Immunization Information System Inventory Management Operations

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

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    - **Michigan Care Improvement Registry (MCIR)**
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Executive Summary

Background

The Modeling of Immunization Registry Operations Work Group (MIROW) was formed in 2005 by 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) to develop a best practices guidebook for immunization information systems (IIS). This document is one chapter of the guidebook. It provides consensus-based best practice recommendations for IIS to support grantee immunization program requirements for provider organizations' vaccine inventory management and associated IIS reports that support the vaccine inventory management needs of provider organizations and grantee immunization programs.

Policies, regulations, and technical implementations related to ordering, distribution, and management of publicly-funded vaccines have evolved rapidly over the past few years. These changes led to requirements for better vaccine supply visibility and accountability. Grantees' immunization programs need to adapt to VFC program requirements to use National Drug Codes (NDC), lot numbers, and dose-level reporting for inventory management operations. Additional challenges for the IIS community are related to roll-out of the new VTrckS public vaccine ordering system, which will replace the existing VACMAN system. IIS are uniquely positioned to support efforts of the Vaccines for Children (VFC) program and immunization programs of CDC grantees in meeting the new requirements and adapting to the evolving technical landscape. The integration of vaccine management practices within an IIS will also decrease the burden for provider organizations and partners in meeting accountability and reporting requirements.

The topic of inventory management is considered in the context of provider organizations recording/reporting vaccine inventory management information in/to an IIS, which, in turn, maintains and aggregates this information and provides reports to support the needs of provider organizations and grantee immunization programs. This report aims to provide IIS with best practice recommendations formulated by leading experts in the IIS community. The report also includes valuable experiences of grantees that are piloting VTrckS or preparing for VTrckS deployment.

Benefits of managing vaccine inventory with IIS

Adoption of these best practice guidelines will:

- Encourage use of IIS to support VFC and grantee immunization programs.
- Provide standard consensus-based practices for inventory management through IIS that can be referenced as requirements when developing IIS applications (direct data entry) and EHR systems (for electronic transfer to IIS).
- Reduce the reporting burden on provider organizations since their reporting to IIS will result in providing inventory data for a grantee immunization program and the VFC program.
- Improve inventory data quality and accountability for the VFC and grantee immunization programs.

- Ensure that inventory management practices are comparable across all grantees and all provider organizations. The guidelines will assist IIS in aligning practices through adherence to a set of common recommendations and guidelines.

Key outcomes and accomplishments

The work group accomplished the following:

- Developed and reconfirmed key definitions for inventory management through IIS, such as inventory transaction, provider organization IDs, public/private inventory indicator, bonus dose, and over-estimated dose.
- Developed a state/event model that represents the particular state of a vaccine at the dose level and the major stages through which it goes. The model describes **11 states** and **20 events**.
- Formulated **8 principles** and **25 business rules** to guide inventory management operations (e.g., what information to record, how often to conduct inventory reconciliations, and how to handle borrowing).
- Formulated **23 general recommendations** for IIS functionality and operations related to inventory management.
- Described **20 key inventory management reports**, with a focus on accountability reports to support inventory management, accountability reports that support the ordering process, allocation reports, and reconciliation reports.
- Developed expanded considerations for implementing National Drug Codes (NDC) and handling borrowing between publicly-funded and privately-purchased vaccine stocks.
- Described barriers to implementing inventory management guidelines, and how the guidelines address implementation barriers.

Highlights of recommendations

The Work Group formulated key principles (P) for inventory management through IIS. These principles provide high-level direction that helps to guide the development of the more specific business rules. Examples of principles are:

- Accurate accounting principle: Provider organization's physical inventory should be accurately reflected in the IIS (P704).
- NDC supremacy principle: Vaccine inventory management should be based on the National Drug Code (NDC) (P701).
- Dose-lot number accountability principle: Every vaccine dose should be accounted for with the associated lot number information (P702).
- Completeness principle: The inventory management information submitted to an IIS must contain the minimum/mandatory set of data items in order to be accepted by the IIS (P703).

Based on these principles, the work group developed **business rules (BR)** that represent specific requirements and decision-making logic for various aspects of IIS processes for inventory management. Examples of business rules are:

- A lot number for every vaccine dose administered must be documented and reported by the provider organization to the IIS (BR704).

- Lot number for every vaccine dose utilized by a provider organization must be matched/mapped to NDC for a specific inventory entry and the appropriate transaction should be created to adjust the inventory appropriately (BR702).
- Minimum set of data items for every vaccine dose: For every vaccine dose the minimum/ mandatory set of data items recorded and reported to the IIS for the purposes of inventory management should include lot number (to be matched/mapped to NDC), lot number expiration date, patient eligibility status (for administered vaccines), provider organization responsible for the inventory, and public/private inventory indicator (optional) (BR711).
- Reconciliation frequency: Provider organizations should reconcile their entire physical inventory to 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 (BR723). Provider Organizations must reconcile their entire physical inventory to the IIS inventory immediately prior to ordering (BR722).
- For an EHR submission for an opt-out patient, IIS should decrement inventory without updating the patient record (BR720).
- When a multi-dose vial is involved, borrowing should be done at the single-dose level (BR725).

Along with business rules that provide specific process-related requirements, this document contains general recommendations (GR) for IIS inventory management functionality and operations. Examples of general recommendations are:

- Manual data entry should be minimized and manual entry of inventory data that is already known should be avoided (GR710).
- IIS inventory management functionality should support accountability at the dose/lot number level, but aggregate reporters (provider organizations) will have to be accommodated during the phase-in of accountability at the dose/lot number level for all provider organizations (GR702).
- Data quality assurance metrics (as determined by CDC and grantee immunization programs) should be utilized to measure and track data quality from any shipping entity, including a centralized distributor (currently McKesson) ─ e.g., entering lot numbers and other data items. These metrics should be used to improve data quality from any shipping entity (GR717).
- IIS application should have reports available to support detailed analysis by the grantee program of a provider organization practices (GR719). For example:
    - No inventory vaccine report (1.1).
    - Pending inventory/transfers (1.2).
    - Vaccine loss (1.5) - specifically for review of waste.
    - Borrowed/replaced report (2.1).

In addition to principles, business rules and general recommendations, the document contains recommendations for reports in the following areas:

- Accountability reports to support inventory management (for purposes other than ordering and reconciliation, reports 1.1 – 1.6).
- Reconciliation reports (reports 2.1 – 2.4).
- Accountability reports that support the ordering process (3.1 – 3.6).

- Allocation reports (i.e., to allocate vaccines during shortages and to issue a recall based on lot numbers, reports 4.1-4.4).

Conclusion

The Work Group brought together experts from the IIS community, grantee immunization programs and IT vendors. The resulting best practices guide is a key step in standardizing practices and reports in the area of inventory management through 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) has included a recommendation to "promote the adoption of a guidebook and best practices for IIS as stated by the CDC/NIP [*now NCIRD*] and AIRA/MIROW Work Group 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.

Navigational Map/Reference

Theme	Reference to a Chapter, Principle (P), Business Rule (BR), General Recommendation (GR), models, and use cases
Best practice recommendations and decision-making logic for various aspects of vaccine inventory management	Principles and Business Rules - Chapter 4, page 35
Best practice recommendations, advice, and suggestions for IIS functionality and operations related to IIS inventory management	General Recommendations - Chapter 5, page 53
Best practice recommendations for IIS reports	Recommendations for IIS Reports - Chapter 6, page 63
Reconciliations	P706, BR717-BR723, State/Event model (ST01, ST03, EV03, EV08), reports 3.1, 2.1-2.4, Process model (PM01, PM02, PM04, PM08, PM09), use cases 3, 3.1.
Borrowing between private and public stocks	Borrowing Considerations – Chapter 8, page 87, P708, BR702, BR707, BR711, BR725, GR701, GR713, GR719, State/Event model (ST01, ST03, ST10, ST11, EV17-20), use cases 1.3, 1.7, reports 2.1, 2.2, 3.2
Transfers between Provider Organizations	BR713, BR714, GR705, GR719, State/Event model (ST02, ST09, EV02, EV04, EV15, EV16), use cases 1.2, 1.8, reports 1.2, 2.2, 2.3, 3.2, 3.5, 3.6
Approaches for deriving the National Drug Code (NDC) for an administered dose of vaccine	NDC Considerations – Chapter 7, page 83
Using the lot number for inventory management purposes	NDC Considerations – Chapter 7, page 83
Acronyms/Abbreviations	Abbreviations table, page 97

Chapter 1: Introduction

About MIROW

The Modeling of Immunization Registry Operations Work Group (MIROW) of the American Immunization Registry Association (AIRA) was formed in partnership with the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention to develop a topic-by-topic best practice guidebook for various aspects of the functionality of immunization information systems (IIS). Since 2005, MIROW has developed several operational guidelines for the following IIS functional areas (see Table 1 below): Patient eligibility for the VFC program and Grantee immunization programs, Reminder/Recall, Incoming Data Quality Assurance, Vaccination Level Deduplication, Patient Immunization Status, and IIS-Vaccine Adverse Event Reporting System Collaboration (pilot project).

The MIROW Web page at http://www.immregistries.org/pubs/mirow.html contains complete recommendations documents for previous topics and abridged mini-guides. "Evaluating IIS Best Practice Operational Guidelines: Emerging Trends and Challenges," a presentation delivered at the 44th National Immunization Conference, also describes MIROW's efforts. The presentation is available at http://cdc.confex.com/cdc/nic2010/webprogram/Paper22530.html.

Table 1. MIROW: topics/workshops overview

	Guideline document released	Face-to-face meeting	Experts' panel size	Guideline document highlights
IIS-VFC/Grantee Programs Collaboration [1.1]	April, 2011	June, 2010 2.5 days Atlanta, GA	14	**26** eligibility screening scenarios **17** business rules **9** general recommendations
Reminder/Recall in IIS [1.2]	April, 2009	October, 2008 2.5 days Tampa, FL	13	**29** Principles **23** Business rules **30** General Recommendations
Data Quality Assurance in IIS: Incoming Data [1.3]	February, 2008	August, 2007 2.5 days Atlanta, GA	11	**13** Principles **32** Business rules
Vaccination Level Deduplication in IIS [1.4]	December, 2006	May, 2006 2.5 days Washington, DC	20	**9** Principles, **20** Business rules, **23** Illustrative scenarios (examples)
Management of Moved or Gone Elsewhere (MOGE) Status and other Patient Designations in IIS [1.5]	December, 2005	August, 2005 2.5 days Atlanta, GA	16	**6** Statuses defined on the Provider level, **5** Statuses on the Geographic Jurisdiction level
IIS-VAERS Guide (pilot project) **[1.6]**	April, 2005	June, 2004 1.5 days Atlanta, GA	21	**10** Functional standards, **8** Business rules, **11** Alternative scenarios (process)

About the MIROW Inventory Management Project
The current report represents MIROW's efforts to develop best practice recommendations for the topic of Inventory Management. The development process consisted of a preliminary phase that included Web-based teleconferences held July–September 2011, face-to-face meetings held September 20-23, 2011 in Atlanta, Georgia, and post-meeting activities to finalize the recommendations**.**

The inventory management topic is especially relevant for the IIS community today because of changing policies, regulations, and technical implementations related to ordering, distribution, and management of publicly-funded vaccines. These changes lead to requirements from the Vaccines for Children (VFC) program for better vaccine supply visibility and accountability. To satisfy these requirements, Grantees' immunization programs need to adapt to use National Drug Codes (NDC), lot numbers, and dose-level reporting for inventory management operations. IIS have established base of Provider Organizations that report immunization data and, therefore, have distinctive capabilities to assist Grantees' immunization programs to achieve inventory management objectives.

Additional challenges for the IIS community are related to roll-out of the new VTrckS vaccine ordering system, which will replace the existing VACMAN system. VTrckS can be used in two distinctly different ways:

- Directly, when Provider Organizations enter ordering information into the VTrckS and then a grantee program approves orders in the VTrckS and checks shipment reports. Pilot grantees for the VTrckS Direct approach include Chicago and Colorado. *This arrangement is out of scope for this topic.*
- Through an external system (ExIS), such as IIS, when Provider Organizations enter ordering information into the IIS (directly or through local EHR systems) and then the grantee program approves orders and exports CSV files from IIS to VTrckS, downloads shipment files from VTrckS and imports shipment information into the IIS. Pilot grantees for the VTrckS ExIS approach include Michigan and Washington. *This arrangement is in scope for this topic.*

Reasons for a Grantee program to select the VTrckS use through the IIS (ExIS approach, second option) include:

- It provides a single grantee (state) presence for communications and other program needs.
- When IIS is already responsible for program data needs, this option leverages the IIS positioning and capabilities.
  - IIS support the grantee's public health role. In a public health emergency, for example, IIS can make available information about the locations of available vaccine doses in case they need to be redirected
  - The IIS can integrate/connect with systems internal to the grantee organization for accounting, reporting, etc.
- When Provider Organizations already enter orders and track inventory through IIS, no re-training for Provider Organizations is needed and double data entry for grantee staff is eliminated.

- It can allow for a comprehensive vaccine management system that links vaccine ordering, inventory management and vaccine administration. The VTrckS Direct option offers no ability to manage vaccine inventories or to auto decrement vaccines from inventory as they are administered.

IIS are uniquely positioned to support efforts of the VFC program and grantee immunization programs in meeting the new requirements and adapting to the evolving technical landscape. This document aims to provide IIS with best practice recommendations formulated by leading experts in the IIS community. The document also includes valuable experiences of Grantees that are piloting VTrckS or preparing for VTrckS deployment.

About this Document

This document provides consensus-based best practice recommendations for IISs to support Vaccine Program requirements for Provider Organizations' inventory management and associated IIS reports that support needs of Provider Organizations and Vaccine Programs.

The recommended best practices are formulated using business modeling instruments:

- Domain model (Appendix A) – documents agreed-upon terms and definitions for the project. It establishes a foundation and a reference source (common vocabulary) for other project materials (e.g., principles, business rules, general recommendations, reports).
- Principles (Chapter 4) – provides a high-level direction that helps to guide the development of more specific business rules.
- Business rules (Chapter 4) – represent specific requirements and decision-making logic for various aspects of IIS processes.
- General recommendations (Chapter 5) – represent requirements, advice, and suggestions for IIS functionality and operations related to IIS inventory management.
- State/Event model (Chapter 3) – documents every state of a Vaccine at the dose level, within the scope of inventory management. It provides a basis and a framework/context for the development of principles, business rules, general recommendations, and IIS reports that are described in chapters 4-6.
- Use-case model (Chapter 2) and Process model (Appendix B) – illustrate and provide insights into the scope of this topic.

The following assumptions reflect MIROW's approach to the development of business rules, general recommendations, 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 IISs.
- 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 general 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.

Implementation/Technology Independence
Developed best practice recommendations are intended to be at the business/operational level and, as a result, are independent from particular 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 developed best practice recommendations will be able to support the wide variety of IIS implementation strategies on different technological platforms.

Intended Audience
The recommendations outlined in this guide are designed to be read by programmatic, technical and operational personnel involved in creating or maintaining an IIS, as well as VFC and Grantee Vaccine Programs staff. The guide intends to bridge the gap between IIS technical and program staff, and IIS and VFC/ Grantee Vaccine Programs. Bridging these gaps will help create a mutual understanding of vaccine inventory management issues and identify actions to implement/apply these recommendations. This guide also can be useful for providers of immunization services and vendors of healthcare information systems.

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 by IIS for staff training, operational documentation, and communication purposes, as well as for providing guidance for vendors and users of electronic health record (EHR) applications.

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

The approach used and results presented are relevant for and can be utilized 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.

Work Group Approach
The Work Group used business engineering and facilitation techniques to analyze IIS processes and develop recommendations. It utilized a pragmatic results-oriented approach that has been effective for modeling of IIS and cancer registration operations. Initial ***preparatory off-line work*** (assembling pertinent materials, producing preparatory notes, analyzing processes and developing preliminary drafts) was conducted by a group of business analysts and subject matter experts (SMEs). During a subsequent ***face-to-face facilitated modeling session*** held on September 20-23, 2011 in Atlanta, Georgia, the entire work group of SMEs used these preparatory materials to frame and scope resources and began developing and formulating consensus-based recommendations. The ***post-session work*** was aimed at finalizing the development of recommendations. The work group was divided into two small groups of SMEs, each addressing a set of remaining tasks during a series of teleconferences. Additional

teleconferences were dedicated to reviewing small-group progress by the full group of SMEs. The work group aimed for a consensus among SMEs regarding best practice recommendations which did not reflect 100% agreement, but rather meant ***"I can live with that and support it."*** While 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 that there were no serious disagreements left among the experts, assuring that experts agreed enough with the recommendation to stand behind it and support it.

Chapter 2: Scope

The scope includes best practices for an IIS to support Grantee Vaccine Program requirements for Provider Organizations' vaccine inventory management and associated IIS reports that support the needs of Provider Organizations and Grantee Vaccine Programs.

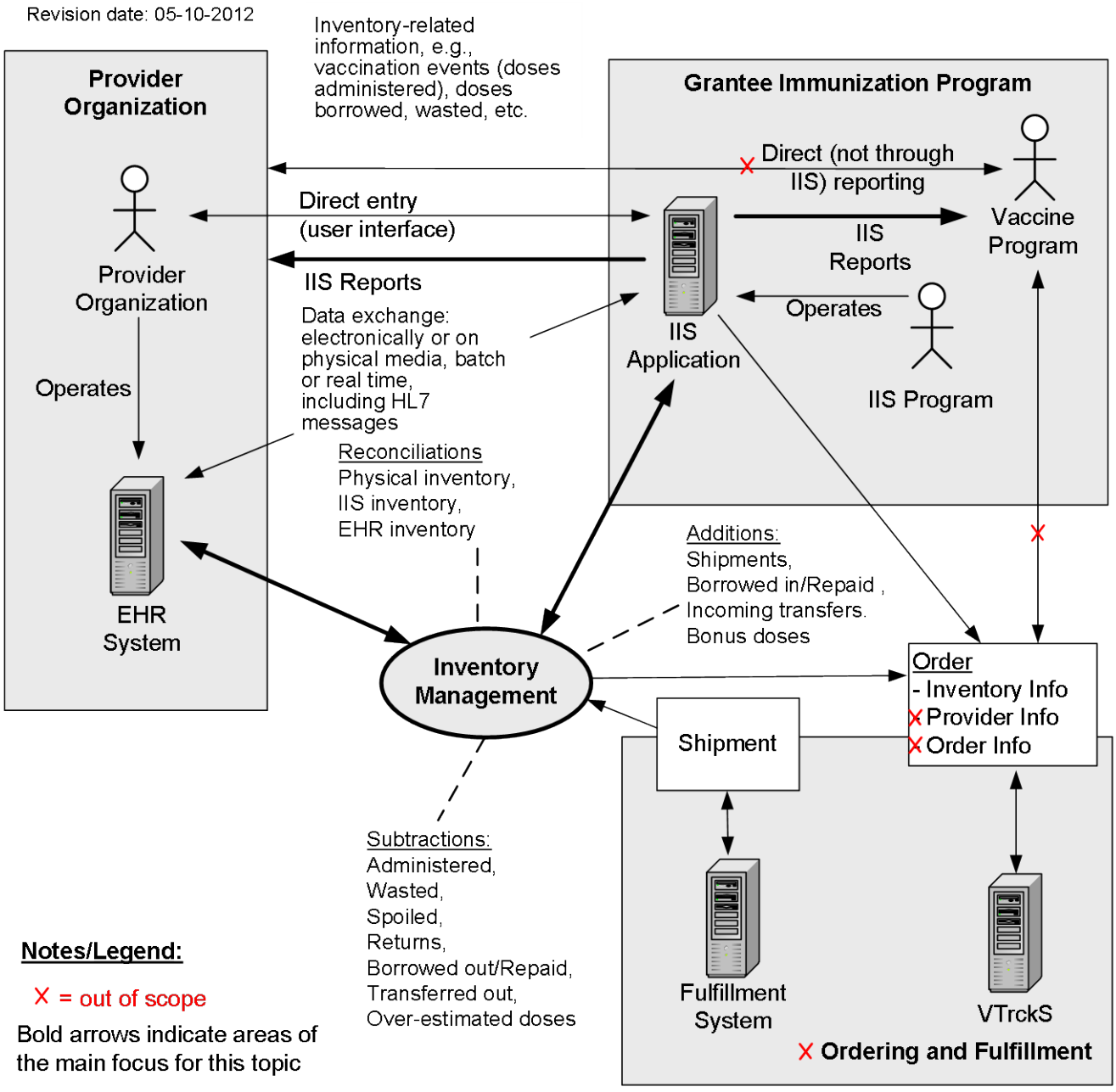
- The focus of this topic is on IIS functionality and data exchange capabilities
- It is not limited to VFC or VTrckS requirements. Recommendations contained within this document are developed with the understanding that VFC requirements as well as VTrckS functionality will be evolving and advancing.

The topic of Inventory Management is considered in the context of Provider Organizations recording/reporting vaccine inventory management information in/to an IIS, which, in turn, maintains and aggregates this information and provides reports to support the needs of the Grantee Vaccine Programs and Provider Organizations. A primary focus of this document is on public vaccines, but private vaccines are included in scope with the understanding that recommendations and solutions developed for managing the public vaccine inventory may be, at the discretion of the Provider Organization, also be applied to managing private vaccine inventory. Additional requirements that are specific to handling private vaccine inventory are out of scope (e.g., since the detailed data fields are not required for a private vaccine inventory items, it is more difficult to track the vaccine inventory dose status). Some of the issues and limitations for managing private vaccine inventory include: missing lot numbers, missing expiration dates, missing NDC codes.

It is outside the scope of this project to change federal statutes, regulations, or policies, including but not limited to those related to the federal program for distribution of pediatric vaccines (Vaccines for Children program).

Figure 1 below illustrates the scope in a context of immunization operations. **Figure 2** presents the essence of the scope with a simplified process sketch. **Figure 3** illustrates the scope with a use case diagram.

A more detailed focus statement can be found in Appendix B of this document.



Abbreviations: EHR = Electronic Health Record; IIS = Immunization Information System; VTrckS = Vaccine Tracking System.

Figure 1. Context diagram: scope in the context of immunization operations

Legend note: solid lines indicate relations between individual processes/activities, dashed/ broken lines indicate relations between processes/activities and parties and products.

Figure 2. Essence of the scope – a simplified sketch

- In scope:
  - Provider Organization utilizes/spends vaccines and manages vaccine inventory. Inventory-related data at the dose level (administered, wasted, etc.) is recorded/reported by the Provider Organization, as well as physical inventory counts to the Immunization Information System (IIS)
  - IIS collects and maintains vaccine inventory data for Provider Organizations
  - Vaccine inventory data collected by IIS is available to Provider Organizations and the Grantee Vaccine Program
    - IIS provides vaccine inventory reports to Provider Organizations and Grantee Vaccine Program
- Out of scope:
  - Grantee Vaccine Program utilizes accumulated inventory information from IIS to manage Vaccine Program inventory
  - Vaccine inventory information reported by Provider Organization directly to the Grantee Vaccine Program (not through the IIS)

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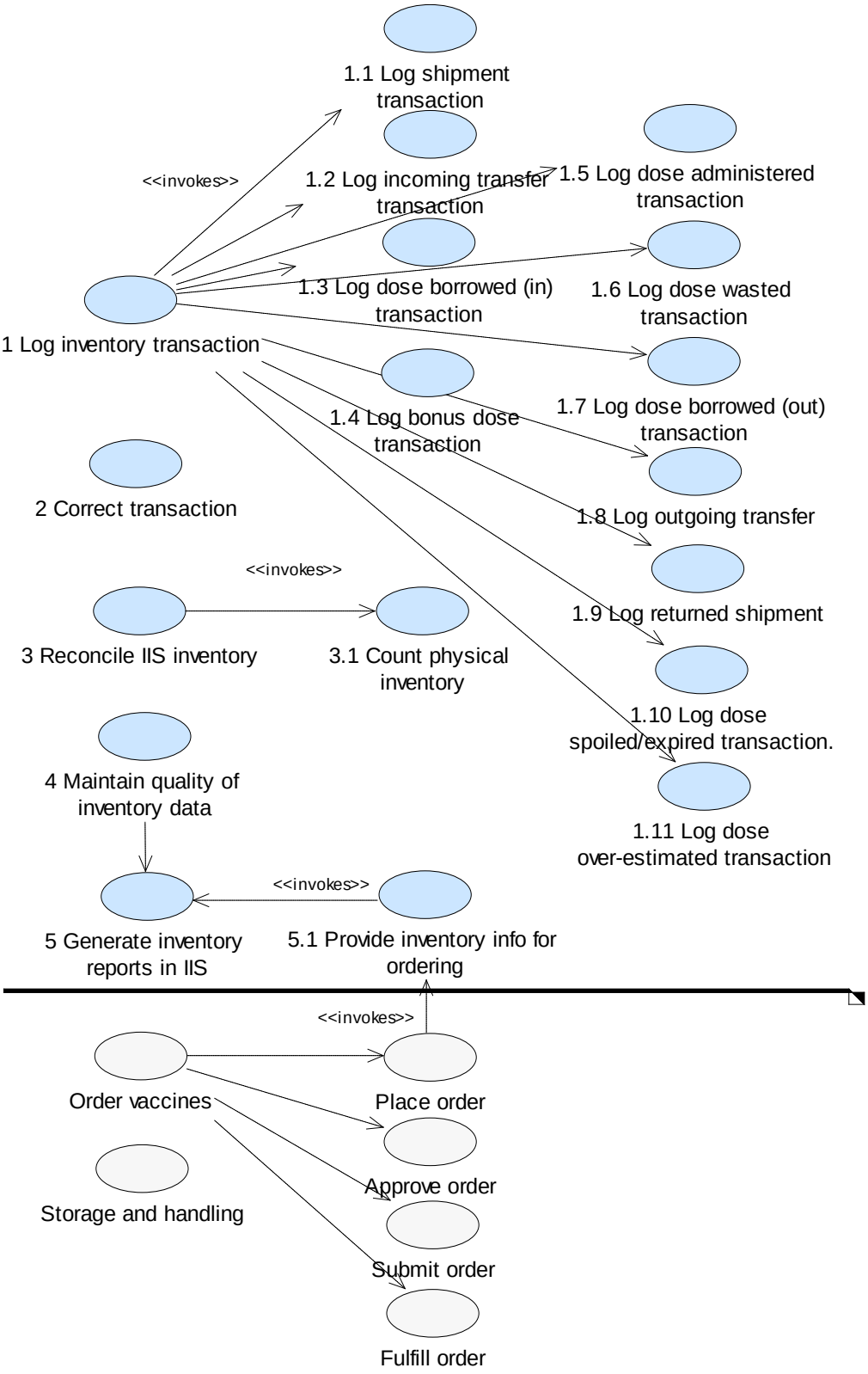

Figure 3. Scope illustrated with a use case diagram

Table 2. Use cases (operational scenarios) for the MIROW inventory management topic
Notes:

- These are high-level use cases that illustrate the scope of this topic.
- The IIS is "the system" that handles inventory management tasks. Information to the IIS can be either a) entered directly by the Provider Organization through the IIS user interface or b) transmitted through an electronic interface by a Provider Organization's EHR system. Additionally, the information for shipment data can be uploaded to the IIS from VTrckS.
- It is important to note in this context that information the EHR system sends to IIS is limited to vaccine doses administered (While it is possible for EHR systems to submit historical immunizations to IIS, that immunizations should not create an inventory transaction since a Provider Organization's current physical inventory levels are not impacted by these immunizations. See business rule BR704 for a discussion). Accordingly, incoming vaccine dose administered information can enter the IIS both from direct entry and EHR message. Shipment logs can be entered through direct entry and from uploading shipment data to the IIS. Other inventory transactions (such as doses wasted, spoiled, etc.) may be allowed through the IIS direct entry only. In other words, currently dose-level reports on administered vaccines and shipment data could come in the IIS manually or electronically; all others transactions – only manually, through the IIS direct user interface (information for shipment data can be uploaded to the IIS from VTrckS). Currently there are no electronic exchange standards that allow for such submissions (non-administered doses); however this would not preclude encouraging such standards to be developed (see comments for the business rule BR718). Also, it should be noted that many EHR do not have the ability to track inventory.

