AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era



Decrementing Inventory via Electronic Data Exchange

Recommendations of the
American Immunization Registry Association (AIRA)
Modeling of Immunization Registry Operations Work Group (MIROW)

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Disclaimer:

This guide is not a mandatory requirements or standards document. It contains a set of guidelines that are recommended operational best practices for immunization information systems.

Executive Summary

Background

The American Immunization Registry Association (AIRA), in partnership with the National Center for Immunization and Respiratory Diseases (NCIRD) at the Centers for Disease Control and Prevention (CDC), formed the Modeling of Immunization Registry Operations Workgroup (MIROW) in 2005 to develop best practice guidance for immunization information systems (IIS). This document is one chapter of the guidebook produced by the workgroup. It provides consensus-based best practice recommendations to support the process of decrementing inventory via electronic data exchange.

IIS Functional Standard 2.3 requires that "the IIS vaccine inventory function automatically decrements as vaccine doses are recorded" [2.1, p.4]. This guide presents best practice recommendations to automate and standardize the process of decrementing a provider organization's vaccine inventory in an IIS via electronic data exchange between the provider organization and the IIS. This document refers to the process as decrementing inventory via electronic data exchange (DI-v-EDE).

Relevance

DI-v-EDE assists immunization programs in maintaining accurate information about provider vaccine inventories, and assists provider organizations in meeting awardee immunization program operational requirements (e.g., vaccine accountability).

The demand for DI-v-EDE by immunization providers has grown with the implementation of Meaningful Use Electronic Health Records (EHR) Incentive Programs (MU) [2.2] and requirements for more accountability in the use of publicly-funded vaccine. MU requires that provider organizations transmit data to an IIS electronically. Provider organizations prefer to use the same electronic data exchange to manage inventory in the IIS rather than managing inventory in the IIS via direct user interface (UI). Advances in electronic data exchanges between immunization provider organizations and IIS make development of this guide timely.

Overview

The DI-v-EDE process is an automated method of decrementing the number of vaccine doses in a provider organization's inventory in the IIS when the organization reports a vaccination event through electronic data exchange from an EHR to the IIS. Each provider organization's vaccine inventory is categorized based on funding indicators. To deduct a vaccine dose from the appropriate stock, the IIS compares vaccination event information that the provider organization submits with the information the IIS has on that provider organization's inventory. The IIS uses data elements such as lot number, lot number expiration date, dose-level eligibility, lot-level public/private indicator, and in some cases, dose-level public/private indicator to match inventory.

The guidelines address the following aspects of DI-v-EDE:

- Fundamentals, including key concepts and principles that provide high-level direction.
- Detailed description of the process.
- Business rules, including the data that must be available from the EHR and in the IIS and how to use the data to decrement inventory.
- Explanation of preapproval and ongoing maintenance processes.
- Typical and challenging operational scenarios applying the guidelines to real situations.
- Discussion of key implementation considerations: key data elements, data quality, Health Level 7 (HL7) immunization messaging, EHR considerations, outreach and education, staff time, and resources.
- Description of reports to assist provider organizations and immunization programs.

Key outcomes and accomplishments

The guidelines discuss key concepts in DI-v-EDE:

- Fund type. Fund type describes the program (or private payer) that paid for a vaccine dose.
- Vaccine storage model. Storage model describes the way vaccine stocks are physically separated from each other in the provider organization's storage unit (e.g., refrigerator, freezer) to achieve better accountability for each dose.

- Dose-level eligibility. Dose-level eligibility describes a patient's eligibility for a funding program; it is determined for each dose administered. Dose-level eligibility reported by a provider organization to an IIS may also serve as a proxy for dose-level public/private indicator or fund type.
- Dose-level public/private indicator. Dose-level public/private indicator is an aggregated reflection of fund type at the vaccine dose-level. It indicates if a provider organization stores a vaccine dose in a public or private stock. Provider organizations assign the dose-level public/private indicator for each administered vaccine dose based on the stock that the particular vaccine dose was pulled from in the provider organization's storage unit. The provider organization's EHR transmits dose-level public/private indicator to the IIS through an EDE if the information is available in the EHR. The term "dose-level public/private indicator" corresponds to the term "funding source" in HL7.
- Lot-level public/private indicator. Lot-level public/private indicator is an aggregated reflection of fund type at the vaccine lot-level. It indicates if vaccine doses with a given lot number are associated with publicly-funded or privately-funded inventory in the IIS. The IIS assigns lot-level public/private indicator. Provider organizations do not transmit these indicators through an EDE.

The guidelines document recommendations using a detailed step-by-step description of the DI-v-EDE process, 26 business rules (representing specific requirements and decision-making logic for IIS processes and operations), nine principles (high-level business rules that help to capture institutional knowledge and to guide the development of more specific business rules), three decision tables, seven reports, and 27 operational scenarios. In addition, the recommendations provide guidance for preapproval and maintenance of provider organizations for DI-v-EDE and implementation considerations, including discussions of key data elements, data quality, and EHR and HL7 considerations.

The following are examples of best practice recommendations in the guidelines:

- The IIS should establish and maintain a preapproval process and provider organization education for DI-v-EDE. A provider organization must be preapproved for DI-v-EDE. P03, BR402, BR403, BR404, BR407
- The IIS should download shipment files from the ordering system (e.g., the federal Vaccine Tracking System [VTrckS]) and upload them into the IIS daily to prepopulate provider organizations' inventory in the IIS. BR102, BR103, BR104
- The IIS should organize a provider organization's inventory by lot number, lot number expiration date, and lot-level public/private indicator. BR101
- A provider organization should verify the physical contents of a shipment against the packing slip (shipping manifest) and the information in the IIS and notify the immunization program and the IIS of any discrepancy. BR105, BR106
- Provider organization submissions to the IIS should include the following data elements to support DI-v-EDE: lot number, dose-level eligibility, dose-level public/private indicator (optional for DI-v-EDE), vaccination event date, CVX code, National Drug Code ([NDC] is optional for DI-v-EDE), provider organization IIS ID, and lot number expiration date. BR202
- The IIS should only decrement active inventory for administered (not historical) immunizations. BR203, BR204
- When an inventory reconciliation is closed, the IIS should freeze the results. Reconciliations should only be opened and inventory adjusted manually by IIS staff who have elevated privileges. BR205, BR302
- Throughout the DI-v-EDE process, the IIS should document and communicate data quality issues and assist provider organizations in resolving data quality issues. Chapter 6: Reports, P08, BR301

The guidelines contain descriptions of recommended reports to support the process of DI-v-EDE for both provider organizations and awardee immunization programs. It is important that IIS have the ability to generate reports for provider organizations to alert them of needed inventory corrections, since some EHR vendors may not give provider organizations access to the information received from the IIS.

Conclusion

MIROW brought together experts from the IIS community, CDC, and IT vendors. The resulting best practices guide is a step in aligning DI-v-EDE practices across IIS. The recommendations are intended for implementation at the business/operational level. As a result, they are independent from specific IIS implementations and technology solutions. Accordingly, the recommendations can support the wide variety of IIS implementation strategies on different technological platforms.

The National Vaccine Advisory Committee (NVAC) recommended that the IIS community "promote the adoption of a guidebook and best practices for IIS as stated by the CDC/NIP [now NCIRD] and AIRA/MIROW Workgroup to adopt consistent operational guidance and quality control procedures that ensure good data quality." This best practices guide is one example of addressing the NVAC recommendation. It is designed to assist IIS in aligning practices through adherence to a set of common recommendations and guidelines. As a result, IIS will be able to better serve the needs of immunization programs and provider organizations.

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  - **Maine Immunization Registry (ImmPact)**
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  - **New Jersey Immunization Information System (NJIIS)**
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  - **Ohio Department of Health Immunization Registry (Impact SIIS)**
  - **Oregon ALERT Immunization Information System (ALERT IIS)**
  - **Vaccine Tracking System (VTrckS)**
  - **Washington State Immunization Information System**
  - **Wyoming Immunization Registry (WyIR)**

Navigation

Navigation Tips

- For a convenient navigation through chapters and sections, activate the navigation pane for this document (e.g., for MS Word via the following menu selections: "View → Navigation Pane <check box>", for Adobe Acrobat via the Bookmarks button).
- After navigating from the Table of Contents or via a hyperlink to a location within this document, use "Alt + ←" keystroke to return to the page where you started (for Adobe Acrobat and MS Word).

Overview of this document

- Executive Summary
  Describes the background, relevance to the immunization community, and key recommendations.
- Chapter 1: Introduction
  Introduces MIROW efforts, the current topic under development, analysis instruments used, intended audience, and principles of the workgroup collaborative consensus-based development approach.
- Chapter 2: Scope
  Presents an overview of the scope of this topic, integration with other initiatives, and inclusion/exclusion designations.
- Chapter 3: Fundamentals
  Introduces DI-v-EDE topic, defines the key concepts and terms needed to describe the process of DI-v-EDE, and provides fundamental principles.
- Chapter 4: Process Model
  Describes an overview of the process of DI-v-EDE.
- Chapter 5: Business Rules
  Provides recommendations for the process of DI-v-EDE as described in business rules.
- Chapter 6: Reports
  Presents best practice recommendations for IIS reports.
- Chapter 7: Preapproval and Maintenance of Provider Organizations
  Offers recommendations to prepare organizations for DI-v-EDE and to ensure that incoming data is of high quality.
- Chapter 8: Operational Scenarios
  Describes typical and challenging operational scenarios that illustrate implementation of best practice recommendations.
- Chapter 9: Implementation Considerations
  Contains implementation considerations, including key data elements, data quality, HL7 immunization messaging, EHR, staff time, resources, and outreach and education.
- Appendix A: Terms and Definitions defined via Domain Model
  Terms and definitions for DI-v-EDE captured through a domain model.
- Appendix B: About MIROW
  Describes MIROW and previously published MIROW guidelines.
- Appendix C: Scope
  Provides a technical description of the scope of the current topic, inclusions and exclusions, emphasized perspectives, and scope of integration.
- Appendix D: Decision-making Example
  Contains a decision table for a two-stock storage model that illustrates analysis and documentation of decrementing inventory and borrowing.
- Appendix E: Handling Doses with Short-dated Lot Number Expiration Dates
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- Appendix F: Barriers to Implementation
  Describes barriers to DI-v-EDE identified at the 2015 AIRA Conference and the SME face-to-face facilitated session and guidance for addressing those barriers.
- Appendix G: 2015 MIROW DI-v-EDE Workshop Participants List
  Lists the participants of the MIROW DI-v-EDE workshop held during the 2015 AIRA National Meeting.

Recommended reading paths

We recommend that various staff read certain portions of this guide, at minimum, as shown below. A reader interested in detailed understanding of the "who, what, why, where, when, how" aspects of DI-v-EDE should read the entire document, starting with Appendix A: Terms and Definitions defined via Domain Model.

Program Managers:

- Executive Summary
- Chapter 3: Fundamentals
- Chapter 9: Implementation Considerations
- Chapter 5: Business Rules

Immunization Program Staff:

- Executive Summary
- Chapter 3: Fundamentals
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Chapter 1: Introduction

About MIROW

The American Immunization Registry Association (AIRA), in partnership with the National Center for Immunization and Respiratory Diseases (NCIRD) at the Centers for Disease Control and Prevention (CDC), formed the Modeling of Immunization Registry Operations Workgroup (MIROW) in 2005 to develop best practice guidance for functional aspects of Immunization Information Systems (IIS). For more information about MIROW and its work products, please see Appendix B: About MIROW.

About this project

IIS Functional Standard 2.3 requires that "the IIS vaccine inventory function automatically decrements as vaccine doses are recorded" [2.1, p.4]. This guide presents best practice recommendations to automate and standardize the process of decrementing a provider organization's vaccine inventory in an IIS via electronic data exchange between the provider organization and IIS. This process will be referred to as "decrementing inventory via electronic data exchange" (DI-v-EDE) throughout this guide.

The primary benefits of DI-v-EDE are as follows:

- DI-v-EDE enables immunization programs to maintain accurate information about provider vaccine inventories.
- IIS can help provider organizations fulfill awardee immunization program operational requirements (e.g., vaccine accountability).

The demand for DI-v-EDE by immunization providers has grown due to the implementation of MU Incentive Programs [2.2] and requirements for more accountability in the use of publicly-funded vaccine. MU requires that provider organizations transmit vaccination event data to IIS electronically. Providers prefer to use the same electronic data exchange to manage inventory in the IIS rather than managing inventory in the IIS manually via direct user interface. Advances in electronic data exchanges between immunization provider organizations and IIS make development of this guide timely.

This document focuses on the following aspects of DI-v-EDE:

- Development of criteria (business rules) for the data elements that should be recorded in, and submitted by, EHR via electronic data exchange with the IIS.
- Development of criteria (business rules) to decrement the number of vaccine doses in the inventory based on the data available from the EHR and in the IIS.
- Explanation of a preapproval and ongoing maintenance process for DI-v-EDE.
- Description of reports to assist provider organizations and awardee immunization programs concerning DI-v-EDE.

The development process consisted of a preliminary phase that included web-based teleconferences held June-July 2015, a face-to-face meeting held July 21-23, 2015, in Decatur, Georgia, and post-meeting activities (August 2015-April 2016) to finalize the recommendations.

About this document

This document provides consensus-based best practice recommendations for DI-v-EDE.

Intended audience

The recommendations outlined in this guide are designed for use by programmatic, technical, and operational personnel involved in creating or maintaining an IIS, awardee immunization program staff, as well as vendors of health care information systems and providers of immunization services. The goal of this guide is to bridge the gap between IIS technical and program staff, IIS and awardee immunization programs, and IIS and their partners. Bridging these gaps will help create a mutual understanding of common issues and identify actions to implement/apply these recommendations.

Intended use

This guide contains a set of recommended operational best practices (including a set of principles and business rules to follow) that are intended as a basis for

requirements in IIS applications and operations. In addition, this guide can be used for staff training, operational documentation, and communication purposes, and for providing guidance for EHR applications.

The implementation of best practice recommendations will vary based on the specifics of a particular IIS and its interaction with EHR vendor technology and application architecture. Additionally, resource constraints and required changes to existing functionality may result in incremental adoption of these guidelines.

Implementation/technology independence

MIROW best practice recommendations are intended to be implemented at the business/operational level and, as a result, are independent from specific IIS implementations and technology solutions. Since this process incorporates an industry-wide strategic approach to capturing and maintaining business knowledge, requirements, and policies/constraints that are independent of implementation architecture and technical solutions, these best practice recommendations will be able to support the wide variety of IIS implementation strategies on different technological platforms.

Business modeling instruments

The recommended best practices were formulated using business modeling instruments:

- Domain model (Appendix A: Terms and Definitions) – documents agreed-upon terms and definitions for the project. Establishes a foundation and a reference source (common vocabulary) for other project materials (e.g., principles, business rules).
- Principles (Chapter 3: Fundamentals) – provide high-level direction that helps to guide the development of more specific business rules.
- Process model (Chapter 4: Process Model) – provides step-by-step description of the DI-v-EDE and related processes.
- Business rules (Chapter 5: Business Rules) – represent specific requirements and decision-making logic for DI-v-EDE.
- Operational scenarios (Chapter 8: Operational Scenarios) – use brief user stories to describe how to apply best practice recommendations in typical and challenging situations.

The following assumptions reflect the MIROW approach to the development of principles and business rules and associated best practices presented in this document:

- The focus should be on recommendations and business rules that have the greatest potential for providing value and use across all IIS.
- The business rules represent an attempt to balance ideal possible practices with pragmatic considerations of what will be possible to implement in an IIS.
- Specific implementation of business rules (and associated best practices) may vary based on resources, goals, needs, and unique implementation concerns.
- The set of business rules and other recommendations presented here is not exhaustive. Each individual IIS may choose to implement additional rules based on its unique requirements and insights.
- Finally, the business rules and associated best practices are not static – they will need to change and evolve over time as business requirements change.

Development approach

MIROW used business engineering and facilitation techniques to analyze IIS processes and develop recommendations. It used a pragmatic, results-oriented approach that has been effective for modeling of IIS and cancer registration operations. Business analysts, public health consultants, and subject matter experts (SMEs) conducted initial preparatory off-line work (assembling pertinent materials, producing preparatory notes, analyzing processes, and developing preliminary drafts). During a subsequent ***face-to-face facilitated modeling session*** held on July 21-23, 2015, in Decatur, Georgia, the workgroup of SMEs used these preparatory materials to frame and scope resources and began developing and formulating consensus-based recommendations. The ***post-session work*** finalized the development of recommendations. The SMEs addressed a set of remaining issues during a series of teleconferences. The goal was a consensus among SMEs regarding best practice recommendations, which did not require 100% agreement, but meant, ***"I can live with that and support it."*** The first part ("can live with that") allowed the group to focus on achieving a consensus in principle, avoiding prolonged discussions on minor issues (when at least no one disagrees strongly enough to veto the agreement).

The second part ("support it") provided a due diligence check to ensure there were no serious disagreements left among the experts, assuring that experts agreed with the recommendation sufficiently to stand behind it and support it.

Over the past several years, awardee immunization programs and staff have become inundated with competing priorities. In 2009, immunization programs faced the H1N1 pandemic. During this time, IIS were used heavily to track the inventory and accountability aspect of the H1N1 influenza vaccine. Awardee immunization programs were scrambling to keep up with this new demand when, "at the same time", CDC was implementing the new federal Vaccine Tracking System (VTrckS) [2.3], which all awardees would be required to use to order publicly-funded vaccines. VTrckS was launched in four pilot states in December 2010; by May 2013, it was implemented in all 64 awardee locations. Awardee immunization programs were required to set up a new process so that provider organizations could order vaccine either directly through VTrckS or through their IIS. Those that chose to use their IIS needed time to develop this capability within their IIS, train provider organizations, and implement the new ordering process. Starting in 2011, the introduction of MU [2.4, 2.5] created an additional demand on IIS program staff. Not only were EHR vendors needing to prove their capability to exchange data electronically, but provider organizations also demanded to be at the front of the line so that they could receive the money available through the MU Incentive Programs [2.5]. As the IIS has become front and center in many aspects of vaccine accountability, it has also become resource-intensive. Due to competing priorities, many SMEs are too busy to participate in any outside knowledge sharing projects/workgroups.

Prior to initiation of these guidelines, the MIROW Steering Committee (SC) determined that due to the increasingly limited availability of the SMEs, it had become necessary to augment the workgroup SME panel with paid public health consultants (PHCs). The goal was to reduce the amount of time required by SMEs to review and comment on the best practice document during the development process.

Chapter 2: Scope Overview

This section provides an overview of the scope of the current topic. A more technical description of the scope of the current topic is included in Appendix C: Scope.

The scope of the current topic includes all to-be processes and information to support:

- Specific elements of the DI-v-EDE process, including:
  - Categorizing provider organizations' inventory in the IIS.
  - Submitting data elements necessary for appropriate matching and deducting the number of vaccine doses in the inventory.
  - Matching of incoming data submission to inventory in the IIS. Inventory is an aggregate term consisting of one or more inventory item(s). See Appendix A: Terms and Definitions.
  - Meeting awardee vaccine accountability requirements.
  - Decrementing inventory based on the data from the EHR and in the IIS, including how to deduct a dose properly when doses with the same lot number exist in both public and private inventory.
  - Identifying and correcting errors in the DI-v-EDE process.
- Preapproval and ongoing maintenance of provider organizations to engage in DI-v-EDE. The preapproval for DI-v-EDE may occur during initial onboarding of a provider organization, or later if a provider organization begins DI-v-EDE after onboarding.
- Reports to assist the IIS, awardee, and provider organizations.

These guidelines recommend data elements to be used in the DI-v-EDE process, with a special focus on dose-level eligibility and funding source. Borrowing vaccine doses between funding sources is addressed, but is not the primary focus of these guidelines. Reconciliation of provider organization physical inventory and inventory in the IIS is limited to aspects relevant to DI-v-EDE. Borrowing and reconciliation are addressed in more detail in the MIROW 2008 Data Quality Assurance Guidelines [1.6]. Reports to support all aspects of DI-v-EDE are in scope, including identification of mismatched inventory data (when information in the Health Level 7 [HL7] message does not match the IIS inventory information).

Selected aspects of provider organization preapproval during the onboarding process and subsequent ongoing maintenance/monitoring are in scope and expand materials contained in the MIROW 2008 Data Quality Assurance Guidelines [1.6]. Preapproval and maintenance themes addressed in the current guidelines are:

- Review of data submissions when a provider organization changes something that affects the EHR-IIS data interchange.
- Monitoring activities, reports, and tools for use after preapproval.

The current topic focuses on publicly-funded vaccines. Privately-funded vaccines are included in scope with the understanding that recommendations and solutions developed for managing publicly-funded vaccine may also be applied, at the discretion of the provider organization, to managing privately-funded vaccine.

The scope of the current topic excludes:

- Inventory transactions for historical, transferred, wasted, spoiled, and returned vaccine.
- Using a direct user interface or submission of a flat file to decrement vaccine inventory.
- Vaccine barcoding.

Most aspects of vaccine ordering and fulfillment, including vaccine receipt and incrementing inventory initially, are outside the scope of these guidelines; however, these guidelines do reference the vaccine ordering and fulfillment process to document how information necessary for the DI-v-EDE process becomes available to the IIS and provider organizations. Specifically, the VTrckS ordering and fulfillment process provides vaccine lot numbers and information about public funding programs used in the DI-v-EDE process.

While systems other than IIS are outside the scope of these guidelines, the DI-v-EDE process should interact and coordinate with other functional areas, including vaccine ordering and fulfillment (VTrckS), the IIS direct user interface, immunization tracking, and vaccine barcoding. The current topic also coordinates with previously developed MIROW guidelines, particularly the MIROW 2012 Inventory Management Guidelines [1.3].

Figure 1 below presents a high-level context diagram for DI-v-EDE from an IIS point of view.

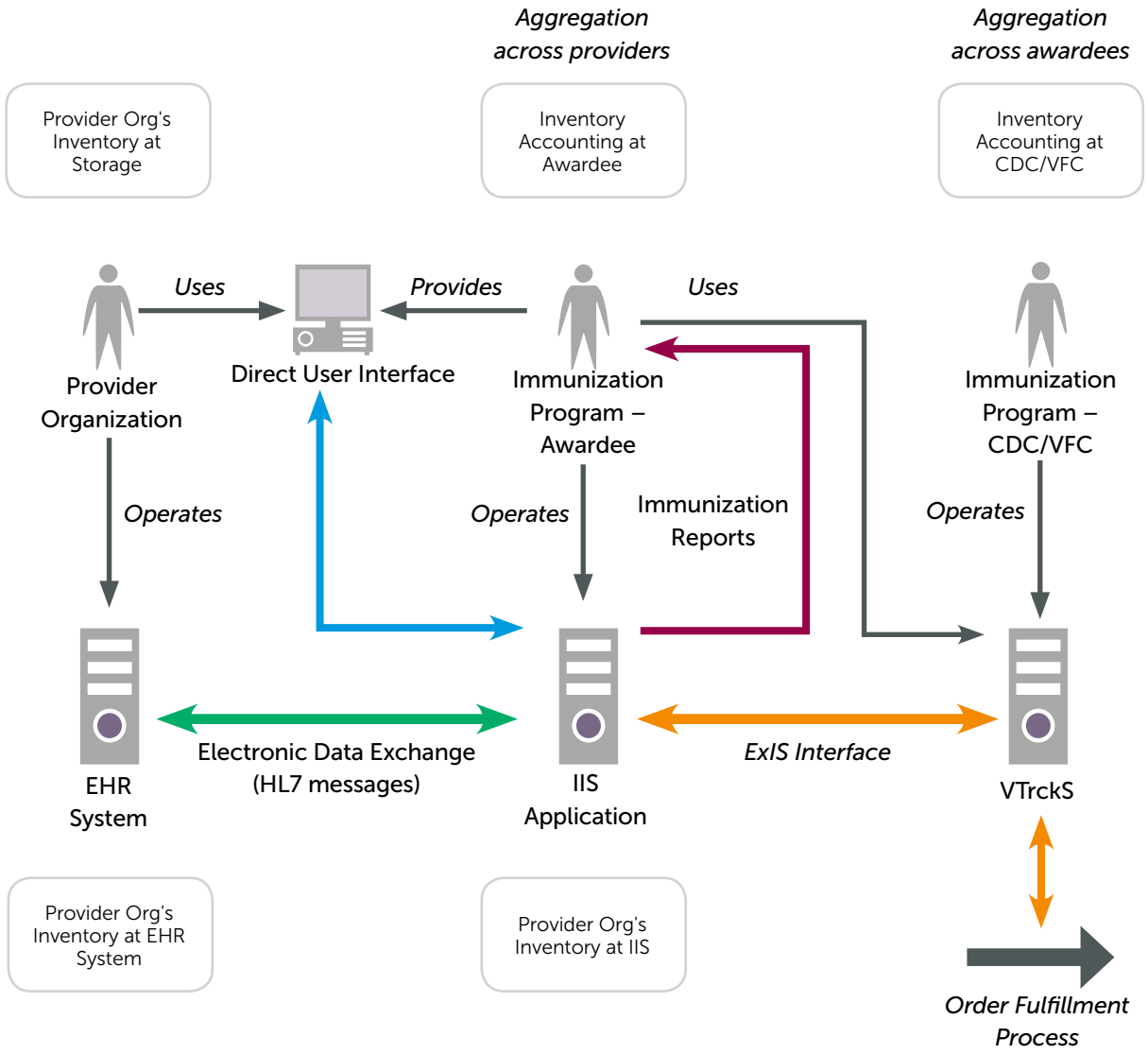


Figure 1. High-level context diagram of DI-v-EDE from an IIS point of view

Chapter 3: Fundamentals

Introduction to key concepts

The DI-v-EDE process is an automated method of decrementing the number of vaccine doses in a provider organization's inventory in the IIS when the organization reports a vaccination event through electronic data exchange from an EHR to the IIS.

For the purposes of automatic inventory decrementing, IIS and provider organizations categorize each provider organization's vaccine inventory based on lot number, lot number expiration date, and funding indicators of various specificity. For example, dose-level public/private indicator (a.k.a. funding source in the HL7 specification) is less specific, and fund type is more specific. The sub-categories of vaccine inventory identified by lot number, lot number expiration date, and dose-level public/private indicator (or fund type) are referred to in this document as "inventory items." To deduct a vaccine dose from the appropriate inventory item, the IIS compares vaccination event information submitted by the provider organization with the information that the IIS has for that provider organization's inventory. Data elements such as lot number, lot number expiration date, dose-level eligibility, lot-level public/private indicator, and in some cases, dose-level public/private indicator (also called funding source in HL7) are used to match inventory.

The key concepts used in the DI-v-EDE process are defined below.

Key concepts and terms

Appendix A: Terms and Definitions (i.e., Table A-1 and section Discussion and notes) describe and discuss in detail terms and definitions for various concepts that are relevant for DI-v-EDE. This section provides a brief introduction of the five key concepts for DI-v-EDE:

- Fund type
- Storage model
- Dose-level eligibility
- Dose-level public/private indicator
- Lot-level public/private indicator

Fund type

Fund type categorizes the program (or a private payer) that paid for the vaccine and is used throughout the life cycle of the dose of vaccine. Each dose of vaccine is paid for with funds from a public program (e.g., VFC, 317, state, or CHIP funds) or from a private funding source [2.6]. For example, a dose of vaccine purchased with VFC funding is described as having a fund type of VFC. Awardee immunization programs assign a fund type to each publicly-funded vaccine dose ordered through VTrckS. Fund type is also indicated for each vaccine dose in a packing slip for publicly-funded vaccine. As an illustration, a provider organization orders 10 doses of vaccine for uninsured adults. The awardee processes the order and pays for the vaccine with 317 funds. When the vaccine is shipped, the packing slip will show the 10 doses as having a fund type of 317. Fund type is not included in the shipment file that awardees upload into the IIS from VTrckS, but can generally be determined by linking ordering and shipment data. When a dose of vaccine is administered, the provider organization can directly assign a fund type to the dose when the vaccination event is submitted in an EDE, or the awardee immunization program can deduce the fund type based on dose-level eligibility (item 3.2). The IIS can aggregate fund type at the provider organization or the immunization program level for reporting purposes using dose-level public/private indicator.

Storage model

When the provider organization receives a vaccine shipment, the doses are quickly stored within a storage unit (i.e., a refrigerator or freezer). Storage model describes the way vaccine stocks are physically separated from each other in the provider organization's storage unit. Provider organizations separate vaccine by lot number and lot number expiration date. However, depending on the awardee's requirements, the provider organization may also need to separate the vaccines by fund type (e.g., separate containers for doses funded by VFC, 317, state, CHIP, and private), or may be allowed to have less specific categories (e.g., VFC public, non-VFC public, and private). All vaccine doses purchased by a particular program are referred to as that program's "stock" or "inventory" (e.g., VFC public stock, non-VFC public stock, and private stock). See the Vaccine storage models section below for more details. Separating vaccines helps to achieve better accountability for each dose and to ensure that only patients that are eligible for a funding program receive a vaccine funded by that particular program. In the case of the 10 doses of 317-funded vaccine for uninsured adults, the doses would be arranged in the storage unit according to the appropriate storage model (e.g., separate from VFC, CHIP, state, and private doses). The Vaccine storage models section of this chapter discusses storage models in more detail.

Dose-level eligibility

Dose-level eligibility describes a patient's eligibility for a funding program (such as VFC, 317, etc.); it is determined for each dose administered (for details, see the MIROW 2011 IIS Collaboration with VFC and Grantee Guidelines [1.4]). Dose-level eligibility is determined for a patient at the time of the vaccination event. In addition to indicating a patient's eligibility for a particular funding program, dose-level eligibility reported by a provider organization to an IIS may also serve as a proxy (i.e., substitute, representation) for fund type.

Dose-level public/private indicator

Once the provider knows the patient's dose-level eligibility, they select the dose of vaccine from the storage unit based on the patient's eligibility. When the provider documents the vaccination event, they may include the specific fund type of the dose administered, or they may document less specific categories (e.g., VFC public, non-VFC public, and private). These less specific categories are referred to as "dose-level public/private indicator," since the data element identifies if the dose administered was purchased with public or private funds. If the data element is included in the provider organization's EHR, it can transmit dose-level public/private indicator to the IIS through an EDE. The term "dose-level public/private indicator" corresponds to the term "funding source" in the HL7 specifications. See Figure 2 below for an example of when inventory is stored in two stocks (public and private).

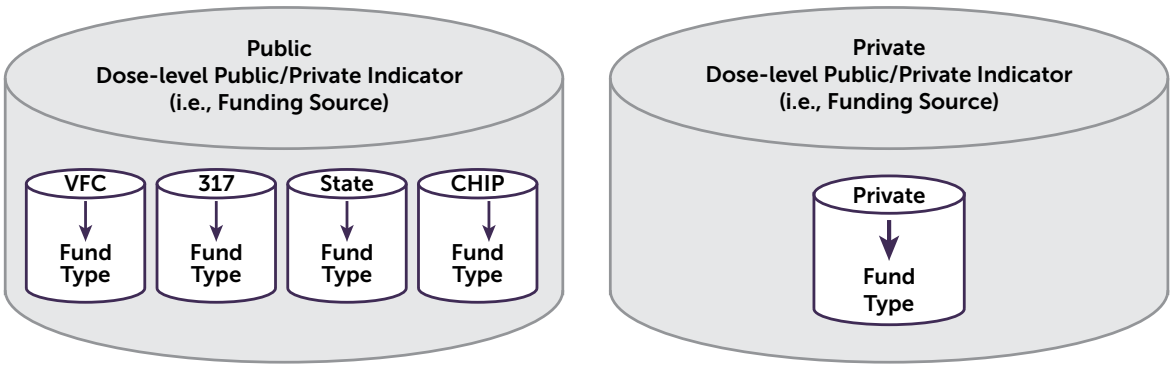


Figure 2. Dose-level public/private indicator (funding source) vs. fund type

The provider assigns the dose-level public/private indicator for each administered vaccine dose based on the stock the particular vaccine dose was pulled from in the provider organization's storage unit. An explanation of how a provider determines how to separate vaccine stocks in a storage unit is in the Vaccine storage model section below. Given the relationship between storage models and fund type, dose-level public/private indicator can be described as an aggregated reflection of fund type at the vaccine dose-level.

While a vaccine dose should be selected from the provider's stock based on the patient's eligibility, there are situations in which this is not the case. In these situations, the dose-level eligibility of the patient does not directly correspond to the dose-level public/private indicator of the dose of vaccine. For example, an uninsured child is eligible for flu vaccine from the VFC program; however, it is early in the flu season, and the provider has only received privately-funded flu vaccine. The provider may opt to borrow from their private stock to vaccinate the child. In this scenario, the dose-level eligibility is VFC, but the dose-level public/private indicator is private.

Lot-level public/private indicator

As mentioned in the "Fund type" section, the IIS does not receive fund type information in the shipment file. While this information can be determined by a combination of ordering and shipment data, not all awardees choose to categorize IIS inventory by fund type. Instead, an inventory can be categorized as publicly or privately funded by the lot-level public/private indicator. The lot-level public/private indicator is an aggregated reflection of fund type at the vaccine lot-level. It indicates if vaccine doses with a given lot number are associated with publicly-funded or privately-funded inventory in the IIS. For example, the lot number ABC123 could contain 5 doses of VFC vaccine, 1 dose of 317 vaccine, 1 dose of state vaccine, 3 doses of CHIP vaccine, and 8 doses of private vaccine. For the two-stock model, the IIS will track two inventory items for that lot number (assuming the vaccine has a single lot number expiration date). For example, lot number ABC123 public inventory item (with a balance of 10 doses, lot number public/private indicator = public) and lot number ABC123 private inventory item (with a balance of 8 doses, lot number public/private indicator = private). The IIS assigns lot-level public/private indicator based on information contained in an ordering and fulfillment system such as VTrckS. A provider organization can adjust lot-level public/private indicator through a direct IIS user interface when the provider organization verifies actual contents and packing slip information for a vaccine shipment. The provider organization does not transmit lot-level public/private indicator in an EDE.

Vaccine storage models

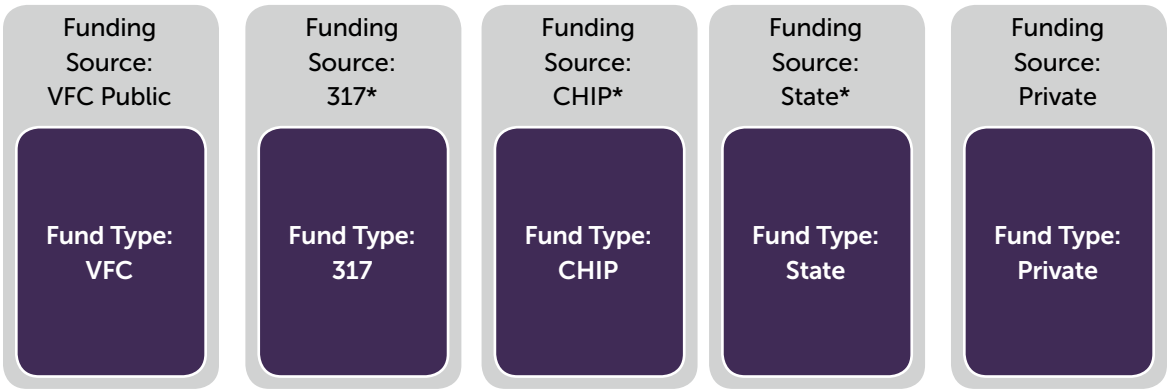
This section describes storage models for partitioning physical vaccine inventory in a provider organization's storage unit (refrigerators, freezers). The workgroup's interest in storage models is limited to the scope of this topic, as described in Chapter 2: Scope. Awardee immunization programs currently use several different vaccine storage models; these models are described in further detail below. The workgroup made DI-v-EDE best practice recommendations in the context of current storage models and possible future developments. ***The workgroup does not recommend any one particular storage model over other models. The awardee immunization program is the source of information on storage models.***

Provider organizations commonly receive and store vaccines paid for by several different payers (i.e., fund types). Awardee immunization programs and provider organizations purchase vaccines with VFC, 317, state, CHIP, and private funds. These fund types can be categorized more generically by funding sources (as discussed in the previous section). Immunization programs have storage requirements for provider organizations that receive publicly-funded vaccines. These requirements describe how to organize physical vaccine inventory to separate vaccines purchased with different funding sources or fund types. The federal VFC program sets requirements that direct state and local immunization program policies with respect to VFC vaccines. As the cost and quantity of vaccine distributed through public programs has increased over the past decade, the accountability requirements have also become more specific. It is likely that these requirements will remain in flux as the publicly-funded vaccine programs change over time. The 2016 Vaccines for Children Program Operations Guide [2.6] includes these requirements.

