNIADV usability team analyzed the findings, referenced best practice user interface design principles, and brainstormed possible updates. Detailed findings and design decisions can be found in the Phase 3 deliverable titled, Formal Deliverable 3A Round 1 Formative Usability Test – Immunization Reconciliation Findings and Planned Prototype Changes. This section summarizes the findings and updates to the application prototypes.
3.2.3.1 Key Finding

A key finding from Round 1 usability testing resulted from an A/B comparison of a reconciliation screen organized by similarity (see Exhibit 9) versus a reconciliation screen organized by vaccine name (see Exhibit 10). Participants preferred using the reconciliation screen organized by vaccine name (see Exhibit 10). No difference was seen in performance.

Exhibit 9, the Similarity Concept, was inspired by the TwinList reconciliation prototype. The first column identifies the degree of similarity (e.g., Identical, Similar, Unique) of the vaccines. The additional columns indicate the different sources of information (e.g., EHR, In-State IIS, Out-of-State IIS, and Parent). Hep B vaccines grouped as Identical share all the same vaccine details (e.g., same administration date, location, etc.). Hep B vaccines grouped as Similar share some but not all vaccine details. Vaccine details that differ between the external sources are highlighted in yellow.

Exhibit 10 presents the Traditional Concept, which was inspired by the CDC Forecast layout. The first column identifies the specific vaccine. Sub-rows of a vaccine represent administrations of the vaccine in the series. Hep B has two sub-rows. The first row is associated with the first Hep B administration in the series. The second row is associated with the second Hep B administration in the series. Each column provides the vaccine details for different sources (e.g., EHR, In-State IIS, Out-of-State IIS, Parent). Differences in vaccine details between different sources are highlighted in yellow.
3.2.3.2 Information Priority

One objective of Round 1 usability testing was to define information needs and priorities that support decision making related to the reconciliation of vaccines from external sources. To achieve this objective, study participants reviewed a low-fidelity prototype designed to support the immunization reconciliation workflow.

The study confirmed that much of the information the participant needed was provided in the initial design concept. Some learning specific to information priority included:

- Some participants mistakenly interpreted the yellow highlight to indicate an adverse event was associated with the administration of that vaccine:
  - The reconciliation concepts tested in Round 1 included yellow highlighting as a visual indicator that vaccine details differed among comparison vaccine details. Participants mistook the yellow highlighting to be a more important indicator, such as an adverse event associated with the administration of that vaccine.

- Participants indicated that Source information (e.g., e.g., In-State IIS, Out-of-State IIS, Parent) is important:
  - As a note of explanation, the initial immunization reconciliation concept included a screen where 1) users compare and select vaccines to accept into the EHR, 2) users review and confirm a list of vaccines marked to be saved into the EHR, and 3) users save their work and the vaccines are displayed in the EHR. Participants indicated that Source information is needed not only on the main reconciliation screen (as in the
initial concept), but also on the confirmation screen (a half click away on hover), and when the vaccine is saved in the EHR (as a field with other the vaccine details).

- Participants indicated Location detail was lower priority and could be displayed one click away:
  - Location detail, the name of the facility at which a vaccine was administered, was displayed on the main screen in the initial concept. Participants indicated this information could be displayed one click away on a Vaccine Detail screen that is accessed by clicking the vaccine name.

- One task asked participants to provide feedback on editing vaccine details after a vaccine was added to the EHR through the reconciliation process. Participants indicated that a number of form fields would not often be used for entering a historical vaccine due to lack of information (e.g., Administering Clinician, Manufacture, see Formal Deliverable 3A Round 1 Formative Usability Test – Immunization Reconciliation Findings and Planned Prototype Changes for the full list of fields).

### 3.2.3.3 User Interface Interactions

A primary objective of Round 1 usability testing was to define information needs and priorities. To that extent a majority of session time was spent discussing what content displayed on the screen was meaning and not meaningful to the participant and how and why pieces of information would be used or not used. Less time was spent having the participant reconcile the immunizations. Even with the lack of interaction, results suggested confusion about action buttons. Specifically, participants were confused by several action button labels and were unable to select the correct element (e.g., a row, a column, or a cell, etc.) with which an action was associated.

### 3.2.3.4 Changes to the Prototype

Based on the Round 1 usability test findings, best practice user interface design principles, and design discussions, the CNIADV team decided to move forward with the Traditional Concept with simplified action buttons and interactions associated with accepting information into the EHR. In terms of detailed design decisions, we decreased the amount of yellow highlighting used to draw attention to vaccine detail differences. In order to gather additional user feedback on the fields – including on the reconciliation and Add/Edits screens – we continued to display all the form fields as indicated by the business requirements.

During design discussions, we decided to investigate an alternative layout for the information on the Reconciliation Screen. We also evaluated a visual indicator that compared the level of similarity a vaccine from an external source has with the vaccine documented in the EHR. See the Round 2 Findings section in this document for descriptions of these alternatives.

### 3.3 Conduct Vaccine Immunization Reconciliation Workflow Formative Usability Test (Round 2)

This section describes the second round of formative usability testing in the UCD process (Round 2). Details can be found in the Phase 3 deliverable titled, Formal Deliverable 3A Round
Formative Usability Test – Immunization Reconciliation Findings and Planned Prototype Changes.

3.3.1 Objectives

Round 2 testing objectives included:

- Understand user needs, issues, and opinions related to design concepts for vaccine immunization reconciliation;
- Further define information needs and priorities that support decision making related to the reconciliation of vaccines from incoming sources; and
- Identify needed changes to design concepts and prototypes for validation in mock summative testing.

3.3.2 Methods

Four end user participants were recruited. Three of the four participants were familiar with immunization or medication reconciliation procedures at their respective practices.

We used remote usability testing to conduct the interactive sessions. During the session, the participant sat at his/her computer, while the usability test team members sat at their computers. The participant viewed and interacted with the prototype application via WebEx, and the usability team members were able to observe these interactions in real time. Each session lasted 30 minutes.

In addition to collecting background information about each end user participant, the CNIADV usability team used a talk-aloud protocol and collected the following information related to the prototype wireframes:

- Participant impressions and reactions to concepts;
- Participant feedback, opinions, and preferences; and
- Usability issues observed by the CNIADV Team.

Quantifiable measures (e.g., task times, number of clicks, etc.) were not collected during this formative test.

3.3.3 Findings

The CNIADV usability team analyzed the findings, referenced best practice user interface design principles, and brainstormed possible updates. Detailed findings and design decisions are available in the Phase 3 deliverable titled, Formal Deliverable 4A Round 2 Formative Usability Test – Immunization Reconciliation Findings and Planned Prototype Changes. This section summarizes the findings and updates to the application prototypes.

3.3.3.1 Key Finding

A key finding from Round 2 testing comes from an A/B comparison of a reconciliation screen organized in a horizontal layout (see Exhibit 11) versus a reconciliation screen organized in a vertical layout (see Exhibit 12). The comparison indicated that participants preferred and performed slightly better using the reconciliation screen organized in a horizontal layout (see Exhibit 11). We observed no difference in performance.
Exhibit 11 illustrates the horizontal layout (inspired by the Traditional Concept from Round 1). The first column identifies the specific vaccine. Each column (horizontally across the page) provides the vaccine details for different sources (e.g., in the EHR, from the In-State IIS). Differences in vaccine details between different sources are highlighted in yellow.

**Exhibit 11. Representative Screen from Immunization Reconciliation Horizontal Layout**

In Exhibit 12, the vertical layout presents each vaccine by source in a different row. Rows are grouped based on the amount of information in the external source vaccine matching the information in the EHR. The lighter rows, which also have circles in them, contain information that is completely new and comes from an external source. Differences in vaccine details between different sources are compared by reviewing information vertically up and down the screen.

Circle icons with different amounts of filling provide a visual indication of differences/matches in vaccine details. Circle icons with no filling indicate the vaccine from the external source contains information that is not in the EHR. Circle icons with partial filling are indicate the vaccine from the external source contains information that conflicts with information in the EHR. Filled circle icons indicate all the vaccine details from the external source match a vaccine documented in the EHR. This feature did not help participants in their review process.
3.3.3.2 Information Priority

The study confirmed that much of the information participants need was provided in the initial design concept. Learnings specific to information priority included:

- Participants use field-by-field comparison to determine whether a specific external vaccine will be accepted by and recorded in the EHR or rejected and not recorded in the EHR. The decreased yellow highlight was an improvement compared to full highlighting used in Round 1.

- The circle icon with fill was intended to assist in comparing vaccines from external sources with vaccines recorded in the EHR. The circle icon approach resulted in mixed feedback.

- Further design research is needed to find an approach to aid the cognitive activity in field-by-field comparison in the reconciliation process.

- Participants continued to indicate specific form fields that would not often be used for entering a historical vaccine due to lack of information (e.g., Administering Clinician, Manufacture, see Formal Deliverable 4A Round 2 Formative Usability Test – Immunization Reconciliation Findings and Planned Prototype Changes for the full list of fields).