	Use Case Name	**Notes**
1	Log inventory transaction	This generic scenario describes addition or subtraction from the inventory account. Specific transactions are described by scenarios 1.1 – 1.11. In order for the IIS to provide the Grantee Vaccine Program as well as Provider Organizations with quality data, it is critical that complete, accurate and timely reports of vaccine inventory transactions are submitted.
1.1	Log shipment transaction	The Provider Organization receives a shipment of vaccines and logs the associated information, adding vaccines received to the inventory count. For regular shipments (from a distributor), IIS pre-populates some of the shipment-related information.
1.2	Log incoming transfer transaction	The Provider Organization receives a transfer of vaccines from another Provider Organization and logs the associated information in the IIS, adding received vaccines to the inventory count.
1.3	Log dose borrowed (in) transaction	The Provider Organization borrows a vaccine from the privately-purchased stock to administer to a Patient who is eligible for a public vaccine (also note that the reverse is true as well). It is assumed that vaccines borrowed from privately-purchased stock will be replaced with publicly-funded vaccines.
1.4	Log bonus dose transaction	The Provider Organization discovers an additional dose of vaccine after the expected number of doses have been drawn from a vial (i.e., a bonus dose emerges due to unexpected amount of vaccine left in a vial).

	Use Case Name	Notes
1.5	Log dose administered transaction	The Provider Organization administers a vaccine to a Patient and logs the associated information (directly into the IIS and/or into an EHR system), subtracting administered vaccine from the Provider Organization's inventory.
1.6	Log dose wasted transaction	Vaccine from the Provider Organization's inventory is wasted. The Provider Organization logs the associated information in the IIS, subtracting wasted vaccine dose from the inventory count.
1.7	Log dose borrowed (out) transaction	The Provider Organization administers a vaccine from the publicly-funded stock to a Patient who is not eligible for a public vaccine. It is assumed that vaccines borrowed from a publicly-funded stock will be replaced with privately-purchased vaccines.
1.8	Log outgoing transfer transaction	The Provider Organization sends (transfers) vaccines to another Provider Organization and logs the associated information in the IIS, subtracting sent vaccines from the inventory count.
1.9	Log returned shipment transaction	The Provider Organization returns a shipment of vaccines and logs the associated information in the IIS. Partial return results in adding the rest of the shipment (received vaccines) to the Provider Organization's inventory count (use case 1.1).
1.10	Log spoiled/expired dose transaction	Vaccine from the Provider Organization's inventory is spoiled/expired. The Provider Organization logs the associated information in the IIS, subtracting the spoiled/expired vaccine dose from the inventory count.
1.11	Log over-estimated dose transaction	The Provider Organization discovers a vial did not contain the expected number of doses (i.e., a vial contained fewer doses than expected). This is the opposite of a bonus dose situation described in the use case 1.4
2	Correct transaction	The Provider Organization (or IIS, or Vaccine Program) corrects erroneous data in an inventory transaction.
3	Reconcile IIS inventory	The Provider Organization compares the IIS count against the actual ending physical inventory on hand. The IIS count is adjusted, and the difference is explained (at the dose level).
3.1	Count physical inventory	The Provider Organization counts the actual ending physical inventory on hand.
4	Maintain quality of inventory data	The Provider Organization, IIS, and Grantee Vaccine Program must ensure the completeness, accuracy, and timeliness of vaccine inventory data. For example, completeness requires that each dose administered is recorded and includes the lot number. A measure of completeness can include number of doses administered with the lot number recorded.
5	Generate inventory reports	The IIS provides reporting functionality for Provider Organizations and the Grantee Vaccine Program. Report examples include: inventory on-hand, monthly reconciliation, expiring soon, wastage report, aggregated counts across Provider Organizations, etc. See chapter 6, Recommendations for IIS Reports.
5.1	Provide inventory information for ordering	The Provider Organization submits inventory information for vaccine ordering. A prerequisite of placing an order in VTrckS is that the Provider Organization has submitted ending inventory data within 14 days prior to placing the order. Grantee Vaccine Programs can require that the ending inventory on hand be submitted in fewer than 14 days before ordering publically-funded vaccines.

Chapter 3: Recommendations Framework – State/Event Model

This chapter contains the State/Event Model, which documents every state of a Vaccine at the dose level, within the scope of inventory management. Figure 4 depicts all states and events and their relationships. Table 3 contains descriptions of possible vaccine states. Table 4 contains descriptions of associated events. Definitions of terms from the state/event model are presented in Appendix A (domain model).

This state/event model provides a basis and a framework/context for the development of principles, business rules, general recommendations, and IIS reports that are described in chapters 4-6.

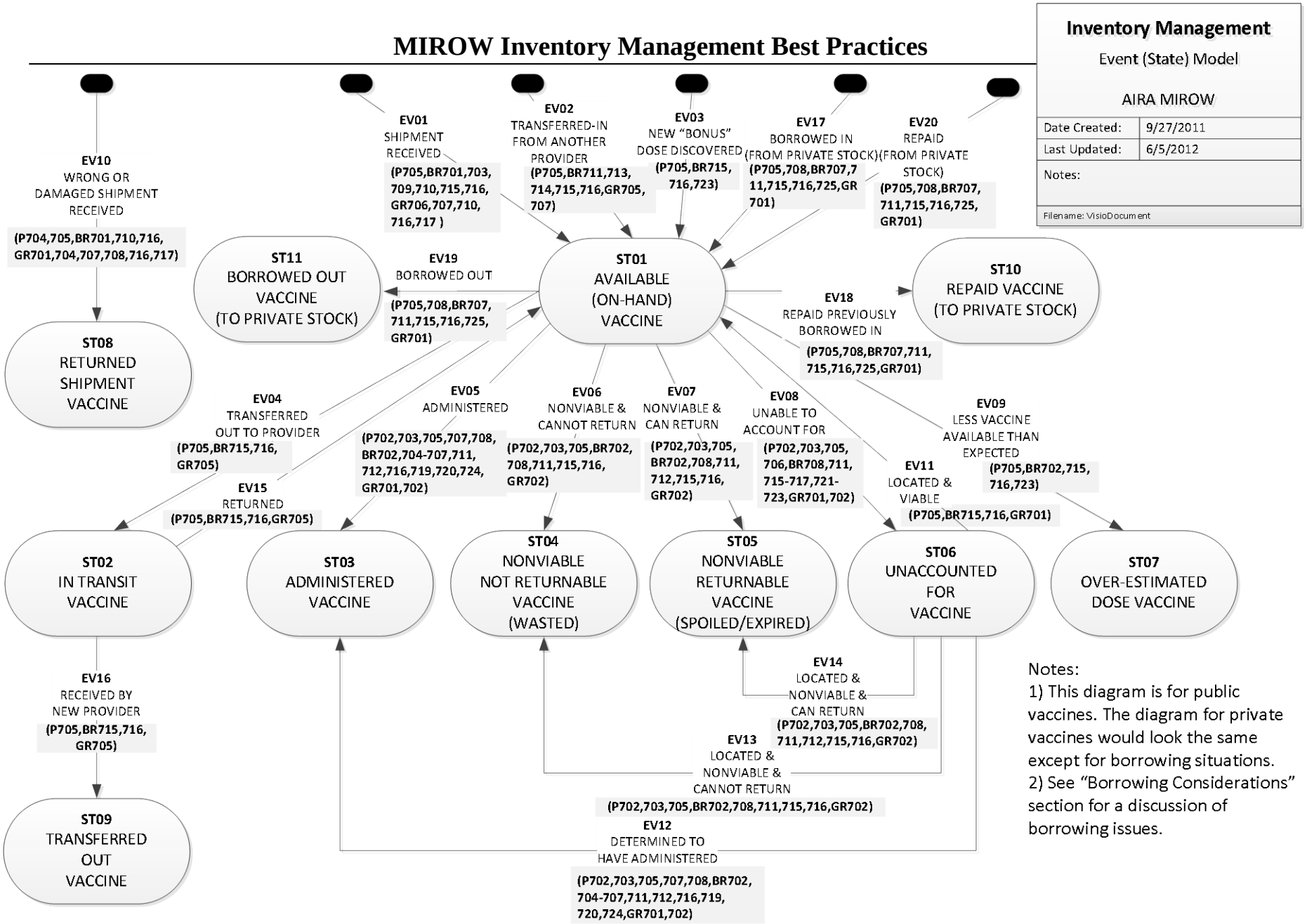

Figure 4. State/event diagram for public vaccines

Table 3. Vaccine state descriptions

ID	State	Description and References	Notes
ST01	Available (on-hand) Vaccine	• Vaccines that are available in the inventory. • EV01-03, EV11, EV15, EV17, EV20	• This state reflects publicly-funded vaccines, including privately-purchased vaccines that have been borrowed from the private stock (EV17) or repaid back from private stock (EV20). • Note that the "addition" of an available volume of inventory as a result of a) the discovery of "bonus" doses or b) borrowing inventory from another funding source will result in moving to an Available (On-Hand) state, regardless of whether that "addition" has yet been reconciled. Stated otherwise, a Provider Organization may administer an "additional" dose of vaccine even if the current volume shows as zero; the current volume may be reconciled later.
ST02	In Transit Vaccine	• Vaccine in the process of being transferred between Provider Organizations. • Shipment is still the responsibility of the sending Provider Organization. • EV04	• In Transit vaccine is vaccine that has been shipped from one Provider Organization to another Provider Organization but has not yet been recoded as "received" in the IIS by the Provider Organization to whom it was shipped. • The sending Provider Organization is responsible for the vaccine inventory until the receiving Provider Organization takes physical possession of the vaccine. Note: there is a conceptual difference between physical receipt and confirming that what is received is what was expected. Process: • The sending Provider Organization initiates transfer out: o Vaccine is considered "in-transit" vaccine in the sending Provider Organization's inventory. • The receiving Provider Organization confirms receipt of the transfer: o Vaccine is considered "transferred out" vaccine in the sending Provider Organization's inventory. o Vaccine is considered "available (on-hand)" vaccine in the receiving Provider Organization's inventory. • If the receiving Provider Organization does not accept the transfer: o Vaccine returns to "available (on-hand)" vaccine in the sending Provider Organization's inventory (or in another appropriate "bucket").

ID	State	Description and References	Notes
			• A time frame is needed – need to receive within a certain number of days. In Transit Vaccine (ST02) Responsible for the inventory: sending Provider Organization Transferred Out Vaccine (ST09) Responsible for the inventory: receiving Provider Organization
ST03	Administered Vaccine	• Vaccine given to a patient and recorded as such. • EV05, EV12	• Vaccine has been administered to either a public or a private patient. Patient eligibility determines whether the vaccine was administered to a public or private patient (see [1.1] – MIROW patients' eligibility guideline). • A note on the patient record when a dose administered has been borrowed or repaid can help with reconciliations (note that how/where EHR systems document data and how they report that data is out of scope for this topic).
ST04	Nonviable, Not Returnable Vaccine (Wasted)	• Nonviable vaccine that is not able to be returned for excise tax credit. • EV06, EV13	• Example: Provider Organization staff draws up vaccine and the dose is not administered and cannot be used (e.g., contaminated).
ST05	Nonviable, Returnable Vaccine (Expired/Spoiled)	• Spoiled, but can be returned. Includes recalls. • EV07, EV14	• Example: Spoiled due to exposure to unacceptable temperature.
ST06	Unaccounted for Vaccine	• A status "unaccounted for" should be assigned to a vaccine dose only when all other means of	• At the time of accounting a Provider Organization does not have a vaccine dose and does not know where it went (but at a different time of accounting it may show up). • Example: When inventory is being counted, Nurse Betty has a vaccine in her hand so that dose does not get counted in inventory for that month. She puts the dose back after

ID	State	Description and References	Notes
		subtraction (e.g., administered, spoiled/expired, wasted, etc.) have been ruled out (see BR708). • EV08	inventory is counted that month and it is counted the next month. • Reports are a snapshot in time. Generally, the amount of unaccounted for vaccine will be over one month and under the next.
ST07	Over-Estimated Dose Vaccine	• Less Vaccine was in the vial than what was expected or indicated by the manufacturer. • EV09	• May be difficult to determine why there is an over-estimated dose: o Could be manufacturer error. o Could be that a nurse did not draw properly – a QA issue. • This is the opposite of a bonus dose.
ST08	Returned Shipment Vaccine	• The Provider received a wrong or damaged shipment. • EV10	• Shipment can be returned to the distributor or manufacturer. • If IIS uses the shipping data from either McKesson or VTrckS, the IIS will automatically upload the vaccine information into the inventory before the vaccine arrives. Action would be needed to remove it from the inventory if upon arrival it was damaged or incorrect.
ST09	Transferred Out Vaccine	• Vaccine transferred from one Provider to Another. • EV16	<u>In Transit Vaccine (ST02)</u> Responsible for the inventory: sending Provider Organization. <u>Transferred Out Vaccine (ST09)</u> Responsible for the inventory: receiving Provider Organization.
ST10	Repaid (previously borrowed in) Vaccine (to private stock)	• See "Borrowing Considerations" section of this document, ST11, EV17-20 for a discussion of borrowing issues. • EV18	• All borrowed doses must be repaid.

ID	State	Description and References	Notes
ST11	Borrowed Out Vaccine (to private stock)	• See "Borrowing Considerations" section of this document, ST10, EV17-20 for a discussion of borrowing issues. • EV19	• See BR725 for a borrowing from a multi-dose vial. • CDC borrowing form can be used as a paper-based back-up to the report 2.1 Borrowed/ Replaced Report described in the IIS Reports section of this guideline. See the VFC Operations Guide, Module 3 – Provider Recruitment and Enrollment, pp. 17-18 at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/07-module-3.pdf.

Table 4. Vaccine event descriptions

ID	Event	Description and references	Notes
EV01	Shipment Received	• Vaccine received from a manufacturer or distributor. o A manufacturer or a Grantee Vaccine Program can act as a distributor. • Input to state ST01: state of vaccine changes to Available (ST01) when a shipment is received. • **P705, BR701, BR703, BR709, BR710, BR715, BR716, GR706, GR707, GR710, GR716, GR717**	• Provider Organization's staff indicates in the IIS the inventory that has been received.
EV02	Transferred In from Another Provider	• Input to state ST01: vaccine is transferred in from another Provider Organization. • **P705, BR711, BR713, BR714, BR715, BR716, GR705, GR707**	• Every transfer must be acknowledged on both ends, by the sender and the receiver. Transferred vaccine that is rejected must be physically returned to the sender. • The receiver may or may not know what is being transferred. • There may or may not be paperwork involved in the transfer. For example a transfer form could be packaged with the vaccine (lot number, number of doses, Shipped form, place for Receiver signature). The IIS can facilitate in a paperless transfer.

ID	Event	Description and references	Notes
			• The Grantee Vaccine Program may or may not be involved in transfers of vaccine between two Provider Organizations. • An audit report is needed to track all transfers in and out (and in transit transfers) - see reports 1.2 and 2.3 in the IIS reports chapter of this document.
EV03	New Bonus Dose Discovered	• Input to state ST01: new Bonus dose is discovered and must be added to the inventory. • It is not always obvious that there will be a bonus dose. Bonus doses are typically discovered when the last doses are drawn from a vial. • Doses per vial can vary when half doses are given to children, because of manufacturer error, or due to a recording error on the part of Provider Organization staff • Example: Vial says 10 doses, but provider gets 11 out of it. • **P705, BR715, BR716, BR723**	• Bonus dose is defined as an additional dose of vaccine discovered after the expected number of doses have been drawn from a vial (i.e., a bonus dose emerges due to an unexpected amount of vaccine left in a vial) • Auditing reports along with monthly reconciliation help to account for bonus doses. See report 3.2 in the IIS reports section. • A "bonus" would not necessarily be identified by provider at the time of vaccine administration. If provider realizes that a vial contains an extra dose, this fact would not be documented at the time of administration.
EV04	Transferred Out to Provider	• Input to state ST02: vaccine is transferred from one Provider Organization to another. • Vaccine transferred can be publicly-funded or privately-purchased • **P705, BR715, BR716, GR705**	• VFC guidelines and Grantee-specific requirements determine the rules for transferring publicly-funded vaccines between Provider Organizations. • Per ST02, the sender is responsible for the vaccine until it is received by the receiver (i.e., responsibility is a Grantee specific requirement). • An audit report is needed to specify all transfers in and out (and in transit transfers). See reports 1.2 and 2.3 in the IIS reports Chapter of this document. • Transfers may be entered into VTrckS manually. If Grantees track transfers in their IIS and are able to generate the needed

ID	Event	Description and references	Notes
			reports, they may not want to track transfers in VTrckS. o Note that the VTrckS transfer functionality may be of little benefit to VTrckS ExIS grantees. Since their Provider Organizations log on to the IIS and not VTrckS, Provider Organizations would not be able to initiate the transfer. If the grantee has this functionality in their IIS already, they should be able to generate the reports they need about transfers.
EV05	Administered	• Input to state ST03: Publicly-funded vaccine or privately-purchased vaccine on hand that is effectively administered. • **P702, P703, P705, P707, P708, BR702, BR704, BR705, BR706, BR707, BR711, BR712, BR716, BR719, BR720, BR724, GR701, GR702**	
EV06	Nonviable and Cannot Return (wasted)	• Input to state ST04. • **P702, P703, P705, BR702, BR708, BR711, BR715, BR716, GR702**	
EV07	Nonviable and Can Return (spoiled/ expired)	• Input to state ST05. • **P702, P703, P705, BR702, BR708, BR711, BR712, BR715, BR716, GR702**	
EV08	Unable to Account For	• Input to state ST06. • Do not know at time of inventory reconciliation what has happened to it. • **P702, P703, P705, P706, BR708, BR711, BR715, BR716, BR717, BR721, BR722, BR723, GR701,**	• BR708: A status "unaccounted for" should be assigned to a vaccine dose only when all other means of subtraction (e.g., administered, spoiled/expired, wasted, etc.) have been ruled out.

ID	Event	Description and references	Notes
		GR702	
EV09	Less Vaccine Available than Expected	• Input to state ST07. • Over-estimated dose. Example: Receive a 10-dose vial, but only get 9 doses out of it o Could be manufacturer error o Nurse drawing incorrectly (QA issue) • **P705, BR702, BR715, BR716, BR723**	• See ST07.
EV10	Wrong or Damaged Shipment Received	• Input to ST08. • **P704, P705, BR715, BR701, BR710, BR716, GR701, GR704, GR707, GR708, GR716, GR717**	• Handling of wrong or damaged shipments varies by Grantee. The Provider Organization, in cooperation with the Grantee may choose to accept some part of the shipment. • GR708: The IIS should support a way to ensure that inventory quantities can be adjusted according to the portions of the shipment that are accepted and rejected. The IIS may include a reason code for returned vaccine.
EV11	Located and Viable	• Input to state ST01: previously "Unaccounted For" (ST06), but now have a correction. Vaccine is still viable and can be administered. • **P705, BR715, BR716, GR701**	
EV12	Determined to Have Administered	• Input to state ST03: previously "Unaccounted For" (ST06), but now have a correction. • **P702, P703, P705, P707, P708, BR702, BR704, BR705, BR706, BR707, BR711, BR712, BR716, BR719, BR720, BR724, GR701, GR702**	• See EV05
EV13	Located and Nonviable	• Input to state ST04: previously "Unaccounted For" (ST06), but now have a correction.	• See EV06.

ID	Event	Description and references	Notes
	and Cannot Return	• **P702, P703, P705, BR702, BR708, BR711, BR715, BR716, GR702**	
EV14	Located & Nonviable & Can Return	• Input to state ST05: Previously "Unaccounted For" (ST06), but now have a correction. • **P702, P703, P705, BR702, BR708, BR711, BR712, BR715, BR716, GR702**	• See EV07.
EV15	Returned (transfer)	• Input to state ST01: Transfer returned to sender. • Could be a damaged shipment, not what expected, etc. • **P705, BR715, BR716, GR705**	• If the receiving Provider Organization rejects the transfer (e.g., the incorrect vaccine was sent by the sending Provider Organization), the receiving Provider Organization would have to physically return vaccine to the sender.
EV16	Received by New Provider Organization	• Input to state ST09. • **P705, BR715, BR716, GR705**	• Every transfer must be acknowledged on both ends.
EV17	Borrowed In (from private stock)	• Input to state ST01. • See "Borrowing Considerations" section of this document, ST10, ST11, EV18-20 for a discussion of borrowing issues • **P705, P708, BR707, BR711, BR715, BR716, BR725, GR701**	• When a Public/Private inventory indicator for a dose administered to a Patient is "private" and Patient eligibility is "public" (or vice versa), a borrowing transaction is created. • Audit reports should be generated to provide the borrowed/repaid information and the Provider Organization must replace the borrowed dose with the opposite inventory stock (see (4.1), (9) Borrowed/replaced report in the IIS reports section). • Note that vaccines borrowed from private stock may not have a lot number documented in the system, so information in the audit reports may be incomplete. • P708: Avoid loaning doses between private and public stock.

ID	Event	Description and references	Notes
EV18	Repaid Previously Borrowed in Vaccine	• Input to state ST10. • See "Borrowing Considerations" section of this document, ST10, ST11, EV17, EV19, EV20 for a discussion of borrowing issues. • **P705, P708, BR707, BR711, BR715, BR716, BR725, GR701**	• All borrowed doses must be repaid.
EV19	Borrowed Out (to private stock)	• Input to state ST11. • See "Borrowing Considerations" section of this document, ST10, ST11, EV17, EV19, EV20 for a discussion of borrowing issues. • **P705, P708, BR707, BR711, BR715, BR716, BR725, GR701**	• When a Public/Private inventory indicator for a dose administered to a Patient is "public" and Patient eligibility is "private" (or vice versa), the borrowing transaction is created. • Audit reports should be generated to provide the borrowed/repaid information and the Provider Organization must replace the borrowed dose with the opposite inventory stock (see(4.1), (9) Borrowed/replaced report in the IIS reports section). • P708: Avoid loaning doses between private and public stock.
EV20	Repaid (from private stock)	• Input to state ST01. • See "Borrowing Considerations" section of this document, ST10, ST11, EV17, EV19 for a discussion of borrowing issues. • **P705, P708, BR707, BR711, BR715, BR716, BR725, GR701**	• All borrowed doses must be repaid.

Chapter 4: Principles and Business Rules

This chapter contains principles and business rules related to the state/event model described in the previous chapter, as well as to process models described in the chapter 2 “Scope” (high-level use-cases), and Appendix B, “Scope – Detailed Focus Statement” (process diagram and description). Business rules represent specific requirements regarding how the business should operate based on laws, policies, regulations, and chosen business/operational style.

A **principle (P)** is a high-level business rule. It is a high-level direction that helps to guide the development of more specific business rules. **Business rules (BR)** represent specific requirements and decision-making logic for various aspects of IIS processes.

