# Data Quality Assurance in Immunization Information Systems: Selected Aspects

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

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**Note:**
This document is not replacing the 2008 MIROW guide "Data Quality assurance in IIS: Incoming Data" (http://www.immregistries.org/AIRA_MIROW_Chap3_DQA_02112008.pdf), but rather supplementing it by covering additional data quality aspects and updating business rules.

# Executive Summary

This report aims to provide immunization information systems (IIS) with best practice recommendations formulated by leading experts in the IIS community based on their experiences and a collective judgment.

**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 IIS. This document is one chapter of the guidebook. It provides consensus-based best practice recommendations to support selected aspects of data quality assurance in IIS.

Specifically, this project focuses on three aspects of data quality:

1. Development of a model (domain model, a.k.a. facts model) that describes main concepts, terms, and definitions related to reporting of immunization and demographic information to IIS.
2. Reporting facility identification management, i.e., how to properly identify an organization associated with reported data in cases of complex submittal chains and organizational hierarchies.
3. Review and update of the business rules for various validations of the incoming to IIS data (initially captured in the earlier MIROW guide on this topic, released in 2008).

The development process consisted of a preliminary phase that included Web-based teleconferences held June-August 2012, face-to-face meetings held August 21-24, 2012 in Decatur, Georgia, and post-meeting activities to finalize the recommendations.

**Relevance**

The data quality assurance topic is especially relevant for the IIS community today because of the Meaningful Use initiative and other efforts aiming to promote and advance the use and exchange of clinical data in the electronic format. These efforts lead to a significant increase in collaborations between IIS and other health information systems, such as electronic health record (EHR) systems. Data quality assurance guidelines will be useful for IIS and their partners to reference as they all strive to meet the requirements of the initiative to exchange and use clinical data in electronic format.

**Key outcomes and accomplishments**

The Work Group accomplished the following:

- Developed and reconfirmed key concepts, terms, and definitions related to various aspects of data quality assurance in IIS. For example, the **new term** IIS-Authorized Organization (IIS-AO) has been introduced to describe any organization that has an agreement with the IIS which allows submittal and/or retrieval of IIS data. This new broad term covers provider organizations that administer vaccinations, as well as all other types of organizations that submit or retrieve IIS data.

- Developed business models and illustrations documenting **3 roles** that IIS-AOs play in the submittal chain of vaccination and demographic information to IIS. These roles include Vaccinator IIS-AO, Recorder IIS-AO, and Submitter IIS-AO. Formulated **8 operational scenarios** that illustrate IIS-AO roles.
- Defined expected /minimum sets of data items for vaccination event submissions based on the key data element - Administered/Historical Indicator. Formulated exceptions when a reduced set of data items may be accepted.
- Formulated **2 principles**, **27 business rules, and 7 general recommendations** to guide provider facility identification management and related data quality assurance efforts. For example (BR820), if two or more IIS-AOs (Org A and Org B) merge to form one new organization, the IIS-AOs (Org A and B) should be de-authorized and a new IIS-AO (Org C) should be created with a new IIS-AO ID.
- Developed considerations for implementing formulated best practice recommendations with current HL7 messaging standard.
- Revised and updated **27 business rules** for validations of the data incoming to IIS (initially captured in the earlier MIROW data quality assurance guide, released in 2008).

**Conclusion**

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

The National Vaccine Advisory Committee (NVAC) 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.

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  - **Minnesota Immunization Information System—Minnesota Immunization Information Connection (MIIC)**
  - **Nevada Immunization Information System—WebIZ**
  - **New York Citywide Immunization Registry (CIR)**
  - **New York State Immunization Information System (NYSIIS)**
  - **Oregon State Immunization Information System—Oregon Immunization ALERT**
  - **Washington State Immunization Registry—CHILD Profile**
  - **Envision Technology Partners, Inc.**
  - **HP Enterprise Services**
  - **Scientific Technologies Corporation**

# 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): Inventory Management, 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).

MIROW recommendations documents, abridged mini-guides, and other materials are available at the AIRA and CDC web sites:
http://www.immregistries.org/resources/aira-mirow,
http://www.cdc.gov/vaccines/programs/iis/activities/mirow.html.

Presentations that describe MIROW's efforts:

- "Development of Best Practices for Immunization Information Systems," AIRA 2012 IIS Meeting
  http://www.immregistries.org/resources/iis-meetings/Final_-_MIROW_Plenary_presentation_at_the_2012_AIRA_Meeting_09-18-2012.pdf
- "Evaluating IIS Best Practice Operational Guidelines: Emerging Trends and Challenges," 44th National Immunization Conference
  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 |
|---|---|---|---|---|
| **Data Quality Assurance in IIS: Selected Aspects (current topic)** | May 2013 | August 2012<br>3.5 days<br>Decatur, GA | 13 | **2** principles<br>**27** business rules<br>**7** general recommendations<br>**27** updated business rules |
| **IIS Inventory Management Operations**<br>**[1.1]** | June 2012 | September 2011<br>3.5 days<br>Atlanta, GA | 14 | **8** principles<br>**25** business rules<br>**23** general recommendations<br>**20** key reports |
| **IIS-VFC/Grantee Programs Collaboration**<br>**[1.2]** | April 2011 | June 2010<br>2.5 days<br>Atlanta, GA | 14 | **26** eligibility screening scenarios<br>**17** business rules<br>**9** general recommendations |
| **Reminder/Recall in IIS**<br>**[1.3]** | April 2009 | October 2008<br>2.5 days<br>Tampa, FL | 13 | **29** principles<br>**23** business rules<br>**30** general recommendations |
| **Data Quality Assurance in IIS: Incoming Data**<br>**[1.4]** | February 2008 | August 2007<br>2.5 days<br>Atlanta, GA | 11 | **13** principles<br>**32** business rules |
| **Vaccination Level Deduplication in IIS**<br>**[1.5]** | December 2006 | May 2006<br>2.5 days<br>Washington, DC | 20 | **9** principles,<br>**20** business rules,<br>**23** illustrative scenarios (examples) |
| **Management of Moved or Gone Elsewhere (MOGE) Status and other Patient Designations in IIS**<br>**[1.6]** | December 2005 | August 2005<br>2.5 days<br>Atlanta, GA | 16 | **6** statuses defined on the Provider level,<br>**5** statuses on the Geographic Jurisdiction level |
| **IIS-VAERS Guide**<br>(pilot project)<br>**[1.7]** | April 2005 | June 2004<br>1.5 days<br>Atlanta, GA | 21 | **10** functional standards,<br>**8** business rules,<br>**11** alternative scenarios (process) |

This document "Data Quality Assurance in IIS: Selected Aspects" (current topic) is not replacing the 2008 MIROW guide "Data Quality assurance in IIS: Incoming Data" [1.4], but rather supplementing it by covering additional data quality aspects and updating business rules.

**About this project: "Data Quality Assurance in IIS: Selected Aspects"**
The current report represents MIROW's efforts to develop best practice recommendations for selected aspects of data quality assurance in IIS.

The data quality assurance topic is especially relevant for the IIS community today because of the Meaningful Use initiative and other efforts aiming to promote and advance the use and exchange of clinical data in the electronic format. These efforts lead to a significant increase in collaborations between IIS and other health information systems, such as electronic health record (EHR) systems. Data quality assurance guidelines will be useful for IIS and their partners to reference as they all strive to meet the requirements of the initiative to exchange and use clinical data in electronic format.

This project focuses on three aspects of data quality:

1. Development of a model (domain model, a.k.a. facts model) that describes main concepts, terms, and definitions related to reporting of immunization and demographic information to IIS.
2. Reporting facility identification management, i.e., how to properly identify an organization associated with reported data in cases of complex submittal chains and organizational hierarchies.
3. Review and update of the business rules for various validations of the incoming to IIS data (initially captured in the earlier MIROW guide on this topic, released in 2008).

The development process consisted of a preliminary phase that included Web-based teleconferences held June-August 2012, face-to-face meetings held August 21-24, 2012 in Decatur, Georgia, and post-meeting activities to finalize the recommendations.

**About this document**
This document provides consensus-based best practice recommendations for selected aspects of data quality assurance in IIS, including issues related to facility identification management and validations of the data incoming to IIS (updates for the 2008 MIROW guide).

The recommended best practices are formulated using business modeling instruments:

- Domain model (Chapter 3) – 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).
- Principles (Chapter 4) – provide a high-level direction that helps to guide the development of more specific business rules.
- Business rules (Chapter 4 and Chapter 5) – represent specific requirements and decision-making logic for various aspects of IIS processes.
- General recommendations (Chapter 4) – represent requirements, advice, and suggestions for IIS functionality and operations related to facility identification management.

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 IIS.

- The business rules represent an attempt to balance ideal possible practices with pragmatic considerations of what will be possible to implement in an IIS.
- Specific implementation of business rules (and associated best practices) may vary, based on resources, goals, needs, and unique implementation concerns.
- The set of business rules and 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, Grantee Vaccine Programs staff, as well as vendors of health care information systems and providers of immunization services. The guide intends to bridge the gap between IIS technical and program staff, IIS and Grantee Vaccine Programs, and IIS and its partners. Bridging these gaps will help create a mutual understanding of data quality assurance issues and identify actions to implement/apply these recommendations.

**Intended use**
This guide contains a set of recommended operational best practices (including a set of principles and business rules to follow) that are intended as a basis for requirements in IIS applications and operations. In addition, this guide can be used 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 business analyst and subject matter experts (SMEs). During a subsequent ***face-to-face facilitated modeling session*** held on August 21-24, 2012 in Decatur, Georgia, the 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

- **Includes:**
  - All data communicated through the direct user interface (UI) and electronic data exchange (EDE) from IIS-Authorized Organizations to IIS (see Table 3 for terms and definitions)
    - Facility identification management (IIS inbound data)
      - i.e., how to properly identify a provider organization associated with reported data in cases of complex organizational hierarchy. For example, in "parent – subsidiary/child" organizations, proper identification is needed to avoid immunization data ownership issues when reported data are not properly attributed.
    - Updates to 2008 DQA guide (IIS inbound data)
  - Primary emphasized perspectives
    - IIS
    - IIS-Authorized Organizations
      - Vaccinators (a.k.a. Provider Organizations)
      - Recorders
      - Submitters
  - Secondary emphasized perspectives
    - IIS-Authorized Organizations
      - Data Consumers

- **Excludes:**
  - Message format and HL7 issues
  - Other outbound data, e.g., reports to Immunization programs or providers of immunization services
  - Emphasized perspectives
    - Non IIS-Authorized Organizations
    - Individual (person) access/submissions to IIS (e.g., by a patient, guardian)

# Chapter 3: Domain Model – Concepts, Terms, and Definitions

**Domain model purpose**

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 meanings).

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

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

A domain model includes:

- Domain diagram(s) that shows major business entities (concepts), their relationships, and responsibilities (Fig. 1 and Fig. 2)
- Table of entities and attributes ─ provides the full descriptive details of the components represented on the diagram (Table 3 and Table 7)
    - Numbering of the entities and attributes on diagrams correspond to numbers in the table of terms and definitions
- Description of the domain diagram(s) (presented below)

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 Fig. 1):

- Relationships between entities are visualized by connecting lines.
- Names associated with these lines describe the types of relationships between entities. Example: A relationship between *IIS-Authorized Organization* and *Vaccination Event* is shown as a connecting line with the word (label) "*conducts*." Such a relationship should be read as "*IIS-Authorized Organization conducts Vaccination Event.*"
- The general convention for interpretation of relationships between entities is to construct such a description by reading clockwise, starting from the first entity name (*IIS-Authorized Organization*), then relationship name—*conducts* (note that the name is shown above the line, supporting a clockwise reading), then the second entity name (*Vaccination Event*).
- If we need to read the same description in the opposite direction, from *Vaccination Event* to *IIS-Authorized Organization*, we would have to place a second name— "*conducted by*" — below the line. In this case, using the clockwise reading rule, a description would be

"*Vaccination Event is conducted by the IIS-Authorized Organization.*" In most cases just one name for a relationship is employed (such as "*conducts*" in the example just considered), assuming that it should be sufficient for a proper interpretation of a relationship in both directions.

**Description of facts depicted on domain diagrams**

Following is a description of facts presented in the simplified version of the domain diagram (Fig. 1). These facts describe relationships between the main entities that are relevant for the scope of this particular topic.

- Patient is vaccinated at Vaccination Event
- Vaccine, which is an instance of a Vaccine Product Type, is administered at Vaccination Event
- During the Vaccination Encounter (office visit) several Vaccination Events can be performed (in some cases - no Vaccination Events, e.g., a Patient's refusal for vaccinations)
- Patient has an Immunization History that contains Vaccination Events
- IIS consolidates Immunization History for Patient and provides a Vaccination Forecast for Patient based on consolidated Immunization History
- IIS-Authorized Organization (IIS-AO) receives Vaccination Forecast from the IIS
- IIS-AO conducts Vaccination Event
- Provider works for IIS-AO and performs Vaccination Event, referencing Vaccination Forecast
- Vaccination Event Submission describes Vaccination Event
- Demographic-only Submission describes Patient
- Data Enterer works for IIS-AO and enters Vaccination Event Submission and Demographic-only Submission into the IIS-AO Electronic Data Exchange (EDE) system or the IIS Direct User Interface (UI)
- Combined Submission contains Vaccination Event Submissions and Demographic-only Submissions
- IIS-AO submits Combined Submissions to IIS
- IIS communicates with IIS-Authorized Organizations (IIS-AO) through IIS Direct User Interface or Electronic Data Exchange

A complete domain diagram (Fig. 2) contains additional information about part of the immunization registration domain which is relevant for this topic. That includes attributes characterizing domain entities, roles that parties can play, as well as additional relationships between entities. Following are facts (in addition to facts described above for Fig. 1) presented on the complete domain diagram (Fig. 2):

- IIS-AO may be a part of another IIS-AO. In this case, one IIS-AO plays a role of a "subsidiary/child" and another IIS-AO plays a role of a "parent."
- IIS-AO plays a role of Vaccinator when it conducts Vaccination Event.
- IIS-AO plays a role of Submitter when it submits Combined Submission.
- IIS-AO may submit Combined Submission for (on behalf of) another IIS-AO. In this case, one IIS-AO plays a role of Submitter and another IIS-AO plays a role of Vaccinator (or Recorder) or another Submitter.

- Provider works for IIS-AO that plays a role of Vaccinator.
- Provider plays a role of Vaccine Administrator when (s)he performs Vaccination Event.
- Provider plays a role of Vaccine Prescriber when (s)he orders (prescribes) Vaccination Event.
- Data Enterer works for IIS-AO that plays a role of Recorder.
- Data Enterer plays a role of UI or EDE User when (s)he enters Vaccination Event Submission or Demographic-only Submission.

## Domain diagrams

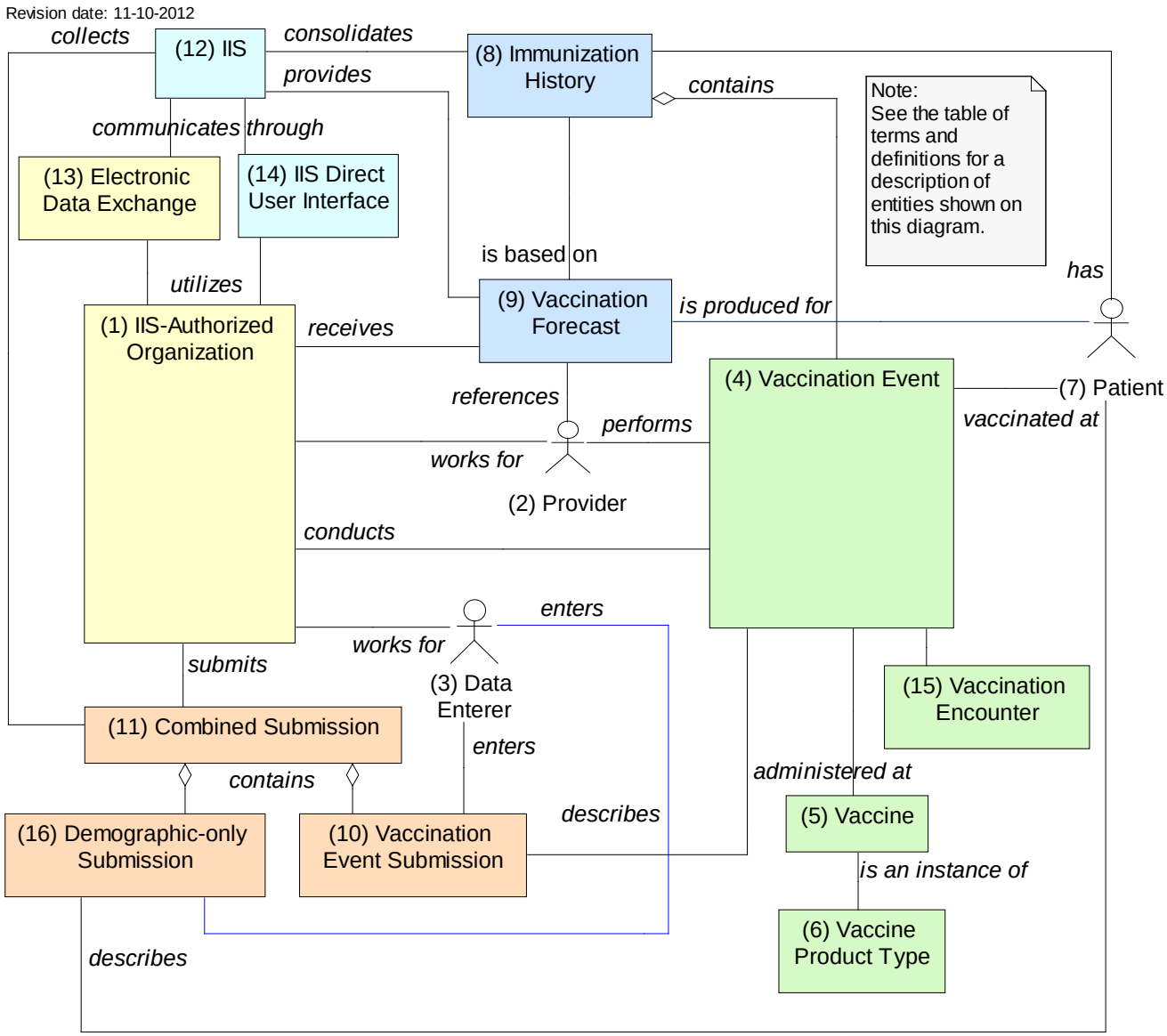


**Figure 1.** Domain Diagram (main concepts and terms) – a simplified version

Revision date: 04-23-2013

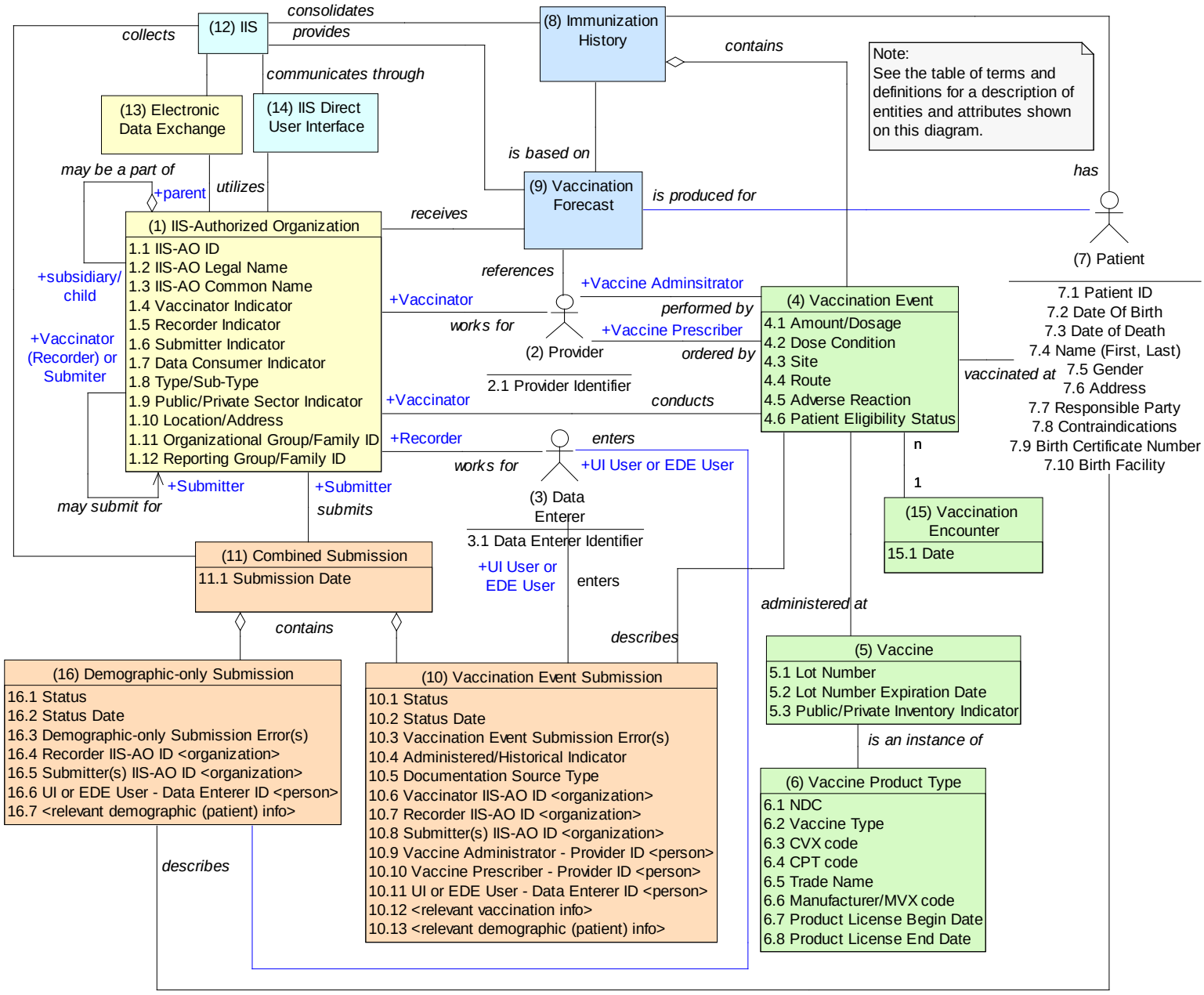


**Figure 2.** Domain Diagram (main concepts and terms)

**Discussion and notes**

This section aims to provide explanations and perspectives for key entities and concepts depicted on the domain diagrams and to complement information in the tables of terms and definitions (Table 3 and Table 7).

**Vaccination Event Submission vs. Vaccination Event (i.e., "reporting" vs. "reality")**

- In the domain model, a Vaccination Event Submission represents the submitted (i.e., "reported") information about a specific Vaccination Event (i.e., "real-world" episode).
- There may be one or more Vaccination Event Submissions for each specific Vaccination Event (e.g., several IIS-AOs report the same event). However, there can only be one Vaccination Event per "real-world" administration.
- The Vaccination Event is represented as an entity with relationships to other entities required for the Vaccination Event to occur, including Patient, Provider, Vaccine, etc.
- Given the Vaccination Event Submission is a "record" of the Vaccination Event, it includes attributes for all of the potentially relevant pieces of information, including Vaccination Event, Patient, Provider, Vaccine, etc.
- However, all Vaccination Event Submissions may not provide data for all of the attributes, especially in cases where the information is not known.