- One participant was not familiar with the acronym, IIS, however, this same participant was familiar with the term, State Registry.

3.3.3.3 User Interface Interactions

Most of the Round 2 usability test session time was spent having participants interact with the prototype. Having participants interact with the prototype rather than having them talk about
their needs, priorities, and use of information – as was done in round 1 – highlighted several fundamental interactions flaws with the immunization reconciliation concept:

- The immunization reconciliation concept violated a strong participant expectation regarding vaccines documented in the EHR:
  - The concept was based on a model where the reconciliation screen was a “worksheet” and any vaccine (i.e., row in the worksheet) was a candidate to be saved into the EHR. This included vaccines that were already documented in the EHR. For example, in the worksheet there was a set of vaccines associated with the source EHR. The worksheet model assumed that participants would select each row to save (i.e., commit to the EHR’s database). Our design thinking was flawed and resulted in participants leaving previously documented vaccines out of the final list of reconciled vaccines. The initial concept and this flaw serves as an example of design mismatch of database type thinking versus user thinking.

- Participants were confused by several actions:
  - Participants could not correctly select the element (e.g., a row, a column, or a cell) with which an action was associated.
  - Participants could not easily discover how to accept a vaccine from an external source to be recorded in the EHR.

- The concept is missing critical functionality:
  - Participants tried to accept pieces of vaccine information from an external source to be appended to the information recorded in the EHR.

- The current concept design may result in the creation of duplicate records:
  - Results indicated that interactions with the current row selection could lead to duplications in the final reconciled list of immunizations in the EHR.

3.3.3.4 Changes to the prototype

Based on the test findings, best practice user interface design principles, and design discussions, the team decided to move forward with the Traditional Concept with a horizontal layout. We implemented simplified action buttons and interactions associated with accepting information into the EHR. We also incorporated mouse over tool tips to provide context specific help regarding Accept and Reject actions.

In order to gather additional user feedback on the fields included on the reconciliation screen and on the Add/Edit screen, we continued to display all the form fields as indicated by the business requirements. See the Round 3 usability testing section in this document for descriptions of these updates.

3.4 Conduct Vaccine Immunization Reconciliation Workflow Mock Summative Usability Test (Round 3)

This section describes the third round of usability testing, which was a mock summative usability test. We consider this a “mock” summative usability test because some best practices were excluded. Primarily, the number of participants who completed the test sessions was significantly fewer than the recommended number of 15 to 20 per user group. Details of the mock summative
usability test can be found in the Phase 3 deliverable titled, Formal Deliverable 5A Round 3 Mock Summative Usability Test – Immunization Reconciliation.

3.4.1 Objectives

We conducted the test with a smaller number of participants to:

1. illustrate differences in the planning and execution of a summative test compared to a formative test;
2. highlight the differences in the artifacts (e.g., test plan, moderator guide, report, etc.) associated with a summative test;
3. provide examples of types of tasks and questions that might be included in the summative test; and
4. provide examples of objective and subjective usability metrics that might be collected as part of an immunization specific summative test.

The primary purpose of an actual summative usability test is to provide objective evidence that the product’s clinical user interfaces can be used in a safe, efficient, and effective manner. In addition, a summative test validates whether usability goals have been achieved.

3.4.2 Methods

One (1) physician and three (3) nurses participated in the usability test. All participants were current or recent medical practitioners who performed relevant or related immunization workflows. Each participant performed simulated but representative tasks specific to their role.

We used remote usability testing to conduct the interactive sessions. During the session, the participant sat at his/her computer, while the usability test team members sat at their computers. The participant viewed and interacted with the prototype application via WebEx, and the usability team members were able to observe these interactions in real time. Each session lasted 30 minutes.

In addition to collecting background information about each end user participant, the CNIADV usability team collected performance data on tasks and subtasks typically conducted with the system. We created and mapped the tasks and subtasks to the following immunization workflow:

- Using the immunization reconciliation functionality to reconcile vaccines from incoming sources into the EHR.

Specific study tasks were constructed that would be realistic and representative of activities a clinician might complete using an EHR with immunization functionality, including:

- Identify which vaccines are in the EHR;
- Identify the sources of incoming vaccine data;
- Identify conflicts between vaccine information in the EHR and incoming vaccine information;
- Select administered vaccines to include in the reconciled list for the patient based on both native and external sources of vaccine information;
- Submit reconciled list to the EHR system.
We selected tasks based on their frequency of use, criticality of function, and those that may be most troublesome for users. Study Procedure

The test moderator introduced the test and instructed participants to complete a series of tasks (given one at a time) using the system. During the session, the test moderator and data logger recorded user performance data on paper and electronically. The test moderator did not instruct the participant about how to complete the task unless the participant stated that s/he was done with the task, asked for help, or was not making progress to complete the task after 60 seconds. If the test moderator determined the participant could accomplish the task in a reasonable amount of time despite a stoppage in progression, s/he would grant 30 additional seconds before providing assistance. The session (including what was showing on the screen and the voice conversation) was recorded for subsequent analysis.

3.4.2.1 Usability Metrics

The following types of data were collected for each participant:

- Effectiveness
- Percentage of tasks successfully completed within the allotted time without assistance (Pass)
- Percentage of task failures (Fail)
- Types of errors
- Efficiency
- Task Time
- Types of errors
- System Satisfaction
- Participant’s satisfaction rating of the system (as indicated with the System Usability Scale [SUS] score)
- Participant’s verbalizations (e.g., comments)

3.4.2.2 Data Scoring

Exhibit 13 details how we scored tasks and evaluated errors.

<table>
<thead>
<tr>
<th>Data Measures</th>
<th>Rationale and Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task Success</td>
<td>• A task was counted as a “Pass” if the participant was able to achieve the correct outcome, without assistance.</td>
</tr>
<tr>
<td>Task Failures</td>
<td>• A task was counted as “Fail” if the participant abandoned the task, did not complete the task goal, or needed at least one assist from the moderator.</td>
</tr>
<tr>
<td></td>
<td>• Failed tasks were discussed with participants at the end of each task.</td>
</tr>
<tr>
<td></td>
<td>• An enumeration of usage errors and usage error types was collected to help better understand the source of the usage errors and possible mitigations.</td>
</tr>
<tr>
<td>Task Time</td>
<td>• Task times were collected.</td>
</tr>
<tr>
<td></td>
<td>• In this study, task time was taken with the time on an iPhone. Minutes were recorded with paper/pen. Task time started when the moderator instructed the participant he/she could begin the task whenever he/she was ready. Task time ended when the</td>
</tr>
<tr>
<td>Data Measures</td>
<td>Rationale and Scoring</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------</td>
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<tr>
<td></td>
<td>participant said “Done” or the participant completed a task and did not say “Done” but exhibited a behavior indicating “Done” and the moderator confirmed by asking, “Are you done?”</td>
</tr>
</tbody>
</table>

**Cautions About Using Task Time**

- Because the industry has not standardized usability test tasks and protocols for measuring task times, the usability test team feels others might misunderstand and/or misuse reported task times.
- Industry usability specialists should educate stakeholders about task time (e.g., the many variables that make up the time i.e., multiple tasks in a scenario, clinical “thinking” time, software “thinking” time, etc. and ways to measure task time and identification of tasks that should be fast compared to tasks where slower times represent safe performance). In addition, industry usability specialists should develop a standard method for collecting and reporting task time so that stakeholders can make meaningful comparisons and decisions.
- We urge caution when comparing the task times in Exhibit 15 across tasks, features, and/or products.

<table>
<thead>
<tr>
<th>SUS Scores</th>
<th>To measure participants’ satisfaction with the system, the usability team administered the System Usability Scale (SUS) post-test questionnaire. The SUS is a reliable and valid measure of system satisfaction.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>In order to access system-level satisfaction as opposed to feature level satisfaction – and as is common practice with the use of the SUS – we administered the questionnaire at the end of the tasks. See Appendix 3 – System Usability Scale Questionnaire.</td>
</tr>
</tbody>
</table>

### 3.4.3 Description of Application Prototype

Exhibit 14 provides a representative screen shot of the design concept evaluated during the mock summative usability test. The initial Traditional Concept was inspired by the CDC Forecast layout and updated based on the two iterations in this UCD process. The first column identifies the specific vaccine. Sub-rows of a vaccine represent administrations of the vaccine in the series. Hep B has two sub-rows. The first row is associated with the first Hep B administration in the series. The second row is associated with the second Hep B administration in the series. Each column provides the vaccine details for different sources (e.g., EHR, In-State IIS, Out-of-State IIS, Parent). Differences in vaccine details between different sources are highlighted in yellow.
3.4.4 Data Analysis

We calculated the results of the mock usability test according to the methods specified in the section of this document titled, DATA SCORING. The results are not valid and are meant to serve as an example. The results are meant to serve as an example of reporting usability performance data. Readers should recognize the difference in the quantitative data from Round 3 summative usability testing reported in this section and the qualitative data from Rounds 1 and 2 formative usability testing reported earlier in this document.