Principles and business are associated in Table 5 in the following order:

- P701: NDC supremacy principle
  - BR701: Use NDC received in the shipment file
  - BR702: Lot number must be matched/mapped to NDC for every dose
  - BR703: Make NDC known prior to arrival of a direct vaccine shipment
- P702: Dose - lot number accountability principle
  - BR704: Capture the lot number for every vaccine dose administered
  - BR705: Capture patient eligibility for every dose administered
  - BR706: Capture Provider Organization responsible for inventory for every dose administered
  - BR707: Track borrowing and replacements at the dose level
  - BR708: Account for wasted, spoiled/expired, and unaccounted for vaccines at the dose level
- P703: Completeness principle
  - BR709: Minimum set of data items for every shipment
  - BR710: Verify shipment information
  - BR711: Minimum set of data items for every vaccine dose
  - BR712: Use (record) short-dated expiration date when present
  - BR713: Minimum data set for vaccine transfers
  - BR714: Verify condition, types, and quantities of transferred vaccine doses
- P704: Accurate accounting principle
  - BR708: Account for wasted, spoiled/expired, and unaccounted for vaccines at the dose level
- P705: Timely accounting principle
  - BR715: Account for non-administrative adjustments on the same day
  - BR716: Track the event date and recording date
- P706: Reconciliation frequency principle
  - BR717: Submit data to IIS before reconciling inventory
  - BR718: Indicate IIS-EHR discrepancies
  - BR719: Account for opt-out patients before reconciling
  - BR720: EHR submission for an opt-out patient
  - BR721: Do physical inventory count for reconciliation on a day boundary
  - BR722: Reconcile inventory immediately prior to ordering
  - BR723: Reconciliation frequency

- P707: Comply with privacy guidelines principle
    - BR724: Ensure accurate inventory count for pre-adoption Provider Organizations
- P708: Avoid loaning doses between private and public stock principle
    - BR725: Borrowing should be done at the single-dose level

Unless otherwise specified, principles and business rules presented in this chapter are applied to all inventory transaction types, not just to dose administered transactions.

Table 5. Principles and Business Rules

ID	Principle/Business Rule Statement	Remarks
P701	**NDC supremacy principle** Vaccine inventory management should be based on the National Drug Code (NDC).	• See BR701, BR702, BR703. • In accordance with VFC program and VTrckS system requirements, vaccine inventory must be reported based on the NDC.
BR701	**Use NDC received in the shipment file** The NDC received from VTrckS (in the shipment file) should be used for receiving, reporting, and tracking inventory.	• See P701: NDC supremacy principle. • BR702, BR703. • Note that the NDC to be used for ordering, reporting inventory or submitting returns is the one in the CDC contract. • In cases where the shipment file has not been received and the vaccine is packaged in a larger container, ***the NDC on the outside packaging (e.g., box) should be used***. • Currently McKesson does not provide (and in many cases does not know) the codes for items inside the package. • State/event model references: EV01, EV10.
BR702	**Lot number must be matched/mapped to NDC for every dose** Lot number for every vaccine dose utilized by a Provider Organization must be matched/mapped to NDC for a specific inventory entry and the appropriate transaction should be created to adjust the inventory appropriately.	• See P701: NDC supremacy principle. • See P702: Dose-Lot Number accountability principle. • The mapping of lot number to NDC and expiration date is needed in order to support inventory on hand reporting to VTrckS. A lot number should be matched to one NDC, as discussed in the NDC Considerations section and in the Appendix A, domain model. • For inventory management, it is not sufficient just to map lot number to NDC: also have to know whether to deduct the transaction from public or private inventory. If lot numbers were always distinctly different for public and private inventory, it would not be a problem. But sometimes the same lot number exists for both public and private stocks. o Example: Kansas IIS has experienced this issue – with providers using the wrong vaccine for VFC and for non-VFC patients in cases where borrowing was not intended. Knowing the VFC eligibility status of the patient helped to resolve these situations. o On the administration side, patient eligibility reporting with dose administered is

ID	Principle/Business Rule Statement	Remarks
		sufficient, except for the "borrowed" situation. For borrowing situations a public/private inventory designation for every dose should be known. • Refer to BR709 for the minimum set of data items for every shipment. • State/event model references: EV05, EV06, EV07, EV09, EV12-14.
BR703	**Make NDC known prior to arrival of a direct vaccine shipment** IIS should make NDC known to Provider Organization prior to arrival of a direct vaccine shipment.	• See P701: NDC supremacy principle. • See BR701, BR702. • IIS knows the NDC based on the Provider Organization's original order. • IIS loads Provider Organization's public inventory with NDC from outer package, Lot Number, Lot Number Expiration Date, and quantity. • State/event model references: EV01.
P702	**Dose-lot number accountability principle** Every vaccine dose should be accounted for with the associated lot number information.	• See BR704 - BR708, GR702. • All additions to and subtractions from inventory levels should be accounted for and measured. • According to the state/event model (Figure 4, Tables 3 and 4), the following vaccine dose states (types/categories) should be measured (further sub-categories may be implemented locally): available (on-hand), in-transit (transferring), administered, wasted (nonviable, not returnable), expired/spoiled (nonviable, returnable), unaccounted for, over-estimated, returned shipment, transferred out, repaid (previously borrowed), and borrowed out. o Some jurisdictions may choose to apply a threshold to some of these categories. When the threshold is reached (e.g., on wasted vaccine doses) certain actions can be initiated. • The lot number must be captured at the dose level for inventory accountability purposes. • Lot number needs to be captured to support the mapping to NDC (can be done behind the scenes). o IIS can enable the mapping by associating lot number to NDC. o Refer to a discussion in the "NDC Considerations" section of this document. • State/event model references: EV05-08, EV12-14.

ID	Principle/Business Rule Statement	Remarks
BR704	**Capture the lot number for every vaccine dose administered** A lot number for every vaccine dose administered must be documented and reported by the Provider Organization to the IIS.	• Action on business rule violation: Reject reporting without lot number. • See P702: Dose-Lot Number accountability principle. • See GR716 for data quality assurance as it relates to lot numbers. • Rule applies to reporting done either electronically or on paper o Will require a major change of mindset because lot number is currently not well populated in IIS. But there are many benefits if this is done. • For historical vaccine doses, the lot number in many cases is not known and is not required. It is not needed for inventory control (these would not be considered administered, but historical doses). o Historical doses - administered at some point in the past and now being entered into a patient's record (e.g., patient moved from one state to another and brings the immunization record). • Encourage Provider Organizations to adopt technologies that can facilitate lot number reporting. Examples: barcoding, new inventory modules, publish tables that describe vaccine products and their lot numbers. That can facilitate implementing drop-down reporting in EHR systems. • For many IIS, decrementing inventory at the dose level based on lot numbers in data exchanged may be new functionality they need to build. • In case of a multi-component vaccine (i.e., a product with diluents or components that must be combined together), each component has its own lot number. However, there is always one lot number and one NDC available that characterize such a multicomponent vaccine. The information about these lot number and NDC should be taken from the label located outside on the package/box, as indicated in a comment for the business rule BR701. • See the discussion regarding lot number assumptions in the NDC Considerations chapter. • State/event model references: EV05, EV12.

ID	Principle/Business Rule Statement	Remarks
BR705	**Capture patient eligibility for every dose administered** A patient eligibility for every vaccine dose administered must be documented and reported by the Provider Organization to the IIS.	• Action on business rule violation: Reject reporting without patient eligibility for immunization administration purposes. • See P702: Dose-Lot Number accountability principle. • See notes for BR702. • Patient eligibility is needed to decrement the appropriate stock (public or private). o It is possible to have the same lot number and NDC for both public and private vaccines. Patient eligibility helps to distinguish between public and private vaccines. • Patient eligibility is not relevant for historically administered vaccines. • Provider Organizations which do not provide dose-level patient eligibility: o May not be able to do automated reporting of dose-level accountability at the lot level in IIS. o May need to make aggregate corrections at the lot level within the IIS (see GR702). • State/event model references: EV05, EV12.
BR706	**Capture Provider Organization responsible for inventory for every dose administered** Provider Organization responsible for the inventory must be associated with every immunization (dose administered transaction)	• Action on business rule violation: o Accept reporting without Provider organization responsible for inventory for immunization administration purposes. o Reporting without Provider Organization responsible for inventory may be accepted for inventory tracking if the Provider Organization responsible for inventory can be determined based on information submitted (e.g. not an umbrella organization). • See P702: Dose-Lot Number accountability principle. • The Provider Organization responsible for the inventory may be different from the Provider Organization administering the vaccine (see discussion in the Appendix A: Domain model). • Whenever possible, and in accordance with VFC policy, vaccine should be shipped to and received by the administering site; situations that include redistribution by a centralized vaccine depot should be minimized. • Organizations that do not report responsible Provider Organization: o Will not be able to implement automated reporting of dose-level accountability at the lot level in IIS.

ID	Principle/Business Rule Statement	Remarks
		○ Will need to make aggregate corrections at the lot level within the IIS. • State/event model references: EV05, EV12.
BR707	**Track borrowing and replacements at the dose level** Borrowing and replacement of borrowed vaccine doses between public and private stocks should be tracked at the dose level.	• See P702: Dose-Lot Number accountability principle. • See P708: Avoid loaning doses between private and public stock principle. • See BR725: Borrowing should be done at the single-dose level. • See VFC Operations Guide for guidance. • See the borrowed/replaced report in the IIS Reports section. • State/event model references: EV05, EV12, EV17-20.
BR708	**Account for wasted, spoiled/expired, and unaccounted for vaccines at the dose level** Inventory adjustment to account for wasted (non-viable and non-returnable), spoiled/expired (non-viable and returnable), and unaccounted for vaccines should be done at the dose level.	• See P702: Dose-Lot Number accountability principle. • See P704: Accurate accounting principle. • A status "unaccounted for" should be assigned to a vaccine dose only when all other means of subtraction (e.g., administered, spoiled/expired, wasted, etc.) have been ruled out. • Measurements of wasted, spoiled/expired, and unaccounted for doses (possibly, against a certain threshold) would help to address the requirement that "Vaccine loss and waste should be minimized and measured" from [2.13] IPOM: Immunization Program Operations Manual, Chapter 2 (http://www.cdc.gov/vaccines/vac-gen/policies/ipom/). See also reports 1.5 Vaccine Loss Report (% Vaccine Loss - based on total doses ordered) and 2.4 Loss/Wasted Report in the Recommendations for IIS Reports section of this document. • State/event model references: EV07, EV08, EV13, EV14.
P703	**Completeness principle** The inventory management information submitted to an IIS must contain the minimum/mandatory set of data items in order to be accepted by the IIS.	• See BR709 - BR714. • The set of required data items should be the same regardless of how these data items have been reported to an IIS. • State/event model references: EV05-08, EV12-14.
BR709	**Minimum set of data items for every shipment**	• Each morning McKesson sends grantees two files (in MS Excel and text format) with information about non-direct vaccine orders shipped the previous day. Grantees can use this

ID	Principle/Business Rule Statement	Remarks
	For every shipment the minimum/mandatory set of data items recorded for the purposes of inventory management should include: • Date shipped • Order ID • Order Line Number (associated with data items below) • NDC • Lot Number • Lot Number Expiration Date • Quantity (in doses) • Public/Private Indicator	information to pre-populate Provider Organization inventory in the IIS and to let Provider Organizations know to expect a shipment. • Shipment data for both direct and non-direct orders is available for download from VTrckS in a time interval that the user specifies. As with the McKesson shipment file, grantees can use VTrckS shipment data to pre-populate Provider Organization inventory in the IIS and to let Provider Organizations know to expect a shipment. • The timeliness of shipment data available through VTrckS continues to improve. It is planned that by fall 2012 all manufacturers will be communicating with VTrckS in a way that will ensure timely shipment data for both direct and non-direct ship orders. For complete and timely shipment data, CDC recommends that the ExIS shipment data file ─ not the McKesson shipping file ─ be imported into the IIS. • The discussion is centered around public-funded vaccine available from the CDC via VTrckS, but the same business rule could also apply to private-funded vaccine shipments. All shipments from VTrckS should be categorized as public (in the public/private indicator).
BR710	**Verify shipment information** Provider Organization should verify in terms of quantity , type, etc. a match between a) Vaccines received in a shipment. b) The information on a package slip. c) Information in the IIS. d) Information in the EHR.	• Action on business rule violation: If vaccines shipped do not match the packing slip and/or expected receipt quantities, types, etc.: a) Inventory in the IIS should be corrected to reflect the actual vaccine received (e.g., correct the lot number). b) Vaccine Program should be notified. • See principle P703: Completeness principle. • See GR716. • Implementation considerations: o Minor issues may be addressed with editable fields (e.g. expiration date, vaccine quantity) in the system. o Major issues may require immediate communication and be in non-editable fields (e.g. vaccine type) in the system. • Vaccine Programs provide guidelines on which issues are classified as major or minor and what actions must be taken when issues occur (e.g. immediate phone call). • State/event model references: EV01, EV10.

ID	Principle/Business Rule Statement	Remarks
BR711	**Minimum set of data items for every vaccine dose** For every vaccine dose the minimum/mandatory set of data items recorded and reported to the IIS for the purposes of inventory management should include: • Lot number (to be matched/mapped to NDC) • Lot Number Expiration Date • Patient eligibility status (for administered vaccines) • Provider Organization (responsible for the inventory) • Public/Private Indicator (optional - see the alternative good practice that involves public/private identification at the lot number level - described in the right column)	• See P703 Completeness principle • VTrckS specification requires that quantity by lot number, lot number expiration date, and NDC all be reported in the current inventory file needed to place vaccine orders. • Lot Number Expiration Date: In some cases this data item would contain a short-dated expiration date. A possible additional data item, expanding the minimum recommended data set, would be a short-dated expiration date or a flag indicating a short-dated expiration date. See BR712: When present, short-dated lot number expiration date should be used for all inventory transactions instead of the original expiration date. Note that two inventory items (vaccine doses) can have the same lot number, but different expiration dates: one – with the original date, another – with the short-dated date (Michigan IIS example). • When a Public/Private inventory indicator for a dose administered to a Patient is "private" and Patient eligibility is "public" (or vice versa), a borrowing transaction is created. • 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. 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

ID	Principle/Business Rule Statement	Remarks
		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 - to capture public/private designation of the inventory. • Although available as a field within some IIS databases, 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 EHRs to store and submit the Public/Private Indicator data item. • EHR use lot numbers for various purposes, including extending the lot number fields to indicate public/private inventory designations. The IIS needs to be able to derive the actual lot number and the actual public/private indicator and document them in two separate fields. • 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. • State/event model references: EV02, EV05-08, EV12-14, EV17-20.
BR712	**Use (record) short-dated expiration date when present** When present, the new short-dated Lot Number Expiration Date must be used (recorded) for all inventory transactions instead of the original expiration date.	• See P703: Completeness principle. • See GR706: Indicate expiration date for short-dated vaccines on the physical packaging. • When a lot number has been short-dated, two expiration dates can be recorded ─ the original expiration date and the short-dated expiration date. Reporting two dates is a "good to have" practice, but is not mandatory. The original expiration date is not currently needed for reporting to VTrckS. • A possible reason for short-dating might be a temporary temperature drop in the refrigerator. • State/event model references: EV01, EV05, EV07, EV12, EV14.

ID	Principle/Business Rule Statement	Remarks
BR713	**Minimum data set for vaccine transfers** The following information should be present for vaccine transfers between Provider Organizations: • Sending Provider Organization VFC Pin (or ID for the Provider Organization) • Receiving Provider Organization VFC Pin (or ID for the Provider Organization) • Lot number (maps to vaccine type, NDC) • Lot Number Expiration Date (maybe a short date) • Quantity (in doses) • Public/Private Inventory Indicator • Timestamps of requests/receipt • Reason for transfer (optional) • Person who initiated transfer (optional)	• See P703: Completeness principle. • See GR705 for the note on related VTrckS functionality. • Inventory adjustments should be made in IIS for both the sending Provider Organization and the receiving Provider Organization. The sending Provider Organization will need transaction recorded to deduct doses from inventory and the receiving Provider Organization will need transaction recorded that will add doses to their inventory. • The Grantee Vaccine Program (or LHD) should be notified of all transfers and receipts of public vaccines (depending on grantee requirements). • It is a good practice to know the ID of the Person at the Provider Organization who initiated the transfer ("pushed the button"). That information can be available through the user interface or through accessing audit tables. • See alternative approaches to track the public/private indicator described in the comments to BR711. • State/event model references: EV02.
BR714	**Verify condition, types, and quantities of transferred vaccine doses** Provider Organizations should verify condition, types, and quantities received in a transfer from another Provider Organization against expected number and type of doses.	• See P703: Completeness principle. • Vaccines received in a transfer between Provider Organizations should match the expected number and type of doses. • Condition refers to viability (e.g., no cracks in box, no ice forming, temperature log with recorded temperatures during transport are within normal limits). • The sending and receiving Provider Organizations should resolve the issues and ensure the resolution is appropriately reflected in the IIS. • State/event model references: EV02.
P704	**Accurate accounting principle** Provider Organization's physical inventory (available/on hand) should be accurately reflected in the IIS.	• See BR708. • Any inventory transaction should be reversible and can be corrected as necessary. • Inventory may be located in one or more cold storage units. • Provider Organization has one inventory in IIS per VFC PIN and IIS ID. Provider.

ID	Principle/Business Rule Statement	Remarks
		Organization's inventory can include both publicly-funded and privately-purchased vaccines. • State/event model references: EV10.
	See business rule BR708 above: Account for wasted, spoiled/expired, and unaccounted for vaccines at the dose level.	
P705	**Timely accounting principle** Provider Organization's inventory should be adjusted in the IIS as soon as an event requiring the adjustment becomes known.	• See BR715, BR716. • Examples include administration, breakage, new inventory, wasted/spoiled doses, bonus doses. • Administration can be reported right away in case of direct data entry, or reporting can be delayed if reporting is arranged through another Provider Organization's level or EHR systems. • State/event model references: EV01-EV20.
BR715	**Account for non-administration adjustments on the same day** All events generating non-administration adjustments to available on hand inventory should be accounted for in the IIS on the same day they occur.	• See P705: Timely accounting principle. • Examples include breakage, bonus doses, wasted/spoiled doses. • State/event model references: EV01-04, EV06-11, EV13-20.
BR716	**Track the event date and recording date** Both the date that an inventory-related event occurred and the date that the transaction was entered into the IIS should be tracked to facilitate reconciliation.	• See P706: Reconciliation frequency principle. • See P703: Completeness principle. • This is to facilitate reconciliation. Important to know for monthly reporting the actual date the event occurred. o Example: At the date of service may think the patient is insured ─ but get a rejection back three months later and now the Provider Organization needs to replace the dose with VFC and designate the patient as uninsured or underinsured. • Good practice: Track at least the date the event occurred. • State/event model references: EV01-20.

ID	Principle/Business Rule Statement	Remarks
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.	• See BR717 - BR723. • P705 reflects already known adjustments. This principle describes a process to discover adjustments that are not already known. • Reconciliation involves counting physical inventory. • Size (e.g., large or small) of a Provider Organization is defined by how many doses this Provider Organization administers in a period of time or size of their orders or frequency of the orders (e.g., if ordering monthly, when it is a large Provider Organization). • Examples of complexities include challenges with EHR systems, multiple refrigerators and freezers, complex Provider Organization structures (umbrella, parent-child relationships), re-distributions of vaccines within health systems. • State/event model references: EV08.
BR717	**Submit data to IIS before reconciling inventory** Provider Organizations must have their immunization data submitted to and processed by the IIS before reconciling their inventory for the corresponding reconciliation period.	• See P706: Reconciliation frequency principle. • State/event model references: EV08.
BR718	**Indicate IIS-EHR discrepancies** When inventory information in an electronic feed from an EHR to IIS cannot be matched to a specific provider lot entry, IIS must provide a mechanism to indicate/flag the discrepancy to the Provider Organization.	• Action on business rule violation: o Best practice: Discrepancies should be addressed immediately. o Good practice: Discrepancies must be addressed before the close of the reconciliation period. • See P706: Reconciliation frequency principle • Short-date is one example of why there might be a discrepancy. “Short-dating” could lead to more than one expiration date for a lot number (BR711, BR712). Another example: an inventory lot is not found in IIS due to a data entry error in the EHR or IIS (wrong lot entered in one system or the other) or because inventory lot was not entered into IIS.

ID	Principle/Business Rule Statement	Remarks
		• Another common problem is inventory lot from EHR matches more than one lot in IIS. IIS will not deduct inventory if it can not match a unique lot. • Therefore lot number alone is not sufficient to determine expiration date. • Currently, dose-level reports on administered vaccines could come into the IIS manually (direct user interface) or electronically (messages from EHR); all other transactions – only manually, through the IIS direct user interface . Currently there are no electronic exchange standards that allow for such submissions of inventory transactions (non-administered doses) in addition to doses administered; however this would not preclude encouraging such standards to be developed.
BR719	**Account for opt-out patients before reconciling** At the appointment time Provider Organization should make inventory adjustments for vaccines administered to opt-out patients before reconciling its inventory for the corresponding reconciliation period.	• See P706: Reconciliation frequency principle. • See P707: Comply with privacy guidelines principle. • Opt-out means a patient has chosen not to be in the registry (IIS). • Legal requirements for handling opt-out (and/or non-consented) patients vary among grantees based on local laws and regulations. Accordingly, approaches to inventory adjustments for opt-out patients vary. o A typical scenario (KS, OR): IIS retains demographic information for opt-out patients. Vaccine doses administered to an opt-out patient are reported to IIS as usual. Because IIS has demographic information for a patient it recognizes that a patient is opted out. IIS decrements the Provider Organization's inventory by one dose, without updating the patient vaccination record. o Another typical scenario (MI): IIS retains the opted-out patients name and DOB and flags these patients as opted-out. When data is transferred from an EHR, IIS will block the transfer of those doses and will not accept the vaccine information for a person who has opted-out (in other words, such a transmission of any information for the opted-out patient is rejected). A provider manually deducts the administered dose from the IIS inventory with a reason "Patient opted-out from IIS". • See also BR720 – relevant for this discussion. • State/event model references: EV05, EV12.

ID	Principle/Business Rule Statement	Remarks
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.	• See P706: Reconciliation frequency principle. • See P707: Comply with privacy guidelines principle. • Good practice: make a manual adjustment with reason of "administered to patient who opted-out of registry." • Good practice: create an audit trail (time stamp, user ID, etc.) to ensure QA in case of questions around reconciliation time. • State/event model references: EV05, EV12.
BR721	**Do physical inventory count for reconciliation on a day boundary** Physical inventory count for reconciliation purposes should always be done on a day boundary (i.e., at the end of a business day or prior to the next business day).	• See P706: Reconciliation frequency principle. • State/event model references: EV08.
BR722	**Reconcile inventory immediately prior to ordering** Provider Organizations must reconcile their entire physical inventories to the IIS inventory immediately prior to ordering.	• See P706: Reconciliation frequency principle. • See GR702: IIS inventory management functionality should support accountability at the dose/lot number level. • VTrckS requirement: Grantee must submit the Provider Organization's physical inventory ("Provider Ending Inventory Data") to VTrckS no more than 14 days prior to order placement. • Good practice: Provider Organizations not utilizing the IIS for inventory management must submit physical inventory counts at the lot level. Some Provider Organizations will opt not to use the inventory module in the IIS, but these same Provider Organizations will need to submit physical counts to VTrckS to support ordering. • State/event model references: EV08.
BR723	**Reconciliation frequency**	• Action on business rule violation: Provider Organizations not complying with monthly accountability requirements may be required to conduct more frequent reconciliations

ID	Principle/Business Rule Statement	Remarks
	Provider Organizations should reconcile their entire physical inventory to 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.	(e.g., once a week). • See P706: Reconciliation frequency principle for the discussion of size and complexity of Provider Organization. • Parameters that describe what is a large or small organization should be established at a grantee level. • More frequent reconciliations could be beneficial in a variety of situations, including: o Provider Organizations with a large volume of transactions. o Provider Organizations with a history of inventory management issues. o Provider Organizations that are new and/or transitioning onto inventory management within the IIS. o Provider Organizations with multiple individuals using inventory or multiple refrigerators. In these cases, more frequent reconciliations are a proven mechanism for helping the Provider Organization identify and resolve any discrepancies. • State/event model references: EV03, EV08, EV09.
P707	**Comply with privacy guidelines principle** Comply with HIPAA interpretations and other privacy-related constraints, e.g., handling adoption and opt-out of IIS cases.	• See BR719, BR720, BR724. • State/event model references: EV05, EV12.
BR724	**Ensure accurate inventory count for pre-adoption Provider Organizations** For adoptions where original patient identity needs to be inaccessible, IIS must ensure that inventory levels are accurately maintained for the pre-adoption Provider Organization(s).	• See P707: Comply with privacy guidelines principle. • Immunization information (without provider information) from original identity should be carried forward to the new identity. • There are many ways to maintain anonymity. One option is to add doses back to the inventory and then subtract these doses back at the lot level; use subtraction reason of "administered to patient who was adopted." • State/event model references: EV05, EV12.
P708	**Avoid loaning doses between private and public stock principle** Borrowing doses between private and public	• See Borrowing Considerations chapter, BR707, BR711, BR725, GR701, Figure 5 – state/event diagram for public vaccines, ST10, ST11, EV17-EV20 for a discussion of

ID	Principle/Business Rule Statement	Remarks
	stock should be avoided.	borrowing issues. • All borrowed doses must be repaid. • See VFC Operations Guide, Module 3 for guidance on borrowing o Excerpt: "At the grantee's discretion, borrowing between the two inventories of vaccines may occur but must be a rare occurrence. Please note: for seasonal influenza vaccine, providers may use private stock seasonal influenza vaccine to vaccinate VFC eligible children if VFC seasonal influenza stock is not yet available. Those private stock doses used on VFC eligible children can later be replaced when VFC stock becomes available. This one-directional borrowing exception is unique to seasonal influenza vaccine. For all other vaccines, limited borrowing may occur bi-directionally. All borrowing, regardless of direction, must be documented on the VFC vaccine borrowing report located at the end of this module." • State/event model references: EV05, EV12, EV17-20.
BR725	**Borrowing should be done at the single-dose level** When a multi-dose vial is involved, borrowing should be done at the single-dose level.	• See P708: Avoid loaning doses between private and public stock principle • See BR707: Track borrowing and replacements at the dose level • A single dose should be borrowed -- not the whole vial. • Current practice in some states (e.g., Pennsylvania) is to borrow the whole multi-dose vial. But this is not a system limitation; it is a policy decision. • State/event model references: EV17-20.

