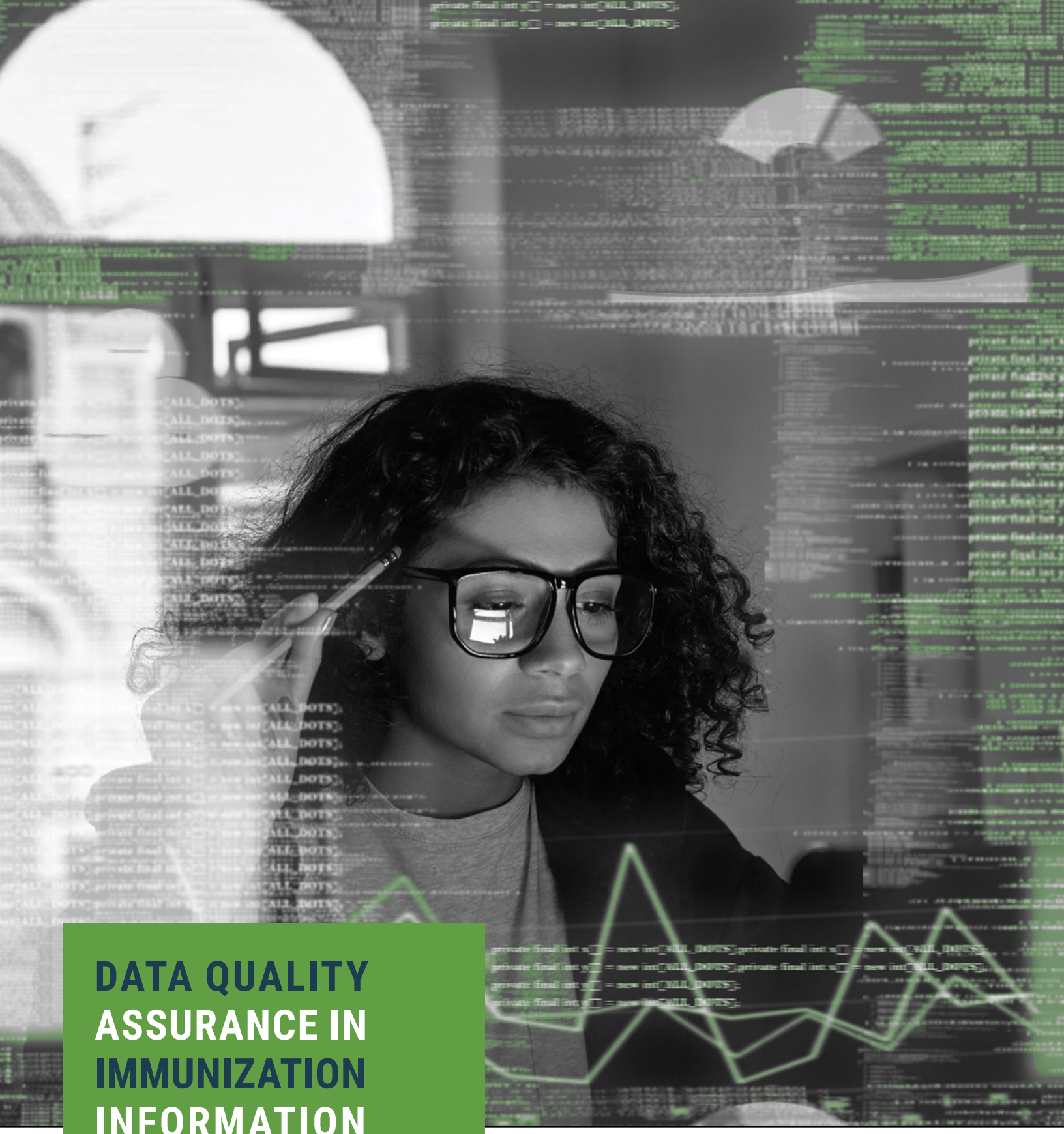

DATA QUALITY ASSURANCE IN IMMUNIZATION INFORMATION SYSTEMS

RECOMMENDATIONS OF THE AIRA MODELING OF IMMUNIZATION REGISTRY OPERATIONS WORKGROUP (MIROW)

AUGUST 2022

AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

IIS data quality is the degree to which data sent to or stored in an IIS meet current standards, support clinical decision-making needs, and can be used to answer key public health questions with high confidence. It also relates to how accurately the data within the IIS reflect vaccination events.

EXECUTIVE SUMMARY

Immunization information systems (IIS)[1] are the main source of comprehensive and consolidated immunization records across the nation.

In addition, IIS collectively offer advanced features that include the management of vaccine inventory, immunization forecasting, automated patient reminder/recall, and population-level vaccine coverage assessments. They also expedite response during an outbreak or pandemic event. IIS information is useful only if users and partners have confidence in the quality of immunization data; therefore, data quality should be a key focus of IIS programs.

Data quality is the degree to which data meet requirements.[2] IIS data quality is the degree to which data sent to or stored in an IIS meet current standards, support clinical decision-making needs, and can be used to answer key public health questions with high confidence. It also relates to how accurately the data within the IIS reflect vaccination events. Data quality assurance is the planning, implementation, and control activities that apply quality management techniques to data in order to assure it is fit for consumption and meets the needs of data consumers.[3]

This guide highlights key areas of focus for improving data quality and ways to implement recommended approaches. By integrating data quality practices throughout all data management processes, IIS will continue to be a robust source of high-quality immunization data.

IMMUNIZATION INFORMATION SYSTEMS

Immunization information systems (IIS) are confidential, population-based, computerized databases for recording information, including immunization history and vaccine doses given by participating health care providers.

[1] The acronym "IIS" can be both singular and plural.
[2] Adapted from the data quality definition in How to Select the Right Dimensions of Data Quality (http://www.dama-nl.org/wp-content/uploads/2020/11/How-to-Select-the-Right-Dimensions-of-Data-Quality-v1.1-d.d.-14-Nov-2020.pdf) by DAMA Netherlands.
[3] Adapted from the data quality definition in the Data Management Body of Knowledge (https://www.dama.org/cpages/body-of-knowledge)

KEY RECOMMENDATIONS

- Assess data quality in relation to the seven data quality characteristics outlined in the Immunization Information Systems (IIS) Data Quality Blueprint[4] developed by the Centers for Disease Control and Prevention.
- Use multiple approaches to ensure and support high data quality, including using programmatic and technical resources.
- Adoption of business rules should be uniform in all IIS programs; however, the selection of violation actions for business rules should be flexible and jurisdiction specific.
- Consider data quality throughout the process of receiving and managing data—from onboarding provider organizations to use data exchange, to receiving incoming data submissions, to evaluating data at rest.
- Prioritize the quality of data elements that have a high interest for public health and safety, technical processes, and/or vaccine accountability.
- Educate provider organizations on specific methods and activities that support submitting high-quality data to the IIS, regularly monitoring data quality, and resolving data quality issues that occur.

IMPLEMENTATION

The recommendations in this guide aim to balance ideal practices with pragmatic considerations of what is realistic to implement. Specific implementation may vary based on IIS resources, goals, needs, and unique jurisdictional requirements and concerns. The recommendations presented here may be adopted incrementally and are not meant to be exhaustive. Finally, the recommendations are not static—they will undoubtedly evolve over time to adapt to new or changing business requirements and technology.

[4] https://www.cdc.gov/vaccines/programs/iis/about.html

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APPENDICES

REVISION HISTORY

This guide updates and replaces the best practices from three previous Modeling of Immunization Registry Operations Workgroup (MIROW) documents:

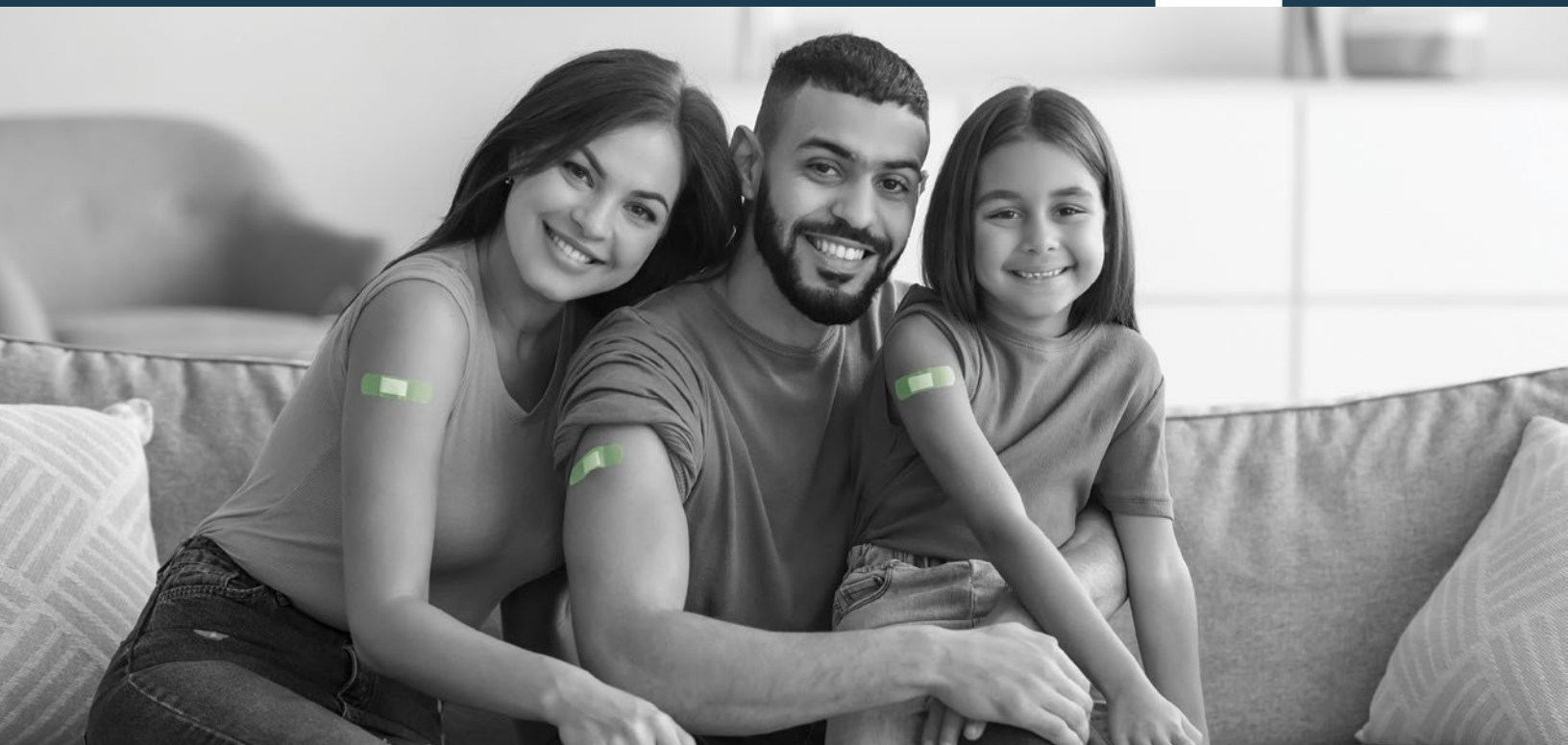
- *Data Quality Assurance in Immunization Information Systems: Incoming Data*
- *Data Quality Assurance in Immunization Information Systems: Selected Aspects*
- *Lot Number Validation Best Practices Micro-Guide*

VERSION	DATE	TITLE	CHANGES/UPDATES	LOCATION
1.1	Feb 2008	*Data Quality Assurance in Immunization Information Systems: Incoming Data*	Initial version of document	AIRA Archives
1.2	May 2013	*Data Quality Assurance in Immunization Information Systems: Selected Aspects*	Initial version of document	AIRA Archives
1.3	May 2014	*Micro-Guide: Lot Number Validation Best Practices*	Initial version of document	AIRA Archives
2.0	August 2022	*Data Quality Assurance in Immunization Information Systems*	Merged guides and updated content	This Guide

Please email info@immregistries.org to request the three archived documents.

1

INTRODUCTION



A key strength of immunization information systems (IIS) is the quantity of immunization and patient data collected. The goal of an IIS is to reflect the complete immunization history of all patients in a jurisdiction.

1 INTRODUCTION

BACKGROUND

A key strength of immunization information systems (IIS) is the quantity of immunization and patient data collected. The goal of an IIS is to reflect the complete immunization history of all patients in a jurisdiction.

This immunization history may be a consolidation of records from several provider organizations over many years and can support a patient's journey throughout a lifetime of care. To meet this goal, IIS programs must develop and implement a wide range of processes and tools to support data quality.

The terms data quality, IIS data quality, and data quality assurance are defined below.

- **Data quality** is the degree to which data meet requirements.[5]
- **IIS data quality** is the degree to which data sent to or stored in an IIS meet current standards, supports clinical decision-making needs, and can be used to answer key public health questions with high confidence. IIS data should reflect the actual vaccination events that occur.
- **Data quality assurance** is the planning, implementation, and control activities that apply quality management techniques to data in order to assure it is fit for consumption and meets the needs of data consumers.[6]

Data quality issues in IIS data can arise from a variety of processes and sources. These range from data entry errors into the electronic health record (EHR)[7] to problems stemming from the electronic interface between the EHR and the IIS. In some instances, problems within the IIS may also cause data quality issues (e.g., incorrect coding of CVX codes). In addition, the collection and use of data elements needs to be further standardized across IIS programs to support the consolidation of immunization data for a patient via interjurisdictional data exchange and to ensure consistent data and practices for large multijurisdictional provider organizations.

[5] Adapted from the data quality definition in How to Select the Right Dimensions of Data Quality (http://www.dama-nl.org/wp-content/uploads/2020/11/How-to-Select-the-Right-Dimensions-of-Data-Quality-v1.1-d.d.-14-Nov-2020.pdf) by DAMA Netherlands.
[6] Adapted from the data quality definition in the Data Management Body of Knowledge (https://www.dama.org/cpages/body-of-knowledge)
[7] Also referred to as electronic medical records (EMRs).

Fortunately, IIS programs have made impressive steps forward in improving data quality over the past decade. Because of this improvement, IIS can use high-quality data to support medical and public health activities which in turn ensure people get the right vaccine at the right time and are protected from vaccine-preventable diseases.

In the *American Immunization Registry Association (AIRA) 2019 Education Survey Summary Report*,[8] IIS staff stated that data quality was one of the top strengths, challenges, and priorities for IIS. Data quality was ranked as the top reported education/assistance need, with 90% of respondents rating it as extremely, very, or moderately needed. The Centers for Disease Control and Prevention (CDC) has also made data quality a top priority for IIS and has developed the Immunization Information Systems (IIS) Data Quality Blueprint[9] as a path to improve data quality.

This guide intends to provide best practice recommendations that support and sustain high-quality data in IIS. In addition, this guide also updates and replaces the best practices from three previous Modeling of Immunization Registry Operations Workgroup (MIROW) documents:

- *Data Quality Assurance in Immunization Information Systems: Incoming Data*
- *Data Quality Assurance in Immunization Information Systems: Selected Aspects*
- *Lot Number Validation Best Practices Micro-Guide*[10]

AIRA has many additional guides that address data quality. Chapter 2: Fundamental Concepts contains information about those guides and how this guide relates to them.

[8] https://repository.immregistries.org/resource/aira-2019-education-survey-summary-report/
[9] https://www.cdc.gov/vaccines/programs/iis/about.html
[10] Please email info@immregistries.org to receive copies the three archived MIROW documents.

HIGHLIGHTS OF THIS GUIDE

- Overview of the key concepts related to data quality (Chapter 2)
- Data quality considerations during the provider organization onboarding process (Chapter 3) and for managing incoming data submissions (Chapter 4)
- Best practices for monitoring and evaluating data at rest (Chapter 5)
- Key concepts related to provider organization management (Chapter 6)
- Principles (P) and business rules (BR) to guide data quality assurance activities (Chapter 7 and Chapter 8)
- Discussion of implementation considerations (Chapter 9)
- Tools, examples, and more in-depth explanations of topics to support the implementation of data quality assurance practices in the appendices

TARGET AUDIENCE

This guide is designed to be used by programmatic, technical, and operational personnel involved in assuring data quality in IIS. The audience includes the following IIS and immunization program staff:

- Onboarding staff
- Technical staff
- Epidemiologists
- Data analyst staff who troubleshoot data quality issues
- Program, education, and training staff that support provider organizations with data quality and data use issues

This guide may also be helpful to other public health programs interested in the quality and usage of IIS data. While this guide may provide helpful insight to the management of data within IIS, it is not intended to be prescriptive for data management within other systems such as EHRs.

INTENDED USE

This guide contains a set of recommended operational best practices, including principles and business rules, that are intended as a basis for standardizing IIS applications and operations. The MIROW best practice recommendations in this guide are independent from specific IIS implementations and technology solutions (i.e., the recommendations can be used regardless of the platform used by an IIS). The specific implementation process for these best practice recommendations will vary based on the IIS program. Resource constraints may also lead to partial or incremental adoption of these guidelines. The IIS program can also use this guide for staff training, operational documentation, communication purposes, and providing guidance for EHR vendors/implementers.

SCOPE

The scope for the MIROW data quality topic includes recommendations for IIS to ensure high-quality data from IIS-authorized organizations (IIS-AOs).[11] The focus is on development of a comprehensive overview of consensus-based best practice recommendations for an IIS to address data quality issues related to onboarding, incoming data, and data at rest analysis. The guide includes recommendations for:

1. Documentation of onboarding and incoming data submission processes with a focus on activities related to data quality
2. Data validation rules for incoming data
3. Aspects of provider organization management including:
   - Verification of an IIS-AO
   - Rules for the roles of recording organization, submitting organization, and vaccinating organization
   - Rules for deauthorization
4. Monitoring quality assessments of incoming submissions and data at rest that lead to sustainable practices that support data quality
5. Best practices for improving the data quality characteristics of accuracy, availability, completeness, consistency, timeliness, uniqueness, and validity[12] and following CDC's Immunization Information Systems (IIS) Data Quality Blueprint[13]

[11] An IIS-AO is an organization that has an agreement with an IIS that allows for the submittal and/or retrieval of IIS information.
[12] The Immunization Information Systems (IIS) Data Quality Blueprint lists the characteristics starting with "available," since data should be available to answer public health questions. The order of characteristics in the Blueprint following "available" is complete, timely, valid, accurate, consistent, and unique.
[13] https://www.cdc.gov/vaccines/programs/iis/about.html

IIS data-processing functionality and deduplication/consolidation algorithms play crucial roles in helping to maintain and ensure quality data in an IIS. Although discussion of deduplication and consolidation is out of the scope of this guide, the data monitoring and evaluation practices described can help IIS programs identify where functionality and algorithm improvements may be advantageous. IIS programs can refer to several resources for guidance on deduplication and consolidation in an IIS, including *Immunization Information Systems Patient-Level De-Duplication Best Practices*,[14] *Vaccination Level Deduplication in Immunization Information Systems*,[15] and *Consolidating Demographic Records and Vaccination Event Records.*[16]

Appendix A includes a more detailed description of the scope.

ABOUT MIROW

AIRA, in partnership with CDC's National Center for Immunization and Respiratory Diseases, formed MIROW to develop best practice guidance for IIS. MIROW has developed several guides for IIS functional areas since 2005. The best practice recommendations in MIROW guides are formulated by bringing together subject matter experts, using consensus-building facilitation techniques, and developing business analysis models. For more information about MIROW and the development process for MIROW guides, see the *MIROW and the Best Practice Development Process*[17] document. Subject matter experts who contributed to this document represent a variety of IIS programs and partner organizations. All contributors are listed in Appendix M.

NOT CLEAR ON THE MEANING OF A WORD?

Discover the meaning of acronyms and abbreviations as well as the definitions of key terms in Appendix D.

[14] https://www.cdc.gov/vaccines/programs/iis/interop-proj/downloads/de-duplication.pdf
[15] https://repository.immregistries.org/resource/vaccination-level-deduplication-in-immunization-information-systems-1/
[16] https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/
[17] https://repository.immregistries.org/resource/mirow-and-the-best-practice-development-process/

2

FUNDAMENTAL CONCEPTS

IIS provide tremendous value to public health by consolidating immunization information from multiple sources. The quality of IIS records is a decisive factor for improving the health of patients, the operation of health care clinics, the response to outbreaks and pandemics, and public health decision-making at local and national levels.

2 FUNDAMENTAL CONCEPTS

IMPORTANCE OF DATA QUALITY IN IIS AND GOALS OF THIS GUIDE

IIS provide tremendous value to public health by consolidating immunization information from multiple sources. The quality of IIS records is a decisive factor for improving the health of patients, the operation of health care clinics, the response to outbreaks and pandemics, and public health decision-making at local and national levels.