Awardee immunization programs require provider organizations to use one of the four storage models described below. These models differ by the categorization scheme used to separate vaccines in the storage unit. Separation of vaccine stocks is managed by using separate storage units, containers, or vaccine labeling [2.7]. An immunization program may incorporate more than one model within its jurisdiction simultaneously (i.e., one type of storage model for some provider organizations and another type of storage model for others).

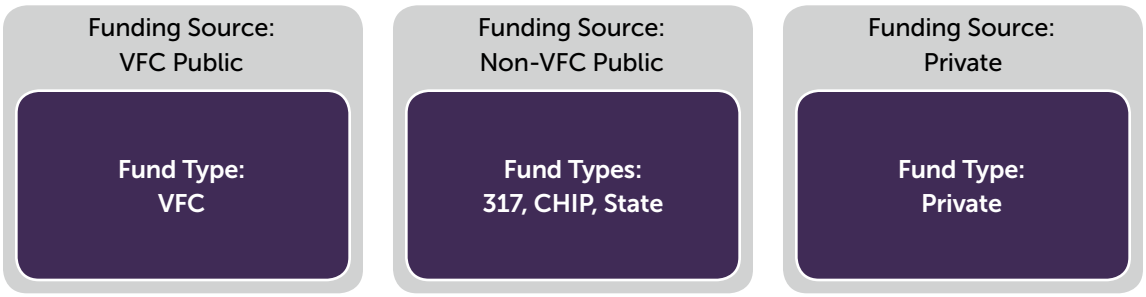
The following descriptions list storage models from the highest level of specificity for physically separating vaccine stocks to the lowest level:

- **Multi-stock (four or more) model:** The provider organization separates vaccines by individual fund type (e.g., VFC, 317, CHIP, state, and private). This model takes advantage of the fact that a provider organization knows the fund type for each vaccine from the packing slip or other source.

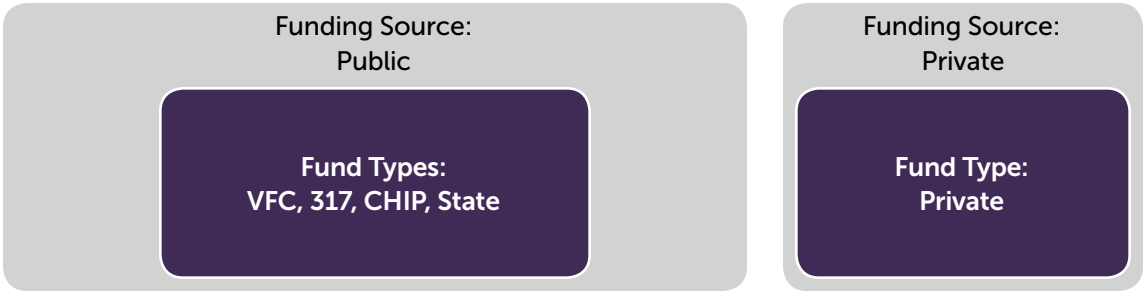


*HL7 Value Set does not currently support these funding sources.

- **Three-stock model:** The provider organization separates vaccines into three funding source categories (e.g., VFC public, non-VFC public, and private stock). This is the only model VFC explicitly recommends [2.6, p. 68]; however, awardees can request to use a model that blends fund types into either two stocks or one stock.



- **Two-stock model:** The provider organization separates vaccines into two funding source categories (i.e., public and private stock).



- **One-stock model:** This model differs from other storage models in that it does not require provider organizations to partition vaccines into multiple stocks within the storage unit. There are two types of one-stock models:
  - **Replacement model:** The provider organization uses privately-funded vaccines to vaccinate all patients and the VFC program replaces privately-funded vaccines administered to VFC-eligible children.
  - **Universal model:** The provider organization only has publicly-funded vaccine (at least for pediatric patients) supplied directly from the awardee immunization program.

Regardless of what storage model is used, the MIROW 2011 IIS Collaboration with VFC and Grantee Guidelines [1.4] recommend that provider organizations report dose-level eligibility for every vaccine dose administered. In addition to indicating a patient's eligibility for a particular immunization program, dose-level eligibility reported by a provider organization to an IIS can also serve as a proxy (i.e., substitute, representation) for the fund type. The relationship between dose-level eligibility and fund type of an administered vaccine does not exist in the one stock model because the fund type of the vaccine is not known at the time of administration.

It is also possible for an immunization program to have a three-stock model, but have certain provider organizations that do not store vaccine from all three funding sources. An example is Minnesota's three-stock model, which includes VFC public vaccines, non-VFC public vaccines, and private vaccines. In this model, a provider organization could have private vaccine, VFC public vaccine (for VFC-eligible children) and non-VFC public vaccine (for uninsured and underinsured adults). However, some provider organizations are not able to order vaccine from all three funding sources. Some organizations are enrolled in the Minnesota VFC program, but not in the Uninsured and Underinsured Adult Vaccine (UUAV) program. Likewise, there are adult-only facilities in the UUAV program that would not receive VFC vaccine. In these provider organizations, there may be fewer than three stocks in the physical inventory; however, the requirement for three-stock storage would still apply if the organization were to receive vaccine from an additional funding source. This same logic would apply to two-stock and multi-stock models in terms of fund types.

The provider organization's storage model determines which vaccines are placed into which physical stock. If the provider organization is using a two-stock storage model (public and private stocks), all inventory received from an order processed through VTrckS is placed in its public stock. If the provider organization is using the three-stock model or the multi-stock model, the provider uses the fund type noted on the packing slip (or other method determined by the immunization program) to determine the appropriate placement of physical inventory in the storage unit.

Fundamental principles

A principle (P) is a high-level business rule. It provides a high-level direction that helps capture institutional knowledge and guides the development of more specific business rules that represent specific requirements and decision-making logic for IIS processes and operations.

Fundamental principles that provide overarching direction for the DI-v-EDE functional area of operations, rather than to specific process steps, are:

- P01. DI-v-EDE should support the awardee program policies.
- P02. DI-v-EDE should support inventory tracking and immunization tracking.
- P03. The IIS must preapprove a provider organization for DI-v-EDE.
- P04. Inventory information in the IIS should map to the storage model used by the provider organization.
- P05. DI-v-EDE should minimize the burden on provider organizations.
- P06. DI-v-EDE should support dose-level accountability.
- P07. The IIS should notify provider organizations of problems in the DI-v-EDE process.
- P08. The IIS should assist provider organizations with correcting data quality issues.
- P09. The IIS should decrement an administered dose only once.

Note: Remarks are an integral part of fundamental principles. It is important to study, reference, and implement each of these principles in their entirety, including information contained in the "Remarks" column.

Table 1. Fundamental principles for DI-v-EDE area of IIS operations

#	Principles	Remarks
P01	**P01. DI-v-EDE should support the awardee program policies.** DI-v-EDE should support the policies of the awardee immunization program.	■ For references see: ▪ VFC program resources [2.6, 2.7]. ▪ General recommendation GR701 in the MIROW 2012 Inventory Management Guidelines [1.3, p. 54].
P02	**P02. DI-v-EDE should support inventory tracking and immunization tracking.** DI-v-EDE should support both inventory tracking and immunization tracking.	■ Inventory tracking means following a dose of vaccine from order fulfillment at the provider's office to administration to a patient or other disposition (e.g., expired, wasted). ■ Immunization tracking means following a dose of vaccine from the vaccination event through entering information about that event in the IIS. ■ A submission from the provider organization to the IIS contains information for both inventory tracking and immunization tracking areas of IIS operations. Development of best practices for DI-v-EDE should take into account the dual use of vaccination event submissions. ■ For references, see: ▪ BR206. Update patient record regardless of inventory-related issues. ▪ Step 2.9 and Scenarios S501, S502, S503, S701, S704, S901, S902, S1001, S1201, S1202, S1203, S1204.
P03	**P03. The IIS must preapprove a provider organization for DI-v-EDE.** A provider organization may participate in the DI-v-EDE process only if the IIS has preapproved the provider organization	■ A preapproval process should be initiated when: ▪ A provider organization enrolls in DI-v-EDE process. ▪ The EHR of a previously approved provider organization changes in a manner that affects the DI-v-EDE process (e.g., changes in the data scheme for storage and retrieval of immunization data). ■ The IIS should indicate that a provider organization is preapproved for DI-v-EDE at the end of a successful preapproval process. ■ If a provider organization is not approved, IIS staff should work with the provider organization to resolve issues that prevented its approval. ■ For references, see: ▪ Chapter 7: Preapproval and Maintenance. ▪ BR401. Establish and maintain a preapproval process for provider organizations. ▪ BR402. Establish a testing environment for the preapproval process. ▪ BR403. Establish a preapproval testing process. ▪ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ▪ Scenario S301.

#	Principles	Remarks
P04	**P04. Inventory information in the IIS should map to the storage model used by the provider organization.** Categorization of information about a provider organization's inventory in the IIS should map to the vaccine storage model used by the provider organization.	■ A single awardee immunization program may have multiple vaccine storage policies, i.e., some provider organizations may have replacement storage, while others have two, three, or multi-stock storage. ■ In theory, an IIS can categorize inventory information in the IIS at a more specific level (fund type) than the storage model used by a provider organization. ■ For references, see: ▪ Vaccine storage models section in this chapter. ▪ BR101. Organize inventory information in the IIS by the lot number, lot number expiration date, and lot-level public/private indicator. ▪ Step 1.3 and Step 1.7.
P05	**P05. DI-v-EDE should minimize the burden on provider organizations.** The DI-v-EDE process should minimize the burden on provider organizations to the extent possible.	■ The DI-v-EDE process should minimize manual interventions by provider organizations at all stages of decrementing inventory from initial population of data elements to correction of errors and reconciliation. ■ There is a trade-off between minimizing manual interventions and the amount of information recorded and submitted by provider organizations to the IIS. ■ For references, see: ▪ General recommendation GR710 in the MIROW 2012 Inventory Management Guidelines [1.3, p. 56]. ▪ Chapter 9: Implementation Considerations. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ BR102. Prepopulate provider organization's inventory in the IIS. ▪ BR103. Download shipment information daily. ▪ BR404. Develop educational/training opportunities. ▪ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ▪ Steps 1.2, 1.3, 2.5, 3.1, and 3.2.
P06	**P06. DI-v-EDE should support dose-level accountability.** DI-v-EDE process should support dose-level accountability for vaccines.	■ For references, see: ▪ General recommendation GR702 and principle P702 in the MIROW 2012 Inventory Management Guidelines [1.3, p. 54; p. 38]. ▪ AIRA White Paper regarding Dose-level Eligibility [3.1]. ▪ BR101. Organize inventory information in the IIS by the lot number, lot number expiration date, and lot-level public/private indicator. ▪ BR202. Submit information to the IIS to support DI-v-EDE. ▪ Step 2.2 and Step 2.12.

#	Principles	Remarks
P07	**P07. IIS should notify provider organizations of problems in DI-v-EDE process.**	■ One or more methods can be used to notify provider organizations of errors and other issues: ▪ Reports (Chapter 6: Reports) ▪ Direct UI ▪ HL7 Acknowledgement (ACK) message sent to EHR ▪ Other mechanism(s) ■ Different types of problems/issues may require different communication methods. ■ In the example of the ACK message sent to an EHR, some EHR vendors do not give provider organizations access to the ACK messages, so there may be an issue with using only ACK messages as a way to relay problems with DI-v-EDE (see HL7 immunization messaging in Chapter 9: Implementation Considerations). ■ The awardee immunization program should review the IIS reports to identify provider organization issues. ■ For references, see: ▪ Alternative paths for Step 2.8, Step 2.9, Step 2.10, Step 2.11, and Step 2.12. ▪ Step 3.1 and Scenarios S401, S402, S403, S501, S502, S503, S701, S702, S703, S704, S801, S901, and S1001
P08	**P08. IIS should assist provider organizations with correcting data quality issues.** IIS should assist provider organizations with correcting data quality issues that affect DI-v-EDE.	■ IIS should provide reports and direct UI to assist provider organizations in reconciling inventory to address data quality issues. ■ IIS should support the following: ▪ Preapproval process ▪ Educational activities ▪ Inventory reconciliation ■ For references, see: ▪ P05. DI-v-EDE should minimize the burden on provider organizations. ▪ Alternative paths for Step 2.8, Step 2.9, Step 2.10, Step 2.11, and Step 2.12. ▪ BR301. Resolve data quality issues before reconciling. ▪ Step 3.2 and Scenarios S401, S402, S403, S501, S502, S503, S702, S703, S901, and S1001.
P09	**P09. The IIS should decrement an administered dose only once.** Every administered dose should be decremented from a provider organization's inventory only once.	■ Since a vaccination event record can be sent to an IIS multiple times over the lifespan of the patient, it is important that the IIS ensures the administered dose is only decremented one time from inventory, rather than every time it is sent to the IIS. ■ For references, see: ▪ Step 2.12 and Scenario S1101.

Chapter 4: Process Model

DI-v-EDE is one of the key processes in the inventory management functional area of IIS operations. Likewise, DI-v-EDE is closely interconnected with vaccine ordering and fulfillment, vaccine accountability, inventory tracking, and immunization tracking. Inventory tracking is a function of managing vaccine inventory, and includes recording the disposition of vaccine (i.e., shipment receipt, administered, wasted, transferred, returned, and expired). Immunization tracking is a function of tracking the administration of a vaccine (vaccination event). Vaccine accountability is the documentation of information used to ensure that doses purchased with public funds are used appropriately to vaccinate individuals who meet the eligibility criteria for public funding programs.

Before reading this chapter, a reader may benefit from a review of Chapter 3: Fundamentals and Appendix A: Terms and Definitions.

Materials in this chapter are organized in the following way:

- An overview of DI-v-EDE.
- An explanation of how the IIS and provider organization obtain relevant inventory information from vaccine orders and shipments.
- A description of the detailed process of DI-v-EDE.
- A summary of how to resolve DI-v-EDE issues.

The step-by-step description of the DI-v-EDE process in this chapter uses process diagrams, references to business rules (Chapter 5: Business Rules), and other materials that support decision making. The process diagrams use a color coding scheme to indicate which steps occur within the IIS (green) and which ones occur at the provider organization level (blue).

Process in a nutshell

The DI-v-EDE process is an automated method of decrementing the appropriate number of vaccine doses from a provider organization's inventory in the IIS when the organization reports a vaccination event through electronic data exchange from an EHR to the IIS.

The IIS and provider organizations categorize each provider organization's vaccine inventory based on funding indicators of various specificity. For example, dose-level public/private indicator (a.k.a. funding source) is less specific, and fund type is more specific. In order to deduct a vaccine dose accurately from the appropriate inventory item, the IIS compares vaccination event information submitted by the provider organization with the information IIS has about the inventory of that provider organization. The IIS uses lot number, dose-level eligibility, lot-level public/private indicator, and in some cases, dose-level public/private indicator (also called "funding source" in HL7) to match inventory items.

The IIS identifies and logs process issues and presents them via IIS reports. For example, if in some cases, the IIS is unable to match the vaccine lot number in the vaccination event information submitted by the provider organization to information it has about the provider organization's inventory, the IIS should log the issue in a report accessed by the provider organization. The provider organization can reference IIS reports to correct these process issues via additional electronic submission (through the EHR system) or manually (through IIS Direct UI).

Process 1: Add shipment information to IIS

This process model describes vaccine ordering and fulfillment through the federal VTrckS. The steps in the process could be adapted to other ordering and distribution systems. While most of the ordering and fulfillment processes are out of scope for this topic, it is important to understand the origin of the information needed for DI-v-EDE. The IIS and provider organization receive information about lot numbers, fund type, and other data elements from the vaccine ordering system (for example, VTrckS) and the shipment packing slip. Figure 3 and Figure 4 provide process map illustrations for Process 1.

Fund type

- Describes a program (or a private payer) that paid for vaccine.
- See Chapter 3: Fundamentals and Appendix A: Terms and Definitions.

Step 1.1: Place order.

A provider organization places an order in the IIS and the awardee uploads the order data to VTrckS. Each order line item contains, among other items, NDC and the quantity of doses requested. The awardee immunization program assigns fund types (VFC, 317, state, and CHIP) for each order line through various methods.

Decision support references: VTrckS guidelines [2.3] and awardees' policies.

Step 1.2: Upload shipment data from VTrckS into the IIS.

When the order is shipped from the supplier (i.e., vaccine distributor or manufacturer), VTrckS generates an electronic shipment data file. An IIS staff member downloads the shipment data file from VTrckS and then uploads it into the IIS.

Decision support references: P05, BR102, BR103, GR710 in MIROW 2012 Inventory Management Guidelines [1.3].

Step 1.3: Update provider organization's inventory in IIS.

The IIS associates the data from the shipment file with the appropriate provider organization's inventory item. This data includes NDC, lot number, expiration date, and quantity of doses. VTrckS only processes orders for publicly-funded vaccines; therefore, the lot-level public/private indicator for VTrckS shipments is always public. The shipment file does not include fund type information. Awardees who want to track their inventory at the fund type level can have the IIS link the shipment file data to the order data to retrieve the fund type and populate the fund type for each dose.

Lot-level public/private Indicator

- Lot-level public/private indicator is an aggregated reflection of fund type at the vaccine lot-level.
- See Chapter 3: Fundamentals and Appendix A: Terms and Definitions.

For example, the lot number ABC123 (which has a single lot number expiration date) could contain 5 doses of VFC vaccine, 1 dose of 317 vaccine, 1 dose of state vaccine, 3 doses of CHIP vaccine, and 8 doses of private vaccine. For the two-stock model, the IIS will track two inventory items for that lot number: lot number ABC123 public inventory item (with a balance of 10 doses, lot number public/private indicator = public) and lot number ABC123 private inventory item (with a balance of 8 doses, lot number public/private indicator = private).

Note: New inventory items may be created due to transfers from one provider organization to another or short-dating.

Decision support references: P04, P05, BR101, BR102, BR104, S102.

Step 1.4: Designate lot numbers in IIS as available for decrementing.

IIS may choose to handle designation of lot numbers as available for decrementing in two ways:

- Mark lot numbers as "active" right away, thereby making the lot numbers in inventory available for decrementing.
- Mark lot numbers as "pending." At this point, a "pending" lot number is waiting for a provider organization to "claim" it. These lot numbers will be later marked as "active" by the provider organization as described in Step 1.8 below.

Decision support references: BR204, S502.

Step 1.5: Verify physical shipment vs. packing slip.

The provider organization receives the physical shipment. The provider verifies the shipment packing slip against the actual contents of the shipment (NDC, lot numbers, quantities of received vaccines).

Alternate path:
1.5A. Packing slip and physical shipment do not match or shipment is damaged.

The provider organization notifies the awardee of discrepancy:

- If shipment needs to be returned or discarded, the new inventory item in IIS that was added at Step 1.3 is removed. Process 1 ends.
  - Note: There may be special circumstances when vaccine is returned and the information about the replacement doses is not in a shipment file. A manual intervention may be necessary.
- If shipment is kept, continue with the next step while resolving the discrepancy. Correct new inventory in IIS added at Step 1.3 as necessary, using IIS Direct UI.

Decision support references: BR105, BR106, S101.

Step 1.6: Verify physical shipment vs. information in IIS,

Provider verifies that the physical vaccine shipment received matches inventory in IIS using IIS Direct UI.

Alternate path:
1.6A. Vaccines received do not match inventory in IIS.

Using Direct UI, correct new inventory in IIS added at Step 1.3 as necessary, including updates for lot number public/private indicators.

Decision support references: BR105, BR106, S101.

Step 1.7: Place vaccines in the appropriate storage unit.

The provider organization places vaccines in the storage unit (i.e., refrigerator, freezer).

If the provider organization is using a two-stock storage model (public and private), all doses received are placed in the provider organization's physical public stock (since VTrckS orders are for publicly-funded vaccines only). If the provider organization is using the three-stock model or the multi-stock model, the provider organization uses the fund type on the packing slip (or another approach recommended by the awardee) to determine where to place the vaccine in storage.

Vaccine storage model

- Describes the way vaccine stocks are physically separated from each other in the provider organization's storage unit (e.g., refrigerator, freezer).
- See Chapter 3: Fundamentals and Appendix A: Terms and Definitions.

Decision support references: Storage model section in Chapter 3: Fundamentals, P04.

Step 1.8: Confirm new inventory is available for decrementing.

The provider organization confirms that a new inventory item is available for decrementing through IIS Direct UI. The provider organization should do this after discrepancies (if any) are resolved (Step 1.5A).

- If lot numbers are marked as "pending" (Step 1.4), the provider organization updates the status of lot numbers in inventory to "active" (i.e., "claiming" received vaccines).
- If lot numbers are already marked as "active" (Step 1.4), no action is necessary.

The inventory item is available for decrementing. Process 1 ends.

Decision support references: BR204, S502.

Note: Figure 3 and Figure 4 below include process map illustrations of this process. Figure 3 is a simplified version and Figure 4 is a detailed version that includes referenced principles, business rules, and scenarios.

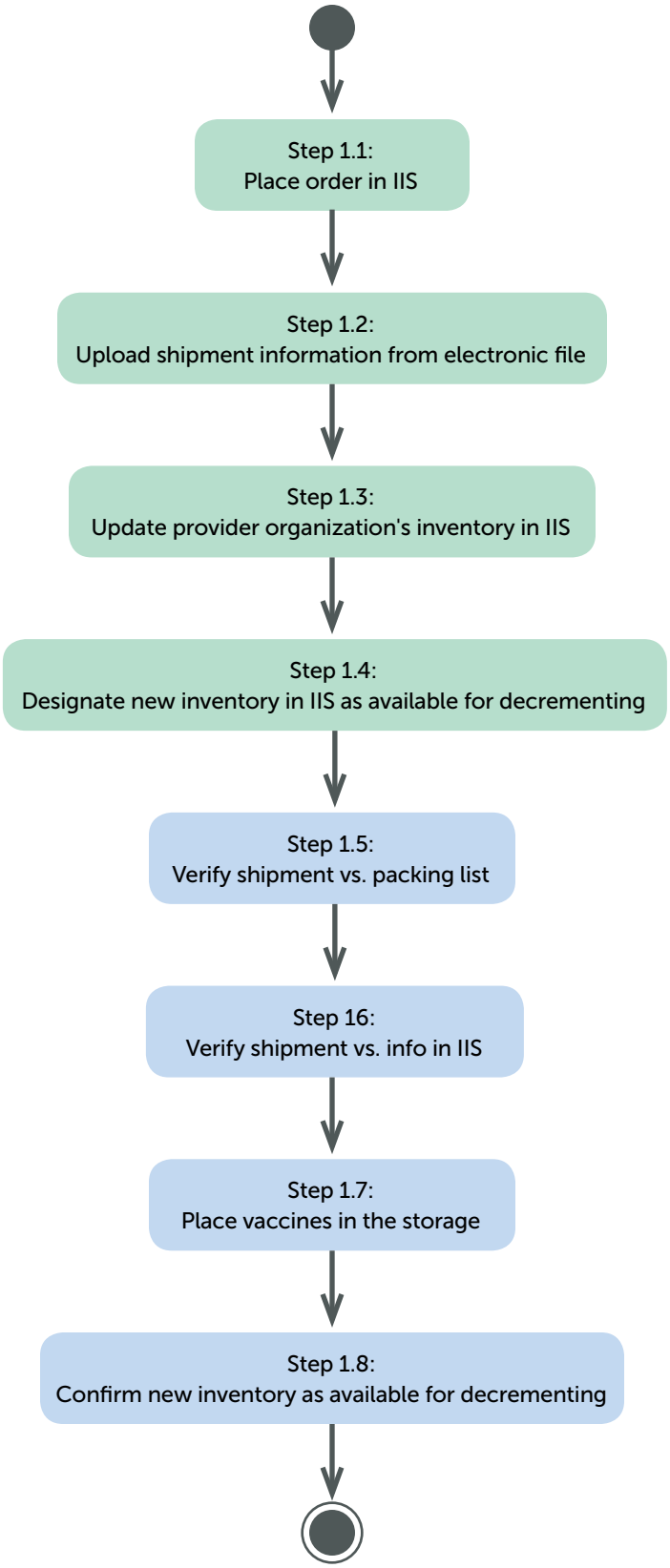


Figure 3. Simplified process 1 map—Add shipment information to IIS

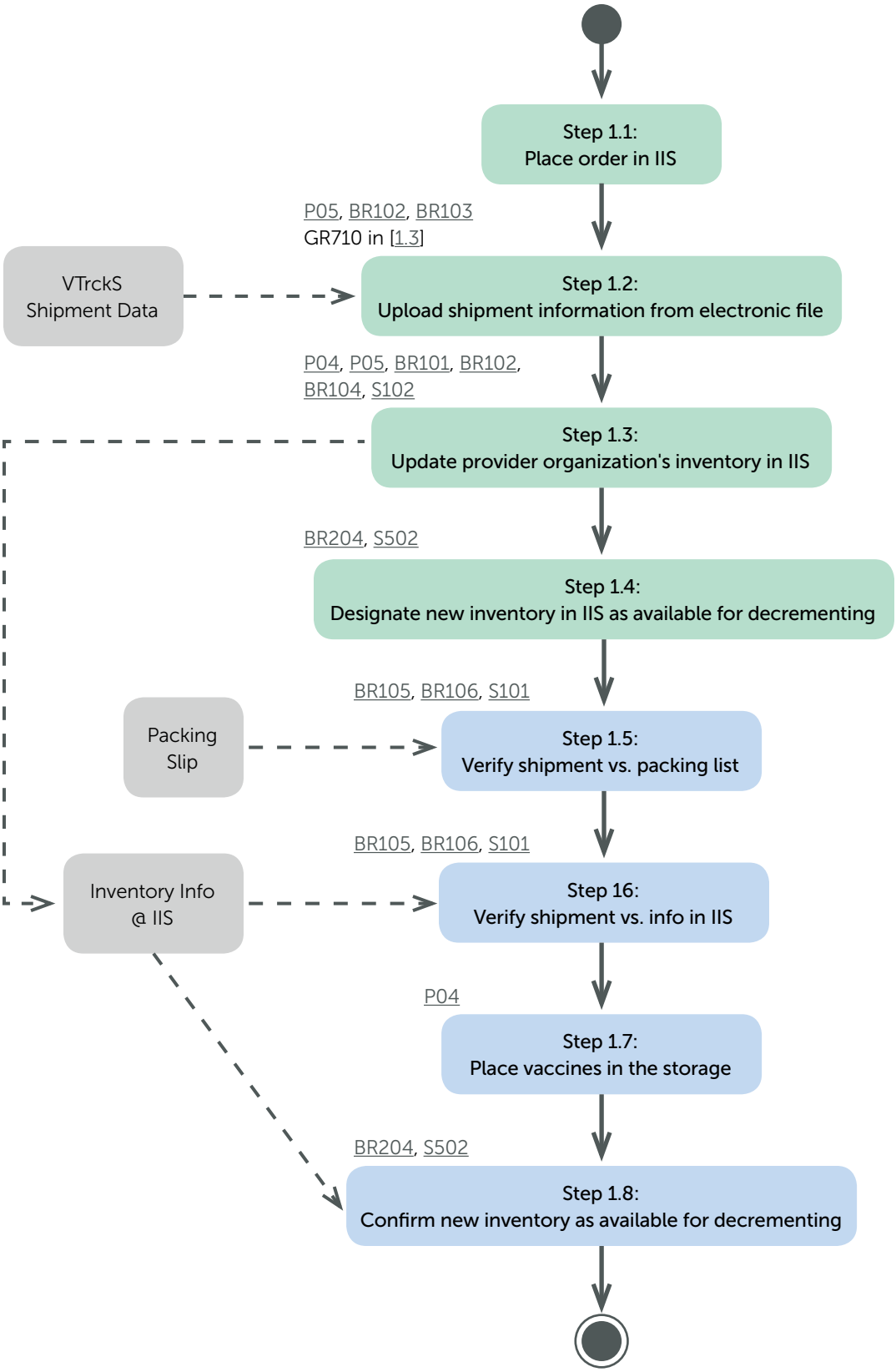


Figure 4. Detailed process 1 map—Add shipment information to IIS

Process 2: Decrement inventory via electronic data exchange (DI-v-EDE)

This is the main process for this topic. To provide context, some clinical work-flow steps that are out of scope for this topic—"Determine needed vaccine," "Determine dose-level eligibility," "Administer vaccine," and "Update patient record"—are shown. The process starts when a provider sees a patient needing vaccination(s). Figure 5 and Figure 6 provide process map illustrations for this process.

Step 2.1: Determine needed vaccine (out of scope).

Provider determines needed vaccine based on patient's age and immunization history. This step is out of scope for this topic.

Decision support references: Clinical decision support for immunization (CDSi) documentation [2.8].

Step 2.2: Determine dose-level eligibility (out of scope).

Provider determines the dose-level eligibility for a patient for a needed vaccine. This step is out of scope for this topic.

Decision support references: MIROW 2011 IIS Collaboration with VFC and Grantee Guidelines [1.4], P06.

Step 2.3: Pull vaccine from storage.

Provider pulls vaccine from the stock that corresponds to the dose-level eligibility for the vaccination event. Note that a provider may unintentionally pull vaccine from the wrong stock.

- For example, in the two-stock model, if dose-level eligibility is uninsured (or any other VFC-eligible status), the provider pulls vaccine from the public stock and, if dose-level eligibility is private, the provider pulls vaccine from the private stock.

  Alternate path:
  2.3A. No vaccine available in the appropriate stock.

  Provider follows awardee's policy regarding borrowing.

  - If borrowing is permitted, provider borrows vaccine from alternate stock and continues with next step.
  - If borrowing is not permitted, Process 2 ends. For guidance, see awardee and VFC program guides.

Decision support references: MIROW 2012 Inventory Management Guidelines [1.3], Storage model section in Chapter 3: Fundamentals, BR101.

Step 2.4: Administer vaccine (out of scope).

Provider administers vaccine to patient. This step is out of scope for this topic.

Step 2.5: Document vaccination event.

Provider documents vaccination event within the EHR system by recording lot number, dose-level eligibility, dose-level public/private indicator (optional for DI-v-EDE), lot number expiration date, and other data elements that describe the vaccination event.

- At this point, the provider documents the information necessary not only for decrementing inventory, but also for immunization tracking and other aspects of inventory management. Note: decrementing inventory is not the only function that uses information about a vaccination event.

Decision support references: BR711 in the MIROW 2012 Inventory Management Guidelines [1.3], P05, BR201, BR202, S201, S701, S702, S703, S704.

Dose-level eligibility

- Dose-level eligibility describes a patient's eligibility for a funding program (such as VFC, 317, etc.); it is determined for each dose administered.

Dose-level public/private indicator

- Dose-level public/private indicator is an aggregated reflection of fund type at the vaccine dose-level.

See Chapter 3: Fundamentals and Appendix A: Terms and Definitions.

Step 2.6: Send submission describing vaccination event to the IIS.

EHR system sends vaccination event data to the IIS using HL7 specification, either in real time or as a part of a batch schedule.

Decision support references: CDC HL7 implementation guide [2.9, 2.10], BR202.

Step 2.7: Receive vaccination event submission.

IIS receives vaccination event submission.

Decision support reference: S301.

Step 2.8: Validate vaccination event data for errors.

IIS validates vaccination event message for errors (for example, invalid format [e.g. not HL7] and missing required field(s) for decrementing inventory).

Notes:

- While focus here is on one specific vaccination event, in practice, a submission may include multiple vaccination events for either the same patient or multiple patients.
- Deduplication is out of scope for this topic. Duplicate immunizations should be resolved using MIROW 2006 Vaccine De-duplication Guidelines [1.7].

Alternate path:
2.8A. Vaccination event data is not valid:

- IIS rejects all or part of the submission and sends error message to EHR system. EHR system will process acknowledgement of rejected messages. Additionally, provider organization uses IIS reports to review issues. The provider organization then will take action to fix the problem and resubmit. If the complete submission is rejected, then Process 2 ends.

Decision support references: For guidance, see MIROW 2006 Vaccine De-duplication Guidelines [1.7], MIROW 2013 Data Quality Assurance Guidelines [1.2], CDC HL7 implementation guide [2.9, 2.10], and CDC HL7 implementation guides, P07, P08, S401, S402, S403, S701, S702, S703, S704.

Step 2.9: Update patient record (out of scope).

IIS validates that the administered/historical indicator (item 14.2, domain model, Appendix A: Terms and Definitions) for the vaccination event is marked as "administered" and updates the patient record with new patient and/or vaccination event data for an administered dose. Updating patient record is out of scope for this topic:

- This step occurs before matching inventory for decrementing to ensure capture of vaccination event for immunization tracking purposes, even if inventory issues exist.

Alternate path:
2.9A. Vaccination event submission reflects a historical dose.

- IIS updates patient record for historical dose (out of scope). Process 2 ends.
- Only administered doses trigger the DI-v-EDE process.

Decision support references: P02, P07, P08, BR203, BR206, S501, S502, S503, S701, S704, S801, S901, S902, S1001.

Step 2.10: Match lot number to decrement.

IIS finds a match between the lot number in the vaccination event submission and the lot number in the IIS inventory for the provider organization. Note: this step is only looking at matching a lot number. Additional data elements are matched in Step 2.12.

- Lot number presentation for vaccine's unit of use may have to be mapped to the lot number presentation for unit of sale. See MIROW 2015 Lot Number Patterns Micro Guide [1.9].

Alternate paths:

2.10A. Lot number is not found in IIS inventory for the provider organization.

- Log issue.
- Notify provider organization that no match was found for lot number in provider organization's inventory (i.e., inventory decrementing report, Chapter 6: Reports). Process 2 ends but processing of the submission continues for purposes of tracking the vaccination event.

Decision support references: MIROW 2015 Lot Number Patterns Micro Guide [1.9], P07, P08, S704, S1001.

Step 2.11: Validate lot number and vaccination event date (cross-field validation).

IIS verifies that vaccination event date is after the most recent reconciliation closed date. IIS policies vary regarding whether reconciliations are allowed to be closed or not. For those IIS that do allow the reconciliations to be closed there is additional variability in the allowance of decrementation during the closed reconciliation period. Additionally, IIS verifies that there is no contradiction between matched lot number, NDC (if sent), and/or CVX code for the vaccine. Lot numbers should contain information about lot number only. It is not the best practice to accept lot numbers that contain other information; however, IIS may accept different lot number formats during a transition phase and perform data validation in accordance with the MIROW lot number validation best practices guidelines. See MIROW 2015 Lot Number Validation Micro Guide [1.10]. For example, some provider organizations may add characters to the lot number to distinguish public lot numbers from private lot numbers.

Alternate path:

2.11A. Vaccination event date is before most recent reconciliation closed date.