Table 6. Data items for a vaccine dose – required reporting/recording for inventory management purposes

	Data Item	BR References	Notes
Minimum/mandatory set of data items for every vaccine dose	Lot Number	BR711 BR704 BR702	BR702: Lot number to be matched with NDC.
	Lot Number Expiration Date	BR711 BR712	BR712: When present, short-dated lot number expiration date should be used for all inventory transactions instead of the original expiration date. Note: Michigan IIS can have two inventory items (vaccine doses) with the same lot number, but different expiration dates (one with the original date, another with the short-dated date).
	Patient Eligibility Status	BR711 BR705	Required for administered vaccines only.
	Provider Organization (responsible for inventory)	BR706	For administered vaccines, VFC PIN (or ID for Provider Organization).
	Public/Private Inventory Indicator (optional)	BR711	See alternative "good practice" approaches to track the public/private indicator described in the comments for BR711.
Data set for Transfers	Sending Provider Organization	BR713	VFC PIN (or ID for Provider Organization).
	Receiving Provider Organization	BR713	VFC PIN (or ID for Provider Organization).
	Lot Number	BR713	Maps to vaccine type, NDC.
	Lot Number Expiration Date	BR713	Maybe a short date.
	Quantity	BR713	In doses
	Public/Private Inventory Indicator	BR713	See alternative "good practice" approaches to track the public/private indicator described in the comments to BR711.
	Timestamp of request	BR713	
	Timestamp of receipt	BR713	
	Reason for transfer (optional)	BR713	
	Person who initiated transfer (optional)	BR713	
Data set for shipments	Date shipped	BR709	
	Order ID	BR709	
	Order Line Number	BR709	
	NDC	BR709	
	Lot Number	BR709	
	Lot Number Expiration Date	BR709	When present, short-dated lot number expiration date should be used
	Quantity	BR709	In doses
	Public/Private Indicator	BR709	See BR711 (comments) for alternative approaches

Chapter 5: General Recommendations

This chapter contains general recommendations (GR) for IIS functionality and operations related to inventory management.

General recommendations (GR) represent requirements, advice, and suggestions for IIS functionality and operations related to IIS inventory management.

General recommendations are arranged in Table 7 in the following order (these general recommendations are not listed by order of importance):

- GR701: IIS inventory management functionality should reflect policies and practices of a Grantee Vaccine Program
- GR702: IIS inventory management functionality should support accountability at the dose/lot number level
- GR703: IIS should utilize 5-4-2 format for NDC
- GR704: IIS should support corrections to existing inventory transactions
- GR705: IIS should reflect transfers of vaccines
- GR706: IIS should be able to record both the original and short-dated expiration dates
- GR707: Receipt of orders should be reflected based on physical receipt of the shipment
- GR708: Functionality to adjust inventory based on the quantity of accepted and rejected vaccine doses in the shipment
- GR709: IIS should follow MIROW Data quality guidelines
- GR710: Minimize manual inventory data entry
- GR711: Validate data at the time of recording and periodically
- GR712: Validate individual and aggregated data
- GR713: IIS should have functionality that prevents duplicate lot numbers
- GR714: Establish QA process for data from non-IIS systems
- GR715: IIS should test all aspects of the inventory management-related functionality
- GR716: Quality assurance measures for vaccine shipments
- GR717: Data quality assurance metrics
- GR718: Access to reports
- GR719: Use IIS reports to analyze Providers' practices
- GR720: Generate aggregated reports from IIS
- GR721: IIS inventory management functionality should be available for non-VFC Provider Organizations
- GR722: IIS should produce materials demonstrating the value of inventory management to Provider Organizations
- GR723: Multiple training options should be offered to Provider Organizations for inventory management

Table 7. General Recommendations

ID	General Recommendation Statement	Notes
GR701	**IIS inventory management functionality should reflect policies and practices of a Grantee Vaccine Program** IIS inventory management functionality should reflect specifics policies and practices of a Grantee Vaccine Program.	• The IIS should be aware of and consider these standards policies and practices when building reporting functionality into the IIS. For example, the IIS should have a report indicating each dose of borrowed/replaced vaccine to assist the VFC program (see report 2.1 in the IIS Reports chapter of this document). • Having the Grantee's Vaccine Program heavily involved in any implementation, training, etc. is critical for the inventory management functionality in the IIS to be successful. • State/event model references: EV05, EV08, EV10-12, EV17-20
GR702	**IIS inventory management functionality should support accountability at the dose/lot number level** IIS inventory management functionality should support accountability at the dose/lot number level, but aggregate reporters (Provider Organizations) will have to be accommodated during the phase-in of accountability at the dose/lot number level for all Provider Organizations.	• See principle P702 and associated business rules • State/event model references: EV05-08, EV12-14 • Definition of an aggregate reporter: A Provider Organization that does not report administered immunizations in the IIS in such a way that it decrements from the inventory. • Reasons for aggregate reporters (Provider Organizations): EHRs that do not support inventory functionality at the dose level, or no EHRs, or no Internet. • Even though this document focuses on publicly-funded inventory, the inventory management functionality should be available for privately-purchased inventory as well. See GR721.
GR703	**IIS should utilize 5-4-2 format for NDC** IIS should utilize 5-4-2 format for NDC	• VTrckS inventory files require 5-4-2 format • EHR implementations may use other formats and IIS should have the ability to display/communicate NDC in the standard 5-4-2 format.
GR704	**IIS should support corrections to existing inventory transactions** IIS should support corrections to existing inventory transactions at the	• Depending on transaction type, corrections could include: o Edit with history of changes o Creation of offsetting/corrective transactions • State/event model references: EV10

ID	General Recommendation Statement	Notes
	o Dose level o Lot level o Patient level	
GR705	**IIS should reflect transfers of vaccines** IIS should reflect the transfer and receipt of vaccines between Provider Organizations.	• See GR707, BR714, BR713, State/Event model (ST02, ST09, EV02, EV04, EV15, EV16), reports 1.2, 2.3 • State/event model references: EV02, EV04, EV15, EV16
GR706	**IIS should be able to record both the original and short-dated expiration dates** IIS should be able to record both the original and short-dated lot number expiration dates for some or all of the remaining doses within the lot number	• See BR712
GR707	**Receipt of orders should be reflected based on physical receipt of the shipment** IIS should reflect the receipt of orders in the receiving Provider Organization's inventory based on physical receipt of the shipment.	• See GR705, BR714, BR713, State/Event model (ST02, ST09, EV02, EV04, EV15, EV16), reports 1.2, 2.3 • Vaccine should not be added to the Provider Organization's available inventory until it has been physically received at the location.
GR708	**Functionality to adjust inventory based on the quantity of accepted and rejected vaccine doses in the shipment** The IIS should support functionality to ensure that inventory can be adjusted based on the quantity of accepted and rejected vaccine doses in the shipment	• The IIS may include a reason code for returned vaccine. o Wrong or damaged shipment received: Cracked vial, discoloration/ particulate in solution, incorrect number of doses shipped, etc. • See P704, P705, P703, BR715, BR708, BR716. • State/event model references: EV10.

ID	General Recommendation Statement	Notes
	(when a part of the shipment is accepted or rejected).	
GR709	**IIS should follow MIROW Data quality guidelines.** IIS should follow MIROW Data Quality Assurance in Immunization Information Systems: Incoming Data guidelines.	• See [1.3] – MIROW data quality guideline • Accessing previous MIROW Guidelines will help with electronic submissions for immunization entry. • Guidelines are helpful in standardizing the information necessary to receive a message from an electronic source with the Provider Organization who wishes to engage decrementing lot number from EHR
GR710	**Minimize manual inventory data entry** Manual data entry should be minimized and manual entry of inventory data that is already known should be avoided.	• The general recommendation is to populate inventory data in the IIS from electronic files. However, the IIS should allow for manual entry of inventory data when an electronic file is not available in a timely manner or in cases when quality of the data in the electronic file is poor as judged by the Grantee Vaccine Program. Examples are: o In the rare case where a shipment arrives before the shipment information is available in the IIS, it may be appropriate for the Provider Organization to delay accepting receipt of the shipment in the IIS for up to 24 hours o If the Provider Organization is required to enter inventory information manually, the information must be collected according to BR709. o Regardless of the method of entry, NDC Number must be associated with all public lots in inventory. • State/event model references: EV01
GR711	**Validate data at the time of recording and periodically** The Provider Organization and IIS should validate inventory management information • At the time of recording, to ensure most complete and accurate data.	• For electronic entry, this may be implemented via application logic (e.g. required fields, call out common mistakes, etc.). • This helps decrease the problems found in data quality aggregate reports (e.g. report of Vaccines shipped to Provider Organization versus Vaccines administered by Provider Organization, doses administered out of age range). • Potential validation: o Ensure Lot Number is for VFC (in cases where a clear distinction between lot

ID	General Recommendation Statement	Notes
	• By routinely running reports to proactively ensure they have produced the appropriate information (e.g., monthly).	numbers for public and private stock, as well as between various public funding sources can be made). ➢ See BR110, BR116 from MIROW Data Quality Assurance guidelines [1.2, pp. 38, 40]. o NDC points to a Vaccine Type, so it can be used to validate eligibility of a Vaccine to be administered under a program. o VFC-funded Vaccines should have NDC associated with the VFC contract. o Note that NDC and lot numbers are duplicated in both VFC Vaccines and in privately purchased Vaccines. This duality increases the opportunity for error. • Reference BR704, BR701, BR702, BR705, BR706, BR723, BR722, BR721, BR717, BR708, BR718, as well as all State and Event rules.
GR712	**Validate individual and aggregated data** The IIS application should have functionality to validate inventory management data for individual transactions, as well as aggregated information for a Provider Organization and for selected subsets of Provider Organizations.	• Analysis of submitted data can be used to identify poor reporters and develop appropriate interventions. o If VFC Provider Organizations have no VFC Vaccines administered. o If doses reported from VFC Provider Organizations are missing eligibility information. • Data can be validated at either point of entry (for instance, rejecting a record that is missing a lot number) and/or retrospectively (for instance, ensuring that the anticipated Provider Profile ratios of VFC versus non-VFC vaccine are submitted) • Reference P703, BR709 – BR714.
GR713	**IIS should have functionality that prevents duplicate lot numbers** IIS should have functionality that prevents duplicate lot number for two different vaccine types.	• IIS should have a validation to prevent the same lot number from being associated with two or more vaccine types. The same lot numbers for different vaccine types are usually indicate a manual entry error. This type of validation would require more QA to determine how to proceed. • Note that duplicate lot numbers can also exist for the same vaccine type. Examples to consider: o Replacing borrowed or wasted doses. Take a dose from one inventory and put a few doses that need replacing in the other inventory. This results in the same lot number in both inventories (public and private)

ID	General Recommendation Statement	Notes
		○ Short dated lot numbers, e.g., because some doses may have been exposed to temperatures out of acceptable range. Now you have two inventory items with the same lot number, but they have different expiration dates. • Value added with implementation of this business rule: ○ Minimizes data quality issues (i.e., typographical errors). ○ Reduces providers' entry of lot numbers when using a master table.
GR714	**Establish QA process for data from non-IIS systems** QA process should be in place to assure that information that has been provided as compiled by non-IIS systems is accurate	• This should be a collaborative effort between IIS Program, the Provider Organizations community, and the IIS and EHR vendor community. • Example: practice management systems are operated based on CPT codes. This information should be cross-checked with IIS information. • The QA process would be more extensive by examining the accuracy of data at all points: Point of care, initial recording (paper or digital into third party electronic data source), validation at each point of data transformation/mapping in the third party data source, data extraction to send to the IIS, data messaging to the IIS, data import into the IIS.
GR715	**IIS should test all aspects of the inventory management-related functionality** IIS should test all aspects of the inventory management-related functionality regularly and in response to any system change (e.g., with new product releases).	• Testing - how the changes in the inventory management functionality affects other IIS functions. • Any upgrade or enhancement requires regression testing of the system prior to release to ensure functionality has not been affected adversely.
GR716	**Data quality assurance measures for vaccine shipments** For vaccine shipments (from any shipping entity)	• This general recommendation applies to the following: ○ Regular shipments (from a distributor [currently McKesson]). ○ Direct shipments (from manufacturers). ○ Shipments of publicly-funded and privately-purchased vaccines.

ID	General Recommendation Statement	Notes
	data quality assurance measures should be implemented at: 1) Distributor – to minimize manual lot number entry errors; 2) IIS – to ensure that the lot number is associated with one and only one NDC (associating the same lot number with more than one NDC should be prevented) 3) Provider Organization • If vaccine shipment information is received through the IIS, then actual lot numbers for vaccines in the shipment should be validated and then problems should be manually fixed. For example: o Delete/inactivate inventory with incorrect lot number and re-enter it with the correct lot number. o Edit the lot number and correct any errors prior to lot number being attached at the dose level. • If vaccine shipment information is received from a different source than the IIS, then the data should be loaded manually as appropriate. Actual lot numbers for vaccines in the shipment should be validated and then problems fixed manually.	• See "NDC Considerations" chapter. • See BR701, BR702, BR710, P703, P708. • State/event model references: EV01, EV10.
GR717	**Data quality assurance metrics** Data quality assurance metrics (as determined by CDC and grantee Vaccine Programs) should be	• See "NDC Considerations" chapter. • See P703, BR710. • This would also help to measure performance of manufacturers when they begin to provide electronic files.

ID	General Recommendation Statement	Notes
	utilized to measure and track data quality from any shipping entity, including a centralized distributor (currently McKesson) ─ e.g., entering lot numbers and other data items. These metrics should be used to improve data quality from any shipping entity.	• State/event model references: EV01, EV10.
GR718	**Access to reports** IIS reports that are limited to data from a single Provider Organization can be either • "Pulled" ─ generated in IIS by the Provider Organization, IIS, or Grantee Vaccine Program, or • "Pushed" ─ generated in IIS by IIS or Grantee Vaccine Program and sent to a Provider Organization. Reports that include information from multiple Provider Organizations can be generated only by the IIS and/or the Grantee Vaccine Program.	• This relates to IIS functionality that facilitates responsibility for and access to the information. • Provider Organizations can run reports for data that is within their scope of access as defined by the user's role and privileges.
GR719	**Use IIS reports to analyze Providers' practices** IIS application should have reports available to support detailed analysis by the Vaccine Program of a Provider Organization practices. For example: • No inventory vaccine report (1.1). • Pending inventory/transfers (1.2). • Vaccine loss (1.5) – specifically for review of waste. • Borrowed/replaced report (2.1).	• Refer to chapter 6 IIS Reports.

ID	General Recommendation Statement	Notes
GR720	**Generate aggregated reports from IIS** Aggregated reports that support the Vaccine Program should be generated from the IIS application (as compared to reports that aggregate information directly reported from the Provider Organization to the Vaccine Program).	• Good Practice: Generate the majority of aggregated reports from the IIS (with a limited number of reports directly from the Provider Organization to the Vaccine Program). • Completeness of reporting from all Provider Organizations is crucial to enable IIS support of Vaccine Programs and Provider Organizations with quality data for aggregated reporting purposes. Not every Provider Organization may report regularly or completely to the IIS. • Refer to chapter 6 IIS Reports.
GR721	**IIS inventory management functionality should be available for non-VFC Provider Organizations** IIS inventory management functionality should be available for non-VFC Provider Organizations.	• IIS inventory management functionality could help to encourage a Provider Organization not previously interested in using the IIS to become an active participant.
GR722	**IIS should produce materials demonstrating the value of inventory management to Provider Organizations** IIS should produce materials demonstrating the value of inventory management to Provider Organizations	• Provider Organizations will be able print out reports electronically that otherwise they would have to do manually. • Provider Organizations will eventually go paperless. • Allow to see what happens with Provider Organizations vaccines more clearly. • Allow to keep track of the inventory of privately-purchased vaccines in IIS. • May be helpful to implement better QA in the office.
GR723	**Multiple training options should be offered to Provider Organizations for inventory management** Multiple training options should be offered to Provider Organizations in order to support learning	• Several training options should be made available to accommodate various learning styles (e.g., group or individual training sessions, on-line or in-person, as well as self-paced on-line tutorial, CD, Webcasts, person-to-person [regional and local], and Help Desk). • Training materials should include all inclusive manuals, one or two-page training tip sheets, on-line training vignettes.

ID	General Recommendation Statement	Notes
	and incorporating inventory management through IIS.	• Having the Grantee's Vaccine Program heavily involved in any implementation, training, etc. is critical for the inventory management functionality in the IIS to be successful.

Chapter 6: Recommendations for IIS Reports

This chapter contains descriptions of recommended inventory-related reports that IIS produces to support needs of Provider Organizations and Vaccine Programs of CDC grantees.

The focus is on conceptual reports. In the actual IIS implementations, multiple conceptual reports could be covered by one implemented report. It was important for the group to focus first on the purpose of the conceptual report, then the target audiences (primary target audience and additional audience), key data elements and other value-add features (e.g., highlighting of out of threshold line items) to support the original purpose of the report most effectively. The ultimate goal is to create reports which better enable the work performed rather than reports which simply provide the data being stored.

The following recommendations apply to all types of IIS Inventory-related reports:

- Formatting of reports should be used to call attention to significant elements on reports. For example:
  - Highlighting expiration date.
  - Varied shading of public versus private.
  - Sort order.
- IIS should produce all reports in print out format (PDF) and data format (Excel)
- All report filters should be shown in headers/title
- All reports should show date run
- All data elements should be displayed on the report even if blank
- Provider organizations should only see their own data, except for umbrella organizations.

The nomenclature of recommended reports is presented in **Table 8** below. The reports are classified in the following categories:

- Accountability reports to support inventory management (for purposes other than ordering and reconciliation).
  - 1.1 No Inventory Vaccine (report of vaccination entries that do not decrement inventory).
  - 1.2 Pending Transfers.
  - 1.3 Inventory Last Balanced/Reconciled Dates. Last inventory balance/reconciliation dates by Jurisdiction and inventory type.
  - 1.4 Non-Reported Doses Administered (ability to track “reallocated” doses from IIS due to adoptions and opt-outs).
  - 1.5 Vaccine Loss. % Vaccine Loss (based on total doses ordered).
  - 1.6 Cost Report (value of inventory distributed).
- Reconciliation reports.
  - 2.1 Borrowed/Replaced Report.
  - 2.2 Inventory Transaction History by Lot Number. Inventory Transaction Detail Report.
  - 2.3 Inventory Transfer Report (report of transfers).
  - 2.4 Loss/Wasted Report.

- Accountability reports for ordering (reports that support the ordering process).
  - 3.1 Physical Inventory (physical inventory on hand).
  - 3.2 Ending Inventory Transactions Summary (summary of transactions by lot ─ monthly inventory report).
  - 3.3 Provider Order Status (report of orders submitted by Provider Organizations).
  - 3.4 VTrckS Order Status (report of orders submitted to VTrckS compared to shipments).
  - 3.5 Pending Shipments (vaccine shipped but not yet accepted).
  - 3.6 Shipped Vaccine Usage (doses distributed versus reported).
- Allocation reports (i.e., to allocate vaccines during shortages, to issue a recall based on lot numbers). Describe where vaccines are versus where vaccines need to go.
  - 4.1 Soon to Expire Vaccine Report.
  - 4.2 Vaccine Lot Recall Site Report. Vaccine Lot Recall Where On-Hand.
  - 4.3 Vaccine Lot Recall Patient Report.
  - 4.4 Lot Number Allocation (report to help deal with allocations during shortages).

Several report types are out of scope for this topic (for example, Provider Profile Report).

Table 8. IIS Inventory-Related Reports

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
1	**Accountability reports to support inventory management (for purposes other than ordering and reconciliation)**			
1.1	**No Inventory Vaccine** User vaccination details report. Report of vaccination entries that do not decrement inventory. • To identify vaccines that should have had an impact on the inventory, but did not for various reasons (e.g., administered vaccinations that were entered as historical). • When possible, identify a person within Provider Organization responsible for erroneous entries.	• IIS Program • Provider Organization	Key Data Elements: • Provider Organization ID • Updating user ID (where available) • Date • Patient ID • Vaccine Trade Name • Vaccine Date • Patient Eligibility • Explanation of the administration error • Public/Private Inventory Indicator Major Filters: • Timeframe • Provider Organization • ID of Provider Organization or updating user (where available) Value Added: • Identify users that require re-training • Incorrectly administered vaccinations that need to be corrected o Historical that should be administered o Administered after inventory has been balanced/reconciled o Off-label administrations o Administration of vaccine that is not expected to be in inventory (i.e. PCV7 rather than PCV13) • Identify EHRs with the incorrect configuration (e.g., on CPT,	• Report will be more accurate if users can be accurately identified – where IIS functionality makes such identification available. This is about reporter, not administrator.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
			CVX codes)	
1.2	**Pending Transfers** Purpose is to see if all the transfers have been completed, if there are any problems with the transfers	• Provider Organization • Vaccine Program • IIS	Key Data Elements: • Provider Organization sending transferred vaccines • VFC PIN (and/or IIS ID) for Provider Organization sending transferred vaccines • Provider Organization receiving transferred vaccines • VFC PIN (and/or IIS ID) for Provider Organization receiving transferred vaccines • Vaccine Type • Lot Number • Lot Number Expiration Date (optional) • Number of doses • Date sent • Transfer status (i.e., transferred or in-transit) • Public/Private Inventory Indicator Major Filters: • By time frame • Date sent • By Vaccine Type • By Provider Organization(by VFC PIN and/or IIS ID) • By Jurisdiction(s) • By Lot Number Value Added: • Number of transfers not completed within a specific timeframe (e.g., 48 hours) • Number of transfers pending by VFC PIN and/or IIS ID.	• Assumption is that all transfers are done through the IIS. • Assumption is that we have the VFC PIN (or IIS ID) of both the sender and receiver of the transfer.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
1.3	**Inventory Last Balanced/Reconciled Dates** Last inventory balance/reconciliation dates by Jurisdiction and inventory type	• Vaccine Program	Key Data Elements: • Date • VFC PIN (or IIS ID) • Provider Organization Name • Provider Organization Phone Number • Date last balanced/reconciled by inventory type/funding type (i.e., public/private [one column for each type]) Major Filters: • Jurisdiction • Inventory Type funding type (i.e. public/private) • Inventory Status (determined based on lot numbers that are active – means that doses are available and not past the expiration date, and lot numbers that are inactive – means that no doses available or past the expiration date) • Timeframe (e.g., over the last three-month, or six-month, or twelve-month period) Value Added: • Monitor compliance with ordering schedule • Identify potential training needs	• This report shows information on the VFC Provider Organizations with active inventory and last date when inventory has been reconciled. • Lot numbers are not shown in this report (see report 3.2 for that). • Not all IIS may have a date stamp as required by this report. • This report can be used to find a pattern over time between ordering and reconciliations and to identify training needs
1.4	**Non-Reported Doses Administered** Ability to track doses at the Provider Organization level that are not captured at the	• Provider Organization • Vaccine Program	Key Data Elements: • Provider Organization (VFC PIN and/or IIS ID) • Vaccine Type • Quantity of Doses which were used but not located at patient level. • Vaccine Lot Number • Vaccination date	• This report is to assist Provider Organizations to better track their lot numbers and make changes appropriately to each vaccine lot number.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
	patient level due to opting out/blocked or patient adoption (e.g., to support providers that do not know that an adoption has occurred or a patient has been blocked/opted out). Note: In some IIS the processing of adopting records differs and this may not be applicable.		• Number of Blocked/Opt Out patients • Number of Adopted patients. <u>Major Filters:</u> • Time Frame • Vaccine Type • Provider Organization (VFC PIN and/or Facility ID) • Lot Number <u>Value Added:</u> • To aggregate by Lot Number and Vaccine Type the number of vaccines that were not attributed at the patient level. These totals would then be used to reconcile their lot numbers accordingly.	• Note: This report can be used as an adjunct to the reconciliation report in assisting the clean-up of the physical inventory to the IIS inventory. • Get a report of the number of Vaccine Types/Lot Numbers that were given but not entered into the IIS due to opted out or blocked records.
1.5	**Vaccine Loss** Percentage of vaccine loss (based on total doses ordered). Identifying the highest areas of vaccine loss based on total doses ordered versus total doses administered/accounted for at the Provider Organization/ county/jurisdiction level.	• Vaccine Program • Provider Organization	<u>Key Data Elements:</u> • Vaccine Type • Lot Number • Provider Organization VFC PIN and /or IIS ID • Doses Ordered • Doses Administered • Doses Received • Doses Transferred Out • Doses wasted (any of State Diagram Options) <u>Major Filters:</u> • Vaccine Type • Lot Number • Provider Organization VFC PIN and /or IIS ID • Time Frame	• This should be run after reconciliation of lot numbers.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
	Addresses the requirement that "Vaccine loss and waste should be minimized and measured" from [2.13] IPOM: Immunization Program Operations Manual, Chapter 2 http://www.cdc.gov/vaccines/vac-gen/policies/ipom/.		• County/Jurisdiction Value Added: • Identify Provider Organizations that have a dose difference of more than a certain percentage (i.e., 5%). • Identify counties/jurisdictions that have a dose difference of more than a certain percentage (i.e., 5%).	
1.6	**Cost Report** Value of inventory distributed (to support QA visits and promote value of program or cost/impact of wasted vaccine).	• Provider Organization • Vaccine Program	Key Data Elements: • Provider Organization • Vaccine Type • NDC • Number of Doses • Cost per dose • Cost per vaccine type • Lot Number Expiration Date Filters: • By Time frame of vaccine receipt or entry • By Time frame of expiration date • By Provider Organization • By Order Number • By Vaccine Type	• Cost of vaccines should be updated in a timely manner. • Should be calculated on cost per dose at the time of the vaccine shipment.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
			Value Added: • Aggregate vaccine cost per time frame of vaccine receipt or entry • Aggregate vaccine cost per vaccine type • Aggregate vaccine cost per NDC • Aggregate vaccine cost of vaccines due to expire in the next 30/60/90 days.	
2	**Reconciliation reports** (see also report 3.1 Physical Inventory)			
2.1	**Borrowed/Replaced Report** Purpose: • Track loans/repayments within the same Provider Organization between private and public stocks. • Helps make sure that loans are repaid.	• Provider Organization • VFC Program	Key Data Elements (Line list style report): • Date of Loan/Repayment • Quantity on hand (doses) • Provider Organization • Vaccine Name • Lot Number/NDC • Public/Private Indicator • Number of borrowed/loaned • Identifier of the patient receiving the vaccine • Patient eligibility • Reason no appropriate stock vaccine was available • Total (for all lines) Major Filters: • Provider Organization • Jurisdiction • Date Range • Vaccine Name Value Added: • Ensure all borrowed stock is replaced in a timely manner	• This report can either be an aggregate report with total counts that are borrowed or a detail-level report showing where each vaccine dose went. • CDC borrowing form can be used as a paper-based back-up to this report 2.1. See the VFC Operations Guide, Module 3 – Provider Recruitment and Enrollment, pp. 17-18 at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/07-module-3.pdf.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
2.2	**Inventory Transaction History by Lot Number** Inventory Transaction Detail Report (at Provider Organization level, at program level, etc.) Purpose: • Records every event at every state for each lot number (i.e., line listing). • Ensures appropriate event categorization during use of inventory module. • Determines accountability. • QA use of inventory module, especially for unaccounted for vaccines.	• Provider Organization • Vaccine Program • IIS Program	Key Data Elements: • Provider Organization (for transfers, both sending/receiving organizations) • Date • Vaccine Type • NDC • Lot Number • Manufacturer • Lot Number Expiration Date • State (transaction type) • Number of doses • Order Number (if applicable for that state) • User • Tally of lost/wasted/borrowed (flag to indicate per transaction if this is a lost/waste/borrow event) Filters: • By timeframe • By Provider Organization • By Jurisdiction • Public versus Private (Public/Private Indicator) • Vaccine Type • NDC • Lot Number • Lot status • Manufacturer • By state	

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)

			Value Added:
			• Emphasize problem states designated by set thresholds specified by IIS or Vaccine Program.
			  o For example, Provider Organizations where number of event corrections/total number of events > threshold (e.g., 50%).
			  o For example, ratio of total number of doses for a state to corrected transactions > threshold.
			• Monitor Provider Organization reconciliations to ensure the integrity of the adjustment choices that the providers are making.
			• Investigate discrepancies when Provider Organizations are having difficulty balancing a particular lot number.	