**Vaccination Event Submission and Demographic-only Submission**

- Given the similarity of the contents of these two constructs, they may be combined into one during implementation. In which case, the combined structure would likely have more or less information depending on whether it was for Vaccination Event or Demographic-only submission.

**Combined Submission**

- Vaccination Event Submissions could be done one at a time or several at a time.
- Ultimately, this group of event submissions could be for:
    - One Patient's Vaccination Encounter (i.e., 1 or more Vaccination Events)
    - One Patient's Vaccination History (i.e., 1 or more Vaccination Encounters)
    - One Provider Organization's Patients (i.e., multiple Vaccination Events or Vaccination Encounters across patients)
- The Combined Submission allows for the submittal of these various sets of data, whether for one Vaccination Event or many (e.g., dozens).
- The system implementation will dictate what ways this information can be filtered, grouped, sorted, etc.
- Similarly, Demographic-only submissions could be done one at a time or in a batch at a time.
- This construct (Combined Submission) also supports the possibility of a mix of Vaccination Event Submissions and Demographic-only Submissions being submitted together.

**Electronic Data Exchange (EDE) and IIS User Interface**

- These are viewed as two interfaces via which Vaccination Event and Demographic-only information can be communicated between the IIS-AO and the IIS, as illustrated in Fig. 3.
- There may be one or more systems along the EDE path and there may be one or more protocols and file formats (e.g., flat file, HL7) used in the communication.

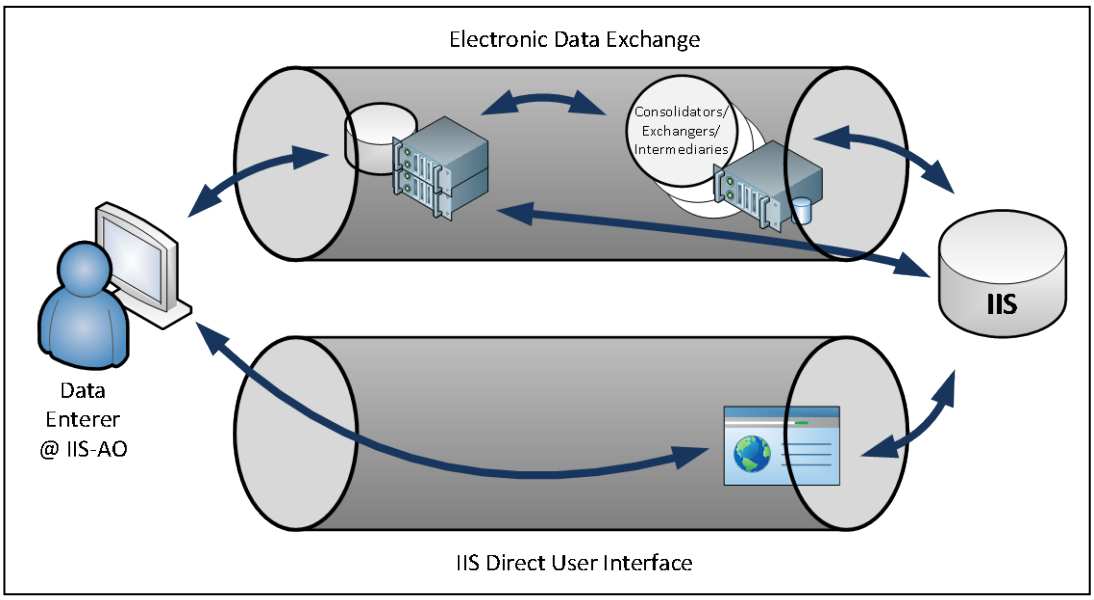


**Figure 3.** Two interfaces between IIS-AO and IIS

**IIS-AO Roles: Vaccinator, Recorder, Submitter**

This section describes roles that an IIS-AO can play in the chain of reporting vaccination and demographic information to IIS. These roles are: Vaccinator, Recorder, and Submitter. Roles are depicted on the domain diagram (Fig. 2) with the blue font.

Note that:

- One organization can, and often does, perform more than one role.
- Each role can be performed by different organizations.

There are essentially three valid paths, as illustrated below (Fig. 4), including:

- Reporting of Administered Vaccination Event
  - Note that for this path Vaccinator and Recorder are always the same IIS-AO.
- Reporting of Historical Vaccination Event
  - Note that for historical Vaccination Events, even if the Recorder IIS-AO in general performs vaccinations, it is not the Vaccinator for the historical Vaccination Event. The Vaccinator for the historical Vaccination Event is the organization that originally administered the vaccination. In many cases, it is unknown. In some cases, e.g., out-of-state vaccinations, Vaccinator IIS-AO is irrelevant.
- Reporting of Demographic-only information

In reality, these essential paths play out in multiple ways. Table 2 illustrates various combinations of IIS-AOs which may be reported as part of a Vaccination Event Submission or a Demographic-only Submission.

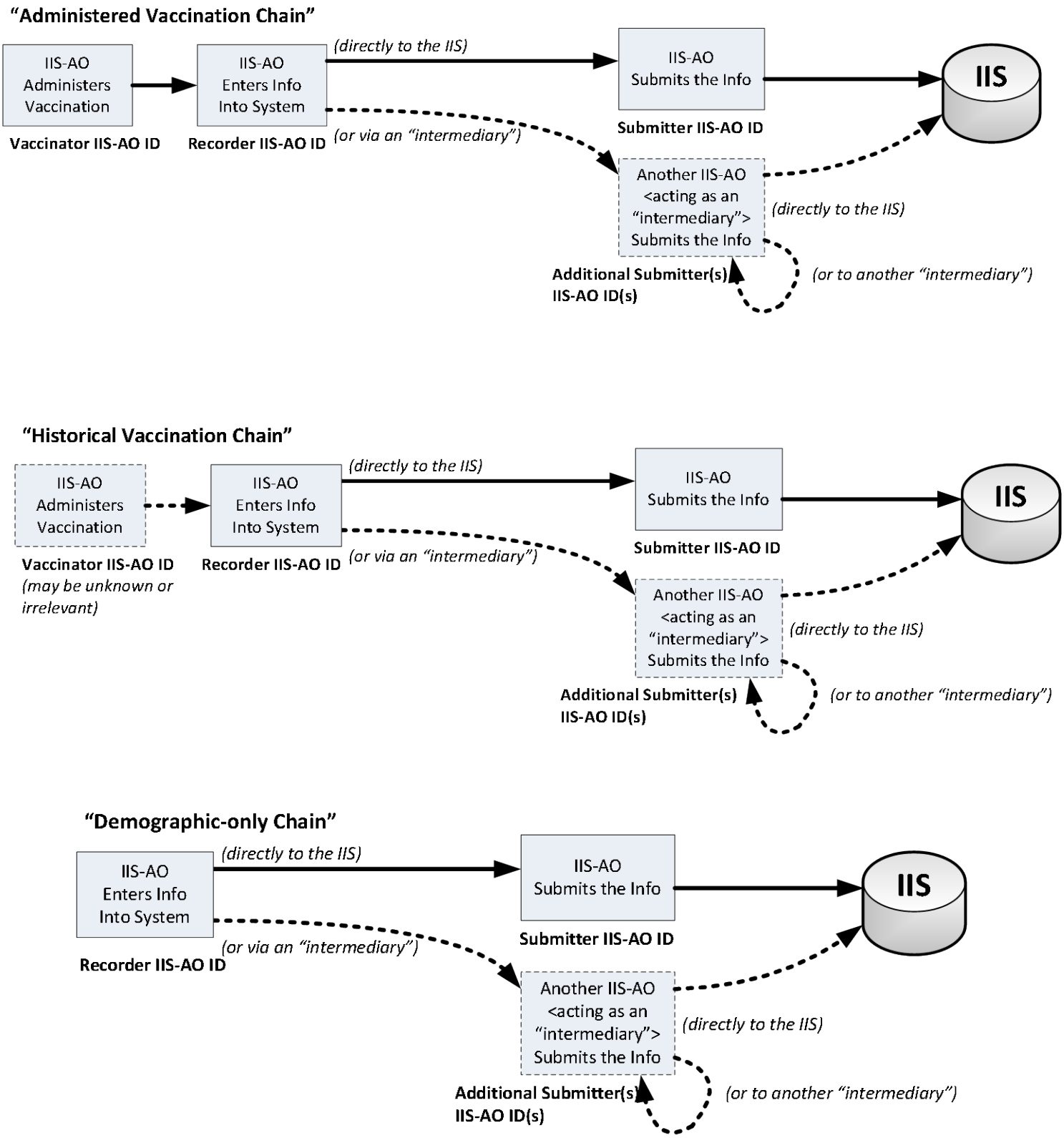


**Figure 4.** Submission chains from IIS-AO to the IIS

**Table 2.** Illustrative operational scenarios: Roles that IIS-AO can play in the chain of reporting vaccination and demographic information to IIS
Notes:

- The outcome of these operational scenarios does not change if the submitting IIS-AO ("Org") is also a vaccinator or provides "reporting" services only.
- Specific examples can be found in the chapter 4, HL7 considerations section.

| | **Vaccination Event Submission or Demographic-only Submission** | | |
|---|---|---|---|
| **Sample Scenarios** | **Vaccinator** | **Recorder** | **Submitter(s)** |
| 1. Org A is a self-reporting Vaccinator. | Org A | Org A | Org A |
| 2. Org B is submitting administered vaccination information to the IIS on behalf of Org A. | Org A | Org A | Org B |
| 3. Org B is submitting administered vaccination information to the IIS on behalf of Org A. Org B submits via Org C. | Org A | Org A | Org B, Org C |
| 4. Org A is entering and submitting historical vaccination information. Org B was the original Vaccinator and is known. | Org B | Org A | Org A |
| 5. Org A is entering and submitting historical vaccination information. The original Vaccinator is unknown. | N/A | Org A | Org A |
| 6. Org A is entering historical vaccination information, Org B is submitting it on behalf of Org A, and the original Vaccinator is unknown. | N/A | Org A | Org B |
| 7. Org A is reporting demographic-only information directly to the IIS. | N/A | Org A | Org A |
| 8. Org B is submitting demographic-only information on behalf of Org A. | N/A | Org A | Org B |

**IIS-AO: Organizational and functional hierarchies**

- Recursive ("self-similar") relationship that is shown in Fig. 2 (domain diagram) indicates that an IIS-Authorized Organization (a "subsidiary/child") can be a part of another IIS-Authorized Organization (a "parent"). That allows IIS to accommodate multi-level organizational hierarchies in a simple and flexible way.
- IIS needs to identify the IIS-Authorized Organization that a) administered the vaccine dose (IIS-AO Vaccinator role), b) enters the immunization or demographic data into the IIS-AO EDE system or the UI (IIS-AO Recorder role), and c) submitted information about that Vaccination Event to IIS (IIS-AO Submitter role). A specific level of the hierarchy for the IIS-Authorized Organization that administered vaccine and IIS-Authorized Organization that submitted that Vaccination Event information to IIS is not that important for purposes of this topic: Each of these IIS-Authorized Organizations can be an Organization or Organizational Unit of an Organization. What is important for this

topic from the IIS perspective is a functional role that each of these IIS-Authorized Organizations performs, i.e., Vaccinator (IIS-AO - conductor of a Vaccination Event), Recorder (IIS-AO that enters information into EDE system or UI), and Submitter (IIS-AO that submits the information to the IIS). Each IIS-AO that serves one or more of these functional roles could introduce different data quality issues into the IIS. Knowing the specific functional role(s) that each IIS-AO plays allows the IIS to more effectively and efficiently identify and resolve data quality problems.

- Accordingly, the emphasis of these efforts is on functional hierarchy that is based on the shared services/functions (such as reporting to IIS service/function), rather than on the business organizational/structural hierarchy.
- The domain diagram in Fig. 2 illustrates that aspect with introducing a functional hierarchy of shared services and functions between IIS-Authorized Organizations in administering vaccines and submitting information about Vaccination Events. That functional hierarchy is shown with a recursive ("self-similar") relationship, indicating that one IIS-AO ("Submitter") may submit information for another IIS-AO ("Vaccinator" [Recorder] or "Submitter").

**IIS-AO – Organizational Group/Family ID and Reporting Group/Family ID**

As an implementation consideration, there are various mechanisms which can be used to aid the end user when working within an environment that supports both organization structural hierarchies (e.g., sub-units) and functional "reporting" hierarchies. Two possibilities include:

- Use of Identifiers (e.g., Organizational Group/Family ID) that would be shared between all organizations within the group
    - The primary benefit of this approach is that end users may be able to learn to recognize such IDs and enter them quickly.
    - However, these tend to be more difficult to maintain over time, e.g., if structures change (e.g., because of mergers, acquisitions).
    - The Organizational Group/Family ID and Reporting Group/Family ID are provided here as one example of how these relationships between IIS-AOs could be implemented.
- Use of "join-tables" or forming relationships within the data structures that represent the association between multiple organizations
    - These tend to more naturally fit how users think of the world, but often require more support via a user interface to enable.

**Administered/Historical Indicator**

Administered/Historical Indicator (item 10.4 on Fig. 2 and Table 3) describes an association between a Vaccination Event and the IIS-AO that originates a Vaccination Event Submission for this Vaccination Event:

- "Administered" value for the Administered/Historical Indicator points out that the IIS-AO submits its own Vaccination Event, i.e., attests that it conducted the Vaccination Event ("I am the Vaccinator IIS-AO").
    - In this case, expanded set of data items for a Vaccination Event Submission would be expected (this is the Best Practice -- see BR105R1, chapter 5).
    - In some cases, IIS-AO submits its own Vaccination Event ("administered"), but does not have all expected information for the expanded set of data items. Following are

three situations when a reduced set of data items for an "administered" Vaccination Event submission may be allowed (see BR105R2, chapter 5):

- Legacy immunizations. Example is an IIS-AO that begins reporting to (comes onboard) IIS and wants to submit information about Vaccination Events it conducted some time ago, before entering into an agreement with IIS.
- Limited EHR capacity. In some cases, EHR that IIS-AO uses does not support expanded set of data elements, so IIS-AO is not able to send them. IIS still wants the data and cannot mandate upgrade to EHR.
  - ✓ This situation would be for a limited time period, as established by the IIS.
  - ✓ Example from one of the states: One of the largest health systems is not on 2014 certified EHR. It will take 12-18 months to transition to 2014 platform. IIS cannot expect to receive complete set of data elements until mid to late 2014.
- Birth Doses. HepB and other hospital birth doses may not have all required data elements available.
- Notes:
  - ✓ Rules for accepting or rejecting "Administered" Vaccination Event Submissions with less than the expanded data set should be the same for Electronic Data Exchange and Direct User Interface submissions.
  - ✓ When reduced set of data items is reported for the "Administered" Vaccination Event, an error message should always be sent or displayed in the UI. Also, other methods of communicating data quality problems should be employed, i.e., monthly reports.

- "Historical" value for the Administered/Historical Indicator points out that the IIS-AO originates a Vaccination Event Submission for a Vaccination Event that was administered (and therefore, owned) by some other IIS-AO ("I am NOT Vaccinator IIS-AO; I am just Recorder IIS-AO").
  - In this case, a reduced set of data items for a Vaccination Event Submission would be expected (see BR105R2, chapter 5).

**Table of terms and definitions**

**Table 3.** Domain model - terms and definitions (see Fig. 2)
Note: See Appendix A, Table 7, for the domain model's terms and definitions listed in alphabetical order.

| ID | Name | Description | Remarks |
|---|---|---|---|
| 1 | IIS Authorized Organization | IIS-Authorized Organization (IIS-AO) is a new term introduced to describe any organization that has an agreement with the IIS which allows submittal and/or retrieval of the IIS data. For the purposes of this Data Quality MIROW Guide, retrieval and submittal are limited to vaccination and/or demographic information.<br><br>In previous MIROW Guides, an IIS-AO in the role of Vaccinator was called a Provider Organization. Provider Organization is an organization that provides vaccination services or is "accountable" for an entity which provides vaccination services. Provider Organizations include a collection of related Providers (e.g., clinicians – physicians, nurses). | • This term indicates that IIS has granted that organization permission to submit and/or retrieve IIS data.<br>• An IIS-Authorized Organization may include a number of other IIS-Authorized Organizations, such as different clinical offices/sites and physician groups ("parent – subsidiary/child" relationship).<br>• IIS-AOs can play multiple roles. These may be overlapping (i.e., an IIS-AO plays multiple roles at once, e.g., Vaccinator and Submitter) and they may change over time. The roles include:<br>o Vaccinator<br>o Recorder<br>o Submitter<br>o Data Consumer<br>• In the domain model, each clinic (organizational unit, i.e., a unit of a "provider organization") that we care to know about is an IIS-AO. A clinic (organizational unit) that is an IIS-AO can have an organizational "subsidiary/child" that is not an IIS-AO. In this case, the IIS is not aware of that "child" organization, and does not need to take any action with respect to that child organization (arguably, IIS doesn't care about it). All organizations and organizational units that IIS cares about should be set up as IIS-AOs. See also "Organizational and functional hierarchies" section on page 22.<br>• See GR802, chapter 4: "Establish written agreements with Submitters, Recorders, and Vaccinators."<br>• Agreement between IIS and IIS-AO may or may not be a legal contract. |

| ID | Name | Description | Remarks |
|---|---|---|---|
| 1.1 | IIS-AO ID | Identifier assigned by IIS to the IIS-Authorized Organization.<br><br>Identifier (ID) that labels and establishes the identity of an IIS-AO. | • Also known as Facility/Site Organization ID. The assumption is that each facility/site is an IIS-AO (see the last bulleted note for IIS-AO).<br>• IIS-AO ID is assigned to any IIS-Authorized Organization that has access to IIS. There are organizations, e.g., schools, which do not administer vaccines, but do have IIS-AO ID.<br>• Distinct IIS-AO ID is assigned to an IIS-Authorized Organization that is a part of another IIS-Authorized Organization (both have unique IIS-AO IDs). A decision to assign the IIS-AO ID to an Organizational Unit is made collaboratively by IIS and an IIS-Authorized Organization.<br>• Beyond IIS-AO ID, each IIS AO may have multiple inventory-based IDs (i.e., VTrckS IDs) used to track inventory for federal (VFC, 317, STD, etc.) and state-funded vaccines. The IIS-AO ID should be cross-linked to these inventory-related IDs.<br>• See chapter 4, Facility Identification Management, for considerations. |
| 1.2 | IIS-AO Legal Name | The legal name of the IIS-Authorized Organization. | • Currently may be implementation limitations on length (e.g., 40 characters in VTrckS) |
| 1.3 | IIS-AO Common Name | The common name of the IIS-Authorized Organization. | • This would be the name IIS-AO is known by in the community. |
| 1.4 | Vaccinator Indicator | Indicates if an IIS-AO provides vaccination services.<br><br>In previous MIROW Guides, an IIS-AO acting in the role of Vaccinator was called a Provider Organization. Provider Organization is an organization that provides vaccination services or is "accountable" for an entity which provides vaccination services. Provider | Vaccinator (IIS-AO) may:<br>• Submit vaccination (and/or demographic) information to IIS for itself and/or other IIS-AOs<br>or<br>• Delegate submitting its vaccination (and/or demographic) information to other IIS-AOs |

| ID | Name | Description | Remarks |
|---|---|---|---|
| | | Organizations include a collection of related Providers (e.g., clinicians – physicians, nurses). | |
| 1.5 | Recorder Indicator | Indicates if an IIS-AO enters the immunization or demographic data into the IIS-AO EHR system or the UI. | • Recorder can be on behalf of itself (e.g., for administered vaccinations) or on behalf of other organizations (e.g., for historical vaccinations). |
| 1.6 | Submitter Indicator | Indicates if an IIS-AO submits Vaccination Event Submissions and/or Demographic-only submissions to the IIS or to intermediary Submitter(s) with IIS as a final destination. | • Submittal is generally referred to as "reporting."<br>• Submission can be on behalf of the IIS-AO itself (in the case of a Vaccinator or Recorder) or on behalf of other organizations. |
| 1.7 | Data Consumer Indicator | Indicates if an IIS-AO retrieves information from the IIS. | • Data Consumer is authorized to access IIS data.<br>• Some IIS-AOs are only Data Consumers, and thus are not authorized to submit information to IIS. |
| 1.8 | Type/Sub-Type | Describes a combination of patient population and services provided by the IIS-AO. | • Knowing the type of practice can help determine whether immunizations being reported are typical/expected. In the 2008 MIROW data quality guide [1.4], business rule BR113 relates to this.<br>• May be sufficient to assign only the type (e.g., Specialty Provider); in these cases, the sub-type is not needed.<br>• Note that best practices for defining type /sub-type have not been developed at this time and, until determined, it is left up to the IIS to define types/sub-types for their IIS-AOs.<br>• Example:<br>o Type = Specialty Provider, Sub-type = OB/GYN<br>o Type = Hospital, Sub-type= ER<br>• There could be multiple layers to one IIS-AO (e.g., family practice may be OB/GYN also). |

| ID | Name | Description | Remarks |
|---|---|---|---|
| 1.9 | Public/Private Sector Indicator | Describes sector/funding source for the IIS-AO. | • This is not the same as the funding source for vaccines or Public/Private Inventory Indicator (see item 5.3). |
| 1.10 | Location/ Address | The address of the IIS-AO. | • Possible fields to include with address are city, state, county, country, zip code, telephone, and Jurisdiction. |
| 1.11 | Organizational Group/Family ID | Identifies a conglomerate of IIS-AOs that belong to the same Organization. | • This is one possible mechanism for linking and quickly identifying the organizational family members (e.g., Parent/Subsidiary/Child relationships) of an IIS-AO.<br>• This is separate from the IIS-AO ID.<br>• This attribute is not a part of reporting; rather, it is defined at the IIS and tied to the IIS-AO ID.<br>• See the section "IIS-AO – Organizational Group/Family ID and Reporting Group/Family ID" in chapter 3 for a discussion.<br>• Also see item 1.12. |
| 1.12 | Reporting Group/Family ID | Identifies a conglomerate of IIS-AOs that are sharing a reporting service for Vaccination Event submissions and/or Demographic-only submissions. | • This is one possible mechanism for linking and quickly identifying organizations that share a reporting service.<br>• This is separate from the IIS-AO ID.<br>• This is a way for the IIS to designate which IIS-AOs are submitting data via other IIS-AOs. So, IIS-AO "A" submits on behalf of IIS-AO "1" and IIS-AO "2." This ID would be separate from "A," "1," or "2," but would designate the relationship between these IIS-AOs.<br>• See the section "IIS-AO – Organizational Group/Family ID and Reporting Group/Family ID" in chapter 3.<br>• Also see item 1.11. |
| 2 | Provider | A person – medical professional, clinician – who works for a Vaccinator (IIS-AO).<br>. | • Provider and Data Enterer are entities ("actors") with distinct responsibilities: Provider is responsible for performing Vaccination Events and Data Enterer is responsible for entering information about the Vaccination Event into the submission chain. These are distinct functional sets (or "roles") that real people |