In particular, the broader use of electronic data exchange has resulted in better access to consolidated patient immunization information in the IIS, which, in turn, ensures that the data being received and used are reliable.

All MIROW guides use a business analysis framework to create best practice recommendations in standardized processes, principles, and business rules for implementation across IIS. These best practices can be very helpful in creating or updating IIS functionality and processes. To create this guide, a group of data quality subject matter experts used the business analysis framework to structure the updated recommendations.[18] The goal of this guide is to update, consolidate, and replace three existing MIROW guides related to data quality:

- *Data Quality Assurance in Immunization Information Systems: Incoming Data*
- *Data Quality Assurance in Immunization Information Systems: Selected Aspects*[19]
- *Lot Number Validation Best Practices Micro-Guide*[20]

There have been many advances in how IIS and IIS programs manage data quality assurance since these guides were published. By updating the MIROW guides, the workgroup hopes to capture the knowledge and experience gained since that time.

[18] For more information about business analysis, see MIROW and the Best Practice Development Process (https://repository.immregistries.org/resource/mirow-and-the-best-practice-development-process/).

[19] Specific topics related to provider organization management within *Data Quality Assurance in Immunization Information Systems: Selected Aspects* were not updated for this guide. While many topics related to provider organization management are included in this guide, certain business rules have not been updated. This guide does not include recommendations on how to manage and maintain complex organizational structures. Due to the sizable scope and importance of provider organization management, it is recommended that a separate guide be created that further delves into this issue.

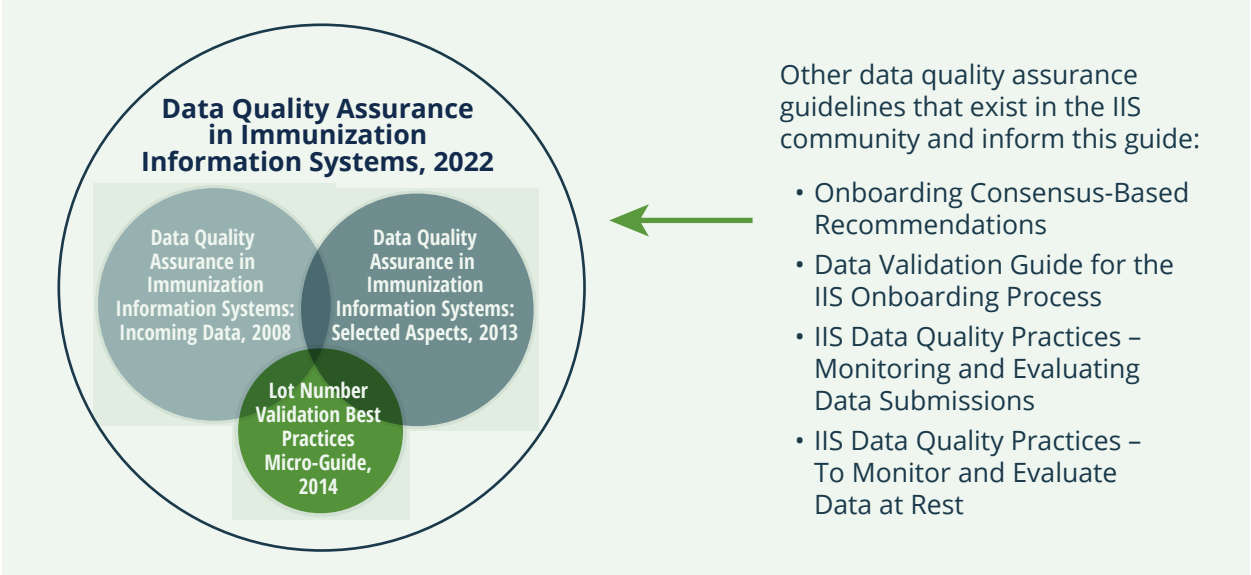
[20] Please email info@immregistries.org to receive copies the three archived MIROW documents.

Over the past decade, many other non-MIROW AIRA data quality guides have been developed which provide useful detailed information on specific data quality issues. **This guide does not replace those guides but, rather, synthesizes materials drawn from them into a comprehensive resource for the IIS community.** Previous guides include:

- *Onboarding Consensus-Based Recommendations*[21]
- *Data Validation Guide for the IIS Onboarding Process*[22]
- *IIS Data Quality Practices – Monitoring and Evaluating Data Submissions*[23]
- *IIS Data Quality Practices – To Monitor and Evaluate Data at Rest*[24]

Appendix B: Summarized AIRA Data Quality Resources includes descriptions of these guides.

Figure 1 | *Relationship between data quality guides*



An additional goal of this guide is to provide a comprehensive road map to IIS data quality assurance. There are currently guides on many individual aspects of data quality, but it can be hard to understand the overall landscape. While this guide will not explore the breadth of data quality issues in detail, it will provide references to resources where more information can be found.

[21] https://repository.immregistries.org/resource/onboarding-consensus-based-recommendations/
[22] https://repository.immregistries.org/resource/data-validation-guide-for-the-iis-onboarding-process/
[23] https://repository.immregistries.org/resource/iis-data-quality-practices-monitoring-and-evaluating-data-submissions/
[24] https://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/

DATA QUALITY CHARACTERISTICS

The best practice recommendations made in this guide support the Immunization Information Systems (IIS) Data Quality Blueprint[25] developed by CDC. The blueprint identifies seven characteristics of data quality that are important for IIS. These are recognized terms used by data management professionals in the IIS community to describe a feature of data quality that can be measured or assessed against defined standards to determine the quality of data. The Immunization Information Systems (IIS) Data Quality Blueprint[26] identifies four main characteristics (available, complete, timely, valid) and three enabling characteristics (accurate, consistent, unique).

MAIN CHARACTERISTICS

- **Availability:** IIS data can be readily used by authorized users to inform IIS and immunization program activities.
- **Completeness:** The IIS contains all (historic and new) vaccination and demographic records for persons residing in the jurisdiction, and all vaccination and demographic records contain complete data fields.
- **Timeliness:** Patient records are established, and vaccination events are recorded in the IIS within specified time frames.
- **Validity:** Vaccination and demographic records in the IIS conform with generally accepted standards (e.g., Advisory Committee on Immunization Practices recommendations, United States Postal Service standards).

[25, 26] https://www.cdc.gov/vaccines/programs/iis/about.html

ENABLING CHARACTERISTICS

- **Accuracy:** The IIS correctly reflects the demographic information of patients and data related to all aspects of their vaccination events.
- **Consistency:** The IIS receives, stores, and processes data in accordance with established standards.
- **Uniqueness:** Each patient and their corresponding vaccinations are recorded only once in the IIS.

ACCURACY **CONSISTENCY** **UNIQUENESS**

This guide will address the four main characteristics in detail. The three enabling characteristics are not covered in similar detail for the following reasons:

- **Accuracy:** Confirming accuracy requires reviewing the source data (i.e., patient records kept by the IIS-AO) to confirm that the IIS record directly reflects reality. This type of in-person review is time and staff intensive so not performed often. Patient record reviews, which can check for accuracy, are addressed in Chapter 3: Onboarding Provider Organizations.
- **Consistency:** Adherence to established standards for IIS is extremely important; however, several of the methods of meeting the goal of consistency concern message conformance (the structure of the message and the technical response to the message) rather than the approaches to data quality covered in this guide. The AIRA Measurement and Improvement Initiative[27] provides IIS with information and guidance to align with standards to improve consistency.
- **Uniqueness:** Patient- and vaccination-level deduplication help to ensure that no vaccination event (BR144) or person is recorded more than once in an IIS and that each event/person is thus considered unique. The data quality rules that need to be developed to identify potential duplicate records are extensive and very complex. For that reason, the detailed process of identifying duplicate records will not be discussed further in this document; however, it is expected that every IIS has a mechanism in place to ensure each record is unique within the IIS. *Immunization Information Systems Patient-Level De-Duplication Best Practices*,[28] *Vaccination Level Deduplication in Immunization Information Systems*,[29] and *Consolidating Demographic Records and Vaccination Event Records*[30] include guidance on deduplication and consolidation.

[27] https://www.immregistries.org/measurement-improvement
[28] https://www.cdc.gov/vaccines/programs/iis/interop-proj/downloads/de-duplication.pdf
[29] https://repository.immregistries.org/resource/vaccination-level-deduplication-in-immunization-information-systems-1/
[30] https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/

There is a balance to be found between all seven data quality characteristics. The aim is to improve all data quality characteristics together, not at the expense of other characteristics.

When an IIS program seeks to improve one characteristic, it is important to be aware of potential side effects that could impact the other characteristics. For example, a focus on improving completeness by mandating the submission of a data element (e.g., race) could lead to a decrease in accuracy and validity if IIS-AOs were to send incorrect data to meet the requirement when they do not know the actual information (e.g., they did not ask the patient's race at the time of the vaccination event).

ACTORS AND THEIR ROLES

In this guide, a provider is a person who is a medical professional or clinician who works for a provider organization. A provider organization is an organization that either provides vaccination services, is responsible for an entity that provides vaccination services, or manages inventory for an entity that provides vaccination services. Once an organization is enrolled in the IIS, it becomes an IIS-AO.

IIS-AUTHORIZED ORGANIZATION (IIS-AO)

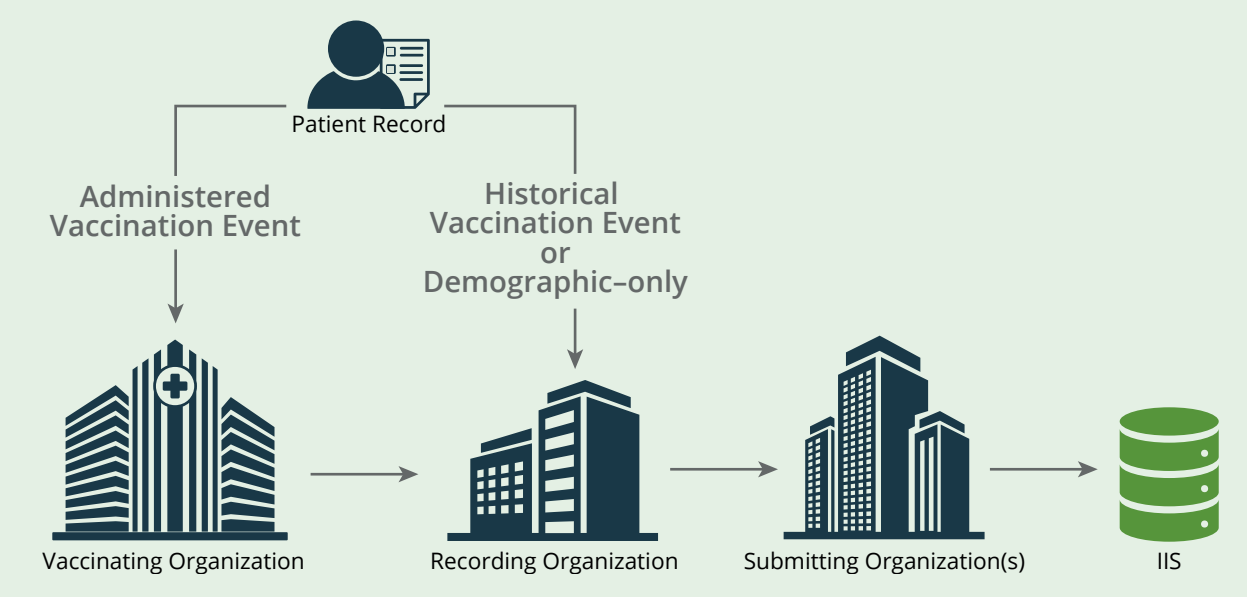
An organization that has an agreement with an IIS that allows for the submittal and/or retrieval of IIS information. For example, a provider organization, vital records office, hospital, or school.

It is important to distinguish the various roles an IIS-AO can perform during the vaccination event and data exchange process.

- A **vaccinating organization** is an IIS-AO that vaccinates a patient.
- A **recording organization** is an IIS-AO that records information for submission to an IIS.
- A **submitting organization** is an IIS-AO that submits information to an IIS or to an intermediary submitter with an IIS as the destination.
- A **data consumer** is an IIS-AO that has access to patient immunization history.

The typical data flow from an IIS-AO to an IIS involves a vaccinating organization, a recording organization, and one or more submitting organizations. A vaccination event is considered an administered vaccination event if the vaccinating organization is also the recording organization and a historical vaccination event if the vaccinating organization is not the recording organization. Submitting organizations submit vaccination events and patient demographic information to IIS via electronic data exchange and IIS direct user interface. Electronic data exchange is the model for collection of all immunization-related data, and thus is the primary method of submission discussed in this guide.

Figure 2 | *Diagram of the relationship between IIS-AO roles' process of incoming data submission*

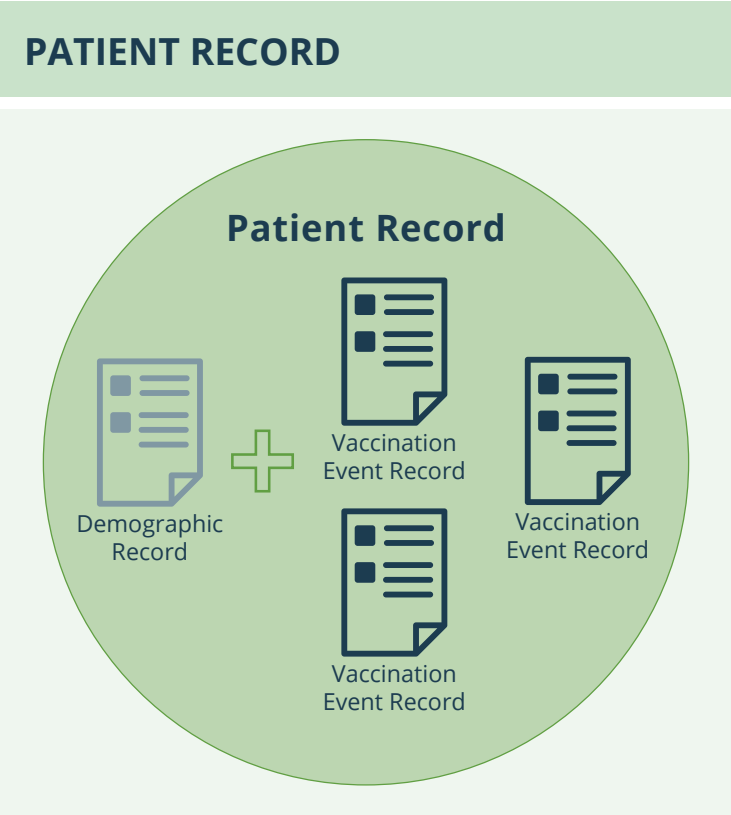


TYPES OF RECORDS AND SUBMISSIONS

Three categories of records will be discussed in this guide: demographic, vaccination event, and patient record.[31]

- A **demographic record** is a group of data elements that represent information about a patient.
- A **vaccination event record** is a group of data elements that represent information about a vaccination event.
- A **patient record** is a combination of a demographic record for a patient and vaccination event record(s) for that patient. Each patient record contains one demographic record and zero, one, or more vaccination event records.

Figure 3 | *Relationship between a patient record and demographic and vaccination event records*



Records are populated in the IIS via submissions received from an IIS-AO. A submission must have a demographic submission and may have vaccination event submissions. A demographic submission contains demographic information about the patient (e.g., patient name). A vaccination event submission contains data about a vaccination event (e.g., vaccine type). It is possible to receive a demographic-only submission, which would include a demographic submission but no associated vaccination event submissions.

[31] Additional information on types of records can be found in *Consolidating Demographic Records and Vaccination Event Records* (https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/).

DATA ELEMENTS

A data element is the general term for a component of a record. For example, date of birth is a data element in a demographic record. The priority of validating a data element is related to the data element's significance in clinical decision-making, public health assessments, and research (P02).

An important characteristic of a data element is its data source. The data source is indicated by the IIS-AO ID. Data sources may include, but are not limited to, vital records, birthing hospitals, provider organizations, pharmacies, schools, and health plans. IIS programs often have higher confidence in certain data elements if they originate with specific types of data sources. For example, vital records should be considered the definitive source for a patient's date of birth and date of death (P18).[32]

PHASES OF DATA QUALITY

Data quality should be ensured throughout the reporting and processing of immunization data and is the responsibility of both the IIS-AOs submitting data and the IIS program. This guide focuses on three phases of data quality in an IIS:

- Onboarding of IIS-AOs
- Submission of incoming data
- Review of data at rest within the IIS

Though IIS programs and IIS-AOs are both involved in all three phases, each actor's role changes depending on the phase.

[32] *Consolidating Demographic Records and Vaccination Event Records* (https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/) contains detailed information regarding using data sources to make data quality decisions related to deduplication and consolidation of records.

From the perspective of an IIS-AO, the first phase where data quality can be addressed is the onboarding process. This phase allows IIS-AOs to submit incoming data to the IIS, which then resides in the IIS as data at rest.

From the perspective of an IIS program, the phases overlap. IIS program staff onboard IIS-AOs, then start receiving data submissions from the IIS-AOs, and data at rest accumulates within the IIS. At the same time, the IIS program staff continue to onboard IIS-AOs.

Figure 4 | *Phases of data quality from the perspective of an IIS-AO*

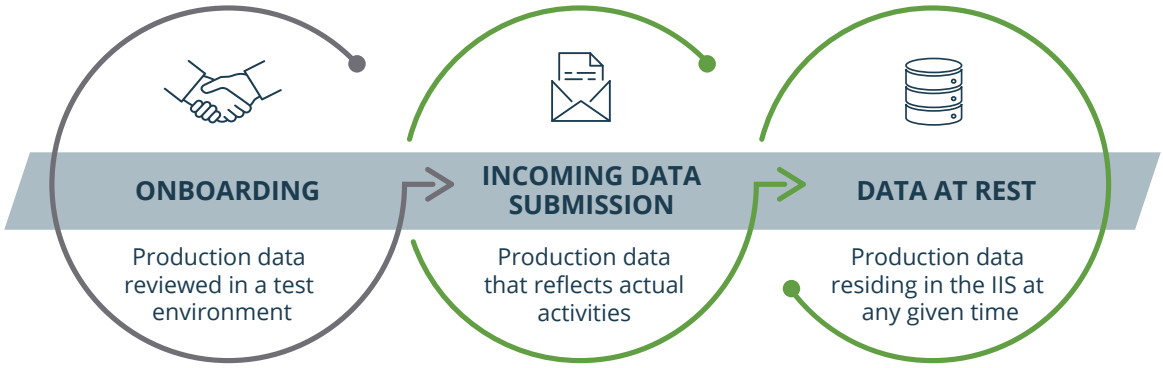
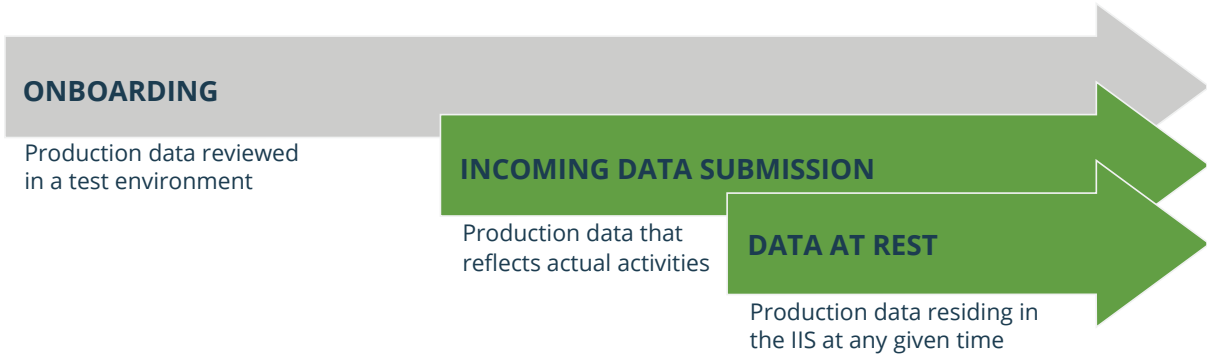


Figure 5 | *Phases of data quality from the perspective of an IIS program*



ONBOARDING

Onboarding is a term used to describe processes and activities related to preparing an IIS-AO to implement electronic data exchange between an IIS-AO's EHR system and a jurisdiction's IIS. Chapter 3: Onboarding Provider Organizations includes an overview of the key elements of data quality in onboarding IIS-AOs.

SUBMISSION OF INCOMING DATA

Once an IIS-AO has been onboarded and is sending data to the IIS, processes should be in place to uphold the quality of incoming data. Chapter 4: Incoming Data Submission provides a process model and outlines the steps an IIS takes when validating a submission. Although data validation during submission is particularly important when an IIS-AO first begins submitting data to the IIS after onboarding, submissions should be continuously monitored for missing data and other issues.