2.3	**Inventory Transfer Report** Report of transfers (could be variation of 2.2 Inventory Transaction History by Lot Number report). Purpose: • Tracking total pending transfers to ensure completion of transfers.	• IIS Program • Provider Organization • Vaccine Program	Key Data Elements: • Provider Organization Transfer out ID • VFC ID for the Provider Organization transferring out • Provider Organization Transfer in ID • VFC ID for the Provider Organization transferring in • Vaccine Type • Lot Number • Lot Number Expiration Date (optional) • Supply State (off of the State/event diagram – Fig. 4) • Number of Doses • Cost per dose Filters: • By Time frame • By Provider Value Added: • Emphasize transfers which have been pending > threshold number of	• Once a transfer has been identified as failed or not complete, communication with the Provider Organizations involved may be needed. • Assumption: all transfers and their completion are tracked in IIS.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
			days. • Emphasize Provider Organizations that have total number of pending transfers > threshold. • Number of transfers sent that were not reported as received.	
2.4	**Loss/Wasted Report** Loss/Wasted report Purpose: • Provide greater detail on reasons for wasted and lost for oversight purposes. Addresses the requirement that "Vaccine loss and waste should be minimized and measured" from [2.13] IPOM: Immunization Program Operations Manual, Chapter 2 http://www.cdc.gov/vaccines/vac-gen/policies/ipom/.	• Vaccine Program • Provider Organization	Key Data Elements: • Type of non-viability o Spoilage o Lost/damaged in transit o Failure to store properly upon receipt o Refrigerator failure o Lost or unaccounted for o Other (e.g., drawn but not used, broken) o Expired • Date • Subtotal by o Non-viable/not returnable o Non-viable/returned o Unaccounted for (if this information is attainable) • Quantity (in doses) • Cost per Dose • Lot Number/NDC • Lot Number Expiration Date • Vaccine Type Filters: • By Time frame • By Provider Organization • By Vaccine Type • By type of non-viability (from the State Diagram)	• The type of non-viability may distill down to different viability options depending on state IIS and VFC structure (for example, wasted disposed, wasted returned, wasted expired).

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
			Value Added: • Aggregate cost of vaccine lost/wasted per vaccine type • Aggregate cost of vaccine lost/wasted – total	
3	**Accountability reports for ordering (reports that support the ordering process)**			
3.1	**Physical Inventory** Physical inventory on hand (Reconciliation Worksheet) Purpose: • Support Ordering. • Make it easier for a Provider Organization to compare its on hand count versus physical count. • May also be used to identify soon-to-expire vaccine. Possible usage: Provider takes this	• Provider Organization	Key Data Elements: Header • Date run • Provider Organization • Location/ Facility info (in the form of IIS ID) • Public/Private Indicator Output • Vaccine Type • Lot Number/NDC • Lot Number Expiration Date • On-hand Quantity (in doses) Default Sort order • Vaccine Type • Lot Number Expiration Date • Lot Number Value Added: • Option to allow the Provider Organization to print and enter actual	• If just for ordering, only public and active by definition. • Report automatically limits by provider based on who is looking at it. • Frequency – this report would be a useful tool to implement every time reconciliation involving counts of a physical inventory is conducted. • This report should contain data from IIS that should be compared with actual physical inventory. • Physical inventory report will be a first step in the balancing process and then lead to reconciliation of discrepancies and the

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
	worksheet, goes to a refrigerator, and populates a blank field with actual physical counts (at the lot level). This allows comparison of the pre-printed quantities with actual quantities.		inventory count on-line. • Subtotal the vaccine groups (for example, HPV, including doses from all lot numbers). • The format of the form is necessary to enhance the Provider Organization's ability to easily compare between its on hand count versus physical count.	inventories.
3.2	**Ending Inventory Transactions Summary** Summary of transactions by lot - monthly inventory report (transactions) – by vaccine type (started with x, received x, transferred x, ended with x). Needs to accommodate "aggregators." Purpose: • Inventory on-hand accountability (currently used from orders). • Monitor waste	• Provider Organization • VFC Vaccine Program: approving orders and referencing it for general accountability • Training/QA at grantee (both VFC/IIS)	<u>Key Data Elements:</u> Header • Report Name • Provider Organization Name • Report Period Ending Date • Date Run • Inventory Type (Public/Private Indicator) Output • Vaccine Type • NDC • Lot Number • Manufacturer • Lot Number Expiration Date • Provider Organization Name (optional, if not in header) • Public versus private (public/private indicator, optional, if not in header) • Beginning Inventory • Column for each state (e.g., shipped, administered, waste, etc.) o Bonus Doses	Examples would be: • Kansas – Monthly Inventory Report. • Washington – Lot Number Summary Report.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
	(identify waste problems; see Transaction Report for more detail). • Understand/justify on-hand inventory.		o Doses In (shipments and transfers received) o Doses Out (shipments returned and transfers out) o Administrations o Borrowed/replaced o Unusable/lost/wasted ▪ Disposed/returned/expired • Ending inventory/current on-hand <u>Major Filters:</u> • By Lot Number • Vaccine Type o Option to multi-select (if listed by specific vaccine rather than family) • Date Range (reporting period) • Provider Organization (hierarchy) • Public/private/all <u>Value Added – Report Features:</u> • Sort options o Vaccine Type o Lot Number o Expiration Date • Aggregation options o By Vaccine Type o By "child (Patient)" Provider Organization (Site, i.e., IIS ID) o By Month <u>Value Added – Report Uses:</u> • Monitor patterns such as borrowed/replaced and loss/waste to identify training needs	

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
3.3	**Provider Order Status** Report of orders submitted by Provider Organizations.	• Provider Organization • Vaccine Program	Key Data Elements: • Provider Organization • Time frame • Order number • Vaccine type • Quantity (number of doses) • Vaccine status (e.g., exception, backordered, cancelled/rejected) • Order status (e.g., order placed, order approved by grantee or grantee designee, cancelled, shipped, received/accepted/ completed) - to clarify Major Filters: • By timeframe • By Vaccine Type • By Provider Organization • By Jurisdiction(s) • By Order Status Value Added: • Orders where the order status has been "shipping" for more than an set time frame (e.g. 48 hours)	• Location of orders: Order status can be used here (e.g., received, accepted, exception, backordered, cancelled, completed). • Ordering status types may differ by grantee.
3.4	**VTrckS Order Status** Report of orders submitted to VTrckS compared to shipments.	• Vaccine Program	Key Data Elements: • Provider Organization VFC PIN and Name • Date ordered • Date shipped • Vaccine Type	

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
			• Lot Number • Quantity (number of doses ordered) • Number of doses approved (by state/local jurisdiction) • Quantity (number of doses shipped by VTrckS/McKesson) Filters: • By time frame • By Vaccine Type • By Provider Organization • By Jurisdiction Value Added: • Highlight/special indicator for rows where ordered/approved/shipped do not match. • Ability to filter to include only orders where shipment does not match order quantities.	
3.5	**Pending Shipments** Vaccine shipped but not yet accepted. Purpose: • To ensure completion of shipments/ receipt of vaccine.	• Provider Organization • Vaccine Program	Key Data Elements: • Date ordered • Date shipped • Lot Number • Quantity (number of doses) • Vaccine Type • Provider Organization VFC PIN and/or IIS ID, Name • Shipment ID • Shipment Type (i.e., regular shipment, direct shipment) Filters: • By time frame • By Vaccine Type	• Displays only orders shipped (for publicly-funded vaccines - by McKesson or Merck) that have not yet been received into inventory by the Provider Organization.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
			• By Provider Organization • By Jurisdiction <u>Value Added:</u> • Emphasize timeframe from shipped date by Provider Organization that hasn't completed transaction > threshold. • Provider Organizations that have open shipments (not completed) > threshold. • Alerts to remind Provider Organizations that shipments are pending receipt. • Optional sorts by VFC PIN, vaccine, date.	
3.6	**Shipped Vaccine Usage** Doses distributed versus reported. Purpose: ▪ To ensure vaccine reporting matches distribution for accountability. ▪ To ensure what is being ordered matches what is needed for vaccine administration. ▪ To increase	• Provider Organization • Vaccine Program for accountability • IIS for participation	<u>Key Data Elements:</u> • Doses shipped • Doses administered with a lot number • Doses administered without a lot number • Doses on hand (at beginning of filtered time frame) • Doses wasted (nonviable/not returnable) • Doses spoiled/expired (nonviable/returnable) • Doses over-estimated (10-dose vial actually contains 9-doses. Could be manufacturer issue, could be provider's technique) • Doses returned (returned shipment) • Doses transferred out, including in-transit doses • Doses unaccounted for • Total doses received – doses reported • Vaccine type (summary or detail) • Lot number (summary or detail)	• On demand References: • See New York City paper [4.2], Selected References section of this document.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
	reporting to the IIS.		Major Filters: • By time frame • By Vaccine Type • By Provider Organization • By Jurisdiction(s) • By private vs. public supply source (public/private indicator) • By Provider Organization type (e.g., local health provider organization) Value Added: • Provider Organizations that have a quantity of doses shipped that is some percentage larger than doses reported.	
4	**Allocation reports (i.e., to allocate vaccines during shortages, to issue a recall based on lot numbers). Describe where vaccines are versus where vaccines need to go**			
4.1	**Soon to Expire Vaccine Report** Soon to expire vaccine report. Purpose: • To minimize the amount of vaccine that expires prior to administration. • To prevent expired vaccine from being administered.	• Vaccine Program • Provider Organization	Key Data Elements: • Lot Number • NDC • Vaccine Type/ Trade Name • VFC PIN (or IIS ID) • Expiration date • Public/private indicator • Quantity on hand (in doses) • Provider Organization (VFC PIN and/or IIS ID) Major Filters: • Expiration date range • Vaccine Type/ Trade Name • Public/private indicator	• On demand and periodically. • No less than once during reconciliation. • Report generation from the IIS to forecast 90 days out.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
	• To provide ability to reallocate vaccine due to expiration date.		• Provider Organization (VFC PIN and/or IIS ID)	
4.2	**Vaccine Lot Recall Site Report** Vaccine Lot Recall Where On-hand Purpose: • To identify Provider Organizations that have a specific lot number. • In order to follow-up with providers and give guidance.	• Vaccine Program • Provider Organization	Key Data Elements • Lot number • Vaccine type • Provider Organization (VFC PIN and/or IIS ID) • Public/Private Indicator • Quantity on hand (doses) Major filters • Lot number(s) • Provider Organization (VFC PIN and/or IIS ID) • County/zip code/ jurisdiction	• Frequency – when a lot has been recalled o Voluntary o Mandatory o Cold Chain Failure
4.3	**Vaccine Lot Recall Patient Report** Vaccine Lot Recall – to identify patients who have received a specific lot number. Purpose: • To follow up with patients or for other reasons, e.g., for	• Vaccine Program • Provider Organization	<u>Key Data Elements:</u> • Lot Number • Patient information (for mailing labels or phone calls) • IIS ID • Immunization data o Date o Type o Administering facility o Provider Organization (VFC PIN and/or IIS ID) <u>Major filters:</u> • Lot number(s) – active, inactive, and expired • Provider Organization (VFC PIN and/or IIS ID)/ practice	• Frequency – on demand.

#	Report Name and Purpose	Target Audience	Key Data Elements, Major Filters, Value Added	Remarks (e.g., frequency/timing)
	practices that either had or still have a recalled product.		• Immunization date range • County/zip code/ jurisdiction	
4.4	**Lot Number Allocation** Report to help deal with allocations during shortages (e.g., to know who's hoarding, how to move around) – state-wide view. Purpose: • To ensure ability of Vaccine Program to allocate/reallocate vaccine to those in need. Guiding Value/Principle: • Ensure appropriately dispersed.	• Vaccine Program	<u>Key Data Elements:</u> • Doses on hand • By Provider Organization (VFC PIN/IIS ID) • Estimated doses to be administered by time frame • Vaccine Type • Public versus private (Public/Private Indicator) • Lot Number <u>Filters:</u> • Time frame • By Grantee • By Jurisdiction • Public vs. private (Public/Private Indicator) • Lot Number <u>Value Added – Emphasize:</u> • Pocket of need areas to target allocation distribution • Provider Organization that has a certain number of doses by vaccine type > threshold. • Provider Organization that has a certain number of doses by vaccine type < threshold.	• Private reallocation would be voluntary. • May fall into repayment arena.

Chapter 7: NDC Considerations

In accordance with VFC program and VTrckS system requirements, vaccine inventory must be reported based on the National Drug Code (NDC).

Background

This topic involves two areas of IIS functionality ─ inventory tracking and immunization tracking:

- Inventory tracking is based on the VFC/VTrckS requirements. Key data elements for the inventory tracking are NDC, Lot Number, and Lot Number Expiration Date. NDC is not included in the IIS/NVAC core data set http://www.cdc.gov/vaccines/programs/iis/stds/coredata.htm.
- Immunization tracking (i.e., tracking of vaccines administration) is based on the IIS/NVAC core data elements. Key data elements for immunization tracking are Vaccine Type (CVX code), Manufacturer (MVX code), Lot Number, Lot Number Expiration Date, and Trade Name.
  - Trade Name is not included in the IIS/NVAC core data set, but may be deduced based on a combination of CVX/MVX codes.
  - Although CVX is the preferred code set, the CPT is still an acceptable (but less reliable for immunization tracking purposes) code set. Mapping of some CPT codes to CVX codes can be found at http://www2a.cdc.gov/vaccines/IIS/IISStandards/vaccines.asp?rpt=cpt

In accordance with VFC program and VTrckS system requirements, vaccine inventory must be reported based on the NDC. However, when a Provider Organization administers a vaccine to a patient, it typically does not capture the NDC directly (with the exception of some pharmacy chains, which report administered immunizations using the NDC code set). Therefore, data items recorded for immunization tracking purposes should be mapped and converted to the respective NDC in order to be used for inventory tracking purposes (this should be done by the IIS in the background); or, alternatively, the NDC should be documented directly during vaccine administration.

A note regarding NDC data accessibility, from the Vaccine Identification Standards Initiative (VISI) at http://wiki.medpedia.com/Vaccine_Identification_Standards_Initiative_VISI: "The main obstacle to the use of the NDC within the scope of the VISI was the lack of an authoritative, universally accessible, free of charge, easy to use, up-to-date database linking NDC numbers to the corresponding manufacturer, product identity, and other information (and vice versa). Such a database would have been helpful for developers of software programs for medical practice record-keeping and billing, and for immunization registries. Such software will require "lookup tables" to translate NDC numbers received from barcode scanners into their plain-English screen identities and HL7 codes, CPT codes, and perhaps other code sets."

Definition

As defined in the domain model (see Appendix A), National Drug Code (NDC) is a unique numeric identifier of the Vaccine Product Type. NDC has three segments to identify the labeler,

product, and trade package size:

- The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including re-packers or re-labelers), or distributes (under its own name) the vaccine.
- The second segment, the product code, is assigned by a manufacturer. It identifies a specific strength, dosage form, and formulation of a vaccine for a particular firm.
- The third segment, the package code, is assigned by a manufacturer. It identifies package sizes and types (also known as "presentation").

The federal VFC program and VTrckS management system use 5-4-2 format for NDC identifiers (i.e., five digits for the first segment, four digits for the second segment, and two digits for the third segment). Other formats for NDC codes exist (e.g., 4-4-2, 5-3-2, or 5-4-1) and should be accounted for (need to be translated to the 5-4-2 format). In some cases there are "fillers", such as an asterisk (*), or leading zeros (0s) used within the 5-4-2 characters string, most often – in the second segment. CDC pads NDCs with leading zeros which results in an 11-digit NDC in the 5-4-2 format. Reference the following web site for a discussion of these issues: http://www.rxkinetics.com/code128.html.

One vaccine type from a particular manufacturer may have multiple NDCs because its product code (second NDC segment) differs for various pediatric and adult formulations (also known as "intention"), and its package code (third NDC segment) distinguishes single-dose, multi-dose, 10-pack of single doses, prefilled syringes, and other presentations (see comment for BR711 for handling half and double doses when vaccine has not been used in accordance with the "intention").

Specific examples of NDC identifiers can be found at (these lists include information for publicly-funded and privately-purchased vaccines):

- CDC Vaccine Price List: http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm.
- National Drug Code Directory: http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm.
- HL7 Standard Code Set. Mapping NDC to CVX and MVX: http://www2a.cdc.gov/vaccines/IIS/IISStandards/vaccines.asp?rpt=ndc.

Approaches to getting the NDC for an administered dose of vaccine (applied to publicly-funded and privately-purchased vaccines):
Possible approaches to get NDC for a vaccine dose administered include:

1. Find the NDC based on the vaccine Lot Number
   - This approach represents the recommended best practice and is discussed in subsequent sections of this chapter.
   - A Lot Number is linked to an NDC at the point in time when a shipment is received. This link can be tracked again from Lot Number to NDC at the point in time when a vaccine is administered.
   - NDC identifies a Vaccine Product Type; Lot Number identifies a Vaccine (a specific instance of a Vaccine Product Type [refer to the domain model in Appendix A for a discussion]). The lot number provides a basis for the most logical and direct mapping to the NDC (thereby mapping from an instance of a product to a product type).

- See the discussion below regarding situations (rare exceptions) when the lot number maps to more than one NDC.

2. Find the NDC based on the CVX/MVX pair, plus "presentation" (i.e., package sizes and types) and "intention" (i.e., adult or pediatric use).
   - This approach would be sufficient to provide a mapping to the NDC in most situations, but it cannot be recommended since it does not involve the use of a lot number for mapping (**refer to assumptions below)**. The MIROW panel of experts believes that any NDC mapping approach that does not use the lot number cannot be recommended as a best practice.
   - The lot number must be captured for every administered dose of vaccine (see Dose-Lot Number accountability principle P702).
3. Record the NDC directly during vaccine administration in addition to the lot number and lot number expiration date. CVX and MVX link should occur in the IIS background.
   - It is not suggested as a best practice to task Provider Organizations to manually capture additional data items (such as NDC) for vaccine doses administered. However, this approach can be realized today with existing technologies, as well as through using scanned or uploaded data.
   - It is not sufficient to capture NDC without the lot number. For example, the lot number is needed for recall purposes.

Assumptions

The following assumptions represent logical common-sense requirements for the inventory management functional area. These assumptions proved to be correct in a vast majority of real-life situations. However, human error can upset the expected logic. First, we have listed a set of assumptions. A discussion and recommendations of how to address exceptions follows.

1. A single lot number is associated with one NDC
   - The logic behind this assumption is that each instance of a product belongs to one and only one product type (refer to a domain model, Appendix A, for a discussion). NDC identifies a Vaccine Product Type; Lot Number identifies a Vaccine (a specific instance of a Vaccine Product Type). Therefore, Lot Number should be associated with one and only one NDC.

2. No two vaccine manufacturers have the same lot number. (While they do not consciously try to prevent this, in practice it would be a very rare event).
   - This is how it should be to enable a proper lot number to NDC mapping.

3. A lot number is unique to a presentation for a vaccine.
   - In other words, for a given Vaccine Product Type (NDC), specific Vaccines packaged as a single-dose, multi-dose, and prefilled syringes, each will have different and unique lot numbers.

Examples of violations of assumptions 2 and 3 usually reflect data quality issues (data entry).

How to address issues and exceptions

- The NDC label for the contents of a box (i.e., for the dose unit container, such as a vaccine vial or syringe) can be different from the NDC label on the outside of the box (or secondary package). The recommended best practice (see business rule BR701) is to use the NDC on

the outside of the box for inventory control purposes. This assures that the lot number still will be associated with one single NDC.

- Products with diluents or components that must be combined together may have their own NDC numbers (e.g., Pentacel -multiple NDCs are used, one for powder and one for liquid). The important issue regarding any vaccine with multiple NDCs for different pieces or components is that the only NDC that can be used to place an order, to report inventory, or to submit vaccine returns is the one on the CDC contract. NDC indicated by vaccine manufacturer in the package insert can be used; this NDC must indicate a complete vaccine once all components are combined.
- Centralized distributor staff (currently McKesson) can sometimes make errors that result in incorrect lot number data in the system. So, despite efforts to assign unique lot numbers by manufacturer and by vaccine product type, there is always the potential for human error. Employing certain quality control measures can help to address this problem (see general recommendations GR716 and GR717):

  GR716: For vaccine shipments (from any shipping entity) data quality assurance measures should be implemented at:
  1) Distributor – to minimize manual lot number entry errors;
  2) IIS – to ensure that the lot number is associated with one and only one NDC (associating the same lot number with more than one NDC should be prevented);
  3) Provider Organization.
  If vaccine shipment information is received through the IIS, then actual lot numbers for vaccines in the shipment should be validated and then problems should be manually fixed. For example:
  - Delete/inactivate inventory with incorrect lot number and re-enter it with the correct lot number.
  - Edit the lot number and correct any errors prior to lot number being attached at the dose level.

  If vaccine shipment information is received from a different source than the IIS, then the data should be loaded manually as appropriate. Actual lot numbers for vaccines in the shipment should be validated and then problems fixed manually.
  GR717: Data quality assurance metrics (as determined by CDC and grantee Vaccine Programs) should be utilized to measure and track data quality from any shipping entity, including a centralized distributor (currently McKesson) ─ e.g., entering lot numbers and other data items. These metrics should be used to improve data quality from any shipping entity.
- Lot number in most cases is uniquely mapped to an NDC, but in some cases knowing the lot number may only narrow the possible lot number/NDC association. At that point, the IIS should offer a choice to Grantee and Provider Organization staff in selecting NDC among a few candidates. Referencing NDC from a package insert can help in these situations.

Chapter 8: Borrowing Considerations

In this document borrowing issues are addressed in several places. The following principles (P), business rules (BR), and general recommendations (GR) address borrowing issues: P708, BR702, BR707, BR711, BR725, GR713, GR701, and GR719. Also, borrowing aspects are reflected in the state/event model (see ST01, ST03, ST10, ST11, EV18-20), use cases 1.3, 1.7, and reports 2.1, 2.2, 3.2. This chapter intends to summarize borrowing considerations concisely.

Borrowing between private and public vaccine stocks at a Provider Organization originates in following situations:

- Inventory shortages.
- Delays with outcomes of private insurance claims. This provides for situations when child who initially was perceived as having private insurance coverage for a Vaccine, actually does not have that coverage. As a result, borrowing occurs: a Vaccine from the private stock is used when, actually, a Vaccine from the public stock should have been used. In other words, child eligibility was private coverage (not VFC-eligible), but in fact, the child might be under-insured and, depending on a grantee program, might be eligible for a publicly-funded Vaccine.

Borrowing between private and public vaccine stocks at a Provider Organization should be done according with the VFC program guidelines and Grantee Vaccine Program policies. The VFC Operations Guide, Module 3, provides guidance on borrowing. The following is an excerpt: “At the grantee’s discretion, borrowing between the two inventories of vaccines may occur but must be a rare occurrence. Please note: for seasonal influenza vaccine, providers may use private stock seasonal influenza vaccine to vaccinate VFC eligible children if VFC seasonal influenza stock is not yet available. Those private stock doses used on VFC eligible children can later be replaced when VFC stock becomes available. This one-directional borrowing exception is unique to seasonal influenza vaccine. For all other vaccines, limited borrowing may occur bi-directionally. All borrowing, regardless of direction, must be documented on the VFC vaccine borrowing report located at the end of this module.” Note that grantees cannot always guarantee replacement for seasonal influenza vaccine based on the same type and brand, as well as replacement of vaccine borrowed at the end of the year.

- **Limited borrowing may occur bi-directionally**
- **All borrowed doses must be repaid**

IIS should have functionality in place to assist

- The Grantee Vaccine Program with monitoring of Vaccine borrowing between the public and private stocks, and
- Provider Organizations to meet reporting and accountability requirements for Vaccine borrowing and replacement.