| ID | Name | Description | Remarks |
|---|---|---|---|
| | | | can play.<br>• Examples of roles that a Provider entity (a person) can play: Vaccine Administrator (administered vaccine, e.g., nurse) and Vaccine Prescriber (ordered/prescribed vaccine to be administered, e.g., clinician; should have appropriate credentials, e.g., MD; a.k.a. Ordering Clinician)<br>  o These two roles are described in the IIS Functional Standards, 2013-2017 (http://www.cdc.gov/vaccines/programs/iis/func-stds.html) with the following IIS Core Data Elements: Vaccine Administering Provider Name and Vaccine Ordering Provider Name.<br>• The same person can play roles of Provider and Data Enterer (item 3). |
| 2.1 | Provider Identifier | Identifier (ID) that labels and establishes the identity of a Provider (a person).<br><br>This is a Provider's (person's) identification for IIS purposes. | • Provider Identifier (ID) should include:<br>  o **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>  o **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>• The National Provider Identifier (NPI) registry at https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do may be considered for use by an IIS for the purpose of establishing Provider Identifiers, providing a consistent approach across the country. Provider Identifier is generally used only internally within the IIS. Additionally, an IIS may not track every Provider in its jurisdiction.<br>• See also items 10.9 and 10.10: Vaccine Administrator – Provider Identifier and Vaccine Prescriber – Provider Identifier. |
| 3 | Data Enterer | A person who works for a Recorder (IIS-AO) and enters immunization or demographic data via the direct user interface (UI) or Electronic Data Exchange (EDE, e.g., EHR) to submit vaccination and/or demographic information to IIS. | • Data Enterer and Provider are entities ("actors") with distinct responsibilities: Provider is responsible for performing Vaccination Event and Data Enterer is responsible for entering information about the Vaccination Event into the submission chain. These are distinct functional sets (or "roles") that real people can play.<br>• The same person can play roles of Provider (item 2) and Data Enterer. |

| ID | Name | Description | Remarks |
|---|---|---|---|
| | | Data Enterer can play a role of UI or EDE User. | |
| 3.1 | Data Enterer Identifier | Identifier (ID) that labels and establishes the identity of a Data Enterer (a person).<br><br>This is a Data Enterer's (person's) identification for IIS purposes. | • Data Enterer Identifier (ID) should include:<br>o **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>o **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>• Since there is no universal list of IDs for Data Enterers (across jurisdictions), the IIS does not necessarily track every Data Enterer in its jurisdiction. Therefore, Data Enterer ID is generally only used internally to the IIS.<br>• See also item 10.11: UI User or EDE User –Data Enterer Identifier. |
| 4 | Vaccination Event | Vaccination Event is a medical occurrence of administering one Vaccine to a Patient. | • Several Vaccination Events can happen during one office visit (see Vaccination Encounter – item 15). |
| 4.1 | Amount/ Dosage | The measurement of how much vaccine was administered. | • Examples: 1 mL, .5 mL, 1 microgram<br>• Examples: 1 dose, 2 doses, 0.5 doses<br>• IIS should maintain a consistent measurement method for recording all vaccine amount/dosage administered and not use measures for dose magnitude in some cases and dose quantity in others. |
| 4.2 | Dose Condition | A "compromised" indicator. Indicates that a dose administered to a patient is considered substandard and therefore, not a valid dose. | |
| 4.3 | Site | Anatomical site where the immunization was administered. | • A.k.a. Vaccine Site of Administration |
| 4.4 | Route | The method of administration (e.g., intramuscular, intranasal, oral, etc.). | • A.k.a. Vaccine Route of Administration |

| ID | Name | Description | Remarks |
|---|---|---|---|
| 4.5 | Adverse Reaction | An Adverse Reaction is a negative health consequence experienced by the patient related in time to administration of vaccine(s). | • "In time" means that it happens in some reasonable time after the Vaccination Event. It might not be related to a specific Vaccine dose administered in cases when the patient receives several shots in one visit.<br>• See http://vaers.hhs.gov/resources/vaersmaterialspublications for the Vaccine Adverse Event Reporting System (VAERS).<br>• Adverse Reaction is also known as Adverse Event or Vaccine Reaction. |
| 4.6 | Patient Eligibility Status | Patient's eligibility for a funding program | • For IIS-AOs that are participating in the federal or state public immunization program<br>• See MIROW guide [1.2]. |
| 5 | 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<br>• Vaccine is designated by use of both the Vaccine Product Type and the Lot Number. |
| 5.1 | Lot Number | The lot number is the number assigned by the manufacturer to a specific batch of Vaccine Product Type. | • Lot Number can be used by IIS to track administered vaccines. |
| 5.2 | 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.<br>• 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. |
| 5.3 | Public/Private Inventory Indicator | Indicates if a vaccine dose belongs to a public or private stock. | • When a Public/Private inventory indicator for a dose administered to a Patient is "private" and Patient eligibility status is "public" (or vice versa), the borrowing transaction is created.<br>• 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. |

| ID | Name | Description | Remarks |
|---|---|---|---|
| | | | • See MIROW Inventory Management guide [1.1] for details. |
| 6 | Vaccine Product Type | Vaccine Product Type is a category of the vaccine product that is ordered, shipped, administered, etc.<br>• An IIS-AO (a "provider organization") indicates the Vaccine Product Type when placing vaccine orders.<br>• An IIS-AO (a "provider organization") receives Vaccine (item 5), which contains specific batches or lots of this Vaccine Product Type. | • Vaccine Product Type, for inventory tracking/ management purposes, is characterized by the NDC code (see item 6.1).<br>• Vaccine Product Type, for immunization tracking purposes, is characterized by the Vaccine Type (or CVX code, or CPT code), Manufacturer (MVX code), and Trade Name (see 6.2 – 6.6).<br>• An instance of the Vaccine Product Type – a Vaccine (see item 5) – is characterized by the Lot Number and Lot Number Expiration Date.<br>• Examples of Vaccine Product Types that belong to the same Vaccine Type (item 6.2), but have different NDC codes (source – "IIS: HL7 Standard Code Set Mapping NDC to CVX and MVX" at http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc)<br>Vaccine Product Type 1<br>o 6.1 NDC = 58160-0820-11<br>o 6.2 Vaccine Type = HepB<br>o 6.3 CVX code = 08<br>o 6.4 CPT code = 90744<br>o 6.5 Trade Name = ENGERIX B-PEDS<br>o 6.6 Manufacturer/MVX code = SKB<br><br>Vaccine Product Type 2<br>o 6.1 NDC = 00006-4981-00<br>o 6.2 Vaccine Type = HepB<br>o 6.3 CVX code = 08<br>o 6.4 CPT code = 90744<br>o 6.5 Trade Name = RECOMBIVAX-PEDS<br>o 6.6 Manufacturer/MVX code = MSD |
| 6.1 | NDC | NDC (National Drug Code) is defined as a unique numeric identifier of the Vaccine Product Type. | • Each drug product is assigned a unique three-segment number. This number, known as the NDC, identifies the labeler, product, and trade package size.<br>• The first segment, the labeler code, is assigned by the FDA. A labeler is any firm |

| ID | Name | Description | Remarks |
|---|---|---|---|
| | | For specific NDC examples, see CDC Vaccine Price List at http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm. | (including re-packers or re-labelers) that manufactures or distributes (under its own name) the vaccine.<br>• The second segment, the product code, identifies a specific strength, dosage form, and formulation of a drug for a particular firm.<br>• The third segment, the package code, identifies package sizes and types ("presentation").<br>• VTrckS uses the 5-4-2 NDC format. Other formats for NDC codes exist and should be accounted for. |
| 6.2 | Vaccine Type | The Vaccine Type is defined as a category of Vaccine.<br><br>A single Vaccine Type may be associated with many Vaccine Product Types (i.e., different manufacturers, different packaging).<br><br>Vaccine (item 5) is an instance of Vaccine Product Type. | • The Vaccine Type may indicate a generic or specific type of vaccine (e.g., pneumococcal or PCV13 or PPSV23).<br>• The Vaccine Type can include single types of Vaccines as well as combination vaccines, e.g., IPV or IPV-DTaP-HepB.<br>• Examples of Vaccine Type names: HIB-HBOC, HIB-HepB, HepB-Peds. |
| 6.3 | CVX Code | A numerical code that describes a Vaccine Type. | • CVX codes are assigned by CDC to support electronic messaging of immunization histories via HL7. See http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx.<br>• Vaccine Type maps to a CVX code. There is normally one CVX code per one Vaccine Type. |
| 6.4 | CPT Code | A numerical string that describes the procedure (a billable service) of administering a vaccine. | • CPT (Current Procedural Terminology) codes are developed by the American Medical Association to bill for medical or psychiatric procedures performed by health care practitioners.<br>• Some CPT Codes have been re-used.<br>• There are vaccines that do not have CPT codes. |

| ID | Name | Description | Remarks |
|---|---|---|---|
| | | | • CPT codes can be mapped to CVX codes, but this is not one-to-one mapping and use of CPT codes for this purpose is not the best practice. See "CPT Codes Mapped to CVX Codes" at http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt. |
| 6.5 | 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<br>• If Trade Name is not actively collected by a particular IIS, it can be derived from other variables (e.g., NDC or Vaccine Type [CVX code] and Manufacturer Name [MVX code]). |
| 6.6 | Manufacturer (MVX code) | Manufacturer is defined as an organization that develops and distributes vaccines. | • CDC assigns an MVX code to specific vaccine manufacturers.<br>• An MVX code can be paired with the CVX code to derive a specific Trade Name.<br>• There may be several manufacturers of a particular vaccine type.<br>• See http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=mvx |
| 6.7 | Product License Begin Date | Date when the Trade Name or Product License began. | |
| 6.8 | Product License End Date | Date when the Trade Name or Product License ended. | |
| 7 | Patient | An Individual who is the actual or potential recipient of an administered dose of Vaccine from a Vaccinator (IIS-AO). | • For purposes of Data Quality, Patients are assumed to be deduplicated. Refer to the guidelines on patient-level deduplication (http://www.immregistries.org/resources/iis-meetings/Fred_Grant_AIRA_De-Duplication_Presentation.pdf).<br>• IIS-AOs may report Patient demographic information without Vaccination Event information. |
| 7.1 | Patient ID | An identifier code associated with the Patient; may be assigned by the IIS or by IIS-AOs. | • IIS may contain more than one Patient ID for each Patient; IDs assigned by IIS-AOs should be considered the primary ID.<br>• **Best practice** is to have an identifier code, ID type (e.g., medical record number, patient's IIS ID), and an assigning authority. |

| ID | Name | Description | Remarks |
|---|---|---|---|
| | | | |
| 7.2 | Date of Birth | The birth date of the patient. | • A.k.a. DOB<br>• Date of Birth received from Vital Records is considered more accurate than other sources of Date of Birth.<br>• Used for purposes of Data Quality; e.g., immunizations given before date of birth or that violate ACIP or state law minimum spacing requirements are invalid.<br>• Used for the purpose of forecasting |
| 7.3 | Date of Death | The date of the patient's death.<br>. | • Date of Death received from Vital Records is considered more accurate than other sources of Date of Death. |
| 7.4 | Name | Patient's first, middle, and last name:<br>• Name, First<br>• Name, Middle<br>• Name, Last | • Patient's first, middle, and last name are IIS Core Data Set Elements – see http://www.cdc.gov/vaccines/programs/iis/func-stds-appxB.pdf. |
| 7.5 | Gender | Patient's sex. | • IIS may have following values for this item: Female, Male, Unspecified, Other (note that "other" is no longer in the current HL7 guide [2.5]). |
| 7.6 | Address | A place where a patient may be communicated with, e.g., the residence of the patient. | • Data elements include: Number, street, city, zip or postal code, state, and county or public health entity area of responsibility.<br>• IIS may capture historical addresses as well as current address. |
| 7.7 | Responsible Party | An individual who is responsible for a patient. | • For example, a parent, a guardian, self<br>• A.k.a. Responsible Person |
| 7.8 | Contraindications | A contraindication is a condition in a patient that greatly increases the chance of a serious adverse event. | |
| 7.9 | Birth Certificate Number | A registration number for an official document of a patient's date and place of birth and parentage. | |
| 7.10 | Birth Facility | A place where a patient was born, e.g., hospital, home. | |

| ID | Name | Description | Remarks |
|---|---|---|---|
| 8 | Immunization History | Immunization History is a collection of one or more Vaccination Events for a patient. Immunization History describes vaccine doses administered, the dates the doses were administered, associated adverse events (if any), and acquired immunity to disease (if any). | • Immunization History is a part of Medical History.<br>• There are two types of Immunization History:<br>  • IIS Consolidated Immunization History<br>  o Represents the IIS's consolidated view of the patient's Immunization History<br>  o Consolidated from multiple IIS-AOs<br>  o Consolidation requires a process which assures that only a single record exists for each Vaccination Event. Refer to MIROW Vaccine-Level Deduplication guide.<br>  • Provider Organization Immunization History<br>  o Represents the patient Immunization History as known to the Provider Organization<br>  o Provider Organization (or other IIS-AO) may update patient's Medical History with Immunization History as gathered from IIS. |
| 9 | Vaccination Forecast | Vaccination Forecast is the result of the process of applying rules to determine dates for the next vaccine dose(s) to be administered to a Patient.<br><br>Vaccination Forecast may also include a reason why the next dose in a series is or is not recommended and recommended Trade Name for the next vaccine in a series. | • Vaccination Forecast for an individual patient is based on that patient's Immunization History and other factors, such as age, gender, contraindications.<br>• Vaccination forecast for all patients in IIS is guided by recommendations of the Advisory Committee on Immunization Practices (ACIP).<br>• Forecast may also be dependent on additional state-specific guidelines.<br>• Attributes may include: Antigen/Series/Dose Number, Earliest Date, Recommended Date, Latest Date, Past Due Date, Comments/Disclaimers.<br>• Refer to http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html for details. |
| 10 | Vaccination Event Submission | Vaccination Event Submission is the submittal of all relevant information that is known regarding a single Vaccination Event to the IIS as a final destination. | • The same Vaccination Event can be submitted more than once by a Provider Organization and other parties.<br>• IIS should only record a unique Vaccination Event once. Refer to AIRA-MIROW guideline Vaccination Level Deduplication in Immunization Information Systems [1.5]. |

| ID | Name | Description | Remarks |
|---|---|---|---|
| 10.1 | Status | Represents the status of a Vaccination Event Submission in the process of being accepted within the IIS. | Types of Status:<br>• Accepted: An accepted Vaccination Event Submission means that the data conformed to the IIS data submission guidelines and were or will be uploaded into the IIS.<br>• Rejected: A rejected Vaccination Event Submission means that the vaccine event data did not conform to the IIS data submission guidelines and were not or would not be uploaded into the IIS.<br>• Accepted with Errors: An accepted with errors Vaccination Event Submission means that the IIS identified errors in the Vaccination Event Submission but these errors were not severe enough to reject the Submission. Data were uploaded into the IIS. |
| 10.2 | Status Date | The date that the Vaccination Event Submission status was updated in the IIS. It either represents the date the data were accepted, rejected, or accepted with errors. | • This date may not be visible to the user from the Direct User Interface (UI) and therefore, may not be available.<br>• This date should not be confused with the Vaccination Event Date.<br>• This is not necessarily the date the Submission was sent.<br>• This is not necessarily the date the Submission was received. |
| 10.3 | Vaccination Event Submission Error(s) | Indicates the type of error(s) that occurred in the receipt and attempted acceptance of the Vaccination Event Submission.<br><br>Include any errors (structural issues, content issues) that occurred in the receipt and attempted acceptance of the Vaccination Event Submission, as well as reason for errors. | Types of Errors:<br>• Connection Error. We assume that as the message reaches the IIS, that connectivity has been established already. Connectivity is out of scope for this data quality assurance topic. If we can't see the data we can't comment on it/send error message.<br>• Unreadable/invalid format (header, not HL7 or expected format)<br>• Something inside the message is wrong (can be errors that are informational but allow the data in, errors that cause the data to be rejected by the IIS).<br>• IIS should return error message to Submitter; Submitter should have some mechanism for relaying error message to Recorder IIS-AO so that error can be resolved as needed. |
| 10.4 | Administered/ Historical Indicator | Administered/Historical Indicator describes an association between a Vaccination Event and the IIS-AO that | • See a detailed discussion of the Administered/Historical Indicator in the "Discussion and notes" section in chapter 3.<br>• Situations when more than one IIS-AO claims to have administered a |

| ID | Name | Description | Remarks |
|---|---|---|---|
| | | originates a Vaccination Event Submission for this Vaccination Event:<br>Values: Administered or Historical.<br>• "Administered" value for the Administered/Historical Indicator points out that the IIS-AO records and/or submits its own Vaccination Event, i.e., attests that it conducted the Vaccination Event ("I am Vaccinator IIS-AO").<br>• "Historical" value for the Administered/Historical Indicator points out that the IIS-AO originates a Vaccination Event Submission for a Vaccination Event that is owned by some other IIS-AO, i.e., attests that it did not conduct the Vaccination Event ("I am NOT Vaccinator IIS-AO; I am just Recorder IIS-AO"). | Vaccination Event should be investigated.<br>• If more than one IIS-AO reports a historical shot, this is not a problem, since IIS will reject duplicates. See MIROW vaccination level deduplication guide [1.5].<br>o Example: ALERT IIS (Oregon) tracks within 14 days for duplicate shots. If more than one IIS-AO claims to have administered the same shot on the same day or within a pre-determined timeframe, IIS triggers a warning about entering a duplicate shot and allows IIS-AO to override and enter duplicate dose in the patient record.<br>• Administered/Historical Indicator is described in the IIS Functional Standards, 2013-2017 (http://www.cdc.gov/vaccines/programs/iis/func-stds.html with the following IIS Core Data Element: Vaccination Event Information Source (i.e., administered or historical).<br>• "Administered" value for the Administered/Historical Indicator means that the IIS-AO submits its own Vaccination Event ("I am Vaccinator IIS-AO").<br>• "Historical" value for the Administered/Historical Indicator means that the IIS-AO originates a Vaccination Event Submission for a Vaccination Event that was administered by some other IIS-AO, i.e., it did not conduct the Vaccination Event ("I am NOT Vaccinator IIS-AO; I am just Recorder IIS-AO"). |
| 10.5 | Documentation Source Type | This is the originating source of the data.<br>Values:<br>o Billing/Claim<br>o Clinical<br>o Patient-provided (formerly known as "Transcribed") | • This is useful when assigning a confidence level to records in order to aid in de-duplicating vaccinations.<br>• The same Vaccination Event can be reported first by administering IIS-AO (Clinical), then by another IIS-AO (Patient-provided), and then yet by another IIS-AO (Billing/Claim).<br>• Patient-provided - describes second-hand information. Example of the "Patient-provided" Documentation Source Type would be a paper record: chart or immunization card. This type of immunization information is always "Historical." |

| ID | Name | Description | Remarks |
|---|---|---|---|
| 10.6 | Vaccinator IIS-AO ID | IIS ID for the IIS-AO that conducted the Vaccination Event. | • This would be the same as the Submitter in the case of a self-submitting IIS-AO.<br>• It is helpful to corroborate an IIS-AO ID with another data item, such as the IIS-AO Common Name or Legal Name. |
| 10.7 | Recorder IIS-AO ID | IIS ID for the IIS-AO that entered the Vaccination Event information into the IIS-AO Data Exchange system or the IIS UI. | • Vaccinator and Recorder are always the same for the administered vaccination. See section "IIS-AO Roles: Vaccinator, Recorder, Submitter" for this and other scenarios. |
| 10.8 | Submitter(s) IIS-AO ID | IIS ID for the IIS-AO that submitted information about the Vaccination Event to the IIS or to intermediary Submitter(s) with IIS as a final destination. | • There can be one or more Submitters depending on the submittal chain from the originating Vaccinator or Recorder through Submitters until reaching the IIS.<br>• Example of a reporting chain with multiple submitters: Providers' data go to an EHR vendor hub; the EHR vendor submits to an HIE; HIE submits to the IIS.<br>• See chapter 4, Facility Identification Management, for more details. |
| 10.9 | Vaccine Administrator – Provider Identifier | Identifier (ID) that labels and establishes the identity of a Provider (a person) that has performed the Vaccination Event. | Vaccine Administrator – Provider Identifier (ID) should include:<br>• **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>• **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>• See also items 2 and 2.1: Provider and Provider Identifier.<br>• The Vaccine Administrator role is described in the IIS Functional Standards, 2013-2017 (http://www.cdc.gov/vaccines/programs/iis/func-stds.html) with the following IIS Core Data Element: Vaccine Administering Provider Name. |
| 10.10 | Vaccine Prescriber – Provider Identifier | Identifier (ID) that labels and establishes the identity of a Provider (a person) that has prescribed/ordered the vaccination. | Vaccine Prescriber – Provider Identifier (ID) should include:<br>• **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>• **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>See also items 2 and 2.1: Provider and Provider Identifier.<br>• The Vaccine Prescriber role is described in the IIS Functional Standards, 2013-2017 (http://www.cdc.gov/vaccines/programs/iis/func-stds.html) with the following IIS Core Data Element: Vaccine Ordering Provider Name. |

| ID | Name | Description | Remarks |
|---|---|---|---|
| 10.11 | UI or EDE User –Data Enterer Identifier | Identifier (ID) that labels and establishes the identity of a Data Enterer (a person) that has entered the Vaccination Event's information either via the direct user interface (UI) or via a system (e.g., EHR) using Electronic Data Exchange (EDE) to submit data to IIS. | UI User or EDE User –Identifier (ID) should include:<br>• **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>• **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>See also items 3 and 3.1: Data Enterer and Data Enterer Identifier. |
| 10.12 | <relevant vaccination info> | Relevant data items (of interest for IIS) described by other entities, such as (2) Provider, (4) Vaccination Event, (5) Vaccine, (6) Vaccine Product Type, and (15) Vaccination Encounter (see the domain diagram). | • This attribute is a placeholder which represents all of the relevant Vaccination Event information that could be submitted.<br>• Reference updated business rule BR105 of the 2008 DQA Guide (see Table 6 in this document) for the recommended minimum/mandatory set of data. |
| 10.13 | <relevant demographic (patient) info> | Relevant data items describing the demographics of the entity (7) Patient (see the domain diagram). | • This attribute is a placeholder which represents all of the relevant demographic information that could be submitted, e.g., Patient Info.<br>• Reference updated business rule BR104 of the 2008 DQA Guide (see Table 6 in this document) for the recommended minimum/mandatory set of data. |
| 11 | Combined Submission | Collection of one or more Vaccination Event Submissions and/or Demographic-only Submissions that have been submitted at the same time. | • Via electronic data exchange or user interface<br>• Examples of combined submissions include direct entry into the UI of one patient's vaccination or demographic information, an entry of a single electronic batch file with thousands of patients and shots, or a single electronic message.<br>• Includes demographic information<br>• Could include information about one or more Vaccination Events, Encounters, Patients, Providers.<br>Combined Submission can contain:<br>o Single Vaccination Event submission<br>o Multiple Vaccination Events for a patient encounter (visit)<br>o Multiple encounters (visits) for a single patient<br>o Multiple patients for a single IIS-AO (provider organization)<br>o Multiple IIS-AOs (provider organizations)<br>• Is submitted by a Submitter IIS-AO, which may or may not be a Vaccinator IIS- |