DATA AT REST

Data at rest refers to data residing in the IIS at any given time. Comprehensive data quality analysis can be performed to assess and improve the quality of data at rest within the IIS. This also presents an opportunity to identify issues that IIS-AOs can resolve in their messages being sent to the IIS or their processes to improve the quality of data that is submitted to the IIS. The process of using data for analysis, evaluation, and immunization coverage improvement enables otherwise overlooked data quality issues to be identified and resolved. Data quality plans should also be developed to describe the activities needed for analyzing data and ensuring that data reviews are happening regularly, as well as communicating the findings of the review to IIS-AO staff. Guidance on this is included in Chapter 5: Data at Rest.

The data quality of a data element can be checked in one or more of the three processes outlined above. For example, a vaccine type could be validated during incoming data submission to ensure it is appropriate for the patient's age. By contrast, data at rest analysis uses reports and thresholds to evaluate whether the volume of vaccination events with a specific vaccine type makes sense for a particular IIS-AO based on its patient population.

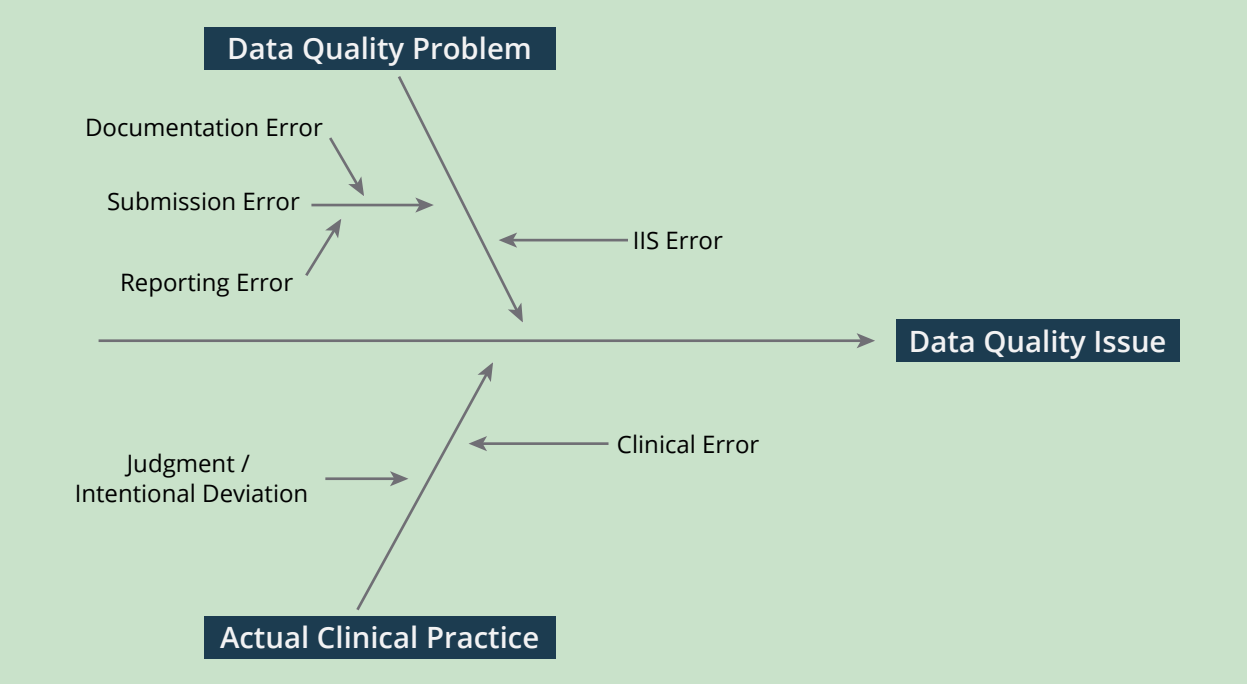
The data quality of a data element can be checked in one or more of the three processes outlined above.

CAPTURING AND REPORTING DATA ERRORS

The goal of an IIS is to reflect the actual immunization history of a patient. When data in an IIS are identified as not valid (i.e., not conforming with generally accepted standards), it is important to determine whether the data are accurate (i.e., describe reality).

When data reach an IIS and are identified as not valid, there are many potential reasons for the issue. The issue could be a data quality problem such as a documentation, reporting, submission, or IIS error. Alternatively, the issue could be an actual clinical practice such as a clinical error or an intentional deviation from normal clinical guidelines. If the issue is a data quality problem, the data are not accurate. If the issue reflects actual clinical practice, then the data are accurate. Figure 6 illustrates the sources of data quality issues. This diagram shows high-level groups of errors. However, errors will vary between IIS and may change over time. Each IIS program should conduct an aggregate analysis to understand the most common types of errors that are causing data quality issues.

Figure 6 | *Fishbone diagram of the potential reasons for a data quality issue*



Since it can be challenging to determine whether data that are identified as invalid are accurate or inaccurate, it can be helpful to split errors into two categories:

- **Impossible errors** are situations where data submitted are not possibly correct in any circumstance due to the laws of time and nature. For example, a vaccine dose that is administered before the patient's date of birth (BR111) is an impossible error. These issues are invalid and inaccurate and either should not enter the IIS or should be flagged and rectified by an IIS-AO or IIS program.[33]
- **Possible errors** are errors that could occur in the process of administering a vaccination event. The submission describes a vaccination event that does not meet a clinical best practice (e.g., a dose administered after the lot number expiration date) or common practice (e.g., providing a vaccine outside of the recommended age range), but which may have happened as described. These issues are not valid but could be accurate. Because a vaccination event submission should accurately reflect the vaccination event that occurred even if it does not meet clinical best or common practices, the data should not be rejected (P10). Such data should be flagged for review or identified via IIS reports that check for concerning trends. Data confirmed to accurately reflect the vaccination event as it happened in a clinical setting should not be altered.

Data quality issues should be addressed via both programmatic approaches (e.g., running reports and following up with individual providers) and technical approaches (e.g., cross-field validations flagging data in a submission) (P01).

When IIS program staff are working with IIS-AO staff to determine and fix issues, it is important to identify the underlying cause of the issue and rectify the problem rather than just correcting the existing data in the IIS.

ADDITIONAL FEATURES OF THIS GUIDE

Principles and business rules related to data quality are noted throughout this guide. Principles give a high-level direction that helps to capture institutional knowledge and guide the development of more specific business rules. Business rules represent specific requirements and decision-making logic for IIS processes and operations. A list of principles is in Chapter 7, and a list of business rules is in Chapter 8.

[33] There are likely exceptions to this statement. Less important data elements may not be subjected to these violation actions if the impact of "bad" data is not as serious. Business Rule Violation Actions in Chapter 8 includes more information about violation actions.

These principles and business rules are based on previous data quality guides and include new recommendations. The business rules based on immunization recommendations do not duplicate the Advisory Committee on Immunization Practices recommendations but, rather, are data-quality related rules that have been developed based on the Advisory Committee on Immunization Practices recommendations. In comparison with previous data-quality related business rules, some rules have been reworded to focus more on data quality than on the clinical perspective. It is important to note that there are times when it is valid to receive a submission that goes against a business rule (e.g., off-label use of a vaccine in a rare clinical circumstance). The IIS should be an accurate record of what occurs during a vaccination event with a patient, even if that event goes against clinical guidance and/or business rules.

Chapter 9 delves deeper into the practicalities of implementing the data quality assurance process. The appendices include tools and examples that provide in-depth explanations of topics related to the implementation of data quality assurance practices.

MEASUREMENT AND IMPROVEMENT INITIATIVE

AIRA's Measurement and Improvement Initiative[34] provides IIS with information and guidance to align with the IIS Functional Standards.[35] The IIS Functional Standards are a set of specifications that describe the operations, data quality, and technology needed by IIS to support immunization programs, vaccination providers, and other immunization stakeholders. As of spring 2022, the Measurement and Improvement Initiative has three content areas which can help IIS improve their overall data quality, with more planned in the future (e.g., patient and vaccine saturation).

- **Submission and Acknowledgment:** Focuses on HL7 conformance ensuring IIS are following national standards for HL7, including returning meaningful acknowledgment messages.
- **Data Quality Incoming/Ongoing:** Focuses on IIS ability to detect data quality issues on a per-message basis. The IIS will be presented with messages that contain intentional data quality errors (e.g., vaccination date before date of birth), and the IIS is expected to detect these errors.
- **Data at Rest:** Focuses on the quality of data residing within an IIS regardless of how the data arrived in the IIS.

[34] https://www.immregistries.org/measurement-improvement
[35] https://www.cdc.gov/vaccines/programs/iis/func-stds.html

3

ONBOARDING PROVIDER ORGANIZATIONS

Onboarding is a term used to describe the process and activities related to establishing electronic data exchange between an IIS-AO's EHR system and a jurisdiction's IIS.

3 ONBOARDING PROVIDER ORGANIZATIONS

Onboarding is a term used to describe the process and activities related to establishing electronic data exchange between an IIS-AO's EHR system and a jurisdiction's IIS.

This chapter describes the data quality elements of onboarding an IIS-AO. The onboarding process begins when an IIS-AO already enrolled in the IIS[36] registers to establish an electronic interface. The onboarding process ends when the IIS-AO can successfully send quality data to and/or receive data from the IIS production environment. An IIS program may accept a submission via electronic data exchange from an IIS-AO only if the IIS-AO has been approved for electronic data exchange submissions (BR105).

The onboarding process[37] includes:

- **Discovery and Planning:** The IIS program collects information from the IIS-AO and prepares the IIS-AO for the upcoming steps in the onboarding process. Sharing onboarding documentation during this step provides a road map for achieving high data quality throughout the onboarding process.
- **Development and Testing:** Development and testing ensures that the EHR-IIS interface is correctly configured. IIS program staff work with the IIS-AO and EHR vendor to confirm that messages can be sent by the EHR and received by the IIS, messages are formatted correctly to be understood by the IIS, and data quality issues are identified and rectified.
  - **Data Quality Review:** Submissions are analyzed to identify data quality issues. From the perspective of data quality assurance, this review is the most important part of onboarding. This chapter includes a detailed description of the data quality review component of the onboarding process.

[36] Before accessing IIS data or submitting data to the IIS, a provider organization must be enrolled to use the IIS (BR101). A provider organization that is enrolled in the IIS is referred to as an IIS-AO. Chapter 6: Provider Organization Management includes more information about enrollment.
[37] For a more detailed process description, please read *Onboarding Consensus-Based Recommendations* (https://repository.immregistries.org/resource/onboarding-consensus-based-recommendations/).

- **Production Approval and Go-Live:** Production approval and go-live verifies the completion of all activities related to approving an interface and transitioning an interface to the production environment as well as close monitoring of the new interface in the production environment.
- **Ongoing Monitoring:** Ongoing monitoring ensures that technical or data quality issues after an interface goes live are quickly identified and addressed.

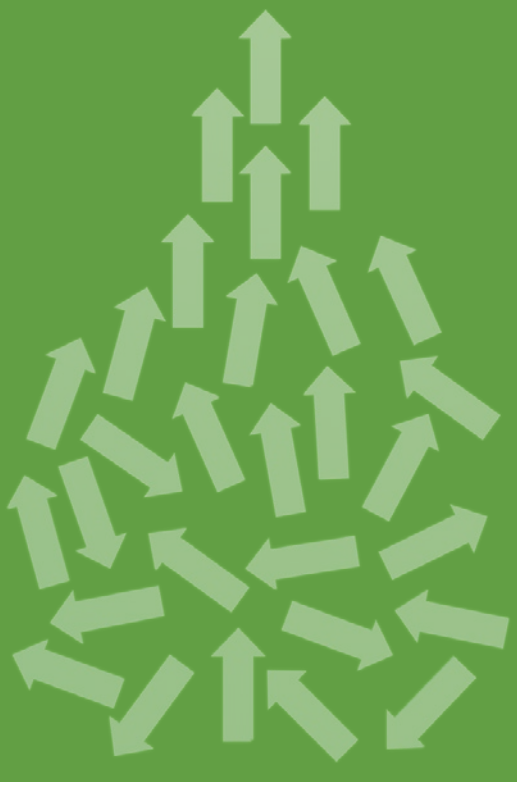
Onboarding is an opportunity for an IIS program to set and document expectations for the IIS program and IIS-AO (P15). Onboarding can also be used as a time to provide training to IIS-AO staff to avoid data quality issues in the future. It also is a good time to document and update the provider organization profile as described in Chapter 6: Provider Organization Management. The onboarding process may need to be repeated when an existing interface is changed.

AIRA ONBOARDING RESOURCES

Data Validation Guide for the IIS Onboarding Process[38] (2017) provides a detailed look at the data quality review process in onboarding.

Onboarding Consensus-Based Recommendations[39] (2018) offers a detailed overview of the full onboarding process.

This guide provides current best practices for data quality aspects of onboarding. The Onboarding Shared Services Program website[40] should be the primary source of information about onboarding processes.



[38] https://repository.immregistries.org/resource/data-validation-guide-for-the-iis-onboarding-process/
[39] https://repository.immregistries.org/resource/onboarding-consensus-based-recommendations/
[40] https://www.immregistries.org/onboarding-shared-services

DATA QUALITY REVIEW

Although the entire onboarding process is an opportunity to ensure high-quality data through education and training, the data quality review period provides an additional opportunity to review and improve an IIS-AO's data quality. The primary purpose of the data quality review is to examine the submissions for data issues related to:

- Data quality of patient records
- Data needed for the Vaccines for Children (VFC) program, vaccine management, decrementing of inventory, and other important functions of the IIS and immunization programs
- Verifying submissions align with the IIS-AO's provider organization type (e.g., pediatrics)

The data quality review looks for issues with the content of the message. The data quality review typically relies on reviewing data quality and inventory reports based on production EHR data in the IIS interface and, in some cases, manual comparison of selected patient records between the EHR and IIS.[41] Some portions of the data quality review process can be automated using a data quality report (see Appendix E) or a data quality analysis tool.[42] These tools are designed to assist IIS in monitoring and analyzing the quality of data submissions. This phase of testing is helpful for identifying issues that cannot be identified or resolved through the HL7 acknowledgment (ACK) message review.[43]

The IIS program may require records to be submitted over a certain period of time (which varies by IIS-AO size and/or type) followed by feedback to the IIS-AO staff about issues that need correction. The testing period should be extended until issues are resolved. The IIS program may also require that submissions reach a certain level of completeness and accuracy before the IIS-AO is permitted to go live. Each IIS program will determine what level of data quality must be achieved by the IIS-AOs.[44]

[41] Appendix F includes information about manual comparison of selected patient records.
[42] More information about tools, including sample screens/reports, a list of current users, and references to learn more, is available in Appendix D of *IIS Data Quality Practices – Monitoring and Evaluating Data Submissions* (https://repository.immregistries.org/resource/iis-data-quality-practices-monitoring-and-evaluating-data-submissions/).
[43] ACK Messages in Chapter 9: Implementation Considerations includes additional information about ACK messages.
[44] Additional guidance can be found at the Onboarding Shared Services Program website (https://www.immregistries.org/onboarding-shared-services).

The data quality review is largely programmatic (e.g., record review, workflows) and therefore requires that programmatic staff from the IIS-AO and IIS program be involved. As issues are identified, adjustments to the provider organization data set, EHR or HL7 interface software code/configurations, or clinical workflows/data flows may be needed. If issues are found, the IIS program provides clear guidance to the IIS-AO regarding which changes are needed to ensure the data quality review is successful. Feedback to the IIS-AO may be in the form of aggregate reports and/or patient-record-specific reports. A call may be held with the IIS program and IIS-AO staff to discuss interpretation of the reports and determine the next steps to correct errors and to improve data quality. In some cases, the IIS program may ask the IIS-AO to pull patient records for submission to the IIS program for comparison. Appendix F contains more information about performing a patient record review.[45]

In response to the data quality review performed by the IIS program, the provider works with its technical staff and clinical staff to fix issues that have been identified. This could be an opportunity for the EHR vendor to provide training to the IIS-AO staff on topics such as proper data entry. After changes have been made, messages should be retested to ensure that the issues have been satisfactorily resolved. This process can be repeated for as many cycles as needed until quality data is achieved.

The IIS onboarding process should strike a balance between the time and effort required to validate an IIS-AO's data and the implications of potentially introducing low quality data into the IIS. IIS program staff should determine the level of testing that is appropriate for the onboarding process by assessing which aspects of data quality can be most improved during onboarding. This will reduce the need for data quality correction activities later.

[45] Section 4 of *IIS Data Quality Practices – Monitoring and Evaluating Data Submissions* (https://repository.immregistries.org/resource/iis-data-quality-practices-monitoring-and-evaluating-data-submissions/) also contains information about patient record review.

ONBOARDING AND THE FOUR MAIN DATA QUALITY CHARACTERISTICS

AVAILABILITY

Onboarding is an excellent opportunity to introduce IIS-AO staff to IIS reports and to educate them on how to use these resources to improve their data quality. IIS programs should educate IIS-AO staff on how to use data quality and assessment reports and on general expectations for data quality of submissions (P14).

COMPLETENESS

Issues that could lead to low levels of completeness can be identified and remedied during the data quality review. The IIS program should educate the IIS-AO about the importance of completeness for data elements that have a high importance for medical or public health purposes, IIS technical processes, or vaccine accountability (BR171). Table 2 in *Data Validation Guide for the IIS Onboarding Process*[46] includes recommended completeness levels for specific data elements during onboarding.

Throughout the onboarding process, the IIS program should emphasi the importance of an IIS-AO collecting and submitting as much information as possible for the demographic and vaccination event submissions (P08).

TIMELINESS

The IIS program should communicate the expectation that data be submitted to the IIS in a timely manner (P03). An initial submission fo a vaccination event that has the administered/historical indicator as "administered" should be made within one day of the vaccination eve (BR106). The timeliness of messages can also be closely monitored during the ongoing monitoring period, and any delays in data submission can be quickly addressed.

[46] https://repository.immregistries.org/resource/data-validation-guide-for-the-iis-onboarding-process/

VALIDITY

Like completeness, issues related to validity can be identified and fixed during data quality review. Useful business rules for reviewing validity include:

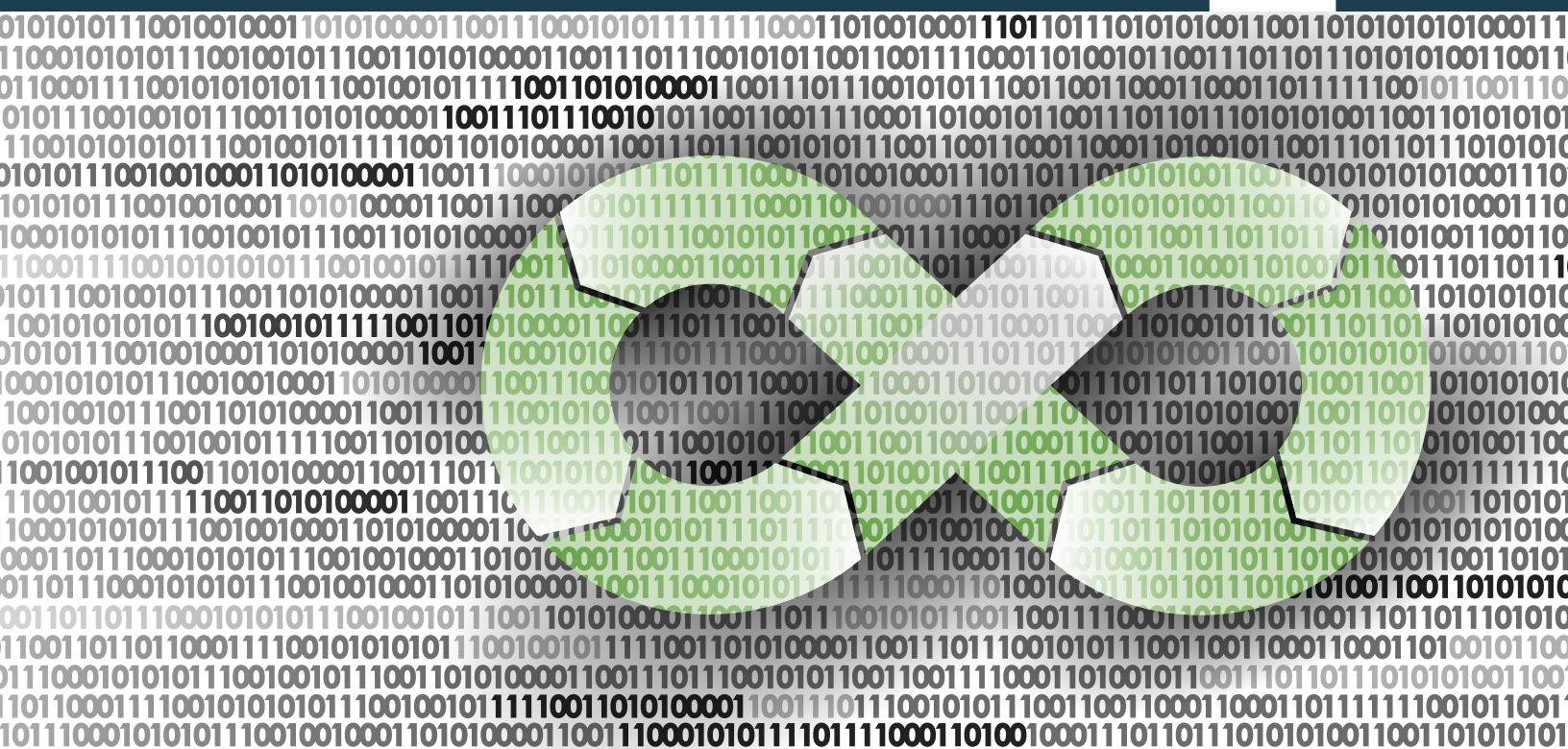
- BR110 – Valid calendar dates in a submission
- BR111 – Vaccination event date not before patient's date of birth
- BR112 – Submission not in advance of date of birth
- BR113 – Submission not in advance of vaccination event
- BR114 – Vaccination event date not after patient's date of death
- BR115 – Vaccination event date not after lot number expiration date
- BR116 – Vaccination event date for birth vaccine types
- BR118 – Specified formulation for administered
- BR120 – Combination vaccine reported as single vaccination event
- BR121 – Vaccine type available in United States
- BR124 – Vaccine product type manufacturer
- BR125 – Patient age within recommended range
- BR126 – Vaccine information should be consistent
- BR128 – Approved vaccine administration method
- BR129 – Lot number validation
- BR130 – Number contains information for only one lot number
- BR132 – Lot number accuracy
- BR133 – Vaccine product license
- BR135 – Consistent vaccine eligibility
- BR144 – Same antigen on same day

PROVIDER ORGANIZATION PROFILE

The provider organization profile (BR102) can be useful for assessing validity. For example, if a provider organization profile identifies the provider organization type as "pediatric," then the IIS program should investigate submissions with vaccine product types that are only for adults.