Such functionality also would be helpful for monitoring and analyzing Provider Organization’s borrowing practices.

Case Study: Michigan IIS captures every borrowing of a dose from the public inventory. When Vaccine is shipped from McKesson, the inventory information is uploaded automatically into the Provider Organization's public inventory (lot numbers are identified as public). This provides the starting point for public stock and initiating accountability of the inventory items. When a dose from the public inventory is administered to a private pay Patient, it creates a borrowing transaction. IIS counts such transactions and reports them to CDC in the Management Survey (currently, monitoring of borrowing activities have moved from the VFC Management Survey to the VFC Site Visit Questionnaire). It was a huge number: around 20,000 doses were borrowed from public and given to private pay Patients. There is a transaction in the IIS to allow for replacement, so the Provider Organization can show that they have replaced the borrowed doses. The inventory report for Providers displays the number of doses borrowed and they must show replacement for all borrowed doses. Issues to consider: there are cases when public and private Vaccines have the same lot number. Also borrowing from the private stock should be accounted for, as Provider Organizations must have inventory in IIS to properly track and account for bi-directional borrowing and replacement.

Borrowing and replacement of borrowed vaccine doses between public and private stocks should be tracked at the dose level. When a multi-dose vial is involved, borrowing should be done at the single-dose level. This level of accountability could become more difficult as the IIS community continues to mature with interoperability between EHR and IIS systems. Many EHR systems lack a strong inventory module to separate Vaccine inventory by funding source.

Assignment of a Public/Private Inventory Indicator and Patient eligibility status for every dose administered facilitates origination of a borrowing transaction. When a Public/Private Inventory Indicator for a dose administered to a Patient is "private" and Patient eligibility is "public" (or vice versa), the borrowing transaction is created.

Best practice for the IIS is to use a separate variable, such as a Public/Private Inventory Indicator (not the lot number) to capture public/private designation of the inventory. EHR use lot numbers for various purposes, including extending the lot number fields to indicate public/private inventory designations. The IIS needs to be able to derive the actual lot number and the actual public/private indicator and document them in two separate fields.

- **Track borrowing and replacements at the dose level**
- **Use Public/Private Inventory Indicator and Patient eligibility status to track borrowing and replacements**

Audit reports should be generated to provide the borrowed/repaid information and the Provider Organization must replace the borrowed dose with the opposite inventory stock (see report 2.1 Borrowed/Replaced report in the IIS Reports section). Note that vaccines borrowed from private stock may not have a lot number documented in the system, so information in the audit reports may be incomplete.

CDC borrowing form can be used as a paper-based back-up to the report 2.1 Borrowed/ Replaced Report described in the IIS Reports section of this guideline. See the VFC Operations Guide, Module 3 – Provider Recruitment and Enrollment, pp. 17-18 at http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/07-module-3.pdf.

As a state/event model indicated earlier in this document, the "addition" of an available volume of inventory as a result of borrowing inventory from another funding source will result in moving a vaccine dose to an available (on-hand) state, regardless of whether that "addition" has yet been reconciled. Stated otherwise, a provider may administer an "additional" dose of vaccine even if the current volume shows as zero (0); the current volume may be reconciled later.

All borrowed vaccine doses have to be reimbursed. At the implementation level, some systems would have to reclassify the vaccine dose or patient eligibility public/private designation. A Michigan example: A patient was assessed to be privately-covered (non-VFC-eligible), a vaccine dose from the private stock administered and insurance was billed. Payment for the vaccine is rejected by an insurance company. Then the patient is in fact now under- insured. Michigan IIS allows for the patient's eligibility to be changed for the dose rejected from insured to under-insured. This creates a borrowing transaction and indicates that a public inventory owes a dose of public vaccine to the private inventory. Borrowed dose is replaced via the "Replaced Borrow" transaction which deducts the dose from public inventory; then a "Transfer In-Replaced Borrow" transaction is performed to add the dose back into the private stock.

Chapter 9: Barriers to Implementation of Best Practice Recommendations

Barriers to implementation of the inventory management best practice recommendations occur at IIS, Provider Organization, and Vaccine Program. Typical barriers include:

IIS

- Limited resources and competing priorities for those limited resources.
- Underlying data structure which does not support recommended business rules for inventory management.
- Import process modifications are necessary.
- Lack of training.

Provider Organization

- Limited resources and competing priorities for those limited resources.
- No perceived benefits to the Provider Organization for following recommended best practices.
- Problems such as some temporary inability to process and report data properly
- Low level of commitment to quality reporting to the IIS.
- Lack of training, staff turnover.
- Use of an EHR system that is unable to capture and transmit required data elements.

Vaccine Program

- The Vaccine Program staff must devote time and resources to defining IIS functionality that meet their needs. They too have competing priorities and resource limitations.

The following are some specific issues/barriers of the inventory management functionality, and some possible ways (*shown in italics*) to address these barriers based on MIROW best practice recommendations for this topic:

- Incorrect shipping data from McKesson (e.g., incorrect lot number or expiration date) uploads to IIS, causing the need for IIS to correct the data.
    - *See GR716, 714.*
- Redistribution of vaccines, causing all parties involved to account for the doses properly.
    - *See GR705, GR707, BR714, BR713, State/Event model (ST02, ST09, EV02, EV04, EV15, EV16), reports 1.2, 2.3*

The following are examples of barriers to implementation of some of the best practice recommendations and suggested resolutions (*shown in italics*). These examples have been developed against the list of inventory management "pains" that was developed during the earlier stages of this project.

- In opt-in (voluntary) states (e.g., Kansas) there is no legislation requiring participation in the registry. Lot number reporting is strongly encouraged, but not mandated. At the same time, business rule BR704 states that a lot number for every vaccine dose administered must be documented and reported by the Provider Organization to the IIS. *A grantee IIS policy adaption and enforcement is needed. A change in legislation can be considered to achieve the recommended best practice standards.*

- BR706: Capture Provider Organization responsible for inventory for every dose administered. Barrier: Organizations that do not report the responsible Provider Organization because the Provider Organization responsible for inventory differs from the organization that administers the vaccine, will not be able to do automated reporting of dose-level accountability at the lot level in the IIS. Suggested r*esolution: Provider organization responsible for inventory will need to make aggregate corrections at the lot level within the IIS.*
- BR711: Minimum set of data items for every dose. Barrier: EHRs use lot numbers for various purposes, including extending the lot number fields to indicate public/private inventory designations. *Suggested resolution: The IIS needs to be able to derive the actual lot number and the actual public/private inventory indicator and document them in two separate fields.*
- BR705: Capture patient eligibility for every dose administered. Barrier: Provider Organizations which do not provide dose-level patient eligibility may not be able to do automated reporting of dose-level accountability at the lot level in the IIS. *Suggested resolution: Such organizations may need to make aggregate corrections at the lot level within the IIS.*
- GR703: IIS should utilize 5-4-2 format for NDC.
  P701: NDC supremacy principle.
  Barrier: NDC codes change and knowing what is current is difficult.
  Suggested resolution: CDC provides email updates for those who sign up to receive them at the following website:
  http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc
  CDC IISSB is planning to develop an updated NDC map to CVX/MVX, as well as to maintain that map on a regular basis.
- BR715: Account for non-administration adjustments on the same day.
  BR707: Track borrowing and replacements at the dose level.
  BR716: Track the event date and recording date.
  Barrier: How to record and account for inventory when providers give two doses of a pediatric vaccine for an adult dose.
  Suggested Resolution: IIS can either build in a dose trigger function (designate dose size as a half, full, or double) or Provider Organizations will manually decrement the second dose from the inventory.
- BR715: Account for non-administration adjustments on the same day.
  BR719: Account for opt-out patients before reconciling.
  BR720: EHR submission for an opt-out patient.
  BR716: Track the event date and recording date.
  BR724: Ensure accurate inventory count for pre-adoption Provider Organizations.
  Barrier: How to account for doses taken from inventory for opt-out patients.
  Suggested Resolution: Either the IIS has the capability of decrementing a dose from an inventory when it is reported on an Opt-Out record, or the dose is manually deducted from the IIS inventory.
- BR715: Account for non-administration adjustments on the same day.
  Barrier: Having the appropriate transactions in the inventory module to fit each and every scenario that can occur with vaccine management.

Suggested Resolution: Need standardization of reasons for non-administration transactions nationally.

- *BR707:* Track borrowing and replacements at the dose level.
  BR711: Minimum set of data items for every dose
  EV17-20.
  Barrier: CDC goals for inventory management in IIS have been VFC driven. Not all registries treat private and public inventory management equally.
  Suggested Resolution: IIS should not limit the vaccine management capability to VFC sites only.
- BR717: Submit data to IIS before reconciling inventory.
  BR718: Indicate IIS-EHR discrepancies.
  GR714: Establish QA process for data from non-IIS systems.
  Barrier: In what ways does an IIS inventory management system compete with an EHR inventory management system?
  Suggested Resolution: Minimize the amount of time the Provider Organization needs to enter the data into two systems. Receiving the order from a vaccine ordering module of IIS reduces the time and error associated with manual entry of lot numbers into the inventory management system.
  Note: Provider Organizations are going to use their local EHR systems more and more. These systems in many cases have inadequate inventory management capabilities. Accordingly, resistance to using these functions online in IIS may increase.

Conclusions

The guidelines offer best practices to use immunization information systems (IIS) as a base for handling inventory management activities through IIS – such as providing vaccine inventory information for ordering, logging received shipment, logging various inventory transactions (e.g., doses administered, wasted, spoiled, transferred, borrowed), conducting inventory reconciliation, and providing reports to support needs of provider organizations, VFC and grantee immunization programs. 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 Work Group:

- Developed and reconfirmed key definitions for inventory management through IIS, such as inventory transaction, provider organization IDs, public/private inventory indicator, bonus dose, and over-estimated dose.
- Developed a state/event model that represents the particular state of a vaccine at the dose level and the major stages through which it goes. The model describes **11 states** and **20 events**.
- Formulated **8 principles** and **25 business rules** to guide inventory management operations (e.g., what information to record, how often to conduct inventory reconciliations, and how to handle borrowing).
- Formulated **23 general recommendations** for IIS functionality and operations related to inventory management.
- Described **20 key inventory management reports**, with a focus on accountability reports to support inventory management, accountability reports to support the ordering process, allocation reports, and reconciliation reports.
- Developed expanded considerations for implementing National Drug Codes (NDC) and handling borrowing between publicly-funded and privately-purchased vaccine stocks.
- Described barriers to implementing inventory management guidelines, and how the guidelines address implementation barriers.

The Work Group brought together experts from the IIS, grantee immunization programs and IT vendors. The resulting guidelines represent a key step in standardizing practice and reports in the area of inventory management through 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) has included a recommendation to "Promote the adoption of a guidebook and best practices for IIS as started by the CDC/NIP and AIRA/MIROW Work Group to adopt consistent operational guidance and quality control procedures that ensure good data quality." This guide is one example of addressing this recommendation in the area of VFC-IIS collaboration.

Selected References

Previously developed guidelines

The MIROW web page at http://www.immregistries.org/pubs/mirow.html contains complete recommendations documents for previous topics and abridged mini-guides.

1.1) AIRA Modeling of Immunization Registry Operations Work Group (eds). Immunization Information System ***Collaboration with Vaccines for Children Program*** and Grantee Immunization Programs. Atlanta, GA: American Immunization Registry Association. April, 2011. http://www.immregistries.org/docs/AIRA-MIROW IIS-VFC Best Practice Guide 04-14-2011.pdf.

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1.3) AIRA Modeling of Immunization Registry Operations Work Group (eds). ***Data quality assurance*** in Immunization Information Systems: Incoming Data. Atlanta, GA: American Immunization Registry Association. February, 2008. http://www.immregistries.org/pdf/AIRA_MIROW_Chap3_DQA_02112008.pdf .

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1.6) AIRA Vaccine Safety and Registry Community Work Group (eds). ***IIS-VAERS Collaboration For Vaccine Adverse Events Reporting***. Functional and Process Recommendations. Atlanta, GA: American Immunization Registry Association. April, 2005. http://www.immregistries.org/docs/IISVAERS_Collaboration_final_VASRECWG_042005.doc.

General IIS/VFC and inventory management–specific references

2.1) VFC Operations Guide.
http://www.cdc.gov/vaccines/programs/vfc/operations-guide.htm

Module 6 - Vaccine Management.
http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/10-module-6.pdf

Appendix 2 - Provider Profile - Vaccines for Children Program.
http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/18-appx-2-provider-profile.pdf

2.2) Epidemiology and Prevention of Vaccine-Preventable Diseases: The Pink Book: Course Textbook.
http://www.cdc.gov/vaccines/Pubs/pinkbook/default.htm

Chapter 5. Vaccine Storage and Handling.
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Appendix C: Vaccine Storage and Handling
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Abbreviations

Abbreviation	Definition
ACIP	Advisory Committee on Immunization Practices
AIRA	American Immunization Registry Association
BR	Business Rule
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
CPT code	Current Procedural Terminology code
CVX	Health Level Seven code for Vaccine Administered
EMR/EHR	Electronic Medical Record/Electronic Health Record
EOQ	Economic Ordering Quantity
ExIS	External Information System (Interface to VTrckS)
DOB	Date of Birth
DT	Decision Table
EHR	Electronic Health Record
GR	General Recommendation
HIE	Health Information Exchange
HL7	Health Level Seven International; global authority on standards for interoperability of health information technology
IIS	Immunization Information System
LHD	Local Health Department
MIROW	Modeling of Immunization Registry Operations Work Group
MVX	Health Level Seven code for Vaccine Manufacturer
N/A, NA, na	Not Applicable
NDC	National Drug Code
P	Principle (high-level business rule)
SME	Subject Matter Expert
UML	Unified Modeling Language
VFC	Vaccines for Children
VTrckS	Vaccine Tracking System
Y/N	Yes/No
VACMAN	Vaccine Management System
VIM	Vaccine Inventory Module
VMBIP	Vaccine Management Business Improvement Project
VODS	Vaccine Ordering and Distribution System
VOFA	Vaccine Ordering Forecasting Application

Appendix A: Domain Model – Vocabulary, Main Terms and Concepts

The MIROW took as a starting point existing models constructed for topics of Patient active/inactive immunization status (MOGE), vaccination level deduplication, data quality assurance, and reminder/recall [1.2 – 1.5] between 2005 and 2010. Members of the inventory management expert panel (SMEs) referenced these models that were harmonized, modified, and partially simplified to fit needs of the topic at hand. The work of experts conducted during the series of pre-meeting web-based teleconferences resulted in a domain model (also known as fact model, vocabulary) for the inventory management topic (see **Figures 5-A1 – 9-A5** and **Table 9-A1 – 10-A2**).

Domain model purpose

The purpose of employing a domain model (also known as fact 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 (e.g., principles, business rules, general recommendations, reports).

A domain is an area of knowledge or activity characterized by a set of concepts and terminology understood by the business practitioners in the area.

A domain model captures a business vocabulary—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 meaning).

A domain model includes:

- Domain diagram(s) that shows major business entities, their relationships and responsibilities (**Figure 5-A1 and Figure 9-A5**).
- A table of entities and attributes that provides the full descriptive details of the components represented on the diagram (**Table 9-A1 and Table 10-A2)**.
- A description of the domain diagram(s).

Unlike a data model diagram that depicts storage of information, or a workflow/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) involved in the immunization process, including a description of how these "things" (entities) are related. It is important to note that the domain diagram is not a technical specification. Instead, the domain diagram provides the foundation for other modeling diagrams and materials.

How to read and interpret the domain diagram

(see Figure 6):

- Relationships between entities are visualized by connecting lines.
- Names associated with these lines describe the type of the relationship between entities. For example, a relationship between *Shipment Line* and *Order Line* is shown as a connecting line

with the word (label) "*fulfills*". Such a relationship should be read as "*Shipment Line fulfills Order Line.*"

- The general convention for interpretation of relationships between entities is to construct such a description by reading clockwise, starting from the first entity name (*Shipment Line*), then relationship name—*fulfills* (note that the name is shown below the line, supporting a clockwise reading), then the second entity name (*Order Line*).
- If we need to read the same description in the opposite direction, from *Order Line* to *Shipment Line*, we would have to place a second name— "*fulfilled by*" — above the line. In this case, using the clockwise reading rule, a description would be "*Order Line is fulfilled by Shipment Line."* In most cases just one name for a relationship is employed (such as "*fulfills*" in the example just considered), assuming that it should be sufficient for a proper interpretation of a relationship in both directions.

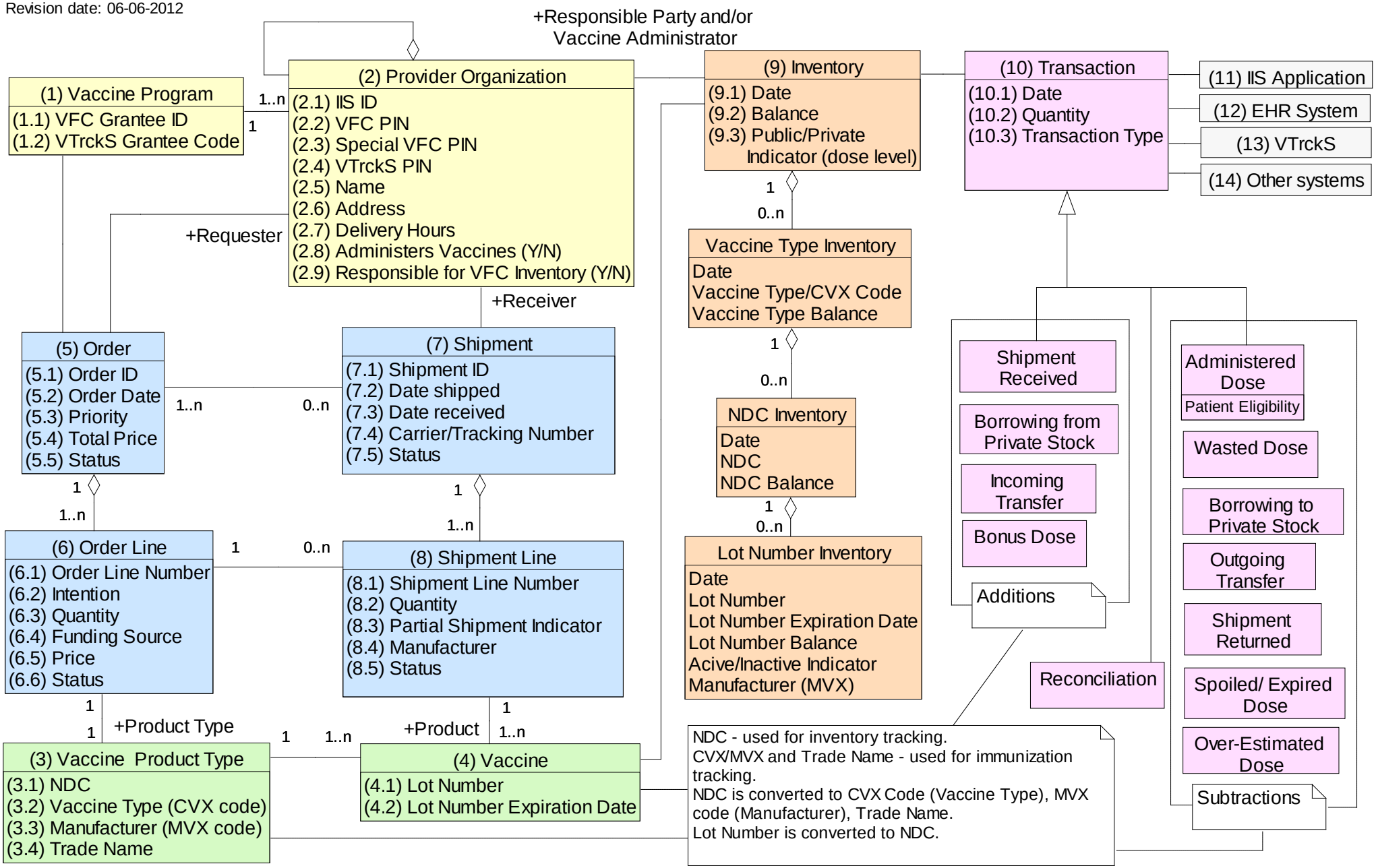


Figure 5-A1. Domain model for the Inventory Management functional area.

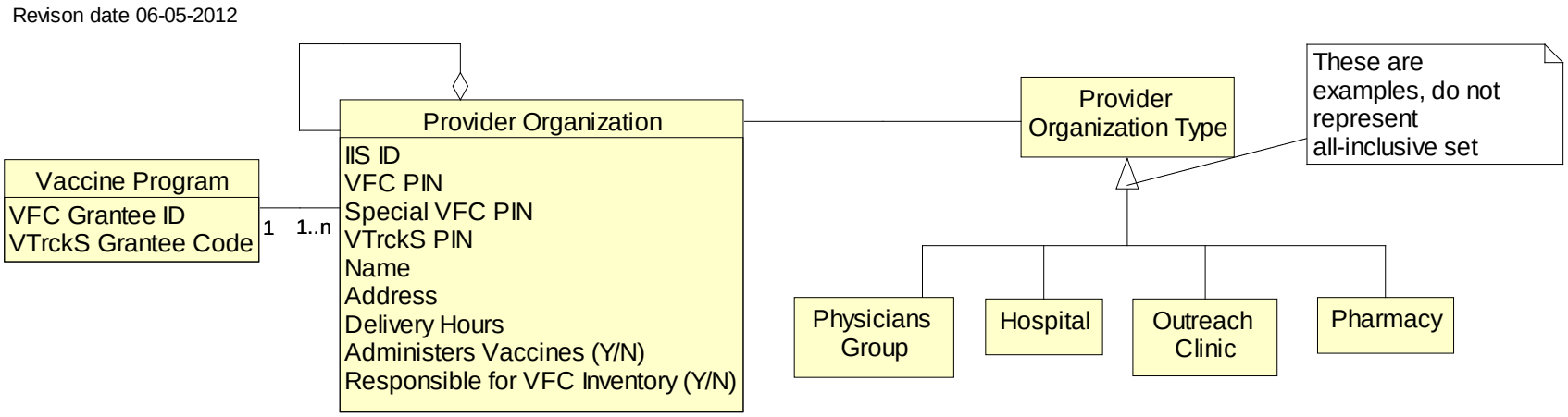
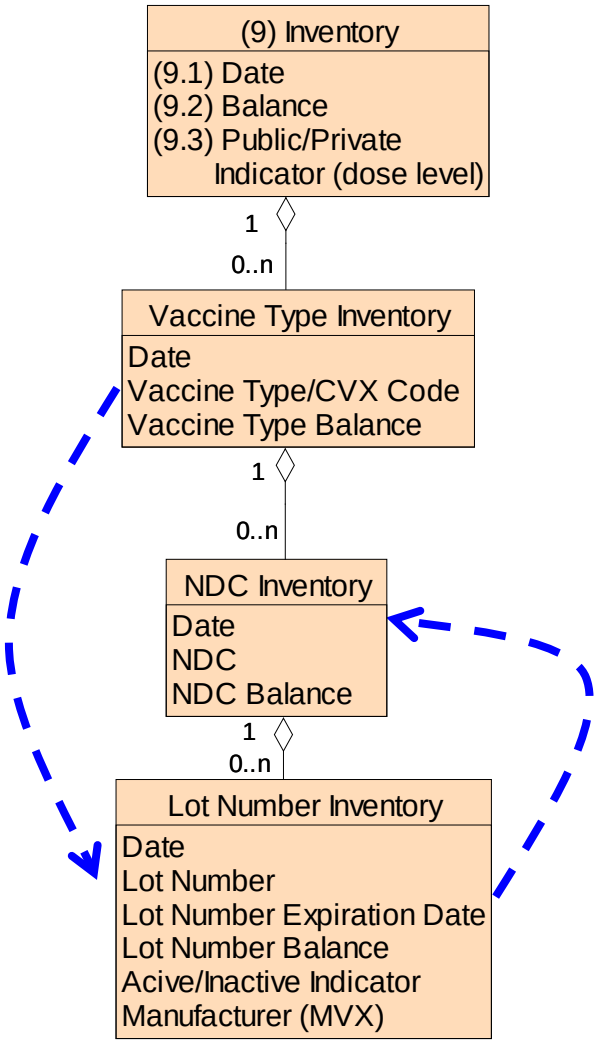


Figure 6-A2. A Provider Organization fragment of the domain diagram

- Vaccine Program is identified by VFC Grantee ID and VTrckS Grantee Code.
- Vaccine Program is related to one or more Provider Organizations. Provider Organization relates to one and only one Vaccine Program (Grantee).
- Provider Organization may include other Provider Organizations.
    - A Provider Organization may report for several other Provider Organizations (e.g., "parent/umbrella" organization may report for several "child" organizations [sites, facilities, clinics]). Each of these may have its own IDs (VFC PIN, IIS ID, etc.). Pharmacies are an example.
    - Provider Organization may place an order for another Provider Organization, which then receives a shipment. For example, an "umbrella" organization places orders for its sites (facilities, clinics).
- Provider Organization types include, but are not limited to, physician group, hospital, outreach clinic, pharmacy.
- Provider Organization plays a role of requester for Orders, a role of receiver for Shipments, and a role of Responsible Party and/or Vaccine administrator for the Inventory (see the domain diagram on Figure 5-A1).
- For the purposes of this project, the main characteristics of a Provider Organization are IIS ID, VFC PIN, Special VFC PIN, VTrckS code, Name, Address, Delivery Hours, and two indicators – Administers Vaccines (Y/N) and Responsible for VFC Inventory (Y/N)
- IIS ID, VFC PIN, and VTrckS Code - are identifiers in different databases.