| ID | Name | Description | Remarks |
|---|---|---|---|
| | | | AO |
| 11.1 | Submission Date | Submission Date is the date when the data were received (but not necessarily loaded) by the IIS. | • IIS may delay processing inbound data for reasons including technical problems or system overload. |
| 12 | Immunization Information System (IIS) | Immunization information systems (IIS) are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area. | • At the point of clinical care, an IIS can provide consolidated immunization histories for use by a vaccination provider in determining appropriate client vaccinations.<br>• At the population level, an IIS provides aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease".<br>• See http://www.cdc.gov/vaccines/programs/iis/about.html. |
| 13 | Electronic Data Exchange | Electronic Data Exchange is the interface in which data can be communicated electronically between a third party system and the IIS (e.g., EHR, HIE, Billing System). | • "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. Ross. Immunization Registries Can Be Building Blocks For National Health Information Systems. HEALTH AFFAIRS 29, NO. 4 (2010): 676–682.<br>• ***For the purposes of this project, the term "EHR system" will be used to refer to both EHR and EMR systems.***<br>• Different EDE formats, e.g., flat file, HL7<br>• Different EDE types, e.g., outbound, inbound, bi-directional |
| 14 | IIS Direct User Interface | This is the application for the user to submit data directly to or retrieve data directly from the IIS, i.e., this is usually accessed via the Web. | • User interface, although not entirely error-free, is an opportunity for human evaluation and decision.<br>• Throughout the document this term is referenced in abbreviated forms as IIS Direct UI, Direct UI, or UI |
| 15 | Vaccination Encounter | Represents one Patient office visit during which Vaccination Events occurred. | • During the Vaccination Encounter (office visit) several Vaccination Events can be performed (in some cases - no Vaccination Events, e.g., a Patient's refusal for vaccinations) |
| 15.1 | Date | Date when Vaccination Encounter occurred. | |

| ID | Name | Description | Remarks |
|---|---|---|---|
| 16 | Demographic-only Submission | Demographic-only Submission is the submittal of demographic information regarding a single Patient to the IIS or to intermediary Submitter(s) with IIS as a final destination. | • The same demographic information can be submitted more than once by an IIS-AO and other parties.<br>• This does not include Vaccination Event information.<br>• Examples:<br>o Notification of a birth via Vital Records that doesn't contain birth dose Hep B<br>o EHR submits an updated address to the IIS<br>o Name change submitted to an MPI system |
| 16.1 | Status | Represents the status of the Demographic-only Submission in the process of being accepted within the system. | Types of Status:<br>• Accepted: An accepted Demographic-only Submission means that the data conformed to the data guidelines.<br>• Rejected: A rejected Demographic-only Submission means that the demographic data did not conform to the IIS data submission guidelines and were not or would not be uploaded into the IIS.<br>• Accepted with Errors: An accepted with errors Demographic-only Submission means that data did not conform to the data submission guidelines of the IIS but data were loaded into the IIS; errors would be followed up and resolved at a later date. |
| 16.2 | Status Date | The date that the Submission status was updated. It either represents the date the data were accepted, rejected, or accepted with errors. | • This date may not be visible to the user from the Direct User Interface (UI) and therefore, may not be available.<br>• This is not necessarily the date the Submission was sent.<br>• This is not necessarily the date the Submission was received. |
| 16.3 | Demographic-only Submission Error(s) | Indicates the type of error(s) that occurred in the receipt and attempted acceptance of the Demographic-only Submission.<br><br>Include any errors (structural issues, content issues) that occurred in the | Types of Errors:<br>• Connection Error. We assume that as the message reaches the IIS, that connectivity has been established already. Connectivity is out of scope for this data quality assurance topic. If we can't see the data we can't comment on it/send error message.<br>• Unreadable/invalid format (header, not HL7 or expected format)<br>• Something inside the message is wrong (can be errors that are informational but |

| ID | Name | Description | Remarks |
|---|---|---|---|
| | | receipt and attempted acceptance of the Demographic-only Submission, as well as reason for errors. | allow the data in, errors that cause the data to be rejected by the IIS).<br>• IIS should return error message to Submitter; Submitter should have some mechanism for relaying error message to Recorder IIS-AO so that error can be resolved as needed. |
| 16.4 | Recorder IIS-AO ID | IIS ID for the IIS-AO that entered the Demographic-only (Patient) information into the IIS-AO Data Exchange system or the IIS UI. | • See section "IIS-AO Roles: Vaccinator, Recorder, Submitter." |
| 16.5 | Submitter(s) IIS-AO ID | IIS ID for the IIS-AO that submitted information about the Patient to the IIS or to intermediary Submitter(s) with IIS as a final destination. | • There can be one or more Submitters depending on the submittal chain from the originating Recorder through Submitters until reaching the IIS.<br>• Example of a reporting chain with multiple submitters: Providers' data go to an EHR vendor hub; the EHR vendor submits to an HIE; HIE submits to the IIS.<br>• See chapter 4, Facility Identification Management, for more details. |
| 16.6 | UI or EDE User – Data Enterer Identifier | Identifier (ID) that labels and establishes the identity of a Data Enterer (a person) that has entered the Demographic-only (Patient) information either via the direct user interface (UI) or via a system (e.g., EHR) using Electronic Data Exchange (EDE) to submit data to IIS. | UI or EDE User –Identifier (ID) should include:<br>• **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>• **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>See also items 3 and 3.1: Data Enterer and Data Enterer Identifier. |
| 16.7 | <relevant demographic (patient) info> | Relevant data items describing the demographics of the entity (7) Patient (see the domain diagram). | • This attribute is a placeholder which represents all of the relevant demographic information that could be submitted, e.g., Patient Info.<br>• Reference updated business rule BR104 of the 2008 DQA Guide (see Table 6 in this document) for the recommended minimum/mandatory set of data. |

# Chapter 4: Facility Identification Management

The essence of the problem with Facility Identification Management in IIS is the challenge of properly associating the correct IIS-AO with data reported to the IIS. This is true especially in cases when:

- Several organizations are involved in a data submission chain
- Organizations have a complex organizational hierarchy

This chapter reflects best practice recommendations for the IIS-AO Facility Identification Management. Presented materials are based on the concepts, terms, and definitions described in chapter 3 of this document. Therefore, a reader is advised to review chapter 3 before studying this chapter.

**Process model**

The purpose of this process model (**Fig. 5**) is to provide a context for the development of best practices expressed as principles, business rules, and general recommendations. It specifies high-level processes within the scope of Facility Identification Management, as well as some key inputs and outputs. This model is not tied to any specific implementation of IIS or interfacing EHR System. It serves as a framework for principles, business rules, and general recommendations presented in the next section.

Desired outcome of the process is to enable accurate identification of the IIS Authorized Organizations (IIS-AO) which:

- Administer vaccines
- Submit Vaccination Event Submissions
- Submit Demographic-only Submissions

Scope of the process model includes activities involved in Facility Identification Management:

- From the time an IIS-Authorized Organization is recognized by IIS
- Until the IIS-AO is no longer IIS-authorized
- Excluding: IIS sends data to IIS-AO

Note that while the model explicitly shows Vaccination Event Submissions, the same actions/steps also can be applied for Demographic-only Submissions.

Following is a list of the steps in the Process Model presented in Fig. 5:
PM 1.0 ─ IIS: Set Up IIS-AO
PM 2.0 ─ IIS-AO: Administer Vaccine
PM 3.0 ─ IIS-AO: Record Vaccination Event
PM 4.0 ─ IIS-AO: Send Vaccination Event Submission to Organization's Submitter
PM 5.0 ─ IIS-AO: Submit Vaccination Event Submission to IIS
PM 6.0 ─ IIS: Validate Vaccination Event Submission
PM 7.0 ─ IIS: Decide on Action (Accept, Reject, Partially accept)
PM 8.0 ─ IIS: Notify Submitter and/or Vaccinator
PM 9.0 ─ IIS: Resolve Vaccination Event Submission Errors

PM 10.0 – IIS: Record Vaccination Event Submission Info
PM 11.0 – IIS: Update Organization's Details
PM 12.0 – IIS: De-authorize IIS-AO

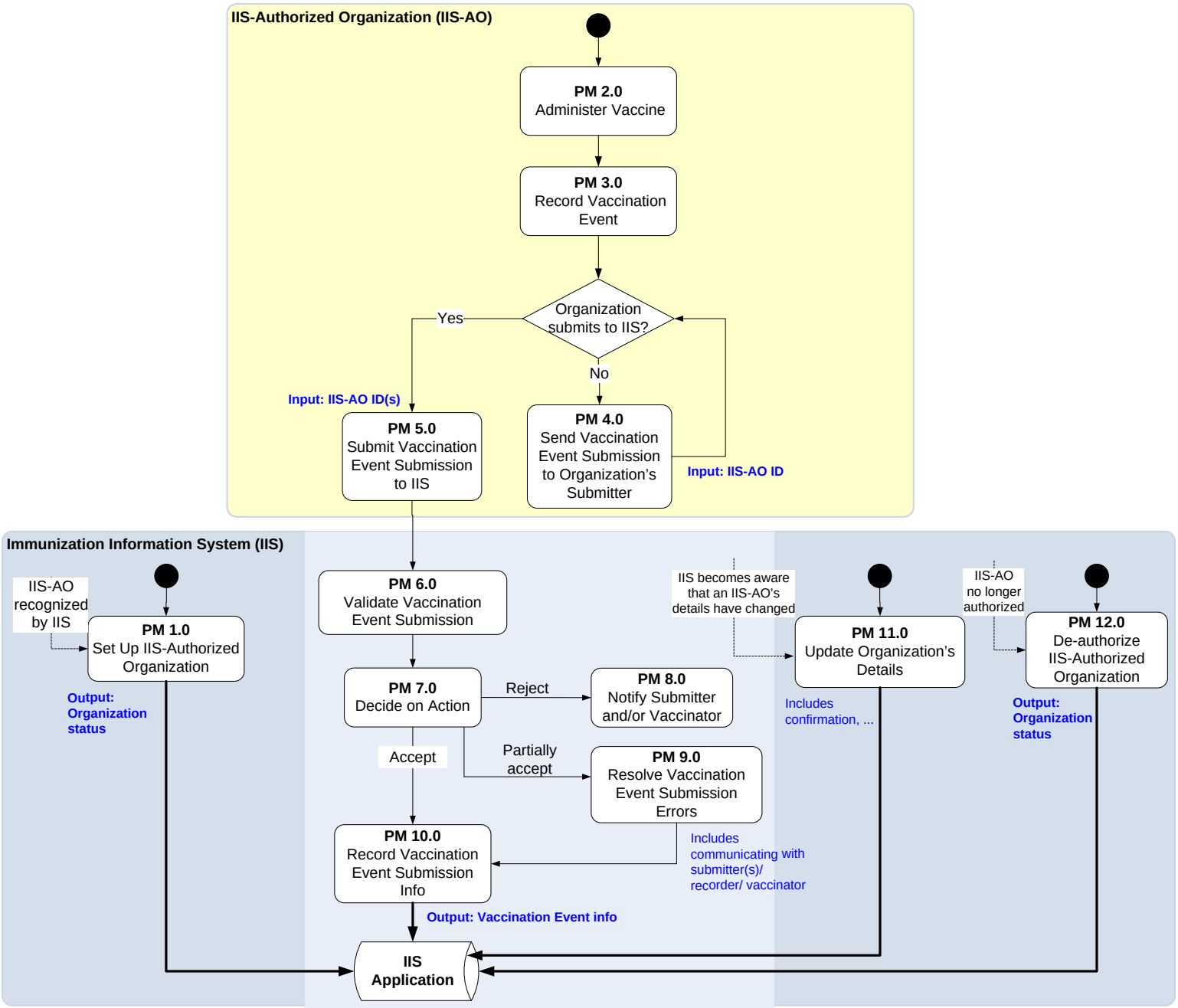


**Figure 5.** Process model for Facility Identification Management

**Principles, Business Rules, and General Recommendations**

Recommended best practices for Facility Identification Management are captured in the form of principles, business rules, and general recommendations:

- 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.
- **General recommendations (GR)** represent requirements, advice, and suggestions for IIS functionality and operations.

Following principles, business rules, and general recommendations aim to address issues related to Facility Identification Management and their implications for data quality in IIS.

In developing best practice recommendations, the Work Group considered the following aspects of the impact of mergers, acquisitions, and restructuring (assuming that IIS has been notified of the change):

- Possibilities:
  - Org A acquires/absorbs Org B
  - Org A merges with Org B to form Org C
  - Org A spins off a sub-unit into a new Org B
  - A portion of Org A splits off into a sub-unit B of existing Org C
  - Org A dissolves
  - Org A restructures internally
- Impact on Orgs:
  - Change of name
  - Change of structural hierarchy
  - Change of submitting relationships
  - IIS-AO ID
  - Type of submission may change (e.g., non-standard file to HL7, vendors, IIS Direct UI)
  - Change of roles (Vaccinator, Recorder, Submitter, Data Consumer)
- Problems:
  - Linking “life” (data, patients) of old organization to “life” of new organization
  - Updating all of the characteristics of the acquiring and acquired organization

Specific recommendations are presented in Table 4, where principles, business rules, and general recommendations are placed in the following order (this order represents grouping of items from the same area together, from establishing agreement with IIS, to addressing changes in IIS-AO organizational structure, and, finally, to IIS de-authorizing IIS-AO):

- P801: Consistency principle
- P802: Document approaches used principle
- GR801: Document expectations between IIS and IIS-AO
- GR802: Establish written agreements with Submitters, Recorders, and Vaccinators
- GR803: Have agreement with IIS-AO to review error logs
- BR801: Conduct a pre-certification process

- BR802: Maintain IIS-AO DQA profile
- GR804: Monitor submissions for anomalies
- BR803: Review the submission logs for error trends daily
- BR804: Track participants in the submittal chain
- BR805: All Submitters should be identified
- GR805: IIS should be able to track IIS-AO roles
- BR806: Track Recorder IIS-AO
- BR807: Track status and status date for all submissions
- BR808: Include Vaccine Administrator and Vaccine Prescriber in the submission
- BR809: Record submission error and reason for error
- BR810: Maintain unique medical record numbers for IIS-AO patients
- BR811: IIS-AO IDs must be unique
- BR812: IIS-AO IDs should not embed information about the IIS-AO
- BR813: User must be associated with IIS-AO
- BR814: Maintain both legal and common names for an IIS-AO
- GR806: Accommodate various and different hierarchical structures of IIS-AOs
- BR815: Validate organizational and reporting structure periodically
- BR816: Validate organizational and reporting structure on rejection
- GR807: IIS should be notified about IIS-AO organizational changes
- BR817: Update IIS-AO when a structural change occurs
- BR818: Org B is a part of Org A, is acquired intact by Org C
- BR819: Stand-alone Org A is “acquired” as an intact sub-unit by another Org
- BR820: Org A and Org B merge to form one new organization
- BR821: Org B is part of Org A, becomes a new stand-alone entity
- BR822: Portion of Org A is acquired by and becomes a sub-unit of another Org
- BR823: Org A and Org B, containing sub-org units, merge to form one new organization
- BR824: De-authorize IIS-AO if it dissolves
- BR825: De-authorize IIS-AO if it no longer plays any of IIS-AO roles
- BR826: Do not de-authorize IIS-AO that is required to submit but not submitting
- BR827: Assess necessity to de-authorize IIS-AO that is not required to submit and is not submitting

Obviously, this list does not provide an exhaustive set of best practice recommendations for the topic of Facility Identification Management, but rather, aims to cover the most challenging and important aspects.