Exhibit 15 presents the usability test results for each subtask.

<table>
<thead>
<tr>
<th>Task Description</th>
<th>Number Attempting Task</th>
<th>Percent Pass</th>
<th>Percent Fail</th>
<th>Mean Task Time (sec)</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify which vaccines are in the EHR</td>
<td>4</td>
<td>100%</td>
<td>0%</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>Identify the sources of incoming vaccine data</td>
<td>4</td>
<td>100%</td>
<td>0%</td>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>Identify conflicts between vaccine information in the EHR and incoming vaccine information</td>
<td>4</td>
<td>25%</td>
<td>75%</td>
<td>27</td>
<td>25</td>
</tr>
<tr>
<td>Select administered vaccines to include in the reconciled list for the patient, based on both native</td>
<td>4</td>
<td>75%</td>
<td>25%</td>
<td>36</td>
<td>12</td>
</tr>
<tr>
<td>Task</td>
<td>Number Attempting Task</td>
<td>Percent Pass</td>
<td>Percent Fail</td>
<td>Mean Task Time (sec)</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>------</td>
<td>------------------------</td>
<td>--------------</td>
<td>--------------</td>
<td>----------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>and external sources of vaccine information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submit reconciled list to the EHR system</td>
<td>4</td>
<td>100%</td>
<td>0%</td>
<td>22</td>
<td>14</td>
</tr>
</tbody>
</table>

### 3.4.4.1 System Usability Scale (SUS)

One (1) physician and three (3) nurses completed the SUS questionnaire. The SUS is a reliable and valid measure of system satisfaction. Sauro ([http://www.measuringusability.com/sus.php](http://www.measuringusability.com/sus.php), accessed August 22, 21016) reports an average SUS score of 68 – this is from 500 studies across various products (e.g., websites, cell phones, enterprise systems) and across different industries. A SUS score above a 68 is considered above average and anything below 68 is below average. The CNIADV team encourages teams not to focus on the comparison to the cross industry average SUS of 68 reported by Sauro. Instead, we encourage teams to use the SUS as a measure to compare their own usability improvement in the application as changes are made.

The reconciliation system scored an average of 66 (SD=25) based on four participant responses.

### 3.4.4.2 Findings and Areas for Improvement

Critical errors and inefficiencies were observed during the mock summative usability test. These areas highlight areas that should receive attention during the design and development of immunization reconciliation function. Observed use errors and possible mitigations include:

<table>
<thead>
<tr>
<th>Critical Error</th>
<th>Mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Unable to interpret vaccines representing the same dose in a series</td>
</tr>
<tr>
<td>2</td>
<td>Inadequate review of all missing or conflicting vaccine details or for immunizations from different sources and other information conflicts</td>
</tr>
<tr>
<td>3</td>
<td>Efficiency-related errors due to redundant ability to add detailed information from an incoming source</td>
</tr>
<tr>
<td>4</td>
<td>Unable to interpret vaccines representing the same dose in a series</td>
</tr>
</tbody>
</table>
4 IMMUNIZATION INVENTORY MANAGEMENT WORKFLOW

4.1 Discovery and Definition of Inventory Management Workflow User Requirements

This section describes the discovery and definition activities conducted to help define user requirements for the inventory management workflow. The CNIADV usability team completed the following activities in order to discover and define the users, user environments, user workflows, user tasks, and user information needs to inform immunization reconciliation design concepts:

- Observation and contextual interview;
- Understand end user(s);
- Task analysis;
- Task mapping;
- Risk assessment; and
- Additional discovery activities.

4.1.1 Observation and Contextual Interview for Inventory Management Workflow

For this project, we visited a pediatric practice to observe select inventory management tasks and conducted an interview with a nurse staff member responsible for aspects of inventory management. During the visit, we gathered information to inform our remaining discovery and definition activities.

4.1.2 Understand End User(s) of Inventory Management Workflow

We identified users by examining prior project use cases and documentation, consulting with subject matter experts, reviewing our experience with previous UCD immunization activities, and contextual interview. We identified two user groups that regularly engage in inventory management workflows:

1. Nurse or other staff member assigned to enter and update inventory data; and
2. Nurse or other staff member assigned to order, manage, and track inventory.

The scope of this UCD process was to provide information related to the inventory management workflow. We did not include workflows for ordering and administering vaccines to patients in the scope.

4.1.3 Task Analysis Activities for the Inventory Management Workflow

As described previously, a task analysis is a breakdown of the tasks and subtasks required to successfully operate a system. The CNIADV team conducted a cognitive task analysis for the immunization inventory management workflow.

The task analysis informed the early design concepts (e.g., prioritization and layout of information on a display). Exhibit 16 illustrates the documentation of a cognitive task analysis. The complete analysis can be found in in the Phase 3 deliverable titled, User-Centered Design (UCD) Description of Initial Designs of Initial Prototype for Workflow 1 and Workflow 2 Formal Deliverable 2.
### 4.1.4 Task Mapping Activities for Inventory Management Workflow

As previously described, a task map is a diagram showing the tasks and subtasks users might perform in a given system workflow. Exhibit 17 presents the task map CNIADV created for the immunization inventory management workflow. The sub-workflows include 1) activities aimed at maintaining accurate tracking of local inventory and 2) activities aimed at assuring adequate stock is available in the provided setting. The task map further provides the sub-steps within each of the sub-workflows.

<table>
<thead>
<tr>
<th>Step/Substep</th>
<th>Cognitive Demands</th>
<th>Sensory/Perceptual Demands</th>
<th>Response Demands</th>
<th>Potential Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Produce vaccine inventory report</td>
<td>LTM, selective attention, mental model, decision-making: Recall from previous experience which contexts require the generation of a report. Recall the steps for selecting and viewing the inventory, including the location of appropriate tools (e.g., dropdown menu item, icon) to facilitate the task. Discriminate between other menu items/buttons and the correct one.</td>
<td>Vision &amp; perceptual recognition: The user will need to locate the tools/icons that are associated with the &quot;View inventory&quot; page (e.g., dropdown menu item, button)</td>
<td>Fine motor skills: Clicking a link/icon/button</td>
<td>Attentional failures are likely to lead to failure to notice on-screen indicators. Perceptual error could lead to indicators being missed, ignored or misperceived.</td>
</tr>
<tr>
<td>1.1 Select and view inventory</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2 Generate report</td>
<td>LTM, selective attention, mental model, decision-making: Recall the steps for generating a report, including the location of appropriate tools (e.g., dropdown menu item, icon) to facilitate the task. Discriminate between other menu items/buttons and the correct ones.</td>
<td>Vision &amp; perceptual recognition: The user will need to locate the tools/icons that are associated with generating a report (e.g., dropdown menu item, report icon/button)</td>
<td>Fine motor skills: Clicking a link/icon/button</td>
<td>Incorrect mental model could lead to choosing the wrong report for the given task.</td>
</tr>
<tr>
<td>2. Reconcile IIS inventory</td>
<td>LTM, selective attention, mental model, decision-making: Recall from previous experience the steps and tools necessary for reconciling inventory. Recall the steps for selecting and viewing the inventory, including the location of appropriate tools (e.g., dropdown menu item, icon) to facilitate the task. Discriminate between other menu items/buttons and the correct ones.</td>
<td>Vision &amp; perceptual recognition: The user will need to locate the tools/icons that are associated with the &quot;View inventory&quot; page (e.g., dropdown menu item, button)</td>
<td>Fine motor skills: Clicking a link/icon/button</td>
<td>Attentional failures are likely to lead to failure to notice on-screen indicators. Perceptual error could lead to indicators being missed, ignored or misperceived.</td>
</tr>
<tr>
<td>2.1 Select and view inventory</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2 Generate report</td>
<td>LTM, selective attention, mental model, decision-making: Recall the steps for generating a report, including the location of appropriate tools (e.g., dropdown menu item, icon) to facilitate the task. Discriminate between other menu items/buttons and the correct ones.</td>
<td>Vision &amp; perceptual recognition: The user will need to locate the tools/icons that are associated with generating a report (e.g., dropdown menu item, report icon/button)</td>
<td>Fine motor skills: Clicking a link/icon/button</td>
<td>Incorrect mental model could lead to choosing the wrong report for the given task.</td>
</tr>
</tbody>
</table>
The task map helped the CNIADV team understand the detailed steps in a user’s progression through the immunization inventory management workflow. For example, the task map visually displayed activities aimed at maintaining accurate tracking of local inventory, as well as activities aimed at assuring adequate stock is available in the provided setting. This allowed the team to develop an early design concept to include in prototypes for testing and eliciting end user feedback. The task map also aided the team in developing the tasks that were included in formative and summative usability tests.