- Log issue.
- Notify provider organization with appropriate error or info message. Process 2 ends.

2.11B. Lot number, NDC, and/or CVX codes do not match.

- Depending on the awardee's policy, either flag data quality issue and continue with next step or do not decrement and respond with an error message (in this case, Process 2 ends; provider organization will need to address the issue and resubmit).

Decision support references: MIROW 2015 Lot Number Validation Micro Guide [1.10], P07, P08, BR205, BR302.

Step 2.12: Determine inventory item to decrement.

IIS determines provider organization's inventory item to decrement based on a) submitted information, such as lot number, lot number expiration date, dose-level eligibility, and optionally for DI-v-EDE, dose-level public/private indicator for the vaccine, and b) information about provider organization's inventory in IIS, such as lot number, lot number expiration date, and lot-level public/private indicator.

- For example, if provider organization uses a two-stock model (i.e., public and private stocks) and lot number has doses in both public and private stocks:
  - When submitted dose-level eligibility is a VFC-eligible status and dose-level public/private indicator is public, the IIS should decrement public inventory for this lot number (i.e., inventory that has lot-level public/private indicator for that lot number = public).
  - When submitted dose-level eligibility is a VFC-eligible status and dose-level public/private indicator is private, the IIS should decrement private inventory for this lot number (i.e., inventory that has lot-level public/private indicator for that lot number = private). Note: This example is assuming the IIS tracks private inventory.
- See Step 1.3 and Step 1.6 of Process 1: "Add shipment information to IIS" for assigning lot number public/private indicator.
- When appropriate, IIS creates a borrowing transaction. In the example above, when submitted dose-level eligibility is a VFC-eligible status and dose-level public/private indicator is private, a borrowing transaction can be created. For guidance on borrowing, see awardee and VFC program guides, as well as MIROW 2012 Inventory Management Guidelines [1.3].
- The simplest situation is when a provider organization uses a one-stock model. In this case, there is only one inventory to select.

  Alternate path:
  2.12A. IIS could not determine inventory item to decrement.
  - Log issue or error.
  - Notify provider organization with appropriate error or info message.
  - Process 2 ends but processing of the submission continues for purposes of tracking the vaccination event.

Decision support references: P06, P07, P08, P09, Chapter 5: Business Rules, Chapter 9: Implementation Considerations, S701, S801, S1101, Appendix D: Decision Making.

Step 2.13: Decrement selected inventory item.

IIS confirms the selected inventory item is "active" and that the balance for the inventory item is greater than zero. IIS decrements balance for the selected inventory item by one. An inventory item is designated as inactive when all vaccine doses associated with the inventory item are spent (the balance is "0") or when the doses have expired (beyond the lot number expiration date).

- Multidose vials may require rounding or partial dose tracking (e.g., flu, HepB). Some IIS have incorporated the ability to decrement partial doses in their IIS; however, this was not discussed in depth as most IIS decrement based on single doses only.
- Depending on the awardee's policy, it may be possible to decrement an inactive inventory item, but this is NOT the recommended best practice.

Decision support references: See Table 3 in Chapter 5: Business Rules. BR204, S501, S502, S503.

Note: Figure 5 and Figure 6 below include process map illustrations of this process. Figure 5 is a simplified version and Figure 6 is a detailed version that includes referenced principles, business rules, and scenarios.

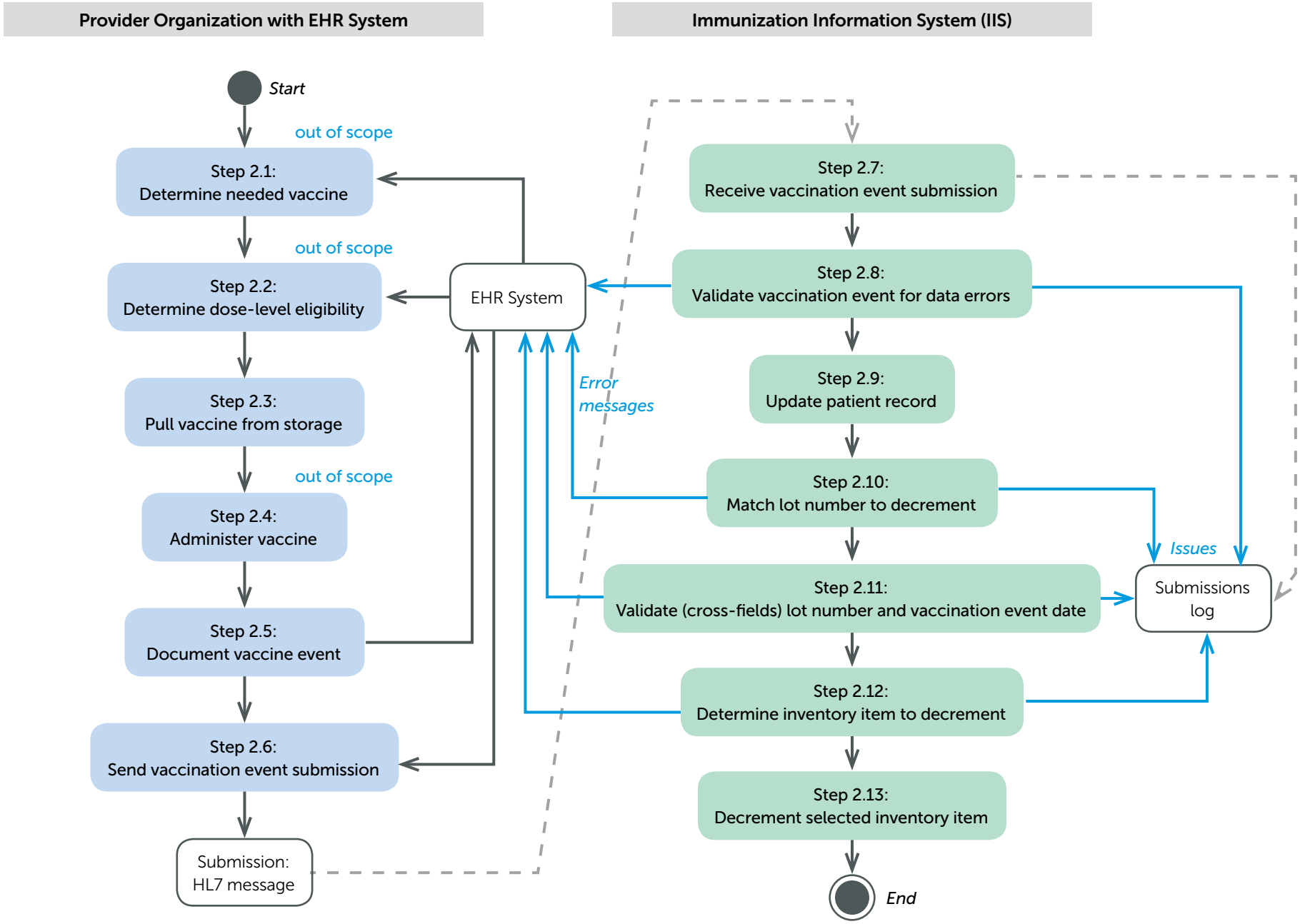


Figure 5. Simplified process 2 map

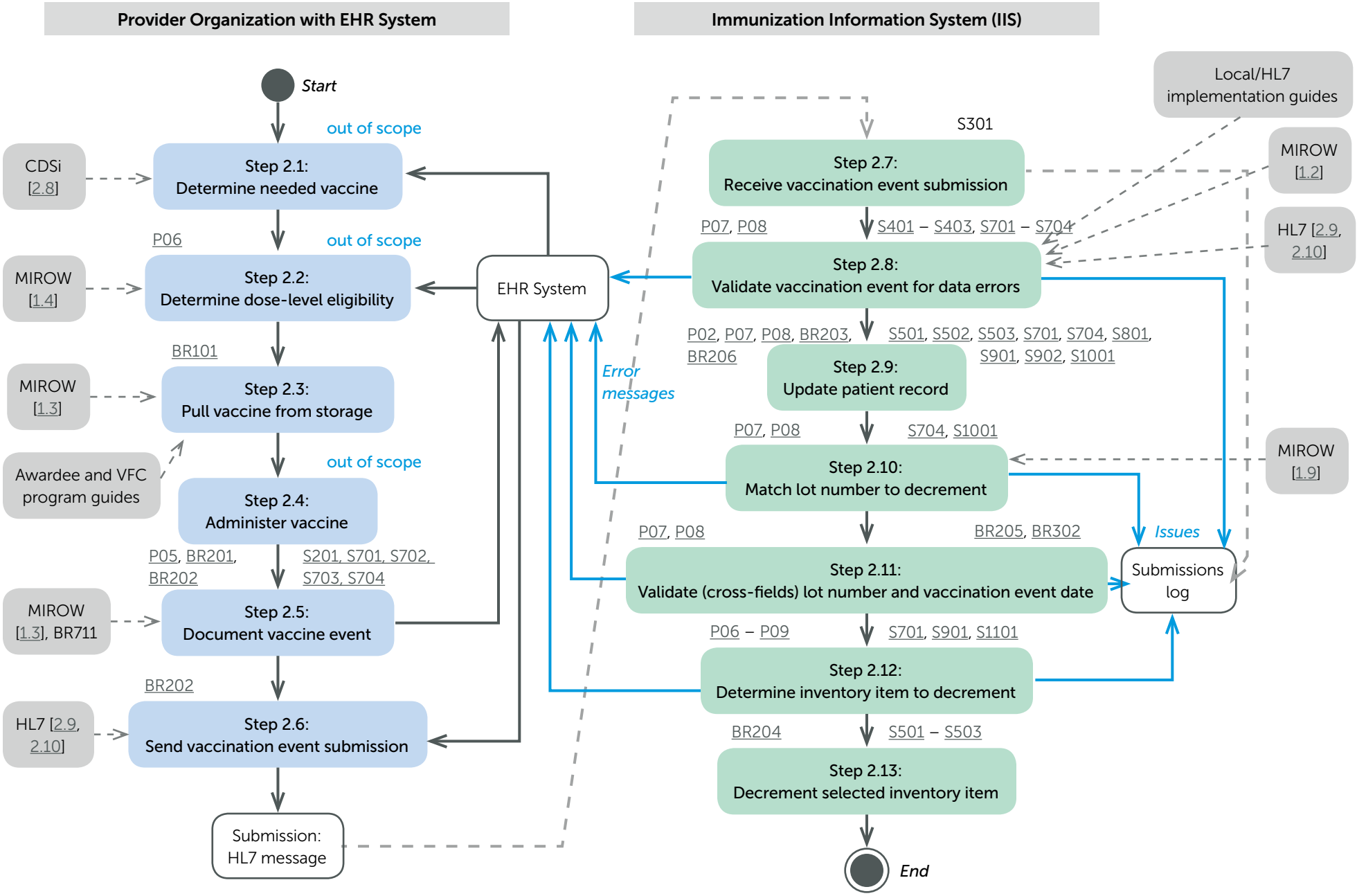


Figure 6. Detailed process 2 map

Process 3: Address issues and errors

This is essentially a two-phase process:

- During the DI-v-EDE process (described above), the IIS documents any data quality issues in each provider organization's inventory so that the provider organization may resolve as many of those issues as possible prior to reconciliation.
- The reconciliation process serves as an opportunity for the provider organization to catch and fix all remaining issues. The provider organization compares the number of vaccine doses in the physical storage unit with information in the IIS. The provider organization makes any needed adjustments to the inventory balances and establishes the reconciliation end date.

Figure 7 and Figure 8 provide process map illustrations for this process.

Step 3.1: Document and communicate data quality issues.

During the DI-v-EDE process, IIS documents and communicates data quality issues to the provider organization.

- The IIS communicates issues in the DI-v-EDE process through a) error messages sent from IIS to the EHR and b) reports produced based on the log of issues.

Decision support references: P05, P07, Chapter 6: Reports, S401, S402, S403, S501, S502, S503, S701, S702, S703, S704, S801, S901, S1001.

Step 3.2: Resolve data quality issues.

The provider organization, in collaboration with IIS, resolves data quality issues using IIS Direct UI and/or EHR. This also can include resubmission of corrected vaccination event information to IIS.

Decision support references: MIROW 2012 Inventory Management Guidelines [1.3], MIROW 2008 Data Quality Assurance Guidelines [1.6], and MIROW 2013 Data Quality Assurance Guidelines [1.2], P05, P08, BR301, S401, S402, S403, S501, S502, S503, S701, S702, S703, S704, S801, S901, S1001.

Step 3.3: Reconcile inventory.

Reconciliation includes the following sequence of actions performed for the provider organization inventory, which can include more than one inventory item:

- IIS provides reports of the provider organization's inventory balances in the IIS, categorized by inventory item (lot number, lot number expiration date, and lot-level public/private indicator).
- Provider compares physical vaccine inventory to inventory in IIS categorized by inventory item (lot number, lot number expiration date, and lot-level public/private indicator and/or fund type).
- Provider resolves inventory discrepancies for each inventory item using IIS Direct UI or EHR.
- Provider marks inventory reconciliation in IIS as "completed" or "closed."
  - Note: Practices vary regarding whether reconciliations are closed, and if closed, whether they can be reopened to make manual corrections.
- Each IIS should discuss this issue with the awardee's VFC program to determine how to deal with these issues. IIS produces report of final reconciliation results.

Decision support references: For guidance on reconciliation, see MIROW 2011 IIS Collaboration with VFC and Grantee Guidelines [1.4] and MIROW 2012 Inventory Management Guidelines [1.3], BR302, BR303, S1203, S1204, S1301.

Note: Figure 7 and Figure 8 below include process map illustrations of this process. Figure 7 is a simplified version and Figure 8 is a detailed version that includes referenced principles, business rules, and scenarios.

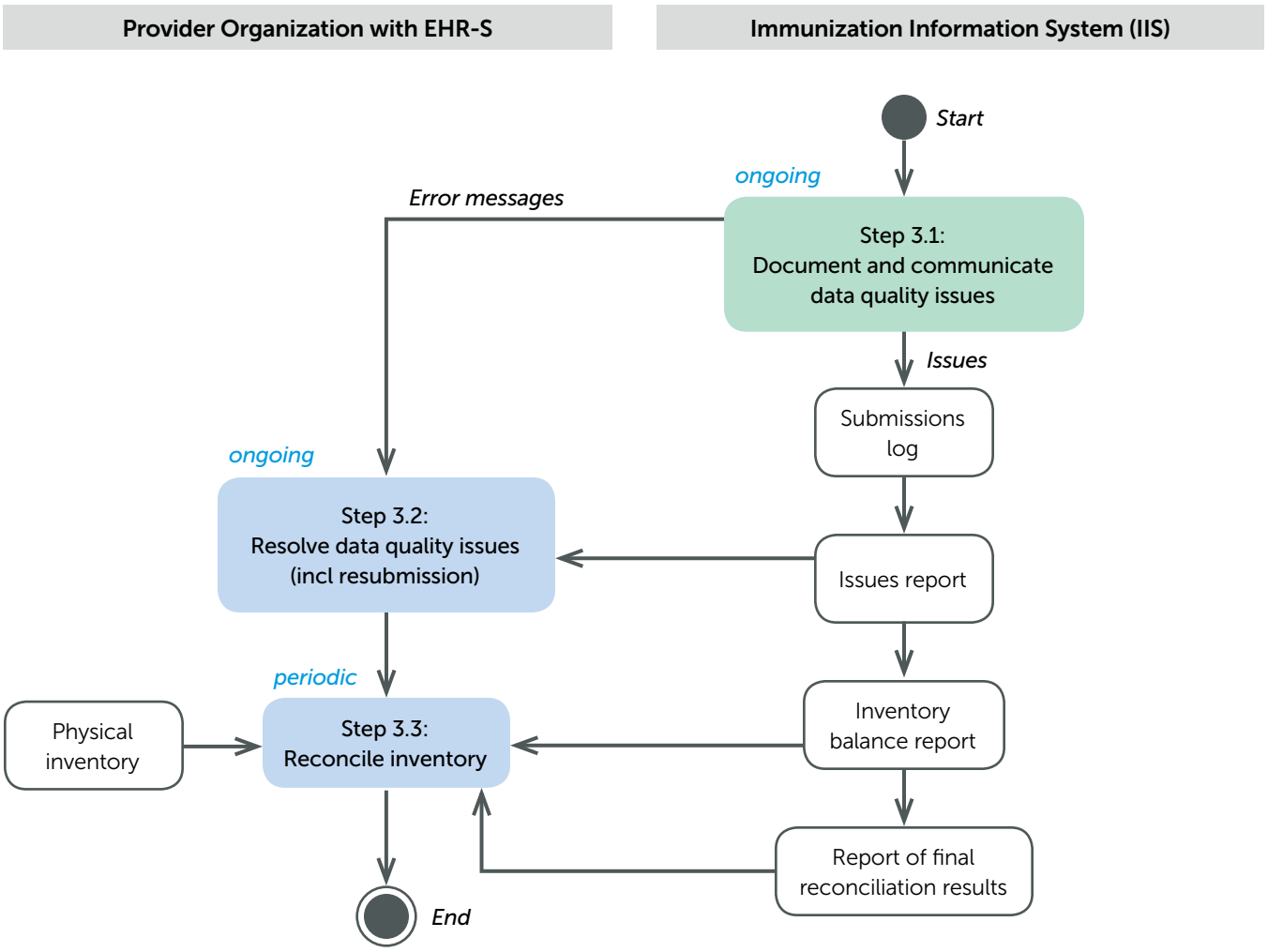


Figure 7. Simplified process 3 map

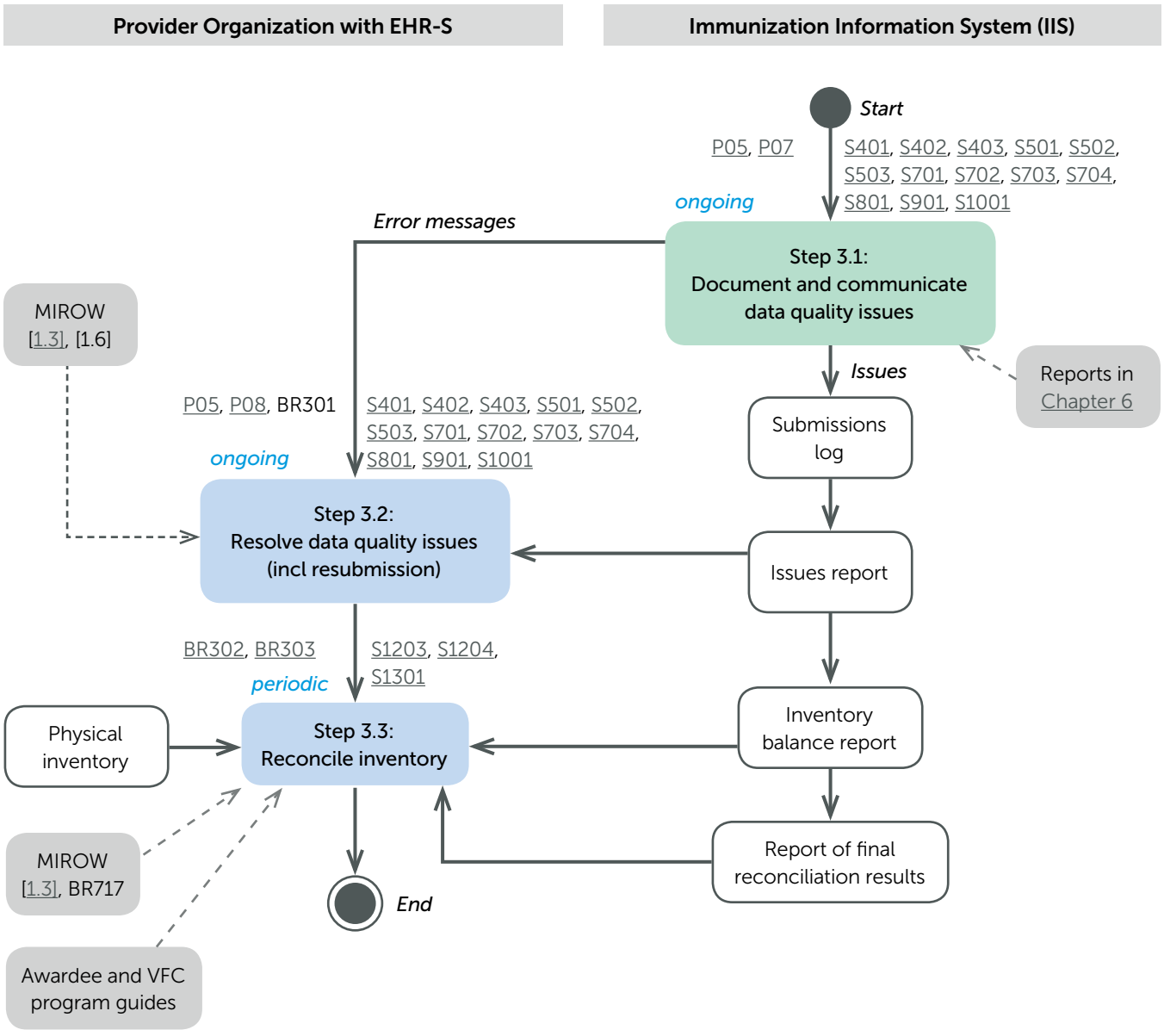


Figure 8. Detailed process 3 map—Address issues and errors

Chapter 5: Business Rules for the DI-v-EDE Process

This chapter contains business rules and decision tables that support specific process steps described in Chapter 4: Process Model. In contrast to fundamental principles (P) that provide overarching direction for the DI-v-EDE functional area of operations (Chapter 3: Fundamentals), business rules (BR) represent specific requirements and decision-making logic for various steps of the DI-v-EDE process. Additionally, this chapter contains business rules that provide general recommendations for IIS functionality required to support the DI-v-EDE process. Some of the business rules are presented in the form of decision tables, which are collections of business rules organized in a tabular format.

Table 2 presents business rules in the following order:

Add shipment information to IIS (Process 1, Chapter 4)

- BR101. Organize inventory information in IIS by the lot number, lot number expiration date, and lot-level public/private indicator.
- BR102. Prepopulate provider organization's inventory in IIS.
- BR103. Download shipment information daily.
- BR104. Increment inventory item balance with shipment information.
- BR105. Verify physical contents of a vaccine shipment.
- BR106. Notify awardee VFC program and IIS of discrepancies between physical contents and packing slip and/or IIS.
- BR107. Create new inventory item for short-dated doses.
- BR108. Calculate inventory item balance after creating new inventory item for short-dated doses.

Decrement inventory (Process 2, Chapter 4)

- BR201. Document the vaccination event after vaccine administration.
- BR202. Submit information to IIS to support DI-v-EDE.
- BR203. Decrement only "administered" vaccines.
- BR204. Decrement only "active" inventory.
- BR205. Do not automatically decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date.
- BR206. Update patient record regardless of inventory-related issues.

Address issues and errors (Process 3, Chapter 4)

- BR301. Resolve data quality issues before reconciling.
- BR302. Freeze reconciliation results.
- BR303. Reopen reconciliation that is closed.

General recommendations

- BR401. Establish and maintain a preapproval process for provider organizations.
- BR402. Establish a testing environment for the preapproval process.
- BR403. Establish a preapproval testing process.
- BR404. Develop educational/training opportunities.
- BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality.
- BR406. Manage deletion of a patient's record from IIS.
- BR407. Examine all data elements of a DI-v-EDE submission during preapproval.
- BR408. Manage deletion of a vaccination event from IIS.
- BR409. Manual corrections made in the IIS should also be made in the EHR.

Note: Remarks are an integral part of business rules. It is important to study, reference, and implement each of these business rules in their entirety, including information contained in the "Remarks" column.

Table 2. Business rules for the DI-v-EDE process

#	Principles	Remarks
Add shipment information to IIS		
BR101	**BR101. Organize inventory information in IIS by the lot number, lot number expiration date, and lot-level public/private indicator.** Inventory information should be organized in IIS by the lot number, lot number expiration date, and lot-level public/private indicator.	■ For example, a provider organization using the two-stock model has lot number ABC123 (with the same lot number expiration date) in both public and private stocks. The IIS should categorize the doses within inventory items to replicate the physical inventory in provider organizations' storage unit: 1) lot number ABC123, lot-level public/private indicator = public, and 2) lot number ABC123, lot-level public/private indicator = private. ■ For three-stock and four-stock storage models, the assignment of a lot number to the appropriate inventory item in IIS should be based on the fund type designated in the order. The IIS may determine the appropriate inventory item based on the vaccine order or the provider organization can determine the appropriate inventory item based on the shipment packing slip. ■ Since VTrckS shipments contain only public vaccines, for the two-stock storage model, the IIS assigns lot numbers to the public inventory item. ■ For references, see: ▪ P04. Inventory information in the IIS should map to the storage model used by the provider organization. ▪ P06. DI-v-EDE should support dose-level accountability. ▪ BR104. Increment inventory item balance with shipment information. ▪ BR107. Create new inventory item for short-dated doses. ▪ BR108. Calculate inventory item balance after creating new inventory item for short-dated doses. ▪ Step 1.3 and Step 2.3. ▪ Scenario S102.
BR102	**BR102. Prepopulate provider organization's inventory in IIS.** Provider organization's inventory in the IIS should be prepopulated based on the shipment data uploaded in the IIS from VTrckS.	■ DI-v-EDE should minimize manual data entry by provider organizations. ■ Prepopulation can occur through either new shipment data or a transfer from another provider organization. ■ For references, see: ▪ GR710 in MIROW 2012 Inventory Management Guidelines [1.3]. ▪ See P05. DI-v-EDE should minimize the burden on provider organizations. ▪ BR103. Download shipment information daily. ▪ BR104. Increment inventory item balance with shipment information. ▪ Step 1.2 and Step 1.3. ▪ Scenario S102.
BR103	**BR103. Download shipment information daily.** IIS should at least daily download shipment information from VTrckS and update provider organization's inventory in IIS by uploading shipment file into IIS.	■ The exception to the daily download would be when VTrckS has planned or unplanned downtime. ■ For references, see: ▪ P05. DI-v-EDE should minimize the burden on provider organizations. ▪ BR102. Prepopulate provider organization's inventory in IIS. ▪ BR104. Increment inventory item balance with shipment information. ▪ Step 1.2 and Scenario S102.

#	Principles	Remarks
BR104	**BR104. Increment inventory item balance with shipment information.** Balance for an existing inventory item should be incremented by quantity of doses in the shipment, identified by lot number, lot number expiration date, and lot-level public/private indicator.	■ For example, a provider organization using the two-stock model has lot number ABC123 in both public and private stocks. If the provider organization receives a new shipment containing 5 VFC doses, 3 317 doses, and 4 state doses with the same lot number ABC123, the balance for the lot number ABC123 inventory item for a public stock (i.e., lot number public/private indicator = public) should be incremented by 12 doses. ■ To avoid duplication of lot numbers, inventory items can be incremented for active or inactive lot numbers. ■ For references, see: ▪ BR101. Organize inventory information in IIS by the lot number, lot number expiration date, and lot-level public/private indicator. ▪ BR102. Prepopulate provider organization's inventory in IIS. ▪ BR103. Download shipment information daily. ▪ Step 1.3 and Scenario S102.
BR105	**BR105. Verify physical contents of a vaccine shipment.** A provider organization should verify the physical contents of a shipment against the packing slip and the information in the IIS by the close of business on the day of receipt.	■ For references, see: ▪ Step 1.5 and Step 1.6. ▪ Scenario S101.
BR106	**BR106. Notify awardee VFC program and IIS of discrepancies between physical contents and packing slip and/or IIS.** A provider organization should notify the awardee VFC program and the IIS immediately upon discovery of any discrepancy between physical contents of a shipment and the packing slip and/or information in the IIS.	■ For references, see: ▪ Step 1.5 and Step 1.6. ▪ Scenario S101.

#	Principles	Remarks
BR107	**BR107. Create new inventory item for short-dated doses.** Awardee staff or provider organization should create a new inventory item for short-dated doses.	■ The new inventory item is identified by the same lot number and lot-level public/private indicator as an original inventory item, but with a different lot number expiration date. See domain model, item 8.0 Inventory. ■ The vaccine manufacturer initially establishes lot number expiration date and all doses in a lot have the same expiration date. In some cases, vaccine is subject to temperature variations in storage that are outside the recommended range. The doses of vaccine that were subject to the temperature variations may be given a new expiration date that is sooner than the original expiration date (short-dated). ▪ According to BR712, MIROW 2012 Inventory Management Guidelines [1.3, p.44]: "When present, the short-dated lot number expiration date must be used (recorded) for all inventory transactions instead of the original lot number expiration date". ▪ For additional discussion of short-dated lot number expiration date, see MIROW 2012 Inventory Management Guidelines [1.3], specifically, BR711, p. 43, BR712, p. 44, GR706, p. 55, and BR718, p. 47 ■ When vaccine doses are compromised (usually, due to a temperature excursion), there are three possible outcomes: a) all affected doses are viable and don't need to be short-dated, or b) all affected doses are viable and get short-dated, or c) all affected doses are non-viable and are considered to be wasted. Our focus, from perspective of the DI-v-EDE process, is on scenario (b) handling short-dated doses. See Table 3 for additional considerations. ■ In rare circumstances, the lot expiration dates can be given an extension by the Federal Drug Administration, particularly in the case of a pandemic with vaccine that is part of the Strategic National Stockpile. ■ For further references, see: ▪ BR101. Organize inventory information in IIS by the lot number, lot number expiration date, and lot-level public/private indicator. ▪ BR108. Calculate inventory item balance after creating new inventory item for short-dated doses. ▪ Scenario S601. ▪ Appendix E. Handling Doses with Short-dated Lot Number Expiration Dates.

#	Principles	Remarks

BR108	**BR108. Calculate inventory item balance after creating new inventory item for short-dated doses.**
	When the IIS creates a new inventory item for short-dated doses, the original inventory item balance should be calculated as a current quantity of doses minus the number of short-dated doses (compromised, but viable, and reassigned to the new inventory item).
		■ Short-dated doses should be reassigned to the new inventory item with the same lot number and lot number public/private indicator, but with a different expiration date (see BR107).
		■ The IIS should reduce the balance of the original inventory item by the number of compromised, but still viable, doses that are now grouped in the new inventory item with the short-dated expiration date.
		■ If the original inventory item (with the original expiration date) still has a positive balance, it should remain active; otherwise, it should be deactivated.
		  ▪ To ensure that short-dated vaccines are used before doses with the original expiration date, some IIS temporarily deactivate the original inventory item (with the original expiration date) even when it has a positive balance.
		  ▪ If the lot number expiration date is not included in an HL7 message, the inactive and active flag on the lot number can be used to distinguish between inventory item with original and short-dated expiration date.
		■ For references, see:
		  ▪ BR101. Organize inventory information in IIS by the lot number, lot number expiration date, and lot-level public/private indicator.
		  ▪ BR107. Create new inventory item for short-dated doses.
		  ▪ Scenario S601.
		  ▪ Appendix E. Handling Doses with Short-dated Lot Number Expiration Dates.

Decrement Inventory		
BR201	**BR201. Document the vaccination event after vaccine administration.** The provider organization should document a vaccination event (enter it in the EHR) after the vaccine is administered (not at the point when the vaccination is prescribed by the provider).	■ Sometimes the actual vaccine administered is different from what was ordered by the provider. ■ This should be part of provider training. ■ Not all clinical work-flows support this approach. ■ For references, see: ▪ Step 2.5.

#	Principles	Remarks

BR202	**BR202. Submit information to IIS to support DI-v-EDE.**
	
	To support the DI-v-EDE process, submission of vaccination event information should include:
	■ Lot number
	■ Dose-level eligibility
	■ Dose-level public/private indicator (optional for DI-v-EDE)
	■ Vaccination event date
	■ CVX code
	■ NDC (optional for DI-v-EDE)
	■ Provider organization IIS ID
	■ Lot number expiration date
		■ This list includes only data elements relevant for inventory tracking purposes. Submission may include additional information for vaccination event tracking.
		■ For the recommended minimum set of data items for every vaccine dose, see BR711, MIROW 2012 Inventory Management Guidelines [1.3, p. 43].
		■ Vaccination event date is used to:
		  ▪ Determine if the vaccine was administered before or after the reconciliation date.
		  ▪ Validate against lot number expiration date.
		  ▪ Log when the transaction occurred for auditing purposes.
		■ CVX code:
		  ▪ If the lot number is incorrect, the IIS can still store the vaccination using CVX code.
		  ▪ Used for data quality validation.
		  ▪ EHR already have the ability to store and transmit, so no reengineering required.
		■ NDC:
		  ▪ See MIROW 2012 Inventory Management Guidelines [1.3].
		  ▪ NDC is proposed as a replacement for CVX in MU Stage 3, so NDC would replace CVX as the required vaccine coding system for HL7. If providers have to enter this manually, it would be an opportunity for errors.
		  ▪ Currently, lot number ties to only one NDC in IIS; could be used for additional validation [1.3].
		■ The following excerpt was taken from the MIROW 2012 Inventory Management Guidelines [1.3].
		  ▪ Possible additional data item: In situations when Provider Organization gives two doses of a pediatric vaccine for an adult dose or a half-dose of an adult vaccine for a pediatric dose (e.g., when vaccine has been used not according with the adult/ pediatric "intention"), IIS can either use a dose trigger function (designate dose size as half, full, or double) or manually decrement the second dose or a half-dose from the inventory.
		■ For discussion of short-dated lot number expiration date, see MIROW 2012 Inventory Management Guidelines [1.3], specifically, BR711, p. 43, BR712, p. 44, GR706, p. 55, and BR718, p. 47.
		■ For discussion of provider organization ID, see MIROW 2013 Data Quality Assurance Guidelines [1.2].
		■ For further references, see:
		  ▪ P06. DI-v-EDE should support dose-level accountability.
		  ▪ BR407. Examine all data elements of a DI-v-EDE submission during preapproval.
		  ▪ Step 2.5 and Step 2.6.
		  ▪ Scenarios S201, S701, S702, S703, and S704.

BR203	**BR203. Decrement only "administered" vaccines.**
	
	Only "administered" doses should result in automatic decrementing of inventory through the DI-v-EDE process.
		■ For references, see:
		  ▪ Item 14.2 Administered/ Historical Indicator in Appendix A: Terms and Definitions.
		  ▪ Step 2.9 and Scenarios S201, S901, and S902

#	Principles	Remarks
BR204	**BR204. Decrement only "active" inventory.** Only "active" inventory may be decremented.	■ Administering a vaccine from a lot that has not yet been accepted in the inventory can cause duplication and complications in the reconciliation. ■ Some programs have policies that allow decrementing inactive inventory, but this is NOT a best practice. ■ Clinical errors may result in administration of inactive inventory (for example, administration of vaccine past its expiration date). The IIS should reflect what actually happened in the clinical encounter, even if it was a clinical error. The provider organization should manually decrement inactive inventory to reflect clinical practice. ■ IIS may consider implementing a validation rule that allows decrementation of inventory if the date of vaccine administration is prior to the date the lot number was made inactive. Note: For IIS that close reconciliations, BR205 may be a factor in this validation rule. ■ For references, see: ▪ 8.3 in Appendix A: Terms and Definitions. ▪ Step 1.4, 1.8, and 2.13. ▪ Scenarios S201, S501, S502, and S503.
BR205	**BR205. Do not automatically decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date.** The IIS should prevent automatic decrementing of inventory and log an issue when the vaccination event date is prior to or on the end date of the most recent closed reconciliation period.	■ Submitting vaccination event info after reconciliation date leads to decrementing issues. ■ Reconciliations can be reopened after they have been closed to make any potential data corrections. ■ If this occurs, an issue should be logged for manual intervention. ■ Current practices vary regarding whether reconciliations are closed, and if they are closed, whether they can be reopened to make manual corrections. ■ Each IIS should discuss this issue with the awardee's VFC program to determine how to deal with these issues. ■ For discussion of reconciliation end dates, see MIROW 2012 Inventory Management Guidelines [1.3], specifically, BR717 and BR721. ■ For references, see: ▪ BR302. Freeze reconciliation results. ▪ BR303. Reopen reconciliation that is closed. ▪ Step 2.11. ▪ Scenario S1203 and S1204.
BR206	**BR206. Update patient record regardless of inventory-related issues.** The IIS should update a patient record with demographic and immunization information reported in a submission regardless of any inventory-related issues with the submission.	■ Decrementing inventory is not the only function that uses submitted vaccination event data. ■ See HL7 Immunization Messaging in Chapter 9: Implementation Considerations. ■ For references, see: ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ Step 2.9. ▪ Scenarios S201, S501, S502, S503, S701, S704, S801, S901, and S1001.