**Table 4.** Principles, Business Rules, and General Recommendations Related to Facility Identification Management

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
|---|---|---|---|
| P801 | Consistency principle<br>IIS should be consistent in the approaches followed for Facility Identification Management. | | P802 |
| P802 | Document approaches used principle<br>IIS should clearly document the approaches followed for Facility Identification Management. | • Could be documented as a policy, procedure, or manual; so that IIS staff registering facilities and maintaining facility tables will act consistently. | P801 |
| GR801 | Document expectations between IIS and IIS-AO<br>When enrolling a new IIS-AO, current and future communication expectations should be documented and agreed upon by the IIS and the IIS-AO. | • E.g., notification of structural or functional organization changes<br>• A communication policy should be established by the IIS and distributed/maintained to all IIS-AOs that describes the notification expectations when organizational structures/functions change. | PM 1.0, GR802, GR803, GR807, BR803 |
| GR802 | Establish written agreements with Submitters, Recorders, and Vaccinators<br>IIS should establish written agreements with Submitter, Recorder, and Vaccinator IIS-AOs that describe an agreed-upon procedure to address data quality issues if they arise. | • Re-examine as needed when submission method changes.<br>• Possible submission chains (routes) should be determined when IIS is setting up (recognizing) the IIS-AO.<br>• Agreements should be established between all parties in the submission chain; confidentiality policies should be addressed in these agreements. | PM 1.0, PM 11.0, GR805, GR806, GR807 |
| GR803 | Have agreement with IIS-AO to review error logs<br>IIS should have an agreement with the IIS-AO that the IIS-AO will review all error logs upon receipt. | • **Best Practice**: Both Submitter and Vaccinator agree to review<br>• **Good Practice**: Either Vaccinator or Submitter agree to review<br>• Applies to electronic submissions | PM 1.0, PM 8.0, PM 9.0, GR801 |
| BR801 | Conduct a pre-certification process<br>IIS should conduct a pre-certification process in order for the IIS-AO system to submit data to the IIS via Electronic Data Exchange | • Would help set expectations prior to the submittal of data<br>• Pre-certification process would assess whether:<br>  o The vendor's system can capture and submit the appropriate information | PM 1.0, PM 5.0, PM 6.0, GR804 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
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| | | o Each IIS-AO using the system is entering the appropriate content<br>• Refer to 2008 DQA Guide [1.4], chapter 6, page 58. | |
| BR802 | Maintain IIS-AO DQA profile<br>IIS should identify and maintain baseline (IIS-AO DQA Profile) data for comparison later. Measures for this baseline data may include (not an exhaustive list):<br>• Frequency of submissions<br>• Content of data<br>• Volume of Vaccination Events<br>• Volume of Demographic events<br>• Method of reporting<br>• EHR vendor | • Baseline data can be captured when an IIS-AO is establishing the Electronic Data Exchange or IIS Direct UI interfaces and should be **periodically** updated.<br>o When an IIS-AO is transitioning from one submission method to another, the baseline data should be re-established.<br>• For VFC provider (Vaccinator IIS-AO), data could be captured from the provider profile developed during VFC certification process and updated during the **annual** VFC re-certification process.<br>• For Non-VFC provider (Vaccinator IIS-AO), use the applicable portions of the VFC profile and update **annually** if possible.<br>• For details on the IIS-AO DQA Profile, refer to 2008 DQA Guide [1.4], chapter 6, page 58. | PM 1.0, PM 6.0, PM 11.0, GR804 GR807 |
| GR804 | Monitor submissions for anomalies<br>IIS should regularly monitor submissions for anomalies in submission trends and volumes as compared to baselines. When anomalies are found, IIS should work to identify and resolve possible causes. | • Approach may differ based on whether batch, real-time, or IIS Direct UI submission.<br>• Examples of anomalies:<br>o When timeliness of submissions falls below a threshold<br>o When activity/usage falls below a threshold<br>o When provider organization has not submitted for some period<br>▪ Could be by IIS-AO<br>▪ Could be by average across IIS-AOs<br>o Mass rejection of submissions<br>o Mass volume changes<br>• Examples of causes:<br>o Changes in the current organizational structure (entities and relationships)<br>o Improper coding | PM 6.0, PM 8.0, PM 9.0, GR801, BR801 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
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| | | o Staff turnover<br>o Changes in IIS-AO's EHR systems<br>• Requires identification of baseline values<br>• See BR113 of the 2008 MIROW DQA guide [1.4]. | |
| BR803 | Review the submission logs for error trends daily<br>The IIS should review the submission logs for error trends on a daily basis. | • Trends for EDE and UI submitters should be monitored (for errors and accepted submissions alike)<br>• Examine rejection rate, processing rate, etc.<br>• This could be done automatically (depending on available IT resources). | PM 8.0, PM 9.0 |
| BR804 | Track participants in the submittal chain<br>Vaccination Event Submission for "administered" Vaccination Events must have the Vaccinator, Recorder, and Submitter(s) IIS-AO ID. | • Tracking all participants of the submittal chain (i.e., Vaccinator, Recorder, and all Submitters) reflects the **Best Practice**. It would allow the IIS to identify all participants that could introduce data quality issues.<br>• **Good Practice** that accommodates capabilities of the HL7 standard is to track Vaccinator, Recorder, and first and/or last Submitters (see the HL7 Considerations section of this chapter).<br>• Information about submittal chains can be stored in IIS. It is recommended to determine possible submission chains (routes) when IIS is setting up (registering) IIS-AO (see GR802).<br>• For examples of submittal chains, see Illustration in the section "IIS-AO Roles: Vaccinator, Recorder, Submitter" of the domain model.<br>• For Demographic-only submissions, Recorder and Submitter(s) should be tracked. | PM 2.0-6.0, GR802, BR801, BR802, BR805, |
| BR805 | All Submitters should be identified<br>All Submitters in the submission chain should be identified. | • **Good Practice:** Identify at least one Submitter<br>o If only one submitter can be identified, it should be the first submitter in the submittal chain.<br>o Note that upcoming updates to the HL7 standard would allow handling information about two submitters. That should cover | PM 4.0-6.0, GR801, GR802, BR804 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
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| | | most of the real-life situations (see the HL7 Considerations section of this chapter).<br>• Some information may be contained within the HL7 message; some may be maintained outside of the message - within the IIS. For example, "parent – subsidiary/child" organizational relationships should be stored in the IIS.<br>o **Best Practice** is to include IIS-AO IDs of Vaccinator, Recorder, and all Submitters (if possible) in each HL7 submission.<br>o A possible **Good Practice** is to include initiating IIS-AO ID (Vaccinator/Recorder and some of the Submitters) in each HL7 submission and document its Submitter relationships (submittal chains/routes) in the IIS, or in some other database, based on an agreement between IIS and IIS-AO.<br>o Note that it is recommended to determine possible submission chains (routes) when IIS is setting up (recognizing) IIS-AO (see GR802). | |
| GR805 | <u>IIS should be able to track IIS-AO roles</u><br>IIS should be able to track roles of Vaccinator, Submitter, Recorder, and Data Consumer. | • Multiple simultaneous roles should be supported. | PM 1.0, PM 11.0 GR802, GR806, BR802, BR804 |
| BR806 | <u>Track Recorder IIS-AO</u><br>For Vaccination Event Submissions, the IIS-AO that enters information into the IIS-AO system or IIS Direct UI should be tracked as the Recorder IIS-AO ID. | • Vaccinator IIS-AO ID is not required for Historical Vaccination Event Submissions and Demographic-only Submissions.<br>• For Direct UI entry, the Recorder IIS-AO ID is the same as the Submitter IIS-AO ID.<br>• In the case of a self-submitting IIS-AO, Vaccinator is the same as the Submitter and Recorder. | PM 3.0, PM 5.0, PM 6.0, GR802 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
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| BR807 | Track status and status date for all submissions<br>Status (i.e., accepted, accepted with errors, rejected, etc.) and Status Date should be tracked for all Vaccination Event Submissions. | • For data submitted electronically<br>• Validation may have more than one phase. | PM 5.0, PM 6.0, PM 10.0 |
| BR808 | Include Vaccine Administrator and Vaccine Prescriber in the submission<br>Vaccine Administrator and Vaccine Prescriber should be included in the Vaccination Event Submission. | • Core data elements as adopted by CDC and approved by NVAC<br>• In support of:<br>o VFC requirements<br>o VAERS requirements | PM 2.0, PM 5.0, PM 6.0 |
| BR809 | Record submission error and reason for error<br>IIS should record error and reason for error of a Vaccination Event Submission and Demographic-only Submission. | • For data submitted electronically<br>• IIS should return error message to Submitter; Submitter should have some mechanism for relaying error message to Recorder IIS-AO so that error can be resolved as needed. | PM 6.0, PM 8.0, PM 9.0, GR804, BR803, |
| BR810 | Maintain unique medical record numbers for IIS-AO patients<br>During the pre-certification process, the IIS should review with a Submitter the process to be followed to ensure that they maintain unique medical record numbers for patients. | • Reassigning medical record numbers within an IIS-AO could result in inaccurate deduplication of patient records in the IIS. | PM 1.0 |
| BR811 | IIS-AO IDs must be unique<br>All IIS-AO IDs must be unique and must never be reused. | • If the IIS-AO is re-authorized by the IIS, a new IIS-AO ID should be assigned. A link between the previous ID and the new one should be established. | PM 1.0<br>BR824 |
| BR812 | IIS-AO IDs should not embed information about the IIS-AO<br>IIS-AO IDs should not embed information about the IIS-AO. | • E.g., relationship to other organizations (submitter for, parent of), location, jurisdiction<br>• Because relationships, locations, etc., can change, retaining information about the IIS-AO within the IIS-AO ID could require revising IIS-AO IDs on a regular basis, which is not consistent with | BR818-23 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
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| | | best practices.<br>• IIS-AO ID should be randomly or sequentially generated. | |
| BR813 | User must be associated with IIS-AO<br>A User who is submitting and/or retrieving data from the IIS must be associated with the IIS-AO that is responsible for those records. | • For direct user interface, this is a requirement because users must access IIS in association with an IIS-AO.<br>• For real-time data exchange, this may not be possible. Access is via the IIS-AO and the responsibility for an individual using that access falls to the IIS-AO.<br>• It is possible for one user to be associated with multiple IIS-AOs (i.e., nurse that serves multiple sites). | PM 3.0 |
| BR814 | Maintain both legal and common names for an IIS-AO<br>An IIS should maintain both legal and common names for an IIS-AO. | • For implementation, may need to shorten legal name in systems that have character limits, e.g., VTrckS allows 40 characters.<br>• An IIS should display enough of the name for the IIS-AO to be accurately identified. | PM 1.0 |
| GR806 | Accommodate various and different hierarchical structures of IIS-AOs<br>IIS should accommodate various and different hierarchical structures of IIS-AOs. | • E.g., parent – subsidiary/child, corporate-sub-unit, affiliations | PM 1.0, GR805 |
| BR815 | Validate organizational and reporting structure periodically<br>IIS should proactively validate the current organizational and reporting structure for existing IIS-AOs on a quarterly basis. | • **Best Practice**: Quarterly<br>• **Good Practice**: Annually<br>• Whenever engaging with IIS-AO, take the opportunity to validate organizational and reporting structure (e.g., Help Desk, Training Session, User Group Meetings, Tech Support)<br>• For IIS Direct UI and Electronic Data Exchange<br>• Potential Implementations:<br>o Ask verbally when interaction initiated via phone<br>o Basic reminder e-mail quarterly and formal e-mail once a year<br>o Force users (or a super user) to verify certain information when they log in<br>o Develop provider contact checklist for IIS staff to follow when | PM 11.0, BR802, BR804, BR805 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
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| | | talking to providers | |
| BR816 | Validate organizational and reporting structure on rejection<br>IIS should validate the current organizational and reporting structure when a submission gets rejected due to an invalid or unknown IIS-AO ID. | • For electronic submissions | PM 8.0<br>GR803,<br>GR804,<br>BR803 |
| GR807 | IIS should be notified about IIS-AO organizational changes<br>IIS should require that IIS-AOs notify the IIS whenever they make changes to their organization or organizational relationships. | • E.g., open, close, move, acquire, sell, merge<br>• Candidate Implementation:<br>o IIS should specify in their MOUs the requirement for IIS-AOs to notify the IIS of changes to their organization.<br>• Repercussions: Lack of such notifications leads to a need to clean up data that were attributed to a wrong IIS-AO. IIS can request IIS-AO that failed to notify IIS about changes to clean up data through the user interface – a very time-consuming effort. | PM 1.0,<br>PM 11.0,<br>PM 12.0,<br>GR801<br>BR804 |
| BR817 | Update IIS-AO when a structural change occurs<br>IIS-AO attributes and relationships should be updated, where necessary, any time a structural change occurs regarding one or more organizations and/or organizational sub-units. | • E.g., name, structural hierarchy, submitting relationship, type of submission, change of roles<br>• IIS should have a formal agreement with IIS-AOs requiring such notifications (see GR801, GR802). | PM 11.0,<br>GR801,<br>GR802,<br>GR805,<br>GR806,<br>GR807 |
| BR818 | Org B is a part of Org A, is acquired intact by Org C<br>If an IIS-AO (Org B) which is part of an existing IIS-AO (Org A) is "acquired" intact by a different IIS-AO (Org C), the IIS should follow one of the following approaches:<br>• Option 1: De-authorize acquired IIS-AO (Org B) and | • For example: | P801,<br>PM 1.0,<br>PM 11.0,<br>PM 12.0 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
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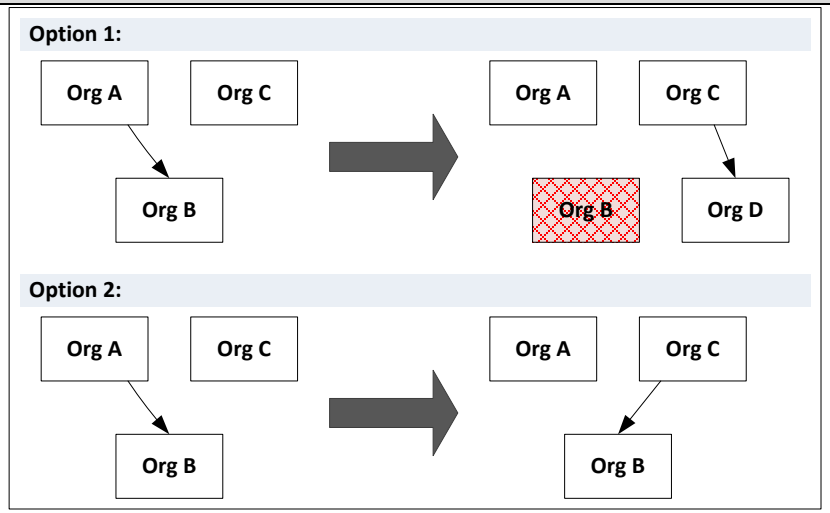
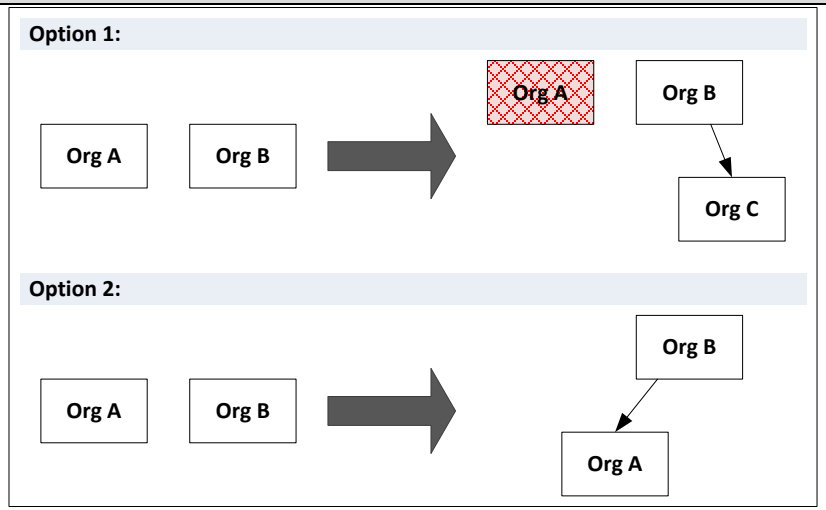
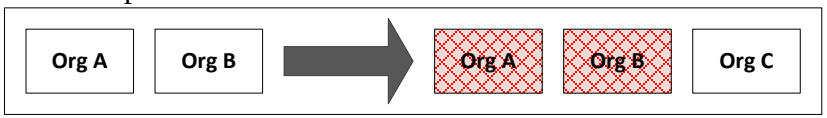
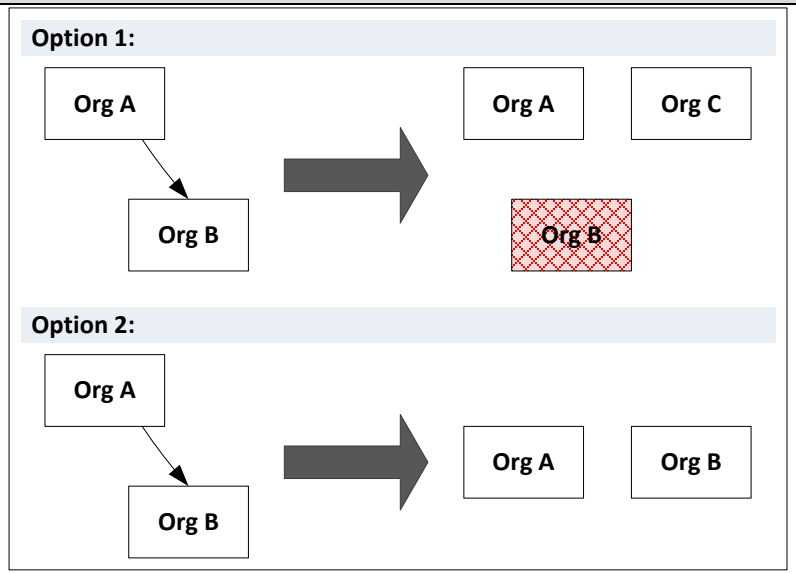
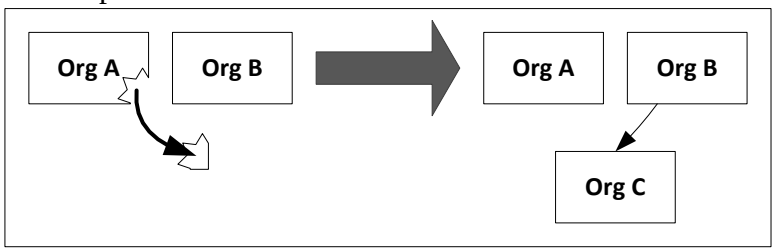
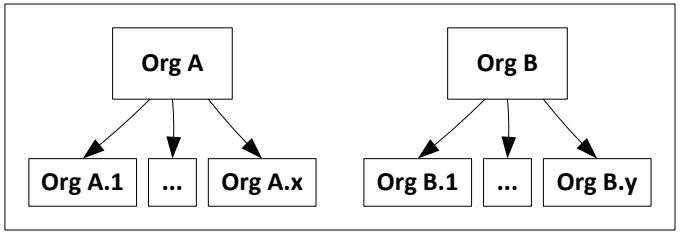
| | create a new IIS-AO (Org D) with a new IIS-AO ID, and associate it with the acquiring IIS-AO (Org C).<br>• Option 2: Update the structural hierarchy of the acquired (Org B) and acquiring (Org C) IIS-AOs and maintain the acquired IIS-AO ID. |  <br>• Consideration needs to be given to impact on master/patient index, as well as to other concerns (e.g., patient's consent to share, primary care physician, reminder/recall, Medical Record Number) | |
| BR819 | <u>Stand-alone Org A is "acquired" as an intact sub-unit by another Org</u><br>If a stand-alone IIS-AO (Org A) is "acquired" as an intact sub-unit by another IIS-AO, the IIS should follow one of the following approaches:<br>• Option 1: De-authorize the acquired IIS-AO (Org A) and create a new IIS-AO (Org C) with a new IIS-AO ID, and associate it with the acquiring IIS-AO (Org B).<br>• Option 2: Establish a structural hierarchy between the acquired (Org A) and acquiring (Org B) IIS-AOs and retain the acquired IIS-AO ID. | • For example: | P801,<br>PM 1.0,<br>PM 11.0,<br>PM 12.0 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
|---|---|---|---|
| | |  <br>• Consideration needs to be given to the nature of the structural change and applicable jurisdictional rules, etc., to ensure integrity of patient's association with the appropriate IIS-AO. | |
| BR820 | <u>Org A and Org B merge to form one new organization</u><br>If two or more IIS-AOs (Org A and Org B) merge to form one new organization, the IIS-AOs (Org A and Org B) should be de-authorized and a new IIS-AO (Org C) should be created with a new IIS-AO ID. | • For example:<br>  | PM 1.0,<br>PM 11.0,<br>PM 12.0 |
| BR821 | <u>Org B is part of Org A, becomes a new stand-alone entity</u><br>If an IIS-AO (Org B) which is part of an existing IIS-AO (Org A) becomes a new stand-alone entity, the IIS should follow one of the following approaches:<br>• Option 1: De-authorize the original sub-unit (Org B) and create a new IIS-AO (Org C) with a new IIS-AO ID.<br>• Option 2: Remove the structural linkage between the | • For example: | P801,<br>PM 1.0,<br>PM 11.0,<br>PM 12.0 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
|---|---|---|---|
| | spun-off IIS-AO (Org B) and its prior parent IIS-AO (Org A) and maintain the IIS-AO ID of the spun-off IIS-AO. |  <br>Note: Option 2 will maintain association of IIS data with original IIS-AO. Option 1 may not. | |
| BR822 | <u>Portion of Org A is acquired by and becomes a sub-unit of another Org</u><br>If a portion of an IIS-AO (Org A) is acquired by and becomes a sub-unit (Org C) of another IIS-AO (Org B):<br>• Create a new IIS-AO (Org C) with a new IIS-AO ID, and associate it as a child of the acquiring organization (Org B). | • For example:<br>  <br>• Note: This is not the same as Providers (i.e., persons) from one | PM 1.0, PM11.0 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
|---|---|---|---|
| | | organization leaving one IIS-AO and joining another IIS-AO (no changes to be made in this case).<br>• In this scenario, Providers will no longer be associated with data related to the original IIS-AO. | |
| BR823 | <u>Org A and Org B, containing sub-org units, merge to form one new organization</u><br>If two or more IIS-AOs (Org A and Org B), containing sub-org units, merge to form one new organization, each of the sub-units should follow the same best practices which apply. | • For example:<br>  <br><br>• In the above illustration, Org A.1 through Org A.x and Org B.1 through Org B.y would each need to be evaluated separately to determine how to proceed. For example, if Org A.1 is being dissolved, then BR824 should be followed for Org A.1 only. The remaining Org A.2 through Org A.x still need to be evaluated to determine the appropriate action. | BR818-22, BR824 |
| BR824 | <u>De-authorize IIS-AO if it dissolves</u><br>If an IIS-AO dissolves, it should be de-authorized in the IIS. | • E.g., Single Provider Practice retires, clinic site closes permanently.<br>• IIS-AO ID is not reusable for other IIS-AOs (see BR811). | PM 12.0<br>BR811 |
| BR825 | <u>De-authorize IIS-AO if it no longer plays any of IIS-AO roles</u><br>If an existing IIS-AO is no longer a Vaccinator, Submitter, Recorder, or Data Consumer, the IIS-AO must be de-authorized in the IIS. | • The IIS-AO could be re-authorized in the future if necessary and appropriate.<br>• Could result from structural changes<br>• Possible reason - the IIS-AO no longer has a business need to submit or view immunization data | PM 12.0 |
| BR826 | <u>Do not de-authorize IIS-AO that is required to submit but not submitting</u><br>If a Vaccinator is required to submit to the IIS and is not submitting to the IIS, the IIS should not de-authorize the | • May be due to applicable law, policy, or agreement<br>• This supports the IIS maintenance of the denominator of IIS-AOs for reporting purposes.<br>• Grantees (Jurisdictions) should have the right to decide when IIS- | BR827 |

| ID | Principle, Business Rule, or General Recommendation Statement | Remarks | X-ref |
|---|---|---|---|
| | IIS-AO. | AO should be de-authorized, such as when ensuring data quality. | |
| BR827 | Assess necessity to de-authorize IIS-AO that is not required to submit and is not submitting<br>If a Vaccinator is not required to submit to the IIS and is not submitting to the IIS, the IIS should assess the necessity to de-authorize the IIS-AO. | • For security purposes<br>• Only applicable to localities without a reporting mandate | PM 12.0, BR826 |

**HL7 considerations**

This section provides practical considerations on how best practice recommendations from the previous section can be implemented with the HL7 messaging standard [2.5]. As stated on page 13 in the "About this document" section, "The business rules represent an attempt to balance ideal possible practices with pragmatic considerations of what will be possible to implement in an IIS." That balance is represented in the document by defining best practices (what is ideally required, e.g., need to know all participants of the submittal chain) and good practices (what would be possible to implement with HL7 standard today, e.g., sent info to the IIS about only one or two of the multiple submitters); see, for example, business rules BR804 and BR805, where such best and good practices have been discussed.

Correspondence between key terms from the domain model (chapter 3 and Appendix A) and concepts of the HL7 standard are presented in Table 5. This table provides guidance on carrying key information from a domain model in the HL7 message. Two illustrative stories that follow the table present examples of HL7 implementations for some typical scenarios. The proposed introduction of a new field (MSH-22) in the HL7 standard would allow for HL7 messages to carry information about up to two submitters in a submission chain. That should cover a majority of all practical situations that exist today.

Remaining gaps between the best practice recommendations for Facility Identification Management and good practices that reflect current HL7 capabilities (i.e., what is practically possible today) can be addressed in future releases of the HL7 messaging standard. It should be noted that some of the information relevant to Facility Identification Management can be stored in the IIS instead of being transmitted in the HL7 message. For example, data items such as Organizational Group/Family ID (item 1.11) and Reporting Group/Family ID (item 1.12) that describe organizational and reporting hierarchies for IIS-AOs can be stored in the IIS (database or some other data capture method). Another practical approach would be to store the submitter(s') IIS-AO ID(s) in the IIS and to use MSH-4 field to represent the vaccinating organization that initiated the submission.

**Table 5.** Correspondence between key terms from the domain model (chapter 3 and Appendix A) and concepts of the HL7 standard

| Term | Definition (see the domain model – Chapter 3 and Appendix A) | HL7 Home | HL7 Definition | Notes |
|---|---|---|---|---|
| Submitter IIS-AO ID | IIS ID for the IIS-Authorized Organization that submitted Vaccination Event Submissions and/or Demographic-only Submissions to the IIS or to intermediary Submitter(s) with IIS as a final destination. | MSH-4 (Sending Facility) | This field identifies the organization responsible for the operations of the sending application. Locally defined codes may be added to accommodate local needs. | This is the organization that connects to the IIS and submits the record. It could be on behalf of another organization.<br>***MSH-4 always captures information about the last Submitter in a submission chain.***<br>Accordingly, MSH-4 captures the second Submitter in a two-step submission chain (two Submitters).<br>In a one-step submission chain (one Submitter), the values in MSH-4 and MSH-22 will be identical. |
| | IIS ID for the IIS-Authorized Organization that is the first Submitter in a submission chain. | MSH-22 (Responsible Sending Organization)<br><br>***AIRA has not approved inclusion of this field yet.*** | Business organization that originated and is accountable for the content of the message. | This is the organization that entered the information into the information system (such as EHR) and initiates the submittal.<br>***MSH-22 always captures information about the first Submitter in a submission chain.***<br>Accordingly, MSH-22 captures the first Submitter in a two-step submission chain (two Submitters).<br>In a one-step submission chain (one Submitter), the values in MSH-4 and MSH-22 will be identical. |
| Vaccinator IIS-AO ID | IIS ID for the IIS-Authorized Organization that conducted the Vaccination Event. | RXA-11 (Administered at location) | The name and address of the facility that administered the immunization. | HL7: The organization responsible for administering the vaccination (Administering Organization).<br>This is the organization that has IIS-AO ID. It can be a clinic, a site, or an entire organization; as long as it has IIS-AO ID and claims the shot, it is a Vaccinator. |

| Term | Definition (see the domain model – Chapter 3 and Appendix A) | HL7 Home | HL7 Definition | Notes |
|---|---|---|---|---|
| Recorder IIS-AO ID | IIS ID for the IIS-Authorized Organization that enters the information into the data exchange system. | ORC-17 | This field identifies the organization that the enterer belonged to at the time he/she entered/maintained the order, such as medical group or department. | In HL7 this is the provider organization that entered this record/order (Entering Organization).<br>This would enable the capture of recorder for historical immunizations. If a nurse in Clinic A enters a historical dose into the EHR, Clinic A is not the Vaccinator IIS-AO, but the Recorder IIS-AO of the information that gets sent to the IIS.<br>If vaccines were administered, this organization administered them. |
| Vaccine Prescriber – Provider Identifier | Identifier (ID) that labels and establishes the identity of a Provider (a person) that has prescribed/ordered the vaccination (or has written standing orders for immunizations). | ORC-12 (Ordering Provider) | This field contains the identity of the person who is responsible for creating the request (i.e., ordering physician). In the case where this segment is associated with a historical immunization record and the ordering provider is not known, then this field should not be populated. | |
| Vaccine Administrator – Provider Identifier | Identifier (ID) that labels and establishes the identity of a Provider (a person) that has performed the Vaccination Event (administered the vaccine). | RXA-10 (Administering Provider) | This field is intended to contain the name and provider ID of the person physically administering the pharmaceutical. | |

| Term | Definition (see the domain model – Chapter 3 and Appendix A) | HL7 Home | HL7 Definition | Notes |
|---|---|---|---|---|
| Data Enterer Identifier | Identifier (ID) that labels and establishes the identity of a Data Enterer (a person) that has entered the Vaccination Event's information via a system (e.g., EHR) using Electronic Data Exchange (EDE) to submit data to IIS. This person works for a Recorder IIS-AO. | ORC-10 (Entered by) | This identifies the individual that entered this particular order. It may be used in conjunction with an RXA to indicate who recorded a particular immunization. | In HL7 standard this is the person that entered this immunization into the system (Entered By). |

Story 1: Billy Bill is immunized with Hep B peds at MyBigClinic (ID123244). Dr. Susan Someone (NPI = 33225) ordered the vaccination and Bobbie Boing, RN (NPI = 4493322) administered the vaccine and recorded it in the EHR. He also recorded a historical dose of MMR in the EHR. The EHR sent a VXU to the IIS.

| Term | HL7 Home | Value |
|---|---|---|
| Submitter IIS-AO ID | MSH-4 (Sending Facility) | MyBigClinic (ID 123244) |
| | MSH-22 (Responsible Sending Organization) | MyBigClinic (ID 123244) |
| Vaccinator IIS-AO ID | RXA-11 (Administered at location) | Hep B: MyBigClinic (ID 123244) |
| | | MMR: empty |
| Recorder IIS-AO ID | ORC-17 | Hep B: MyBigClinic (ID 123244) |
| | | MMR: MyBigClinic (ID 123244) |
| Vaccine Prescriber – Provider Identifier | ORC-12 (Ordering Provider) | Hep B: Dr. Susan Someone (NPI= 33225) |
| | | MMR: empty |
| Vaccine Administrator – Provider Identifier | RXA-10 (Administering Provider) | Hep B: Bobbie Boing, RN (NPI=4493322) |
| | | MMR: empty |
| Data Enterer | ORC-10 (Entered by) | Hep B: Bobbie Boing, RN (NPI=4493322) |
| | | MMR: Bobbie Boing, RN (NPI=4493322) |

Story 2: Billy Bill is immunized with Hep B peds at MyBigClinic (ID123244). Dr. Susan Someone (NPI = 33225) ordered the vaccination and Bobbie Boing, RN (NPI = 4493322) administered the vaccine and recorded it in the EHR. He also recorded a historical dose of MMR in the EHR. The EHR sent a VXU to the IIS via MyState HIE (ID 999666).

| Term | HL7 Home | Value |
|---|---|---|
| Submitter IIS-AO ID | MSH-4 (Sending Facility) | MyState HIE (ID 999666). |
| | MSH-22 (Responsible Sending Organization) | MyBigClinic (ID 123244) |
| Vaccinator IIS-AO ID | RXA-11 (Administered at location) | Hep B: MyBigClinic (ID 123244) |
| | | MMR: empty |
| Recorder IIS-AO ID | ORC-17 | Hep B:<br>MyBigClinic (ID 123244) |
| | | MMR:<br>MyBigClinic (ID 123244) |
| Vaccine Prescriber – Provider Identifier | ORC-12 (Ordering Provider) | Hep B: Dr. Susan Someone (NPI= 33225) |
| | | MMR: empty |
| Vaccine Administrator – Provider Identifier | RXA-10 (Administering Provider) | Hep B:<br>Bobbie Boing, RN (NPI=4493322) |
| | | MMR: empty |
| Data Enterer | ORC-10 (Entered by) | Hep B:<br>Bobbie Boing, RN (NPI=4493322) |
| | | MMR:<br>Bobbie Boing, RN (NPI=4493322) |

## Chapter 5: Updates and Revisions for the Existing MIROW DQA Guide (2008)

This chapter presents results of the Work Group review and updates of the business rules for various validations of the incoming to IIS data (initially captured in the earlier MIROW guide on this topic [1.4], released in 2008).