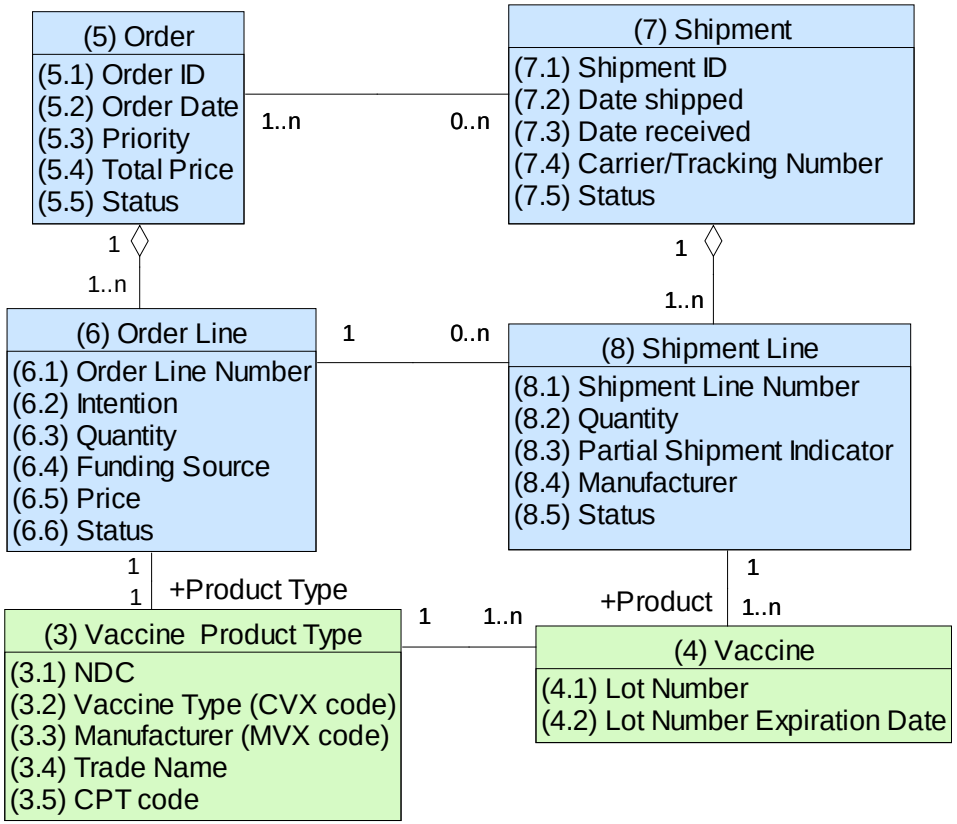
- IIS ID: Assigned to any Provider Organization that has access to IIS. There are organizations (e.g., schools) which do not administer vaccines and are not responsible for VFC inventory, but do have an IIS ID; these organizations are out of scope for this topic.
- VFC PIN: Provider Organization that agrees to take responsibility for the proper storage, handling and accountability for the VFC vaccine inventory should have a unique VFC PIN. The vaccine can be stored on site or at a remote site (such as an outreach clinic).
    - If a Provider Organization is not responsible for VFC inventory (e.g., an outreach clinic), it uses the VFC PIN of its "parent/umbrella" organization.
    - *A Michigan example: Each state was assigned an individual PIN in VACMAN. Michigan used the recommended six-digit system, in which the first two digits indicate the county where the site is located. The PINs that are all zero's after the first two digits indicate the main LHD for that county. If a PIN consists of all nines after the first two digits that indicates the main LHD depot. Michigan used an 8 in the third digit for H1N1 Provider Organizations. This is an effective method of deriving information simply by looking at the PIN. The PIN can provide information about which county to contact, whether the site is a Provider Organization, and previously, whether the site was an H1N1 Provider Organization. For the VTrckS code, Michigan was given a three-letter state code (MIA) that precedes the VFC PIN number when the state transitioned to McKesson shipping and that is still used in VTrckS now, so Michigan PINs now begin in VTrckS with MIA for Michigan and then the six-digit code (e.g., MIA700000, which is Michigan Provider Organization Ottawa County [code 70] and the main LHD [4 zeros]).*
- VTrckS PIN (VTrckS Provider ID): Matches one to one to VFC PIN. Every Provider Organization in VTrckS has a VTrckS PIN (VTrckS Provider ID). Provider organizations created prior to the move to VTrckS also have a VFC PIN (also known as VACMAN PIN). A Provider Organization created in the ExIS and uploaded to VTrckS will have both a VFC PIN (or whatever it is called in the ExIS) and a VTrckS PIN. There is a clear need for grantees to maintain a unique Provider Organization identifier, such as the VFC PIN. The VFC PIN can be associated to VTrckS PIN; IIS don't need to use the VTrckS PIN, but can rely just on VFC PIN (as in Michigan). For example, 40072356 (i.e., eight-digit integer).
- A Special VFC PIN can be assigned to a Provider Organization (e.g., for mass immunizations). For example, the H1N1 campaign.
    - This may create accounting problems. Issue: How to report a vaccine that can be administered under two different VFC PINs. Possible approach: Add new IIS ID every time you assign Special VFC PIN.
    - Instead of issuing a Special VFC PIN, flagging special Provider Organizations can be considered.
- There are three kinds of Provider Organizations (indicators "Administers Vaccines (Y/N)" and "Responsible for VFC Inventory (Y/N)" help to describe them):
    - Administers vaccines and has a responsibility for VFC inventory.

  - Administers vaccines, but is not responsible for VFC inventory. In this case administered vaccines should be accounted for in the inventory of a "parent" ("umbrella") Provider Organization that supplies vaccines (for example, an outreach clinic).
  - Does not administer vaccines, but has responsibility for VFC inventory. These Provider Organizations provide inventory for other Provider Organizations that administer vaccines. Administered vaccines should then be accounted for in the inventory of the supplier Provider Organization (for example, a hospital or pharmacy).
- Whenever possible, and in accordance with VFC policy, vaccine should be shipped to and received by the administering site; situations that include redistribution by a centralized vaccine depot should be minimized.



- Inventory must be reported based on NDC.
- NDC - used for ***inventory tracking.***
- Vaccine Type (CVX) / Manufacturer (MVX) and Trade Name - used for ***immunization tracking.***
- Each Vaccine Type relates to zero or more NDC, and each NDC relates to zero or more Lot Numbers. In the opposite direction: ***each NDC relates to one and only one Vaccine Type and each Lot Number relates to one and only one NDC***.
- Inventory is classified accordingly: by Vaccine Type, by NDC, and by Lot Number
- **The path from Vaccine Type to NDC (dashed arrows): Vaccine Type → Lot Number → NDC. This links the immunization tracking area with the inventory tracking area.**
    - Linkage of vaccine type and lot number to NDC can be done explicitly or behind the scene, at the Provider Organization or at the vaccine program level (see NDC Considerations chapter of this document).
- Example (this example is based on the CDC Vaccine Price List http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm; lot numbers are hypothetical):
    - Vaccine Type = DTaP.
    - NDC = 49281-0298-10. Packaging = 10 pack - 1 dose vials, Manufacturer = Sanofi Pasteur, Trade Name = Tripedia.
        - Lot Number = AC20B160CX
        - Lot Number = AC20B169CY
    - NDC = 58160-0810-11. Packaging = 10 pack - 1 dose vials, Manufacturer = GlaxoSmithKline, Trade Name = Infanrix.
        - Lot Number = AC20B178CA
        - Lot Number = AC20B179CB
    - NDC = 58160-0810-52. Packaging = 10 pack - 1 dose T-L syringes. No Needle, Manufacturer = GlaxoSmithKline, Trade Name = Infanrix.
        - Lot Number = AC20B171CC
        - Lot Number = AC20B174CD

Figure 7-A3. An Inventory fragment of the domain diagram



- Order and Shipment characteristics (attributes) should be matched to the VTrckS specification in the table of terms and definitions.
- Vaccine Product Type vs. Vaccine (i.e., Product Type versus Product).
  - Ordered – Vaccine Product Type; Shipped/Received – Vaccine (instance) of this Vaccine Product Type.
  - Example:
    - Product type = Honda Accord, 2011, LX, silver, …
    - Product = Honda Accord, 2011, LX, silver, …, serial number V123456790.
- For physical ***materials*** such as vaccines, Lot Number plays the same key role that a Serial Number plays for ***discrete items*** such as cars.
  - Example:
    - Product type = DTaP vaccine, NDC = 49281-0298-10.
    - Product = DTaP vaccine, NDC = 49281-0298-10, ***Lot number = AC20B160CX.***
- NDC ─ used for ***inventory tracking.***
- Vaccine Type (CVX) / Manufacturer (MVX) and Trade Name - used for ***immunization tracking.***

Figure 8-A4. A Vaccine Product Type - Vaccine Product fragment of the domain diagram

Table 9-A1. Terms and definitions for Figure 5-A1

	Name	Description	Remarks
1	Vaccine Program	Vaccine Program is defined as a part of the Grantee Immunization Program. It includes two components of the grantee organization (see Figures 9-A5 and 6-A2): • VFC Vaccine Program • Grantee Vaccine Program.	Immunization Program includes Vaccine Program and IIS Program.
1.1	VFC Grantee ID	VFC Grantee identifier.	
1.2	VTrckS Grantee Code	VTrckS Grantee identifier.	VTrckS: Grantee Code
2	Provider Organization	Provider Organization is defined as an organization that administers immunizations and/or responsible for vaccine inventory. ***See the discussion regarding Provider Organizations earlier in this section.***	• Provider Organization may include a number of other Provider Organizations, such as different clinical offices/sites and physician groups (“parent”-“child” relationship). • Provider’s Organization "owns" the immunization. • Provider organization is characterized by Provider Organization Profile which is used for annual re-enrollment in the program and Vaccine ordering. The Provider Organization Profile categorizes children among Patient Eligibility categories. • Provider Organization is a collection of related Providers (clinicians – physicians, nurses).
2.1	IIS ID	Provider Organization identifier assigned by IIS. Also called Facility/Site ID.	• IIS ID is assigned to any Provider Organization that has access to IIS. There are organizations, e.g., schools, which do not administer vaccines and are not responsible for VFC inventory, but do have an IIS ID; these organizations are out of scope for this topic. • Distinct IIS ID is assigned to a Provider Organizations that is

	Name	Description	Remarks
			a part of another Provider Organization (both have unique IIS IDs). .
2.2	VFC PIN (also known as VACMAN PIN)	Provider Organization identifier for the VFC program assigned and maintained by Grantee. See also VTrckS PIN (also known as VTrckS Provider ID) below.	• Provider Organization that agrees to take responsibility for the proper storage, handling and accountability for the VFC vaccine inventory should has a unique VFC PIN. The vaccine can be stored on site or at a remote location/site (such as an outreach clinic). • VFC PIN (also known as VACMAN PIN) has been assigned via the VACMAN system - individually by each grantee. With VTrckS deployment, existing VFC PIN numbers will be transferred to VTrckS. • VFC PIN example: MIA700000 (nine-character, six-digit Provider Organization PIN preceded by the Grantee Code), which is Michigan (MIA), Provider Organization Ottawa County (code 70) and the main LHD (4 zeros). • Every Provider Organization in VTrckS has a VTrckS PIN (VTrckS Provider ID). Provider Organizations created prior to the move to VTrckS will also have a VFC PIN (also known as VACMAN PIN). A Provider Organization created in the ExIS and uploaded to VTrckS will have both a VFC PIN (or whatever it is called in the ExIS) and a VTrckS PIN. • There is a clear need for grantees to maintain a unique Provider Organization identifier, such as the VFC PIN. The VFC PIN can be associated to VTrckS PIN; IIS don't need to use the VTrckS PIN, but can rely just on the VFC PIN (as in Michigan).
2.3	Special VFC PIN	Provider Organization identifier for the VFC program, assigned for special purposes, e.g., for mass immunizations such as the H1N1	• See the discussion earlier in this section. • Instead of issuing a Special VFC PIN, flagging special Provider Organizations can be considered.

	Name	Description	Remarks
		campaign.	
2.4	VTrckS PIN (also known as VTrckS Provider ID)	Provider Organization identifier assigned via VTrckS.	• VTrckS PIN matches one to one to VFC PIN. • VTrckS: VTrckS Provider ID. • Every Provider Organization in VTrckS has a VTrckS PIN (VTrckS Provider ID). Provider Organizations created prior to the move to VTrckS will also have a VFC PIN (also known as VACMAN PIN). A Provider Organization created in the ExIS and uploaded to VTrckS will have both a VFC PIN (or whatever it is called in the ExIS) and a VTrckS PIN. • Example: 40072356 (i.e., 8 digit integer). • There is a clear need for grantees to maintain a unique Provider Organization identifier, such as the VFC PIN. The VFC PIN can be associated to VTrckS PIN; IIS don't need to use the VTrckS PIN, but can rely just on the VFC PIN (as in Michigan).
2.5	Name	The name of the Provider Organization.	
2.6	Address	The address of the Provider Organization.	• Possible fields to include with address are city, state, county, country, ZIP Code, telephone, and Jurisdiction.
2.7	Delivery Hours	Hours when the Provider Organization is available for receiving vaccine shipments.	• a.m. and p.m. hours should be captured. • IIS Application can capture both.
2.8	Administers Vaccines (Y/N)	Indicator/flag. Indicates if Provider Organization administers vaccines.	• Indicators "Administers Vaccines (Y/N)" and "Responsible for VFC Inventory (Y/N)" help to describe three types of the Provider Organization. See the discussion regarding Provider Organizations earlier in this section.

	Name	Description	Remarks
2.9	Responsible for VFC Inventory (Y/N)	Indicator/flag. Indicates if Provider Organization is responsible for the VFC vaccine inventory.	• Indicators "Administers Vaccines (Y/N)" and "Responsible for VFC Inventory (Y/N)" help to describe three types of the Provider Organization. See the discussion regarding Provider Organizations earlier in this section.
3	Vaccine Product Type	Vaccine Product Type is defined as a category of the vaccine product that is ordered, shipped, administered, etc. • Ordered – Vaccine Product Type. • Shipped/Received – Vaccine (instance) of this Vaccine Product Type.	• Vaccine Product Type, for the inventory tracking/ management purposes, is characterized by the NDC code. • Vaccine Product Type, for the immunization tracking purposes, is characterized by the Vaccine Type (CVX code), Manufacturer (MVX code), and Trade Name. • An instance of the Vaccine Product Type – a Vaccine (see below) – is characterized by the Lot Number and Lot Number Expiration Date.
3.1	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 at http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm	• 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 that manufactures (including re-packers or re-labelers), 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. Other formats for NDC codes exist and should be accounted for. • See NDC Considerations chapter of this document.

	Name	Description	Remarks
3.2	Vaccine Type (CVX code)	The Vaccine Type is defined as a specific category of Vaccine. A single Vaccine Type may be associated with many Vaccine Product Types (i.e., different manufacturers, different packaging) Administered Vaccine is an instance of Vaccine Product Type and Vaccine Type.	• Vaccine Type maps to a CVX code. There is normally one CVX code per one Vaccine Type. There are Vaccine Types that do not have a CVX code. • Some sites may send in CPT codes - procedure codes related to the vaccine. CVX codes are preferred over CPT codes. CPT stands for Current Procedural Terminology. CPT codes are developed by the American Medical Association for medical or psychiatric procedures performed by health care practitioners. These are billing codes and are simply tools to find CVX codes. Some CPT Codes have been re-used. There are vaccines that do not have CPT codes. • The Vaccine Type can include single types of Vaccines as well as combination vaccines, e.g., IPV, or IPV, DTaP, HepB. Also the Vaccine Type may indicate a generic or specific type of vaccine (e.g., pneumococcal or PCV7 or PPV23). • Examples of Vaccine Type names: HIB-HBOC, HIB-HepB, HepB-Peds.
3.3	Manufacturer (MVX code)	Manufacturer is defined as an organization that develops and distributes vaccines.	• CDC assigns an MVX code to specific vaccine manufacturers. • A MVX code is paired with the CVX code for Vaccine Type and this pair would indicate a specific Trade Name. • There may be several manufacturers of a particular vaccine type.
3.4	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.	• Example: 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., Vaccine Type [CVX code] and Manufacturer Name [MVX code]).

	Name	Description	Remarks
4	Vaccine	Vaccine is a specific instance of the medicine (instance of the Vaccine Product Type and Vaccine Type) given during a vaccination.	• Examples: Hib-HbOC, HepB-Hib. • Vaccine is designated by use of both the Vaccine Product Type (or NDC) and the Lot Number.
4.1	Lot Number	The lot number is the number assigned by the manufacturer to a specific batch of Vaccine Product Type. See item 9 (Inventory – Lot Number Inventory) in this table for the Lot Number Active/Inactive designation.	• This is currently used as an IIS tracking number of the administered vaccine. CDC (Vaccine Supply and Assurance Branch) researched the format of vaccine lot numbers and found: • All of the manufacturers confirmed that their lot numbers fell within the 10 character limit. • All but one manufacturer have only alphanumeric lot number characters. • The only exception is Sanofi Pasteur, which indicated that lot numbers for some of its products have a dash in the sixth position (which is not the first or the last position).
4.2	Lot Number Expiration Date	This is the date at which the lot is no longer considered potent.	• Manufacturers are required to assign a lot expiration date to each batch (lot) of vaccine. • A short-dated lot number expiration date is a revised original lot number expiration date. The short-dated lot number expiration date aims to indicate that vaccine doses of the lot number are due to expire earlier than the original lot number expiration date. A possible reason for short-dating might be a temporary temperature drop in the refrigerator. See BR712, BR711, BR718, GR706, GR713.
5	Order		
5.1	Order ID	Order identifier.	• Each order will have an ExIS order ID and a VTrckS order ID. The numbers will be different. Each order ID must be unique within its own system.

	Name	Description	Remarks
			• VTrckS: VTrckS Order ID
5.2	Order Date		• Each order will have an ExIS order date and a VTrckS order date. These dates could be different. The former is the date when the Order was entered into the ExIS and the latter is the date the Order was uploaded to VTrckS. • VTrckS: VTrckS Order Date.
5.3	Priority		• VTrckS: Priority Indicator, Priority Reason.
5.4	Total Price	The total cost of the order.	
5.5	Status	For example, received, accepted, exception, backordered, cancelled, completed.	• VTrckS statuses are: Rejected Order, Approved – Request, Complete – Request, Approved by Grantee, Order on Hold • Cancelled – Request.
6	Order Line		
6.1	Order Line Number		• Results in zero or more Shipment Line Number. • VTrckS: VTrckS Order Line Number. • IIS: IIS Order Line Number.
6.2	Intention	For example, adult, pediatric.	• VTrckS: Ordering Intention.
6.3	Quantity	Quantity in doses.	• VTrckS: Quantity.
6.4	Funding Source	For example, VFC, 317, State, ARRA, …	• The variable in VTrckS is called Fund Type. It is only required for direct ship vaccines. Possible values are 317, VFC, and STATE. If a value of STATE is entered for Fund Type, a State PO Reference is also required.

	Name	Description	Remarks
6.5	Price		• From an accounting standpoint, grantees who return certain vaccines would want to capture the amount of the Federal Excise Tax (FET) associated with returns.
6.6	Status	For example, received, open, backordered, shipped, cancelled.	
7	Shipment	Regular shipment – by a distributor. Direct shipment – by a manufacturer. The best practice is for the shipping information to be loaded electronically 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. Currently, provider organizations have to manually enter vaccine information for direct and private shipments. Information for a regular shipment comes electronically from a distributor (McKesson) before a shipment arrives. In the fall of 2012, however, VTrckS shipping information for direct ship vaccines should be as timely as the regular (non-direct) ship information.	• "All vaccines purchased off the federal contract, with the exception of those that must be shipped frozen, are managed by CDC and distributed to end users through a third-party distributor (currently McKesson Specialty). Vaccines that must be kept frozen are shipped directly from the manufacturer to the end user in order to ensure maintenance of the cold chain." VFC Operations Guide, Module 6 – Vaccine Management http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/10-module-6.pdf. • Name of a person who received (signed for) the shipment might be captured .
7.1	Shipment ID	Shipment identifier.	
7.2	Date Shipped		• VTrckS: Date Shipped.
7.3	Date Received		

	Name	Description	Remarks
7.4	Carrier/Tracking Number		• VTrckS: Carrier, Shipment Tracking Number.
7.5	Status	For example, in transit, shipped.	
8	Shipment Line		• Fulfills one and only one Order Line.
8.1	Shipment Line Number		
8.2	Quantity		
8.3	Partial Shipment Indicator	Indicates partial shipments – when just a part of the Order Line is fulfilled by the Shipment Line.	• VTrckS: Partial Shipment Indicator, Order Line Fulfilled.
8.4	Manufacturer		• VTrckS: Manufacturer.
8.5	Status	For example, received, open, backordered, shipped, cancelled.	
9	Inventory	Public inventory – includes publicly-funded vaccine doses (federal, state, or local funds) Private inventory – includes privately-purchased vaccine doses.	• Includes many Vaccine Type Inventories, that includes many NDC Inventories, that includes many Lot Number Inventories. • Lot Number Inventory: A lot number can be designated as active or inactive. This designation can be made at the Vaccine Program level or at the Provider organization level (depending upon grantee's set-up). o The active designation means that there are vaccine doses available for administration under the lot number.

	Name	Description	Remarks
			The active designation is made when a lot number is added to the inventory. o The inactive designation is made when all vaccine doses associated with the lot number are spent or when the lot has expired (beyond the lot number expiration date). Lot number can be re-activated when additional doses of the same lot number are shipped to the Provider Organization.
9.1	Date	Date when inventory is documented.	
9.2	Quantity	Number of vaccine doses.	• Always in vaccine doses.
9.3	Public/Private Indicator	Indicates if a vaccine belongs to a public or private stock. Public/Private Indicator is assigned for every vaccine dose in a Provider Organization's inventory and then associated with every inventory transaction.	• When a Public/Private inventory indicator for a dose administered to a Patient is "private" and Patient eligibility is "public"(or vice versa), the borrowing transaction is created. • There are situations when for the same lot number some vaccine doses are designated as publicly-funded and other vaccine doses are designated as privately-purchased. • See also a comment for BR711.
10	Transaction	Inventory transaction, e.g., additions, subtractions, reconciliations.	
10.1	Date	Date of the transaction.	
10.2	Quantity	Number of vaccine doses for a transaction.	Always in vaccine doses.
10.3	Transaction Type	Additions: Shipment Received, Borrowing from Private Stock, Incoming Transfer, Bonus Dose. Subtractions: Administered Dose, Wasted Dose	• Bonus dose is defined as an additional dose of vaccine discovered after the expected number of doses have been drawn from a vial (i.e., a bonus dose emerges due to an unexpected amount of vaccine left in a vial).

	Name	Description	Remarks
		(Nonviable Not returnable), Borrowing to Private Stock, Outgoing Transfer, Shipment Returned, Spoiled/Expired Dose (Nonviable Returnable), Over-Estimated Dose. Reconciliations: Unaccounted for doses (corrections).	○ For example, a 10-dose vial that actually contains 11 doses. The bonus dose will not be discovered until after the first 10 doses are drawn. • Over-Estimated dose is a term that describes a situation opposite from a bonus dose – when a vial contains fewer number of doses than expected. ○ E.g., 10-dose vial that actually contains 9 doses. • Vaccine doses that are not wasted, expired, administered, transferred out, or in transit are considered unaccounted for (see business rule BR708). • Shipment Returned transaction leads to a subtraction only if shipment data has been accepted first (pre-loaded into the IIS). • Historical doses - administered at some point in the past and now being entered into a patient's record (e.g., patient moved from one state to another and brings the immunization record). Historical doses do not create inventory transactions. • Throughout this document, "borrowing" indicates a transaction within a Provider Organization and "transfer" – a transaction between Provider Organizations.
11	Immunization Information System (IIS)	Immunization Information Systems or Immunization Registries are confidential, computerized information systems that collect vaccination data within a geographic area.	• See http://www.cdc.gov/Vaccines/programs/iis/what-iis.htm. • IIS Program includes IIS Application (see the scope illustration in Figure 1 and a domain diagram in Figure 9-A5).
12	Electronic Health Records System (EHR System)	Electronic Health Record (EHR) System maintains electronic records of health-related information on an individual that can be created, gathered, managed, and consulted by	• "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." Alan R. Hinman and David A.

	Name	Description	Remarks
		authorized clinicians and staff.	Ross. Immunization Registries Can Be Building Blocks For National Health Information Systems. HEALTH AFFAIRS 29, NO. 4 (2010): 676–682. ***For the purposes of this project, the term "EHR system" will be used to refer for both EHR and EMR systems.***
13	Vaccine Tracking System (VTrckS)	VTrckS is an information technology system that integrates the entire publicly-funded vaccine supply chain from purchasing and ordering to distribution of the vaccine.	• VTrckS was launched at four pilot grantee sites on December 13, 2010. • See http://www.cdc.gov/vaccines/programs/vtrcks/index.html.
14	Other Systems	For example, electronic inventory system.	

