



Decrementing Inventory via Electronic Data Exchange

AIRA

AMERICAN
IMMUNIZATION
REGISTRY
ASSOCIATION

Immunization Information Systems for a New Era





MIROW: Helping IIS Keep Pace with Evolving Health Initiatives and Technology

In 2005, the American Immunization Registry Association (AIRA) formed the Modeling of Immunization Registry Operations Workgroup (MIROW) to identify areas for improvement in IIS operations and develop best practice recommendations. MIROW regularly assembles workgroups of subject matter experts from the immunization information system (IIS) community to examine, discuss, and develop consensus-based best practices for IIS operations.

The guide presents best practice recommendations to automate and standardize across immunization programs the process of decrementing a provider organization's vaccine inventory in an IIS via electronic data exchange between the provider organization and IIS. This process is referred to as decrementing inventory via electronic data exchange (DI-v-EDE).

Relevance of DI-v-EDE

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

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

High-level Scope

The scope of the DI-v-EDE guidelines includes all to-be processes and information to support:

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

Key Concepts in DI-v-EDE

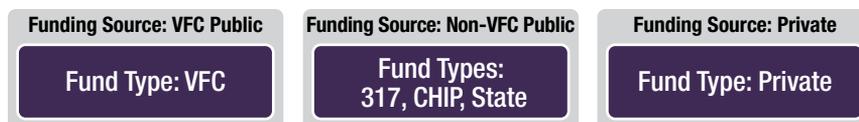
FUND TYPE.

Fund type describes the program (or private payer) that paid for a vaccine dose.

VACCINE STORAGE MODEL.

Storage model describes the way vaccine stocks are physically separated from each other in the provider organization's storage unit (e.g., refrigerator, freezer) to achieve better accountability for each dose. Awardee immunization programs currently use several different vaccine storage models. These models differ by the categorization scheme used to separate vaccines in the storage unit. An immunization program may incorporate more than one model within its jurisdiction simultaneously (i.e., one type of storage model for some provider organizations and another type of storage model for others). Two storage model examples are illustrated below. For a full list and description of the storage models please see the full guide.

Three-stock model



Two-stock model



Learn more about DI-v-EDE

This mini guide provides an overview of the in-depth, technical information related to these best practices found in the full best practice guide. To download, visit the AIRA web site at: <http://www.immregistries.org/resources/aira-mirow>.

Full Guide Features

The guidelines document recommendations using:

- a detailed description of the DI-v-EDE process
- 9 principles (high level business rules that help to capture institutional knowledge and to guide the development of more specific business rules)
- 26 business rules (representing specific requirements and decision-making logic for IIS processes and operations)
- 3 decision tables
- 7 reports
- 27 operational scenarios

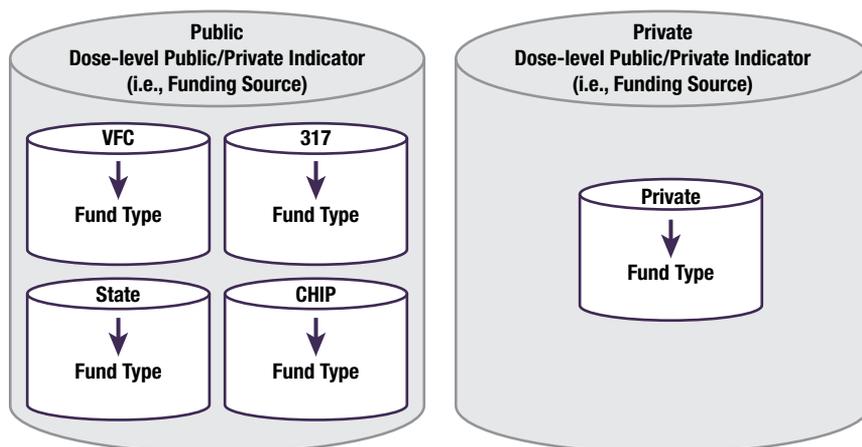
In addition, the recommendations provide guidance for pre-approval and maintenance of provider organizations for DI-v-EDE and implementation considerations, including discussions of key data elements, data quality, and EHR and HL7 considerations.

DOSE LEVEL ELIGIBILITY.