#	Principles	Remarks
Address issues and errors		
BR301	**BR301. Resolve data quality issues before reconciling.** The provider organization should resolve data quality issues prior to reconciling inventory.	■ For references, see: ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ Step 3.2. ▪ Scenario S1301. P07 in MIROW 2012 Inventory Management Guidelines [1.3] accurate accounting. Any inventory transaction should be reversible and can be corrected as necessary. ▪ BR101 (and associated notes), MIROW 2008 Data Quality Assurance Guidelines [1.6].
BR302	**BR302. Freeze reconciliation results.** The IIS should freeze the reconciliation results after the reconciliation process is closed. Updates subsequent to the reconciliation date should not affect ordering.	■ Freeze (meaning prevent further changes) inventory after close of a reconciliation period. ■ IIS should store reconciliation "completed" or "closed" date to ensure the integrity of the reconciliation. ■ The results of a "frozen" reconciliation are a snapshot of a provider organizations' ending inventory at that time. The ending inventory is required by VTrckS to place new vaccine orders. ■ Current practices vary regarding whether reconciliations are closed, and if they are closed, whether they can be reopened to make manual corrections. Each IIS should discuss this issue with the awardee's VFC program to determine how to deal with these issues. ■ For references, see: ▪ BR205. Do not automatically decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date. ▪ BR303. Reopen reconciliation that is closed. ▪ Step 2.11 and Step 3.3. ▪ Scenarios S1203, S1204, and S1301. ▪ BR717 in the MIROW 2012 Inventory Management Guidelines [1.3].
BR303	**BR303. Reopen reconciliation that is closed.** Once reconciliation is closed, it may be reopened only by IIS staff with elevated privileges (admin).	■ Reopening of a closed reconciliation should be done manually (not through the EDE). ■ If reconciliation is reopened after being closed, an issue should be logged for manual intervention. ■ This business rule is an exception to BR302. ■ For references, see: ▪ BR205. Do not automatically decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date. ▪ Step 3.3 and Scenarios S1203, S1204, and S1301.
General recommendations		
BR401	**BR401. Establish and maintain a preapproval process for provider organizations.** IIS should establish and maintain a preapproval process for provider organizations that intend to submit vaccination event information electronically to IIS.	■ For references, see: ▪ P03. The IIS must preapprove a provider organization for DI-v-EDE. ▪ BR402. Establish a testing environment for the preapproval process. ▪ BR403. Establish a preapproval testing process. ▪ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ▪ Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ▪ Scenario S301.

#	Principles	Remarks
BR402	**BR402. Establish a testing environment for the preapproval process.** IIS should establish a testing environment (technical and operational components) to support the preapproval process for provider organizations.	■ The testing environment should have a copy of production data, including active lot numbers, so provider organizations can simulate real-case scenarios of administering a vaccine and having that vaccination event submitted to the IIS and, in turn, decremented appropriately. ■ For references, see: ▪ Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ▪ P03. The IIS must preapprove a provider organization for DI-v-EDE. ▪ BR401. Establish and maintain a preapproval process for provider organizations. ▪ BR403. Establish a preapproval testing process. ▪ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ▪ Scenario S301.
BR403	**BR403. Establish a preapproval testing process.** IIS should establish a preapproval testing process, which includes testing individually with EHR vendor test data and provider organization data.	■ For references, see: ▪ Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ▪ P03. The IIS must preapprove a provider organization for DI-v-EDE. ▪ BR401. Establish and maintain a preapproval process for provider organizations. ▪ BR402. Establish a testing environment for the preapproval process. ▪ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ▪ Scenario S301.
BR404	**BR404. Develop educational/training offerings.** IIS should develop educational/training offerings to support DI-v-EDE process for participating provider organizations.	■ Materials should include troubleshooting information and what to do when DI-v-EDE issues are identified. ■ IIS should consider providing ongoing user training via video format (prerecorded or live webinar style) to accommodate learning styles and to build community partnerships. ■ For references, see: ▪ P05. DI-v-EDE should minimize the burden on provider organizations. ▪ Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance.
BR405	**BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality.** IIS should document requirements and instructions for using the DI-v-EDE IIS functionality for provider organizations and EHR vendors.	■ For references, see: ▪ P05. DI-v-EDE should minimize the burden on provider organizations. ▪ Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance.

#	Principles	Remarks
BR406	**BR406. Manage deletion of a patient's record from IIS.** If a patient's record is deleted from IIS, associated vaccination events that have been already accounted for via automatic decrementing should be unassociated from a patient's record and retained for inventory accounting purposes.	■ Deletion both applies to electronic deletions and via direct UI. ■ IIS needs to retain linkage between dose administered and decremented inventory. ■ State laws vary with respect to treatment of patient data (i.e., adoptions, opt-out, etc.). Some require deletion of the record, and some allow the retention of that record. ■ For references, see: ▪ BR408. Manage deletion of a vaccination event from IIS. ▪ Scenarios S1201, S1202, and S1203.
BR407	**BR407. Examine all data elements for a DI-v-EDE submission during preapproval.** During the preapproval process, the IIS should examine all data elements of a DI-v-EDE submission for accuracy and consistency.	■ For references, see: ▪ P03. The IIS must preapprove a provider organization for DI-v-EDE. ▪ BR202. Submit information to IIS to support DI-v-EDE. ▪ BR401. Establish and maintain a preapproval process for provider organizations. ▪ BR402. Establish a testing environment for the preapproval process. ▪ BR403. Establish a preapproval testing process. ▪ Scenarios S201 and S301.
BR408	**BR408. Manage deletion of a vaccination event from IIS.** If a vaccination event is deleted from IIS, associated inventory item should be incremented.	■ Balance of a lot number inventory should be incremented by one when a vaccination event associated with that lot number inventory is deleted. ■ For references, see: ▪ BR406. Manage deletion of a patient's record from IIS. ▪ Scenarios S1201, S1202, and S1203.
BR409	**BR409. Manual corrections made in the IIS should also be made in the EHR.** A provider organization should correct the data in the EHR to match any manual changes made in the IIS.	■ For references, see: ▪ Data Quality section in Chapter 9: Implementation Considerations.

As documented in BR204 above, only active inventory should be decremented. However, Table 3 below presents some examples of scenarios for decrementing inactive inventory items that reflect current practices in some IIS. It should be noted that this table is not all inclusive just some examples that occur. Each column in the following decision table below describes a single scenario determined by a combination of conditions (for example, whether the IIS allows inactive inventory to be decremented) and whether the conditions result in inventory decrementing and/or error messages to the provider organization. Some programs have policies that allow decrementing inactive inventory, but this is NOT a best practice. Business rules assembled in this decision table support Step 2.13, "Decrement selected inventory item," which occurs after the administered immunization has already been matched to a lot number in the IIS inventory (Step 2.10).

Table 3. Decrement selected inventory item

	A	B	C	D	E	F	G
CONDITIONS							
Selected inventory item is active? Y/N	Y	Y	Y	Y	Y	N	N
Decrementing inactive allowed? Y/N	–	–	–	–	–	Y	N
Inventory item balance: >0, =0, <0, (<0 and at lower limit)	>0	=0	=0	<0	<0 and LL	>0	–
Negative balances allowed? Y/N	–	N	Y	Y	Y	–	–
ACTIONS							
1. Decrement inventory item balance by 1	X		X	X		X	
2. Log issue or error		X	X	X	X	X	X
3. Notify provider organization with appropriate error or info message		X	X	X	X	X	X

Notes:

- Legend: "Y" = yes, "N" = no, "-" = does not matter, yes or no.
- Each column in this decision table represents a single scenario, which is determined by a combination of conditions and results in one or more of the actions; conditions and actions are defined in the left column. For example:
  - Scenario A. This is a typical "sunny day" scenario. Inventory item is active and inventory item balance is above zero. In this case, the inventory item balance should be decremented by one. It does not matter in this scenario if decrementing inactive inventory is allowed or not (second condition from the top).
  - Scenario E. Inventory is active; inventory item balance is below zero and it is at the lower limit allowed. Negative inventory balances are allowed by awardee's policy. In this case, inventory item is not decremented because the balance is at the lower limit. The IIS should log the issue/error and notify the provider organization with the appropriate error or information message.
    - For IIS that allow inventory item balance to go below zero, the lower limit is the lowest number that an IIS allows the inventory to fall below zero.

Chapter 6: Reports

This chapter contains descriptions of recommended reports to support the process of DI-v-EDE for both provider organizations and awardee immunization programs. These reports focus on issues specific to the management of vaccine inventory when decrementing through electronic data exchange. These reports build off several of the recommended reports described in the MIROW 2012 Inventory Management Guidelines [1.3]; however, these guidelines do not include inventory reports outside the scope of this topic (i.e., vaccine lost/wasted report). Based on discussions during and after the face-to-face meeting, it is clear that a comprehensive data quality report would be beneficial for DI-v-EDE; however, it was determined that such a report was beyond the scope of this guide.

It is not fully understood how many EHR vendors actually manage and parse ACK messages back from the IIS into actionable information for provider organizations (see EHR in Chapter 9: Implementation Considerations). Due to these unknowns, it is important that IIS have the ability to generate reports for provider organizations to alert them of needed inventory corrections. Reports are also a way for an IIS to aggregate other identified focus areas that are useful not only for provider organizations, but also for the awardee immunization program.

It is important to recognize that the reports included in these guidelines are conceptual in nature and can be implemented in a myriad of ways, which could include multiple components of what is illustrated into one physical report in an IIS. The titles of the reports below are just examples and awardee programs can implement what they feel is appropriate for their own IIS.

The reports included in this document are:

1. Vaccine Shipment Status (Accepted/Pending)
2. Inventory Decrementing Issues
3. Inventory Transaction History
4. Ending Inventory Transactions Summary
5. Inventory Last Balanced/Reconciled Dates
6. Patient Listing for Reconciliation
7. Physical Inventory

Each report section includes the following areas:

- An overview of how the report is often used.
- Applicable data inputs, elements, outputs, criteria, and parameters.
- One or more samples of output formats. Note: These are only examples and should not be considered best practice recommendations for implementation.

Vaccine shipment status (accepted/pending):

This report identifies the status of vaccine orders throughout the ordering and shipment process. Immunization program and provider organization staff can use this report to learn what stage of the distribution process the order is going through (for example, submitted, approved, denied, sent to distributor, shipped, accepted). This report is useful to the immunization program and the provider organization for several reasons:

- It offers a simple way for users to check on the status of their order.
- It decreases calls to the immunization program about the status of orders.
- It allows immunization program staff to see if vaccine orders have successfully been filled and shipped or if there is a problem with distribution.

This report is especially useful for IIS where incoming lot numbers from the shipment data file are marked as "pending" and require the provider organization to "claim" or "accept" the doses to make them active (Step 1.7). The report allows the IIS to identify which provider organizations may have inaccurate inventory and may need additional training on the process. It also indicates when provider organizations have unaccepted doses and/or missing shipments.

Table 4. Vaccine shipment inputs/parameters

	Elements
Data Inputs/Outputs	Provider Organization
	■ Provider organization ■ PO-IIS ID ■ VFC PIN
	Vaccine
	■ Vaccine type ■ Vaccine product type ■ NDC/CVX
	Shipment
	■ Shipment ID ■ Date shipped ■ Date made active ■ Quantity in doses
Parameters/Criteria	■ Provider organization ■ Date shipped (date range) ■ Date made active (date range) ■ Vaccine type ■ Vaccine product type ■ NDC/CVX ■ Shipment status

Vaccine shipment status sample

Orders

Order Number	Site	Order Date	Order Status	Who
20160126340010281BAL	[redacted]	01/26/2016	Awaiting Distributor Shipment	DHHS
2016012763112328 7BZ8	[redacted]	01/27/2016	Awaiting Distributor Shipment	DHHS
201602013500001QFA5Y	[redacted]	02/01/2016	Awaiting Distributor Shipment	DHHS
201601286300142INFOG	[redacted]	01/28/2016	Awaiting Distributor Shipment	DHHS
201601284102232PM2C2	[redacted]	01/28/2016	Awaiting Distributor Shipment	DHHS
20160129130063197RAC	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
201601298205441PC99M	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
201601298405251UU05P	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
201601298400001WPPBP	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
20160129600000220POHO	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
20160129840469220HMB	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
201601298405352D76HT	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
201601297520002IBSU8	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
201601297100042IOZ85	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
201601295001712NP8VI	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
201601294102192OVEPR	[redacted]	01/29/2016	Awaiting Distributor Shipment	DHHS
20160130040001 22ZKL3	[redacted]	01/30/2016	Awaiting Distributor Shipment	DHHS
201601308203802 7KGSY	[redacted]	01/30/2016	Awaiting Distributor Shipment	DHHS

Figure 9. Order status report (from Michigan IIS)

Inventory decrementing issues

This report allows for the identification of issues that prevent administered doses from correctly decrementing from inventory as well as doses that did decrement from inventory successfully. Detailed information is provided about what is preventing doses from decrementing from inventory. This allows the provider organization to fix errors and reconcile their inventory. IIS staff can also use this report to recognize problems and support provider organizations in fixing ongoing issues.

Submission errors that could be included are as follows:

- Invalid vaccination event data (e.g., errors that are due to issues in the RXA segment).
- Vaccination events submitted as historical rather than administered (e.g., with current date).
- Lot number is not in the IIS inventory.
- Conflict between NDC/CVX and lot number.
- Lot number is inactive.

Table 5. Inventory decrementing issues inputs/parameters

	Elements
Data Inputs/Outputs	Provider Organization
	■ Provider organization ■ PO-IIS ID ■ VFC PIN
	Patient
	■ First name ■ Last name ■ Patient ID ■ Medical record number ■ Date of birth ■ Gender/sex
	Vaccination Event
	■ Date of vaccination ■ Dose-level eligibility ■ Vaccine type ■ Vaccine product type ■ Lot number ■ Lot number expiration date ■ Dose-level public/private indicator ■ NDC/CVX
	Submission

	■ Submission date (date vaccination was submitted to the IIS)
	■ Historical/administered indicator
	■ Submission error(s) preventing doses from decrementing
	■ Inventory decrementing status
	  ▪ Decremented: matched to inventory and decremented
	  ▪ Not decremented with explanation of issue

Parameters/Criteria	■ Provider organization ■ Vaccination date range ■ Submission date range ■ Vaccine type ■ NDC/CVX ■ Lot number ■ Dose-level eligibility ■ Dose-level public/private indicator ■ Error reason

Inventory decrementing issues sample

Report run on 2013-12-11

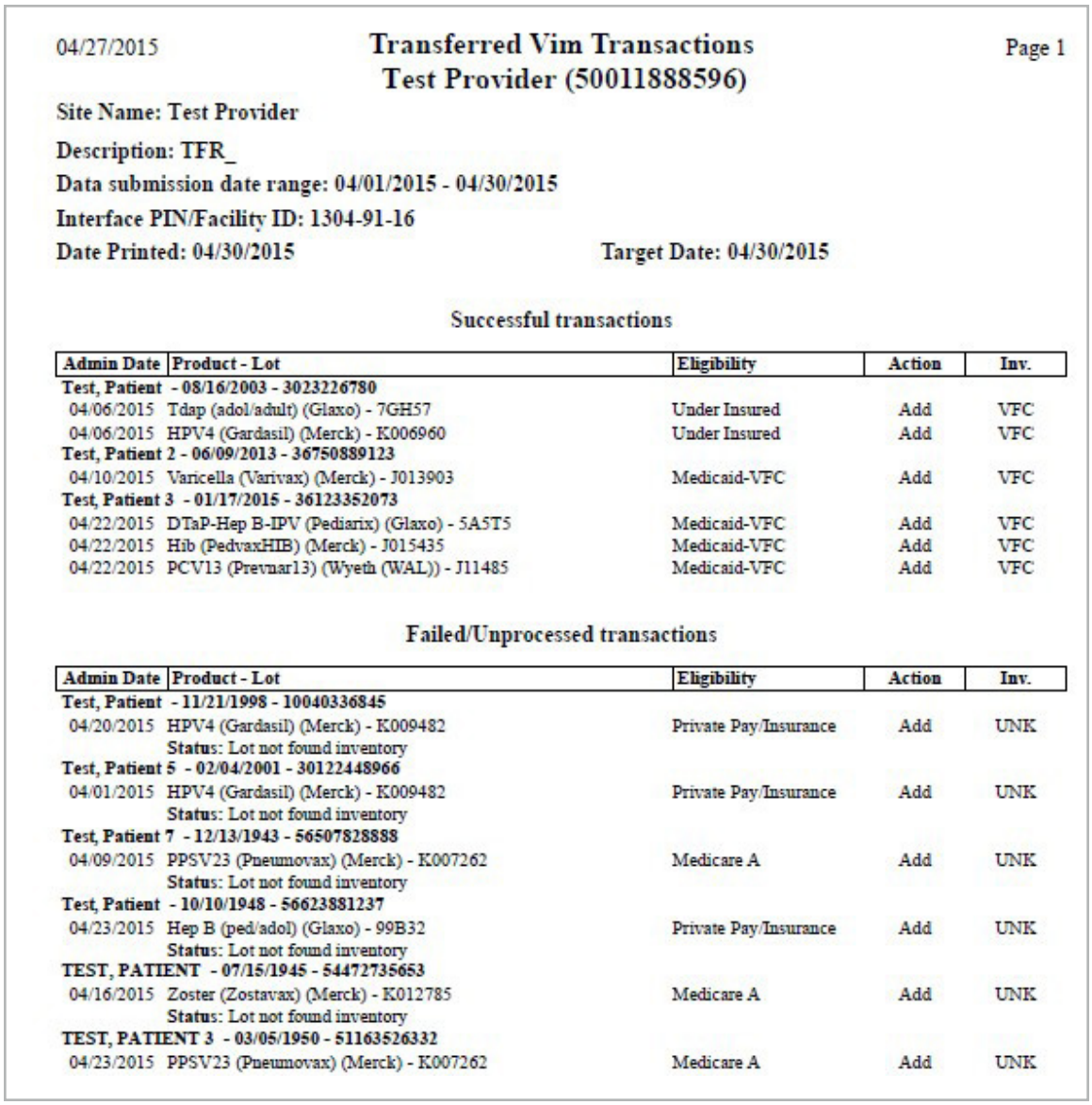
Organization MAINE MEDICAL PARTNERS

Sites(s) MMP SACO PEDIATRICS

MMP SACO PEDIATRICS 10131

Date	Client	Vaccine	Lot#	Vaccinator	Rejection Reasons
2013-11-26	zingy zing	Tdap > 7 years	AC52B088AA		Funding Program code in OBX did not match any vfc eligibility codes: V10
2013-07-26	wonton wontiz	Hep A	AhAvB536AA		The site does not have any lots matching lot number AhAvB536AA
2013-07-26	wonderful wonder	Hep A	AhAvB536		The site does not have any lots matching lot number AhAvB536
2013-11-26	silly sillow	Tdap > 7 years	AC52B088AA		The site does not have any lots matching lot number AC52B088AA
2013-11-26	hibby hibbit		UH765AA		The site does not have any lots matching lot number UH765AA

Figure 10. DES-Decrement detail report (from Maine IIS)



04/27/2015 **Transferred Vim Transactions** Page 1
Test Provider (50011888596)

Site Name: Test Provider

Description: TFR_

Data submission date range: 04/01/2015 - 04/30/2015

Interface PIN/Facility ID: 1304-91-16

Date Printed: 04/30/2015 **Target Date: 04/30/2015**

Successful transactions

Admin Date	Product - Lot	Eligibility	Action	Inv.
Test, Patient - 08/16/2003 - 3023226780				
04/06/2015	Tdap (adol/adult) (Glaxo) - 7GH57	Under Insured	Add	VFC
04/06/2015	HPV4 (Gardasil) (Merck) - K006960	Under Insured	Add	VFC
Test, Patient 2 - 06/09/2013 - 36750889123				
04/10/2015	Varicella (Varivax) (Merck) - J013903	Medicaid-VFC	Add	VFC
Test, Patient 3 - 01/17/2015 - 36123352073				
04/22/2015	DTaP-Hep B-IPV (Pediarix) (Glaxo) - 5A5T5	Medicaid-VFC	Add	VFC
04/22/2015	Hib (PedvaxHIB) (Merck) - J015435	Medicaid-VFC	Add	VFC
04/22/2015	PCV13 (Prevnar13) (Wyeth (WAL)) - J11485	Medicaid-VFC	Add	VFC

Failed/Unprocessed transactions

Admin Date	Product - Lot	Eligibility	Action	Inv.
Test, Patient - 11/21/1998 - 10040336845				
04/20/2015	HPV4 (Gardasil) (Merck) - K009482 **Status**: Lot not found inventory	Private Pay/Insurance	Add	UNK
Test, Patient 5 - 02/04/2001 - 30122448966				
04/01/2015	HPV4 (Gardasil) (Merck) - K009482 **Status**: Lot not found inventory	Private Pay/Insurance	Add	UNK
Test, Patient 7 - 12/13/1943 - 56507828888				
04/09/2015	PPSV23 (Pneumovax) (Merck) - K007262 **Status**: Lot not found inventory	Medicare A	Add	UNK
Test, Patient - 10/10/1948 - 56623881237				
04/23/2015	Hep B (ped/adol) (Glaxo) - 99B32 **Status**: Lot not found inventory	Private Pay/Insurance	Add	UNK
TEST, PATIENT - 07/15/1945 - 54472735653				
04/16/2015	Zoster (Zostavax) (Merck) - K012785 **Status**: Lot not found inventory	Medicare A	Add	UNK
TEST, PATIENT 3 - 03/05/1950 - 51163526332				
04/23/2015	PPSV23 (Pneumovax) (Merck) - K007262	Medicare A	Add	UNK

Figure 11. Transferred VIM transactions (from Michigan IIS)

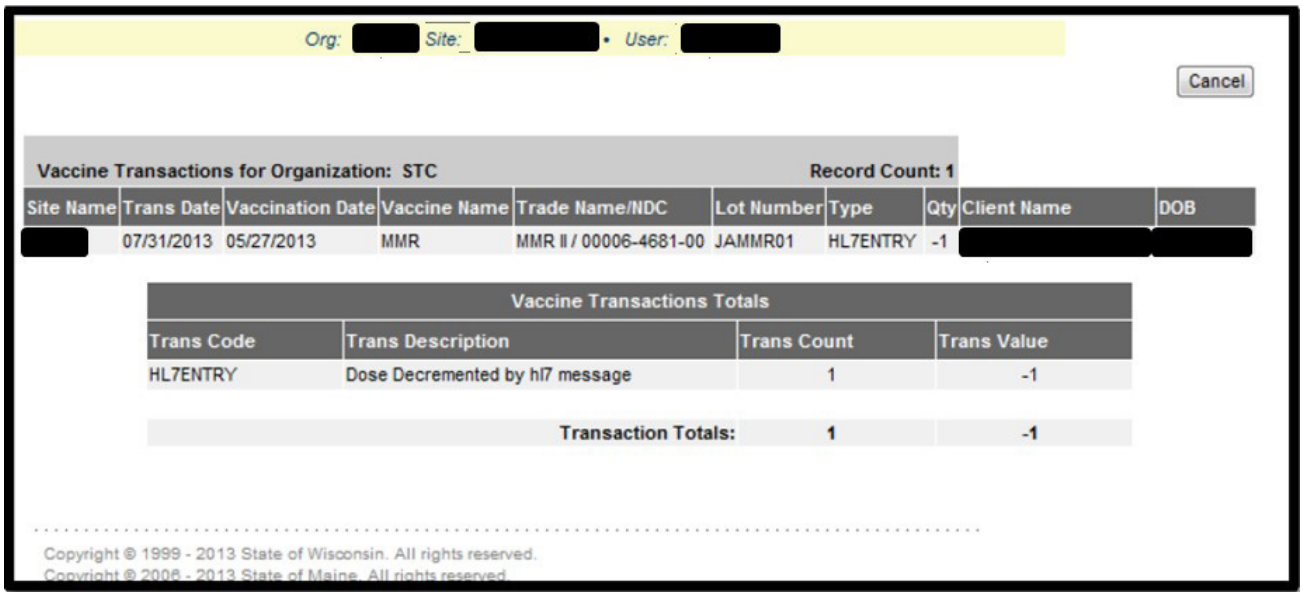
Inventory transaction history

This report allows the IIS and the provider organization to see all inventory transactions, which may be used to verify that doses were decremented from the correct inventory lot numbers. The report records every transaction event for each lot number. This report provides the detailed information needed for the provider organization to reconcile its inventory correctly.

Table 6. Inventory transaction history inputs/parameters

	Elements
Data Inputs/Outputs	Provider Organization
	■ Provider organization ■ PO-IIS ID ■ VFC PIN
	Inventory
	■ Vaccine type ■ Vaccine product type ■ NDC/CVX ■ Lot number ■ Lot number expiration date ■ Transaction date/time ■ Transaction type (e.g., administered, wasted) ■ Lot-level public/private indicator
Parameters/Criteria	■ Provider organization ■ Transaction date range ■ Lot-level public/private indicator ■ Vaccine type ■ Vaccine product type ■ NDC/CVX ■ Lot number ■ Transaction type

Inventory transaction history sample



Org: [redacted] Site: [redacted] • User: [redacted]

Cancel

Vaccine Transactions for Organization: STC **Record Count: 1**

Site Name	Trans Date	Vaccination Date	Vaccine Name	Trade Name/NDC	Lot Number	Type	Qty	Client Name	DOB
[redacted]	07/31/2013	05/27/2013	MMR	MMR II / 00006-4681-00	JAMMR01	HL7ENTRY	-1	[redacted]	[redacted]

Vaccine Transactions Totals

Trans Code	Trans Description	Trans Count	Trans Value
HL7ENTRY	Dose Decremented by hl7 message	1	-1
	Transaction Totals:	**1**	**-1**

Figure 12. Transaction report (from Maine IIS)

Vaccine Transactions for Organization: [redacted]

Site Name	Trans Date	Lot \ Funding Source \ Trade Name	Type	Qty
[redacted]	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1
	11/02/2015	2729X \ State \ Boostrix	Immunize	-1
	11/02/2015	L016428 \ State \ Gardasil 9	Immunize	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1
	11/02/2015	2729X \ State \ Boostrix	Immunize	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Borrowed	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1
	11/02/2015	UI431AE \ Private \ Fluzone Quad MDV	Immunize	-1

Figure 13. Vaccine transaction (from Oregon IIS)

Ending inventory transactions summary

This report is an aggregated summary of inventory transactions by lot number and contains the following information:

- The beginning balance of doses.
- The number of doses grouped by each transaction type (e.g., administered, borrowed, transferred, unaccounted for).
- The ending balance of doses.

This report is helpful for determining whether the current physical inventory matches the IIS inventory (i.e., if submitted vaccination events were documented correctly at an aggregate level). Likewise, the VFC program can use this report to monitor issues with vaccine wastage.

Table 7. Ending inventory transactions summary inputs/parameters

	Elements
Data Inputs/Outputs	Provider Organization
	■ Provider organization ■ PO-IIS ID ■ VFC PIN
	Vaccination Event
	■ Date of vaccination
	Inventory
	■ Transaction date ■ Vaccine type ■ Vaccine product type ■ NDC/CVX ■ Lot number ■ Lot number expiration date ■ Lot-level public/private indicator ■ Transaction type ■ Active lot indicator ■ Beginning inventory ■ Summary of doses in (shipments, transfers in) ■ Summary of doses out (returned shipments, transfers out) ■ Summary of administered doses ■ Summary of borrowed/replaced doses ■ Ending inventory
Parameters/Criteria	■ Provider organization ■ Transaction date range ■ Lot-level public/private indicator ■ Vaccine type ■ Vaccine product type ■ NDC/CVX ■ Lot number ■ Transaction type

Ending inventory transactions summary sample

Vaccine Transactions Totals			
Trans Code	**Trans Description**	**Trans Count**	**Trans Value**
REC	Receipt of Inventory	0	0
Immunize	Immunizations Given	940	-940
Delete	Immunizations Deleted	0	0
TRA	Doses Transferred	0	0
3	Spoilage reported by provider	0	0
4	Expiration reported by Provider	0	0
5	Lost or damaged in transit to Provider	0	0
6	Failure to store properly upon receipt by Provider	0	0
7	Refrigeration failure reported by Provider	0	0
11	Lost or unaccounted for in Provider inventory	0	0
12	Other - Not Usable, reported by Provider	0	0
RECALL	Doses Recalled	0	0
ADMIN	Doses Administered	0	0
TRAEXP	Expired Doses Transferred	0	0
BORROWEDIN	Borrowed In	0	0
BORROWEDOUT	Borrowed Out	0	0
BORROWED	Borrowed Imm Given	59	-59
RET	Doses Returned	0	0
ERR	Error Correction	0	0
RECON	Doses Reconstituted	0	0
LOTDELETE	Lot Deleted	0	0
	Transaction Totals:	**999**	**-999**

Figure 14. Vaccine transactions (from Oregon IIS)

Provider = [redacted], Inventory Location = [redacted] Vaccine = Hep A-Hep B, Funding Source = 317, Manufacturer = GlaxoSmithKline, Lot = A4XD4

Trans ID	Src Inventory Location	Dest Inventory Location	Trans Date	Vaccine	Mfg	NDC	Lot No	Fund Src	Exp Date	Type	Doses
2661020	[redacted] COMMUNITY OUTREACH		10/17/2015	Hep A-Hep B	SKB	58160-0815-11	A4XD4	317	10/07/2017	VAC	(1)
Created By: AMANDA HARRIS (WEBIZ) on 10/17/2015 13:30:27 **Updated By:** AMANDA HARRIS (WEBIZ) on 10/17/2015 13:31:00			**Comments:** Created from update on vaccination of Patient [redacted] on 10/17/2015								
2687613	[redacted] COMMUNITY OUTREACH		10/17/2015	Hep A-Hep B	SKB	58160-0815-11	A4XD4	317	10/07/2017	VAC	(1)
Created By: [redacted] on 11/10/2015 13:10:54 **Updated By:** [redacted] on 11/10/2015 13:11:11			**Comments:** Created from update on vaccination of Patient [redacted] on 10/17/2015								
2686062	[redacted] COMMUNITY OUTREACH		10/16/2015	Hep A-Hep B	SKB	58160-0815-11	A4XD4	317	10/07/2017	VAC	(1)
Created By: [redacted] on 11/09/2015 11:46:47 **Updated By:** [redacted] on 11/09/2015 11:48:02			**Comments:** Created from update on vaccination of Patient [redacted] on 10/16/2015								
2686072	[redacted] - COMMUNITY OUTREACH		10/16/2015	Hep A-Hep B	SKB	58160-0815-11	A4XD4	317	10/07/2017	VAC	(1)
Created By: [redacted] on 11/09/2015 11:49:59 **Updated By:** [redacted] on 11/09/2015 11:50:22			**Comments:** Created from update on vaccination of Patient [redacted] on 10/16/2015								
2627012	[redacted] - COMMUNITY OUTREACH		09/10/2015	Hep A-Hep B	SKB	58160-0815-11	A4XD4	317	10/07/2017	ADJ	50
								Adjustment Reason:		Add Initial Inventory	
Created By: [redacted] on 09/10/2015 14:24:35 **Updated By:** [redacted] on 09/10/2015 14:24:35			**Comments:**								

Figure 15. Inventory transaction inquiry report (from Nevada IIS)

02/12/2016

Ending Inventory Report

Page 1

xxxxxxxxxxxxxxxxxxxxxxxxx(99999)

Inventory: Private

Report Period : 10/28/2015 - 12/06/2015

DTaP (pediatric)										
			Doses							
Lot Number	Expiration Date	Begin Balance	Doses In	Doses Out	Admins	Brwd/ Rplcd	Unusable LW	Balance	Dose Count	Diff
JD527	12/03/2016	0	0	0	0	0	0	0	0	0
FA545	05/07/2017	10	0	0	10	0	0	0	0	0
5775L	10/16/2017	30	40	0	21	0	0	49	49	0
TOTAL		40	40	0	31	0	0	49	49	0

DTaP-Hep B-IPV (Pediarix)										
			Doses							
Lot Number	Expiration Date	Begin Balance	Doses In	Doses Out	Admins	Brwd/ Rplcd	Unusable LW	Balance	Dose Count	Diff
5F5F3	02/06/2017	0	0	0	0	0	0	0	0	0
2PY24	03/27/2017	0	1	0	1	0	0	0	0	0
N2LK2	08/27/2017	45	0	0	45	0	0	0	0	0
23Y4D	10/28/2017	0	70	0	37	0	0	33	33	0
TOTAL		45	71	0	83	0	0	33	33	0

DTaP-IPV (Kinrix)										
			Doses							
Lot Number	Expiration Date	Begin Balance	Doses In	Doses Out	Admins	Brwd/ Rplcd	Unusable LW	Balance	Dose Count	Diff
5TD93	09/10/2017	41	0	0	32	1	0	8	8	0
MH9T7	09/29/2017	0	40	0	0	0	0	40	40	0
TOTAL		41	40	0	32	1	0	48	48	0

Figure 16. Ending inventory report (from Michigan IIS)

Inventory last balanced/reconciled dates

This report provides information to the awardee and provider organization about when provider organizations last reconciled their inventory. This is a high-level report that identifies when provider organizations may need additional support and/or training. Many IIS also require that provider organizations reconcile inventory before placing an order, and this report can be used as proof of reconciliation.

Table 8. Inventory last balanced/reconciled dates inputs/parameters

	Elements
Data Inputs/Outputs	Provider Organization
	■ Provider organization ■ PO-IIS ID ■ VFC PIN
	Inventory
	■ Date of last reconciliation
Parameters/Criteria	■ Provider organization ■ Reconciliation end date range ■ Vaccine and vaccine lot number

Inventory last balanced/reconciled dates sample

Description	Beg Date	End Date	Authorized By
DECEMBER 2015	12/01/2015	12/31/2015	[redacted]

Practice/Facility:
[redacted] CLINIC MAIN
[redacted] NV #2
[redacted] ST
CARSON CITY, NV 89706County: Carson City
Phone: 775-[redacted]
Fax: 775-[redacted]
Contact: [redacted]
Email: [redacted]

Inventory Detail

Line No.	Vaccine (Brand) | Mfg | NDC | Lot | Exp Date	Beginning Inventory	Inventory Received	Inventory Administered	Inventory Transferred	Inventory Returned/ Expired/Recalled	Inventory Wasted	Inventory Unaccounted	Inventory Difference (+/-)	Ending Inventory
317										
1	Hep A-Hep B | SKB | 58160-0815-11 | 925P2 | 03/22/2016	69	0	(9)	0	0	(1)	0	0	59
2	Hep A-Hep B | SKB | 58160-0815-52 | 797K7 | 04/29/2017	22	0	(1)	0	0	0	0	0	21
3	Hep A-Hep B | SKB | 58160-0815-11 | 3EX72 | 03/22/2016	20	0	0	0	0	0	0	0	20
4	Hep A-Hep B | SKB | 58160-0815-11 | A4XD4 | 10/07/2017	100	0	0	0	0	0	0	0	100
5	HPV (Gardasil) | MSD | 00006-4045-41 | J015378 | 04/09/2016	63	0	(5)	0	0	0	0	0	58
6	HPV (Gardasil) | MSD | 00006-4045-41 | K008931 | 03/04/2017	30	0	0	0	0	0	0	0	30
7	Influenza Quad Inj P | SKB | 58160-0903-52 | C75ES | 06/05/2016	17	0	(31)	30	0	0	0	0	16
8	PCV-13 (Prevnar 13) | PFR | 00005-1971-02 | L99259 | 02/28/2017	10	0	(3)	0	0	0	0	0	7
9	PPSV23 | MSD | 00006-4943-00 | K015368 | 05/04/2016	2	0	(1)	0	0	0	0	0	1
10	PPSV23 | MSD | 00006-4943-00 | L003227 | 10/13/2016	10	0	0	0	0	0	0	0	10
11	Zoster (Shingles) | MSD | 00006-4963-41 | L021609 | 09/10/2016	9	0	(2)	0	0	0	0	0	7

Figure 17. Inventory reconciliation worksheet (from Nevada IIS)

Patient listing for reconciliation

This report provides a list of patients that have a vaccination event associated with their record for the time frame indicated. It allows for the identification of specific issues that may have affected decrementing inventory. This supports the process of reconciliation.