4

INCOMING DATA SUBMISSION



After an IIS-AO has been onboarded and is sending data to the IIS, certain processes should be in place to uphold the quality of incoming data.

4 INCOMING DATA SUBMISSION

After an IIS-AO has been onboarded and is sending data to the IIS, certain processes should be in place to uphold the quality of incoming data.

This chapter provides a process model and outlines the steps involved for an IIS to validate a submission, beginning with an IIS-AO recording a patient encounter through the validation of the submitted message. There are opportunities to ensure data quality at various points in the incoming data submission process.

Two key principles drive the incoming data submission process.

- Data quality in an IIS should be accomplished via multiple approaches and use both programmatic and technical resources (P01). The submission process is largely a technical process in which automated data quality rules determine which data are accepted or rejected. However, the development and usage of reports, in the final steps of this process, require programmatic resources and manual processes. Throughout the data quality life cycle, a combination of technical and programmatic approaches are used to support high data quality.
- The priority of validating a data element is related to the data element's significance in clinical decision making, public health assessments, and IIS functions (P02). The amount of effort an IIS program spends validating a data element should be proportionate to its ultimate value.

To simplify the description of the incoming data submission process, a few standards have been built in this chapter:

- All provider organizations are referred to as IIS-AOs.[47]
- The submission is reported using electronic data exchange. Although this chapter does not address data submitted via other methods (e.g., user interface), all submissions submitted to an IIS should be subject to the same business rules regardless of how they are reported to the IIS (P07).[48]
- This chapter follows the path of data submission from the IIS-AO into the IIS. Once data are accepted into the IIS, they become data at rest (addressed in Chapter 5).

[47] In some jurisdictions, all vaccinating provider organizations are mandated to report to the IIS. However, these mandates do not exist in all jurisdictions, so it is possible for a vaccinating organization to not be enrolled in the IIS. Hopefully, this will become increasingly uncommon as there is greater participation of all types of provider organizations in IIS.

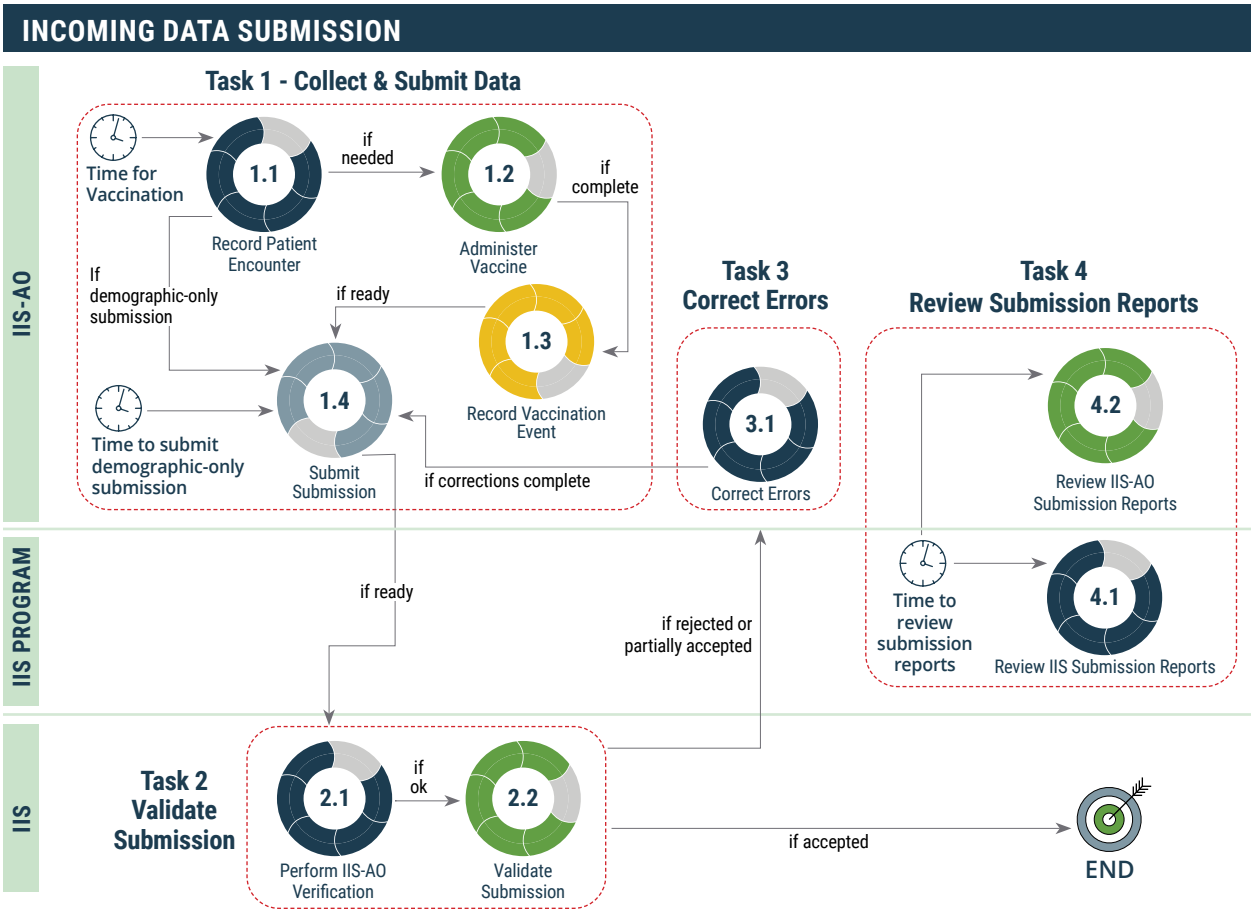
[48] For example, if a data element is mandatory for submissions via electronic data exchange, the data element should also be mandatory for submissions via other methods. The technical processes may differ, but the result should be the same.

Four tasks are included in incoming data submission, and each task involves one or more steps. The tasks and steps are described in this chapter. The tasks are:

- Task 1: Collect and submit data
- Task 2: Validate submission
- Task 3: Correct errors
- Task 4: Review submission reports

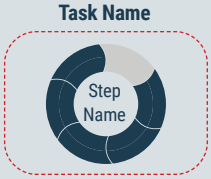
The diagram below shows the high-level tasks associated with the incoming data submission process. See Appendix G for a summary of the inputs and outputs by step.

Figure 7 | *Tasks and steps in the incoming data submission process*



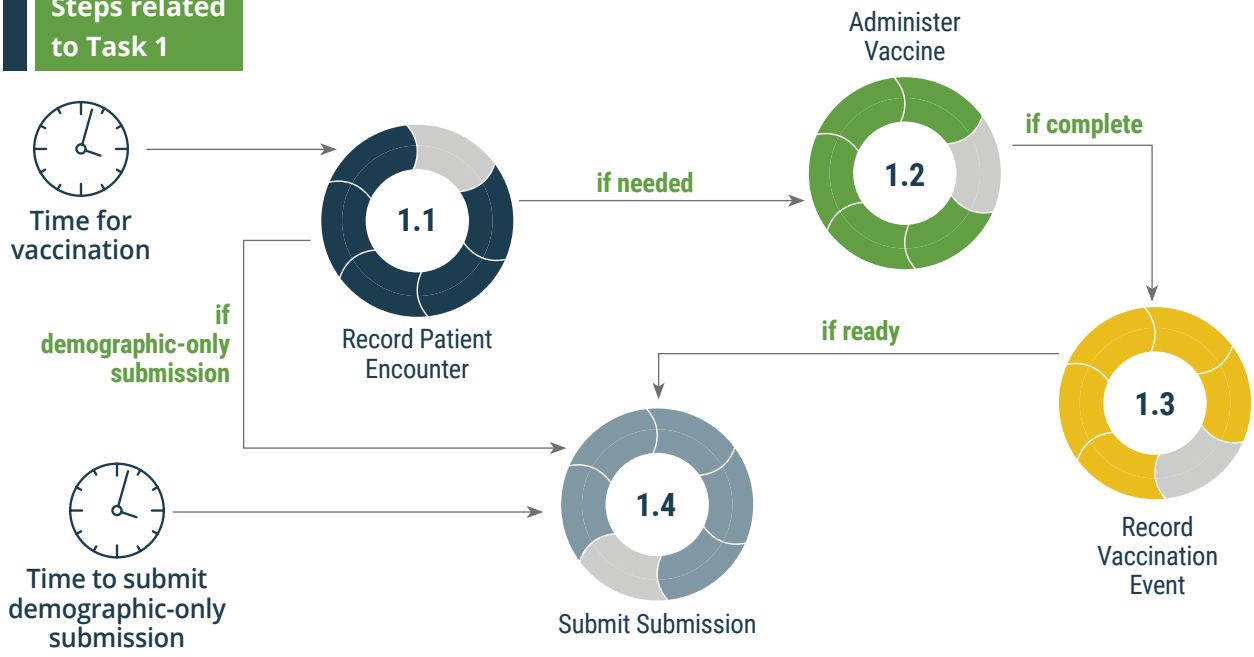
Legend on following page

Figure 7 | *Tasks and steps in the incoming data submission process* *(Continued from previous page)*

SYMBOL	NAME	DEFINITION
	Swimlane	A graphical container for partitioning a set of activities from other activities
	Task	A grouping of steps that are performed together in a task
	Step	An atomic activity that is included within a process. A step is used when the work in a task is broken down into a finer level of detail
	Sequence Flow	A connecting object that shows the order in which activities are performed in a process
	Timer	An event that indicates where a particular process starts based on time
	End Event	An event that indicates where a path in the process will end

TASK 1:
COLLECT AND SUBMIT DATA

Steps related to Task 1



DESCRIPTION

The purpose of this task is to document demographic and vaccination event information and submit that information to the IIS. In the process of collecting and submitting data, it is vital that the vaccination event that occurred be accurately represented by vaccine event submission (P10). Likewise, the IIS-AO should be aware of an expectation to collect and submit as much information as possible for the demographic and vaccination event submissions (P08). This task describes a simplified workflow for collecting and submitting data, but alternative workflows are possible depending on the needs of the IIS-AO and EHR.

In the process of collecting and submitting data, it is vital that the vaccination event that occurred be accurately represented by vaccine event submission (P10).

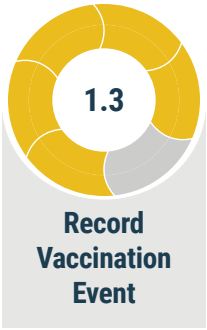
STEP 1.1: RECORD PATIENT ENCOUNTER

Actor: IIS-AO
Description: When a patient enters an IIS-AO facility, the first step that often occurs is a review of the patient demographic information to ensure it is current and accurate. The IIS-AO staff note any changes that are needed.

If the patient does not require vaccination, any updated patient information can be recorded and submitted by the IIS-AO to the IIS as a demographic-only submission (Step 1.4). If the patient will be receiving a vaccination, the process proceeds to Step 1.2.

STEP 1.2: ADMINISTER VACCINE

Actor: IIS-AO
Description: A provider vaccinates its patient.[49]



STEP 1.3: RECORD VACCINATION EVENT

Actor: IIS-AO
Description: IIS-AO staff records the vaccination encounter of the patient. In an administered vaccination event, the IIS-AO that administers the vaccine is the same as the IIS-AO that records the vaccination event. In a historical vaccination event, the IIS-AO that administers the vaccine is not the same as the IIS-AO that records the vaccination event. For more information about administered and historical vaccination events, see Actors and their roles in Chapter 2.

[49] This is a simplification of this step and does not describe the full set of activities performed by the provider.

STEP 1.4: SUBMIT SUBMISSION[50]

Actor: IIS-AO

Description: IIS-AO staff submit the demographic and vaccination event information to the IIS.[51] Many EHRs have an automated process to submit data to the IIS (e.g., data are automatically submitted when saved). The submissions should contain the minimum/mandatory set of data elements to be accepted by the IIS (P05, BR001). In addition to the minimum/mandatory data set, IIS-AOs should be strongly encouraged to collect and submit as much information as possible for demographic and vaccination event submissions (P08).

Data should be submitted to the IIS in a timely manner (P03). An initial submission for a vaccination event that has the administered/historical indicator "administered" should be made within one day of the vaccination event (BR106). By providing timely data, the IIS-AO ensures that the IIS has the most up-to-date information about the patient's immunization history and that future vaccinations are forecasted based on accurate information.

Tracking roles in a submission

A submission should contain information that allows for the identification of the key IIS-AO roles.

Tracking the organizations involved in vaccinating patients, recording information, and submitting data to the IIS allows IIS programs to identify where data quality issues may originate and identify options for fixing the errors.

- For an administered vaccination event, the vaccinating organization and submitting organization should be identified in the submission.
- For a historical vaccination event, the recording organization and submitting organization should be identified in the submission.

It is beneficial to identify all submitting organizations if there is more than one organization involved in the process of submitting the data to the IIS (P21, BR175). For more information about the logistics related to communicating about multiple submitting organizations via HL7, please see Appendix I.

[50] A submission is a collection of information sent from an IIS-AO to an IIS. Types of Records and Submissions includes additional information about the data within a submission.
[51] The IIS-AO may be utilizing a pass-through system (e.g., an electronic health information exchange) if it does not have the technical ability to submit HL7 data directly to the IIS.

Demographic-only submission

An IIS-AO may submit demographic information for a patient without submitting vaccination event information. This is commonly referred to as a demographic-only submission but is technically an Admit, Discharge, and Transfer (ADT) message per the HL7 Standard.[52] Because no vaccination event occurs in such cases, the submission does not include the IIS-AO ID of a vaccinating organization but should include the IIS-AO ID of the submitting organization.[53]

Resubmissions

If a submission requires correction on the part of the IIS-AO, there should be a resubmission of those corrections. For more information about the action codes involved in resubmitting data to the IIS, see Action Codes (RXA-21) in Chapter 9: Implementation Considerations.

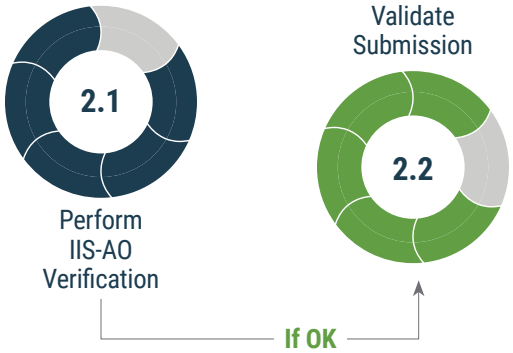
[52] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=92
[53] A vaccination event cannot be submitted without demographic information.

NO ONE IS PERFECT

Although most of the errors discussed in this guide originate with an IIS-AO or EHR, IIS and IIS programs are also fallible. For example, an incorrect NDC code entered in the IIS code set for an influenza vaccine would lead to the rejection of submissions. When an error originates with the IIS, it is beneficial to correct the underlying issue that caused the error, then fix any resulting data quality problems. IIS programs should set policy and procedures for managing situations in which an IIS-based issue leads to rejection of data.

TASK 2:
VALIDATE SUBMISSION

Step related to Task 2



DESCRIPTION

The IIS electronically validates the submission based on rules developed by the IIS program. Depending on the formatting and content of the submission, the IIS may:

- Accept the entire submission and all included data elements
- Accept the submission but reject data elements that have errors
- Reject the entire submission

The IIS should return an ACK message to the IIS-AO to inform them of the status of their submission, whether any data were rejected, and any problems with the submission (regardless of whether they led to rejection of data). The IIS should track all submission errors and the status of all submissions (BR161), and all submissions should be retained per jurisdictional policy, along with the identified errors (P22).

If a submission is accepted, it goes through a deduplication and consolidation process to determine whether the incoming records match any existing records.[54]

[54] The Scope in Chapter 1: Introduction references several resources for deduplication and consolidation.

STEP 2.1: PERFORM IIS-AO VERIFICATION

Actor: IIS
Description: The IIS checks the submission message to confirm that the IIS-AO ID matches an approved IIS-AO ID. An IIS program should accept submissions from authorized organizations only (BR101). In addition, the IIS should verify any other pertinent details about the IIS-AO submitting organization. The IIS-AO and IIS-AO ID are validated in this step.

The verification will also include confirmation that the message is one of the current HL7 versions supported by the IIS[55] and that the whole message has been validated and fulfills the technical requirements of the IIS.

STEP 2.2: VALIDATE SUBMISSION

Actor: IIS-AO
Description: The submission is validated. Validation involves:

- **Confirmation of minimum/mandatory data elements:** The submission should contain the mandatory set of data elements to be accepted by the IIS (P05, BR001).
- **Validation of individual data elements:** Confirming that the value submitted for a data element meets the data quality requirements for that data element.
  - Example: A patient first name and a patient last name in a demographic record each should be at least two characters long (BR148).
- **Cross-field validation:** Cross-field validations compare two or more different data elements for incongruencies to identify if one or more of the data elements is potentially documented in error.
  - Example: A vaccination event date should not be before (less than) the patient's date of birth (BR111).

Many of the business rules in Chapter 8 could be used for validation of a submission. The Business rules violation actions section of Chapter 8 includes information on how to manage situations in which business rules are violated.

The results of validation are provided to the IIS-AO in an ACK message.

[55] IIS programs should also work with EHR vendors to ensure that they are using the most up-to-date version of HL7 specification (P20).

TASK 3:
CORRECT ERRORS

Steps related to Task 3

Correct Errors

DESCRIPTION

The purpose of this task is for the submitting organization to review the status of the submission via an ACK message and correct issues associated with the submission.