Dose-level eligibility describes a patient's eligibility for a funding program; it is determined for each dose administered. Dose-level eligibility reported by a provider organization to an IIS may also serve as a proxy for dose-level public/private indicator or fund type.

DOSE LEVEL PUBLIC/PRIVATE INDICATOR.

Dose-level public/private indicator is an aggregated reflection of fund type at the vaccine dose-level. The term "dose-level public/private indicator" corresponds to the term "funding source" in HL7. It indicates if a provider organization stores a vaccine dose in a public or private stock. Provider organizations assign the dose-level public/private indicator for each administered vaccine dose based on the stock that the particular vaccine dose was pulled from in the provider organization's storage unit. The provider organization's EHR transmits dose-level public/private indicator to the IIS through an EDE if the information is available in the EHR.



LOT LEVEL PUBLIC/PRIVATE INDICATOR.

Lot-level public/private indicator is an aggregated reflection of fund type at the vaccine lot-level. It indicates if vaccine doses with a given lot number are associated with publicly-funded or privately-funded inventory in the IIS. The IIS assigns lot-level public/private indicator. Provider organizations do not transmit these indicators through an EDE.

DI-v-EDE Process

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

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

The guidelines describe vaccine ordering and fulfillment through the federal VTrckS to illustrate how the IIS and provider organization receive information about lot numbers, fund type, and other data elements from the vaccine ordering system and the shipment packing slip. The steps in the process could be adapted to other ordering and distribution systems.

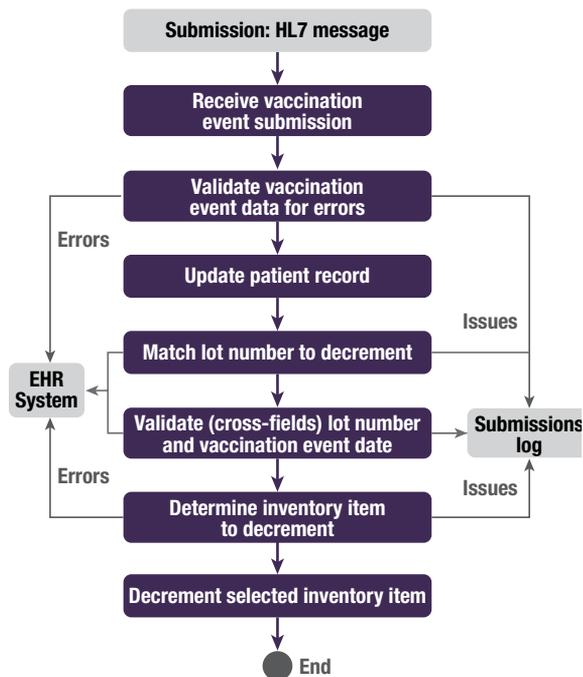
DI-v-EDE starts when a provider determines which vaccine is needed by a patient and what the dose-level eligibility is of that patient. The provider pulls vaccine from the stock that corresponds to the dose-level eligibility for the vaccination event and administers the vaccine. The provider documents the vaccination event within the EHR system by recording lot number, dose-level eligibility, dose-level public/private indicator (optional for DI-v-EDE), lot number expiration date, and other data elements

that describe the vaccination event. The EHR system sends vaccination event data to the IIS using HL7 specification, either in real time or as a part of a batch schedule. The IIS then does the following:

- receives submission and validates the vaccination event message for errors.
- validates that the vaccination was "administered" and updates the patient record with new patient and/or vaccination event data for an administered dose.
- finds a match between the lot number in the submission and the lot number in the IIS inventory for the provider organization.
- verifies that the vaccination event date is after the most recent reconciliation closed date, if required by the awardee.
- verifies that there is no contradiction between matched lot number, NDC (if sent), and/or CVX code for the vaccine.
- determines provider organization's inventory item to decrement based on
 - submitted information, such as lot number, lot number expiration date, dose-level eligibility, and, optionally for DI-v-EDE, dose-level public/private indicator for the vaccine, and
 - information about provider organization's inventory in IIS, such as lot number, lot number expiration date, and lot-level public/private indicator.
- confirms the selected inventory item is "active" and that the balance for the inventory item is greater than zero.
- decrements balance for the selected inventory item by one.
- documents any data quality issues in each provider organization's inventory so that the provider organization may resolve as many of those issues as possible prior to reconciliation.