Table 9. Patient listing for reconciliation inputs/parameters

	Elements
Data Inputs/Outputs	Provider Organization
	■ Provider organization ■ PO-IIS ID ■ VFC PIN
	Patient
	■ First name ■ Last name ■ Patient ID ■ Date of Birth ■ Gender/sex
	Vaccination Event
	■ Date of vaccination ■ Dose-level eligibility ■ Vaccine type ■ Vaccine product type ■ NDC/CVX ■ Lot number ■ Lot number expiration date ■ Dose-level public/private indicator
Parameters/Criteria	■ Provider organization ■ Vaccination event date range ■ Birthdate range ■ Vaccine type ■ Vaccine product type ■ NDC/CVX ■ Lot number ■ Dose-level public/private indicator

Patient listing for reconciliation sample

Report Type	Provider Organization	Started	Completed	Status	Row Count
LIST	AMJEN MEDICAL CLINIC	01/26/2016 03:36 PM	01/26/2016 03:36 PM	DONE	0
LIST	AMJEN MEDICAL CLINIC	01/26/2016 03:37 PM	01/26/2016 03:38 PM	DONE	1

Ad Hoc Report Results

What would you like to do with this report?

Export as Text Export as a Spreadsheet Display as a PDF

Report 204027

ALERT Immunization Information System
Report generated on 01/26/2016
Report generated by Tracy Little
AMJEN MEDICAL CLINIC - AL9999 - Test10

Filter conditions used for this report:

Patients associated with AMJEN MEDICAL CLINIC
Active Status EQUALS Yes
AND
Owned Immunization EQUALS Yes
AND
Vaccination Date AFTER 01/01/2015
Sort order: Vaccination Date ascending

Report 204027; Results 1 - 1 of 1

No	Patient ID	Birth Date	Vaccination Date	Vaccine	Vaccine Lot	Vaccine Eligibility	Historical Immunization	From Inventory
1	BUG4726	01/01/2014	03/30/2015	Flu trivalent injectable	12D23	M	No	No

Figure 18. Patient listing for reconciliation (from Oregon IIS)

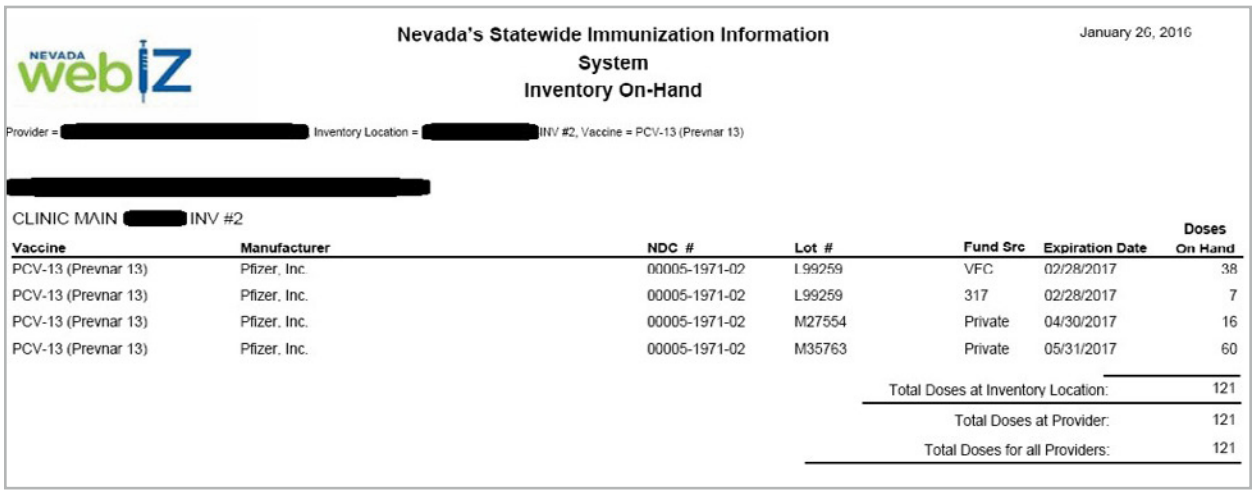
Physical inventory

This report lists the IIS inventory and can be printed to allow the provider organization to compare its IIS inventory with its physical inventory. The report is a helpful tool for reconciliation. Provider organizations can also use this report to identify vaccine that is nearing the expiration date.

Table 10. Physical inventory inputs/parameters

	Elements
Data Inputs/Outputs	Provider Organization
	■ Provider organization ■ VFC PIN ■ PO-IIS ID
	Inventory
	■ Vaccine type ■ NDC/CVX ■ Lot number ■ Lot number expiration date ■ Dose-level public/private indicator ■ Fund type (dose) ■ Balance (in doses)
Parameters/Criteria	■ Provider organization ■ Transaction date range ■ Vaccine type ■ Vaccine product type ■ Lot number ■ Dose-level public/private indicator

Physical inventory sample



NEVADA webIZ

Nevada's Statewide Immunization Information System
Inventory On-Hand

January 26, 2016

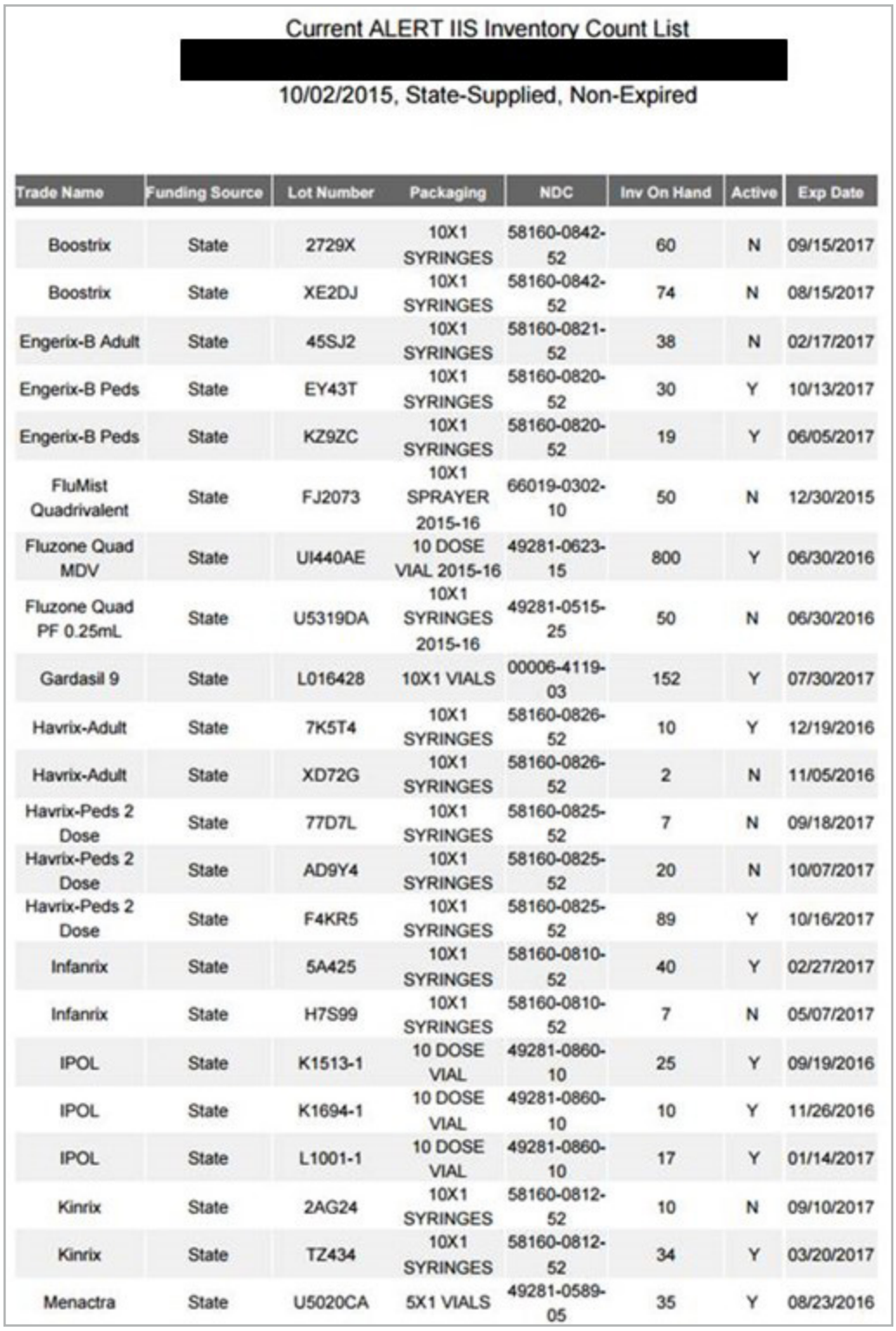
Provider = [redacted] Inventory Location = [redacted] INV #2, Vaccine = PCV-13 (Prevnar 13)

[redacted]

CLINIC MAIN [redacted] INV #2

Vaccine	Manufacturer	NDC #	Lot #	Fund Src	Expiration Date	Doses On Hand
PCV-13 (Prevnar 13)	Pfizer, Inc.	00005-1971-02	L99259	VFC	02/28/2017	38
PCV-13 (Prevnar 13)	Pfizer, Inc.	00005-1971-02	L99259	317	02/28/2017	7
PCV-13 (Prevnar 13)	Pfizer, Inc.	00005-1971-02	M27554	Private	04/30/2017	16
PCV-13 (Prevnar 13)	Pfizer, Inc.	00005-1971-02	M35763	Private	05/31/2017	60
					Total Doses at Inventory Location:	121
					Total Doses at Provider:	121
					Total Doses for all Providers:	121

Figure 19. Inventory on-hand report (from Nevada IIS)



Current ALERT IIS Inventory Count List

[redacted]

10/02/2015, State-Supplied, Non-Expired

Trade Name	Funding Source	Lot Number	Packaging	NDC	Inv On Hand	Active	Exp Date
Boostrix	State	2729X	10X1 SYRINGES	58160-0842-52	60	N	09/15/2017
Boostrix	State	XE2DJ	10X1 SYRINGES	58160-0842-52	74	N	08/15/2017
Engerix-B Adult	State	45SJ2	10X1 SYRINGES	58160-0821-52	38	N	02/17/2017
Engerix-B Peds	State	EY43T	10X1 SYRINGES	58160-0820-52	30	Y	10/13/2017
Engerix-B Peds	State	KZ9ZC	10X1 SYRINGES	58160-0820-52	19	Y	06/05/2017
FluMist Quadrivalent	State	FJ2073	10X1 SPRAYER 2015-16	66019-0302-10	50	N	12/30/2015
Fluzone Quad MDV	State	UI440AE	10 DOSE VIAL 2015-16	49281-0623-15	800	Y	06/30/2016
Fluzone Quad PF 0.25mL	State	U5319DA	10X1 SYRINGES 2015-16	49281-0515-25	50	N	06/30/2016
Gardasil 9	State	L016428	10X1 VIALS	00006-4119-03	152	Y	07/30/2017
Havrix-Adult	State	7K5T4	10X1 SYRINGES	58160-0826-52	10	Y	12/19/2016
Havrix-Adult	State	XD72G	10X1 SYRINGES	58160-0826-52	2	N	11/05/2016
Havrix-Peds 2 Dose	State	77D7L	10X1 SYRINGES	58160-0825-52	7	N	09/18/2017
Havrix-Peds 2 Dose	State	AD9Y4	10X1 SYRINGES	58160-0825-52	20	N	10/07/2017
Havrix-Peds 2 Dose	State	F4KR5	10X1 SYRINGES	58160-0825-52	89	Y	10/16/2017
Infanrix	State	5A425	10X1 SYRINGES	58160-0810-52	40	Y	02/27/2017
Infanrix	State	H7S99	10X1 SYRINGES	58160-0810-52	7	N	05/07/2017
IPOL	State	K1513-1	10 DOSE VIAL	49281-0860-10	25	Y	09/19/2016
IPOL	State	K1694-1	10 DOSE VIAL	49281-0860-10	10	Y	11/26/2016
IPOL	State	L1001-1	10 DOSE VIAL	49281-0860-10	17	Y	01/14/2017
Kinrix	State	2AG24	10X1 SYRINGES	58160-0812-52	10	N	09/10/2017
Kinrix	State	TZ434	10X1 SYRINGES	58160-0812-52	34	Y	03/20/2017
Menactra	State	U5020CA	5X1 VIALS	49281-0589-05	35	Y	08/23/2016

Figure 20. Lot number listing (from Oregon IIS)

Additional design considerations and recommendations

The following are helpful considerations when designing IIS reports:

- Formatting of reports should call attention to significant elements in those reports. For example:
  - Highlighting expiration date.
  - Varied shading of public versus private.
  - Sort order.
- An IIS should produce all reports in a printable format (PDF) and, when feasible, an extractable format (Excel or .csv).
- Reports should use plain language to the extent possible, since technical expertise will vary among users.
- Reports should include or link to user instructions describing the parameters/filters and what calculations are performed by the report.
- All report outputs should display the name of the report, the report's time frame and filters/parameters, and the date the report was run. It is also important that the report display the name of the provider organization or jurisdiction represented in the report.
- Include all data elements on the report, even if some are blank.
- Provider organizations should only see their own data, except for associated organizations (i.e., parent-child).
- Provider organizations should be able to run reports at the site level or parent organization level.
- Provider organizations should have the ability to fix the issue by directly linking to the IIS data whenever appropriate (i.e., interactive fix tool).

Chapter 7: Preapproval and Maintenance of Provider Organization

Before integrating any outside dataset into an IIS, it is important to evaluate the incoming data for quality (accuracy and completeness) and conformance to IIS requirements. This general process is often called preapproval (previously known as precertification in MIROW 2013 Data Quality Assurance Guidelines [1.2]) and, once a submitter passes this process, they are allowed to regularly submit data to the IIS production environment. The purpose of preapproval is to identify missing data and/or fix errors before sending data to the production environment. It is also important that IIS programs continue to monitor ongoing provider organization data submissions in the production environment to identify any new error patterns or changes made to ensure reporting accuracy. This chapter will describe the preapproval and monitoring process for DI-v-EDE and highlight some best practice recommendations as appropriate.

Preapproval and monitoring process

Before loading data to the production IIS, every provider organization must go through the process of preapproval, which includes an analysis of the submitted data. During preapproval, the IIS examines data submissions in a test environment for format conformance, accuracy, and completeness. If possible, data received should be compared with the original source of the data (i.e., the data in the EHR or paper source) to validate content. Once data submissions reach IIS data quality thresholds (see BR125, MIROW 2008 Data Quality Assurance Guidelines [1.6]), the IIS can process the provider organization's data in the production environment. Every IIS should have a preapproval process in place (see BR801, MIROW 2013 Data Quality Assurance Guidelines [1.2]). This will ensure that a high quality of data is loaded into the IIS and provides the opportunity to correct errors before loading. Cleaning erroneous data from a production IIS is difficult and resource-intensive; it is preferable not to allow these data to be loaded in the first place.

During preapproval, a data source gets a great deal of individualized attention, and the IIS can isolate and address many issues that would otherwise be difficult to identify. The level of examination in preapproval is in-depth; it is generally impractical to have this process in place during normal data processing. It is important to note that some EHR may have already been onboarded for normal ongoing data exchange, but they may need to go through preapproval again specifically for DI-v-EDE. The IIS should document the process for provider organizations and/or EHR vendors to address data quality issues that arise (see GR802, MIROW 2013 Data Quality Assurance Guidelines [1.2]). This process will vary among IIS implementations.

For a detailed description of all the stages involved in the preapproval process for EDE, please refer to the MIROW 2008 Data Quality Assurance Guidelines [1.6] and MIROW 2013 Data Quality Assurance Guidelines [1.2].

When considering testing and preapproval for DI-v-EDE, an IIS should have a test environment that includes the inventory management module. Ideally, the inventory management module in the test environment will have a copy of production data, including active lot numbers. This will also allow provider organizations to simulate real-case scenarios (production data) of administering a vaccine and having that vaccination event submitted to the IIS and, in turn, decremented appropriately. It is important to note that for security purposes, some IIS do not have a copy of production data in their test environment. Additionally, an IIS should not only test with EHR vendors, but also with provider organizations directly, as the data are often different. The EHR vendor test data may be generic and may not allow an IIS to identify true issues with the provider organization's coded values and/or data quality issues. Likewise, each provider organization may have different system configurations, so each site should be treated individually.

The following examples illustrate when preapproval of data submissions should occur:

- A new submitting provider organization enrolls with the IIS.
- A previously approved submitter has a major change or modification to the EHR that affects the DI-v-EDE process. This can include when a submitter that previously did not wish to initiate DI-v-EDE decides to do so.
- The patient population for a provider organization changes.
- The data structure of the IIS changes.

This document focuses on the first two scenarios mentioned above. In addition, IIS can incorporate validation checks on the incoming data, message by message, and review aggregated records periodically to ensure ongoing good data quality and identify trends and/or patterns of data quality issues. This process is referred to as ongoing monitoring or maintenance of electronic data submissions.

The preapproval and monitoring process should incorporate the following aspects with regard to DI-v-EDE:

- Education, outreach, and collaboration—Identifies education, outreach, and collaborative efforts needed to establish and maintain DI-v-EDE between provider organizations (with their EHR vendor) and the IIS.
- Key testing steps—Outlines key implementation steps of the IIS preapproval and monitoring process.

Education, outreach, and collaboration

It is important to develop a long-lasting collaborative relationship with provider organizations and their respective EHR vendors to ensure quality data exchanges. This can include early outreach and education on the preapproval process and, more specifically, the DI-v-EDE process. The education effort should make clear that the testing process is not just a one-time testing and cleansing of the data; rather, it is a long-term collaboration toward timely and accurate inventory management. This can take many forms, such as phone calls, webinars, in-person trainings, written documentation, or e-mail exchange.

Outreach and education may begin with an initial phone call with the provider organization and its EHR vendor and/or technical person. This discussion should cover the roles and responsibilities of all the individuals involved and identification of the appropriate contact person(s) for the issues that may occur. It is important to note that, due to the high number of provider organizations, this individualized attention may only occur until the preapproval process has been successfully completed and before moving the submission to a production environment. Information regarding roles and responsibilities is generally documented and available for all individuals interested in exchanging data. However, it is also useful to review this information verbally with all active submitters to express the importance of keeping the contact person(s) on file up to date. Documentation allows new submitters to understand the process and key elements that will be tested so they can work ahead of time toward meeting these requirements.

During the education phase, the IIS will train the provider organization on the process of adding initial inventory to the IIS (e.g., via shipment file or direct entry, when appropriate) and, subsequently, how the data submitted electronically will be decremented from that inventory. This step may also involve reviewing the EHR software to learn what processes occur within the EHR to trigger data being sent to the IIS and how the EHR handles errors reported back from the IIS. This process will help the IIS staff and provider organizations understand the source of any issue and how to mitigate the issue as quickly as possible.

It is helpful to provide educational materials to provider organizations and EHR vendors to prevent a delay in issue resolution if an IIS staff member is not available for assistance. The materials should outline troubleshooting information and what to do when DI-v-EDE issues are identified. Additionally, user training materials should be provided to new contacts when there are changes in staffing. IIS staff should also consider providing ongoing user training via video format (pre-recorded or live webinar) to accommodate different learning styles and to build community partnerships.

Ongoing monitoring requires collaboration between all parties so that when issues are identified, efforts are coordinated to correct them in the IIS and EHR as appropriate. IIS can generate reports that help identify potential issues in DI-v-EDE (Chapter 6: Reports). The reports can be used both by provider organizations to identify issues while reconciling their inventory, and by the awardee to identify trends within provider organizations that indicate additional training and support are needed. Some of these trends include tracking timeliness of data submissions by provider organizations, or when changes are made in the provider organization EHR systems that cause issues with decrementing inventory. It takes collaborative efforts to diagnose the causes of these issues and resolve them. Sustaining provider relationships and quality data exchanges requires ongoing outreach, education, and collaboration.

Key validation steps

After provider organizations have been vetted and approved to begin testing, they receive a test account with appropriate credentials. The process described from here forward is meant to take place after the account credentials have been issued to a provider organization and connection to the IIS has been made. A provider organization subsequently submits sample messages for IIS staff to review. Although both patient and vaccine level de-duplication (MIROW 2006 Vaccine De-duplication Guidelines [1.7]) are reviewed during the preapproval process, they are not in scope of this topic and, thus, are not discussed further.

The following items outline some of the key validation checks conducted specifically for DI-v-EDE before submissions are approved to go to production. The checks listed below appear in the order they may occur during the testing process.

Formatting, accuracy, and completeness of required data fields for DI-v-EDE

Initially, an IIS will validate that the submitted messages contain all the required fields and that the data within those fields are formatted correctly. It is also important to note that some EHR may have difficulty meeting all the completeness requirements based on what fields they have available, so this should be tested in the preapproval process (see the EHR section in Chapter 9: Implementation Considerations). Although outside the scope of this document, some of those checks can include errors that indicate data (or a complete message) was rejected. It is important to note these rejections can occur, since they may prevent a vaccination from being appropriately decremented from inventory. If an error is found, the data/issue should be corrected and resubmitted so that the data can be received and the dose decremented.

After a message is reviewed in its entirety for required formatting and structure, IIS staff then look to make sure all required data fields are submitted on administered doses specifically required for DI-v-EDE. Business rule BR202 recommends that the IIS use the following items for DI-v-EDE:

- Lot number
- Dose-level eligibility
- Dose-level public/private indicator (optional for DI-v-EDE)
- Vaccination event date
- CVX code
- NDC (optional for DI-v-EDE)
- Provider organization IIS ID
- Lot number expiration date

Note: The data elements listed above as optional are not required for DI-v-EDE, but some IIS may choose to implement these in their matching algorithm. They are discussed further in Chapter 9: Implementation Considerations under Key Data Elements and EHR.

Table 11 below lists some specific checks that can be incorporated in the preapproval and ongoing monitoring processes for correct formatting and accuracy of the required data fields. This process coincides with Step 2.8 in Chapter 4: Process Model.

Table 11. Sample formatting and accuracy checks on required data fields

Data Validation Check	Description	Action Taken
Invalid vaccine code	Vaccine NDC/CVX code is not recognized.	Reject individual vaccine event
Vaccine date	Date of vaccine administration is null or in the wrong date format.	Reject individual vaccine event
Missing lot number	Vaccine lot number is missing for administered dose.	Record vaccination event but acknowledge decrementing did not take place
Missing dose-level eligibility	Dose-level eligibility on an administered dose is missing or code is not recognized.	Record vaccination event but acknowledge decrementing did not take place

Note: This is not an exhaustive list, but deemed the most common checks by the workgroup.

Incoming data matching to active inventory in IIS

An IIS evaluates whether the data submitted matches active inventory in the IIS only after incoming data has been validated and meets all the checks noted above, along with checks noted in Chapter 8: Operational Scenarios. Specific scenarios addressed in Chapter 8: Operational Scenarios, which identify specific tests that should be conducted during the preapproval and ongoing monitoring process and for purposes of reducing redundancy, will not be repeated here.

Aggregated data analysis for identifying error trends/patterns

During the preapproval process and ongoing monitoring process, aggregated data are analyzed using reports (Chapter 6: Reports) and other analysis functions. Aggregate analysis can be used to help identify cases where doses have not been decremented or, specifically, when submission errors have occurred and need to be corrected. For example, an IIS could compare error messages received on a monthly or quarterly basis for any given provider organization to determine which errors occur most often for the provider organization and provide outreach and education to fix the issues for future submissions. Likewise, an IIS could compare errors across all submitting provider organizations to see if the errors are widespread or only occurring for specific submitters, and thus, identify problems that could be addressed by outreach and education. Often, this helps to identify problems at specific practices or with specific end users.

Chapter 8: Operational Scenarios

This chapter presents typical and challenging DI-v-EDE operational scenarios. Using real situations to evaluate principles (Chapter 3: Fundamentals), business rules (Chapter 5: Business Rules), and reports (Chapter 6: Reports) will help the user of this guide to test and explore these best practice recommendations.

The operational scenarios presented in Table 12 do not constitute an exhaustive set of all possible scenarios related to DI-v-EDE. Rather, they are a limited set of typical and challenging situations and recommended resolutions based on principles and business rules described in Chapter 3: Fundamentals and Chapter 5: Business Rules. Individual IIS can expand this set of scenarios for training and operational purposes.

In reviewing these scenarios, keep in mind that DI-v-EDE encompasses several aspects of IIS operations:

- Specific elements of the DI-v-EDE process, including:
  - Categorizing provider organizations' inventories in the IIS.
  - Submitting data to the IIS by an EHR.
  - Matching incoming data submission to an inventory in the IIS.
  - Meeting awardee vaccine accountability requirements.
  - Decrementing inventory based on the data from the EHR and in the IIS.
  - Identifying and correcting errors in the DI-v-EDE process.
- Preapproval and ongoing maintenance of provider organizations engaging in DI-v-EDE. Preapproval for DI-v-EDE may occur during initial onboarding of a provider organization or later.
- Reports to assist the IIS, awardee, and provider organizations.

This chapter groups operational scenarios in the following categories:

Vaccine receipt issues

S101. Physical vaccine received does not match IIS inventory for provider organization.

S102. Increment active and inactive lot numbers—matching expiration dates.

Best case scenario

S201. Typical best case scenario for DI-v-EDE.

Provider organization is not preapproved for DI-v-EDE

S301. Provider organization is not preapproved for DI-v-EDE.

Vaccination event date issues

S401. Vaccination event date is before the patient date of birth.

S402. Vaccination event date is after patient date of death.

S403. Vaccination event date is after date of submission.

Inactive lot number

S501. The vaccination event date in a submission is greater (later) than the lot number expiration date for a lot matched in the provider organization inventory in the IIS.

S502. Lot number in submission matches a lot number in provider organization inventory in the IIS that is not active.

S503. Lot number in submission matches lot number in provider organization inventory in the IIS that has a zero balance.

Scenario for short-dated lot number

S601. Vaccine that has been short-dated because of issues at a provider organization.

Missing data

S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator.

S702. Vaccination event date is null or in the wrong date format.

S703. CVX/NDC code is not recognized.

S704. Submission does not contain a lot number.

Inconsistent data

S801. Mismatch of dose-level eligibility and lot-level public/private indicator.

Historical vaccination event

S901. Date of submission is same as vaccination event date, but vaccine dose is marked as historical.

S902. Vaccine dose is indicated as historical in submission.

Lot number does not match

S1001. Lot number in submission does not match any lot number in provider organization inventory in the IIS.

Repeated vaccination event

S1101. Vaccination event received in a previous message is received again.

Deletions and updates

S1201. Immunization record is deleted in the IIS.

S1202. Provider organization submission contains a delete action code to delete an immunization record in the IIS. The submission is received by the IIS before an applicable reconciliation end date.

S1203. Provider organization submission deletes immunization record after reconciliation is closed.

S1204. Submission received after a reconciliation end date includes a vaccination event before reconciliation end date.

S1205. Updated dose-level eligibility or dose-level public/private indicator.

S1206. Updated lot number with same dose-level eligibility or dose-level public/private indicator.

Reconciliation

S1301. Reconciliation timeliness.

Note: Remarks are an integral part of business rules. It is important to study, reference, and implement each of these business rules in their entirety, including information contained in the "Remarks" column.

Table 12. Selected operational scenarios

#	Scenario	Recommended Action	Remarks
Vaccine receipt issues			
S1101	**S101. Physical vaccine received does not match IIS inventory for provider organization.**	**Consequences:** ■ Provider organization uses direct UI to correct information in the IIS, including updates for lot-level public/private indicator.	■ For references, see: ▪ BR105. Verify physical contents of a vaccine shipment. ▪ BR106. Notify awardee VFC program and IIS of discrepancies between physical contents and packing slip and/or IIS. ▪ Step 1.5 and Step 1.6.
S1102	**S102. Increment active and inactive lot numbers—matching expiration dates.** ■ Provider organization has lot number ABC123 inventory in the IIS and lot-level public/private indicator = public. ■ The lot number is inactive. ■ Provider organization receives a new shipment containing 5 new doses with the lot number ABC123 and lot-level public/private indicator = public. ■ Expiration date for lot number in the IIS matches the expiration date for the lot number in the new shipment.	**Consequences:** ■ IIS should increment public inventory balance for lot number ABC123 by five and make it active.	■ The consequences would be the same if the provider organization received the vaccine through a transfer instead of a shipment. ■ For references, see: ▪ BR101. Organize inventory information in IIS by the lot number, lot number expiration date, and lot-level public/private indicator. ▪ BR102. Prepopulate provider organization's inventory in IIS. ▪ BR103. Download shipment information daily. ▪ BR104. Increment inventory item balance with shipment info. ▪ Step 1.3.

#	Scenario	Recommended Action	Remarks
Best case scenario			
S201	**S201. Typical best case scenario for DI-v-EDE.** ■ Submission contains consistent information for all of the following: Lot number, dose-level eligibility, dose-level public/private indicator (optional for DI-v-EDE), vaccination event date, CVX (or NDC) code, lot number expiration date, and provider organization IIS ID. ■ Dose is administered. ■ Dose-level eligibility and dose-level public/private indicator indicate that the appropriate vaccine stock was used for the patient (for example, an uninsured child received vaccine from the public stock). ■ Lot number in submission matches lot number in provider organization inventory in IIS with lot-level public/private indicator (e.g., public). ■ Inventory is active. ■ Balance is greater than zero. ■ Provider organization is preapproved in the IIS for DI-v- EDE.	**Effect on immunization record:** ■ Record immunization information in patient record. Effect on provider organization inventory: ■ Decrement appropriate lot number of public inventory. **Consequences:** ■ No other consequences.	■ For references see: ▪ BR202. Submit information to IIS to support DI-v-EDE. ▪ BR203. Decrement only administered vaccines. ▪ BR204. Decrement only active inventory. ▪ BR206. Update patient record regardless of inventory-related issues. ▪ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ▪ Step 2.5. ▪ See BR105, MIROW 2013 Data Quality Assurance Guidelines [1.2, p.72].
Provider organization is not preapproved for DI-v-EDE			
S301	**S301. Provider organization is not preapproved for DI-v-EDE.**	**Effect on immunization record:** ■ IIS will not know that the provider organization has sent data; there will be no effect on any immunization record. **Effect on provider organization inventory:** ■ Dose not decremented. **Consequences:** ■ IIS will not know that the provider organization has sent data.	■ All other scenarios assume that the provider organization is indicated in the IIS as preapproved for DI-v-EDE. ■ For references, see: ▪ P03. The IIS must preapprove a provider organization for DI-v-EDE. ▪ BR401. Establish and maintain a preapproval process for provider organizations. ▪ BR402. Establish a testing environment for the preapproval process. ▪ BR403. Establish a preapproval testing process. ▪ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ▪ Step 2.7.

#	Scenario	Recommended Action	Remarks
Vaccination event date issues			
S401	**S401. Vaccination event date is before the patient date of birth.**	**Effect on patient record and immunization record:** ■ Reject the patient record and all related vaccination records or reject the vaccination event, depending on factors discussed in BR101, MIROW 2013 Data Quality Assurance Guidelines [1.2]. **Effect on provider organization inventory record:** ■ Dose not decremented. **Consequences:** ■ IIS notifies provider organization/EHR of error.	■ For references, see: ▪ BR101, MIROW 2013 Data Quality Assurance Guidelines [1.2, p.70]. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ Steps 2.8, 3.1, and 3.2.
S402	**S402. Vaccination event date is after patient date of death.**	**Effect on patient record and immunization record:** ■ Reject the patient record and all related vaccination events. **Effect on provider organization inventory record:** ■ Dose not decremented. **Consequences:** ■ IIS notifies provider organization/EHR of error.	■ For references, see: ▪ BR102, MIROW 2013 Data Quality Assurance Guidelines [1.2, p.70]. ▪ The recommended actions from S401 in accordance with the factors discussed in BR101. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ Steps 2.8, 3.1, and 3.2.
S403	**S403. Vaccination event date is after date of submission.**	**Effect on immunization record:** ■ Record information in patient record and reject the vaccination event. **Effect on provider organization inventory record:** ■ Dose not decremented. **Consequences:** ■ IIS notifies provider organization/EHR of error.	■ For references, see: ▪ See BR103, MIROW 2013 Data Quality Assurance Guidelines [1.2, p.71]. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ Steps 2.8, 3.1, and 3.2.

#	Scenario	Recommended Action	Remarks
Inactive lot number			
S501	**S501. The vaccination event date in a submission is greater (later) than the lot number expiration date for a lot matched in the provider organization inventory in the IIS.** The lot number is inactive.	**Effect on immunization record:** ■ Record information in patient record while indicating an administered, non-viable (non-potent) dose instead of administered dose. **Effect on provider organization inventory record:** ■ Dose not decremented. **Consequences:** ■ IIS notifies provider organization/EHR of error. ■ The provider organization should investigate and determine the cause of the error. ▪ If the vaccination event date is incorrect, the provider organization should correct the error in the EHR and resubmit or manually correct it in the IIS. ■ If the provider organization administered vaccine after its expiration date, the provider organization should consult with the VFC program to determine how to account for the vaccine, and manually decrement inventory in the IIS.	■ For references, see: ▪ BR118, MIROW 2013 Data Quality Assurance Guidelines [1.2, p.81]. ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ BR204. Decrement only active inventory. ▪ BR206. Update patient record regardless of inventory-related issues. ▪ Steps 2.9, 2.13, 3.1, and 3.2. ▪ Definition of "active lot indicator" in Appendix A: Terms and Definitions (8.3), which states that a lot becomes inactive when it has passed the lot number expiration date.
S502	**S502. Lot number in submission matches a lot number in provider organization inventory in the IIS that is not active.**	**Effect on immunization record:** ■ Record information in patient record. **Effect on inventory:** ■ Do not decrement. **Consequences:** ■ IIS notifies provider organization/EHR that inventory is not active and that decrementing did not take place.	■ Provider organization may need to accept inventory in the IIS. ■ For references, see: ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ BR204. Decrement only active inventory. ▪ BR206. Update patient record regardless of inventory issues. ▪ Steps 1.4, 1.8, 2.9, 2.13, 3.1, and 3.2.