Correct Errors

STEP 3.1: CORRECT ERRORS

Actor: IIS-AO

Description: The IIS-AO staff (or EHR staff) working for the submitting organization receives an ACK message that contains feedback from the submission to the IIS.[56]

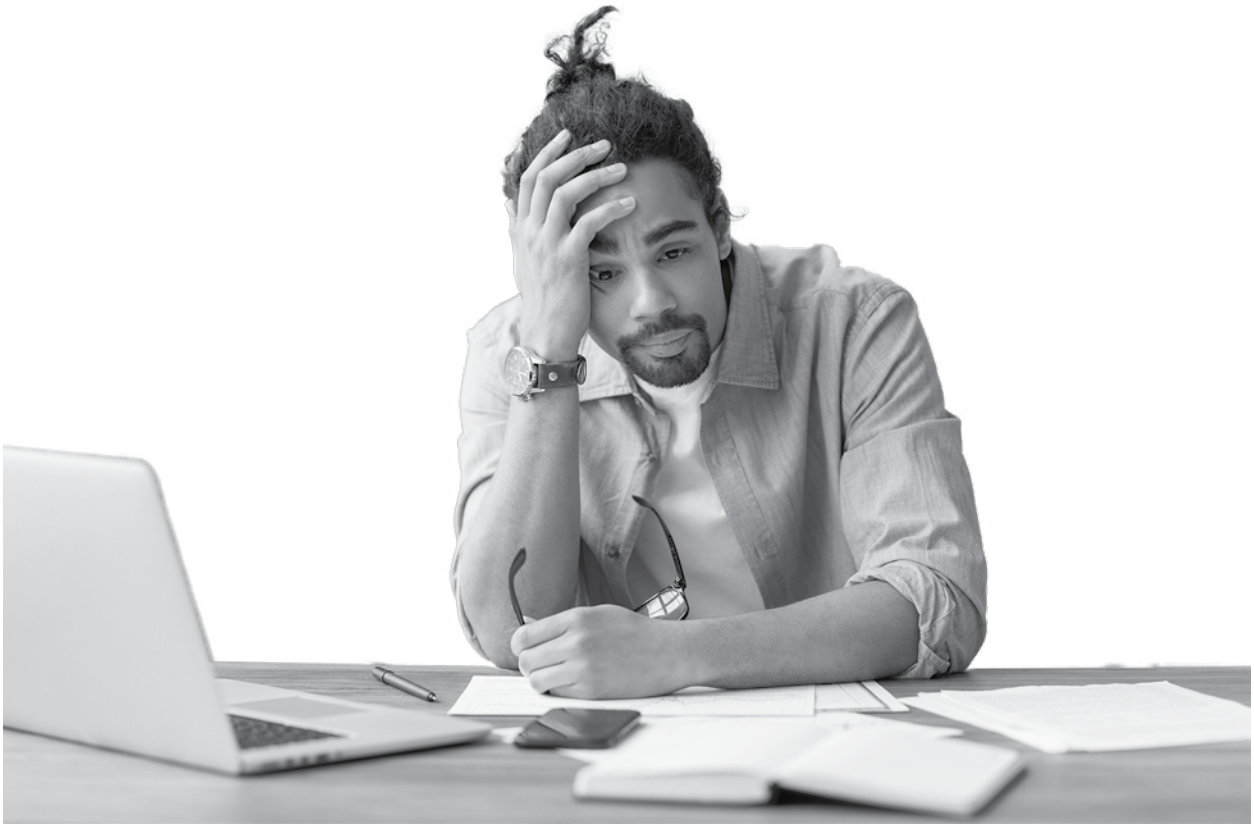
- If a submission has been rejected, staff should correct the data and resubmit the submission.
- Some issues communicated in the ACK message are intended to inform the submitting organization that there may be a problem with the submitted data even though the submission was not rejected. For example, an ACK message may inform the submitting organization that a lot number expiration date was not present in a vaccination event submission, but the submission was still accepted into the IIS. These issues should be resolved to improve data quality; however, they may not rise to the same level of importance for a submitting organization as a rejected record.

[56] Aggregate Immunization Acknowledgment Message Reports Guidance White Paper (https://www.himss.org/resources/aggregate-immunization-acknowledgment-message-reports-guidance-white-paper) provides guidance for clinical software, IIS, and third-party system developers who want to support better access and usage of ACK message data.

Correctly understanding and interpreting the data in an ACK message can be challenging. It is helpful for the IIS-AO to have staff who can comprehend the meaning of the data, identify the underlying issues causing data to be rejected, and connect with the appropriate people at the IIS-AO, EHR, or IIS program to solve issues. This process can be supported by:

- IIS programs implementing comprehensible standardized ACK messages
- IIS-AOs and EHR vendors creating reports and/or tools that can parse ACK messages for the most important information or trends[57]

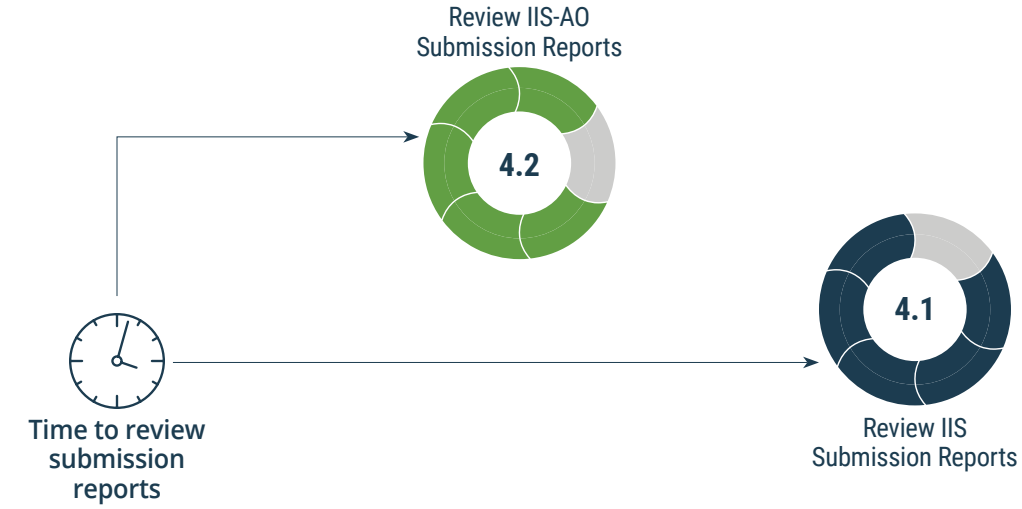
The submitting organization should work with the vaccinating and recording organizations to fix any issues associated with their submissions.



[57] The AIRA Discovery Session: Data Quality Improvement Success Story: Collaborating through the Immunization Integration Program (https://repository.immregistries.org/resource/aira-discovery-session-data-quality-improvement-success-story-collaborating-through-the-immunization/) provides a useful example of a partnership to use ACK messages to improve data quality. The Foundational Guidance for Minimum Functionality to Improve Visibility and Access to Information from Acknowledgment Messages (https://repository.immregistries.org/resource/foundational-guidance-for-minimum-functionality-to-improve-visibility-and-access-to-information-from-acknowledgment-messages/) describes the process of summarizing ACK messages in aggregate reports produced by IIS, EHRs, and third parties.

TASK 4:
REVIEW SUBMISSION REPORTS

Step related to Task 4



DESCRIPTION

The purpose of this task is to review submission-related reports to ensure that issues are identified quickly and corrected. This task relates to reports that are specific to incoming data submission (e.g., the percentage of rejected submissions). The reports to identify data quality issues in data at rest are discussed in Chapter 5: Data at Rest.

For this task to be successfully performed, it is essential that data quality reports are available to both IIS program staff and to IIS-AO staff (P11, P12). Likewise, it is vital that both sets of staff be well trained on how to interpret and use these reports. Section 3: Monitoring & Evaluation in *IIS Data Quality Practices – Monitoring and Evaluating Data Submissions*[58] provides a wealth of information about methods to conduct ongoing monitoring and evaluation of data submissions as well as a recommended protocol for this practice.

[58] https://repository.immregistries.org/resource/iis-data-quality-practices-monitoring-and-evaluating-data-submissions/

STEP 4.1: REVIEW IIS SUBMISSION REPORTS

Actor: IIS program
Description: An IIS program should review submission reports for error trends (BR163) and review submissions that have been rejected or have errors within five business days of the submission date (BR162).

On a weekly basis, IIS program staff should review reports that identify submission issues and provide outreach and education to IIS-AOs with significant issues. The reports available to the IIS program staff may be broader than those available to IIS-AO staff. For example, a report for IIS program staff may allow the staff to view the submission rejection rate for all IIS-AOs that submitted data during a time period, whereas the reports available to IIS-AO staff would contain only information specific to their IIS-AO(s).

Likewise, IIS program staff should review submissions monthly to identify trends related to submissions. For example, IIS program staff could monitor variance in frequency and volume of reporting for an IIS-AO over time. This type of review can identify if an IIS-AO may have had a technical issue that prevented any submissions from being sent to the IIS. It can also identify when an IIS-AO is having an increasing number or rate of rejections or other issues possibly signaling an underlying problem that needs to be addressed by the IIS-AO staff.[59] The monthly review is also an opportunity to analyze and evaluate the submission data via several business rules (BR163, BR164, BR165, BR166, BR167).

IIS program staff also can review the timeliness of submissions in a monthly review. Ideally this would occur as soon as possible so that timely data are available for additional users of the system (P04). An initial submission for an administered vaccination event should be made within one day of the event (BR106). Reports and queries can be developed to summarize, on average, how quickly an IIS-AO is submitting their vaccination event data.

[59] If there are changes to an existing EHR interface, the onboarding process may need to be repeated and submissions reviewed in detail.

STEP 4.2: REVIEW IIS-AO SUBMISSION REPORTS

Actor: IIS-AO

Description: The IIS-AO staff review reports that are pertinent to their organization, including reports related to any vaccinating organizations and recording organizations for which the IIS-AO is submitting data. This review of reports is in addition to the review that IIS-AO staff should be doing of the ACK messages related to each submission (Step 3.1).

ADDITIONAL REVIEW OF DATA IN THE IIS

IIS programs and IIS-AO staff should also regularly run reports to identify data quality issues in the data that are stored in the IIS (i.e., data at rest). Chapter 5 provides information on how to manage data at rest.

Incoming Data Submission and the Four Main Data Quality Characteristics

- **Availability:** Two key steps support availability of IIS data to users. By providing useful and understandable ACK messages to IIS-AO staff, errors can quickly be identified and corrected so records can be resubmitted. Likewise, IIS-AO staff should be given access to data-quality submission reports in Step 4.2.
- **Completeness:** Completeness can be encouraged in the submission process by requiring the submission of certain data elements (i.e., minimum/mandatory data elements) and by communicating to IIS-AO staff when other data elements are missing.
- **Timeliness:** Submission reports should be regularly reviewed by IIS program staff to identify issues with timeliness (Step 4.1). IIS program staff should then work with IIS-AO staff to ensure data are submitted in a timely manner.
- **Validity:** Some issues related to validity can be identified during Task 2: Validate submission.

5

DATA AT REST

It is important to note that not all the data-quality principles and business rules discussed in this document existed when IIS were created. For this reason, data at rest should be reviewed for issues that may have been introduced prior to implementation of specific validation rules and for data that may have accidentally bypassed validation rules.

5 DATA AT REST

In simple terms, data at rest are the data sitting in the IIS at any given moment.

Data at rest include, but are not limited to, demographic and vaccination event information, vaccine inventory, provider organization profiles, and user profile data. For the purposes of this guide, the primary focus of data at rest analysis will be the data quality of the demographic and vaccination event information.

DATA AT REST
Data residing in the IIS at any given time.

In contrast to incoming data submissions,[60] which may restrict or reject some data from entering the IIS due to quality issues, data at rest analysis includes all data that have reached the IIS, good or bad. For this reason, data at rest analysis creates opportunities for a comprehensive review of data and allows for assessments that are not possible during incoming data submission. With data at rest analysis, the IIS program can measure the completeness of any given data element that a specific IIS-AO is submitting over time or identify patterns of data quality concerns. Identifying and addressing data quality errors enables IIS to provide accurate data that can be used to inform larger-scale public health needs. In addition, by identifying clinical practice errors, interventions can be implemented to improve patient care and safety, thereby increasing vaccination coverage rates across a community.

Data at rest analysis uses all the data in the IIS regardless of the method of submission to the IIS (e.g., electronic data exchange). The same principles and business rules are applied to all the data in the same way, irrespective of how the data were submitted to the IIS (P07).

It is important to note that not all the data-quality principles and business rules discussed in this document existed when IIS were created. For this reason, data at rest should be reviewed for issues that may have been introduced prior to implementation of specific validation rules and for data that may have accidentally bypassed validation rules.

[60] See Phases of Data Quality for a summary of what is contained in each phase of data quality.

DATA AT REST BY DATA QUALITY CHARACTERISTIC

As mentioned in the Chapter 2: Fundamental Concepts, data quality is defined by four main characteristics: availability, completeness, timeliness, and validity. The following section is structured to address these four characteristics in relation to data at rest.

AVAILABILITY

The main purpose of availability is ensuring that IIS data are readily available to authorized users. The upcoming section on Internal Programmatic Processes for Data at Rest includes information on data at rest reports for IIS-AOs.

COMPLETENESS

Completeness means having all vaccination and demographic records for persons residing in the jurisdiction contained within an IIS and within records having completed data fields.

Through aggregated data analysis, data at rest analysis can give a comprehensive picture of data completeness within an IIS both at an individual data element level and at a jurisdictional level.

Data element completeness

Completeness can be measured for individual data elements within the IIS and for each IIS-AO (BR170) to easily identify the gaps where data may be missing. For example, reminder/recall is most effective if an IIS-AO has complete contact information (e.g., address information, phone, email address) for most of its patients (BR154). Similarly, a high level of completeness of demographic elements can be beneficial in identifying pockets of need or targeting vaccination outreach during a vaccine-preventable disease outbreak (BR170, BR171). For this reason, a set of high-interest data elements is utilized for data at rest completeness monitoring (BR170). Some IIS have even developed thresholds for each data element to ensure the level of completeness. Recommended thresholds are included in *IIS Data Quality Practices – To Monitor and Evaluate Data at Rest*.[61]

[61] https://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/

High levels of completeness for any of the measures above or for any one data set does not ensure high-quality data in the IIS. All data quality characteristics need to be addressed to support a healthy data quality ecosystem. The higher the data quality for all characteristics, the more useful the data will be for public health analyses.

Jurisdictional completeness

When IIS were initially implemented, an increase in the number of provider organizations submitting data to an IIS was used as a measure of increasing vaccination and demographic record completeness. An increase in the number of provider organizations submitting data in a jurisdiction generally meant an increase of patients and vaccinations recorded in the IIS (also referred to as saturation). However, over time some IIS began reporting an oversaturation of demographic records (i.e., over 100% of the population) compared to an estimated known population (e.g., census data).

A notable problem was a high number of patient and vaccination duplication errors. Patient and vaccination level deduplication was developed to help to ensure that no vaccination event or person is recorded more than once in an IIS. One way to find potential vaccination event duplicates is by looking at antigens administered on the same date (BR144).[62]

Another factor contributing to the inflated saturation rates was inaccurate or out-of-date patient statuses. Patient status is a term to describe the accountability for a vaccination by a provider organization but can also be discussed in terms of patient status at the jurisdiction level (i.e., residing within that jurisdiction). When a patient moves out of the jurisdiction but the patient record is not updated to reflect the change within the IIS, a mismatch with the census data can cause skewed results. Additional recommendations and information about managing patient status are available in *Management of Patient Status in Immunization Information Systems*[63] and *Patient Status in Immunization Information Systems*.[64]

[62] Deduplication is outside of the scope of this guide. The Scope in Chapter 1: Introduction references several resources for deduplication and consolidation.
[63] https://repository.immregistries.org/resource/management-of-patient-status-in-immunization-information-systems/
[64] https://repository.immregistries.org/resource/patient-status-in-immunization-information-systems/

Completeness at the jurisdictional level can also be measured by using vaccination records for persons residing in the jurisdiction (i.e., vaccination coverage rates). An IIS can compare vaccination coverage rates for various age cohorts with coverage rates from sources such as CDC immunization surveys[65] to determine vaccine coverage rates for different age cohorts across a jurisdiction. If the IIS vaccination data is underreported compared to the immunization survey data, then the vaccination data could be incomplete. The process of analyzing vaccination coverage assessment is out of scope for this guide, but several other guides cover the process in detail.[66]

Timeliness

Timeliness refers to how quickly an event of interest (i.e., a vaccination event) is recorded in the IIS compared to when it occurred (P03). Reports and queries can be developed to summarize, on average, how quickly an IIS-AO is submitting its vaccination event data (P11 and P12).

Validity

Data that conform with generally accepted standard guidelines are considered valid. Data that do not conform to standard guidelines (i.e., are not valid) could be either accurate or inaccurate.[67] Determining whether data are valid is useful because it allows IIS program staff to identify potentially inaccurate data.

There are several ways for an IIS program to identify invalid data. Validation of individual data elements and cross-field validation (P06) can flag data that do not meet standard guidelines. Likewise, IIS program staff can analyze data at rest to identify data that do not match expected patterns or immunization standards of practice.

[65] For example, the National Immunization Survey (https://www.cdc.gov/vaccines/programs/iis/activities/nis-study.html).

[66] *Identifying Immunization Pockets of Need – Small Area Analysis of IIS Data to Detect Undervaccinated Populations* (https://repository.immregistries.org/resource/identifying-immunization-pockets-of-need-small-area-analysis-of-iis-data-to-detect-undervaccinated-p/); *Preparing for Vaccination Coverage Assessments: A VFC Provider's Guide to Success* (https://repository.immregistries.org/resource/preparing-for-vaccination-coverage-assessments-a-vfc-providers-guide-to-success/); *Comparing and Communicating Vaccination Coverage Estimates from IIS, NIS, and Related Assessments* (https://repository.immregistries.org/resource/comparing-and-communicating-vaccination-coverage-estimates-from-iis-nis-and-related-assessments/)

[67] Capturing and reporting data errors in Chapter 2 contains more information about the relationship between validity and accuracy.

Some data elements must conform to specific formats or standard value sets. For instance, a date in a submission should be a valid calendar date (BR110), name fields cannot contain certain special characters (BR145), first and last name fields require at least two characters (BR148), and phone number fields can contain only numbers (BR158). Standard value sets constrain the values a field can have (BR109).

Cross-field validations compare two or more different data elements to identify incongruencies that suggest one or more of the data elements might have been documented in error. Several cross-field validation rules involve comparing two date fields. For example, a vaccination event date can be compared to a patient's date of birth (BR111).

If a vaccination event date precedes the patient's date of birth, one of the dates, or potentially both, were entered in error. These types of validations are easy to develop once all the different date fields have been identified and defined in terms of cross-field validations (BR111, BR112, BR113, BR114, BR115).

Additional cross-field validation rules are based on a knowledge of the relationship between data elements and the allowable value combinations. For example, dose-level public/private indicator and dose-level eligibility should be congruent (BR135). When these standard practices and value combinations are known, validation rules can be written and reports or queries developed to identify when these instances occur. When thinking about implementation of these practices, the *IIS Data Quality Practices – To Monitor and Evaluate Data at Rest*[68] provides examples of IIS reports.

Analysis of data at rest to detect data that fall outside normal patterns for IIS data can help identify potential data quality issues. For example, an aggregate report of vaccination events across patient cohorts for a provider organization might reveal inconsistencies between vaccination event practices and provider organization type (BR102). For example, adult vaccinations might be found to have been administered when the provider organization type is a pediatric clinic.

[68] https://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/

Immunization standards of practice such as the Advisory Committee on Immunization Practices schedule (P09)[69] inform IIS program staff which vaccines should be given by a specific age (BR140, BR141, BR143) and which vaccines should or should not be administered based on age or interval (BR125, BR142). Such information helps IIS program staff identify data that conflict with recommendations or fall outside normal immunization practices. For example, it would be uncommon for a patient to receive a varicella vaccine before one year of age (BR125).

Similarly, standard practices and clinical guidance dictate that some events should not occur. Reference source materials are utilized to compare recorded data to the correct vaccine route of administration, vaccine site of administration, vaccination event dosage, and patient age (BR128). As an example, rotavirus vaccine should only be given orally, never administered in the deltoid.

IIS program staff can use known patterns or standard practices to identify and investigate potential data quality issues. These activities hopefully lead to the correction of data quality errors or clinical errors.

[69] CDC Advisory Committee on Immunization Practices Schedule (https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html)

INTERNAL PROGRAMMATIC PROCESSES FOR DATA AT REST

One of the most effective ways to examine large volumes of data for potential issues is aggregate data review (P11, P12, BR163). Performing aggregate data review can be time-intensive and challenging; however, this analysis allows for the identification of large-scale patterns and/or important trends. Identifying patterns of errors enables an IIS program to find the root cause, which may be difficult or impossible to recognize during earlier phases of data quality analysis. Most IIS have developed queries or reports (P11) that either are set to run automatically at a specific frequency or are available as needed, reducing time required for program staff to develop and run the reports. Though conducted less frequently than ongoing submission evaluation, such analyses are a worthwhile use of staff time and can also provide reports and error resolution for IIS-AOs (P12).

DATA AT REST ANALYSIS PLAN

IIS staff should develop a data quality plan (P13) that factors in frequency of analysis, prioritizes metrics of highest interest or impact, and tracks progress and change over time, both at the IIS level and on an IIS-AO-by-IIS-AO basis. *IIS Data Quality Practices – To Monitor and Evaluate Data at Rest*[70] describes specific steps for developing and implementing a data at rest analysis plan. Many IIS have internal reports readily available for this type of analysis, and some have data extract capabilities for use with statistical analysis programs such as SAS to help IIS staff perform these assessments. Appendix F in the *Data Validation Guide for the IIS Onboarding Process*[71] document contains a sample of data quality reports used by different IIS programs.