Business rules under review are those in Table 3 of the original DQA guide (pages 34-47). Revised business rules are placed in Table 6 below. Implementers should use direct comparison of original and updated business rules – rule by rule. See the original DQA guide for a discussion of these tables' structure, prioritization scheme ("Pri" column in the table 6), categories ("Cat" column in the table 6), references to sections, explanatory materials, and other aspects. For all business rules, the terminology has been adjusted to match the current domain model presented in chapter 3 and Appendix A of this document. Note that the 2008 MIROW DQA guide [1.4] prescribes (pages 29-30) that error messages should be sent in cases of complete or partial rejection of a submission.

**Table 6.** Revised Business Rules from the 2008 MIROW DQA Guide [1.4]

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| A | BR101 | Vaccination Encounter Date must not be before Patient Date of Birth.<br><br>Data items:<br>• Vaccination Encounter Date<br>• Patient Date of Birth | • EDE (batch or real-time one-by-one submissions): Reject the patient and all related Vaccination Event submissions (new/incoming).<br><br>• UI: Reject the Vaccination Event<br>.<br><br>*See note at the end of Table 3 in the 2008 MIROW DQA guide [1.4].* | • Implementation Example<br>o Iterate through each Vaccination Event in the record being validated; reject if any Encounter Date precedes Date of Birth<br>• Possible interpretations:<br>o Vaccination Encounter Date is incorrect<br>o Patient Date of Birth is incorrect<br>o Patient Date of Birth and Vaccination Encounter Date are incorrect<br>o Patient identification is incorrect (e.g., could be a sibling)<br>• Research may include:<br>o Check existing patient for high confidence date of birth<br>• Principle(s): P01, P02, P03, P04 | P-VE |
| A | BR102 | Vaccination Encounter Date should not be after the Patient Date of Death.<br><br>Data items:<br>• Vaccination Encounter Date<br>• Patient Date of Death | • EDE (batch or real-time one-by-one submissions): Reject the patient and all related Vaccination Event submissions (new/incoming).<br><br>• UI: Reject the Vaccination Event | • Implementation Example<br>Check:<br>o If Vaccination Encounter Date is after Date of Death<br>o If Date of Death is after Vaccination Encounter<br>o Iterate through each Vaccination Event in the record being validated; reject if any Encounter Date is later than the Date of Death.<br>• Possible interpretations:<br>o Date of Death is recorded incorrectly or patient is not actually deceased. | P-VE |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | | | o Vaccination Encounter Date is incorrect.<br>o Error in software used to report encounter to IIS<br>o Two distinct patients are reported (one who received the vaccination and one who is deceased).<br>• Research may include:<br>o Determine if the patient is deceased and the correct date of death.<br>o Determine if the patient identification (match) is correct.<br>• Principle(s): P01, P02, P03, P04<br>• Other: This is rare. | |
| A | BR103 | Vaccination Encounter Date must be less than or equal to (before or the same as) the Submission Date.<br><br><u>Data items:</u><br>• Submission Date<br>• Vaccination Encounter Date | • Reject the Vaccination Event submission. | • Principle(s): P01, P03, P04<br>• Other:<br>o If the system (IIS) does not capture the submission date, the default should be system's date at the time of validation. | S-VE |
| A | BR104 | The <u>minimum/mandatory set</u> of data items for the Demographic-only submission includes:<br>• IIS-AO ID (Recorder)<br>• Patient Date of Birth<br>• Patient Name, First<br>• Patient Name, Last<br>• Birth Certificate Number<br>• Birth Facility (code, name, address) | • When less than minimum/mandatory set is received, the whole submission should always be rejected. | • For a recommended (not minimum) set of data items, refer to the list of core data elements [2.1], HL7 standard (IG Implementation Guide) [2.5], local manuals, and other materials.<br>• Patient ID has not been included in this minimum/mandatory data set, but it could be a key data item to match a patient.<br>• This minimum/mandatory data set does not contain every required data element listed in the HL7 standard (IG Implementation Guide). Missing data elements required by HL7 that are not in this | Misc |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | • Gender | | minimum/mandatory data set should not cause rejection of the whole submission.<br>• Vital Records should be considered the authoritative source for demographic information at the time of birth.<br>• Demographic-only Submissions can be originated by many IIS-AO types, not only Vital Records.<br>• Gender, Birth Facility, and Birth Certificate Number are only required from Vital Records. | |
| A | BR105 | BR105R1<br>The minimum/mandatory set of data items for the "administered" Vaccination Event submission must include:<br>• IIS-AO ID (Vaccinator/Recorder)<br>• Patient Name, First<br>• Patient Name, Last<br>• Patient Date of Birth<br>• Vaccination Encounter Date<br>• Vaccine Type<br>• Administered/Historical Indicator = "Administered"<br>• Lot Number<br><br>BR105R2<br>The minimum/mandatory set of data items for the "historical" Vaccination Event submission must include: | • When less than minimum/mandatory set is received, the whole submission (e.g., Vaccination Event) should always be rejected. | • For a recommended (not minimum) set of data items, refer to the list of core data elements [2.1], HL7 standard (IG Implementation Guide) [2.5], local manuals, and other materials.<br>• See the section "Administered/Historical Indicator" in chapter 3 for a discussion (page 27).<br>o Rules for accepting or rejecting "Administered" Vaccination Event Submissions with less than the expanded data set should be the same for Electronic Data Exchange and Direct User Interface submissions.<br>o When a reduced set of data items is reported for the "Administered" Vaccination Event, an error message should always be sent or displayed in the UI. Also, other methods of communicating data quality problems should be employed, i.e., monthly reports.<br>• Vaccine Type can be expressed as a CVX code (preferably) or CPT code (not recommended since it identifies a service, not a product).<br>• At the time the MIROW Work Group made these recommendations, not all sending systems, either | Misc |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | • Patient Name, First<br>• Patient Name, Last<br>• Patient Date of Birth<br>• Vaccination Encounter Date<br>• Vaccine Type<br>• Administered/Historical Indicator = "Historical" | | billing, clinical or EHRs, were submitting Lot Number with administered doses. Few IIS rejected immunization records that did not include Lot Number. The MIROW Work Group recognized that Lot Number is a critical element and that IIS will need to receive Lot Number in the future. In other words, the inclusion of the Lot Number in the minimum/mandatory data set for administered vaccinations was done with the understanding that it was a goal and future expectation that IIS-AOs will move toward being able to capture and submit Lot Number to the IIS. This recommendation was in line with a note in the "Intended Use" section of this document (page 13): "Resource constraints and required changes to existing functionality may result in incremental adoption of these <MIROW> guidelines." In the transitional period, IIS should query IIS-AOs' systems during on-boarding about ability to send Lot Number and, if the IIS-AO is unable to capture and/or submit the Lot Number to the IIS, the IIS may temporarily implement a good practice of designating Lot Number as a recommended but not required data element. In the transitional period, the IIS should periodically review the temporary practice to determine when it can move to the best practice of requiring Lot Number as a required data element.<br>• Capturing Patient Eligibility Status at the dose level (for each vaccine dose administered) is the recommended Best Practice [1.2]. Information about Patient Eligibility Status is important and necessary | |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | | | for using vaccine inventory functionality [1.1]. However, this data item was not included in the minimum/mandatory data set because the MIROW Work Group is not recommending full rejection of the Vaccination Event Submissions without that information. | |
| A | BR106 | ***BR106 – to be deleted – reference revised BR104-BR105 for guidance.***<br><br>The minimum/mandatory set of data items for the Electronic Medicaid/Billing Records must include:<br>• Provider Organization Name/ID<br>• Patient Name, First<br>• Patient Name, Last<br>• Patient Date of Birth<br>• Vaccine Encounter Date<br>• Vaccine Type | • If the demographic data items are incomplete (patient can't be identified): Reject the Patient's record (complete rejection of submitted information).<br>• If the demographic data items are complete (patient can be identified): Reject those Vaccination Events that are incomplete (partial rejection of submitted information). | • Principle(s): P01, P03, P12<br>• Other: note – see P13<br>• Additional state-specific items can be added to the set. | Misc |
| A | BR107 | Every administered vaccine should be recorded as a single Vaccination Event.<br><br>Data Items:<br>• Vaccination Event Submission - Administered/ Historical Indicator | • Accept and flag for investigation (to follow up with submitter) | E.g., COMVAX®, which contains HepB and Hib, would be recorded as one Vaccination Event rather than two Vaccination Events.<br><br>Principles: Principle(s): P01, P05 | Misc |
| A | BR108 | Vaccinations submitted via electronic data exchange to IIS | • Examine the process and determine the cause (IIS | • Principle(s): P01, P11 | S-VE |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | **Condition** | **Recommended Action** | | |
| | | that do not perform a manual review should appear in the IIS within 2 business days of the Submission Date. Vaccinations submitted via electronic data exchange to IIS that perform manual reviews should appear in the IIS within 2 weeks of the Submission Date.<br><br><u>Data Items:</u><br>• Submission Date<br>• Vaccination Event Submission Date Loaded | monitors its data processing to determine when and why there are delays). | • Manual review may require increased work on the part of IIS. | |
| B | BR109 | ***BR109– to be deleted – it is no longer applicable since administered/historical indicator became a mandatory data item (see BR105).***<br><br>Vaccination Event reported by Provider assumed to be "Historical" until attested or proven otherwise.<br><br><u>Data Items:</u><br>• Vaccination Event Submission - Administered/ Historical Indicator | • When value is missing, accept and set Administered/ Historical Indicator to "Historical." | • "Administered/Historical Indicator" information should be reported explicitly or derived implicitly.<br>• Individual IIS should establish a criterion of sufficient proof to count a shot as "Administered," e.g., presence of specific information, such as lot number, manufacturer, expiration date, site, or a time period of less than 30 days between vaccination date and submission date. | Misc |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| B | BR110 | ***BR110– to be deleted – Lot Number has been added to BR105.***<br><br>VFC-eligible children should have the manufacturer and lot number reported with Vaccination Event.<br><br>Data Items:<br>• Vaccination Encounter Date<br>• VFC Eligibility – Start Date<br>• VFC Eligibility – End Date<br>• Vaccine Manufacturer<br>• Vaccine Lot Number | • Reject the Vaccination Event submission.<br><br>This applies to administered immunizations only. | • This information is needed for inventory management and vaccine accountability.<br><br>• The IIS may choose to relax this requirement for some submitters who are unable to provide the data items.<br><br>• In the future, this requirement most likely will be more restrictive.<br><br>• Principle(s): P01, P03, P04 | Misc |
| B | BR111 | Adverse reactions reported on administered vaccines should be identified for tracking and provider follow-up.<br><br>Data items:<br>• Vaccination Event - Adverse Reaction<br>• Vaccination Event Submission - Administered / Historical Indicator | • Accept<br>• Flag for tracking | See Vaccine Safety Registry Committee (VASREC) document on the AIRA web page: http://www.immregistries.org/resources/IIS-VAERS_Collaboration_-_VASREC_Workgroup_04-20-2005.pdf.<br><br>Principle(s): (none) | Misc |
| B | BR112 | The percentage of Vaccination Event Submissions from Vital Records with hepatitis B birth doses should be within an expected threshold level (to be | • If threshold is deviated by 10%, then immediately follow up with Vital Records department. | • See BR123 for other Vital Records thresholds.<br>• Principle(s): P01, P05 | Misc |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | determined by each IIS).<br>Data items:<br>• Vaccine Type<br>• IIS-AO Type/Sub-Type | | | |
| B | BR113<br><br>generic | If the IIS-AO (Vaccinator) is a "specific," (e.g., pediatric) practice, the currently administered vaccinations should match a pattern in similar practices.<br><br>Note: This could apply to many practices. A practice includes a unique combination of various groups of the population.<br><br>Data items:<br>• Vaccine Type<br>• Date of Birth<br>• Vaccination Encounter Date<br>• IIS-AO Type/Sub-Type<br>• Administered/Historical Indicator | • Accept and flag for investigation (initiate research of provider's records). | • See section "Precertification and Providers' Profiles" and Appendices E and F for specific distributions for various practices and for possible approaches to utilize providers' profiles.<br><br>• Possible approaches may include:<br>o Dialogue with IIS-AO (Vaccinator) to determine if the reported percentages reflect actual clinical activity (e.g., inventory shortage or manual coding errors).<br>o Review data exchange logs for error messages (application errors, system outages) on IIS side and IIS-AO side.<br>Funding and staffing restrictions should be taken under consideration. NYC experience of communicating with IIS-AO regarding their profiles should be considered.<br><br>• Principle(s): P01, P05, P06 | Pr-VE |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| B | BR114 | Vaccination Encounter Date should not be the same as the Patient Date of Birth unless it is on the list of vaccines recommended for administration on the date of birth, e.g., Hep B.<br><br><u>Data items:</u><br>• Vaccination Encounter Date<br>• Patient Date of Birth<br>• Vaccine Type (or CVX …) | • EDE (batch or real-time one-by-one submissions): Accept and flag for investigation if Vaccine Type is not an expected birth dose vaccine.<br>• UI: Accept (after issuing a warning if Vaccine Type is not an expected birth dose vaccine). | • Possible interpretations:<br>  o Clinical error<br>  o Professional decision which differs from common practice<br>  o Vaccination Encounter date mistyped<br>  o Date of birth is mistyped as the date of service or other typographical error.<br>  o Provider's EHR may not support data validation for these fields.<br>• Research may include:<br>  o Provider reviewing patient chart<br>  o Provider contacting patient or other source to validate Date of Birth<br>• Principle(s): P01, P02, P04, P05, P10<br>• IIS should have functionality to flag a submission for the investigation.<br>• Other:<br>  o A date of birth from a Vital Records source, such as a birth certificate, is a trusted source.<br>  o Closely related to BR101<br>  o There may be exceptions to this rule (typically old rules that no longer apply, other countries, etc.).<br>  o This is related to ACIP. | P-VE |
| B | BR115 | For administered Vaccination Event submissions, Submission Date should be within 14 days of Vaccination Encounter Date.<br><br><u>Data Items:</u><br>• Submission Date | • Accept and flag for investigation. | • There are Batch submissions from small IIS-AOs that only submit on a monthly basis. It does not make sense for them to submit more frequently when there would be only a handful of doses at the end of the month.<br>• The 14 days is on average; seasonal highs may be outside this average. | S-VE |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | • Vaccination Encounter Date<br>• Administered/Historical Indicator | | • IIS should have ability to run reports on timeliness of Vaccination Event Reporting, whether data are reported via EDE or UI.<br>• Principle(s): P01, P04, P11<br>• Other:<br>o See NVAC recommendations.<br>o Keep in the source profile the average time until submission.<br>o This is an issue for investigation and training. | |
| B | BR116 | Trade Name, Manufacturer, CVX Code, CPT Code, and Vaccine Type should not contradict one another.<br><br><u>Data Items:</u><br>• Trade Name<br>• Manufacturer /MVX Code<br>• CVX Code<br>• CPT Code<br>• Vaccine Type (Hib – PRP-OMP)<br>• NDC | • Reject the Vaccination Event submission. | • Possible interpretations:<br>o Typographical error<br>o Code translation (or other) error in software<br>o Provider's EHR system may not be a current version and may be incomplete or include invalid values/choices.<br>• Research may include:<br>o Review of source document(s)<br>o Review of all submissions from provider to detect systematic errors<br>• Principle(s): P01, P04, P13 (CVX codes are preferred over CPT codes)<br>• Other:<br>o We need to know the vaccination type.<br>o Not all data items are available all the time.<br>o Multiple CPT codes can map to the same CVX code.<br>o Combination vaccines should always be documented with their own unique CVX/CPT/MVX/NDC codes and not | V |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | | | represented as single antigens.<br>o Changes of codes not updated to current code (CVX, NDC, MVX)<br>• This is a hard BR to enforce. The burden will rely on the IIS and vendor community to manage the internal edits. | |
| B | BR117 | The same patient should not receive the same antigen more than once in a single day.<br><br><u>Data items:</u><br>• Vaccination Encounter Date<br>• Vaccine Type (in order to derive the antigen)<br>• Dose Condition | • Follow best practice recommendations in the MIROW deduplication materials.<br><br>(This is not the Accept/Reject situation.) | • Antigen's administration might be conducted by the same or different Vaccinator IIS-AOs.<br>• There are instances where the vaccination was compromised and the repeat dose given the same day.<br>• Implementation Example<br>See the following MIROW publication:<br>AIRA Modeling of Immunization Registry Operations Workgroup (eds). Vaccination level deduplication in Immunization Information Systems. Atlanta, GA: American Immunization Registry Association. December 2006, p. 21. Available at: http://www.immregistries.org/resources/AIRA-BP_guide_Vaccine_DeDup_120706.pdf<br><br>• Possible interpretations:<br>o Incorrect or incomplete vaccination deduplication<br>o Invalid dose or incomplete immunization<br>o Two separate pediatric doses on the same date to an adult<br>o Poor clinical practice (Pediarix and IPV)<br>o Data is from different Patients<br>• Principle(s): P01, P05, P10<br>• Other: | VE-V |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | | | o Deduplication may remove some or all of this.<br>The match needs to be made at the antigen level, so the antigen needs to be determined from the vaccine type that is reported. | |
| B | BR118 | Vaccination Encounter Date should not be after the lot number expiration date.<br><br><u>Data items:</u><br>• Vaccination Encounter Date<br>• Lot Number Expiration Date | • EDE (batch or real-time one-by-one submissions): Accept and flag for investigation.<br>• UI: Accept (after issuing a warning). | • Possible interpretations:<br>o Expired vaccine was used.<br>o Typographical error<br>• Research may include:<br>o Discuss with provider possibility of sub potency.<br>• Principle(s): P01, P02, P04, P05 | VE-V |
| B | BR119 | Route and Site should not contradict each other for a given Vaccine Type and Patient's age.<br><br><u>Data items:</u><br>• Route<br>• Site<br>• Vaccine Type<br>• Patient Date of Birth<br>• Vaccination Encounter Date | • EDE (batch or real-time one-by-one submissions): Accept and flag for investigation.<br>• UI: Accept (after issuing a warning) and flag for investigation. | • Implementation Example<br>Hep B site reported as subcutaneous, not intramuscular.<br>• Possible interpretations:<br>o Typographical error<br>o Systematic code translation (or other) error in software<br>o Clinical error<br>o Provider's EHR system may not be a current version and may be incomplete or include invalid values/choices.<br>o Provider's EHR may not support data validation for these fields.<br>• Research may include:<br>o Reference to source document(s)<br>o Review of all submissions from provider to detect systematic errors | V-VE |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | | | • Principle(s): P01, P02, P04, P05<br>• Other:<br>o See Appendix G for Vaccine Site/Route Guide (adapted from the 2003 Red Book and ACIP General Recommendations, MMWR 2006:51 [No.RR-2]:15–18).<br>o Updated reference: Recommendations of the Advisory Committee on Immunization Practices (ACIP), Recommendations and Reports, January 28, 2011 / 60(RR02);1-60. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm?s_cid=rr6002a1_w | |
| B | BR120 | Vaccination Encounter Date should be within the Vaccine Product License Date range: after the Vaccine Product License Begin Date and before the Vaccine Product License End Date.<br><br>Data items:<br>• Vaccination Encounter Date<br>• Vaccine Product License Begin Date<br>• Vaccine Product License End Date | • EDE (batch or real-time one-by-one submissions): Accept and flag for investigation.<br><br>• UI: Accept (after issuing a warning). | • Implementation Example<br>CVX code = 51 (Hep B-Hib) recorded as given in 1957 (it was implemented in USA around 1989)<br>• Possible interpretations:<br>o Incorrect coding<br>o Typographical error<br>o Unexpired vaccine used after Product License End Date<br>o Expired vaccine was used<br>o It could be a vaccine given in another. country: DTaP-Hib-IPV licensed in Canada and Mexico but not in USA at this point<br>o Experimental drug trial<br>o CPT code has been changed (re-used)<br><br>o Research may include:<br>o Reference to source documents<br>• Principle(s): P01, P02, P04, P05 | V-VE |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | | | • Other:<br>o The vaccine should be given within the period when the vaccine is in use.<br>o There is no single, authoritative source for many Vaccine Product License Dates.<br>o There may be different operational ways to implement this rule.<br>o This is for administered vaccines only, not historical.<br>o There are instances when investigational vaccines are used outside of the range.<br>Doses should not be recorded as given before or after U.S. licensure.<br>Red Book® Online Table – Status of Licensure and Recommendations for New Vaccines<br>http://aapredbook.aappublications.org/news/vaccstatus.shtml | |
| B | BR121 | Administered vaccinations should have specific Vaccine Types, e.g., Hib PRP-OMP;<br>unspecified vaccine types, e.g., Hib, UF (unspecified formulation), are not appropriate.<br><br>Data Items:<br>• Administered/Historical Indicator<br>• Vaccine Type | • Accept and flag for investigation – during production.<br>• Investigate - during precertification. | • Implementation Example<br>o Vaccine Type is Hib, UF (unspecified formulation), and Administered/Historical Indicator is Administered. The vaccinator would have known which Hib was given and this should have been reported.<br>• Possible interpretations:<br>o The submitting system does not support the specific code so the recorder was forced to select the unspecified type.<br>o The recorder did not know what specific vaccine was given.<br>o The submitting system incorrectly reports the vaccine type. | V-VE |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | | | o The vaccine was not administered, but instead was copied from a historical source. It is being incorrectly reported as administered.<br>• Research may include:<br>o Contacting submitter to examine recording process and determine at which step the vaccine event become unspecified<br>• Principle(s): P01<br>• Other:<br>o Vaccine type cannot be unspecified if you are recording vaccine information from vaccination inventory module.<br>o HIB PRP-OMP: OMP = meningococcal outer membrane protein complex<br>o HIB, NOS: NOS = not otherwise specified<br>• Encourage recording a specific vaccine type.<br>• Clinical trials of new vaccines should be considered. | |
| C | BR122 | A patient's eligibility for a public program (e.g., VFC program, state program) should be consistent with the administered vaccine dose's designation for a stock type (e.g., public, private).<br><br><u>Data items:</u><br>• Patient Eligibility Status (for administered vaccine dose) | • EDE (batch or real-time one-by-one submissions): Accept and flag for investigation.<br><br>• UI: Accept (after issuing a warning). | • This is a state-specific business rule – some states allow this; some don't.<br>• This BR is more about program's policy, and less about data quality.<br>• VFC vaccines should be given to VFC-eligible children; this is specific to the vaccine.<br>• Borrowing situations should be taken into consideration. See MIROW guide on Inventory Management for details.<br>o When a Public/Private Inventory Indicator for a | Misc |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | • Public/Private Inventory Indicator (for administered vaccine dose) | | vaccine dose administered to a patient is "private" and patient's eligibility is "public" (or vice versa), a borrowing transaction is created.<br>• Principle(s): P01, P02, P04, P05 | |
| C | BR123 | The volume of reporting from the Vital Records feed should be within an expected threshold level (to be determined by each IIS).<br><br><u>Data items:</u><br>• Report Submission Date | • If the rate of reporting significantly deviates from the threshold, follow up with Vital Records department.<br>• This is not an Accept/Reject situation. | See also BR112.<br><br>Principle(s): P01, P11 | Misc |
| C | BR124 | The percentage of Vaccination Events in which the responsible party name is the same as the patient name should be within an expected threshold level (to be determined by each IIS). | • If threshold is exceeded significantly, initiate investigation.<br><br>• This is not an Accept/Reject situation. | • When importing incoming data into parent or guardian fields in an IIS, first identify the actual data definitions and usage of similar fields (guardian, responsible party, parent, payer) by the source agency.<br>• This rule is especially useful during the precertification process.<br>• The threshold should be determined based on the patient population of the IIS. For instance, a pediatric registry versus a lifetime registry.<br>• See GR804 in this guide.<br>• Principle(s): P01, P05 | Misc |
| C | BR125 | The percentage of rejected Vaccination Events submissions in a Combined Submission should be within an expected threshold level. | • This is not an Accept/Reject situation.<br><br>Precertification:<br>• If more than 10% of the | • During precertification, determine the quality of the existing data and the extract and formatting process. Rejection of records because they already exist should not be considered in this rate.<br>• The process of extracting and formatting data is | |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| | | Data items:<br>• Vaccination Event Submission - Accepted/Rejected | Vaccination Event submissions are rejected for errors, initiate an investigation.<br>Post-certification:<br>• If a batch contains at least 50 Vaccination Event submissions and more than 10% are rejected for errors, stop processing and investigate. | fraught with risk. One way to find systematic errors is to look for unusual rates of bad data. Precertification evaluation for unacceptable rates of rejected records is one measure that can be used. While records may be rejected because they are unacceptable in format or content, this may reflect accurately the data in the source record. However, if the rate of errors is high enough, our confidence in the process to produce the data is challenged. There is no best level to use for record rejection rate. It is obvious that a batch of 10 records with 2 rejected records is probably not the same concern as 10,000 records with a 20% rejection rate.<br>• It might be interesting to consider weekly rejection rates for each data source.<br>• The threshold level may be dependent on IIS-AO type and size, as well as on error types.<br>• Principle(s): P01 | |
| C | BR126 | An administered vaccine should not have a medical contraindication for a patient.<br><br>Data items:<br>• Vaccination Event Submission - Administered/Historical Indicator<br>• Vaccine Type<br>• Contraindication | • EDE (batch or real-time one-by-one submissions): Accept and flag for investigation.<br><br>• UI: Accept (after issuing a warning). | • However, it may be reflective of an actual clinical incident.<br>• Applicable to all vaccines<br>• IIS should have the ability to flag a contraindicated vaccine.<br>• Principle(s): P01, P02, P04, P05 | V-P |