#	Scenario	Recommended Action	Remarks
S5003	**S503. Lot number in submission matches lot number in provider organization inventory in the IIS that has a zero balance.**	**Effect on immunization record:** ■ Record information in patient record. **Effect on provider organization inventory record:** ■ Dose not decremented. **Consequences:** ■ IIS notifies provider organization/EHR that lot has a zero balance (i.e., inactive).	■ For references, see: ▪ Definition of "active lot indicator" in Appendix A: Terms and Definitions (8.3), which states that a lot becomes inactive when it reaches a zero balance. ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ BR204. Decrement only active inventory. ▪ BR206. Update patient record regardless of inventory-related issues. ▪ Steps 2.9, 2.13, 3.1, and 3.2..
Scenario for short-dated lot number			
S6001	**S601. Short-dated vaccine because of issues at a provider organization.** Vaccine in a provider organization's inventory is compromised (for example, out-of-range temperature in the provider organization's storage unit). The compromised vaccine is viable.	**Consequences:** The provider organization notifies the immunization program and the IIS. The immunization program and the provider organization determine the correct short-date for the vaccine based on guidance from the manufacturer. ■ The IIS creates a new inventory for the provider organization with the new (short-dated) lot number expiration date. Note, that for short-dated doses, the lot number, dose-level public/private indicator on the provider organization side and lot-level public/private indicator on the IIS side remain the same as in original inventory. ■ The IIS decrements the balance of the original inventory by the number of compromised doses and increments the new inventory by the same number of doses.	■ For references, see: ▪ BR107. Create new inventory for short-dated doses. ▪ BR108. Calculate inventory balance after creating new inventory for short-dated doses. ▪ Appendix E. Handling Doses with Short-dated Lot Number Expiration Dates.

#	Scenario	Recommended Action	Remarks
Missing data			
S701	**S701. Submission does not contain either dose-level eligibility or dose-level public/ private indicator.**	**Effect on immunization record:** ■ Record information in immunization record. **Effect on provider organization inventory record:** ■ Dose not decremented. **Consequences:** ■ IIS notifies provider organization/EHR that required data are missing.	■ For references, see: ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ BR202. Submit information to IIS to support DI-v-EDE. ▪ BR206. Update patient record regardless of inventory-related issues. ▪ Steps 2.5, 2.8, 2.9, 2.12, 3.1, and 3.2.
S702	**S702. Vaccination event date is null or in the wrong date format.**	**Effect on immunization record:** ■ Reject individual vaccination event. **Effect on provider organization inventory record:** ■ Dose not decremented. **Consequences:** ■ IIS notifies provider organization/EHR that required data are missing.	■ For references, see: ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ BR202. Submit information to IIS to support DI-v-EDE. ▪ Steps 2.5, 2.8, 3.1, and 3.2. ▪ BR105, MIROW 2013 Data Quality Assurance Guidelines [1.2, p.72].
S703	**S703. CVX/NDC code is not recognized.**	**Effect on immunization record:** ■ Reject individual vaccination event. **Effect on provider organization inventory record:** ■ Dose not decremented. **Consequences:** ■ IIS notifies provider organization/EHR that required data are missing.	■ For references, see: ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ BR202. Submit information to IIS to support DI-v-EDE. ▪ Steps 2.5, 2.8, 3.1, and 3.2. ▪ BR105, MIROW 2013 Data Quality Assurance Guidelines [1.2, p.72].

#	Scenario	Recommended Action	Remarks
S704	**S704. Submission does not contain a lot number.**	**Effect on immunization record:** ■ Record vaccination event. **Effect on provider organization inventory record:** ■ Dose not decremented. **Consequences:** ■ IIS notifies provider organization/EHR that required data are missing.	■ For references, see: ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ BR202. Submit information to IIS to support DI-v-EDE. ▪ BR206. Update patient record regardless of inventory-related issues. ▪ Steps 2.5, 2.8, 2.9, 2.10, 3.1, and 3.2. ▪ BR105, MIROW 2013 Data Quality Assurance Guidelines [1.2, p.72].
Inconsistent data			
S801	**S801. Mismatch of dose-level eligibility and lot-level public/private indicator.** ■ Submission from provider organization indicates a dose-level eligibility and/or dose-level public/private indicator = public. Lot number matched in the provider organization inventory in the IIS has a lot-level public/private indicator = private.	**Effect on immunization record:** ■ Record information in patient record. **Effect on inventory:** ■ If awardee does not allow borrowing, dose is not decremented. ■ If awardee does allow borrowing, decrement private inventory. **Consequences:** ■ If awardee does not allow borrowing, the IIS notifies provider organization/EHR of errors and that no decrementing occurred. ■ If awardee does allow borrowing, the IIS records a borrowing transaction and generates a report for the borrowing transaction.	■ For references, see: ▪ BR122, MIROW 2013 Data Quality Assurance Guidelines [1.2, p.84]. If dose-level eligibility and dose-level public/private indicator are not consistent, accept the information and flag for follow-up. ▪ Appendix D: Decision making. ▪ Borrowing policies and practices vary significantly across awardees and are not in scope for this topic. ▪ VFC and local materials should be referenced for borrowing-related guidance; additionally, borrowing-related recommendations are available in the MIROW 2012 Inventory Management Guidelines [1.3]. ▪ Ending inventory transactions summary in Chapter 6: Reports. ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ BR206. Update patient record regardless of inventory-related issues. ▪ Steps 2.9, 2.12, 3.1, and 3.2.

#	Scenario	Recommended Action	Remarks
Historical vaccination event			
S901	**S901. Date of submission is same as vaccination event date, but vaccine dose is marked as "historical."** No prior submissions of this vaccination event have occurred.	**Effect on immunization record;** ■ Record information in patient record. **Effect on inventory:** ■ Dose not decremented. **Consequences:** ■ IIS notifies provider organization and/or EHR that no decrementing occurred.	■ For references, see: ▪ BR105, MIROW 2013 Data Quality Assurance Guidelines [1.2], p.72. IIS should set a criterion of proof to establish a vaccine dose as administered rather than historical. ▪ Inventory decrementing issues report in Chapter 6: Reports. ▪ Education, outreach, and collaboration in Chapter 7: Preapproval and Maintenance. ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ BR203. Decrement only administered vaccines. ▪ BR206. Update patient record regardless of inventory-related issues. ▪ Steps 2.9, 3.1, and 3.2.
S902	**S902. Vaccine dose is indicated as historical in submission.**	**Effect on immunization record;** ■ Record information in patient record. **Effect on inventory:** ■ Dose not decremented. **Consequences:** ■ No other consequences.	■ For references, see: ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ BR203. Decrement only administered vaccines. ▪ Step 2.9.
Lot number does not match			
S1001	**S1001. Lot number in submission does not match any lot number in provider organization inventory in the IIS.**	**Effect on immunization record:** ■ Record information in patient record. **Effect on inventory:** ■ Do not decrement. **Consequences:** ■ IIS notifies provider organization/EHR of error.	■ For references, see: ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ P07. IIS should notify provider organizations of problems in DI-v-EDE process. The notification can be through various methods. ▪ P08. IIS should assist provider organizations with correcting data quality issues. ▪ BR206. Update patient record regardless of inventory issues. ▪ Steps 2.9, 2.10, 3.1, and 3.2.

#	Scenario	Recommended Action	Remarks
Repeated vaccination event			
S1101	**S1101. Vaccination event received in a previous message is received again.**	**Effect on immunization record:** ■ None **Effect on provider organization inventory:** ■ None ■ Provider organization inventory is decremented once. **Consequences:** ■ IIS should monitor and determine whether there is a need for additional provider organization training.	■ Since a vaccination event record can be sent to an IIS multiple times over the lifespan of the patient, it is important that the IIS ensures the administered dose is only decremented one time from inventory, rather than every time it is sent to the IIS. ■ For references, see: ▪ P09. The IIS should decrement an administered dose only once. ▪ Education, outreach, and collaboration in Chapter 7: Preapproval and Maintenance.
Deletions and updates			
S1201	**S1201. Immunization record is deleted in the IIS.** Patient information and immunization information can be deleted for various reasons. In some jurisdictions, patient information and immunization information are deleted when a patient opts out of the IIS.	Effect on immunization record: ■ Demographic record may or may not be deleted; immunization records associated should be unassociated but retained for vaccine decrementing purposes. Effect on provider organization inventory: ■ None Consequences: ■ No other consequences.	■ For references, see: ▪ BR719 in MIROW 2012 Inventory Management Guidelines [1.3]. Account for opt-out patients prior to reconciliation. ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ BR406. Manage deletion of a patient's record from IIS. ▪ BR408. Manage deletion of a vaccination event from IIS.
S1202	**S1202. Provider organization submission contains a "delete" action code to delete an immunization record in the IIS. The submission is received by the IIS prior to an applicable reconciliation end date.**	Effect on immunization record: ■ Immunization record is deleted. Effect on provider organization inventory: ■ Transaction is reversed; delete transaction and increment matching lot number (including matching lot-level public/private indicator). Consequences: ■ IIS should review to determine whether there is a need for additional training.	■ For references, see: ▪ P07 in MIROW 2012 Inventory Management Guidelines [1.3] accurate accounting. Any inventory transaction should be reversible and can be corrected as necessary. ▪ HL7 immunization messaging in Chapter 9: Implementation Considerations. ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ BR406. Manage deletion of a patient's record from IIS. ▪ BR408. Manage deletion of a vaccination event from IIS.

#	Scenario	Recommended Action	Remarks
S1203	**S1203. Provider organization submission deletes immunization record after reconciliation is closed.** BR205 states that an IIS should not decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date.	**Effect on immunization record:** ■ Immunization record is deleted. **Effect on provider organization inventory:** ■ IIS opens reconciliation and manually reverses inventory transaction and returns dose to inventory. **Consequences:** ■ IIS should review to see whether additional training is required.	■ Opening a reconciliation is a rare occurrence, but may be done to correct errors. ■ Opening a closed reconciliation results in a number of transactions to be reversed/corrected, and has an impact on external systems such as VTrckS. ■ For references, see: ▪ P07 in MIROW 2012 Inventory Management Guidelines [1.3] accurate accounting. Any inventory transaction should be reversible and can be corrected as necessary. ▪ HL7 immunization messaging in Chapter 9: Implementation Considerations. ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ BR205. Do not automatically decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date. ▪ BR302. The IIS should freeze the result of reconciliation process. ▪ BR303. Reopen reconciliation that is closed. ▪ BR406. Manage deletion of a patient's record from IIS. ▪ BR408. Manage deletion of a vaccination event from IIS. ▪ Step 3.3.

#	Scenario	Recommended Action	Remarks
S1204	**S1204. Submission received after a reconciliation end date includes a vaccination event prior to reconciliation end date.** Provider organization submission includes vaccination event with a vaccination event date prior to the most recent reconciliation end date.	**Effect on immunization record:** ■ IIS opens reconciliation and manually adds information to the patient record. **Effect on provider organization inventory:** ■ IIS opens reconciliation and manually adds inventory transaction and deducts dose from appropriate inventory. **Consequences:** ■ IIS should review transaction to see whether additional provider organization training is desirable.	■ Opening a reconciliation is a rare occurrence, but may be done to correct errors. This scenario illustrates an exception to BR205 and BR302, as acknowledged in BR303. ■ Opening a closed reconciliation results in a number of transactions to be reversed/corrected, and has an impact on external systems such as VTrckS. ■ For references, see: ▪ P07 in MIROW 2012 Inventory Management Guidelines [1.3] accurate accounting. Any inventory transaction should be reversible and can be corrected as necessary. ▪ P02. DI-v-EDE should support inventory tracking and immunization tracking. ▪ Chapter 4: Process Model, Process 3. ▪ BR205. Do not decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date. ▪ BR205. The IIS should freeze the result of reconciliation process. ▪ BR303. Reopen reconciliation that is closed. ▪ Chapter 6: Reports. ▪ Step 3.3.

#	Scenario	Recommended Action	Remarks
S1205	**S1205. Updated dose-level eligibility or dose-level public/private indicator.** ■ A submission contains an action code "update." ■ The submission contains a different dose-level eligibility (or dose-level public/private indicator) for a previously reported vaccination event.	**Effect on immunization record:** ■ IIS should automatically correct information in the immunization record. **Effect on provider organization inventory:** ■ Assuming all other BR are met, if no inventory was decremented when the vaccination event was submitted the first time, then IIS should decrement the dose from the appropriate matching lot number. ■ Assuming all other BR are met, if inventory was previously decremented, dose should be incremented back into the inventory for the lot number with previously reported dose-level eligibility or dose-level public/private indicator. Subsequently, the IIS decrements the provider organization inventory for the updated dose-level eligibility or dose-level public/private indicator and lot number.	■ For references, see: ▪ Chapter 9: Implementation Considerations.
S1206	**S1206. Updated lot number with same dose-level eligibility or dose-level public/private indicator.** ■ A submission contains an action code "update." ■ The submission contains a different lot number for a previously reported vaccination event. The IIS receives the submission prior to the applicable reconciliation end date.	**Effect on immunization record:** ■ IIS should automatically correct information in the immunization record. **Effect on provider organization inventory:** ■ Assuming all other BR are met, if no inventory was decremented when the vaccination event was submitted the first time, then IIS should decrement the dose from the appropriate matching lot number. ■ Assuming all other BR are met, if inventory was previously decremented, dose should be incremented back into the inventory for the lot number with previously reported dose-level eligibility or dose-level public/private indicator. Subsequently, the IIS decrements the provider organization inventory for the updated lot number and dose-level eligibility or dose-level public/private indicator.	■ For references see: ▪ Chapter 9: Implementation Considerations.

#	Scenario	Recommended Action	Remarks
Reconciliation			
S1301	**S1301. Reconciliation timeliness.** ■ Provider organization orders vaccine through VTrckS on a regular schedule (e.g., once per month).	**Consequences:** ■ Provider organization must reconcile physical inventory to IIS inventory on the same schedule (e.g., once per month).	■ For references, see: ▪ BR301. Resolve data quality issues before reconciling. ▪ BR302. The IIS should freeze the result of reconciliation process. ▪ BR303. Reopen reconciliation that is closed. ▪ Step 3.3. The following references are from the MIROW 2012 Inventory Management Guidelines [1.3, p.47-50]: ■ See P706: Reconciliation frequency principle. Provider Organizations should reconcile their physical inventories to the IIS at a frequency appropriate to the size and complexity of their practice or clinical setup. ▪ BR717: Submit data to IIS before reconciling inventory. ▪ BR718: Indicate IIS-EHR discrepancies. ▪ BR719: Account for opt-out patients before reconciling. At the appointment time, the provider organization should make inventory adjustments for vaccines administered to opt-out patients prior to reconciling its inventory for the corresponding inventory period. ▪ BR720: EHR submission for an opt-out patient. For an EHR submission for an opt-out patient, IIS should decrement inventory without updating the patient record. ▪ BR721: Do physical inventory count for reconciliation on a day boundary. Physical inventory count should always be done on a day boundary (i.e., at the end of a business day or prior to the next business day). ▪ BR722: Reconcile inventory immediately prior to ordering. Provider organizations must reconcile their entire physical inventories with the IIS inventory immediately prior to ordering. VTrckS requirement is 14 days prior to ordering. ▪ BR723: Reconciliation frequency. Provider organizations should reconcile their entire physical inventory with the IIS at least once a month; large complex provider organizations may consider reconciling more frequently (e.g., weekly) to minimize the risk of inventory errors.

Chapter 9: Implementation Considerations

When considering any new enhancement to an IIS, there are often many implementation considerations. Some may be more daunting than others, and might have different levels of impact on an IIS. Before an awardee immunization program embarks on DI-v-EDE, it should review the following section that outlines key implementation considerations. These items occur both internally and externally to an IIS. At the MIROW 101 Workshop held during the 2015 AIRA Conference and the SME face-to-face facilitated session, the IIS community identified some specific barriers for DI-v-EDE. Due to a large overlap between the identified barriers and the topics of implementation considerations, this chapter attempts to address many of the barriers through a discussion of implementation considerations. Appendix F: Barriers to Implementation includes a table listing the identified barriers and how this guide addresses them.

Key implementation considerations included in this section include the following:

- Key data elements
- Data quality
- HL7 immunization messaging
- EHR
- Outreach and education
- Staff time
- Resources

Key data elements

One of the foundations of implementing DI-v-EDE is to consider which data elements are available through EDE to match to active inventory in the IIS. As seen in Chapter 3: Fundamentals, there is a complex set of data elements that can be used for matching purposes, but that are often used in different ways by different IIS (see BR202). For example, lot number, dose-level eligibility, and lot-level public/private indicator are used by some IIS for matching purposes and, in other cases, dose-level public/private indicator (also called funding source in HL7) is also used to match inventory.

For DI-v-EDE, lot number for an administered dose must be submitted to the IIS by the provider organization's EHR. As mentioned in the Data quality section of this chapter, lot number must be documented accurately for a correct match to occur. For this reason, working with provider organizations and EHR vendors is crucial in ensuring that the submitted lot number is sent in the expected format [1.9, 1.10].

Dose-level eligibility

- Dose-level eligibility describes a patient's eligibility for a funding program (such as VFC, 317, etc.); it is determined for each dose administered.
- See Chapter 3: Fundamentals and Appendix A: Terms and Definitions.
- Additionally, see Eligibility (financial class) in HL7 specification.

The provider organization's EHR must also submit dose-level eligibility for administered doses to DI-v-EDE. The IIS should determine that code values, used to indicate the dose-level eligibility (Financial Class in HL7), are set up in accordance with CDC HL7 implementation guides [2.9, 2.10]. There are also technical issues of how to interpret the submitted data. Financial class, in HL7, is extrapolated through a patchwork of translations. Financial class can be designated at the patient level (per visit) or at the dose-level (per immunization), and this field can be empty. Therefore, an IIS needs to determine what the default behavior should be if this designation is missing and multiple vaccination events are present in the message (see Eligibility [financial class] in HL7 specification for further details). Additionally, an IIS can set up validation constraints on the data field. For example, IIS could validate that the submitted age of the patient is appropriate for the code value of eligibility submitted. If the code value states the patient is VFC-eligible but the patient is over the allowed age for VFC vaccine, the IIS should determine how to handle these data. Some IIS may record the data and then log an error, and some IIS may reject all or some part of the message while logging an error.

Dose-level public/private indicator (also called funding source in HL7) can be designated directly by the provider organization or inferred using one or more other fields in an HL7 submission. (see Funding source in HL7 specification for further details). Lot number and dose-level eligibility are key to matching inventory. It is less clear if dose-level public/private indicator is necessary to differentiate between vaccine stocks that have the same lot number across multiple fund types. Some IIS would like to receive dose-level public/private indicator to document accurately whether public or private stock was administered to the patient. With accurate information about the stock used, an awardee immunization program can determine if the vaccine was given to an eligible patient. However, many EHR do not collect dose-level public/private indicator, and HL7 does not require dose-level public/private indicator. For this reason, many IIS that have implemented DI-v-EDE used the dose-level eligibility data element to infer which vaccine stock was used during vaccine administration. Inferring which vaccine stock was used from dose-level eligibility reduces the burden of reporting to the IIS and allows DI-v-EDE, but does not assist the awardee immunization program with vaccine accountability.

Dose-level public/private indicator

- Dose-level public/private indicator is an aggregated reflection of fund type at the vaccine dose-level.
- See Chapter 3: Fundamentals and Appendix A: Terms and Definitions.
- See Funding source in HL7 specification.

Data quality

Given the importance of data quality in creating successful matches between doses administered data and IIS inventory, an IIS implementing DI-v-EDE will want to consider its plan for supporting provider organizations in submitting accurate data. A mechanism to ensure provider organizations submit accurate data is to require that submitters be preapproved for DI-v-EDE (P03) and then monitored for long-term continuity of data quality and completeness. Chapter 7: Preapproval and Maintenance includes recommendations for the preapproval process, including structural issues and user error.

Structural issues related to data quality are often due to data fields that are problematic for staff to complete—for example, if data entry staff must manually enter lot numbers for each vaccination event into the EHR. Data entry staff may make errors due to misreading the lot number (for example, entering an "O" rather than a zero or incorrectly typing the letters and numbers). To avoid these types of errors, the lot numbers can be presented within a drop-down menu in the EHR for the end user to select. A similar issue occurs when data entry requires the knowledge of specific codes from memory rather than more user-friendly descriptions. The EHR should provide intuitive options to end users and link to the codes in the background.

Users may not understand how to properly enter and submit data to the IIS, which leads to inaccuracy in documentation. The IIS should use the preapproval and monitoring processes (Chapter 7: Preapproval and Maintenance) to decrease the number of user errors by properly educating providers on the correct processes. The IIS should use reports to help provider organizations and the IIS identify user errors (for example, a user selecting incorrect dose-level eligibility codes) and facilitate discussions on how to avoid those errors. Provider organizations should run reports related to DI-v-EDE on a regular basis to identify issues. If the provider organization or the IIS identify problems, the IIS can offer refresher trainings related to the specific issue.

IIS can also reduce data quality issues by downloading shipment data on a daily basis and prepopulating the provider organization's public inventory in the IIS (BR102 and BR103) by uploading the shipment file into the IIS. This decreases the amount of manual entry by the provider organization and streamlines a process that can otherwise lead to many data entry errors. Adding shipment data to the IIS is described in detail in Chapter 4: Process Model, Process 1.

There is a tremendous benefit in preventing errors from happening at the time of data entry since it reduces the number of manual interventions that later need to be made within the IIS. If the update cannot be made through an HL7 message, a provider organization may need to manually correct the error in both the EHR and IIS.

Even in the best-case scenario, it is likely that occasional data quality issues will occur. To best respond to these data quality issues, IIS should have functionality in place to notify provider organizations and awardee staff of problems (P07). This often takes the form of providing

reports that identify issues or other mechanisms developed by the IIS. As HL7 ACK messages become more standardized, they could be used more often in the future to alert the EHR of issues (see HL7 immunization messaging section below). While the goal is for the user to be self-sufficient in identifying and correcting errors, the IIS should also provide support to provider organizations to reconcile data quality issues (P08).

HL7 immunization messaging

The IIS community has adopted the nationally recognized Health Level Seven (HL7) standard for EDE between systems [2.9, 2.10]. However, this guide is not specific to any particular version of HL7 in discussing some of the particular HL7 value sets that are specific to the latest version, 2.5.1 [2.9, 2.10]. It defines common messaging standards and vocabulary when exchanging data and is software/platform-neutral, which theoretically means any two systems should be able to communicate and recognize the submission content. Although the IIS community is working toward interoperability standards, HL7 does present some challenges because not all IIS implement the standard in the same way. For example, an EHR system may not reference the same code tables as those recognized by an IIS; therefore, if invalid or missing code values are sent, data are either rejected, omitted, or incorrectly translated. Additionally, as new values are updated or added to a code table (such as new CVX), there may be a lag time between release and the time EHR and IIS implement them. This can also lead to mismatched or omitted data.

One major issue to consider when implementing DI-v-EDE is how errors are handled in HL7. The IIS should notify the originating provider organization if submitted messages that contain vaccination events that should be decremented from inventory are rejected or have issues. The acknowledgment (ACK) message in HL7 defines how IIS should communicate information back to the sending system, informing the sender that a previously sent message was either 1) accepted without fault, 2) rejected in its entirety, or 3) had issues, but some of the data were accepted [2.9, 2.10]. In the case of a completely rejected message, the message structure is so severely incorrect (i.e., missing crucial data) that it cannot be processed by the receiving system (known by some as a "hard" error). In some cases, the EHR vendor or technical personnel should fix the problem and resend the information. These types of errors are usually discovered and eliminated during the preapproval process. A more common type of error that occurs during regular submissions is the third possibility—the message has issues, but part of the message is accepted. In these situations, the receiving system (i.e., IIS) will send back an ACK message that contains additional details about the issue such as severity and location of error (known by some as a "soft" error). These types of errors occur for many reasons. For example, the message meets the formatting standard, but a validation rule placed on a specific field is not met, so some aspect of the message and/or data is not accepted and other parts are. As noted above, the ACK message can be used to identify when a message has been accepted, when it fails, or when it has errors (and what those errors may be). Unfortunately, the ACK message does not necessarily identify which data are consumed by the receiving system, so it may require investigation on the side of the EHR vendor to determine the complete error and how to fix and resubmit the appropriate data [2.19]. It is not known exactly how many EHR vendors actually review ACK messages or give the provider organization access to those messages, and it was identified from a community interoperability testing project that many IIS still do not align with the National Implementation Guide (IG) for ACK messages [2.19]. ACK guidance was developed for the IIS community to help outline steps for standard alignment [2.19].

The goal is for all IIS to send ACK messages and for EHR vendors to support tools and work-flows to ensure errors are available for end users within the provider organization to review and act on. Additionally, MU Stage 3 mandates that by 2018, EHR vendors should be able to accept ACK messages [2.20]. In the meantime, these guidelines recommend that IIS have reports available for submitting provider organizations to identify issues that affect automatic inventory decrementing.

If the IIS notifies the EHR that a message should be resubmitted, the EHR should resend the message with a field used by the IIS to indicate what action needs to be taken. HL7 uses the concept of an action code (HL7 field RXA-21) to tell the receiving system what the sending system expects to occur with that administered vaccination event [2.9, 2.10]. The value codes for this field are add ("A"), update ("U"), or delete ("D"), and the field is required for all administered vaccinations [2.9, 2.10]. If the action code of add ("A") is sent, it notifies the

receiving system that the vaccine should be added (i.e., the first time the vaccination is sent). The update ("U") action code indicates an update is needed to a previously sent vaccination. Lastly, the action code of delete ("D") indicates that the sending system would like the receiving system to delete the vaccination.

It is not known if all EHR and IIS are able to send/receive multiple types of action codes. Some workgroup members reported that, in their experience, EHR only send one code (often the add "A" code). In addition, most IIS have validation rules around several data items. For example, instead of relying on a sending system to indicate an update ("U") has occurred for a vaccination event, the IIS would first look to see if a vaccine with the same CVX and same vaccination date had already been received. (*Note: Vaccine de-duplication is considered out of scope for this topic, but the group felt it important to add the above example that is often considered part of vaccine de-duplication.*) Next, it might look at which provider organization had originally sent the message, and then compare field by field which data may have changed, if any. As a result, the IIS may update one or more data elements of the vaccination event as appropriate. In addition, if a vaccination event is received that has a vaccination date within a specific time period (approximately 4-14 days) of another vaccine within the IIS, then the IIS may interpret that as a duplicate and not act on that submission. IIS that do receive delete ("D") action codes vary in the action taken. Some IIS apply additional validation rules upon receipt of a delete ("D") action code—for example, allowing a deletion to occur only if the vaccination date is after the end date of the most recently closed inventory reconciliation (see BR301 and BR302)—or an IIS may not allow changes to a dose that has already been decremented. Best practice for use of action codes is not documented and, as a result, incorrect information often needs to be corrected manually in both the EHR and IIS.

The vaccination ID field (known as the Filler Order Number ORC-3 in HL7), described in the CDC HL7 Implementation Guide [2.9, 2.10], was introduced to allow sending systems to designate a unique ID for each vaccination sent. A receiving system uses the vaccination ID in conjunction with the action code for validation and proper identification of the vaccination event in question; however, it is not known if this data field is routinely populated with reliable data, or if it is being used by EHR and IIS as intended. The action code and vaccination ID fields should be examined in more depth in the future to develop a standard of practice around content and usage of those fields.

As with any nationally recognized standard, HL7 undergoes constant review and update. When changes are made to the standard, it often takes months to years for the IIS community to catch up with those changes, requiring an IIS to review current business logic behind many data fields and, in this case, how incoming data are matched to the IIS inventory. As an example, MU Stage 3 Rules [2.20] require National Drug Code (NDC) values on administered vaccinations rather than CVX codes. IIS may require considerable alterations to their data infrastructure to accept and use NDC that may affect their DI-v-EDE functionality.

EHR

The workgroup had considerable discussion about the data elements an IIS could and should use to DI-v-EDE. The workgroup reviewed the data elements available from the majority of EHR systems. EHR vary in the data elements collected and available for data exchange, even among those using the same EHR product. Data elements useful for DI-v-EDE, which are not consistently available in EHR, are listed as optional in these guidelines (see BR206). The workgroup also noted that requiring data elements over and above those necessary for DI-v-EDE increases the burden on both the provider organization and the IIS.

The quality of data within the fields used to match inventory is another consideration. Lot number is a key field used in the matching algorithm of DI-v-EDE. If the EHR allows users to enter lot number by hand, there is a high probability of data quality errors. Requiring the user to choose the lot number from a drop-down list may provide a higher likelihood of inventory matching between the EHR and IIS (see the Data quality section for more examples).

As mentioned earlier in the HL7 immunization messaging section, in order for data to be exchanged as seamlessly as possible, it is important that EHR vendors and IIS work toward shared interoperability standards. Not only should the use of action codes and vaccination IDs be reviewed and discussed, moving toward alignment of ACK standardized messages should be addressed [2.19]. During MU Stage 3, EHR will be required to accept ACK messages; however, it is not known what that will mean

for the IIS community, since some EHR vendors may not give provider organizations access to these messages. If an EHR accepts the messages, but does not share them with the provider organization, important information about errors and necessary resubmissions may be lost. It is recommended that EHR provide user-friendly reporting tools (i.e., dashboards, interface maintenance screens) that parse the ACKs into actionable information on the status of data exchange and inventory deduction for the provider organization.

In this document, the acronym EHR refers to an EHR as implemented at a provider organization site and EHR vendor refers to the entity that provides support for an EHR implementation. This document uses the term EHR vendor if the vendor is to receive notice/information or take an action.

Outreach and education

An essential aspect of implementing DI-v-EDE is ensuring the provider organizations are well educated on the DI-v-EDE process. Provider organizations should be initially trained during the preapproval process, including early outreach and education on the preapproval process and, more specifically, the DI-v-EDE process (Chapter 7: Preapproval and Maintenance). During preapproval, provider organization staff should gain a broad knowledge of the IIS, which will support their understanding of more specific functionality such as DI-v-EDE. This discussion should cover the roles and responsibilities of all the individuals involved and identification of the appropriate contact person(s) for the individual issues that may occur.

IIS should also have all system instructions well documented, along with any documentation that outlines the steps for issue mitigation (BR405). Testing documentation allows submitters to understand the process and key elements that will be tested so they can work ahead of time toward these requirements.

One challenge related to training provider organization staff on DI-v-EDE is how to address the wide array of issues that can arise and how to respond to these issues. An in-depth training on the full range of problems that users may encounter is likely to be an overwhelming amount of information and would require a large time commitment. Rather than directly addressing the wide range of potential issues, IIS may find it more beneficial to train provider organization staff on how to access additional educational materials as needed. It is also helpful to provide educational materials to provider organizations and EHR to prevent a delay in issue resolution if an IIS staff member is not available for assistance. Additionally, user training materials should be provided to new contacts when there are changes in staffing. IIS should also consider providing ongoing user training via video format (prerecorded or live webinar) to accommodate different learning styles and to build community partnerships (BR404). One method of structuring online educational materials is to provide small, specific training modules with links to online training videos.

IIS will also want to consider the timing of the educational process. If staff receive training and do not make use of the knowledge and skills for error correction and reconciliation for several weeks, they may forget how to manage the process appropriately. Optimally, training should be done shortly before staff will have opportunities to practice the skills. However, if that is not possible, it may be beneficial to reach out to the provider organization when it first reconciles its inventory to offer support. Likewise, IIS will want to inform provider staff of how they can access online user guidance (for example, webinars, training videos, and documents).

In addition to training provider organization staff, IIS staff will likely need to provide internal training to other immunization program staff. This will help staff in other areas of the immunization program to communicate accurately about the IIS and possibly assist with certain questions related to vaccine inventory.

Staff time

Inventory management can be a time-intensive process for both provider organizations and immunization programs. An appropriate preapproval process, which includes education and outreach, can decrease downstream issues for both groups. The following section will describe steps that can be taken to decrease the amount of staff time needed to support DI-v-EDE.

Given the broad range of issues related to inventory management, immunization programs vary in terms of which staff answer questions related to DI-v-EDE. In some programs, all issues are managed by IIS staff; other programs have VFC staff to provide support for inventory issues, and only specific technical issues are handled by IIS staff. This guide has no specific recommendation for

how immunization programs should assign staff to manage DI-v-EDE, but we would strongly encourage programs to discuss staffing before implementation so that roles are clear from the beginning. This discussion should address the increased technical skill needed to provide assistance for DI-v-EDE in comparison to inventory through the user interface. Immunization programs will need to ensure there are staff available that can manage the technical complexity of these issues. At the same time, it is important to ensure staff members recognize that not all questions will require an in-depth knowledge of HL7. Staff can often answer providers' questions by looking at the user interface or pulling reports. As an IIS program determines a staffing plan to provide support for DI-v-EDE, they will want to consider what internal training is needed (both for programmatic staff on technical issues and for technical staff on programmatic requirements).

Immunization programs can decrease the amount of staff time spent fixing individual errors by ensuring that provider organization staff are educated about DI-v-EDE. By educating provider organization staff, IIS can make provider organizations more self-sufficient and less likely to make significant errors. This education and outreach begins during preapproval and should continue throughout the relationship between the IIS and provider organization. Likewise, it is important to ensure that staff are able to use reports to identify issues and that staff are aware that it is expected these tools will be used to find and fix issues in a regular and timely manner. IIS can provide technological enhancements that support provider staff in finding and correcting errors (for example, adding interactive fix functionality to reports). More detail about education and outreach can be found in Chapter 7: Preapproval and Maintenance and in the Outreach and education section of this chapter.

Provider organizations can also decrease the amount of staff time spent on DI-v-EDE by working to avoid a proliferation of issues that can be time-consuming to solve. This can be done by taking steps to improve data quality (see Data quality in this chapter) and regularly reconciling their inventory to avoid build-up of errors. Provider organization staff should be educated during preapproval about how to manage their inventory efficiently and reminded during outreach that following best practices will decrease the amount of time spent solving problems.

Resources

To implement DI-v-EDE successfully, an IIS will need access to three key resources: funding, IIS functionality, and data structure enhancements. Depending on the awardee, funding may come from federal grants (i.e., 317 or Prevention and Public Health Funds) or from the state/local area. IIS will want to ensure there is funding both to create DI-v-EDE functionality and to support the long-term infrastructure (for example, staff to provide education and outreach). Functionality will need to be created in the IIS to run DI-v-EDE. This requires the appropriate resources (i.e., funding and staffing) to design, develop, and test the new functionality, as well as to implement a training curriculum for provider organizations. During the process of adding functionality for DI-v-EDE, the IIS will want to make system enhancements to ensure that the new functionality works correctly.

Conclusions

The guidelines offer consensus-based best practice recommendations to support DI-v-EDE in IIS. The guidelines will assist IIS in aligning practices through adherence to a set of common recommendations and guidelines.

The following is a brief description of the key outcomes and accomplishments of the MIROW Workgroup:

- Defined five key concepts in DI-v-EDE: storage model, fund type, dose-level public/private indicator, lot-level public/private indicator, and dose-level eligibility.
- Formulated nine principles, 26 business rules, and three decision tables to guide implementation of the DI-v-EDE process in IIS.
- Developed 27 operational scenarios that illustrate implementation of principles and business rules in some typical and challenging everyday situations.
- Provided implementation considerations for formulated best practices, including discussions of key data elements, data quality, EHR, HL7, outreach and education, staff time, and resources.
- Provided guidance for seven reports to assist immunization programs and provider organizations with DI-v-EDE.
- Provided guidance for preapproval and maintenance processes for provider organizations to engage in DI-v-EDE.

MIROW brought together experts from the IIS community, CDC, and IT vendors. The resulting best practices guide is a step in standardizing practices in the area of DI-v-EDE in IIS. Developed recommendations are intended to be at the business/operational level. As a result, they are independent from particular IIS implementations and technology solutions. Accordingly, the recommendations can be used to support the wide variety of IIS implementation strategies on different technological platforms. The approach and results presented are relevant for and can be used beyond immunization information systems—for developing and documenting best practices and operational requirements for application in public health, health care, and other areas.