[70] https://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/
[71] https://repository.immregistries.org/resource/data-validation-guide-for-the-iis-onboarding-process/

EDUCATION AND TRAINING PLAN FOR IIS-AO

In addition to developing a data at rest analysis plan, the IIS program needs to develop an education and training plan for IIS-AOs (P14) that addresses data quality.

By promoting ownership of the data, the IIS program can build a partnership between all stakeholders to take responsibility for ensuring that data in the IIS are of sufficiently high quality to support clinical decision-making and answer key public health questions.

Data-quality education for IIS-AO staff or stakeholders starts at the beginning, during the onboarding phase, and is a journey throughout the full data sharing process. During the data at rest phase, the IIS has a more complete picture of the IIS-AO's data and can provide direct access to reports and queries that often are more robust than what could be developed in the provider organization's EHR system without a primary focus on immunization data. The IIS-AO training and education section of Chapter 9: Implementation Considerations provides more details about IIS-AO training and education.

CLEANING THE DATA

There is no set way to clean or fix data at rest. In general, if data elements are found to be missing for a specific IIS-AO, then that IIS-AO is contacted to identify why the data are missing. Sometimes, the cause might be as simple as an EHR that does not capture the data or perhaps never was coded to send the data to the IIS. In the latter case, IIS staff should help the IIS-AO configure its EHR to send the missing data. Other times, data might be incorrectly coded, which is often found during the onboarding and incoming data quality phases.

Data at rest analysis can identify larger patterns of data quality issues not identified during onboarding and incoming data submission. Sometimes the issues are related to legacy data uploaded before the recent implementation of validation checks. For example, hepatitis B adult vaccines might be shown as having been administered to pediatric patients. If this is consistently documented for an IIS-AO and they can confirm the hepatitis B pediatric doses actually were administered, then it would be up to the IIS to do a one-time cleanup (i.e., script) to change all the erroneous vaccine product types. However, it should be noted that most IIS have turned to having the IIS-AO fix the data and then send in the appropriate data through HL7.

In general, each IIS must determine for itself the best cleaning method for its data issues, because each issue is different and needs special consideration.

6 PROVIDER ORGANIZATION MANAGEMENT

Provider organization management is the process of documenting information about IIS-AOs in an IIS.

Provider organization management is an important component of data quality because it supports efficient and accurate identification of where data originated and where data quality issues transpired.

6 PROVIDER ORGANIZATION MANAGEMENT

BACKGROUND

Provider organization management[72] is the process of documenting information about IIS-AOs in an IIS. The process encompasses the full life span of an IIS-AO, from initial authorization in the IIS through deauthorization. Provider organization management is an important component of data quality because it supports efficient and accurate identification of where data originated and where data quality issues transpired.[73]

Provider organization management has become an expansive and multifaceted topic over the past decade. Demographic and vaccination event submissions may be transported through multiple organizations and systems before arriving in the IIS, so it is crucial to be able to identify which organization is responsible for the original data and which other organizations may have affected the data. Likewise, the development of tools in the IIS to support the VFC program and vaccine management has added to the complexity of how an IIS-AO is identified and represented in an IIS to best support ordering and inventory reporting. There has also been a nationwide push for greater standardization in all areas of the IIS to simplify and clarify expectations and processes for IIS-AOs and EHR vendors.

The group of subject matter experts for this guide was composed of specialists in data quality and did not represent the full breadth of expertise needed to comprehensively address provider organization management. For this reason, this chapter is specifically focused on best practices for provider organization management from the distinct perspective of data quality. MIROW recommends that a separate project address the broader challenges of provider organization management.[74]

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[72] Provider organization management was formerly called facility identification management.

[73] This chapter focuses on provider organization management for IIS-AOs that are involved in submission of data to the IIS since that is how most data quality issues originate. IIS-AOs that do not vaccinate and use the IIS only to review data (i.e., only have the role of data consumer) also need to be appropriately tracked via provider organization management for security purposes, but given the topic of this guide, these IIS-AOs are not a priority for this chapter.

[74] Six business rules from *Data Quality Assurance in Immunization Information Systems: Selected Aspects* were determined to be out of scope for this guide and would be better addressed in a future guide. The original language for the six rules is in Appendix H.

For ease of reading, all provider organizations referenced in this chapter will be referred to as IIS-AOs.[75] Since most IIS-AOs use electronic data exchange, the best practices in this chapter will focus on that method of submitting data to an IIS.

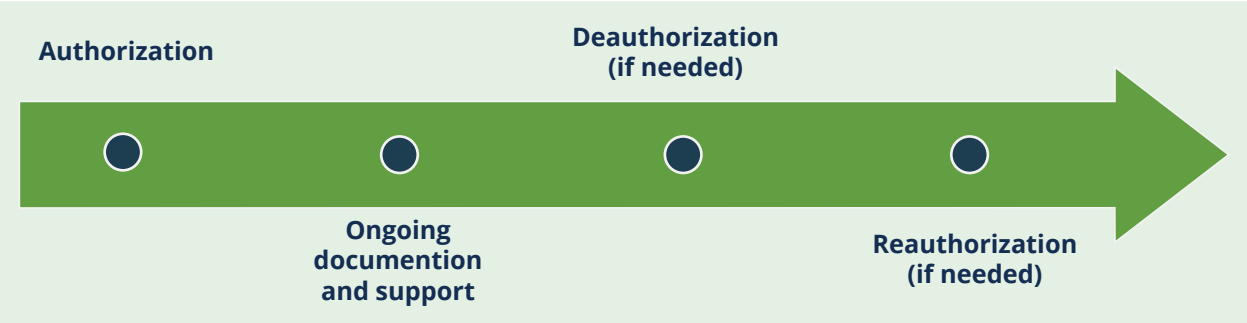
STAGES IN PROVIDER ORGANIZATION MANAGEMENT

IIS programs should document and be consistent in the approaches followed for provider organization management (P17). Since many IIS program staff are involved in tracking and documenting changes to IIS-AOs, it is valuable to create clear procedures for the common stages of provider organization management.

There are four stages of provider organization management:

- Authorization
- Ongoing documentation and support
- Deauthorization
- Reauthorization

Figure 8 | *Stages of provider organization management*



[75] In some jurisdictions, all vaccinating provider organizations are mandated to report to the IIS. However, these mandates do not exist in all jurisdictions, so it is possible for a vaccinating organization and a recording organization not to be enrolled in the IIS. Hopefully, this will become increasingly uncommon as there is greater participation of all types of provider organizations in IIS.

HOW TO IDENTIFY AN INDIVIDUAL IIS-AO

A challenge for IIS programs is determining how to consistently identify individual IIS-AOs. In some situations, all the specialties owned by the same organization and housed at the same address are considered a single IIS-AO. Alternatively, each individual specialty within the organization and address may be identified as an individual IIS-AO. This is often shaped by the preferences of the provider organization or health system. There are pros and cons to both approaches (i.e., lumping or splitting). Identifying IIS-AOs on a more granular level (e.g., by specialty or location within an address) can proving more insight into issues related to data quality and vaccine management. Likewise, greater granularity can make it easier to develop and run reports on individual IIS-AOs to isolate data quality issues. A challenge of this more granular approach is that more upfront work is required to identify IIS-AOs and potentially more work is needed to keep information up to date. Likewise, there may be differences between how the IIS program and the organization want to identify IIS-AOs. This guide does not provide best practices for this topic, because a broader range of expertise would be beneficial in developing those recommendations.

AUTHORIZATION

An IIS program should accept submissions from authorized provider organizations only (BR101). Authorization occurs when an IIS-AO is enrolled in the IIS. The enrollment process includes attending required trainings and completing legal and policy documents (BR103). A provider organization that is enrolled in the IIS is referred to as an IIS-AO since it is authorized to use the IIS. During the enrollment process, the IIS program should collect all information from the IIS-AO needed to support IIS functionality and IIS program communication. Once the IIS program has collected all pertinent initial information, the IIS program can create an IIS-AO ID and provider organization profile for the new IIS-AO.

An IIS program should accept submissions from authorized provider organizations only (BR101).

IIS-AO IDs: When an IIS-AO has been authorized to use the IIS, it should be assigned a unique IIS-AO ID (BR172, BR173). IIS-AO IDs should not include information about the IIS-AO (BR174). When IIS-AO IDs include information that could change over time, there is a risk that IIS programs will have to change IIS-AO IDs for reasons unrelated to the IIS. For example, an IIS-AO ID should not be based on IDs that the health system assigns sites.

IIS-AO names: The IIS should store the legal and common names for an IIS-AO (BR176).

Provider organization profile: A provider organization profile should be created for a new IIS-AO (BR102). Details about the information to include in the profile are listed in BR102. Maintaining information about IIS-AOs is critical for IIS to understand what data to expect, how to interpret data submitted, and with whom to follow up regarding data quality issues. Each IIS-AO, depending on the age and type of population served, is expected to administer a certain range of vaccine types and in specific proportions. The IIS can maintain this information in the provider organization profile and compare incoming data files for conformity to that profile. Some IIS have fields to capture frequency of data submissions in their provider organization profiles and have automated profile checks to help to quickly identify variance from expected patterns. When data do not match what is expected based on the profile, the IIS can identify and highlight the issue.

EHR VENDOR IN THE PROVIDER ORGANIZATION PROFILE

Capturing EHR vendor information in the provider organization profile is useful when looking at issues across the same platform. Although some data quality issues are specific to individual IIS-AOs, other issues can span otherwise unrelated organizations that share the same EHR platform. Maintaining a log of EHR system-specific issues can be helpful in tracking and resolving such issues. While this is most applicable to EHR vendors, it is useful to track any type of health IT modules (e.g., school IT systems).

During the authorization process, the IIS program collects a substantial amount of information from the IIS-AO and should ensure that the IIS-AO staff are aware that they should contact the IIS program if this information changes over time. When enrolling a new IIS-AO, current and future expectations should be documented and agreed upon by the IIS program and IIS-AO (P15).

ONGOING DOCUMENTATION AND SUPPORT

Baseline data, such as frequency of submission of records, can be captured when an IIS-AO is onboarded with the IIS program and should be periodically updated. The baseline data should be reestablished when an IIS-AO is transitioning from one submission method to another or when the IIS-AO's patient population changes (BR102). For VFC providers, data could be captured from the profile developed during VFC certification process and updated during the annual VFC recertification process.

An IIS-AO should notify an IIS program if the IIS-AO has any organizational changes that could impact its interaction with the IIS program (P16).

Organizational changes could include opening or acquiring new locations, moving, or merging, selling, or closing locations. The IIS-AO's information should be fully reviewed whenever the IIS-AO undergoes a structural change (e.g., name, structural hierarchy, submitting relationship, type of submission). IIS should have a formal agreement with IIS-AOs requiring them to notify the IIS program of changes to their organization. IIS programs should also implement a process to regularly remind IIS-AOs to update their information (BR177).

IIS programs also should consider implementing a contact management system and issue-tracking system due to the magnitude of interactions and documents associated with onboarding the jurisdiction's provider organizations. These systems can track IIS-AO and EHR contacts, previous and current data-quality investigations, and follow-up actions. This helps ensure visibility into current and previous data quality issues.

IIS PROGRAM MONITORING FOR NEW PROVIDER ORGANIZATIONS

Occasionally an existing IIS-AO will send records for other provider organizations within its system rather than following the correct process of enrolling and onboarding the new provider organization. For example, a health system opens or acquires new provider organizations but sends data under existing IIS-AO IDs. Regular monitoring of the quantity of records from IIS-AOs may be able to identify when this happens, because there will likely be an increase in records associated with the IIS-AO. However, it may not always be possible to identify this issue via data monitoring. For this reason, IIS programs should regularly remind IIS-AOs and the associated health systems to check if new provider organizations have been opened or acquired.

DEAUTHORIZATION

Deauthorization of an IIS-AO occurs when an IIS program determines that an IIS-AO no longer exists or no longer is willing or capable of meeting the requirements of the IIS program. When an IIS-AO is deauthorized, it ceases to be able to submit data to the IIS or access data from the IIS.

IIS program staff should review the status of IIS-AOs in their jurisdiction and assess whether to deauthorize IIS-AOs that have dissolved (BR179) or are no longer administering vaccine or viewing, recording, or submitting data to the IIS (BR180). An IIS-AO may no longer have a business need to submit or view immunization data but could be reauthorized in the future if necessary and appropriate. The IIS program can also consider deauthorizing an organization that administers vaccines if the organization is not submitting submissions to the IIS and the organization is not required by the IIS to submit data (BR181).[76]

IIS programs should evaluate the status of IIS-AOs and consider deauthorization to ensure that the IIS has accurate information about IIS-AOs (e.g., that an IIS-AO has closed) and to support data security (e.g., that former IIS-AO staff no longer have access to IIS data after their IIS-AO has closed). IIS program staff should contact an IIS-AO before deauthorizing the IIS-AO to confirm that the IIS-AO is closing, opting not to use the IIS (if not required to submit data), or not capable of meeting the requirements of the IIS (BR178).

REAUTHORIZATION

If a deauthorized IIS-AO later reopens or its ability or willingness to adhere to IIS program requirements improves, the IIS-AO can be reauthorized. This could require revisiting part or all the enrollment and onboarding processes. After the IIS-AO is reauthorized, it can submit and access data in the IIS again.

[76] If the organization is required to submit data to the IIS, the IIS program should not deauthorize the organization.

IIS-AO ROLES

To correctly understand and document how an IIS-AO operates in relation to the IIS, it is important to know which of the four IIS-AO roles it performs. The first three roles relate to the process of incoming data submission, and the fourth role addresses access to data in the IIS.

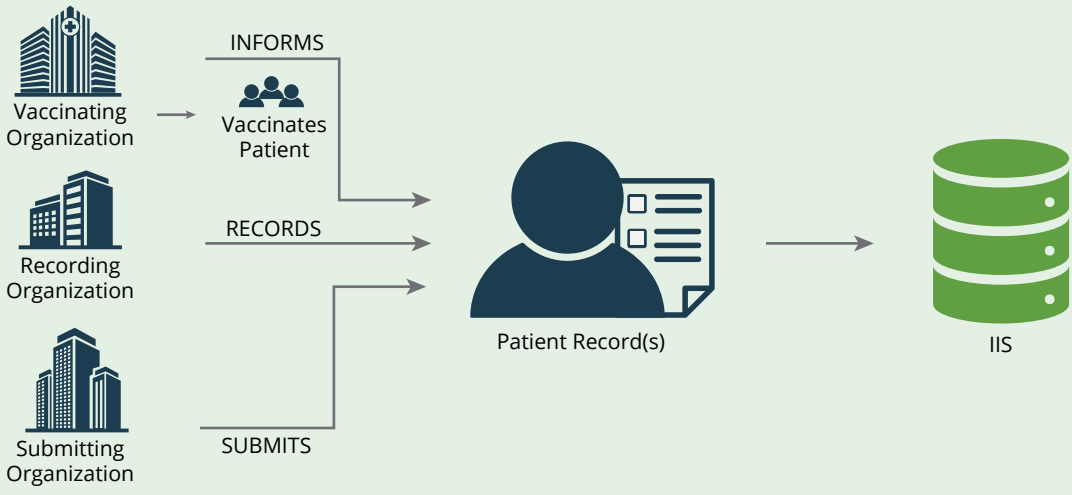
- **Vaccinating organization:** an IIS-AO that vaccinates a patient
- **Recording organization:** an IIS-AO that records information for submission to an IIS
- **Submitting organization:** an IIS-AO that submits information to an IIS or to an intermediary submitter with an IIS as the destination
- **Data consumer:** an IIS-AO that has access to patient immunization history

An IIS-AO can, and often does, perform more than one of these roles; however, it is also possible for different IIS-AOs to perform each role in the process of demographic or vaccination event information entering an IIS.

To identify and remedy data quality issues, the IIS program should identify which IIS-AO:

- Administered the vaccine dose (the vaccinating organization)
- Recorded the demographic and vaccination event information (recording organization)
- Submitted the demographic and vaccination event information to the IIS (submitting organization)

Figure 9 | *Relationship between the IIS-AO roles and the process of submitting records to the IIS*



Each IIS-AO that serves one or more functional roles could introduce different data quality issues into the IIS. Knowing the specific IIS-AO role(s) that each IIS-AO plays allows the IIS to identify and resolve data quality problems more effectively and efficiently. It is beneficial to identify all submitting organizations when more than one organization is involved in the process of submitting the data to the IIS (P21, BR175).

ROLES IN INCOMING DATA SUBMISSION PATHS

To better understand the roles, it is useful to review the actions in the process of incoming data submission.

Reporting of administered vaccination event

An administered vaccination event is one in which an IIS-AO records its own vaccination event. In this path, the vaccinating organization and recording organization are the same IIS-AO. In Figure 10, Org A is both the vaccinating organization and recording organization. The submitting organization may or may not be the same IIS-AO. This is shown as Org A or Org B in Figure 10.

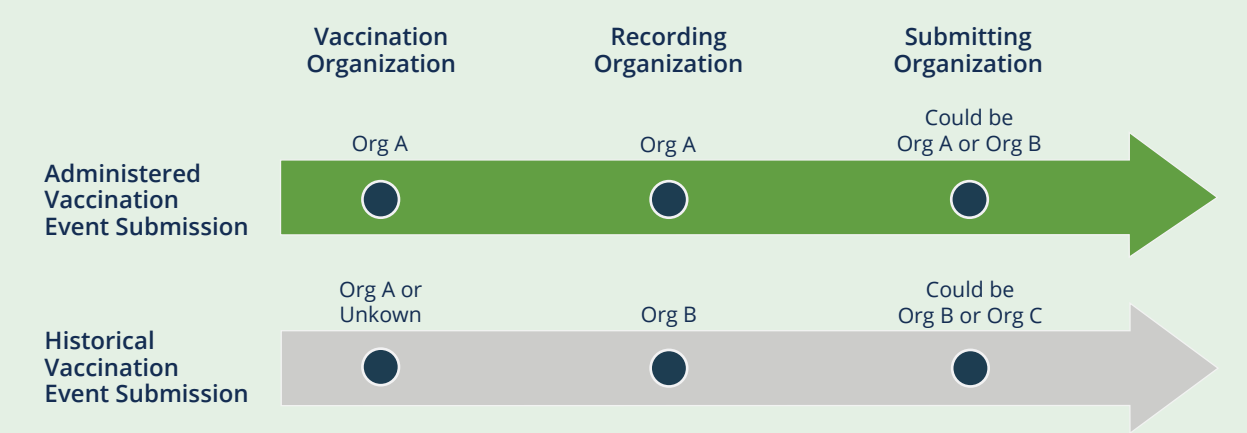
Since more information is generally known about administered vaccination events (e.g., lot number) than historical vaccination events, more data elements are expected to be submitted in administered vaccination event submissions.

Reporting of historical vaccination event

A historical vaccination event is a vaccination event submission that was recorded and submitted by a different organization(s) than performed the vaccination. Because the vaccination is recorded and submitted by organizations other than the vaccinating organization, it is possible for the vaccinating organization to be unknown.

In Figure 10, the vaccinating organization could be either Org A or an unknown organization. The recording organization is Org B because the vaccination event submission is recorded by a different organization than performed the vaccination. The submitting organization is different from the vaccinating organization and may also be different from the recording organization, so it could be Org B or Org C.

Figure 10 | *IIS-AO roles in an administered vaccination event submission and a historical vaccination event submission*



LEGACY DATA

In the past, there have been situations in which IIS-AOs decided to submit administered vaccination events as historical vaccination events because they did not have all the data elements required for an administered vaccination event (e.g., legacy immunizations). However, the updated rules in this guide remove any differences between the vaccination event data elements required for administered and historical vaccination events (BR001). For this reason, there is no reason to incorrectly submit administered vaccination events as historical vaccination events. For more information about current methodologies for the collection of legacy data, please see *Importing Legacy Data to Improve IIS Saturation*.[77]

[77] https://repository.immregistries.org/resource/importing-legacy-data-to-improve-iis-saturation/

Reporting of demographic-only information

A demographic-only submission contains information about the patient (e.g., patient date of birth, patient address) but does not contain any information about vaccines given. Because no vaccination event is reported in a demographic-only submission, there also is no vaccinating organization.

HEALTH INFORMATION EXCHANGES (HIES)

HIEs present unique data-validation challenges. Some act as a simple pass-through from IIS-AO to IIS and back, without changing the data, whereas others transform the data through a program or script to meet submission requirements for the IIS. It is essential to have good and clear communication so that all parties, including and especially IIS-AOs, know who is responsible for each function. When HIEs are involved in the submission process, it can be helpful to clarify and document the HIE's rules and processes as well as who is responsible for the data-quality checks and follow-up with IIS-AOs.[78]

[78] An additional project addressing provider organization management in relation to HIEs could be beneficial.

Table 1 | *IIS-AO roles in different incoming data submission scenarios*

The following table presents scenarios illustrating the roles that IIS-AO can play in the chain of reporting vaccination and demographic information to IIS.