4.1.5 Risk Assessment of the Inventory Management Workflow

As described previously, risk analysis identifies use errors and user interface design issues. It also classifies the severity of the error based on its potential consequence. Use errors that cause subtask failures or that are known industry risk issues are considered more severe than noncritical system usability issues related to efficiency.
The CNIADV team performed continuous analysis to assess risk throughout the UCD process. For each subtask in the inventory management process, the team assessed risks due to cognitive demand (e.g., long term memory and selective attestation, etc.), sensory / perceptual demands (e.g., correctly see, hear, and/or feeling system feedback, etc.), and response demands (e.g., use of fine motor skills, such as moving and clicking the mouse, etc.). In addition, the team used an analytical approach to identify potential usage errors that might impact patient safety.

The findings from the initial risk analysis can be found in the Phase 3 deliverable titled, User-Centered Design (UCD) Description of Initial Designs of Initial Prototype for Workflow 1 and Workflow 2 Formal Deliverable 2.

4.1.6 Additional Discovery Activities for Inventory Management Workflow

As part of the discovery and definition activities, the CNIADV team performed additional reviews and analyses to better understand issues and guidance related to inventory management. These activities included review of:

   b. “AIRA MIROW Chapter 6 (Inventory Management) Mini Guide.pdf”


4. North Carolina Immunization Registry (NCIR) guidelines and information

5. Usability summary reports for vendors who demonstrated some aspects of inventory management functionality in the prior project phase.

6. CNI EHR Certification Project Literature Review “Inventory Data Requirements” worksheet


8. Inventory data requirements for VFC and grantee programs at the provider level, as published by the American Immunization Registries Association (AIRA, 2012).

The analysis helped us define an early immunization inventory management design concept. Previous work by Stone User Experience (Usability Best Practice Catalog, 2016) informed the
initial design concepts. The prototype provided in Usability Best Practice Catalog (2016 - https://partner.cdc.gov/Sites/NCIRD/VEC/UsabilityBestPracticeCatalog/index.htm #t= Usability_Best_Practices_Catalog_v2/Executive_Summary.htm) provided the basis for the team’s initial inventory management concept.

4.1.7 Initial Design Concepts for Inventory Management Workflow

The following requirements apply to inventory management functionality within the EHR system. Note that not all requirements were addressed during the UCD demonstration project:

1. The View Inventory Main Screen should:
   a. Provide a way for the user to display Public and Private Stocks;
   b. Include a graphical indicator for expired lots;
   c. Include a graphical indicator for lots nearing expiration;
   d. Enable users to sort inventory by column;
   e. Include – at a minimum – the following columns/fields:
      i. Vaccine group;
      ii. Vaccine Trade name;
      iii. Packaging Unit Description (e.g. 10 Single Dose Vials);
      iv. NDC code;
      v. Lot #;
      vi. Expiration Date;
      vii. Quantity of Doses in inventory; and
      viii. Notes.

2. The Generate Inventory Report feature should:
   a. Provide regularly-scheduled, pre-built reports for selection by the user, including, but not limited to, the following:
      i. Vaccine Lot # Report;
      ii. Vaccine History Report;
      iii. Vaccine Administration Report;
      iv. Vaccine Reconciliation Report;
      v. Vaccine Usage Report; and
      vi. Above reports by Public or Private stock.
   b. Provide the ability to print any report;
   c. Provide the ability to generate custom reports based on user specified criteria, which include the following criteria at a minimum:
      i. Vaccine group;
      ii. Vaccine trade name;
      iii. Antigen;
      iv. Lot #;
      v. Expiration Date;
      vi. NDC code;
      vii. Funding source (private or public);
      viii. Vaccines administered (by lot #, by patient, during a date range);
      ix. By active vs. inactive;
x. Vaccine reconciliation discrepancies;
xi. Vaccine wasted; and
xii. Vaccine transferred.

3. The Update/Adjust Inventory feature should:
   a. Provide the user with the ability to enter and track public and private stocks;
   b. Include functionality to specify whether received inventory is “active” – for
      administration to patients – or “inactive” – where it cannot be ordered/administered
      by clinicians;
   c. Provide options for adding to inventory as a result of receiving shipments of vaccines;
   d. Provide the option for adding to inventory as a result of a transfer from another
      location;
   e. Provide the ability to decrement inventory as a result of normal administration of
      vaccines;
   f. Provide the ability to decrement inventory as a result of waste, loss, damage, or
      unaccounted for, as well as the ability to document the reason for the decrement;
   g. Provide the ability to create new lots or edit/update existing lots;
   h. Provide the ability to add/update inventory received from a shipment by the following
      methods:
         i. Manual entry from a packing list into system;
         ii. Uploading data from awardee shipment file (e.g., electronic NCIR
             shipment file); and
         iii. Scanning from barcode.
   i. Provide the ability to manually update all data fields including, but not limited to:
      i. the location from which the transfer was received; and
      ii. the reason for transfer.
      iii. the stock from which the vaccine was borrowed;
      iv. reason for borrowing; and
      v. plans for repaying the borrowed stock and estimated date.
   j. Automatically update inventory when doses of vaccine are administered
   k. When updating inventory due to waste/loss, allow a user to update all data fields,
      including the reason the vaccine was wasted/lost (e.g., damaged, expiration,
      mishandling, etc.).

4. The Order Vaccine function should:
   a. Provide the ability for a user to order public stock and private stock;
   b. Provide the ability for a user to place an order for stock;
   c. Provide the ability for a user to approve an order;
   d. Provide the ability to automatically or manually route an order for public stock to the
      appropriate external entity; and
   e. Provide the ability for a user to submit an order.

5. The system should provide the ability to Transfer Vaccines from one location to another,
   specifically:
a. The system should provide the option for a user to update the inventory and all fields when transferring vaccines between locations, including, but not limited to:
   i. the location from which the transfer was received;
   ii. the location to which the vaccine was sent; and
   iii. the reason for the transfer.

6. The Reconcile Inventory function should:
   a. Provide the ability to reconcile the inventory that is stored in the system with the physical inventory on-hand at the location;
   b. Provide the ability to print a worksheet for use when checking the physical inventory in the refrigerator;
   c. Provide the ability for the system to automatically calculate the difference between the system and physical inventories;
   d. Provide an indication where discrepancies occur; and
   e. Provide the ability to take action on the discrepancies and provide notes/reasons for the actions taken.

7. Help
   a. The system should include detailed user documentation that provides a complete functional representation of the system;
   b. The system should include common and user-accessible tools to help novice users learn basic system functionality quickly. Such tools may include, but are not limited to, frequently asked questions, desk guides, “How Do I” guides, start-up guides, quick reference cards, and other common tools.

The CNIADV usability team reviewed the information from the discovery and definition phase, the requirements above, and produced an initial design concept. Exhibit 18 presents a representative screen from initial design concept. Additional screens were included in the prototype to support usability test tasks for inventory management.
4.1.8 Obtain Input from Subject Matter Experts on Early Inventory Management Workflow Concepts

The next step in the UCD process was to conduct a web-based interview with a subject matter expert. This interview aided the team in identifying information needs and priorities for refining early immunization inventory management prototypes to be used in the first formative testing round. The subject matter expert provided opinions and answered questions related to vocabulary, functionality, experience with other products, and what information was needed and when (e.g., persistent on the screen, on mouse over, 1-click away, etc.) in order to make decisions related to what inventory management should be included in the prototype.

4.2 Conduct Inventory Management Workflow Formative Usability Test (Round 1)

This section describes the process used to conduct the first round of formative testing in the UCD process. Details can be found in the deliverable titled, Formal Deliverable 3B Round 1 Formative Usability Test – Inventory Management Findings and Planned Prototype Changes.
4.2.1 Objectives

The objectives of the first round of formative usability testing included:

- To understand user needs, issues, and opinions related to early design concepts for vaccine inventory management;
- To further define information needs and priorities that support decision making related to the management of vaccine inventory; and
- To use the findings to update design concepts and prototypes in support of a second round of formative testing.

4.2.2 Methods

We recruited two end user participants. Each was familiar with the vaccine inventory management procedures at their respective practices.

We used remote usability testing to conduct the interactive sessions. During the session, the participant sat at his/her computer, while the usability test team members sat at their computers. The participant viewed and interacted with the prototype application via WebEx, and the usability team members were able to observe these interactions in real time. Each session lasted 30 minutes.

In addition to collecting background information about each end user participant, the CNIADV usability team used a talk-aloud protocol and collected the following information related to the prototype wireframes:

- Participant impressions and reactions to concepts;
- Participant feedback, opinions, and preferences;
- Participant expressed needs for information display and priority; and
- Usability issues observed by the CNIADV team.

We did not collect any quantifiable measures (e.g., task times, number of clicks, etc.) for this formative test.

4.2.3 Findings

The CNIADV usability team analyzed the findings, referenced best practice user interface design principles, and brainstormed possible updates. Detailed findings and design decisions can be found in the Phase 3 deliverable titled, Formal Deliverable 3B Round 1 Formative Usability Test – Inventory Management Findings and Planned Prototype Changes. This section summarizes the findings and updates to the application prototypes.