The National Vaccine Advisory Committee (NVAC) recommends that the IIS community "promote the adoption of a guidebook and best practices for IIS as stated by the CDC/NIP (now NCIRD) and AIRA/MIROW Workgroup to adopt consistent operational guidance and quality control procedures that ensure good data quality." This best practices guide is one example of addressing the NVAC recommendation. It will assist IIS in aligning practices through adherence to a set of common recommendations and guidelines. As a result, IIS will be able to better serve the needs of immunization programs and provider organizations.

Selected References

Previously developed MIROW guidelines

MIROW recommendations documents for previous topics, abridged mini-guides, and other materials are available at the AIRA and CDC websites [3.2, 3.3, and 3.4]:

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2.3) Vaccine Tracking System (VTrckS). Available at the Centers for Disease Control and Prevention website: http://www.cdc.gov/vaccines/programs/vtrcks/index.html

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2.17) MIROW Best Practices. Available at the American Immunization Registry Association website:
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[2] This document is not available publicly. A user must have log-in credentials to access it. A user may contact CDC directly by filling out the information request at: https://wwwn.cdc.gov/dcs/ContactUs/Form.

Abbreviations

Abbreviation	Full version
317	Section 317 of the Public Health Service Act
AI/AN	American Indian/Alaskan Native
AIRA	American Immunization Registry Association
ACK	Acknowledgment message
AO	Authorized organization
BR	Business rule
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CPT	Current procedure terminology
DI-v-EDE	Decrementing inventory via electronic data exchange
DOB	Date of birth
EDE	Electronic data exchange
EHR	Electronic health record
ExIS	External information system
GR	General recommendation
HIE	Health information exchange
HL7	Health Level 7 International
HMO	Health maintenance organization
IIS	Immunization information system
MIROW	Modeling of Immunization Registry Operations Workgroup
MOGE	Moved or Gone elsewhere
N/A, NA, na	Not applicable
NDC	National Drug Code
Org	Organization
P	Principle (high-level business rule)
PIN	Provider identification number
PO	Provider organization
PPI	Public/Private indicator
SME	Subject matter expert
UI	User interface
VE	Vaccination event
VED	Vaccination event data
VFC	Vaccines for Children
VIM	Vaccine inventory module
VTrckS	Vaccine Tracking System
Y/N	Yes/No

Appendix A: Terms and Definitions Defined via Domain Model

In developing a domain model for this topic, the panel of experts took as a starting point existing models constructed for previous MIROW topics in 2005-2014, with a special focus on models developed for the original MIROW 2012 Inventory Management Guidelines [1.3] and MIROW 2013 Data Quality Assurance Guidelines [1.2].

Domain model purpose

A domain model captures a business vocabulary—agreed upon terms and definitions. It ensures that all terminology and concepts that will appear in the process description, principles, and business rules are known and understood by the domain practitioners (agreed upon definitions and meanings).

The purpose of employing a domain model (a.k.a. as fact model, concept model) is to:

- Document agreed upon terms and definitions for the project.
- Facilitate discussions of the terms and definitions among project participants, and provide tools to capture outcomes of these discussions.
- Establish a foundation and a reference source (common vocabulary) for other project materials.

A domain model includes:

- Domain diagram(s) that shows major business entities, concepts, and terms, and their relationships and responsibilities (Figure A-1).
- Table of terms and definitions provide the descriptive details of the business concepts and terms represented on the diagram (Table A-1 and Table A-2):
  - Numbering of the concepts and terms on diagrams corresponds to numbers in the table of terms and definitions.
- Discussion of key concepts and terms, expanding descriptions presented in the table of terms and definitions (Table A-3).
- Description of the domain diagram.

Unlike a data model diagram that depicts storage of information, or a work flow/process diagram that depicts the sequence of steps in a process, a domain diagram is a high-level static representation of the main "things" (entities/concepts) involved in the immunization process, including a description of how these "things" (entities/concepts) are related. It is important to note that the domain diagram is not a technical specification. Instead, the domain diagram provides the foundation (in the form of a vocabulary) for other modeling diagrams and materials.

How to read and interpret the domain diagram

(see Figure A-1)

- Relationships between entities are visualized by connecting lines.
- Names associated with these lines describe the types of relationships between entities. Example: A relationship between ***provider*** and ***vaccination*** event is shown as a connecting line with the word (label) "***conducts***." Such a relationship should be read as "***Provider conducts vaccination event***."
- The description of relationships between entities can be interpreted by reading clockwise, starting with the first entity name (***provider***), then relationship name (***conducts***—note that the name is shown at the top of the line, supporting a clockwise reading), then the second entity name (***vaccination event***). The arrow symbol, ">," placed after the word "***conducts***" and pointing to the ***vaccination event***, is used to emphasize the direction of reading (i.e., from ***provider*** to ***vaccination event***).
- To read the same description in the opposite direction—from ***vaccination event*** to ***Provider***—we would place a second relationship name, "***conducted by***,"at the bottom of the line. In this case, using the clockwise reading rule, a description would be "***Vaccination event is conducted by the provider***." In most cases, only one name is used to describe a relationship (such as "***conducts***" in the example just given), assuming that will be sufficient for the reader to interpret a relationship in either direction.

Domain diagram

The domain diagram for the DI-v-EDE topic domain is presented in Figure A-1 below. The diagram includes following interconnected parts (a.k.a., domain "neighborhoods") that describe areas of IIS operations relevant for this topic:

- Vaccination event fragment (green color)
- Inventory fragment (blue color)
- Information exchange fragment (yellow color)

A bulleted-style description of facts depicted on the domain diagram follows, relating the DI-v-EDE story.

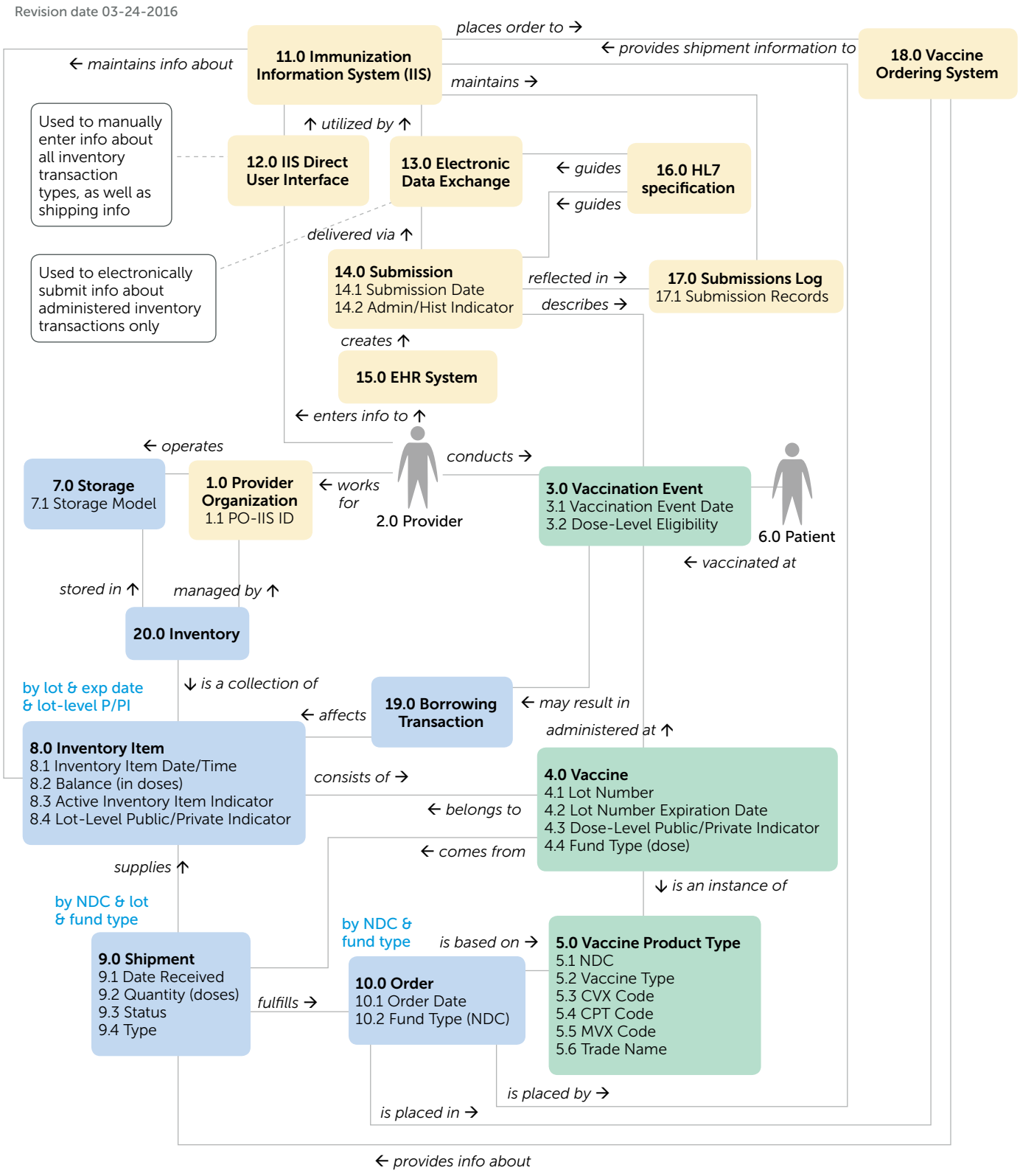

Figure A-1. Domain diagram for the DI-v-EDE topic

Description of facts depicted in the domain diagram

(see Figure A-1 [i.e., the DI-v-EDE story])

- Provider Organization manages Inventory that consists of Vaccines.
- Inventory is stored in the Storage, operated by the Provider Organization.
- IIS maintains info about Provider Organization's Inventory.
- IIS places Provider Organization's Vaccine Orders in Vaccine Ordering System (e.g., VTrckS).
- Order is based on Vaccine Product Type (NDC).
- Shipment fulfills the Order and supplies the Provider Organization's Inventory Items; each Vaccine comes from Shipment.
- Vaccine Ordering System (e.g., VTrckS) provides the Shipment information for the IIS.
- Provider, who works for a Provider Organization, conducts Vaccination Event.
- Patient is vaccinated at Vaccination Event.
- Vaccine, which is an instance of a Vaccine Product Type, is administered at Vaccination Event.
- Vaccination Event may result in a Borrowing Transaction, which affects the Provider Organization's Inventory Items.
- Provider enters information about the Vaccination Event into the EHR system.
- EHR system sends the Submission to the IIS via Electronic Data Exchange.
- Submission describes the Vaccination Event.
- Submission is reflected in the Submission Log, maintained by IIS.
- HL7 Specification guides the Submission and Electronic Data Exchange.
- Provider also communicates with the IIS via IIS Direct User Interface.

Tables of terms and definitions

Table A-1 below presents terms and definitions in numerical order (as numbered in the diagram in Figure A-1); Table A-2 presents terms and definitions in an alphabetical order.

Table A-1. Domain model—terms and definitions (in numerical order; Figure A-1)

ID	Name	Description	Remarks
1.0	Provider Organization	Provider Organization is an organization that provides vaccination services or is accountable for an entity that provides vaccination services. Provider Organizations include a collection of related Providers (e.g., clinicians—physicians, nurses).	■ See MIROW 2013 Data Quality Assurance Guidelines [1.2] for more generic term, IIS-Authorized Organization (IIS-AO), that describes any organization that has an agreement with the IIS that allows submittal and/or retrieval of the IIS data. ▪ IIS-AO in the role of Vaccinator is called a Provider Organization in MIROW 2013 Data Quality Assurance Guidelines [1.2]. ■ For the purposes of this DI-v-EDE guide, submittals include only administered vaccination information.
1.1	PO-IIS ID	Identifier assigned by IIS to the Provider Organization. Identifier (ID) that labels and establishes the identity of a Provider Organization.	■ Also known as Facility/Site Organization ID. ■ Distinct PO-IIS ID is assigned to a Provider Organization that is a part of another Provider Organization (both have unique PO-IIS IDs). ■ Beyond PO-IIS ID, each Provider Organization may have multiple inventory-based IDs (i.e., VTrckS IDs) used to track inventory for federal (VFC, 317, STD, etc.) and state-funded vaccines. The PO-IIS ID should be cross-linked to these inventory-related IDs. ■ See MIROW 2013 Data Quality Assurance Guidelines [1.2], Chapter 3: Fundamentals, Domain model, and Chapter 4: Process Model, Facility Identification Management in MIROW 2013 Data Quality Assurance Guidelines [1.2], for considerations (the term used there is IIS-AO ID).
2.0	Provider	A person—medical professional, clinician—who works for a Provider Organization.	■ The assumption (simplification) is that the same person plays roles of immunization provider (responsible for performing Vaccination Events) and data entry operator (responsible for entering information about the Vaccination Event into the submission chain).
3.0	Vaccination Event	Vaccination Event is a medical occurrence of administering one Vaccine to a Patient.	■ Several Vaccination Events can happen during one office visit (Vaccination Encounter).
3.1	Vaccination Event Date	Date when Vaccination Event occurred.	
3.2	Dose-level Eligibility	Patient's eligibility for a funding program (such as VFC, 317, etc.), which is determined for each dose administered.	■ See MIROW 2011 IIS Collaboration with VFC and Grantee Guidelines [1.4]. ■ Dose-level eligibility corresponds to the HL7 eligibility concept (which is messaged using Financial Class). See section Eligibility (Financial Class) in HL7 specification in this appendix. ■ In addition to indicating patient's eligibility for a particular immunization program, dose-level eligibility reported by a Provider Organization to IIS also serves as a proxy (i.e., substitute, representation) for the fund type.

ID	Name	Description	Remarks
4.0	Vaccine	Vaccine is a specific instance of the medicine (instance of the Vaccine Product Type and Vaccine Type) given during a vaccination.	■ A.k.a. vaccine dose ■ Examples: MMR, HepB-Hib ■ A single vaccine dose does not have a unique identifier. Vaccine doses within the Inventory Item (see item 8.0) have the same lot number, lot number expiration date, and lot-level public/private indicator.
4.1	Lot Number	The lot number is the identifier assigned by the manufacturer to a specific batch of Vaccine Product Type.	■ Lot Number is used by IIS to track vaccines for inventory management purposes. ■ A single vaccine dose does not have a unique identifier.
4.2	Lot Number Expiration Date	This is the date on which the lot is no longer considered potent.	■ Manufacturers are required to assign a lot expiration date to each batch (lot) of vaccine. ■ The vaccine manufacturer initially establishes lot number expiration date and all doses in a lot have the same expiration date. In some cases, vaccine is subject to temperature variations in storage that are outside the recommended range. The immunization program determines a procedure for use of the vaccine. The immunization program often calls the manufacturer and explains the situation. The immunization program and the manufacturer determine the effectiveness of the vaccine product. The doses of vaccine that were subject to the temperature variations may be given a new expiration date that is sooner than the original expiration date ("short-dated"). ■ When present, the short-dated lot number expiration date must be used (recorded) for all inventory transactions instead of the original lot number expiration date. The IIS must be able to record both the original and the short-dated lot number expiration dates for the lot number. ■ For discussion of short-dated lot number expiration date, see MIROW 2012 Inventory Management Guidelines [1.3], specifically, BR711, p. 43, BR712, p. 44, GR706, p. 55, and BR718, p. 47. ■ Vaccine doses can be short-dated (i.e., lot number expiration date for some doses can be changed to an earlier date). This usually happens due to temperature excursions in a Provider Organization's Storage or some other issue at the manufacturer's site or during shipment/transport. As a result, if some doses are short-dated, it is possible to have two inventories with the same lot number and lot-level public/private indicator, but different expiration dates—one with the original expiration date and another with a short-dated expiration date.

ID	Name	Description	Remarks
4.3	Dose-level Public/ Private Indicator	Dose-level Public/Private Indicator is an aggregated reflection of the Fund Type (item 4.4). It indicates whether a vaccine dose belongs to a public or private stock in the Provider Organization's Storage (i.e., it corresponds to Storage Model (item 7.1). In essence, it is a funding indicator that is less specific than Fund Type (see items 4.4).	■ This is at the dose-level. It is assigned by the Provider Organization for each administered vaccine (dose) based on location of that particular vaccine (dose) in the Storage. ■ See item 8.4 Lot-level Public/Private Indicator for a lot number level indicator. ■ The term Dose-level Public/Private Indicator corresponds to the term Funding Source in the HL7 specification; see section Funding source in HL7 specification in this document. ■ See section Dose-level public/private indicator in this document for an expanded discussion. ■ At present, as our research indicated, there are four storage models in practice: ▪ Two-stock—one for publicly-funded and another for privately-funded vaccine doses. ▪ Three-stock—one for publicly-funded VFC, another for publicly-funded non-VFC, and a third for privately-funded vaccine doses. ▪ Multi-stock (4 or more) model—vaccines are separated by individual fund type (e.g., VFC, 317, CHIP, state, and private inventories). ▪ One-stock—some awardees allow Provider Organizations to use a one-stock "replacement" model, where all vaccine doses are stored as one stock, regardless of Fund Type, and Provider Organizations are reimbursed by the VFC program for vaccines administered to VFC-eligible patients. ■ When a Dose-level Public/Private Indicator for a dose administered to a Patient is private and Patient eligibility status is public (or vice versa), the borrowing transaction is created (in two-, three-, and multi-stock models). ■ There are situations where some vaccine doses are designated as publicly-funded and other vaccine doses with the same lot number are designated as privately purchased. ■ Dose-level Public/Private Indicator can evolve over time (as program requirements and Provider Organizations' storage practices change) to include additional values. ■ See MIROW 2012 Inventory Management Guidelines [1.3, p. 43], BR711 remarks for details.
4.4	Fund Type (dose)	A program (or a private payer) that paid for the vaccine. This is at the dose-level.	■ This term is from the VTrckS ExIS Specification (possible values for direct ship orders: VFC, 317, state, CHIP). ▪ There are also publicly-purchased vaccines that are not purchased through VTrckS. ■ Provider Organization learns Fund Type for each dose of vaccine from the shipments' packing slip [2.7]. It can be assigned (deduced) by the awardee's immunization program based on the Dose-level eligibility (item 3.2) reported by the Provider Organization.

ID	Name	Description	Remarks
5.0	Vaccine Product Type	Vaccine Product Type is a category of the vaccine product that is ordered, shipped, administered, etc. ■ A Provider Organization indicates the Vaccine Product Type when placing vaccine orders. ■ A Provider Organization receives Vaccine Doses, which are associated with specific batches or lots of this Vaccine Product Type.	■ Vaccine Product Type, for inventory tracking/management purposes, is characterized by the NDC code. ■ Vaccine Product Type, for immunization tracking purposes, is characterized by the Vaccine Type (or CVX code or CPT code), Manufacturer (MVX code), and Trade Name. ■ An instance of the Vaccine Product Type—a Vaccine Dose—is characterized by the Lot Number and Lot Number Expiration Date. ■ Examples of Vaccine Product Types that belong to the same Vaccine Type but have different NDC codes [2.11]. **Vaccine Product Type 1** ▪ 5.1 NDC = 58160-0820-11 ▪ 5.2 Vaccine Type = HepB ▪ 5.3 CVX Code = 08 ▪ 5.4 CPT Code = 90744 ▪ 5.5 Manufacturer/MVX code = SKB ▪ 5.6 Trade Name = ENGERIX B-PEDS **Vaccine Product Type 2** ▪ 5.1 NDC = 00006-4981-00 ▪ 5.2 Vaccine Type = HepB ▪ 5.3 CVX Code = 08 ▪ 5.4 CPT Code = 90744 ▪ 5.5 Manufacturer/MVX code = MSD ▪ 5.6 Trade Name = RECOMBIVAX-PEDS
5.1	NDC	NDC (National Drug Code) is defined as a unique numeric identifier of the Vaccine Product Type. For specific NDC examples, see CDC Vaccine Price List [2.12].	■ Each drug product is assigned a unique three-segment number. This number, known as the NDC, identifies the labeler, product, and trade package size. ■ The first segment, the labeler code, is assigned by the FDA. A labeler is any firm (including re-packers or re-labelers) that manufactures or distributes (under its own name) the vaccine. ■ The second segment, the product code, identifies a specific strength, dosage form, and formulation of a drug for a particular firm. ■ The third segment, the package code, identifies package sizes and types (presentation). ■ VTrckS uses the 5-4-2 NDC format. Note: There are several other formats for NDC codes.
5.2	Vaccine Type	The Vaccine Type is defined as a category of Vaccine. A single Vaccine Type may be associated with many Vaccine Product Types (i.e., different manufacturers, different packaging). Vaccine (item 5) is an instance of Vaccine Product Type	■ The Vaccine Type may indicate a generic or specific type of vaccine (e.g., pneumococcal or PCV13 or PPSV23). ■ The Vaccine Type can include single types of Vaccines as well as combination vaccines (e.g., IPV or IPV-DTaP- HepB). ■ Examples of Vaccine Type names: MMR, Hib-HepB, HepB-Peds.

ID	Name	Description	Remarks
5.3	CVX Code	A numerical code that describes a Vaccine Type.	■ CVX Codes are assigned by CDC to support electronic messaging of immunization histories via HL7 [2.13]. ■ Vaccine Type maps to a CVX Code. There is normally one CVX Code per one Vaccine Type.
5.4	CPT Code	A numerical string that describes the procedure (billable service) of administering a vaccine.	■ CPT (Current Procedural Terminology) Codes are developed by the American Medical Association to bill for medical or psychiatric procedures performed by health care practitioners. ■ Some CPT Codes have been reused. ■ There are vaccines that do not have CPT Codes. ■ CPT Codes may be mapped to CVX Codes; however, it is important to note that this is not a one-to-one mapping. Using CPT Codes in this manner is not considered the best practice [2.14].
5.5	MVX Code (Manufacturer)	An alpha code that designates manufacturer i.e., Sanofi = PMC. Manufacturer is defined as an organization that develops and distributes vaccines.	■ CDC assigns an MVX Code to specific vaccine manufacturers. ■ An MVX Code can be paired with the CVX Code to derive a specific Trade Name. ■ There may be several manufacturers of a particular vaccine type [2.15].
5.6	Trade Name	Trade Name reflects the manufacturer's proprietary name and, in some cases, its intended use (e.g., Adults, Pediatrics) is included in the name.	■ Examples: ActHIB, Comvax, EngerixB-Peds, EngerixB-Adult. ■ If Trade Name is not actively collected by a particular IIS, it can be derived from other variables (e.g., NDC or Vaccine Type [CVX Code] and Manufacturer Name [MVX Code]).
6.0	Patient	An Individual who is the actual or potential recipient of an administered Vaccine from a Provider Organization.	■ For purposes of this guide, Patients are assumed deduplicated. Refer to the guidelines on patient-level deduplication [3.5].
7.0	Storage	A refrigerator or freezer used to store vaccine.	■ A place where a Provider Organization stores vaccines. ■ Storage and storage unit are used interchangeably throughout the document.

ID	Name	Description	Remarks
7.1	Storage Model	Describes the way vaccine stocks are physically separated from each other in the Provider Organization's storage (i.e., refrigerator, freezer). Public/Private Indicator (see item 4.3; a.k.a. Funding Source in the HL7 messaging specification) is used to describe the association of an administered vaccine dose with the Storage's partition that dose was taken from (e.g., from public or private stock).	■ At present, as our research indicated, there are four storage models in practice: ▪ Two-stock—one for publicly-funded and another for privately-funded vaccine doses. ▪ Three-stock—one for publicly-funded VFC, another for publicly-funded non-VFC, and a third for privately-funded vaccine doses. ▪ Multi-stock (4 or more) model—vaccines are separated by individual Fund Type (e.g., VFC, 317, CHIP, state, and private inventories). ▪ One-stock—some awardees allow provider organizations to use a one-stock "replacement" model, where all vaccines doses are stored as one stock, regardless of Fund Type, and Provider Organizations are reimbursed by the VFC program for vaccines administered to VFC-eligible patients. ■ Storage Model (i.e., how vaccines are stored in Provider Organization's Storage units) directly influences reporting specificity for Fund Types from Provider Organization to IIS. ■ Note that, in many cases (depending on awardee's policies and Provider Organization's vaccine storage practices), it is not clear to the provider whether a particular dose administered was actually funded by VFC, 317, CHIP, or state program (i.e., in many cases, provider is "blind" to the actual Fund Type within the public stock).
8.0	Inventory Item	A collection of vaccine doses with the same lot number, lot-level public/private indicator, and lot number expiration date.	■ Inventory Item is a part of the Inventory (see item 20.0). ■ Inventory Item's balance is decremented in the DI-v-EDE process.
8.1	Inventory Item Date/Time	Date and time when Inventory Item's balance is changed, (for example, when a transaction such as vaccine administration is accounted against the Inventory Item or a date and time when Inventory Item's balance is documented).	
8.2	Balance	Number of vaccine doses currently on hand for the Inventory Item.	
8.3	Active Inventory Item Indicator	Designates an Inventory Item as "active," "pending," or "inactive." See remarks for definitions of these terms.	■ This designation can be made at the program (i.e., IIS) level or at the Provider Organization level (depending upon awardee's setup). ▪ The active designation means that there are vaccine doses available for administration under the Inventory Item. The active designation is made when an Inventory Item is added to the inventory. ▪ The pending designation requires a Provider Organization to confirm receiving a shipment. ▪ The inactive designation is made when all vaccine doses associated with the Inventory Item have been used or when the doses have expired (beyond the Lot Number Expiration Date). Inventory Item can be reactivated when additional doses for the same Inventory Item are shipped to and received by the Provider Organization.

ID	Name	Description	Remarks
8.4	Lot-level Public/ Private Indicator	Lot-level Public/Private Indicator is an aggregated reflection of the Fund Type (item 9.3). It indicates whether vaccine doses for a given Inventory Item belong to a public or private stock. In essence, it is a funding indicator that is less specific than Fund Type (see item 9.3). When Lot-level Public/Private Indicator has value, "public," it indicates that vaccine doses for the Inventory Item have been funded by one of the public Fund Types (i.e., payers): VFC, 317, state, CHIP).	■ This is at the lot number level. ■ Lot-level Public/Private Indicator is assigned by IIS based on the shipment's electronic file. It can be adjusted as the Provider Organization verifies the shipment, based on actual contents and the packing slip. ■ See item 4.3 Dose-level Public/Private Indicator. ■ See MIROW 2012 Inventory Management Guidelines [1.3, p. 43], BR711 remarks for details.
9.0	Shipment	Shipment can come from a distributor (currently, McKesson) or a manufacturer.	■ The information in Shipment's packing slip (hard copy enclosed with every Shipment, also known as packing list or packing manifest) is organized by NDC, then by lot number, then by fund type. See Separating VFC Stock visual aid [2.7]. ■ The best practice is for the shipping information to be loaded in IIS electronically from a Vaccine Ordering System (e.g., VTrckS) for all vaccines. However, in some cases (e.g., private vaccine, delays in shipping data being available from VTrckS, etc.), it may be necessary for the Provider Organization to enter the data manually via the Direct UI. ■ Shipment does not always come from VTrckS; other ordering systems are used, too.
9.1	Date Received	Date when the Shipment has been received by the Provider Organization.	
9.2	Quantity (doses)	Quantity of doses per the lot number.	
9.3	Status	Characterizes condition of the Shipment at a particular time.	■ For example, pending, in transit, delivered.
9.4	Type	Regular or Direct Shipment	■ Regular Shipment—by a distributor (currently McKesson). ■ Direct Shipment—by a manufacturer.
10.0	Order	Request for vaccines from a provider organization.	■ Order information is organized by NDC and Fund Type (at the NDC level). ■ Fund Type split approach is used to determine fund types for NDC portions.
10.1	Order Date	Date when the order for vaccine doses has been placed.	
10.2	Fund Type	A program (or a private payer) that paid for the vaccines.	■ See item 4.4 for a Fund Type at the dose-level (@ Vaccine) and item 9.3 for a Fund Type at the lot number level (@ Shipment). ■ This term is from the VTrckS ExIS Specification; possible values for direct ship orders are VFC, 317, state, CHIP. ■ Fund Type split method is often used for orders.

ID	Name	Description	Remarks
11.0	Immunization Information System (IIS)	Immunization Information Systems (IIS) are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area.	■ At the point of clinical care, an IIS can provide consolidated immunization histories for use by a vaccination provider in determining appropriate patient vaccinations. ■ At the population level, an IIS provides aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease. ■ See *About Immunization Information Systems* [2.16].
12.0	IIS Direct User Interface	This is the application for the user to submit data directly to or retrieve data directly from the IIS (i.e., this is usually accessed via the Web).	■ User Interface, although not entirely error-free, is an opportunity for human evaluation and decision. ■ Throughout the document, this term is referenced in abbreviated forms as IIS Direct UI, Direct UI, or UI.
13.0	Electronic Data Exchange	Electronic Data Exchange is the interface in which data can be communicated electronically between a third-party system and the IIS (e.g., EHR, HIE, Billing System).	■ Different EDE formats (e.g., flat file, HL7). ■ Different EDE types (e.g., outbound, inbound, bidirectional).
14.0	Submission	Submission of information about a single Vaccination Event to the IIS.	■ The same Vaccination Event can be submitted more than once by a Provider Organization and other parties. ■ IIS should only record a unique Vaccination Event once. Refer to MIROW 2006 Vaccine De-duplication Guidelines [1.7].
14.1	Submission Date	Submission Date is the date when the data were received (but not necessarily loaded) by the IIS.	■ This date should not be confused with the Vaccination Event date. ■ This is not necessarily the date the Submission was sent.
14.2	Administered/ Historical Indicator	Administered/Historical Indicator describes an association between a Vaccination Event and the Provider Organization that originally initiates a Submission for this Vaccination Event: Values: Administered or Historical: ■ Administered value for the Administered/ Historical Indicator points out that the Provider Organization records and/or submits its own Vaccination Event (i.e., attests that it conducted the Vaccination Event). ■ Historical value for the Administered/ Historical Indicator points out that the Provider Organization initiates a Submission for a Vaccination Event conducted by some other Provider Organization (i.e., attests that it did not conduct the Vaccination Event).	■ Only administered vaccine doses are relevant for this topic. ■ See a detailed discussion of the Administered/Historical Indicator in the "Discussion and notes" section in MIROW 2013 Data Quality Assurance Guidelines [1.2], Chapter 3: Fundamentals. ■ Administered/Historical Indicator is described in the IIS Functional Standards, 2013-2017 [2.1] with the following IIS Core Data Element: Vaccination Event Information Source (i.e., administered or historical).

ID	Name	Description	Remarks
15.0	EHR System	Electronic Health Records system used by the Provider Organization.	■ Some EHR systems have an inventory module, and some do not. In addition, third-party inventory systems used by Provider Organizations (e.g., VaxCare) will be considered a part of EHR for purposes of this topic. ■ There are EHR that send Electronic Edits (deletes and adds) and EHR that send only add-type messages (see, for example, MI materials). ■ "There is no commonly understood distinction between the concepts of an electronic health record and an electronic medical record, and no such distinction has been made uniformly in the literature [3.6]." ■ *For purposes of this project, the term "EHR System" refers to both EHR and EMR Systems.*
16.0	HL7 Specification	Health Level 7 (HL7) is a nationally recognized standard for Electronic Data Exchange between systems housing health care data.	■ HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5, Published November 5, 2014 [2.9, 2.10].
17.0	Submissions Log	A collection of records for submission-related decrementing activities.	
17.1	Submission Records	Records of submissions, including DI-v-EDE – related issues/errors.	
18.0	Vaccine Ordering System	VTrckS or some other ordering system.	■ The most prevalent way to order vaccines is through the Vaccine Tracking System (VTrckS) [2.3], which is an information technology system that integrates the entire publicly-funded vaccine supply chain from purchasing and ordering to distribution of the vaccine. ■ VTrckS may not integrate all publicly-funded vaccines.
19.0	Borrowing Transaction	Borrowing describes use of a Vaccine during a Vaccination Event from a vaccine stock that does not correspond to a Patient's Dose-level Eligibility.	■ For example, when a Patient has Dose-level Eligibility as Medicaid, but a Vaccine administered during the Vaccination Event was taken from the private vaccine stock, a Borrowing Transaction should be created between the privately-funded and publicly-funded vaccine stocks. ■ Reference MIROW 2012 Inventory Management Guidelines [1.3, p. 87] for details.
20.0	Inventory	A collection of Inventory Items.	■ See item 8.0 for the Inventory Item term. ■ Stock is the alias term for the Inventory. It is commonly used to refer to "public stock" or "private stock" of vaccine doses in the Provider Organization's inventory.

Table A-2. Domain model—terms and IDs in alphabetical order; Figure A-1

Term Name	ID
Active Lot Indicator	8.3
Administered/ Historical Indicator	14.2
Balance	8.2
Borrowing Transaction	19.0
CPT Code	5.4
CVX Code	5.3
Date Received	9.1
Dose-level Eligibility	3.2
Dose-level Public/Private Indicator (dose)	4.3
EHR System	15.0
Electronic Data Exchange	13.0
Fund Type	10.2
Fund Type (dose)	4.4
HL7 Specification	16.0
IIS Direct User Interface	12.0
Immunization Information System (IIS)	11.0
Inventory	20.0
Inventory Item	8.0
Inventory Date/Time	8.1
Lot-level Public/Private Indicator	8.4
Lot Number	4.1
Lot Number Expiration Date	4.2
MVX Code (Manufacturer)	5.5
NDC	5.1

Term Name	ID
Order	10.0
Order Date	10.1
Patient	6.0
PO-IIS ID	1.1
Provider	2.0
Provider Organization	1.0
Quantity (doses)	9.2
Shipment	9.0
Status	9.3
Storage	7.0
Storage Model	7.1
Submission	14.0
Submission Date	14.1
Submission Records	17.1
Submissions Log	17.0
Trade Name	5.6
Type	9.4
Vaccination Event	3.0
Vaccination Event Date	3.1
Vaccine	4.0
Vaccine Ordering System	18.0
Vaccine Product Type	5.0
Vaccine Type	5.2

Discussion and notes

Comparison of operational level (MIROW) and technical level (HL7 spec) terms

Table A-3. Comparison of operational level (MIROW) and technical level (HL7 spec) terms

Concept	Operational-level term (MIROW)	Technical-level term (HL7 spec)	Remarks
Patient's eligibility for a funding program, which is determined for each dose administered. Values (one of the following): Medicaid, AI/AN, Underinsured, Uninsured, state program, CHIP, private pay (insurance or out of pocket), ...	Dose-level Eligibility (see item 3.2 in the table of terms and definitions)	**Eligibility statuses at the dose administered level** ■ Patient eligibility for a funding program at the dose administered level ■ Eligibility for each immunization administered ■ Eligibility with each vaccine administered ■ Eligibility for each immunization ■ Patient eligibility in association with the dose administered	In HL7, it is expressed by the Financial Class code value for each individual vaccination event. See Eligibility (financial class) in the HL7 specification section below.
A value that indicates whether a vaccine dose belongs to a public or private stock in the provider organization's storage. It is an aggregated reflection of the Fund Type. Values (one of the following): ■ Public, Private, or ■ VFC-public, non-VFC-public, Private	Dose-level Public/ Private Indicator (see item 4.3 in the table of terms and definitions)	**Funding Source** ■ Immunization funding source ■ Funding source for immunization ■ Funding source for a specific immunization ■ Vaccine funding source	In essence, it is a funding indicator that is less specific than Fund Type. When Dose-level Public/Private Indicator has value "public," it indicates that a vaccine dose has been funded by one of the public Fund Types (i.e., payers): VFC, 317, state, CHIP. See the Funding Source in HL7 specification section below
A program (or a private payer) that paid for the vaccine. Values (one of the following): ■ VFC ■ 317 ■ State ■ CHIP ■ Private	Fund Type (see item 4.4 in the table of terms and definitions)	**<Not applicable>** Fund Type is not transmitted in HL7 messages.	In many cases, Fund Type is assigned (deduced) by awardee based on the Dose-level Eligibility and Dose-Level Public/Private Indicator reported by the provider organization.