The following diagram describes a portion of the DI-v-EDE process as described in the full guide.

Immunization Information System (IIS)



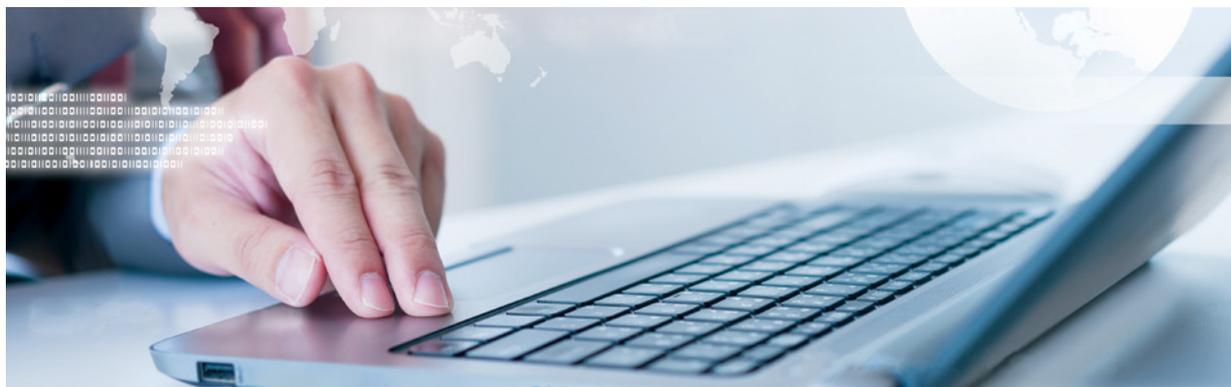
The reconciliation process serves as an ultimate mechanism to catch and fix all remaining issues. The provider organization conducts the reconciliation process, and compares the number of vaccine in the physical storage with information in the IIS. The provider organization makes ongoing adjustments to inventory items to ensure accurate inventory balances and the reconciliation is then completed.

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

Fundamental Principles

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

P#	DESCRIPTION
P01	DI-v-EDE should support the awardee program policies.
P03	The IIS must preapprove a provider organization for DI-v-EDE.
P04	Inventory information in the IIS should map to the storage model used by the provider organization.
P06	DI-v-EDE should support dose-level accountability.
P07	The IIS should notify provider organizations of problems in the DI-v-EDE process.
P08	The IIS should assist provider organizations to correct data quality issues.



Business Rules

In contrast to fundamental principles, business rules (BR) represent specific requirements and decision-making logic for various steps of the DI-v-EDE process. The following are some key business rules.

BR#	DESCRIPTION
BR101	The IIS should organize a provider organization's inventory by lot number, lot number expiration date, and lot-level public/private indicator.
BR102 AND BR103	IIS should download shipment files from the ordering system (for example, the federal Vaccine Tracking System, VTrckS) and upload them into the IIS daily to prepopulate provider organizations' inventory in the IIS.
BR105 AND BR106	A provider organization should verify the physical contents of a shipment against the packing slip and the information in the IIS and notify the immunization program and the IIS of any discrepancy.
BR202	Provider organization submissions should include the following data elements to support DI-v-EDE: lot number, dose-level eligibility, dose-level public/private indicator (optional for DI-v-EDE), vaccination event date, CVX code, National Drug Code ([NDC] optional for DI-v-EDE), provider organization IIS ID, and lot number expiration date.
BR203 and BR204	The IIS should only decrement active inventory for administered (not historical) immunizations.
BR205 and BR302	When an inventory reconciliation is closed, the IIS should freeze the results for automatic decrementing and make adjustments manually.
BR401	The IIS should establish and maintain a preapproval process and provider organization education for DI-v-EDE.

Operational Scenarios

Operational scenarios can help the reader explore the best practice recommendations through real situations. The following represent a few key scenarios outlined in the full best practice guidelines.