4.2.3.1 Key Finding

Round 1 usability testing confirmed that the initial design concept is on the right path for supporting the information needs to manage inventory. Exhibit 19, inspired by the Usability Best Practice Catalog prototype, provides an example screen from the concept. The main screen lists immunization inventory, provides details for each vaccine, and allows the user to initiate actions (e.g., Add New Vaccine, Reconcile Inventory, and Generate Reports). Additional screens were included in the prototype to support the usability test tasks.
4.2.3.2 Information Priority

One objective of this round of usability testing was to define information needs and priorities that support decision making related to inventory management. The study confirmed that much of the information that participants needed was provided in the initial design concept. Sample learnings associated with detailed design of terminology and information needs include:

- Participants were confused by some terminology:
  - Confusion was associated with vaccine designators that did not match what is included in the federal vaccine list, trade names, and brand names.

- Additional Status options are needed to differentiate vaccine inventory:
  - Participants described needed options such as Not Yet Active for Use, Inactive Expired, Inactive Wasted.

- The column label, Quantity on Hand, was ambiguous:
  - Participants could not correctly determine if Quantity referred to quantity of doses, boxes, or some other unit.
The findings suggested that mouse over tool tips might be a viable interaction to aid the display of information:
- The current design introduced the use of mouse over tool tips as a means to provide additional details. Design changes will assure the information displayed in a mouse over tool tip is sufficiently detailed, concise, and adds value.

Information needs for adding and editing the vaccine details in inventory will require a relatively large amount of screen space:
- The results indicated the need for a large amount of screen space (dialog box vs. full screen form) and terminology confusion associated with several form fields.

4.2.3.3 User Interface Interactions
Findings related to user interface interactions include:
- Participants described the need to filter by Status to support the inventory review process.
- Inventory management includes complex data entry. Manual data entry should be avoided, the system should auto-populate when data are available and likely to be accurate.

4.2.3.4 Borrowing Vaccines from Different Inventory
One usability task collected feedback on user interface elements related to ordering, transferring, and borrowing vaccines from different inventory. Participants had strong and varying opinion about borrowing vaccines from different inventory. Some participants stated they would never borrow. Other participants stated they would borrow if the practice allowed them to do so. Additional policy guidance and user research is needed on the topic of borrowing vaccines from different inventory.

4.2.3.5 Changes to the Prototype
Based on the test findings, best practice user interface design principles, and design discussions, the team continued to move forward with the initial concept. we made detailed design changes to column headings, drop down options, and mouse over tool tips to make visual and functional improvements on the prototype application. We also added additional detail to the screens that support inventory reconciliation.

4.3 Conduct Inventory Management Workflow Formative Usability Test (Round 2)
This section describes the second round of formative testing in the UCD process (Round 2). Details can be found in the Phase 3 deliverable titled, Formal Deliverable 3B Round 1 Formative Usability Test – Inventory Management Findings and Planned Prototype Changes.

4.3.1 Objectives
Round 2 testing objectives included:
- Understand user needs, issues, and opinions related to early design concepts for vaccine inventory management;
Further define information needs and priorities that support decision making related to the management of vaccine inventory; and

- Identify needed changes to design concepts and prototypes in support of the third round of mock summative testing.

### 4.3.2 Methods

Six people participated in Round 2 of the usability testing. Each participant was an end user familiar with the vaccine inventory management procedures.

We used remote usability testing to conduct the interactive sessions. During the session, the participant sat at his/her computer, while the usability test team members sat at their computers. The participant viewed and interacted with the prototype application via WebEx, and the usability team members were able to observe these interactions in real time. Each session lasted 30 minutes.

In addition to collecting background information about each end user participant, the CNIADV usability team used a talk-aloud protocol and collected the following information related to the prototype wireframes:

- Participant impressions and reactions to concepts;
- Participant feedback, opinions, and preferences; and
- Usability issues observed by the CNIADV Team.

We did not collect quantifiable measures (e.g., task times, number of clicks, etc.) during this formative test.

### 4.3.3 Findings

The CNIADV usability team analyzed the findings, referenced best practice user interface design principles, and brainstormed possible updates. Detailed findings and design decisions can be found in the Phase 3 deliverable titled, Formal Deliverable 4B Round 2 Formative Usability Test – Inventory Management Findings and Planned Prototype Changes. This section summarizes the findings and updates to the application prototypes.

#### 4.3.3.1 Key Findings

The key findings from Round 2 testing confirmed that the inventory management design concepts in the prototype would support the tasks within the workflow. Participants expressed favorable views toward the prototype, and they stated that the prototype provided most of the information needed to conduct inventory management activities.

Exhibit 20 presents a sample screen from the inventory management concept as implemented in the prototype. The main screen lists immunization inventory, provides details for each vaccine, and allows the user to initiate actions (e.g., Add New Vaccine, Reconcile Inventory, and Generate Reports, etc.). Additional screens were included in the prototype to support the usability test tasks.
4.3.3.2 Information Priority

Sample learnings associated with the design of terminology and information needs include:

- **Missing information included par levels:**
  - Participants explained that par levels indicate the number of doses the facility typically keeps in stock. Participants need this information to aid decision making about replenishing stock.

- **Fields that caused confusion included the NDC field and On Hold fields:**
  - Participants were confused if the NDC field referred to the package NDC or the NDC + unit (e.g., vial NDC).
  - Participants were confused about the meaning of On Hold date and status fields.

- **Mouse over tool tips successfully provided additional information to participants:**
  - The concept relies heavily on mouse over tool tips to provide additional information to users. Attention to this approach needs to investigate the benefits and trade-offs of this approach.

4.3.3.3 User Interface Interactions

Findings related to user interface interactions include:

- **Participants described the need to filter on status to support the inventory review process.**
- **Inventory management includes complex data entry.**
  - Bar code functionality should be considered as a design solution for manual data entry with system auto-populate functionality.
4.3.3.4 Borrowing Vaccines from Different Inventory
Borrowing vaccines from different inventory continued to be an area where participants expressed strong and varying opinion about borrowing vaccines from different inventory. Additional policy guidance and user research is needed on the topic of borrowing vaccines from different inventory.

4.3.3.5 Changes to the Prototype
Based on the usability test findings, best practice user interface design principles, and design discussions, the CNIADV team continued to move forward with the initial concept. We made several detailed design changes to specific fields, as well as to mouse over tool tips aimed at improving discoverability of features, clarifying terminology, and making visual and functional improvements on the prototype application.

4.4 Conduct Inventory Management Workflow Mock Summative Usability Test (Round 3)
This section describes the third round of usability testing, which was a mock summative usability test. We consider this a “mock” summative usability test because some best practices were excluded. Primarily, the number of participants who completed the test sessions was significantly fewer than the recommended number of 15 to 20 per user group. Details of the mock summative usability test can be found in the Phase 3 deliverable titled, Formal Deliverable 5B Round 3 Mock Summative Usability Test – Inventory Management.

4.4.1 Objectives
We conducted the test with a smaller number of participants to:

(1) illustrate differences in the planning and execution of a summative test compared to a formative test;
(2) highlight the differences in the artifacts (e.g., test plan, moderator guide, report) associated with a summative test;
(3) provide examples of types of tasks and questions that might be included in the summative test; and
(4) provide examples of objective and subjective usability metrics that might be collected as part of an immunization specific summative test.

The primary purpose of an actual summative usability test is to provide objective evidence that the product’s clinical user interfaces can be used in a safe, efficient, and effective manner. In addition, a summative test validates whether usability goals have been achieved.

4.4.2 Methods
Four (4) nurses and one (1) information technology manager participated in the usability tests. The nurses are current medical practitioners who performed the relevant immunization workflows. The information technology manager works at a pediatrics practice and is also familiar with the relevant immunization workflows. Each participant performed simulated but representative tasks specific to their user role.
We used remote usability testing to conduct the interactive sessions. During the session, the participant sat at his/her computer, while the usability test team members sat at their computers. The participant viewed and interacted with the prototype application via WebEx, and the usability team members were able to observe these interactions in real time. Each session lasted 30 minutes.

In addition to collecting background information about each end user participant, the CNIADV usability team collected performance data on tasks and subtasks typically conducted with the system. We created and mapped the tasks to the following immunization workflow:

- Using the inventory management functionality to manage vaccine inventory.

Specific study tasks were constructed that would be realistic and representative of activities a nurse might complete using an EHR with immunization functionality, including:

- Vaccine stock assessment;
- Indicate unavailable vaccines;
- Indicate single dose NDC for DAPTACEL;
- Correct DAPTACEL information;
- Navigate to inventory reconciliation screen;
- Enter inventory count;
- Identify the visual indicator of the discrepancy; and
- Fix the discrepancy between physical count and system count and update the inventory.

We selected tasks based on their frequency of use, criticality of function, and those that may be most troublesome for users.