| Pri | # | Business Rule | | Comments | Cat |
|---|---|---|---|---|---|
| | | Condition | Recommended Action | | |
| C | BR127 | Hepatitis B birth doses from the Vital Records feed should be reported within an agreed-upon timeframe.<br><br>Data items:<br>• Vaccine Type<br>• Submitter Type<br>• Vaccination Encounter Date<br>• Report Submission Date | • This is not an Accept/Reject situation.<br>• If Vital Records feed is not reported within 3 business days of agreed-upon timeframe, then follow up immediately with Vital Records department. | • This applies only in settings where Vital Records reports Hep B immunizations.<br>• See also BR112 and BR123.<br>• Principle(s): P01, P11 | V-VE |

## Conclusions

The guidelines offer consensus-based best practice recommendations to support selected aspects of data quality assurance in IIS. The guidelines will assist IIS in aligning practices through adherence to a set of common recommendations and guidelines.

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

- Developed and reconfirmed key concepts, terms, and definitions related to various aspects of data quality assurance in IIS.
- Developed business models and illustrations documenting **3 roles** that IIS-AOs play in the submittal chain of vaccination and demographic information to IIS. Formulated **8 operational scenarios** that illustrate IIS-AO roles.
- Defined expected/minimum sets of data items for Vaccination Event submissions based on the key data element "Administered/Historical Indicator." Formulated exceptions when a reduced set of data items may be accepted.
- Formulated **2 principles**, **27 business rules, and 7 general recommendations** to guide provider's Facility Identification Management and related data quality assurance efforts.
- Developed considerations for implementing formulated best practice recommendations with current HL7 messaging standard.
- Revised and updated **27 business rules** for validations of the data incoming to IIS (initially captured in the earlier MIROW guide on this topic, released in 2008).

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

The National Vaccine Advisory Committee (NVAC) 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.

## Selected References

**Previously developed guidelines**

MIROW recommendations documents for previous topics, abridged mini-guides, and other materials are available at the AIRA and CDC websites:
http://www.immregistries.org/resources/aira-mirow
http://www.cdc.gov/vaccines/programs/iis/activities/mirow.html

1.1) AIRA Modeling of Immunization Registry Operations Work Group (eds). Immunization Information System **Inventory Management Operations**. Atlanta, GA: American Immunization Registry Association. June 2012.
http://www.immregistries.org/AIRA-MIROW-Inventory-Management-best-practice-guide-06-14-2012.pdf

1.2) 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/AIRA-MIROW_IIS-VFC_Best_Practice_Guide_04-14-2011.pdf

1.3) AIRA Modeling of Immunization Registry Operations Work Group (eds). ***Reminder/Recall*** in Immunization Information Systems. Atlanta, GA: American Immunization Registry Association. April 2009.
http://www.immregistries.org/resources/AIRA-MIROW_RR_041009.pdf

1.4) 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/AIRA_MIROW_Chap3_DQA_02112008.pdf

1.5) AIRA Modeling of Immunization Registry Operations Work Group (eds). ***Vaccination level deduplication*** in Immunization Information Systems. Atlanta, GA: American Immunization Registry Association. December 2006.
http://www.immregistries.org/resources/AIRA-BP_guide_Vaccine_DeDup_120706.pdf

1.6) AIRA Modeling of Immunization Registry Operations Work Group (eds). ***Management of Moved or Gone Elsewhere (MOGE) Status and Other Patient Designations*** in Immunization Information Systems. Atlanta, GA: American Immunization Registry Association. December 2005.
http://www.immregistries.org/resources/MIROW-MOGE_Chapter_Final_122005_rev1.doc

1.7) 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/resources/IIS-VAERS_Collaboration_-_VASREC_Workgroup_04-20-2005.pdf

**General references**

2.1) Immunization Information System (IIS) Functional Standards
http://www.cdc.gov/vaccines/programs/iis/func-stds.html

2.13) IPOM: Immunization Program Operations Manual
http://www.cdc.gov/vaccines/vac-gen/policies/ipom/

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

2.4) Epidemiology and Prevention of Vaccine-Preventable Diseases: The Pink Book: Course Textbook
http://www.cdc.gov/vaccines/pubs/pinkbook/index.html

2.5) HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.4 Published August 1, 2012
http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-4-2012-08.pdf

## 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 |
| DOB | Date of Birth |
| DT | Decision Table |
| EDE | Electronic Data Exchange |
| EHR | Electronic Health Record |
| GR | General Recommendation |
| HIE | Health Information Exchange |
| HL7 | Health Level Seven International |
| IIS | Immunization Information System |
| IIS-AO | IIS-Authorized Organization |
| LHD | Local Health Department |
| MIROW | Modeling of Immunization Registry Operations Work Group |
| MPI | Master Patient Index |
| MVX | Health Level Seven code for Vaccine Manufacturer |
| N/A, NA, na | Not Applicable |
| NDC | National Drug Code |
| NPI | National Provider Identifier |
| P | Principle (high-level business rule) |
| SME | Subject Matter Expert |
| UI | User Interface |
| UML | Unified Modeling Language |
| VFC | Vaccines for Children |
| Y/N | Yes/No |

## Appendix A: Terms and definitions listed in alphabetical order

**Table 7.** Terms and definitions listed in alphabetical order
Note: see Table 3 for the terms and definitions listed in numerical order – according with the domain diagram in Fig. 2.