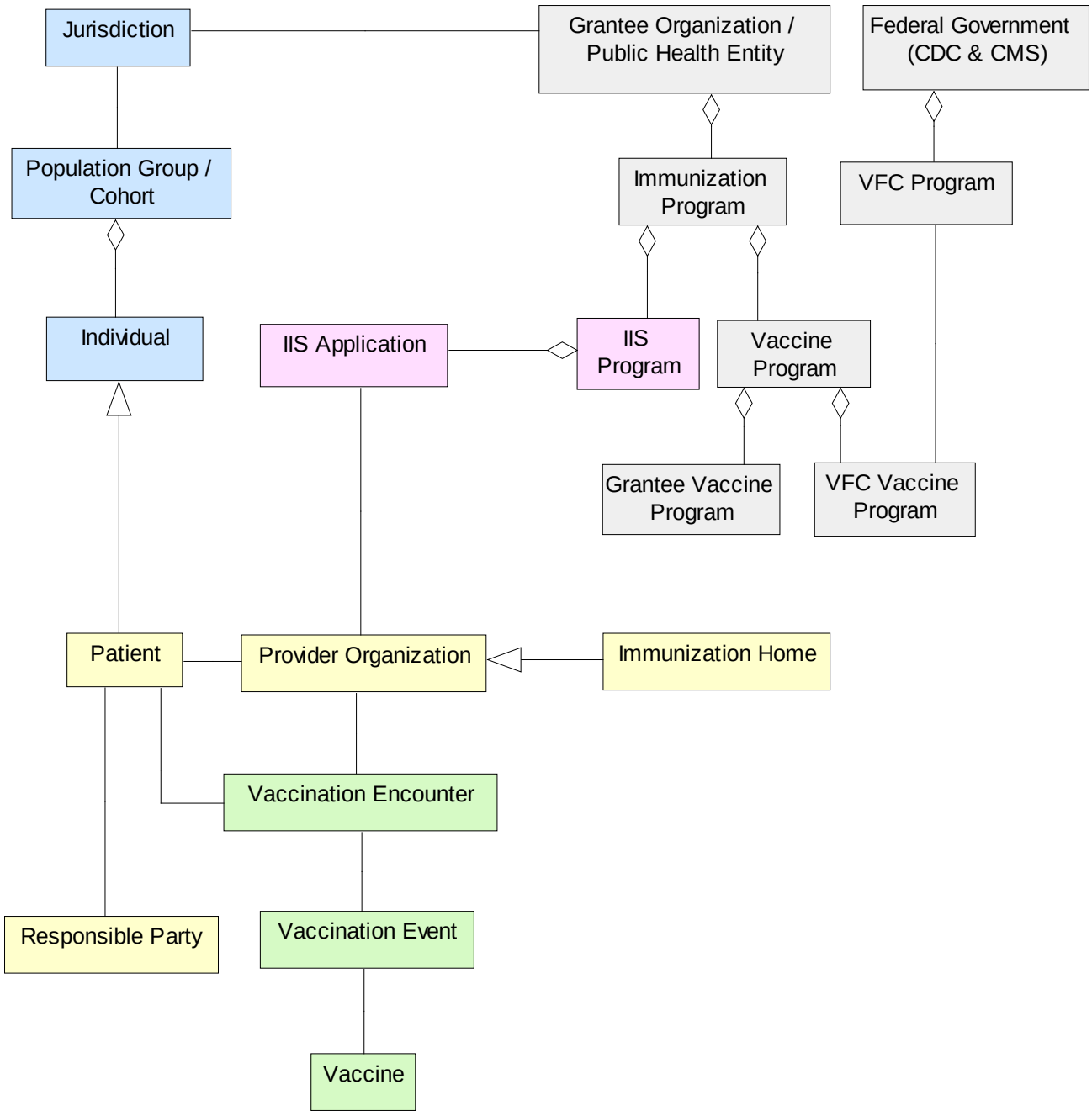


Figure 9-A5. Immunization domain overview diagram

Notes:

- This diagram was developed by the MIROW in 2008-2010. It is placed here for general reference purposes
- See Table 10-A2 for terms and definitions

Table 10-A2. General immunization terms and definitions for Figure 9-A5

Name	Description	Remarks
Federal Government (CDC and CMS)	Implements the VFC Program.	CDC: Centers for Disease Control and Prevention, www.cdc.gov. CMS: Centers for Medicare and Medicaid Services, www.cms.gov.
Grantee Organization/Public Health Entity	A Grantee Organization/Public Health Entity is a governmental agency that receives 317 funds under Public Health Service Act. It is a governmental agency with public health oversight or management responsibilities over a particular public health Jurisdiction (e.g., state, city) and associated Population (Individuals).	Grantee Organization/Public Health Entity receives federal funds for the Grantee Immunization Program. Currently there are 64 Grantee Organizations: 50 states, 6 cities, 5 U.S. territories, and 3 freely-associated compact nations in the Pacific.
Grantee Vaccine Program Policies (State Program Policies)	Define which Vaccines are eligible for a Grantee Program (Vaccine Eligibility).	There are six types of Grantee Immunization Program Policies: Universal, Universal-select, VFC & Underinsured, VFC& Underinsured-select, VFC only, Other. See [2.11], pp. 6-7 for detailed definitions.
IIS Program	Immunization Information Systems or Immunization Registries are confidential, computerized information systems that collect vaccination data within a geographic area.	See http://www.cdc.gov/Vaccines/programs/iis/what-iis.htm IIS Program includes IIS Application (see also the scope illustration in Figure 1).
Immunization Home	An Immunization Home is the practice (Provider) where the Patient receives immunization services. A Patient can be active with many Providers, but only one Provider will be considered as the Immunization Home.	See [1.5, page 29 and page 42]. Also called Medical Home, defined as a Provider Organization that accepts primary responsibility for an individual's health care. In an ideal situation, Immunization Home and Medical Home are the same for a Patient. In practice, they often are not.

Name	Description	Remarks

Immunization Program	Immunization Program at the Grantee level includes (see also the scope illustration, Fig. 1):
	• Vaccine Program, including
	  o VFC Vaccine Program
	  o Grantee Vaccine Program.
	• IIS Program, including
	  o IIS Application.
		VFC Program is implemented on federal, Grantee, and Provider Organization levels.
		
		Immunization Programs of Grantees = CDC Grantee Immunization Programs = Immunization Programs of CDC Grantees.

Individual	A person. Population is comprised of Individuals. A Patient is a type of (sub-group) individual.	Entity/Party ─ An individual or organization of interest (e.g., Patient, Clinic). Organization ─ A type of Entity/Party (e.g., clinic, foster home, etc.).
Jurisdiction	The geographic Jurisdiction could be a State, a metropolitan area (New York City, Chicago, etc.), a county within a State, or some other subdivision of a larger Jurisdiction.	A Jurisdiction might encompass the entire country, as is the case with nationwide Jurisdictions such as the Jurisdictions of the Veterans Administration ("non-geographic Jurisdiction").
Patient	An Individual who is associated with a Provider (e.g., immunized by a Provider).	The VFC Program covers Patients aged 0-18.
Population Group / Cohort	Part of the population (individuals) within a Jurisdiction.	
Provider	A medical practitioner (e.g., physician, nurse) who administers the immunization (conducts Vaccination Event).	IIS captures Provider information associated with a Vaccine administered to a Patient. VFC Program captures the Provider information associated with Provider Organization (Practice). Scenario: VFC audit. Questions about Provider John Doe, his practices. IIS can provide information to VFC – breakdown of Vaccines administered by Provider John Doe over the

Name	Description	Remarks
		years, by a month, Patient ages, etc.
Provider Organization	An Organization that administers immunizations. A Provider Organization is a collection of related Providers (clinicians – physicians, nurses) that are treated as an entity that administer immunizations. It may include a number of different clinical offices/sites and physician groups. Some IIS set up a Provider Organization for every site; ***for the purposes of this project a site has the same definition as a Provider Organization***. • A public Provider Organization is funded by a governmental agency directly. A unit of government is responsible for managing operations. • A private Provider Organization is funded privately and indirectly by a governmental agency (for instance, CMS). A non-governmental unit is responsible for managing operations.	Provider's organization "owns" the immunization. Practice Type, e.g., Family Practice, Internal Medicine, etc. VFC-enrolled Provider Organization maintains two inventories of Vaccine: publicly funded and privately funded. Provider Organization Profile: used for the annual re-enrollment in the program and Vaccine ordering. The profile categorizes children among Patient Eligibility categories.
Responsible Party	Entity/Party responsible for an Individual/Patient	Examples include Parent/Guardian, foster home.
Vaccination Encounter	Interaction between a Provider and Patient resulting in one or more Vaccination Events.	Examples include an office visit, at school, at work or in a grocery store. Reference [1.3] for a detailed description.
Vaccination Event	Administration of one Vaccine to a Patient.	Several Vaccination Events can happen within one Vaccination Encounter. Reference [1.3] for a detailed description.
Vaccine	A product that produces an immune response in a Patient. (also called dose administered).	Reference [1.3] for a detailed description. Vaccine Type classifies Vaccines (e.g., using CVX codes). A Patient is eligible for a type of Vaccine not the specific

Name	Description	Remarks
		Vaccine.
Vaccine Program	Vaccine Program includes (see Fig. 8): • VFC Vaccine Program. • Grantee Vaccine Program.	
VFC Program	The VFC Program is a federally funded program that provides Vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay.	VFC = Vaccines for Children http://www.cdc.gov/Vaccines/programs/vfc/default.htm.

Appendix B: Scope – Detailed Focus Statement

The following focus statement concisely describes the boundaries of the inventory management topic:

1) **Breadth:**
   a) All **to-be** activities and data involved in inventory management and associated reporting for vaccines.
      i) **From:** Provider Organization is placing a vaccine order (and needs to provide vaccine inventory information).
      ii) **To:** Vaccine Program has received IIS reports describing vaccine inventory and accountability.
      iii) **Including (Processes):**
         (1) Log inventory transactions (at the dose level).
            (a) Additions – shipment, transferred (in), borrowed (in), bonus doses.
            (b) Subtractions – administered, wasted, borrowed (out), transferred (out), returned, spoiled/expired, over-estimated doses.
            (c) Minimum data set.
            (d) Log in IIS or in EHR system (administration at dose level for transmission to IIS).
         (2) Correct inventory transactions.
         (3) Reconcile IIS inventory: -- ending inventory for a given reporting period.
            (a) IIS count versus Provider Organization's actual physical count.
         (4) Maintain quality of inventory data.
         (5) Generate inventory reports, including accountability reports.
         (6) Provide vaccine inventory information when ordering.
         (7) Maintain vaccine stock (separate stocks for public and private vaccines).
      iv) **Borderline:** n/a.
      v) **Excluding:**
         (1) Ordering vaccines.
         (2) Fulfilling vaccine order.
         (3) Storing and handling vaccines.
         (4) Forecasting (system generates what will be needed).
         (5) Barcoding issues.
      vi) **Including (Data):**
         (1) Dose level data from Providers to the IIS.
         (2) Dose level and aggregated IIS data to the Vaccine Program.
         (3) Data quality and completeness requirements for all information collected.
         (4) Cost of vaccines (as it relates to use of IIS reports on distributed and wasted/lost vaccines).
      vii) **Including (Socio-Political):**
         (1) Individual Provider Organizations, umbrella Provider Organizations, partnered ("joint account") Provider Organizations.

2) **Problem Set:**
   a) **Including:**
      i) Publicly-funded vaccines.

ii) Privately-purchased vaccines, but not requirements specific to handling private vaccine inventory.

b) Excluding:

i) All anti-virals, masks, hazardous - are out-of-scope.

3) Emphasized Perspectives:

a) IIS.
b) Grantee Vaccine Programs.
c) Provider Organizations.

4) Scope of Integration:

a) Data exchange with EHR systems.
b) Data exchange with VTrckS.
c) Data exchange with fulfillment/shipping systems (McKesson file).
   i) Short-term until replaced by VTrckS.

5) Depth: Conceptual level requirements – not emphasizing implementation details (e.g. position in HL7 Record).

The following statement provides expanded/detailed scope considerations:

- **In-Scope**
  - Managing current inventory, including:
    - Subtractions (vaccine doses administered, wasted, returns, borrowed from the public stock, outgoing transfers, spoiled/expired, over-estimated doses).
      - ✓ Tracking dose by volume (i.e., pediatric dose [as half-dose]).
    - Additions (shipments, incoming transfers, borrowed between stocks [e.g., from a private stock or between stocks with different funding sources, bonus doses]).
    - Reconciliations – balancing of inventory data compared to physical inventory, including balancing of inventory data across systems, including:
      - ✓ IIS inventory reconciliation for Provider Organizations submitting data via direct entry/user interface (IIS count Versus Provider Organization's actual physical count).
      - ✓ IIS inventory reconciliation for Provider Organizations submitting data for administered vaccines via electronic data exchange (i.e. using EHR system).
      - ✓ Reconciliations between doses distributed and reported.
      - ✓ Categories to adjust the inventory (e.g., spoiled in transit [including a responsible party], spoiled in refrigerator, many transfer-related categories, etc.).
      - ✓ Expired versus non-expired inventory.
      - ✓ Fixing errors when the wrong data has been reported (e.g., lot number, vaccine type – this is about flexibility and maintainability).

- Inventory reports (e.g., inventory on-hand, monthly reconciliation, expiring soon, wastage report, aggregated counts across Provider Organizations, reports on returned shipments, etc.).
- Quality and completeness of inventory data (e.g., entry of lot numbers [in both the IIS and a Provider Organization EHR]), including impacts of:
  - Tracking inventory at the NDC level, including NDC code changes and re-labeling by distributors.
  - New information available through VTrckS.
  - Eligibility reporting.
- Data streams through:
  - Direct entry (user interface).
  - Data exchange with electronic health records systems (EHR): electronic or on physical media, batch or real time.
    - ✓ Include exchanges with pharmacies (pharmacies are unique from the perspective of electronic data exchange).
  - Inventory-related data exchange with ordering (VTrckS) and fulfillment/shipping systems.
- The granularity of clinic versus site management, when one umbrella Provider Organization manages inventory at "sub" locations, or when several Provider Organizations have one joint account (each Provider Organization [site] might have a unique VFC PIN, or several Provider Organizations [sites] might have the same VFC PIN).
- Inventory information that is exchanged with VTrckS (e.g., required inventory reports to submit an order – in VTrckS, information about lot number and expiration date – out of VTrckS) is in-scope; the data that will eventually need to be exchanged should be accounted for.
- The Provider Organization providing dose/shot level data to IIS (which, in turn, provides aggregated and detailed data to the Grantee Vaccine Program) is in-scope, but the Provider Organization reporting directly to the Grantee Vaccine Program is out of scope.
- How to measure effectiveness of the inventory management systems.
  - How to keep vaccine information up-to-date (e.g., pricing, NDC numbers).
- Private vaccine inventory. Included in scope with understanding that a model (recommendations and solutions) developed for managing the public vaccine inventory can also be applied to the management of private vaccine inventory. This is how it is currently done in Kansas, Michigan, and Pennsylvania (e.g., a private/public flag can be used). Including private inventory in scope would allow Provider Organizations to use a single solution for both public and private vaccines. Additional requirements that are <u>specific</u> to handling private vaccine inventory should not be accommodated and will be out of scope.

- **Borderline items** – n/a.

- **Out of Scope**:
  - Vaccine ordering capabilities within IIS (beyond providing inventory information needed to submit an order to VTrckS).

  - ✓ Entering shipment information into the system is in-scope.
- Fulfillment of vaccine orders.
- Storage and handling best practices (e.g., maintaining cold chain, keeping inventory in refrigerators [but expired versus non-expired inventory is in scope]).
- VTrckS functionality (but inventory information needed to submit an order to VTrckS is in-scope).
- Reports that do not directly address the needs of inventory management, but general reports that help manage inventory are in-scope.
- Information that is submitted by a Provider Organization directly to the Grantee Vaccine Program is out of scope, but information submitted by a Provider Organization directly to an IIS is in-scope. (Note: reconciliations between the Grantee Vaccine Program and the IIS are in-scope, recognizing the fact that some reporting is going from Provider Organizations directly to the Grantee Vaccine Program ─ not through the IIS).
- Forecasting (system generates what will be needed).
- Barcode issues are out of scope, but it should be taken into consideration that as barcode initiatives progress, the quality, timing, and specificity of the vaccine inventory data will increase.
- Additional requirements that are specific to handling private vaccine inventory should not be accommodated and will be out of scope (see in-scope private vaccines item above).

The following model (**Figure 10-B1 and Table 11-B1**) of the inventory management process activities that utilize IIS provides additional insights into the scope of this topic as have been discussed by the group during the face-to-face session in September 2011 (Atlanta, Georgia). Definitions of terms used in describing and discussing various aspects of the process are presented in Appendix A (domain model).

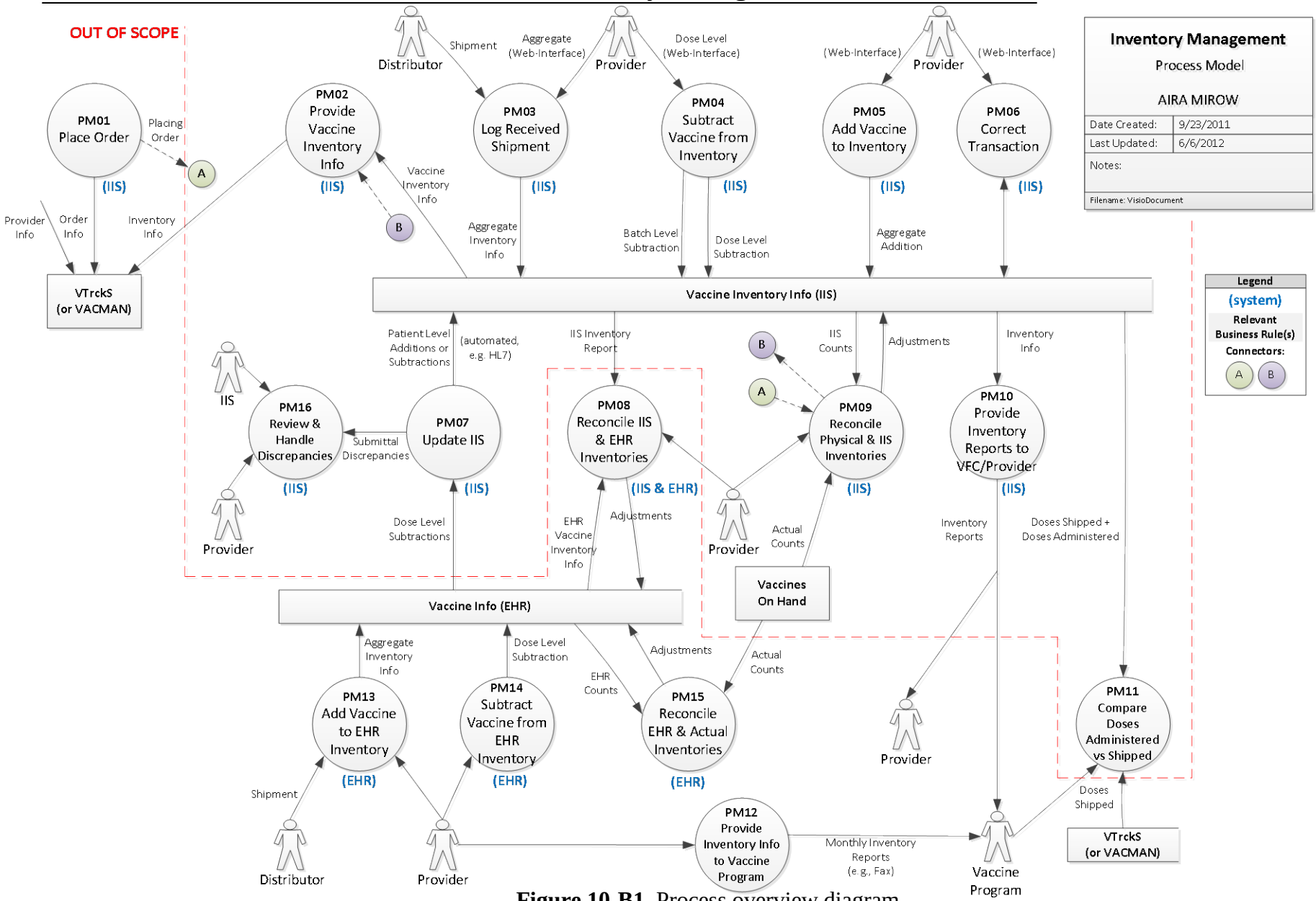


Figure 10-B1. Process overview diagram

Table 11-B1. Description of process activities on Figure 10-B1

ID	Name	Description	Notes
PM01	Place Order	• Out of Scope • Tasks o Provider Organizations must provide information about their entire physical inventories to the IIS. • Other considerations: o A prerequisite of placing an order in VTrckS is that the Provider Organization has submitted ending inventory data within 14 days prior to placing the order. Note, that BR722 recommends that Provider Organizations must reconcile their entire physical inventories to the IIS inventory immediately prior to ordering. o Order forms (either paper or electronic) for some grantees include spaces for also entering ending inventory information.	• Role: IIS • Output: Order Info.
PM02	Provide Vaccine Inventory Information (Generate Provider Ending Inventory Data)	• In Scope • Tasks o Grantee staff upload Provider Organization ending inventory data from the IIS into VTrckS • Other considerations o See comment for PM01 above. o Vaccine inventory data required by VTrckS is: ▪ Inventory Date. ▪ NDC. ▪ Lot Number. ▪ Quantity (in doses). ▪ Lot Number Expiration Date.	• Role: IIS • Inputs: Inventory Information from IIS, Reconciled Physical and IIS Inventory Information. • Output: Inventory Info to VTrckS or VACMAN.
PM03	Log Received Shipment	• In Scope • Tasks o Provider staff indicates in the IIS the inventory that has	• Role: IIS • Inputs: VTrckS Shipment Data, Provider Information.

ID	Name	Description	Notes
		been received. • Other Considerations o When Grantee staff has preloaded shipment data from VTrckS into the IIS, Provider Organizations are able to match inventory received with inventory shipped. o VTrckS shipment data includes information about direct and indirect shipments.	• Output: Aggregated Inventory Info.
PM04	Subtract Vaccine from Inventory	• In Scope • Tasks o For vaccines subtracted from inventory as a result of dose administration: ▪ Provider Organization staff administers a dose of vaccine and enters the dose administered directly into the IIS. ▪ The IIS subtracts the dose from available inventory. o For vaccine subtracted from inventory as a result of reconciliation: ▪ Provider staff enter doses wasted, spoiled, etc. into the IIS. ▪ The IIS subtracts the doses from available inventory. • Other considerations o A dose subtracted from inventory for any reason other than patient-specific administration (as opposed to aggregated dose administration data) will not be tied to a patient record. o Refer to the State/Event Model for the Vaccine States that result in a subtraction of vaccine from inventory (ST03-ST07, ST09).	• Role: IIS • Input: Dose level from Provider Organization via web-interface. • Outputs: Dose level and batch level subtractions.
PM05	Add Vaccine to Inventory	• In Scope • Tasks o Provider staff indicates in the IIS that additional vaccine has	• Role: IIS • Input: Provider via IIS user interface.

ID	Name	Description	Notes
		been identified as a result of a transfer from another Provider Organization site, receipt of a shipment, identification of bonus doses, favorable shipping discrepancy, etc. • Other considerations o Refer to PM03 for shipments received; PM05 covers all other ways in which vaccine is added to the inventory.	
PM06	Correct Transaction	• In Scope • Tasks o Provider identifies an incorrectly-recorded vaccination to a patient and deletes the vaccination. o The IIS prompts the user if the dose should be returned to inventory. o If yes, the IIS adjusts the inventory levels accordingly. • Other considerations o Implementation of corrections varies by IIS and software package. A correction might require both a deletion and an addition.	• Role: IIS • Input: Provider via IIS user interface. • This is to correct a vaccination transaction.
PM07	Update IIS	• In Scope • Tasks o Once dose administration information is received from an EHR, the IIS uses this information to subtract inventory based on doses administered. • Other considerations o Updating an IIS based on EHR information on doses administered could be an automated process.	• Role: IIS • Inputs: Dose level subtractions submitted by EHR. • Outputs: Dose level subtraction from the IIS, discrepancies submitted for a review. • The submitter of HL7 data should have (1) good visibility about reported vaccinations that did not match known vaccination lots and (2) a simple process to resolve the problem.
PM08	Reconcile IIS and EHR Inventories	• Out of Scope, except for creating reconciliation reports in support of this activity • Tasks	• Role: IIS and EHR • Input: IIS Inventory Report, EHR Vaccine Inventory Information.

ID	Name	Description	Notes
		o Provider staff generates reports from the IIS and EHR system, determine if there are discrepancies, and make adjustments, as needed. • Other considerations o Many EHR do not have the ability to track inventory.	• Outputs: Reconciliation between IIS and EHR results in adjustments to EHR (out of scope).
PM09	Reconcile Physical and IIS Inventories	• In Scope • Tasks o Provider staff generates reports from IIS, count inventory on hand, determine if there are discrepancies, and make adjustments, as needed. • Other considerations o This step must be performed prior to submitting an order.	• Role: IIS • Input: IIS Counts, Actual Counts– A Provider's on-hand vaccines. • Outputs: adjustments to IIS.
PM10	Provide Inventory Reports to VFC/ Provider	• In Scope • Tasks o Grantee staff generates reports for VFC program. o Provider staff generates reports for VFC program.	• Role: IIS • Inputs: Inventory Information from IIS. • Outputs: Inventory Reports to Provider and Vaccine Program.
PM11	Compare Doses Administered versus Shipped	• In Scope • Tasks o Compare doses administered versus shipped.	• Role: IIS • Inputs: Doses shipped and administered from IIS, Doses Shipped from VTrckS/VACMAN, Vaccine Program. • See report 3.6 Shipped Vaccine Usage. Doses distributed versus reported. • See article [4.2].
PM12	Provide Inventory Info to Vaccine Program	• Out of Scope • Tasks o Not applicable since this step is out of scope.	• Role: EHR • Input: Provider. • Output: Monthly inventory reports – could be faxed.

ID	Name	Description	Notes
PM13	Add Vaccine to EHR Inventory	• Out of Scope • Tasks o Not applicable since this step is out of scope.	• Role: EHR • Input: Provider, Shipment from Manufacturer.
PM14	Subtract Vaccine from EHR Inventory	• Out of Scope • Tasks o Not applicable since this step is out of scope.	• Role: EHR • Input: Provider. • Output: Dose Level Subtraction.
PM15	Reconcile EHR & Actual Inventories	• Out of Scope • Tasks o Not applicable since this step is out of scope.	• Role: EHR • Inputs: EHR Counts – Inventory counts in a Provider's EHR that is used to Reconcile to their actual inventories, Actual Counts– A Provider's on-hand vaccines.
PM16	Review and Handle Discrepancies (before reconciliation)	• In Scope	• Role: IIS • Inputs: IIS with inputs from Provider, Submittal Discrepancies.

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