4.4.2.1 Study Procedure

The test moderator introduced the test and instructed participants to complete a series of tasks (given one at a time) using the system. During the session, the test moderator and data logger recorded user performance data on paper and electronically. The test moderator did not instruct the participant about how to complete the task unless the participant stated that s/he was done with the task, asked for help, or was not making progress to complete the task after 60 seconds. If the test moderator determined the participant could accomplish the task in a reasonable amount of time despite a stoppage in progression, s/he would grant 30 additional seconds before providing assistance. The session (including what was showing on the screen and the voice conversation) was recorded for subsequent analysis.

4.4.2.2 Usability Metrics

The following types of data were collected for each participant:

- Effectiveness
- Percentage of tasks successfully completed within the allotted time without assistance (Pass)
- Percentage of task failures (Fail)
- Types of errors
- Efficiency
- Task Time
- Types of errors
- System Satisfaction
- Participant’s satisfaction rating of the system (as indicated with the System Usability Scale [SUS] score)
- Participant’s verbalizations (e.g., comments)

### 4.4.2.3 DATA SCORING

Exhibit 21 details how we scored tasks and evaluated errors.

<table>
<thead>
<tr>
<th>Data Measures</th>
<th>Rationale and Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task Success</td>
<td>• A task was counted as a “Pass” if the participant was able to achieve the correct outcome, without assistance.</td>
</tr>
<tr>
<td>Task Failures</td>
<td>• A task was counted as “Fail” if the participant abandoned the task, did not complete the task goal, or needed at least one assist from the moderator. • Failed tasks were discussed with participants at the end of each task. • An enumeration of usage errors and usage error types was collected to help better understand the source of the usage errors and possible mitigations.</td>
</tr>
<tr>
<td>Task Time</td>
<td>• Task times were collected. • In this study, task time was taken with the time on an iPhone. Minutes were recorded with paper/pen. Task time started when the moderator instructed the participant he/she could begin the task whenever he/she was ready. Task time ended when the participant said “Done” or the participant completed a task and did not say “Done” but exhibited a behavior indicating “Done” and the moderator confirmed by asking, “Are you done?”</td>
</tr>
<tr>
<td>SUS Scores</td>
<td>• To measure participants’ satisfaction with the system, the usability team administered the System Usability Scale (SUS) post-test questionnaire. The SUS is a reliable and valid measure of system satisfaction. • In order to access system level satisfaction – as opposed to feature level satisfaction and as in common practice with the use of the SUS – we administered the questionnaire at the end of the tasks. See Appendix 3 – System Usability Scale Questionnaire.</td>
</tr>
</tbody>
</table>
4.4.3 Description of Application Prototype

Exhibit 22 provides a representative screen shot of the design concept evaluated during the mock summative usability test. The concept was inspired by the Usability Best Practice Catalog prototype and updated based on the two iterations in this UCD process. Screens to support tasks (e.g., Add New Vaccine, Reconcile Inventory, etc.) were included in the prototype. In the screen below, the first column identifies the specific vaccine. The main screen lists immunization inventory, provides details for each vaccine, and allows the user to initiate actions (e.g., Add New Vaccine, Reconcile Inventory, and Generate Reports).

Exhibit 23. Representative Screen from the Design Concept Tested in the Mock Summative Test

![Screen Shot of Design Concept](image)

4.4.4 Data Analysis

We calculated the results of the mock usability test according to the methods specified in the section of this document titled, 3.4.2.2 Data Scoring. The results are meant to serve as an example of reporting usability performance data. Readers should recognize the difference in the quantitative data from Round 3 summative usability testing reported in this section and the qualitative data from Rounds 1 and 2 formative usability testing reported earlier in this document.

Exhibit 23 presents the usability test results for each subtask. The results should be viewed in light of the objectives and goals for this test.
Exhibit 24. Usability Test Results for the Vaccine Stock Assessment Task

<table>
<thead>
<tr>
<th>Task</th>
<th>Number Attempting Task</th>
<th>Percent Pass</th>
<th>Percent Fail</th>
<th>Mean Task Time (sec)</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on the information presented on this screen, assess whether you need to order any vaccine stock</td>
<td>5</td>
<td>80%</td>
<td>20%</td>
<td>28.4</td>
<td>22.1</td>
</tr>
<tr>
<td>Indicate which of the vaccines listed here are not available for administration to patients</td>
<td>5</td>
<td>40%</td>
<td>60%</td>
<td>12.6</td>
<td>12.6</td>
</tr>
<tr>
<td>Indicate the single dose NDC code for DAPTACEL</td>
<td>5</td>
<td>20%</td>
<td>80%</td>
<td>27.8</td>
<td>43.4</td>
</tr>
<tr>
<td>For DAPTACEL, change the lot number to U1181AC and change the expiration date to 10/22/2016</td>
<td>5</td>
<td>100%</td>
<td>0%</td>
<td>59.6</td>
<td>31.8</td>
</tr>
<tr>
<td>Navigate to the Inventory Reconciliation screen</td>
<td>5</td>
<td>100%</td>
<td>0%</td>
<td>3.2</td>
<td>1.8</td>
</tr>
<tr>
<td>Enter a value of 18 into the system for DAPTACEL</td>
<td>5</td>
<td>100%</td>
<td>0%</td>
<td>5.4</td>
<td>5.5</td>
</tr>
<tr>
<td>Identify the visual indicator of the discrepancy</td>
<td>5</td>
<td>100%</td>
<td>0%</td>
<td>25.4</td>
<td>7.2</td>
</tr>
<tr>
<td>Fix the discrepancy between physical count and system count and update the inventory</td>
<td>5</td>
<td>20%</td>
<td>80%</td>
<td>89.4</td>
<td>57.1</td>
</tr>
</tbody>
</table>

4.4.4.1 System Usability Scale (SUS)

Four (4) nurses and one (1) Information Technology Manager completed the SUS questionnaire. The SUS is a reliable and valid measure of system satisfaction. Sauro (http://www.measuringusability.com/sus.php, accessed August 22, 21016) reports an average SUS score of 68 – this is from 500 studies across various products (e.g., websites, cell phones, enterprise systems) and across different industries. A SUS score above a 68 is considered above average and anything below 68 is below average. The CNIADV team encourages teams not to focus on the comparison to the cross industry average SUS of 68 reported by Sauro. Instead, we encourage teams to use the SUS as a measure to compare their own usability improvement in the application as changes are made.

The inventory management system scored an average of 73.0 (SD=8.6) based on 5 responses.

4.4.5 Findings and Areas for Improvement

Critical errors and inefficiencies were observed during the mock summative usability test. These areas highlight areas that should receive attention during the design and development of immunization reconciliation function. Observed use errors and possible mitigations include:

Exhibit 25. Immunization Reconciliation Usability Findings and Mitigation Strategies

<table>
<thead>
<tr>
<th>Critical Error</th>
<th>Mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Unable to interpret vaccines</td>
</tr>
<tr>
<td>Critical Error</td>
<td>Mitigation</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>representing the same dose in a series</td>
<td>vaccine in a row is from the same dose in a series.</td>
</tr>
<tr>
<td>2 Unable to understand the term “On Hold” as an indicator that the vaccine</td>
<td>• Include a warning in a mouse-over pop-up (e.g., Do Not Administer to</td>
</tr>
<tr>
<td>should not be administered to patients.</td>
<td>Patients).</td>
</tr>
<tr>
<td>3 Inadequate understanding of NDC code on the main inventory screen</td>
<td>• Include the word “Package” before the NDC code on the main inventory</td>
</tr>
<tr>
<td>(i.e., the NDC code for the package or the NDC code for the single dose).</td>
<td>screen.</td>
</tr>
<tr>
<td>4 Failure to click the “Reconcile” button to assure the physical count of</td>
<td>• Include a mouse-over explaining the purpose of the reconcile function.</td>
</tr>
<tr>
<td>vaccines on hand matches the information in the computer system.</td>
<td></td>
</tr>
<tr>
<td>5 Failure to click “Update Inventory” button as the last step in reconciling</td>
<td>• Include a warning prompt if the user attempts to leave the page without</td>
</tr>
<tr>
<td>inventory.</td>
<td>updating the inventory (e.g., “Did you forget to click Update Inventory?).</td>
</tr>
<tr>
<td>6 Inadequate understanding of positive and negative indicators for numbers in</td>
<td>• Limit participant ability to edit the Adjust function, or</td>
</tr>
<tr>
<td>the Adjust function (i.e., Adjust from -1 to 1).</td>
<td>• Include a pop-up prompt to indicate exactly what is being adjusted (e.g.,</td>
</tr>
<tr>
<td></td>
<td>physical count or doses on hand).</td>
</tr>
<tr>
<td>7 Failure to add a reason in the reason field when changing the status of a</td>
<td>• Include a warning that entering a reason is required before exiting the</td>
</tr>
<tr>
<td>vaccine.</td>
<td>screen.</td>
</tr>
</tbody>
</table>

5 COMBINED LESSONS LEARNED

Throughout Phase 3, learnings surfaced that may interest immunization reconciliation stakeholders. These learnings inform design and development by highlighting areas needing special attention and/or highlighting areas for further research. They inform buyers of health IT applications by highlighting differences in user interface screen flow that might impact workflow. Finally, learnings inform policy makers by highlighting areas critical for safe, effective, and efficient immunization functionality in health IT applications. This section highlights these learnings for each workflow.