	S#	DESCRIPTION
'Best case' scenario		
	S201	Typical best case scenario for DI-v-EDE.
Inactive lot number		
	S502	Lot number in submission matches a lot number in provider organization inventory in the IIS that is not active.
Inconsistent data		
	S801	Mismatch of dose-level eligibility and lot-level public/private indicator.
Reconciliation		
	S1301	Reconciliation timeliness.

Implementation Considerations

When considering any new enhancement to an IIS there are often many implementation considerations. Before an awardee immunization program embarks on DI-v-EDE, it should review the implementation considerations section in the full guide. Some of the implementation considerations described in the full guide are summarized below.

HL7 Immunization Messaging. Although the IIS community and the full guide support the use of HL7 immunization messaging, HL7 does present some challenges because not all IIS implement the standard in the same way. For example, an EHR system may not reference the same code tables as those recognized by an IIS; therefore, if invalid or missing code values are sent, data are either rejected, omitted, or incorrectly translated. Additionally, as new values are updated or added to a code table (such as new CVX), there may be a lag time between release and the time EHR and IIS implement them. This can also lead to mismatched or omitted data.

**For additional questions,
please contact:**

Warren Williams

Centers for Disease Control
and Prevention
(404) 639-8867
wxw4@cdc.gov

Elaine Lowery

Public Health Consultant
(303) 881-2440
elaine.lowery@comcast.net

Rebecca Coyle

AIRA, Executive Director
202-552-0208
coyler@immregistries.org

AIRA

1155 F Street NW, Suite 1050
Washington, DC 20004

www.immregistries.org
info@immregistries.org



©2016 American Immunization Registry Association

This mini-guide was published by AIRA, an organization founded in July 1999 to advocate for the support of immunization information systems.

Production of this publication was supported by the Cooperative Agreement Number CDC-RFA-1P15-1501 from the Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the American Immunization Registry Association (AIRA) and do not necessarily represent the official views of the CDC.

Another consideration is that IIS should notify the originating provider organization if submitted messages that contain vaccination events that should be decremented from inventory are rejected or have issues. For example, the message meets the formatting standard, but a validation rule placed on a specific field is not met, so some aspect of the message and/or data is not accepted and other parts are. The Acknowledgement (ACK) message in HL7 can be used to identify when a message has been accepted, when it fails, or when it has errors (and what those errors may be). Unfortunately, the ACK message does not necessarily identify which data are consumed by the receiving system, so it may require investigation on the side of the EHR vendor to determine the complete error and how to fix and resubmit the appropriate data. It is not known exactly how many EHR vendors actually review ACK messages or give the provider organization access to those messages. The goal is for all IIS to send ACK messages and for EHR vendors to support tools and work-flows to ensure errors are available for end users within the provider organization to review and act on.

Equally important is the concept of the action code in HL7. If the IIS notifies the EHR that a message should be resubmitted, the EHR should resend the message with a field that is used by the IIS to indicate what action needs to be taken. It is not known if all EHRs and IIS are able to send/receive multiple types of action codes. In addition, most IIS have validation rules around several data items. For example, instead of relying on a sending system to indicate an update (“U”) has occurred with a vaccination event, the IIS would first look to see if a vaccine with the same CVX and same vaccination date had already been received. Best practice for use of action codes is not documented, and as a result, incorrect information often needs to be corrected manually in both the EHR and IIS.

Electronic Health Record (EHR). The workgroup had considerable discussion about the data elements an IIS could and should use to DI-v-EDE and the quality of data within those fields. Lot number is a key field used in the matching algorithm of DI-v-EDE. If the EHR allows users to enter lot number by hand, there is a high probability of data quality errors. Requiring the user to choose the lot number from a drop-down list may provide a higher likelihood of inventory matching between the EHR and IIS.

The full guide contains the additional implementation considerations: key data elements, data quality, outreach and education, staff time and resources.

Other Included Features

In addition, the guidelines contain an explanation of preapproval and ongoing maintenance processes for DI-v-EDE and descriptions of recommended reports to support the process of DI-v-EDE for both provider organizations and awardee immunization programs. Several individual reports are described that can assist with data quality issues and reconciliation.

This mini guide serves as a summary introduction to the more detailed, full guide, available at <http://www.immregistries.org/resources/aira-mirow>.