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| 7.6 | Address | Patient | A place where a patient may be communicated with, e.g., the residence of the patient. | • Data elements include: Number, street, city, zip or postal code, state, and county or public health entity area of responsibility.<br>• IIS may capture historical addresses as well as current address. |
| 10.4 | Administered/ Historical Indicator | Vaccination Event Submission | Administered/Historical Indicator describes an association between a Vaccination Event and the IIS-AO that originates a Vaccination Event Submission for this Vaccination Event:<br>Values: Administered or Historical.<br>• "Administered" value for the Administered/Historical Indicator points out that the IIS-AO records and/or submits its own Vaccination Event, i.e., attests that it conducted the Vaccination Event ("I am Vaccinator IIS-AO").<br>• "Historical" value for the Administered/Historical Indicator points out that the IIS-AO originates a Vaccination Event Submission for a Vaccination Event that is | • See a detailed discussion of the Administered/Historical Indicator in the "Discussion and notes" section in chapter 3.<br>• Situations when more than one IIS-AO claims to have administered a Vaccination Event should be investigated.<br>• If more than one IIS-AO reports a historical shot, this is not a problem, since IIS will reject duplicates. See MIROW vaccination level deduplication guide [1.5].<br>o Example: ALERT IIS (Oregon) tracks within 14 days for duplicate shots. If more than one IIS-AO claims to have administered the same shot on the same day or within a pre-determined timeframe, IIS triggers a warning about entering a duplicate shot and allows IIS-AO to override and enter duplicate dose in the patient record.<br>• Administered/Historical Indicator is described in the IIS Functional Standards, 2013-2017 (http://www.cdc.gov/vaccines/programs/iis/func-stds.html with the following IIS Core Data Element: Vaccination Event Information Source (i.e., administered or historical).<br>• "Administered" value for the Administered/Historical Indicator means that the IIS-AO submits its own Vaccination Event ("I am Vaccinator IIS-AO").<br>• "Historical" value for the Administered/Historical Indicator means that the IIS-AO originates a Vaccination Event Submission for a Vaccination Event that was administered by some other IIS-AO, i.e., it did not |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| | | | owned by some other IIS-AO, i.e., attests that it did not conduct the Vaccination Event ("I am NOT Vaccinator IIS-AO; I am just Recorder IIS-AO"). | conduct the Vaccination Event ("I am NOT Vaccinator IIS-AO; I am just Recorder IIS-AO"). |
| 4.5 | Adverse Reaction | Vaccination Event | An Adverse Reaction is a negative health consequence experienced by the patient related in time to administration of vaccine(s). | • "In time" means that it happens in some reasonable time after the Vaccination Event. It might not be related to a specific Vaccine dose administered in cases when the patient receives several shots in one visit.<br>• See http://vaers.hhs.gov/resources/vaersmaterialspublications for the Vaccine Adverse Event Reporting System (VAERS).<br>• Adverse Reaction is also known as Adverse Event or Vaccine Reaction. |
| 4.1 | Amount/ Dosage | Vaccination Event | The measurement of how much vaccine was administered. | • Examples: 1 mL, .5 mL, 1 microgram<br>• Examples: 1 dose, 2 doses, 0.5 doses<br>• IIS should maintain a consistent measurement method for recording all vaccine amount/dosage administered and not use measures for dose magnitude in some cases and dose quantity in others. |
| 7.9 | Birth Certificate Number | Patient | A registration number for an official document of a patient's date and place of birth and parentage. | |
| 7.10 | Birth Facility | Patient | A place where a patient was born, e.g, hospital, home. | |
| 11 | Combined Submission | Combined Submission | Collection of one or more Vaccination Event Submissions and/or Demographic-only Submissions that have been submitted at the same time. | • Via electronic data exchange or user interface<br>• Examples of combined submissions include direct entry into the UI of one patient's vaccination or demographic information, an entry of a single electronic batch file with thousands of patients and shots, or a single electronic message.<br>• Includes demographic information<br>• Could include information about one or more Vaccination Events, |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| | | | | Encounters, Patients, Providers.<br>Combined Submission can contain:<br>o Single Vaccination Event submission<br>o Multiple Vaccination Events for a patient encounter (visit)<br>o Multiple encounters (visits) for a single patient<br>o Multiple patients for a single IIS-AO (provider organization)<br>o Multiple IIS-AOs (provider organizations)<br>• Is submitted by a Submitter IIS-AO, which may or may not be a Vaccinator IIS-AO |
| 7.8 | Contraindications | Patient | A contraindication is a condition in a patient that greatly increases the chance of a serious adverse event. | |
| 6.4 | CPT Code | Vaccine Product Type | A numerical string that describes the procedure (a billable service) of administering a vaccine. | • CPT (Current Procedural Terminology) codes are developed by the American Medical Association to bill for medical or psychiatric procedures performed by health care practitioners.<br>• Some CPT Codes have been re-used.<br>• There are vaccines that do not have CPT codes.<br>• CPT codes can be mapped to CVX codes, but this is not one-to-one mapping and use of CPT codes for this purpose is not the best practice. See "CPT Codes Mapped to CVX Codes" at http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt. |
| 6.3 | CVX Code | Vaccine Product Type | A numerical code that describes a Vaccine Type. | • CVX codes are assigned by CDC to support electronic messaging of immunization histories via HL7. See http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx.<br>• Vaccine Type maps to a CVX code. There is normally one CVX code per one Vaccine Type. |
| 1.7 | Data Consumer | IIS Authorized | Indicates if an IIS-AO retrieves information from the IIS. | • Data Consumer is authorized to access IIS data.<br>• Some IIS-AOs are only Data Consumers, and thus are not authorized to |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| | Indicator | Organization | | submit information to IIS. |
| 3 | Data Enterer | Data Enterer | A person who works for a Recorder (IIS-AO) and enters immunization or demographic data via the direct user interface (UI) or Electronic Data Exchange (EDE, e.g., EHR) to submit vaccination and/or demographic information to IIS.<br><br>Data Enterer can play a role of UI or EDE User. | • Data Enterer and Provider are entities ("actors") with distinct responsibilities: Provider is responsible for performing Vaccination Event and Data Enterer is responsible for entering information about the Vaccination Event into the submission chain. These are distinct functional sets (or "roles") that real people can play.<br>• The same person can play roles of Provider (item 2) and Data Enterer. |
| 3.1 | Data Enterer Identifier | Data Enterer | Identifier (ID) that labels and establishes the identity of a Data Enterer (a person).<br><br>This is a Data Enterer's (person's) identification for IIS purposes. | • Data Enterer Identifier (ID) should include:<br>o **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>o **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>• Since there is no universal list of IDs for Data Enterers (across jurisdictions), the IIS does not necessarily track every Data Enterer in its jurisdiction. Therefore, Data Enterer ID is generally only used internally to the IIS.<br>• See also item 10.11: UI User or EDE User –Data Enterer Identifier. |
| 15.1 | Date | Vaccination Encounter | Date when Vaccination Encounter occurred. | |
| 7.2 | Date of Birth | Patient | The birth date of the patient. | • A.k.a. DOB<br>• Date of Birth received from Vital Records is considered more accurate than other sources of Date of Birth.<br>• Used for purposes of Data Quality; e.g., immunizations given before |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| | | | | date of birth or that violate ACIP or state law minimum spacing requirements are invalid.<br>• Used for the purpose of forecasting |
| 7.3 | Date of Death | Patient | The date of the patient's death.<br>. | • Date of Death received from Vital Records is considered more accurate than other sources of Date of Death. |
| 16 | Demographic-only Submission | Demographic-only Submission | Demographic-only Submission is the submittal of demographic information regarding a single Patient to the IIS or to intermediary Submitter(s) with IIS as a final destination. | • The same demographic information can be submitted more than once by an IIS-AO and other parties.<br>• This does not include Vaccination Event information.<br>• Examples:<br>o Notification of a birth via Vital Records that doesn't contain birth dose Hep B<br>o EHR submits an updated address to the IIS<br>o Name change submitted to an MPI system |
| 16.3 | Demographic-only Submission Error(s) | Demographic-only Submission | Indicates the type of error(s) that occurred in the receipt and attempted acceptance of the Demographic-only Submission.<br><br>Include any errors (structural issues, content issues) that occurred in the receipt and attempted acceptance of the Demographic-only Submission, as well as reason for errors. | Types of Errors:<br>• Connection Error. We assume that as the message reaches the IIS, that connectivity has been established already. Connectivity is out of scope for this data quality assurance topic. If we can't see the data we can't comment on it/send error message.<br>• Unreadable/invalid format (header, not HL7 or expected format)<br>• Something inside the message is wrong (can be errors that are informational but allow the data in, errors that cause the data to be rejected by the IIS).<br>• IIS should return error message to Submitter; Submitter should have some mechanism for relaying error message to Recorder IIS-AO so that error can be resolved as needed. |
| 10.5 | Documentation Source Type | Vaccination Event Submission | This is the originating source of the data.<br>Values:<br>o Billing/Claim<br>o Clinical<br>o Patient-provided (formerly | • This is useful when assigning a confidence level to records in order to aid in de-duplicating vaccinations.<br>• The same Vaccination Event can be reported first by administering IIS-AO (Clinical), then by another IIS-AO (Patient-provided), and then yet by another IIS-AO (Billing/Claim). |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| | | | known as "Transcribed") | • Patient-provided - describes second-hand information. Example of the "Patient-provided" Documentation Source Type would be a paper record: chart or immunization card. This type of immunization information is always "Historical." |
| 4.2 | Dose Condition | Vaccination Event | A "compromised" indicator. Indicates that a dose administered to a patient is considered substandard and therefore, not a valid dose. | |
| 13 | Electronic Data Exchange | Electronic Data Exchange | Electronic Data Exchange is the interface in which data can be communicated electronically between a third party system and the IIS (e.g., EHR, HIE, Billing System). | • "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. Ross. Immunization Registries Can Be Building Blocks For National Health Information Systems. HEALTH AFFAIRS 29, NO. 4 (2010): 676–682.<br>• ***For the purposes of this project, the term "EHR system" will be used to refer to both EHR and EMR systems.***<br>• Different EDE formats, e.g., flat file, HL7<br>• Different EDE types, e.g., outbound, inbound, bi-directional |
| 7.5 | Gender | Patient | Patient's sex. | • IIS may have following values for this item: Female, Male, Unspecified, Other (note that "other" is no longer in the current HL7 guide [2.5]). |
| 1 | IIS Authorized Organization | IIS Authorized Organization | IIS-Authorized Organization (IIS-AO) is a new term introduced to describe any organization that has an agreement with the IIS which allows submittal and/or retrieval of the IIS data. For the purposes of this Data Quality MIROW Guide, retrieval and submittal are limited to vaccination and/or demographic information. | • This term indicates that IIS has granted that organization permission to submit and/or retrieve IIS data.<br>• An IIS-Authorized Organization may include a number of other IIS-Authorized Organizations, such as different clinical offices/sites and physician groups ("parent – subsidiary/child" relationship).<br>• IIS-AOs can play multiple roles. These may be overlapping (i.e., an IIS-AO plays multiple roles at once, e.g., Vaccinator and Submitter) and they may change over time. The roles include:<br>o Vaccinator<br>o Recorder |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| | | | In previous MIROW Guides, an IIS-AO in the role of Vaccinator was called a Provider Organization. Provider Organization is an organization that provides vaccination services or is "accountable" for an entity which provides vaccination services. Provider Organizations include a collection of related Providers (e.g., clinicians – physicians, nurses). | o Submitter<br>o Data Consumer<br>• In the domain model, each clinic (organizational unit, i.e., a unit of a "provider organization") that we care to know about is an IIS-AO. A clinic (organizational unit) that is an IIS-AO can have an organizational "subsidiary/child" that is not an IIS-AO. In this case, the IIS is not aware of that "child" organization, and does not need to take any action with respect to that child organization (arguably, IIS doesn't care about it). All organizations and organizational units that IIS cares about should be set up as IIS-AOs. See also "Organizational and functional hierarchies" section on page 22.<br>• See GR802, chapter 4: "Establish written agreements with Submitters, Recorders, and Vaccinators."<br>• Agreement between IIS and IIS-AO may or may not be a legal contract. |
| 14 | IIS Direct User Interface | IIS Direct User Interface | This is the application for the user to submit data directly to or retrieve data directly from the IIS, i.e., this is usually accessed via the Web. | • User interface, although not entirely error-free, is an opportunity for human evaluation and decision.<br>• Throughout the document this term is referenced in abbreviated forms as IIS Direct UI, Direct UI, or UI |
| 1.3 | IIS-AO Common Name | IIS Authorized Organization | The common name of the IIS-Authorized Organization. | • This would be the name IIS-AO is known by in the community. |
| 1.1 | IIS-AO ID | IIS Authorized Organization | Identifier assigned by IIS to the IIS-Authorized Organization.<br><br>Identifier (ID) that labels and establishes the identity of an IIS-AO. | • Also known as Facility/Site Organization ID. The assumption is that each facility/site is an IIS-AO (see the last bulleted note for IIS-AO).<br>• IIS-AO ID is assigned to any IIS-Authorized Organization that has access to IIS. There are organizations, e.g., schools, which do not administer vaccines, but do have IIS-AO ID.<br>• Distinct IIS-AO ID is assigned to an IIS-Authorized Organization that is a part of another IIS-Authorized Organization (both have unique IIS-AO IDs). A decision to assign the IIS-AO ID to an Organizational Unit is |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| | | | | made collaboratively by IIS and an IIS-Authorized Organization.<br>• Beyond IIS-AO ID, each IIS AO may have multiple inventory-based IDs (i.e., VTrckS IDs) used to track inventory for federal (VFC, 317, STD, etc.) and state-funded vaccines. The IIS-AO ID should be cross-linked to these inventory-related IDs.<br>• See chapter 4, Facility Identification Management, for considerations. |
| 1.2 | IIS-AO Legal Name | IIS Authorized Organization | The legal name of the IIS-Authorized Organization. | • Currently may be implementation limitations on length (e.g., 40 characters in VTrckS) |
| 8 | Immunization History | Immunization History | Immunization History is a collection of one or more Vaccination Events for a patient. Immunization History describes vaccine doses administered, the dates the doses were administered, associated adverse events (if any), and acquired immunity to disease (if any). | • Immunization History is a part of Medical History.<br>• There are two types of Immunization History:<br>  • IIS Consolidated Immunization History<br>  o Represents the IIS's consolidated view of the patient's Immunization History<br>  o Consolidated from multiple IIS-AOs<br>  o Consolidation requires a process which assures that only a single record exists for each Vaccination Event. Refer to MIROW Vaccine-Level Deduplication guide.<br>  • Provider Organization Immunization History<br>  o Represents the patient Immunization History as known to the Provider Organization<br>  o Provider Organization (or other IIS-AO) may update patient's Medical History with Immunization History as gathered from IIS. |
| 12 | Immunization Information System (IIS) | Immunization Information System (IIS) | Immunization information systems (IIS) are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area. | • At the point of clinical care, an IIS can provide consolidated immunization histories for use by a vaccination provider in determining appropriate client vaccinations.<br>• At the population level, an IIS provides aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease". |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| | | | | • See http://www.cdc.gov/vaccines/programs/iis/about.html. |
| 1.10 | Location/ Address | IIS Authorized Organization | The address of the IIS-AO. | • Possible fields to include with address are city, state, county, country, zip code, telephone, and Jurisdiction. |
| 5.1 | Lot Number | Vaccine | The lot number is the number assigned by the manufacturer to a specific batch of Vaccine Product Type. | • Lot Number can be used by IIS to track administered vaccines. |
| 5.2 | Lot Number Expiration Date | Vaccine | 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.<br>• 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. |
| 6.6 | Manufacturer (MVX code) | Vaccine Product Type | Manufacturer is defined as an organization that develops and distributes vaccines. | • CDC assigns an MVX code to specific vaccine manufacturers.<br>• An MVX code can be paired with the CVX code to derive a specific Trade Name.<br>• There may be several manufacturers of a particular vaccine type.<br>• See http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=mvx |
| 7.4 | Name | Patient | Patient's first, middle, and last name:<br>• Name, First<br>• Name, Middle<br>• Name, Last | • Patient's first, middle, and last name are IIS Core Data Set Elements – see http://www.cdc.gov/vaccines/programs/iis/func-stds-appxB.pdf. |
| 6.1 | NDC | Vaccine Product Type | NDC (National Drug Code) is defined as a unique numeric identifier of the Vaccine Product | • Each drug product is assigned a unique three-segment number. This number, known as the NDC, identifies the labeler, product, and trade |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| | | | Type.<br><br>For specific NDC examples, see CDC Vaccine Price List at http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm. | package size.<br>• The first segment, the labeler code, is assigned by the FDA. A labeler is any firm (including re-packers or re-labelers) that manufactures or distributes (under its own name) the vaccine.<br>• The second segment, the product code, identifies a specific strength, dosage form, and formulation of a drug for a particular firm.<br>• The third segment, the package code, identifies package sizes and types ("presentation").<br>• VTrckS uses the 5-4-2 NDC format. Other formats for NDC codes exist and should be accounted for. |
| 1.11 | Organizational Group/Family ID | IIS Authorized Organization | Identifies a conglomerate of IIS-AOs that belong to the same Organization. | • This is one possible mechanism for linking and quickly identifying the organizational family members (e.g., Parent/Subsidiary/Child relationships) of an IIS-AO.<br>• This is separate from the IIS-AO ID.<br>• This attribute is not a part of reporting; rather, it is defined at the IIS and tied to the IIS-AO ID.<br>• See the section "IIS-AO – Organizational Group/Family ID and Reporting Group/Family ID" in chapter 3 for a discussion.<br>• Also see item 1.12. |
| 7 | Patient | Patient | An Individual who is the actual or potential recipient of an administered dose of Vaccine from a Vaccinator (IIS-AO). | • For purposes of Data Quality, Patients are assumed to be deduplicated. Refer to the guidelines on patient-level deduplication. (http://www.immregistries.org/resources/iis-meetings/Fred_Grant_AIRA_De-Duplication_Presentation.pdf).<br>• IIS-AOs may report Patient demographic information without Vaccination Event information. |
| 4.6 | Patient Eligibility Status | Vaccination Event | Patient's eligibility for a funding program | • For IIS-AOs that are participating in the federal or state public immunization program<br>• See MIROW guide [1.2]. |
| 7.1 | Patient ID | Patient | An identifier code associated with the Patient; may be assigned by | • IIS may contain more than one Patient ID for each Patient; IDs assigned by IIS-AOs should be considered the primary ID. |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
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| | | | the IIS or by IIS-AOs. | • **Best practice** is to have an identifier code, ID type (e.g., medical record number, patient's IIS ID), and an assigning authority. |
| 6.7 | Product License Begin Date | Vaccine Product Type | Date when the Trade Name or Product License began. | |
| 6.8 | Product License End Date | Vaccine Product Type | Date when the Trade Name or Product License ended. | |
| 2 | Provider | Provider | A person – medical professional, clinician – who works for a Vaccinator (IIS-AO).<br>. | • Provider and Data Enterer are entities ("actors") with distinct responsibilities: Provider is responsible for performing Vaccination Events and Data Enterer is responsible for entering information about the Vaccination Event into the submission chain. These are distinct functional sets (or "roles") that real people can play.<br>• Examples of roles that a Provider entity (a person) can play: Vaccine Administrator (administered vaccine, e.g., nurse) and Vaccine Prescriber (ordered/prescribed vaccine to be administered, e.g., clinician; should have appropriate credentials, e.g., MD; a.k.a. Ordering Clinician)<br>o These two roles are described in the IIS Functional Standards, 2013-2017 (http://www.cdc.gov/vaccines/programs/iis/func-stds.html) with the following IIS Core Data Elements: Vaccine Administering Provider Name and Vaccine Ordering Provider Name.<br>• The same person can play roles of Provider and Data Enterer (item 3). |
| 2.1 | Provider Identifier | Provider | Identifier (ID) that labels and establishes the identity of a Provider (a person).<br><br>This is a Provider's (person's) identification for IIS purposes. | • Provider Identifier (ID) should include:<br>o **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>o **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>• The National Provider Identifier (NPI) registry at https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do may be considered for use by an IIS for the purpose of establishing |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
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| | | | | Provider Identifiers, providing a consistent approach across the country. Provider Identifier is generally used only internally within the IIS. Additionally, an IIS may not track every Provider in its jurisdiction.<br>• See also items 10.9 and 10.10: Vaccine Administrator – Provider Identifier and Vaccine Prescriber – Provider Identifier. |
| 5.3 | Public/Private Inventory Indicator | Vaccine | Indicates if a vaccine dose belongs to a public or private stock. | • When a Public/Private inventory indicator for a dose administered to a Patient is "private" and Patient eligibility status is "public" (or vice versa), the borrowing transaction is created.<br>• 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.<br>• See MIROW Inventory Management guide [1.1] for details. |
| 1.9 | Public/Private Sector Indicator | IIS Authorized Organization | Describes sector/funding source for the IIS-AO. | • This is not the same as the funding source for vaccines or Public/Private Inventory Indicator (see item 5.3). |
| 10.7 | Recorder IIS-AO ID | Vaccination Event Submission | IIS ID for the IIS-AO that entered the Vaccination Event information into the IIS-AO Data Exchange system or the IIS UI. | • Vaccinator and Recorder are always the same for the administered vaccination. See section "IIS-AO Roles: Vaccinator, Recorder, Submitter" for this and other scenarios. |
| 16.4 | Recorder IIS-AO ID | Demographic-only Submission | IIS ID for the IIS-AO that entered the Demographic-only (Patient) information into the IIS-AO Data Exchange system or the IIS UI. | • See section "IIS-AO Roles: Vaccinator, Recorder, Submitter." |
| 1.5 | Recorder Indicator | IIS Authorized Organization | Indicates if an IIS-AO enters the immunization or demographic data into the IIS-AO EHR system or the UI. | • Recorder can be on behalf of itself (e.g., for administered vaccinations) or on behalf of other organizations (e.g., for historical vaccinations). |
| 1.12 | Reporting Group/Family | IIS Authorized | Identifies a conglomerate of IIS-AOs that are sharing a reporting | • This is one possible mechanism for linking and quickly identifying organizations that share a reporting service. |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
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| | ID | Organization | service for Vaccination Event submissions and/or Demographic-only submissions. | • This is separate from the IIS-AO ID.<br>• This is a way for the IIS to designate which IIS-AOs are submitting data via other IIS-AOs. So, IIS-AO "A" submits on behalf of IIS-AO "1" and IIS-AO "2." This ID would be separate from "A," "1," or "2," but would designate the relationship between these IIS-AOs.<br>• See the section "IIS-AO – Organizational Group/Family ID and Reporting Group/Family ID" in chapter 3.<br>• Also see item 1.11. |
| 7.7 | Responsible Party | Patient | An individual who is responsible for a patient. | • For example, a parent, a guardian, self<br>• A.k.a. Responsible Person |
| 4.4 | Route | Vaccination Event | The method of administration (e.g., intramuscular, intranasal, oral, etc.). | • A.k.a. Vaccine Route of Administration |
| 4.3 | Site | Vaccination Event | Anatomical site where the immunization was administered. | • A.k.a. Vaccine Site of Administration |
| 10.1 | Status | Vaccination Event Submission | Represents the status of a Vaccination Event Submission in the process of being accepted within the IIS. | Types of Status:<br>• Accepted: An accepted Vaccination Event Submission means that the data conformed to the IIS data submission guidelines and were or will be uploaded into the IIS.<br>• Rejected: A rejected Vaccination Event Submission means that the vaccine event data did not conform to the IIS data submission guidelines and were not or would not be uploaded into the IIS.<br>• Accepted with Errors: An accepted with errors Vaccination Event Submission means that the IIS identified errors in the Vaccination Event Submission but these errors were not severe enough to reject the Submission. Data were uploaded into the IIS. |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
|---|---|---|---|---|
| 16.1 | Status | Demographic-only Submission | Represents the status of the Demographic-only Submission in the process of being accepted within the system. | Types of Status:<br>• Accepted: An accepted Demographic-only Submission means that the data conformed to the data guidelines.<br>• Rejected: A rejected Demographic-only Submission means that the demographic data did not conform to the IIS data submission guidelines and were not or would not be uploaded into the IIS.<br>• Accepted with Errors: An accepted with errors Demographic-only Submission means that data did not conform to the data submission guidelines of the IIS but data were loaded into the IIS; errors would be followed up and resolved at a later date. |
| 10.2 | Status Date | Vaccination Event Submission | The date that the Vaccination Event Submission status was updated in the IIS. It either represents the date the data were accepted, rejected, or accepted with errors. | • This date may not be visible to the user from the Direct User Interface (UI) and therefore, may not be available.<br>• This date should not be confused with the Vaccination Event Date.<br>• This is not necessarily the date the Submission was sent.<br>• This is not necessarily the date the Submission was received. |
| 16.2 | Status Date | Demographic-only Submission | The date that the Submission status was updated. It either represents the date the data were accepted, rejected, or accepted with errors. | • This date may not be visible to the user from the Direct User Interface (UI) and therefore, may not be available.<br>• This is not necessarily the date the Submission was sent.<br>• This is not necessarily the date the Submission was received. |
| 11.1 | Submission Date | Combined Submission | Submission Date is the date when the data were received (but not necessarily loaded) by the IIS. | • IIS may delay processing inbound data for reasons including technical problems or system overload. |
| 1.6 | Submitter Indicator | IIS Authorized Organization | Indicates if an IIS-AO submits Vaccination Event Submissions and/or Demographic-only submissions to the IIS or to intermediary Submitter(s) with IIS as a final destination. | • Submittal is generally referred to as “reporting.”<br>• Submission can be on behalf of the IIS-AO itself (in the case of a Vaccinator or Recorder) or on behalf of other organizations. |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
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| | | | | |
| 10.8 | Submitter(s) IIS-AO ID | Vaccination Event Submission | IIS ID for the IIS-AO that submitted information about the Vaccination Event to the IIS or to intermediary Submitter(s) with IIS as a final destination. | • There can be one or more Submitters depending on the submittal chain from the originating Vaccinator or Recorder through Submitters until reaching the IIS.<br>• Example of a reporting chain with multiple submitters: Providers' data go to an EHR vendor hub; the EHR vendor submits to an HIE; HIE submits to the IIS.<br>• See chapter 4, Facility Identification Management, for more details. |
| 16.5 | Submitter(s) IIS-AO ID | Demographic -only Submission | IIS ID for the IIS-AO that submitted information about the Patient to the IIS or to intermediary Submitter(s) with IIS as a final destination. | • There can be one or more Submitters depending on the submittal chain from the originating Recorder through Submitters until reaching the IIS.<br>• Example of a reporting chain with multiple submitters: Providers' data go to an EHR vendor hub; the EHR vendor submits to an HIE; HIE submits to the IIS.<br>• See chapter 4, Facility Identification Management, for more details. |
| 6.5 | Trade Name | Vaccine Product Type | 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<br>• If Trade Name is not actively collected by a particular IIS, it can be derived from other variables (e.g., NDC or Vaccine Type [CVX code] and Manufacturer Name [MVX code]). |
| 1.8 | Type/Sub-Type | IIS Authorized Organization | Describes a combination of patient population and services provided by the IIS-AO. | • Knowing the type of practice can help determine whether immunizations being reported are typical/expected. In the 2008 MIROW data quality guide [1.4], business rule BR113 relates to this.<br>• May be sufficient to assign only the type (e.g., Specialty Provider); in these cases, the sub-type is not needed.<br>• Note that best practices for defining type /sub-type have not been developed at this time and, until determined, it is left up to the IIS to define types/sub-types for their IIS-AOs.<br>• Example: |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
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| | | | | o Type = Specialty Provider, Sub-type = OB/GYN<br>o Type = Hospital, Sub-type= ER<br>• There could be multiple layers to one IIS-AO (e.g., family practice may be OB/GYN also). |
| 16.6 | UI or EDE User – Data Enterer Identifier | Demographic -only Submission | Identifier (ID) that labels and establishes the identity of a Data Enterer (a person) that has entered the Demographic-only (Patient) information either via the direct user interface (UI) or via a system (e.g., EHR) using Electronic Data Exchange (EDE) to submit data to IIS. | UI or EDE User –Identifier (ID) should include:<br>• **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>• **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>See also items 3 and 3.1: Data Enterer and Data Enterer Identifier. |
| 10.11 | UI or EDE User –Data Enterer Identifier | Vaccination Event Submission | Identifier (ID) that labels and establishes the identity of a Data Enterer (a person) that has entered the Vaccination Event's information either via the direct user interface (UI) or via a system (e.g., EHR) using Electronic Data Exchange (EDE) to submit data to IIS. | UI User or EDE User –Identifier (ID) should include:<br>• **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>• **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>See also items 3 and 3.1: Data Enterer and Data Enterer Identifier. |
| 15 | Vaccination Encounter | Vaccination Encounter | Represents one Patient office visit during which Vaccination Events occurred. | • During the Vaccination Encounter (office visit) several Vaccination Events can be performed (in some cases - no Vaccination Events, e.g., a Patient's refusal for vaccinations) |
| 4 | Vaccination Event | Vaccination Event | Vaccination Event is a medical occurrence of administering one Vaccine to a Patient. | • Several Vaccination Events can happen during one office visit (see Vaccination Encounter – item 15). |
| 10 | Vaccination Event | Vaccination Event | Vaccination Event Submission is the submittal of all relevant | • The same Vaccination Event can be submitted more than once by a Provider Organization and other parties. |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
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| | Submission | Submission | information that is known regarding a single Vaccination Event to the IIS as a final destination. | • IIS should only record a unique Vaccination Event once. Refer to AIRA-MIROW guideline Vaccination Level Deduplication in Immunization Information Systems [1.5]. |
| 10.3 | Vaccination Event Submission Error(s) | Vaccination Event Submission | Indicates the type of error(s) that occurred in the receipt and attempted acceptance of the Vaccination Event Submission.<br><br>Include any errors (structural issues, content issues) that occurred in the receipt and attempted acceptance of the Vaccination Event Submission, as well as reason for errors. | Types of Errors:<br>• Connection Error. We assume that as the message reaches the IIS, that connectivity has been established already. Connectivity is out of scope for this data quality assurance topic. If we can't see the data we can't comment on it/send error message.<br>• Unreadable/invalid format (header, not HL7 or expected format)<br>• Something inside the message is wrong (can be errors that are informational but allow the data in, errors that cause the data to be rejected by the IIS).<br>• IIS should return error message to Submitter; Submitter should have some mechanism for relaying error message to Recorder IIS-AO so that error can be resolved as needed. |
| 9 | Vaccination Forecast | Vaccination Forecast | Vaccination Forecast is the result of the process of applying rules to determine dates for the next vaccine dose(s) to be administered to a Patient.<br><br>Vaccination Forecast may also include a reason why the next dose in a series is or is not recommended and recommended Trade Name for the next vaccine in a series. | • Vaccination Forecast for an individual patient is based on that patient's Immunization History and other factors, such as age, gender, contraindications.<br>• Vaccination forecast for all patients in IIS is guided by recommendations of the Advisory Committee on Immunization Practices (ACIP).<br>• Forecast may also be dependent on additional state-specific guidelines.<br>• Attributes may include: Antigen/Series/Dose Number, Earliest Date, Recommended Date, Latest Date, Past Due Date, Comments/Disclaimers.<br>• Refer to http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html for details. |
| 10.6 | Vaccinator IIS-AO ID | Vaccination Event Submission | IIS ID for the IIS-AO that conducted the Vaccination Event. | • This would be the same as the Submitter in the case of a self-submitting IIS-AO.<br>• It is helpful to corroborate an IIS-AO ID with another data item, such as |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
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| | | | | the IIS-AO Common Name or Legal Name. |
| 1.4 | Vaccinator Indicator | IIS Authorized Organization | Indicates if an IIS-AO provides vaccination services.<br><br>In previous MIROW Guides, an IIS-AO acting in the role of Vaccinator was called a Provider Organization. Provider Organization is an organization that provides vaccination services or is "accountable" for an entity which provides vaccination services. Provider Organizations include a collection of related Providers (e.g., clinicians – physicians, nurses). | Vaccinator (IIS-AO) may:<br>• Submit vaccination (and/or demographic) information to IIS for itself and/or other IIS-AOs<br>or<br>• Delegate submitting its vaccination (and/or demographic) information to other IIS-AOs |
| 5 | Vaccine | 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<br>• Vaccine is designated by use of both the Vaccine Product Type and the Lot Number. |
| 10.9 | Vaccine Administrator – Provider Identifier | Vaccination Event Submission | Identifier (ID) that labels and establishes the identity of a Provider (a person) that has performed the Vaccination Event. | Vaccine Administrator – Provider Identifier (ID) should include:<br>• **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>• **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>• See also items 2 and 2.1: Provider and Provider Identifier.<br>• The Vaccine Administrator role is described in the IIS Functional Standards, 2013-2017 (http://www.cdc.gov/vaccines/programs/iis/func-stds.html) with the following IIS Core Data Element: Vaccine |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
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| | | | | Administering Provider Name. |
| 10.10 | Vaccine Prescriber – Provider Identifier | Vaccination Event Submission | Identifier (ID) that labels and establishes the identity of a Provider (a person) that has prescribed/ordered the vaccination. | Vaccine Prescriber – Provider Identifier (ID) should include:<br>• **Best practice**: Identifier code, Identifier code assigning authority, and person's name<br>• **Good practice**: Both Identifier code and Identifier code assigning authority, or Identifier code and person's name, or just person's name<br>See also items 2 and 2.1: Provider and Provider Identifier.<br>• The Vaccine Prescriber role is described in the IIS Functional Standards, 2013-2017 (http://www.cdc.gov/vaccines/programs/iis/func-stds.html) with the following IIS Core Data Element: Vaccine Ordering Provider Name. |
| 6 | Vaccine Product Type | Vaccine Product Type | Vaccine Product Type is a category of the vaccine product that is ordered, shipped, administered, etc.<br>• An IIS-AO (a "provider organization") indicates the Vaccine Product Type when placing vaccine orders.<br>• An IIS-AO (a "provider organization") receives Vaccine (item 5), which contains specific batches or lots of this Vaccine Product Type. | • Vaccine Product Type, for inventory tracking/ management purposes, is characterized by the NDC code (see item 6.1).<br>• Vaccine Product Type, for immunization tracking purposes, is characterized by the Vaccine Type (or CVX code, or CPT code), Manufacturer (MVX code), and Trade Name (see 6.2 – 6.6).<br>• An instance of the Vaccine Product Type – a Vaccine (see item 5) – is characterized by the Lot Number and Lot Number Expiration Date.<br>• Examples of Vaccine Product Types that belong to the same Vaccine Type (item 6.2), but have different NDC codes (source – "IIS: HL7 Standard Code Set Mapping NDC to CVX and MVX" at http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc)<br>Vaccine Product Type 1<br>o 6.1 NDC = 58160-0820-11<br>o 6.2 Vaccine Type = HepB<br>o 6.3 CVX code = 08<br>o 6.4 CPT code = 90744<br>o 6.5 Trade Name = ENGERIX B-PEDS<br>o 6.6 Manufacturer/MVX code = SKB |

| ID | Name | Entity On Fig. 2 | Description | Remarks |
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| | | | | Vaccine Product Type 2<br>o 6.1 NDC = 00006-4981-00<br>o 6.2 Vaccine Type = HepB<br>o 6.3 CVX code = 08<br>o 6.4 CPT code = 90744<br>o 6.5 Trade Name = RECOMBIVAX-PEDS<br>o 6.6 Manufacturer/MVX code = MSD |
| 6.2 | Vaccine Type | Vaccine Product Type | The Vaccine Type is defined as a category of Vaccine.<br><br>A single Vaccine Type may be associated with many Vaccine Product Types (i.e., different manufacturers, different packaging).<br><br>Vaccine (item 5) is an instance of Vaccine Product Type. | • The Vaccine Type may indicate a generic or specific type of vaccine (e.g., pneumococcal or PCV13 or PPSV23).<br>• The Vaccine Type can include single types of Vaccines as well as combination vaccines, e.g., IPV or IPV-DTaP-HepB.<br>• Examples of Vaccine Type names: HIB-HBOC, HIB-HepB, HepB-Peds. |

## Appendix B: "Parking lot"

This is a "parking lot" of data quality issues that are outside the scope of this topic, but recommended by the group to be explored in some other initiatives.

- EHR system might send a shot when the shot was ordered, not when it was administered. This often results in duplicate immunizations being sent to the IIS. Vaccine level de-duplication rules should catch and flag these situations.
- We at the IIS don't have a way to know if the EHR is handling add/delete/update transactions properly, and conversely, there are no best practices for IIS on knowing how to handle all of the various scenarios. Some states let shots be deleted if the EHR sends the exact same HL7 message but with a D code of delete instead of A for add. However, use of the ORC segments, with the ability to track identifiers for each shot, holds great potential for IIS to know if an incoming immunization is new, an update, or a delete of an existing one. Few, if any, IIS are using it in that manner today.
- Ownership of vaccination records, e.g., who is authorized to change and what pieces of data in the immunization record. That can be especially challenging in cases of multi-level ("parent – subsidiary/child" hierarchy) health care organizations.

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