5.1 Immunization Reconciliation Learnings

When building a health IT application to support immunization reconciliation, teams are solving problems grounded in cognitive activity. A solution to these problems must therefore optimize workflow design, data visualization, and support of cognitive work related to immunization reconciliation. Cognitive activities associated with immunization reconciliation include:

- Identify – users recognize the need for reconciliation;
- Gather – users assimilate immunization information from different sources (In-State IIS, Out-of-State IIS, parent, etc.);
- Match – users associate entries from multiple sources with other like entries;
- Compare – users compare and contrast details from like entries
- Decide – users decide which information to record in the EHR;
- Act – users take action through the user interface elements carry out their decisions (accept and/or reject information from external sources);
- Confirm – users review and confirm actions for accuracy; and
- Save – users commit select immunization information from external sources into a patient’s health record.

Optimizing a solution to support the cognitive activities means designing a solution in which the computer handles the kinds of sub-tasks that computers are good at, while the clinician handles sub-tasks that humans are good at. The health IT application should always present information to the user that is reliable, current, and pertinent to the specific cognitive task being performed, and the Health IT application should update immediately when users commit a change.

5.2 Twinlist Influences

The initial designs for the immunization reconciliation user interface were inspired by a medication reconciliation prototype called Twinlist, which was developed at the Human-Computer Interaction Lab based at the University of Maryland (Markowitz, Powsner, & Schneiderman, 2013). Twinlist is an evidence-backed interface for reconciling medication lists. Details about its operation can be found in Markowitz et al., 2013. The immunization reconciliation interface developed during the first two rounds of formative usability testing used many of the Twinlist model features. The following list describes features shared between the immunization reconciliation design concept and Twinlist:

- A table-style presentation of multiple lists of information meant to optimize visual scanning;
- Display of limited information related to listed items meant to optimize visual scanning;
- Highlighted items which are similar yet differ between lists meant to help users match and compare vaccine entry similarities and differences;
- Color changes accompanying item selections meant to help users review and confirm their actions;
- The ability to reset the entire screen of selections meant to support recovery for errors and changes during decision making; and
- A finalized list screen that helps users review and confirm their actions.

There are elements of Twinlist which the CNIADV team chose not include during formative testing:

- Initial display of immunizations in a single list of immunizations from multiple sources; and
- Animation.

The CNIADV team concluded these elements did not add value to the immunization reconciliation workflow. Twinlist begins with the display of medications in a single list (medications documented in the EHR and medications from other sources). The immunization
Workflow prototype begins with the display of immunizations in multiple columns. Each column represents immunizations from different source of information.

Animation is a central element of Twinlist used to communicate and aid visualization of the single list of medications being sorted in multiple columns. Animation does not provide the same cognitive support for the multiple lists in the immunization reconciliation interface. Additionally, the CNIADV team concluded that animations would contribute to user frustration during the immunization workflow supported in our concepts. Twinlist animations take several seconds. As images on the screen change to give the appearance of movement, the user must wait for the duration of the animation before executing his/her next action. For this reason, animations should only be used when the animation value outweighs the time lost while observing or waiting for the animation to complete. The CNIADV team concluded that the value of immunization reconciliation interface animations did not outweigh the lost time, and animation was therefore not included in the user interface.

5.3 Twinlist Similarity Grouping vs. CNIADV Grouping by Vaccine

In a comparison of a reconciliation screen organized by similarity (see Exhibit 24) versus a reconciliation screen organized by vaccine name (see Exhibit 25), the findings showed that participants preferred using the reconciliation screen organized by vaccine name (see Exhibit 25). No difference was observed in performance.

Exhibit 24, the Similarity Concept, was inspired by the TwinList reconciliation prototype. The first column identifies the degree of similarity (e.g., Identical, Similar, Unique) of the vaccines. The additional columns indicate the different sources of information (e.g., EHR, In-State IIS, Out-of-State IIS, and Parent). Hep B vaccines grouped as Identical share all the same vaccine details (e.g., same administration date, location, etc.). Hep B vaccines grouped as Similar share some but not all vaccine details.
Exhibit 26, the Representative Screen from Immunization Reconciliation Similarity Concept

### Exhibit 26. Representative Screen from Immunization Reconciliation Similarity Concept

<table>
<thead>
<tr>
<th>Grouping</th>
<th>EHR</th>
<th>In-State IIS</th>
<th>Out-of-State IIS</th>
<th>Parent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identical</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTPaP</td>
<td>Administered 03/10/2010 Location – San Fran PG</td>
<td>DTPaP</td>
<td>Administered 03/10/2010 Location – San Fran PG</td>
<td></td>
</tr>
<tr>
<td><strong>Similar</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hib</td>
<td>Administered 03/10/2010 Location – San Fran PG Reaction – Febrile Seizure</td>
<td>Hib</td>
<td>Administered March 2010 Location – San Fran PG</td>
<td>Hib</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pneumococcal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Unique</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Poliovirus</td>
</tr>
</tbody>
</table>

Exhibit 25, the Traditional Concept, was inspired by the CDC Forecast layout. The first column identifies the specific vaccine. Sub-rows of a vaccine represent administrations of the vaccine in the series. Hep B has two sub-rows. The first row is associated with the first Hep B administration in the series. The second row is associated with the second Hep B administration in the series. Each column provides the vaccine details for different sources (e.g., EHR, In-State IIS, Out-of-State IIS, Parent).
The small sample size in each round of testing is a limitation of our studies. In addition, our project was aimed at demonstrating a process. During team discussions, our team hypothesized that participant preferences for the Traditional Concept may be influenced by a clinician’s familiarity with this specific layout. Teams should conduct additional research comparing similarity grouping versus grouping by vaccine to understand each layout and its actual impact, if any, on the immunization reconciliation workflow.

### 5.4 Horizontal vs. Vertical Layout

During Phase 2 of this project (Phase 2: FD-4- EHR Clinical Software Assessment), the CNIADV team observed demonstrations of twelve vendor products with high market share to determine immunization-related function and identify aspects important to usability. We observed two alternative layouts for the information on the Reconciliation Screen: a reconciliation screen organized in a horizontal layout (see Exhibit 26) and a reconciliation screen organized in a vertical layout (see Exhibit 27).

The findings during our Round 2 testing did not strongly support one approach over another. Thus, the team decided to continue with the Twinlist-inspired approach that uses side-by-side comparison.

Exhibit 26 illustrates the horizontal layout (inspired by the Traditional Concept from Round 1). The first column identifies the specific vaccine. Each column (horizontally across the page) provides the vaccine details for different sources (e.g., in the EHR, from the In-State IIS). Differences in vaccine details between different sources are compared by reviewing information side-by-side.
Exhibit 28. Representative Screen from Immunization Reconciliation Horizontal Layout

Exhibit 27, the vertical layout, presents each vaccine by source in a different row. Rows are grouped based on the amount of information in the external source vaccine matching the information in the EHR. The lighter rows – which also have circles in them – are new information coming from an external source. Differences in vaccine details between different sources are compared by reviewing information vertically up and down the screen.
Our results did not strongly support one approach over another. A limitation of our study is that we utilized relatively simple vaccine elements. We did not investigate a use case involving a complex immunization series; nor did we include a use case representing a patient with a complex clinical history. Teams should conduct additional research to fully understand the trade-offs of these alternative layouts might have on the immunization reconciliation process.

5.5 Partial Vaccine Information Reconciliation

Feedback indicated that participants expected to be able to add an individual piece of information from a vaccine from an external source, rather than accepting all the information from the external source. Providing this functionality calls for investigating the best way to display additional details so that users can easily compare, decide and act on immunization details. Exhibit 28 provides an example screen we used for primary investigation of this issue. Additional user research is needed.
5.6 Data Exchange

An important area for investigation during the design and development of an immunization reconciliation feature relates to data exchange. Two questions that arose during our UCD process were:

1. How will the system ensure that data that has been reconciled does not require reconciliation every time the immunizations are reconciled for the patient?
2. How will the EHR handle data from an external source that is not recognized by the EHR?

Participants described some cases when they had to re-reconcile specific entries in the EHR’s Immunization List. The issue seems to be that during the information exchange with the registry, the registry does not accept an updated entry. During the next exchange from the registry to the EHR, a previously reconciled immunization list is overwritten with what the user considers to be out of date immunization detail. Thus, the user must re-reconcile the specific immunization entry. The goal of the system should be to maintain the integrity of the immunization data during exchanges with each entity (e.g., registry, external clinical source, pharmacy, etc.).