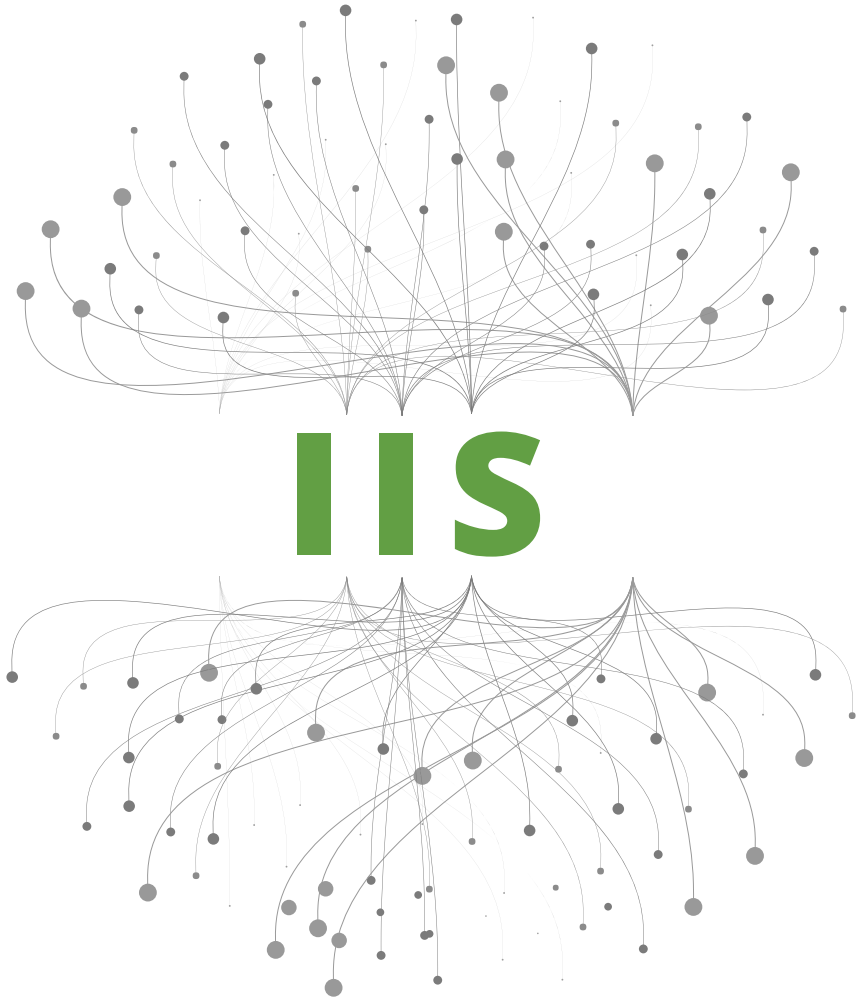
SAMPLE SCENARIOS	VACCINATING ORGANIZATION	RECORDING ORGANIZATION	SUBMITTING ORGANIZATION(S)
Org A is a self-reporting vaccinating organization.	Org A	Org A	Org A
Org B is submitting an administered vaccination event submission to the IIS on behalf of Org A.	Org A	Org A	Org B
Org B is submitting an administered vaccination event submission to the IIS on behalf of Org A. Org B submits via Org C.	Org A	Org A	Org B, Org C[79]
Org B is entering and submitting historical vaccination information. Org A was the original vaccinating organization and is known.	Org A	Org B	Org B
Org A is entering and submitting historical vaccination information. The original vaccinating organization is unknown.	Not Applicable	Org A	Org A
Org A is entering historical vaccination information, Org B is submitting it on behalf of Org A, and the original vaccinating organization is unknown.	Not Applicable	Org A	Org B
Org A is reporting demographic-only information directly to the IIS.	Not Applicable	Org A	Org A
Org B is submitting demographic-only information on behalf of Org A.	Not Applicable	Org A	Org B

COMMUNICATING ROLE INFORMATION IN HL7 MESSAGES

Several HL7 fields can be used to track which IIS-AOs performed which roles for a submission. Although a substantial amount of information about roles can be communicated via HL7, communication challenges arise when multiple IIS-AOs perform the role of submitting organization. When only one submitting organization can be identified, it should be the first submitting organization in the submittal chain. Detailed information about the specific HL7 fields is provided in Appendix I.

[79] This level of detail is not currently possible using HL7. HL7 messaging can communicate that Org B or Org C are the submitting organization but cannot communicate that both are the submitting organizations. Detailed information about the specific HL7 fields is provided in Appendix I.

In summary, provider organization management supports data quality by providing insight into which IIS-AOs interacted with records that were submitted to the IIS and allowing the IIS program to resolve data quality issues more efficiently and effectively.



7 PRINCIPLES

Principles provide high-level guidance. They are broad in scope and reflect business guidelines, practices, or norms that the group chose to follow. Principles guide and direct the development of more specific business rules.

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Principles provide high-level guidance. They are broad in scope and reflect business guidelines, practices, or norms that the group chose to follow. Principles guide and direct the development of more specific business rules.

The table below is organized in the following manner:

- **Principle:**
  - The first part of the rule indicates the statement is a principle (P).
  - The second part is a unique number to identify the principle.
  - The third part is a short name for the principle.
- **Statement:** The principle itself.
- **Remarks:** An observation and/or examples intended to further explain a principle.

PRINCIPLE	STATEMENT	REMARKS
P01 – Multiple approaches to achieve data quality	Data quality should be achieved via multiple approaches such as programmatic and technical resources.	
P02 – Validation priority	The priority of validating a data element is related to the data element's significance in clinical decision-making, public health assessments, and research.	This principle provides priorities for resources that are needed to perform the validation of a data element.
P03 – Timeliness	Data should be reported to the IIS in a timely manner.	Immunization data should be submitted to the IIS on or soon after the vaccination event date to support clinical decision-making and public health assessments.
P04 – Availability	An IIS has the responsibility to ensure data is available to users in a timely manner, once received by the IIS.	
P05 – Mandatory data elements	The submissions should contain the minimum/mandatory set of data elements in order to be accepted by the IIS.	The minimum/mandatory set of data is necessary to support the functionality of an IIS. Additional relevant data, if available, are valuable when they improve the functionality of IIS (i.e., "We do not want minimum data; we want good data"). Additional data elements could be important (e.g., for epidemiologic surveys and school assessments). The goal is to capture all relevant data on patients and their vaccination events.

PRINCIPLE	STATEMENT	REMARKS
P06 – Cross-field validation	Cross-field validation should occur between multiple vaccination events that comprise a patient's immunization history as well as between components of individual vaccination events.	This principle is a basis for all cross-field validations. Examples: • Vaccine type should match administration route (BR128). • Vaccine product type should be paired with the licensed vaccine manufacturer (BR124).
P07 – Consistent application of business rules	All submissions submitted to an IIS should be subject to the same business rules regardless of how the submissions are reported to the IIS.	For example, if a data element is mandatory for submissions via electronic data exchange, the data element should also be mandatory for submissions via other methods. The technical processes may differ, but the result should be the same. For electronic data exchange, the submission would be rejected. In the user interface, the submission could not be submitted without the data element.
P08 – Submit all available information	An IIS program should educate an IIS-AO on collecting and submitting as much information as possible for the demographic and vaccination event submissions.	
P09 – Advisory Committee on Immunization Practices recommendations	Deviations from Advisory Committee on Immunization Practices recommendations and Food and Drug Administration licensure are indications of potential data quality problems.	In general, vaccine doses should be valid per the Advisory Committee on Immunization Practices recommendations. When Advisory Committee on Immunization Practices recommendations are violated, records should be investigated (flagged and researched).
P10 – Accurately reflect vaccination event	A vaccination event submission should accurately reflect the vaccination event that actually occurred.	Even if a vaccination event submission does not meet data quality standards (e.g., correct vaccination site per vaccine type), it is considered accurate if it reflects what occurred at the vaccination event.
P11 – Develop data quality reports	An IIS program should develop data quality and assessment reports and regularly review and update them.	
P12 – Data quality reports for IIS-AOs	An IIS program should develop data quality and assessment reports for IIS-AOs to use.	These are reports that will be available to the IIS-AO for its own internal use.

PRINCIPLE	STATEMENT	REMARKS
P13 – Develop data quality plan	An IIS program should develop and implement a data quality plan that includes the following: • Training of staff • Timely assessment of reports	
P14 – Educate IIS-AO staff	An IIS program should educate IIS-AO staff on general expectations for data quality of submissions and how to use data quality and assessment reports.	
P15 – Document expectations	An IIS program should document expectations of the IIS program and IIS-AO.	When enrolling a new IIS-AO, current and future expectations should be documented and agreed upon by the IIS program and IIS-AO.
P16 – IIS should be notified about IIS-AO organizational changes	An IIS-AO should notify an IIS program if the IIS-AO has any organizational changes that may impact the IIS-AO's interaction with the IIS program.	For example: open, close, move, acquire, sell, merge, or otherwise update. IIS programs should specify in their memorandums of understanding the requirement for IIS-AOs to notify the IIS program of changes to their organization.
P17 – Consistent provider organization management	IIS should document and be consistent in the approaches followed for provider organization management.	
P18 – Vital records	Vital records should be considered the definitive source for a patient's • Date of birth • Date of death	
P19 – Supremacy of medical records	Medical records are a more reliable and accurate source of immunization data than billing records.	
P20 – Vendor update applications	An IIS program should ensure vendors are using the most up-to-date version of HL7 specification.	
P21 – Complete chain of submitting organizations	A submission should identify all submitting organizations.	This principle is referring to the complete "chain" of submitting organizations.

PRINCIPLE	STATEMENT	REMARKS
P22 – Submission retained	Every unique submission should be retained per jurisdictional policy, along with all errors identified.	
P23 – Reference a directory of known lot numbers	A directory of known lot numbers should be created, maintained, and referenced for lot number validation purposes.	Implementation of this principle is challenging. It is difficult to create and manage a directory of this type at a national level; however, it is also hard to accomplish at a jurisdiction level and may be a poor use of resources for each IIS program to individually develop and manage. For more information see Appendix K: Lot Number Data Quality.
P24 – Reference a directory of manufacturer-specific coding schemes for lot numbers	A directory of manufacturer-specific coding schemes for lot numbers should be created, maintained, and referenced for lot number validation purposes.	Further information is available in *Vaccine Lot Number Patterns: Unit of Sale/Unit of Use Guidance*.[80]
P25 – Maintain reliability of reference directories	Reference directories should be periodically reviewed and reconfirmed as reliable reference sources for validating lot numbers.	The objective of this principle is to maintain a level of confidence in the reference source.

[80] https://repository.immregistries.org/resource/guidance-on-unit-of-sale-unit-of-use-lot-numbers/

8

BUSINESS RULES

Business rules represent specific requirements and decision-making logic for IIS processes and operations. The business rules presented in this guide represent best practice guidance.

8 BUSINESS RULES

Business rules represent specific requirements and decision-making logic for IIS processes and operations. The business rules presented in this guide represent best practice guidance.

BR001 Minimum/mandatory data elements: The following table is a decision table identifying the minimum/mandatory data elements required for each type of submission. This table includes data elements that are the absolute minimum needed to process a submission. The table does not include all information that should be sent to an IIS, nor does it reflect HL7 requirements.[81] The section Mandating data elements in Chapter 9 includes important information about mandatory data elements.

	SUBMISSION			
	Demographic-Only	Administered Vaccination Event + Demographic	Historical Vaccination Event + Demographic	Demographic from Vital Records
Vaccinating Organization		X		
Recording Organization			X	
Submitting Organization	X	X	X	X
Patient First Name	X	X	X	X
Patient Last Name	X	X	X	X
Date of Birth	X	X	X	X
Birth Certificate Number				X
Birth Facility				X
Patient Gender				X[82]
Vaccination Event Date		X	X	
Vaccine Type		X	X	
Administered/Historical Indicator		Administered	Historical	

[81] For example, patient ethnicity and patient race are valuable data elements to be included in a submission but are not minimum/ mandatory data elements.

[82] Some jurisdictions may have policy requirements related to patient gender that could impact the implementation of collection of the data element.

The additional business rules are organized in the following manner:

- Rule:
  - The first part of the rule indicates the statement is a business rule (BR).
  - The second part is a unique number to identify the rule.
  - The third part is a short name for the rule.
- Rule Statement: The rule itself.
- Remarks: An observation and/or examples intended to further explain a rule.

The business rules are presented in an order that follows the life cycle of an IIS-AO engaging with an IIS program through to guidance for possible deauthorization of the IIS-AO. There are many ways to organize and categorize the rules, with no one way being superior to another.

RULE	STATEMENT	REMARKS
BR101 – Authorized provider organization	An IIS program should accept submissions from authorized provider organizations only.	Ensuring that all submissions come from provider organizations that have completed enrollment helps set expectations of IIS-AOs prior to the submittal of data. IIS-AOs also go through the onboarding process, which assesses whether: • The EHR can capture and submit the appropriate information to the IIS • Each IIS-AO using the system is entering the appropriate content
BR102 – Establish provider organization profile	An IIS program should have a provider organization profile for each IIS-AO that includes, but is not limited to, the following: • IIS-AO ID • Cross-reference to prior IIS-AO ID(s) • Organizational and reporting structure • Provider organization type • Frequency of submissions • Estimated volume of vaccination event submissions • Estimated volume of demographic submissions • Method of reporting • Health IT modules (e.g., EHR vendor, school IT system) • Decrementing inventory indicator • Site interface configuration • Training needs • IIS last review of provider organization date	Baseline data can be captured when an IIS-AO initially enrolls with the IIS program and should be periodically updated. Not all information will be or needs to be available when the profile is established. The baseline data should be reestablished when an IIS-AO is transitioning from one submission method to another or when the IIS-AO has a change in its patient population or EHR vendor. For VFC providers, data could be captured from the profile developed during VFC certification process and updated during the annual VFC recertification process.

RULE	STATEMENT	REMARKS
BR103 – Establish signed agreements	An IIS program should require a signed agreement with each vaccinating organization, recording organization, and submitting organization that details the procedures for the following: • Reviewing submission errors • Addressing data quality issues within the time frames established by the IIS program	Possible submission chains (routes) should be determined when the IIS program is onboarding the IIS-AO. Agreements should be established between all parties in the submission chain. A specific point of contact (e.g., an IIS-AO staff person) at each organization should be included in the agreement. The signed agreements should be re-examined as needed when submission method changes. An IIS program should establish a method of organizing the signed agreements in order to track if and when an agreement needs to be signed again.
BR104 – Signed security and confidentiality agreement	An IIS program should require a provider organization to sign a security and confidentiality agreement prior to being authorized.	A security and confidentiality agreement describes the security and confidentiality policies of the IIS and applicable federal, state, local, and territorial laws.[83] Exact agreements vary by jurisdiction. An IIS program should establish a method of organizing the signed agreements in order to track if and when an agreement needs to be signed again.
BR105 – IIS-AO approved for electronic data exchange	An IIS program may accept a submission via electronic data exchange from an IIS-AO only if the IIS-AO has been approved for electronic data exchange submissions.	
BR106 – Administered initial submission	An initial submission for a vaccination event that has the administered/historical indicator as "administered" should be made within 24 hours of the vaccination event.	If the vaccination event is reported after this time frame, it should remain as "administered." Resubmission of immunization information may fall outside the 24-hour window.

[83] *Security Guidance Considerations for Immunization Information Systems* (https://repository.immregistries.org/resource/security-guidance-considerations-for-immunization-information-systems/) and *Confidentiality and Privacy: Considerations for IIS* (https://repository.immregistries.org/resource/aira-confidentiality-and-privacy-considerations-for-iis/) contain additional information about IIS security and confidentiality.

RULE	STATEMENT	REMARKS
BR107 – Vaccination event submission of hepatitis B birth dose	An IIS program should communicate to Vital Records that the vaccination event submission of the hepatitis B birth dose should be before the due date for the second dose of hepatitis B.	The rule is specific to Vital Records, which has a different process that takes more time (thus more time is allowed). For any other IIS-AO (e.g., a birth hospital), an administered vaccination should be reported within one day. If Vital Records feed is not reported within the agreed upon time frame, follow up with Vital Records.
BR108 – Vaccination event submission action code	An IIS should record and implement the action code submitted for every vaccination event submission.	This rule applies for data submitted via electronic data exchange. At a minimum, action codes "A" for add and "D" for delete should be supported by an IIS. More information is provided in Action codes (RXA-21) in Chapter 9.
BR109 – Standard value tables	An IIS program should have standard value tables for validation of the following data elements: • Patient gender • Patient race • Patient ethnicity • Dose-level eligibility • Dose-level public/private indicator	Examples: • Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS)[84] • IIS Health Level 7 (HL7) Implementation[85]
BR110 – Valid calendar dates in a submission	A date in a submission should be a valid calendar date.	For example: patient date of birth, vaccination event date. Best practice is to use only complete dates, but if the day is not available, then the 15th of the month can be submitted.[86] Patient date of birth has a separate default business rule (BR152).
BR111 – Vaccination event date not before patient's date of birth	A vaccination event date should not be before (less than) the patient's date of birth.	
BR112 – Submission not before date of birth	A submission should not be submitted before (less than) the patient's date of birth.	

[84] https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.6065
[85] https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html
[86] *Data Quality Assurance in Immunization Information Systems: Incoming Data*, page 57

RULE	STATEMENT	REMARKS
BR113 – Submission not before vaccination event	A submission should not be submitted before (less than) the vaccination event.	
BR114 – Vaccination event date not after patient's date of death	A vaccination event date in a vaccination event record should not be after (greater than) the patient's date of death.	
BR115 – Vaccination event date not after lot number expiration date	A vaccination event record should not have a vaccination event date that is after (greater than) the lot number expiration date.	An IIS should accept submissions that may reflect possible administration errors.
BR116 – Vaccination event date for birth vaccine types	A vaccination event date in a vaccination event record should be the same as (equal to) the patient's date of birth only if the vaccine dose is in the recommended list of birth vaccine types.	Example: hepatitis B. It is possible for vaccines that are not recommended at birth to be given to a patient at birth, and these should be recorded in the IIS.
BR117 – Vaccine type CVX	An IIS program should educate the IIS-AO and other data exchange partners that CVX code is the preferred method of reporting the vaccine type.	This rule reflects the recommendation for using CVX code for vaccine type instead of Current Procedural Terminology (CPT) codes. Billing systems consistently use CVX, but pharmacies and others may send CPT.
BR118 – Specified formulation for administered	The vaccine type in a vaccination event record should be a specified formulation if it is included in an administered vaccination event submission.	"Unspecified formulation" is a CVX code that allows a vaccination to be reported even if the vaccine formulation is not known. For example, CVX45 = "hepatitis B vaccine, unspecified formulation." Unspecified formulation codes should be reserved for use with historical records that lack vaccine formulation information. Further information is found in the CDC code set tables.[87]

[87] https://www.cdc.gov/vaccines/programs/iis/code-sets.html

RULE	STATEMENT	REMARKS
BR120 – Combination vaccine reported as single vaccination event	An IIS program should educate IIS-AO staff to report a combination vaccine dose as a single vaccination event rather than multiple vaccination events.	CDC's *Updated Guidance for Documenting Vaccine National Drug Codes (NDCs) and Lot Numbers in IISs and EHRs*[88] provides additional input on this topic. Example: If a patient is given MMRV, it should be reported as a dose of MMRV vaccine rather than a dose of MMR vaccine and a dose of varicella vaccine.
BR121 – Vaccine type available in United States	An administered vaccination event submission submitted by a vaccinating organization located in the United States should not include a vaccine type that is not now and has never been available for administration in the United States.	
BR122 – Vaccine has vaccine product type	A vaccination event record should include a vaccine that is classified by a vaccine product type (NDC).	
BR124 – Vaccine product type manufacturer	A vaccination event submission should not include a manufacturer that does not produce the vaccine product type.	It is possible for older vaccination events to have a vaccine type or vaccine product type attributed to a manufacturer (MVX) which no longer makes that vaccine type or vaccine product type.
BR125 – Patient age within recommended range	A patient record should not be associated with a vaccination event record where the patient's age is less than or equal to the minimum age or greater than or equal to the maximum age recommended for the vaccine product type.	
BR126 – Vaccine information should be consistent	The vaccine product type, vaccine type, and vaccine manufacturer should be consistent with one another.	
BR127 – Vaccination event dosage	An administered vaccination event submission should have a vaccination event dosage with all the following: • A value that is a positive number • A unit of volume measurement (e.g., mL)	If the value is zero (represented by 999 in HL7), the presumption is that field was not filled.