Eligibility (financial class) in HL7 specification

The aim here is to establish a correspondence between the operational term Dose-level Eligibility (see item 3.2 in Table A-1: Terms and definitions) and terminology used in the HL7 specification, as well as briefly describe handling of dose-level eligibility in the HL7 guide.

This section is based on the *HL7 Implementation Guide for Immunization Messaging, Version 2.5.1. Release 1.5* [2.9, 2.10].

The HL7 guide describes two types of eligibility:

- Patient eligibility—refers to the financial class code value for all services conducted during an individual patient visit (i.e., a vaccination encounter that includes one or more vaccination events).
- Dose-level eligibility for a vaccine funding program—indicates the financial class code value for each individual vaccination event that occurs during a patient visit (i.e., vaccination encounter). Some examples of specific terms found in the HL7 guide that describe eligibility are:
  - Patient eligibility for a funding program at the dose administered level.
  - Eligibility statuses at the dose administered level.
  - Eligibility for each immunization administered.
  - Eligibility for each vaccine administered.
  - Eligibility for each immunization.
  - Patient eligibility in association with the dose administered.

Although both types of eligibility use the same HL7 code set (see User-defined Table 0064 – Financial Class), the data imply different things and can be designated as such via the OBX-17 field:

- When OBX-17 contains the value of "VXC41^per visit^CDCPHINV," it is referencing that the data contained in the OBX segment is referring to Patient Eligibility (i.e., all vaccination events for message on that date should use this financial class code).
- When OBX-17 contains the value "VXC40^per immunization^CDCPHINVS," each OBX segment should use this eligibility for dose-level eligibility at each individual vaccination event (i.e., this allows for different vaccination events conducted during the patient visit to have different financial class values).
- It is also important to note that this field (OBX-17) is a required field when OBX-3 indicates financial class (64994-7), whereas sending the financial class is REQUIRED, so programs need to determine how they handle messages that come in without data in the OBX-17 field and what business rules should be employed.
- Another potential challenge is conflicting information in the OBX-17. For example, the OBX-17 indicates the data should reside at the patient level; however, there are multiple vaccinations, and they have different code values sent in OBX-5.

Eligibility data element is contained in the OBX (Observation Result) segment. The segment has many uses and may be repeated in a single message. In general, OBX-3 contains what data element is being addressed, and OBX-5 is used to identify the actual code set value for that data element.

If the intent is to identify the dose-level eligibility (or financial class) for a vaccination event, this data element would be identified in OBX-3 as 64994-7, and the specific financial class code value identified for that vaccination event would be conveyed in OBX-5 (perhaps as "V01," which codes for Not VFC-eligible).

Funding source in HL7 specification

The aim here is to establish a correspondence between the operational term Dose-level Public/Private Indicator (see item 4.3 in Table A-1, which contains terms and definitions) and terminology used in the HL7 specification, as well as briefly describe handling of the funding information in the HL7 guide.

This section is based on the *HL7 Implementation Guide for Immunization Messaging. Version 2.5.1. Release 1.5* [2.9, 2.10].

The HL7 guide describes the concept of dose-level public/private indicator with the term funding source. Some examples of specific terms found in the HL7 guide include:

- Immunization funding source
- Funding source for immunization
- Funding source for a specific immunization
- Vaccine funding source
- Funding source

Funding source data element is contained in the OBX (Observation Result) segment. The segment has many uses and may be repeated in a single message. In general, OBX-3 contains what data element is being addressed, and OBX-5 is used to identify the actual code set value for that data element.

If the intent is to send information about the vaccine funding source, OBX-3 would contain the value of 30963-3, and the code value identified for this data element submitted through OBX-5 would use codes from the Value Set Name—Immunization Funding Source table (PHVS_ImmunizationFundingSource_IIS). An example on this table is "VXC2" for state-funded.

The code set includes:

- PHC70–Private funds
- VXC1–Federal funds
- VXC2–State funds
- PHC68–Military funds
- VXC3–Tribal funds
- OTH–Other
- Immunization was paid for by funding not listed above.
- UNK–Unspecified

Note that efforts are currently underway to update this code set to include only the following values:

- Public, Private (corresponds to the two-stock model—see item 7.1, Separation type of the domain model).
- VFC-public, non-VFC-public, Private (corresponds to the three-stock model—see item 7.1, Separation type of the domain model).

Dose-level Public/Private Indicator

Following is an excerpt from the MIROW 2012 Inventory Management Guidelines [1.3, p. 43], BR711:

- *Reporting of the Public/Private Inventory Indicator for every inventory transaction at the dose-level, while providing a comprehensive solution, requires that an additional data item be reported/recorded. That is a burden on Provider Organizations and EHR vendors. The alternative recommended good practice, as implemented in Michigan IIS, would be to record public/private designation at the lot number level (as opposed to the dose-level) for every lot number* [lot-level public/private indicator]. *When a vaccine dose is administered to a patient and reported to IIS by a Provider Organization, IIS searches for the lot number in public and private inventories to properly designate the administered dose as public or private. This approach still presents a problem in cases when the same lot number has both public and private doses. In these cases, when a Patient's eligibility is public, Michigan IIS defaults the dose designation to public. (Note that this is only true in instances where a Provider Organization transfers data via their EHR. If a Provider Organization manually enters their data into the IIS, they select the lot number administered from a drop-down box. Lot numbers in the private inventory are indicated with an *). As a result, in this particular scenario, borrowing cannot be identified.*
- *Another option for inferring public/private inventory status in the absence of a dose-level public/private inventory indicator is through dose-level patient's eligibility (i.e., a code of V02 represents patient's eligibility for Medicaid; this can be inferred as a public vaccine dose). However, this does not allow the IIS to audit potential mismatches between public/private patient's eligibility and public/private funding source, so it is not recommended as a best practice.*
- *Best practice for the IIS is to use a separate variable (not the lot number)—Private/Public Indicator* [dose-level public/private indicator]*—to capture public/private designation of the inventory.*
- *Although available as a field within some IIS databases, Public/Private Indicator* [dose-level public/private indicator] *is a data item that is not currently received from or stored in the vast majority of EHR systems. It could be challenging to argue for EHR to store and submit the Public/Private Indicator [dose-level public/private indicator] data item.*

Appendix B: About MIROW

The American Immunization Registry Association (AIRA), in partnership with the National Center for Immunization and Respiratory Diseases (NCIRD) at the Centers for Disease Control and Prevention (CDC), formed the Modeling of Immunization Registry Operations Workgroup (MIROW) in 2005 to develop best practice guidance for various aspects of immunization information systems (IIS). Since 2005, MIROW has developed the following operational guidelines for IIS functional areas (see Table B-1):

- Management of Patient Active/Inactive Status in IIS
- Data Quality Assurance—Selected Aspects
- Inventory Management
- Patient Eligibility for the VFC Program and Grantee Immunization Programs
- Reminder/Recall
- Incoming Data Quality Assurance—Incoming Data
- Vaccination Level De-duplication
- IIS-Vaccine Adverse Event Reporting System Collaboration (pilot project)

MIROW recommendation documents, abridged mini-guides, and other materials are available at the AIRA and CDC websites [2.17, 2.18]. Specific presentations that describe MIROW's efforts are also available [3.2, 3.3, and 3.4].

The approach used and results presented are relevant for and can be used beyond IIS (e.g., for developing and documenting best practices and operational requirements for domain-specific applications in public health, health care, and other areas).

Table B-1. MIROW: Topics/workshops overview

Ref	Title	Guideline document released	Face-to-face meeting	Subject Matter Expert panel size	Guideline document highlights
	Decrementing Inventory via Electronic Data Exchange (current topic)	In Progress	July 2015 2.5 days Decatur, GA	12*	**9** principles **26** business rules **3** decision tables **27** operational scenarios
1.1	**Management of Patient Active/ Inactive Status in IIS** (replaced the 2005 MOGE guide)	April 2015	June 2014 3.5 days Decatur, GA	13	**14** principles **13** business rules **4** decision tables **22** operational scenarios
1.2	**Data Quality Assurance in IIS: Selected Aspects**	May 2013	August 2012 3.5 days Decatur, GA	13	**2** principles **27** business rules **7** general recommendations **27** updated business rules
1.3	**IIS Inventory Management Operations**	June 2012	September 2011 3.5 days Atlanta, GA	14	**8** principles **25** business rules **23** general recommendations **20** key reports
1.4	**IIS-VFC/Grantee Programs Collaboration**	April 2011	June 2010 2.5 days Atlanta, GA	14	**26** eligibility screening scenarios **17** business rules **9** general recommendations
1.5	**Reminder/Recall in IIS**	April 2009	October 2008 2.5 days Tampa, FL	13	**29** principles **23** business rules **30** general recommendations
1.6	**Data Quality Assurance in IIS: Incoming Data**	February 2008	August 2007 2.5 days Atlanta, GA	11	**13** principles **32** business rules
1.7	**Vaccination Level De-duplication in IIS**	December 2006	May 2006 2.5 days Washington, DC	20	**9** principles **20** business rules **23** illustrative scenarios (examples)
1.1	**Management of Patient Active/ Inactive Status in IIS guide—Replacement of 2005 Guidelines**	December 2005	August 2005 2.5 days Atlanta, GA	16	**6** statuses defined on the Provider level **5** statuses on the Geographic Jurisdiction level
1.8	**IIS-VAERS Guide** (pilot project)	April 2005	June 2004 1.5 days Atlanta, GA	21	**10** functional standards **8** business rules **11** alternative scenarios (process)

* Panel included three paid public health consultants. Refer to the Development approach section in Chapter 1: Introduction for more information.

Appendix C: Scope

Breadth

- All **to-be** processes and information in support of decrementing provider organization inventory in the IIS via electronic data exchange (DI-v-EDE).
- All **to-be** processes and information in support of preapproval of provider organizations using DI-v-EDE.

Including (in scope):

(1) Decrementing a provider organization's inventory in IIS via EDE based on administered vaccine doses:
  (a) Utilizing HL7 messages
  (b) Both real-time single message and batch
  (c) Specific operational scenarios:
    (i) What to do when a patient or a vaccination event is deleted in IIS?
    (ii) What to do if a message regarding an administered vaccine dose is sent multiple times? How to avoid multiple subtractions from the inventory?

(2) Identify and address decrementing issues:
  (a) Identifying out-of-sync/mismatched inventory data in EHR and IIS.
  (b) Correction of missing/incorrect inventory data by provider organizations via EDE and Direct UI.
    (i) Avoiding manual intervention as much as possible in the process (e.g., lot numbers).
    (ii) Recommendations for reports to support corrections of mismatched inventory data (e.g., when information in the EHR message does not match the IIS inventory or when data elements in the message do not pass cross-reference validation).
  (c) Reconciliation of provider organization inventory in EHR and IIS— limited to aspects relevant to decrementing inventory via EDE.
  (d) Reconciliation of physical inventory with IIS as necessary for DI-v-EDE.

(3) Requirements for the set of data to DI-v-EDE, including completeness and validations, with a special focus on dose-level eligibility for an administered vaccine and funding source for that dose.

(4) Primarily: Public vaccines.

(5) Secondarily: Private vaccines are included in scope with the understanding that recommendations and solutions developed for managing public vaccine inventory may also, at the discretion of the provider organization, be applied to managing private vaccine inventory.

(6) Selected aspects (pain points related to decrementing inventory) of provider preapproval during the onboarding process and subsequent ongoing monitoring as one of the possible interventions (advancing materials in 2008 MIROW Data Quality Assurance guide). Main themes:
  (a) Monitoring information and activities once a provider organization is approved.
  (b) Monitoring reports and other tools that provider organizations can use to manage issues related to decrementing inventory.
  (c) Review of data submissions in case the provider organization changes something that would affect the EHR IIS data interchange.

(7) Harmonization with previously developed MIROW guides, especially with MIROW 2012 Inventory Management Guidelines [1.3].

Excluding (out of scope):

(1) Decrementing inventory via Direct UI.

(2) Historical doses.

(3) Non-HL7 messages (e.g., flat files).

(4) All inventory transactions beyond administered vaccine doses (i.e., wasted, spoiled, transferred, and returned vaccine doses, except for some limited aspects of borrowing transactions)

(5) Receipt of shipments and incrementing the initial inventory:
   (a) Certain aspects of receipt of shipments and incrementing the initial inventory are in scope, with the aim of documenting how the information used for the DI-v-EDE process is getting to the IIS and provider organizations.

(6) Immunization tracking (i.e., patient immunization record).

(7) Order fulfillment.

(8) Additional details that are specific to managing private vaccine inventory.

Emphasized perspectives

- IIS/immunization program–awardee
- Immunization program–CDC/VFC
- Provider organization

Scope of integration

The scope of integration describes other business initiatives or systems this effort should investigate for the purposes of interfacing, becoming compatible, or coordinating. These efforts are outside our focus, but we anticipate interaction, and therefore, need to plan to assure smooth interaction.

- Vaccine ordering and fulfillment processes (ordering system, e.g., VTrckS):
  - Loading lot numbers based on ordering system, e.g., VTrckS, information on vaccine shipments.
  - Synchronization of timing with ordering system, e.g., VTrckS, to satisfy requirements regarding the submission of inventory to ordering system, e.g., VTrckS, from the IIS.
- Direct UI:
  - Reporting wasted and spoiled doses via Direct UI.
- Immunization tracking process.
- Vaccine barcoding systems.
- Previously developed MIROW guides, especially MIROW 2012 Inventory Management Guidelines [1.3].

Appendix D: Decision-making Example

This appendix contains a decision table for a two-stock storage model developed during the in-person meeting of experts (July 21-23, 2015, in Decatur, Georgia). It aims to illustrate how, based on submitted vaccination event information, intertwined issues of identifying an inventory to decrement and creating a borrowing transaction can be analyzed and documented by awardees.

The panel decided not to spend additional time on developing an initial draft of this decision table further or developing similar decision tables for three- and four-stock storage models because of the following considerations:

- Borrowing policies and practices vary significantly across awardees.
- Borrowing issues are not in focus of the scope for this topic.
- VFC and local materials should be referenced for borrowing-related guidance; additionally, borrowing-related recommendations are available in the MIROW 2012 Inventory Management Guidelines [1.3].

Table D-1. Decision table for the two-stock inventory model

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
Conditions																
VE Dose-level eligibility: ■ Private pay, Public pay (VFC [Medicaid, AI/AN, uninsured, underinsured], Other [317, state, CHIP, etc.])	Pr	Pu	Pu	Pu	Pu	Pu	Pr	Pr	Pr	Pr	Pr	Pu	Pr	Pr	Pu	Pu
VE Dose-level public/private indicator: ■ Public, Private	Pr	Pr	Pr	Pu	Pu	Pu	Pu	Pu	Pr	Pr	Pr	Pu	Pu	Pu	Pr	Pr
Provider IIS inventory that contains lot number (lot number public/private indicator): ■ Public, Private, Both public and private	Pr	Pr	Pr	Pr	Pr	Pu	Pu	Pu	Pu	Pu	B	B	B	B	B	B
Borrowing allowed: Y/N	-	Y	N	Y	N	-	Y	N	Y	N	-	-	Y	N	Y	N
Actions																
1. Select private inventory.	X	X		X							X				X	
2. Select public inventory.						X	X		X			X	X			
3. Create borrowing transaction.		X		X			X		X				X		X	
4. Generate info/error message (not going to decrement).			X		X			X	X	X				X		X
5. Generate info message (going to decrement).													X		X	

Legend: Pr = Private; Pu = Public; B = Both public and private; Y = Yes; N = No; "-" = does not matter, yes or no; VE = Vaccination Event

Notes:

- Business rules assembled in this decision table support Step 2.12, "Determine inventory item to decrement."
- Each column in this decision table represents a single scenario, which is determined by a combination of conditions and results in one or more of the actions; conditions and actions are defined in the left column. For example:
  - Scenario B. Submission describing a vaccination event contains the following information: dose-level eligibility = Public, dose-level public/private indicator = Private. On the IIS side, lot number is listed in the private inventory. The borrowing is allowed by awardee's policy. These conditions result in the following recommended actions: Select private inventory to decrement and create a borrowing transaction.
  - Scenario O. Submission describing a vaccination event contains the following information: dose-level eligibility = Public, dose-level public/private indicator = Private. On the IIS side, lot number is listed in both the private and public inventories. The borrowing is allowed by awardee's policy. These conditions result in the following recommended actions: Select private inventory to decrement, create a borrowing transaction, and generate informational message to the provider organization (to indicate that a private inventory for this lot number, rather than public one, has been decremented).

Appendix E: Handling Doses with Short-dated Lot Number Expiration Dates

The main operational scenario for handling doses with short-dated lot number expiration dates discussed in this document (see BR107, BR108) is:

- Doses are compromised because of temperature excursion in the storage and short-dated.
- The IIS creates new inventory for these short-dated doses. The new inventory has the same lot number and lot-level public/private indicator as the original inventory, but a different lot number expiration date.
- The IIS deducts newly administered vaccines from the new short-dated inventory.

However, there are additional situations related to compromised doses that are less common. For example, a dose may be administered (but not necessarily reported to IIS and deducted from the inventory yet) and then, only after administration, found to be compromised. The decision table below (Table E-1) provides guidance for decision making in such situations.

Table E-1. Handling an administered dose deemed compromised after it was administered

	A	B	C	D
Conditions				
Viable (potent) dose?–Y/N	Y	N	Y	N
Already deducted from inventory?–Y/N	Y	Y	N	N
Actions				
Deduct from the original inventory balance.				X
Deduct from the new short-dated inventory balance.			X	
Do nothing for inventory count.	X	X		
Update patient's record, indicate an administered, non-viable (non-potent) dose instead of administered dose.		X		X
Update patient's record and indicate short-dated lot number expiration date.	X			

Legend: "Y" = yes, "N" = no.

Notes:

- Each column in the decision table describes a single scenario determined by a combination of conditions: whether the dose is viable (potent) and whether it was already deducted from the inventory.
- All scenarios in this decision table are for an administered dose that was deemed compromised after it was administered.
  - There are two kinds of compromised doses: compromised but still viable (or potent), illustrated with scenarios A and C, and compromised and non-viable (non-potent), illustrated with scenarios B and D. The IIS creates new inventory to house compromised but still viable (potent) doses that are short-dated.
  - Note that an administered vaccine, properly deducted from the inventory, may be found non-viable (non-potent), resulting in repeated vaccination of patient.
- Discussion of scenario A: The dose was administered to the patient, was already deducted from the inventory, and later found to be compromised but viable (potent). Nothing should be done for inventory count because the administered dose was already deducted from the inventory (i.e., accounted for from the inventory balance perspective). Accordingly, the vaccination event for this particular dose in the patient's record needs to be updated with short-dated lot number expiration date for the administered dose.

- **Discussion of scenario B:** The dose has been administered to the patient, already deducted from the inventory, and later found to be compromised and non-viable (non-potent). Nothing should be done for inventory count because the administered dose was already deducted from the inventory (i.e., accounted for from the inventory balance perspective). The patient's record needs to be updated to reflect an administered, non-viable (non-potent) dose instead of an administered dose. This allows tracking administered, non-viable (non-potent) vaccines separately from wasted vaccines for VFC purposes. This also allows for proper clinic decision making and patient revaccination.
- **Discussion of scenario C:** The dose has been administered to the patient, but not deducted from the inventory; it was later found to be compromised but viable (potent). All affected doses, administered and not administered, were short-dated. Accordingly, this particular dose needs to be deducted from the new short-dated inventory balance.
- **Discussion of scenario D:** The dose has been administered to the patient, but not deducted from the inventory; it was later found to be compromised and non-viable (non-potent). The dose needs to be deducted from the original inventory balance. The patient's record needs to be updated to reflect an administered, non-viable (non-potent) dose instead of an administered dose. This allows tracking administered, non-viable (non-potent) vaccines separately from wasted vaccines for VFC purposes. Assumption on this scenario is that the vaccination date is prior the reconciliation close date.

Appendix F: Barriers to Implementation

At the MIROW 101 Workshop held during the 2015 AIRA National Meeting and the SME face-to-face facilitated session, the IIS community identified barriers to DI-v-EDE. This appendix includes the identified barriers and specific guidance.

Table F-1. Barriers list

#	Barrier	Guidance
Key Data Elements		
1.1	The IIS needs more clarity on which data elements are the minimum data elements. This requires getting sufficient data to match the administered dose to the vaccine in the IIS inventory.	■ See Key data elements in Chapter 9: Implementation Considerations. ■ See Chapter 3: Fundamentals for definitions of key elements. ■ P02. DI-v-EDE should support inventory tracking and immunization tracking. ■ P05. DI-v-EDE should minimize the burden on provider organizations. ■ BR202. Submit information to IIS to support DI-v-EDE. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator. ■ S702. Vaccination event date is null or in the wrong date format. ■ S703. CVX/NDC code is not recognized. ■ S704. Submission does not contain a lot number.
1.2	The IIS is not receiving the necessary data elements from an EHR to make a match between the administered dose and the vaccine in the IIS inventory.	■ See Key data elements in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ BR202. Submit information to IIS to support DI-v-EDE. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator. ■ S702. Vaccination event date is null or in the wrong date format. ■ S703. CVX/NDC code is not recognized. ■ S704. Submission does not contain a lot number.
1.3	When the same lot number is in the public and private inventory, the IIS is not getting the needed information from the EHR to determine from which inventory the dose should be decremented.	■ See Key data elements in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ BR202. Submit information to IIS to support DI-v-EDE. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator.

#	Barrier	Guidance
1.4	The IIS is not receiving the data elements that are needed to determine if the administered dose was borrowed (for example, the patient was eligible for public vaccine but received a dose from the private stock).	■ See Key data elements in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ BR202. Submit information to IIS to support DI-v-EDE. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator.
Data Quality		
2.1	Staff at the provider organization does not understand how to properly enter and submit data to the IIS, which leads to inaccuracy in documentation.	■ See Data quality in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR301. Resolve data quality issues before reconciling. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S401. Vaccination event date is before the patient date of birth. ■ S402. Vaccination event date is after the patient date of death. ■ S403. Vaccination event date is after date of submission. ■ S501. The vaccination event date in a submission is greater (later) than the lot number expiration date in a lot matched in the provider organization inventory in the IIS. ■ S502. Lot number in submission matches a lot number in provider organization inventory in the IIS that is not active. ■ S503. Lot number in submission matches lot number in provider organization inventory in the IIS that has a zero balance. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator. ■ S702. Vaccination event date is null or in the wrong date format. ■ S703. CVX/NDC code is not recognized. ■ S704. Submission does not contain a lot number. ■ S901. Date of submission is same as vaccination event date, but vaccine dose is marked as historical. ■ S1001. Lot number in submission does not match any lot number in provider organization inventory in the IIS.

#	Barrier	Guidance
2.2	There are various codes in EHR that are often incorrectly entered, leading to data entry errors that affect DI-v-EDE.	■ See Data quality in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR301. Resolve data quality issues before reconciling. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S401. Vaccination event date is before the patient date of birth. ■ S402. Vaccination event date is after the patient date of death. ■ S403. Vaccination event date is after date of submission. ■ S501. The vaccination event date in a submission is greater (later) than the lot number expiration date in a lot matched in the provider organization inventory in the IIS. ■ S502. Lot number in submission matches a lot number in provider organization inventory in the IIS that is not active. ■ S503. Lot number in submission matches lot number in provider organization inventory in the IIS that has a zero balance. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator. ■ S702. Vaccination event date is null or in the wrong date format. ■ S703. CVX/NDC code is not recognized. ■ S704. Submission does not contain a lot number. ■ S901. Date of submission is same as vaccination event date, but vaccine dose is marked as historical. ■ S1001. Lot number in submission does not match any lot number in provider organization inventory in the IIS.

#	Barrier	Guidance
2.3	There are many data entry errors that occur when the administered dose is initially documented that later need to be fixed in the IIS. The IIS would like to reduce the number of errors on front-end to reduce issues downstream.	■ See Data quality in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR301. Resolve data quality issues before reconciling. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S401. Vaccination event date is before the patient date of birth. ■ S402. Vaccination event date is after the patient date of death. ■ S403. Vaccination event date is after date of submission. ■ S501. The vaccination event date in a submission is greater (later) than the lot number expiration date in a lot matched in the provider organization inventory in the IIS. ■ S502. Lot number in submission matches a lot number in provider organization inventory in the IIS that is not active. ■ S503. Lot number in submission matches lot number in provider organization inventory in the IIS that has a zero balance. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator. ■ S702. Vaccination event date is null or in the wrong date format. ■ S703. CVX/NDC code is not recognized. ■ S704. Submission does not contain a lot number. ■ S901. Date of submission is same as vaccination event date, but vaccine dose is marked as historical. ■ S1001. Lot number in submission does not match any lot number in provider organization inventory in the IIS.

#	Barrier	Guidance
2.4	Lot numbers often have poor data quality and there is not an easy automated process to check and correct lot numbers.	■ See Data quality in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR102. Prepopulate provider organization's inventory in IIS. ■ BR103. Download shipment information daily. ■ BR301. Resolve data quality issues before reconciling. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ See MIROW 2015 Lot Number Patterns Micro Guide [1.9]. ■ See MIROW 2015 Lot Number Validation Micro Guide [1.10]. ■ S501. The vaccination event date in a submission is greater (later) than the lot number expiration date in a lot matched in the provider organization inventory in the IIS. ■ S502. Lot number in submission matches a lot number in provider organization inventory in the IIS that is not active. ■ S503. Lot number in submission matches lot number in provider organization inventory in the IIS that has a zero balance.
2.5	Matching doses administered data and inventory data can be challenging when certain data elements do not match correctly (for example, lot number, dose-level eligibility, dose-level public/private indicator, and lot-level public/private indicator).	■ See Data quality in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR301. Resolve data quality issues before reconciling. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S501. The vaccination event date in a submission is greater (later) than the lot number expiration date in a lot matched in the provider organization inventory in the IIS. ■ S502. Lot number in submission matches a lot number in provider organization inventory in the IIS that is not active. ■ S503. Lot number in submission matches lot number in provider organization inventory in the IIS that has a zero balance. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator. ■ S702. Vaccination event date is null or in the wrong date format. ■ S703. CVX/NDC code is not recognized. ■ S704. Submission does not contain a lot number. ■ S1001. Lot number in submission does not match any lot number in provider organization inventory in the IIS.

#	Barrier	Guidance
2.6	Provider organizations wait until the end of the month to correct all of the issues impacting appropriate inventory decrementing. This practice leads to the need for additional work to identify errors and correct them since the provider organization must look through a full month's worth of data to determine issues.	■ See Data quality in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR301. Resolve data quality issues before reconciling. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S1301. Reconciliation timeliness.
2.7	When an error occurs, it requires correction in two separate systems: the IIS and EHR. This means that provider organizations perform double data entry to fix errors since they must do a manual fix in the IIS and a manual fix in the EHR.	■ See Data quality in Chapter 9: Implementation Considerations. ■ See HL7 immunization messaging in Chapter 9: Implementation Considerations for more information about sending updates and deletions through HL7 messaging. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR301. Resolve data quality issues before reconciling. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ BR409. Manual corrections made in the IIS should also be made in the EHR.
EHR		
3.1	EHR do not have the data fields to collect important data elements or the data fields are not required (a.k.a. forced fields).	■ See EHR in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ BR202. Submit information to IIS to support DI-v-EDE. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator. ■ S702. Vaccination event date is null or in the wrong date format. ■ S704. Submission does not contain a lot number.

#	Barrier	Guidance
3.2	Even when EHR collect important data elements, they are not necessarily sending these data elements to the IIS.	■ See EHR in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ BR202. Submit information to IIS to support DI-v-EDE. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator. ■ S702. Vaccination event date is null or in the wrong date format. ■ S704. Submission does not contain a lot number.
3.3	The quality of data from many EHR is poor.	■ See EHR in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR301. Resolve data quality issues before reconciling. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval. ■ S401. Vaccination event date is before the patient date of birth. ■ S402. Vaccination event date is after the patient date of death. ■ S403. Vaccination event date is after date of submission. ■ S501. The vaccination event date in a submission is greater (later) than the lot number expiration date in a lot matched in the provider organization inventory in the IIS. ■ S502. Lot number in submission matches a lot number in provider organization inventory in the IIS that is not active. ■ S503. Lot number in submission matches lot number in provider organization inventory in the IIS that has a zero balance. ■ S701. Submission does not contain either dose-level eligibility or dose-level public/private indicator. ■ S702. Vaccination event date is null or in the wrong date format. ■ S703. CVX/NDC code is not recognized. ■ S704. Submission does not contain a lot number. ■ S901. Date of submission is same as vaccination event date, but vaccine dose is marked as historical. ■ S1001. Lot number in submission does not match any lot number in provider organization inventory in the IIS.

#	Barrier	Guidance
Outreach and Education		
4.1	Provider organizations need to be better informed about how to manage issues with DI-v-EDE. This includes when errors should be identified and managed, who needs to be involved in fixing problems, and what tools are available to support fixing issues with DI-v-EDE.	■ See Outreach and education in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P05. DI-v-EDE should minimize the burden on provider organizations. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality.
4.2	Training on DI-v-EDE can be complex and can require a large amount of time for providers to understand the intricacies of inventory management.	■ See Outreach and education in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P05. DI-v-EDE should minimize the burden on provider organizations. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality.
4.3	It can be challenging to determine which staff in the provider organization to train.	■ See Outreach and education in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ BR401. Establish and maintain a preapproval process for provider organizations.
4.4	The timing of training can lead to issues. If staff receive training and do not make use of the knowledge and skills for error correction and reconciliation for several weeks, they may forget how to manage the process appropriately.	■ See Outreach and education in Chapter 9: Implementation Considerations. ■ See Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P05. DI-v-EDE should minimize the burden on provider organizations. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality.
4.5	Reports supporting inventory reconciliation can be complicated.	■ See Outreach and education in Chapter 9: Implementation Considerations. ■ See Chapter 6: Reports.

#	Barrier	Guidance
Staff Time		
5.1	Cleaning up errors in inventory is a large time and resource commitment for provider organizations.	■ See Staff time in Chapter 9: Implementation Considerations. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P05. DI-v-EDE should minimize the burden on provider organizations. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR301. Resolve data quality issues before reconciling. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval.
5.2	Immunization programs spend a significant amount of staff time and program resources to provide technical assistance to support provider organizations using inventory. This includes help with logging, responding to, and correcting issues.	■ See Staff time in Chapter 9: Implementation Considerations. ■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR402. Establish a testing environment for the preapproval process. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ BR407. Examine all data elements of a DI-v-EDE submission during preapproval.
5.3	VFC program used to handle some errors that are now moving to HL7; required more technically-savvy staff.	■ See Staff time in Chapter 9: Implementation Considerations.
Other		
6.1	Timing can be a challenge for correct decrementing. It is often not the same person who is submitting the data exchange and doing the VFC ordering and the reconciliation of inventory; thus, it can become confusing when the inventory staff person corrects the inventory manually prior to the data file being submitted. This often causes double decrementing and results in the inventory having to be manually edited a second time. If the HL7 data on a vaccine that was given earlier in the day of reconciliation is received afterward, it may be double counted.	■ P03. The IIS must preapprove a provider organization for DI-v-EDE. ■ P05. DI-v-EDE should minimize the burden on provider organizations. ■ P07. The IIS should notify provider organizations of problems in the DI-v-EDE process. ■ P08. The IIS should assist provider organizations with correcting data quality issues. ■ P09. The IIS should decrement an administered dose only once. ■ BR301. Resolve data quality issues before reconciling. ■ BR401. Establish and maintain a preapproval process for provider organizations. ■ BR403. Establish a preapproval testing process. ■ BR404. Develop educational/training offerings. ■ BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. ■ S1301. Reconciliation timeliness.

Appendix G: 2015 MIROW DI-v-EDE Workshop Participant List

Table G-1. Workshop participant list

Name	Organization	E-mail	Can IIS decrement inventory via electronic data exchange?
Alice Stecko	SSG (Strategic Solutions)	astecko@ssg-llc.com	Yes
Amira Elhegausa	Philadelphia Department of Public Health	amira.elhagmusa@phila.gov	No
Andre Wilson	HP (State of Georgia)	andre.wilson@hp.com	Yes
Andrew Luker	Arkansas Department of Health	andrew.luker@arkansas.gov	No
Brittany Ersery	Kansas IIS	bersery@kdheks.gov	No
Carrie Sprague	Idaho Immunization Program	spraguec@dhw.idaho.gov	Yes
Christy Gray	Virginia Department of Health	christy.gray@vdh.virginia.gov	Yes (Only in test environment right now)
Cindy Lesinger	ADPH	cindy.lesinger@adph.state.al.us	No
Dhiraj Adhikari	Noridian Mutual Insurance Company, ND	dhiraj.adhikari@bcbsnd.com	
Gerri Yett	Alaska Immunization Program	gerri.yett@alaska.gov	Yes
Gregory Wong	SSG	gwong@ssg-llc.com	Yes
Harold Affo	NIST	haffo@nist.gov	No (No IIS)
Hilda Veronica Rodriquez	Puerto Rico Health Department	vrodriquez@salud.gov.pr	No
Jason Suchon	Metastar/Wisconsin Imm Registry	jason.suchon@dhs.wisconsin.gov	Yes
Jude Alden	Wyoming Department of Health	jude.alden@wyo.gov	Yes
Judi Greene	LA Department of Health	judi.greene@la.gov	Yes
Karen Meranda	Washington Department of Health	karen.meranda@doh.wa.gov	Yes
Ken Gerlach	CDC	kgerlach@cdc.gov	No (N/A)
Kevin Snow	Envision	ksnow@envisiontechnology.gov	No (Working on it)
Kim Tichy	Iowa Department of Public Health	kimberly.tichy@idph.iowa.gov	Yes
Margaret Wieczkowsi	San Antonio Health District	margaret.wieczkowski@sanantonio.gov	No
Mark Ritter	CDC-DSHS Texas Immunization Branch	mark.ritter@dshs.texas.gov	No
Matthew Verdon	Wisconsin Immunization Registry	matthew.verdon@wi.gov	Yes
Michael Powell	California Department of Health	michael.powell@cdph.ca.gov	No
Mike Garcia	Mississippi IIS	mike.garcia@garciainterop.com	Yes
Nancy McConnell	Utah Department of Health –IIS	nmcconnell@utah.gov	Yes

Name	Organization	E-mail	Can IIS decrement inventory via electronic data exchange?
Nathalie Hantert	State of Tennessee	nathalie.hantert@tn.gov	Yes
Shaina Azam	CDC/Intellix Solutions	sazam@cdc.gov	N/A
Sriram Venkataraman	State of North Carolina	sriram.venkataraman@dhhsnc.gov	Yes
Steve Murchie	Envision	smurchie@envisiontechnology.gov	No
Susan Kepsel	MCIR –Region 1–Oakland	skepsel@hline.org	Yes
Tammy LeBeau	South Dakota Department of Health	tammy.lebean@state.sd.us	No
Terry Brumback	Kentucky Immunization Registry	terry.brumback@ky.gov	Yes (In theory)
Tracy Little	ALERT IIS–Oregon Imm Program	tracy.c.little@state.or.us	Yes
Vai Fuata	American Samoa Immunization Program	vai.fuata@doh.as	Yes

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