During information exchange between health IT systems, there will be situations where information from one system is not compatible with the receiving system. Some of the questions about this issue that we experienced during our UCD process include:

- What if an immunization and its associated detail is transmitted from one health IT system and the receiving system cannot display the information because of data incompatibility? As an example, the sending system includes a vaccine in its database but the receiving system’s vaccine database does not include that vaccine.
What if an immunization detail is coded in such a way that the receiving system does not have corresponding way to display that detail? For example, one health IT system codes the Status as Active/Inactive. In the receiving system Status options are coded as In Progress/Discontinued. The receiving system does not know how to display Status because the data field mapping is incomplete.

During our UCD process some vendors described that they were dealing with this data incompatibility issue with medications and these vendors anticipate similar issues with immunizations.

EHR design and development teams should explore how to handle these potential but rare conditions. As part of the exploration, teams should consider that the user needs to be notified when information is available with which the system is having issue, present the information that the system can receive and display, indicate the specific information at issue, and provide a means for the user to manipulate the information so as to make the information meaningful and allow the user to record and/or reject the information from being saved in the EHR.

### 5.7 Inventory Management Learnings

When building a feature to support inventory management, teams are solving a complex system problem. Inventory management involves real-time communication between multiple systems (IIS, VTrckS, Manufacturer Ordering Site, and EHR), and between stakeholders with competing priorities and objectives. Optimizing the usability of an inventory management feature for one system can result in reduced usability of the feature in another system. Additionally, although the usability of screen-level support for inventory management tasks completed in the EHR plays a role in the design of the feature, task support is only a small piece of the system problem. Also, focusing on screen-level task support would have a correspondingly small impact on the overall effectiveness of an inventory management system. A primary learning of our UCD process is that building an effective inventory management system means prioritizing a solution that ensures data integrity in the communications between stakeholders, while negotiating differences between stakeholder systems, priorities, and objectives.

We started our UCD process for a vaccine inventory management with the assumption that practices use an EHR for immunization ordering and that practices ordered vaccine from two sources: vaccine manufacturers (Private) and government agencies (Public). We also assumed Private and Public inventory were stored separately at the practice. With this in mind, the focus of the UCD process was to inform the following activities:

- Coordinate the inventory information with that required for the ExIS² system, which conceptually addressed the two sources of vaccines;

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² The Centers for Disease Control and Prevention Vaccine Tracking system (VTrckS) ExIS (External Information System) interface is a means for guarantee program awardees to process vaccine requests by uploading data from their Immunization Information System (IIS) to VTrckS. ExIS systems allow providers to manually enter vaccine inventory receipt and usage online. Information is available at: [http://www.cdc.gov/vaccines/programs/vtrcks/topics/exis.html](http://www.cdc.gov/vaccines/programs/vtrcks/topics/exis.html).
- Provide guidance for managing guarantee program and private stock; and
- Inform how the EHR can enable providers to easily order appropriate vaccines for a given patient (e.g., based on eligibility) from on-hand inventory, document administered vaccines, and automatically decrement inventory when documented.

However, as the design process went forward, feedback from inventory management stakeholders indicated that the interplay between the ExIS system and the ordering system differed from practice to practice. This led to bigger ‘integration’ and ‘interoperability’ questions that were beyond the scope of our project, but clearly are critical in supporting the workflow. Throughout our process, these integration and interoperability questions persisted and lead us to conclude that our key learning is not about screen-level usability in an EHR inventory management feature. Rather, our key learning is that there is a need to bring all inventory management stakeholders together and focus on a system-level approach to inventory management that optimizes data integrity.

5.8 Management of Public and Private Vaccines

Based on our initial assumptions regarding the management of public and private stock, our initial wireframe designs were inspired by the team’s research in the area of Public vaccine management. A specific design decision was to separate the user interface associated with managing public stock from the user interface associated with private stock. In addition, the team’s initial thinking was that Public and Private vaccine reconciliation were done separately. Participants comments generally did not support this separation.

As part of the design for management public and private stock, we solicited feedback on the idea of borrowing. That is, a patient who is eligible for an immunization from public stock arrives for a doctor’s appointment. When it comes time to retrieve and administer the immunization from the refrigerator, the particular immunization is not available in the public stock. However, the participant immunization is in the available private inventory. The inventory management prototype included screens to support documenting borrowing and later retuning immunizations between private and public stock.

Some participants stated that borrowing between private and public stock is never allowed. Some participants stated that borrowing between private and public stock occurs. The team explored the user interface functionality around borrowing in order to elicit feedback but did not prioritize this feature. Our learning in this area is that further investigation is needed to inform policy and best practice, as well as to support the detailed design of the user interface. A question of interest to the team is: would accountability and traceability in the EHR (or other) system impact the acceptance of this practice (within limits) to support patient care?

5.9 Inventory Management Integrated into EHRs

Several questions arose during this project about how the ordering of the vaccines occurred and in what system (e.g., the practice’s EHR, a manufacturer’s ordering application, VTrckS, etc.) The use of different ordering systems led to questions regarding ‘integration’ and ‘interoperability’. Similar questions arose about inventory reconciliation and shat system inventory reconciliation takes place. Participant feedback was fairly consistent and the
expectation is that users expect to access all features related to ordering and reconciling inventory to be in one software user interface, and do not expect to use multiple systems. Participants expected this single software user interface to be the EHR.

5.10 Updating EHR System with User Adjustments

The UCD process focused on inventory reconciliation functionality native to the EHR. During the project, we learned of inventory reconciliation functionality not native to the EHR. As we explored these, we identified differences in how systems handle updating information associated with quantity on hand. Some systems update dynamically. That is, they use ‘real-time’ updates to the EHR’s inventory data as soon as a user recorded changes to a specific immunization through the inventory management functionality (i.e., a user counts the number of vials in the refrigerator then types and saves that number into the inventory management screen and that quantity is immediately reflected throughout the system). Dynamic updating also is associated with documenting administration of a vaccine (i.e., a vaccine is administered to the patient and recorded in the EHR, then an updated quantity for that immunization category is immediately reflected throughout the system.)

An alternative approach is pausing the system during key time periods. In this approach, the data presented to the user were kept static/paused during inventory reconciliation. The user would “pause” the system, begin the inventory reconciliation task, and make adjustments to several, if not all, of the vaccines based on counting doses on hand. Once the user completed updates to these quantities, the user would click a Submit Inventory button, which un-pauses the system and the quantity for that immunization category is reflected throughout the system.

Our UCD process revealed a situation where when the participant reconciles private stock, the system operated under the “pause” approach. However, when the participant reconciles public stock the system operated under the “dynamic approach. An effective and efficient system would be consistent and operate under one of these approaches, not both. This observation provides a glimpse into the complexity of the system.

5.11 Additional Questions and Issues for Consideration

The CNIADV team identified a number of other questions and issues that should be considered when developing standards, guidance, and systems to support immunizations inventory management workflows.

1. What are the standard terms to reflect “public” and “private” vaccine inventory?
2. Should CVX code be added for vaccines?
3. Which NDC codes should be shown to the user; Package and/or unit NDC?
4. Use cases for single unit vs. package NDC codes should be clearly defined.
5. The federal vaccine list appears to change quite frequently. Given this, how will the list data be updated in the EHR system?
6. Interoperability efforts should address the use of electronic data exchange (e.g., in real time, with file downloads, etc.) between vaccine vendors and end user systems (e.g.,
EHR products). This will reduce the need for manual addition of inventory information into the end-user system.

7. Some participants clearly stated that borrowing between private and public stock is not allowed. The team explored user interface functionality around borrowing in order to elicit feedback, but did not prioritize this feature. Would accountability and traceability in the EHR (or other) system impact the acceptance of this practice (within limits) to support patient care?

8. Systems should provide decision support to aid end users in making decisions about when to order vaccines based on factors such as usage rate, scheduled patient load, seasonal influences, etc.

9. Use cases, details, and constraints for Transfer and Borrow workflows need to be further defined for both publicly- and privately-funded vaccines.

10. Additional options will be required to capture all possible categories for adjusting inventory (e.g., during reconciliation and non-reconciliation workflows). A standard set is required to support interoperability.
6 REFERENCES

6.1 Reconciliation References


6.2 Immunization Inventory Management References

- References available from the American Immunization Registry Association (AIRA) at [http://www.immregistries.org/search?query=inventory&x=0&y=0]:
  - North Dakota IIS Vaccine Ordering and Inventory Management
  - AIRA Inventory Webinar Slides
  - AIRA MIROW Chapter 6 (Inventory Management) Mini Guide
  - IIS Deduct from Inventory Functionality
  - IL – VFC Inventory in IIS
  - Janet Fath_AIRA IIS September 2012 v5
  - KS – Reconciling Inventory
  - Terri Adams_MIROW Inventory Management presentation for the 2012 AIRA Meeting

- Discussions with Amy Stone (User Experience) regarding ExIS work to inform the workflow; 29February2016 ExIS presentation: [http://www.immregistries.org/events/past-events/webinars/ExISPresentationFinal.pdf](http://www.immregistries.org/events/past-events/webinars/ExISPresentationFinal.pdf).