[88] https://www.cdc.gov/vaccines/programs/iis/2d-barcodes/downloads/guidance-documenting-ndc.pdf

RULE	STATEMENT	REMARKS
BR128 – Approved vaccine administration method	A vaccine route of administration, vaccine site of administration, and vaccination event dosage should be consistent with the vaccine product type and patient age.	The route, site, and dosage should match to CDC's approved usage list.[89] Examples of incorrect combinations: • Hepatitis B site reported as subcutaneous rather than intramuscular. • Vaccine is rotavirus. Route is PO (oral) and site is left deltoid.
BR129 – Lot number validation	A lot number in a vaccination event record should include only the following types of characters: • Alphabetic • Numeric • Dash (-)	IIS programs should educate IIS-AOs that a dash (-) is the only special character that a lot number can contain. Spaces around the dash are not allowed.
BR130 – Number contains information for only one lot number	Lot number in a vaccination event record should contain a single lot number and no other additional information.	A helpful pattern to recognize violations: in some cases, when lot number data element contains information about two or more lot numbers (which is a violation of this business rule), the lot numbers are separated by "/" or ",". Other forms of separation are possible; for example, the second lot number might begin with "AHBV" or another combination of characters. For more information see Appendix K: Lot Number Data Quality.
BR131 – Lot number recommended	Lot number information should be reported for every vaccine dose administered.	Further guidance regarding lot numbers can be found at *Updated Guidance for Documenting Vaccine NDCs and Lot numbers in IIS and EHRs*.[90]
BR132 – Lot number accuracy	Lot number should not be prefixed, appended, or embedded with extraneous character strings.	See Appendix K: Lot Number Data Quality for examples of potential extraneous character strings that may occur.

[89] https://www.cdc.gov/vaccines/hcp/admin/administer-vaccines.html
[90] https://www.cdc.gov/vaccines/programs/iis/2d-barcodes/downloads/guidance-documenting-ndc.pdf

RULE	STATEMENT	REMARKS
BR133 – Vaccine product license	A vaccine product type in a vaccination event record should have all the following: • A vaccine product license begin date before or the same as the vaccination event date • A vaccine product license end date after or the same as the vaccination event date	Example: CVX code = 51 (Hep B-Hib) should not be recorded as given in 1957, because it was implemented in the United States around 1989. This can be a challenging collection of data to maintain over time. An exception to this rule may be vaccines administered as part of a clinical trial.
BR134 – Dose-level eligibility indicated	A dose-level eligibility should be indicated for each administered vaccination event submission.	
BR135 – Consistent vaccine eligibility	The dose-level public/private indicator and dose-level eligibility in a vaccination event record should be consistent with each other.	This rule is important for vaccine accountability. For more information see *Immunization Information System Inventory Management Operations*[91] and *Decrementing Inventory via Electronic Data Exchange*.[92] The recipient of the vaccine should be eligible to receive that vaccine from the program offering it. This rule might not be applicable for pandemic-specific vaccines.
BR136 – Educate IIS-AO on when to use historical	An IIS program should educate IIS-AO staff that they should submit a vaccination event submission with an administered/historical indicator of "historical" only if their IIS-AO did not administer the vaccine dose described in the vaccination event.	
BR137 – Administered/ historical indicator should not be defaulted	An IIS program should not default an administered/historical indicator if it is missing or invalid in a submission.	

[91] https://repository.immregistries.org/resource/immunization-information-system-inventory-management-operations/
[92] https://repository.immregistries.org/resource/decrementing-inventory-via-electronic-data-exchange-1/

RULE	STATEMENT	REMARKS
BR138 – Include vaccine administrator and vaccine prescriber in the submission	A vaccination event submission should include the full name and license number for both the: • Provider who prescribed the vaccine • Provider who administered the vaccine	
BR140 – Expected number of vaccination event records	A patient record should have an expected number of associated vaccination event records based on the patient's age and Advisory Committee on Immunization Practices recommendations.	Example: No more than: • 35 vaccination events before two years of age • 50 vaccination events before five years of age
BR141 – Recommended number of vaccine doses	A patient record should not be associated with more than the recommended number of vaccine doses per vaccine type for the patient's age based on Advisory Committee on Immunization Practices recommendations.	There are rare occasions when a vaccine dose may not have been valid and needed to be repeated or when a patient may be restarting a vaccine series. Example: Seven DTaP vaccines by seven years of age.
BR142 – Minimum intervals for vaccination event records	Vaccination event records for a patient should be at intervals that are equal to or greater than the minimum intervals provided in the Advisory Committee on Immunization Practices recommendations.	
BR143 – Number of vaccine doses in a vaccination encounter	A patient record should not be associated with a vaccination encounter that contains more than the recommended number of vaccine doses.	This business rule is intended to identify outliers. The number of doses recommended per vaccination encounter that would exceed reasonable expectations should be set by the IIS program.
BR144 – Same antigen on same day	A patient record should not be associated with multiple vaccination event records with all the following: • The same vaccination event date • Vaccine product types that include the same antigen	Antigen is determined from the vaccine product type reported, and vaccination event records are matched on antigen. There are instances where the vaccination was compromised and a repeat dose was given on the same day. The vaccines may have been administered by the same or different vaccinating organizations. This rule will often be implemented via the deduplication process.[93]

[93] Scope in Chapter 1: Introduction references several resources for deduplication and consolidation.

RULE	STATEMENT	REMARKS
BR145 – Allowed character for name	All data elements that contain types of names in a demographic record should contain only the following kinds of characters: • Alphabetic • Hyphen "-" • Apostrophe • Accented characters • Space " "	For example: patient first name, mother's maiden name. There may be names that are used that are exceptions to this rule.
BR146 – Use official names	An IIS program should educate IIS-AO staff on the importance of using official patient names.	Because naming requirements vary by jurisdiction, there may be legitimate exceptions to this rule in some jurisdictions. As well, the documentation used to provide the official patient's name may vary by jurisdiction.
BR147 – Patient first name	A patient first name in a demographic record should not remain a generic name after a time period determined by the IIS program.	It can be challenging to determine which names are classified as generic since some terms that are used as placeholder names (e.g., Baby, Male) can also be an official patient first name. IIS programs should establish a specific time period for validating generic names (e.g., three months). The intent is to flag records for the IIS program to inspect, after which the record is not reviewed again for the name anomaly.
BR148 – Patient first and last name two characters	A patient first name and a patient last name in a demographic record each should be at least two characters long.	There may be names that are used that are exceptions to this rule.
BR149 – Mother's name	An IIS program should work with Vital Records to encourage collection and submission of the following: • Mother's maiden name • Mother's first name • Mother's middle name • Mother's last name	

RULE	STATEMENT	REMARKS
BR150 – Leap year age calculation	Date of birth in a demographic record that is February 29 should be assumed as February 28 when calculating age in a non-leap year.	This business rule is intended to assist an IIS that is not currently performing leap year age calculations.
BR151 – Minimum date of birth	Date of birth in a submission should be within a reasonable range based on the current date.	For example, date of birth should be after 1/1/1900.
BR152 – Date of birth default	An IIS program should educate IIS-AO staff to default all the following: • The month of birth to January if the month is not known for the patient • The day of birth to 1 if the day is not known for the patient	This rule applies for patients who do not know their own date of birth. If a date of birth is known by the patient or guardian, it should be used. This rule is not a substitute for collecting and recording a date of birth.
BR153 – More than one patient race	A demographic record should support storing multiple values for patient race.	
BR154 – Complete address	An IIS program should educate IIS-AO staff that a patient address should be valid in order to contact the patient by mail.	
BR155 – International address supported	An IIS should have the ability to store international addresses.	
BR156 – Verified address	An IIS program should verify addresses using a standard address verification service.	This eliminates the need to check for mismatches across address components (e.g., ZIP code and state mismatch). If an IIS program is unable to use a standard address verification service, then it should develop validation rules to verify address in other ways.[94]
BR157 – Patient phone number format	An IIS should have the capacity to include all the following for a patient phone number: • Country code • Area code • Phone number	
BR158 – Patient phone number numeric only	A patient phone number should not include any non-numeric characters (e.g., dashes).	

[94] *IIS Implementation Guidance for a Shared Address Cleansing & Geocoding Service* (https://repository.immregistries.org/resource/iis-implementation-guidance-for-a-shared-address-cleansing-and-geocoding-service/) contains information about address cleansing.

RULE	STATEMENT	REMARKS
BR159 – Educate on use of medical record numbers	An IIS program should educate IIS-AO staff on the following related to medical record numbers: • Maintain unique medical record numbers assigned to a patient and do not reassign the medical record number to another patient. • Do not assign a mother's medical record number to a newborn.	
BR160 – Medical record number not equal to Social Security number	An IIS program should instruct the IIS-AO not to use a patient's Social Security number as a medical record number.	The Social Security Administration communicated that "the card was never intended to serve as a personal identification document—that is, it does not establish that the person presenting the card is actually the person whose name and SSN appear on the card."[95]
BR161 – Record submission errors and submission status	An IIS should record all the following for a submission: • All submission errors • The submission status	IIS-AO should be notified of errors in the submission.
BR162 – Review rejected submissions within five days	A submission should be reviewed by an IIS program within five business days of the submission date if either of the following are true: • The submission has been rejected. • The submission has errors.	There should be a method to review aggregate numbers and identify trends. This review is not intended to examine each submission error.
BR163 – Review the submission reports	An IIS program should review submission reports for errors and deviations in trends.	Submitting organizations should be monitored for trends in errors and accepted submissions alike. Review of information such as the rejection rate and processing rate could be done automatically depending on available IT resources.
BR164 – Hepatitis B birth dose	An IIS program should monitor hepatitis B birth dose vaccination event submissions from Vital Records to identify significant deviations in the number of submissions over time.	

[95] The Story of the Social Security Number (https://www.ssa.gov/policy/docs/ssb/v69n2/v69n2p55.html)

RULE	STATEMENT	REMARKS
BR165 – Vital Records submissions	An IIS program should monitor the number of submissions from Vital Records to identify significant deviations in the number of submissions over time.	
BR166 – Rejected vaccination event submission	An IIS program should monitor the percentage of rejected submissions from an IIS-AO to identify significant deviations in the percentage of rejections over time from the IIS-AO.	
BR167 – Historical vaccination event submissions	An IIS program should monitor the percentage of historical vaccination event submissions from an IIS-AO to identify significant deviations in the number of historical submissions over time from the IIS-AO.	
BR168 – Submissions are appropriate for provider organization type	The administered vaccination event submissions from a vaccinating organization should match all the following for their provider organization type: • Vaccine types • Patient ages	
BR170 – Monitor data element completeness	An IIS program should monitor data element completeness at the IIS and IIS-AO levels for data elements that have a high importance for: • Medical or public health purposes • IIS technical processes • Vaccine accountability	Best practices for an IIS to determine a list of data elements is found in Table 1 of *IIS Data Quality Practices - To Monitor and Evaluate Data at Rest*.[96]
BR171 – Educate, communicate, and perform outreach to improve completeness	An IIS program should educate, communicate, and perform outreach to improve completeness for data elements that have a high importance for: • Medical or public health purposes • IIS technical processes • Vaccine accountability	Best practices for an IIS to determine a list of data elements is found in Table 1 of *IIS Data Quality Practices - To Monitor and Evaluate Data at Rest*.[97]

[96] https://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/
[97] https://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/

RULE	STATEMENT	REMARKS
BR172 – IIS-AO ID issued once authorized	An IIS program should not issue an IIS-AO ID to a provider organization until it is authorized.	
BR173 – IIS-AO IDs should be unique	An IIS program should assign a unique IIS-AO ID to each IIS-AO and never reuse an IIS-AO ID.	
BR174 – IIS-AO IDs should not embed information about the IIS-AO	An IIS program should not embed information about the IIS-AO in the IIS-AO ID.	The intent of this rule is to minimize the need to change IIS-AO IDs over time. For example, information that should not be embedded in the IIS-AOs includes the relationship to other organizations (e.g., submitting organization for or parent of), IIS-AO location, or jurisdiction. Embedding information that can change over time (e.g., relationships, locations) could lead to revising IIS-AO IDs on a regular basis, which is not consistent with best practices. An alternative to embedding information in the IIS-AO ID is to create a new field on the provider organization profile to capture the information.
BR175 – Educate submitting organization to include all IIS-AO IDs	An IIS program should educate the submitting organization on ensuring there are valid IIS-AO IDs included for all IIS-AOs involved in the submission.	
BR176 – Maintain both legal and common names for an IIS-AO	An IIS program should capture all the following for an IIS-AO: • IIS-AO common name • IIS-AO legal name	The common name may need to be shortened in systems with character limits (e.g., VTrckS allows 35 characters). An IIS should display enough of the name for an IIS-AO to be accurately identified.

RULE	STATEMENT	REMARKS
BR177 – Validate organizational and reporting structure regularly	An IIS program should review the organizational and reporting structures of its IIS-AOs on a regular basis.	The organizational and reporting structures are maintained as part of the provider organization profile, which is reviewed on a regular basis. IIS-AOs should be aware that they have a responsibility to report any changes to their IIS program, in addition to the IIS program regular reviews. The IIS program should update IIS-AO attributes and relationships any time a structural change occurs in a provider organization.
BR178 – Contact IIS-AO prior to deauthorizing	An IIS program should contact an IIS-AO before deauthorizing the IIS-AO.	The purpose of contacting the IIS-AO before deauthorization is to confirm that the IIS-AO is closing, opting not to use the IIS (if not required to submit data), or not capable of meeting the requirements of the IIS.
BR179 – Deauthorize IIS-AO if it dissolves	An IIS program should deauthorize an IIS-AO if the IIS-AO dissolves.	Example: The provider at a single provider practice retires, and the site closes permanently.
BR180 – Deauthorize IIS-AO if it no longer plays any IIS-AO roles	An IIS program should deauthorize an IIS-AO if the IIS-AO is not operating in any of the following roles: • Vaccinating organization • Recording organization • Submitting organization • Data consumer	An IIS-AO may no longer have a business need to submit or view immunization data. This could be the result of structural changes. The IIS program determines the appropriate length of time for inactivity. An IIS-AO could be reauthorized in the future if necessary and appropriate.
BR181 – Assess necessity to deauthorize IIS-AO that is not required to submit and is not submitting	An IIS program should consider deauthorizing a vaccinating organization if the vaccinating organization is all the following: • Not required to submit submissions to the IIS • Not submitting submissions to the IIS	This rule applies only to vaccinating organizations (defined as an IIS-AO that vaccinates a patient). This rule is intended to support data security. The IIS program determines the appropriate length of time for inactivity. Applicable only to jurisdictions without a reporting mandate.

BUSINESS RULE VIOLATION ACTIONS

A key element of implementing business rules is determining what action to take if the business rule is violated.

For example, a submission submitted before the vaccination event would violate BR113. Some data quality business rule violations can be identified via review of data (e.g., BR111). Other data quality business rule violations are breaches of policy (e.g., BR107).

A violation action is a response to the breaking of a business rule. Violations can be responded to through technical or programmatic processes.

Technical processes allow business rule violations to be identified and responded to automatically. For example, a violation of the rule that a date in a submission should be a valid calendar date (BR110) could be identified and responded to via technical processes. Programmatic processes for responding to violations can include IIS or immunization program staff calling, emailing, or visiting an IIS-AO. Many business rules in this guide would likely not prompt a violation action. For example, violating BR173, which states that an IIS program should assign a unique IIS-AO ID to each IIS-AO and never reuse an IIS-AO ID, would not lead to a violation action. Because the actor for this rule is the IIS program rather than a system, none of the violation actions discussed in this section would be a logical response.

Given the high priority of standardizing business rules across IIS programs, the data quality subject matter experts[98] discussed whether violation actions also should be standardized or if IIS programs should have flexibility to determine violation actions. The main benefit of standardization would be to ensure that multijurisdictional organizations have the same violation actions in each jurisdiction. The benefits of jurisdiction-level flexibility are that each IIS program can:

- Think strategically about the goals and initiatives of its program
- Determine the pros and cons of each violation action for each business rule based on knowledge about its data and its IIS-AOs
- Avoid overwhelming IIS-AOs by prioritizing which data quality issues should be addressed urgently and which can be addressed later

[98] The subject matter experts who contributed to this document are listed in Appendix M.

The subject matter experts felt the diversity of data quality issues that IIS programs encounter make it reasonable to allow for flexibility in their response. To better support IIS-AOs, especially multijurisdictional organizations, there should be strong communication that explains the violation actions that apply to each business rule. This information should be communicated in the ACK message and in documentation easily accessible by IIS-AOs (e.g., on the IIS program's website) that clearly states the violation action for each business rule. This approach to violation actions allows for business rules and violation actions to evolve over time, so IIS programs are encouraged to develop technical solutions that support their ability to adjust the violation actions associated with a business rule. IIS programs should determine for themselves the violation action taken when a business rule is broken.

VIOLATION ACTION OPTIONS AND CONSIDERATIONS

Four violation actions along with associated considerations are included in Table 2.

Table 2 | *Violation actions and considerations*

TYPE	VIOLATION ACTION	CONSIDERATIONS
Technical solutions	Reject entire submission and return an automated message about issue[99]	• Potential increase in completeness for a specific data element (if that element is mandatory) • Potential decrease in completeness of records if submissions are rejected and not resubmitted • Potential increase in validity if a business rule is related to validity • Potential decrease in validity if IIS-AOs submit invalid data when the real information is unknown or does not meet the requirements of the rule
	Reject only the data in error and return an automated message about issue	• Potential loss of data in error if not resubmitted • Supports keeping the data elements that are valid while removing data elements that are invalid • It is not always possible to reject a data element (e.g., patient first name) without needing to reject the entire submission
	Accept the data and return an automated message about issue	• Allows the IIS program to review data quality issues that need to be corrected • Creates a risk that bad data will enter the IIS and never be corrected
Programmatic solution	Accept the data and communicate and collaborate with the IIS-AO about issue[100]	• Allows for identification of systemic issues (e.g., identifiable via analysis of data at rest) • Creates a risk that bad data will enter the IIS and never be corrected

[99] The automated message is in the form of an ACK message for IIS-AOs that submit via HL7.
[100] Unlike the other three violation actions, which are technical approaches to data quality issues, this response is a programmatic response, which could include an email, phone call, or visit to the IIS-AO.

An additional set of considerations related to selecting a violation action pertains to staff resources. Technical violation actions generally will require the time of technical staff (e.g., developers) to update IIS functionality. Technical violation actions also might require additional IIS staff time to follow up on violations not corrected by the IIS-AO. Programmatic violation actions depend on IIS staff having the time to communicate and collaborate with IIS-AO staff to fix issues.

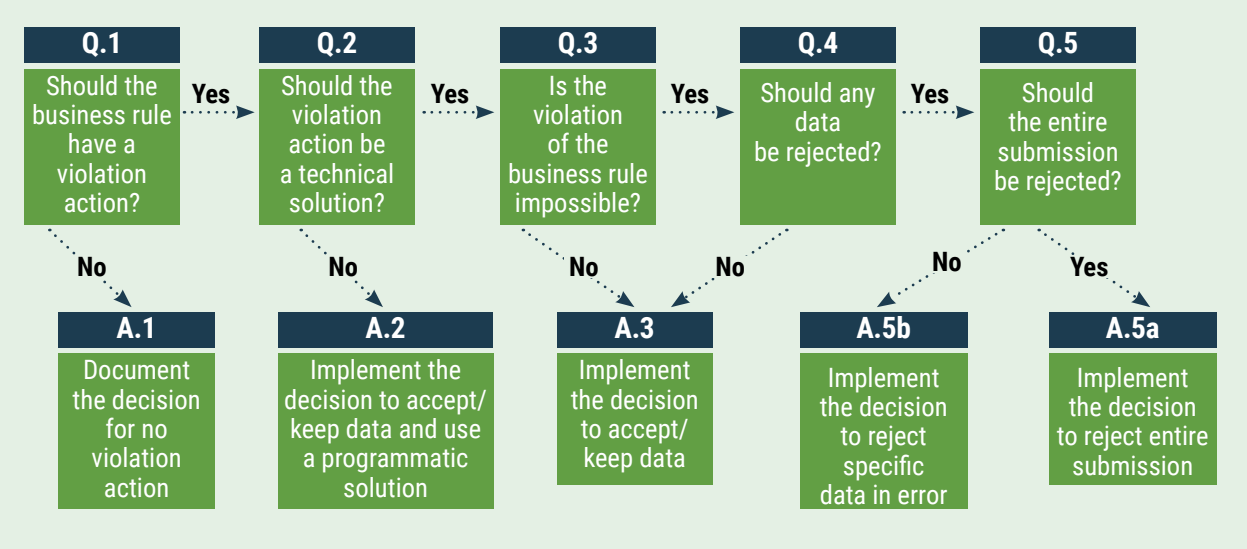
DETERMINE THE VIOLATION ACTION FOR A BUSINESS RULE

The IIS program evaluates each business rule for the impact of a violation before deciding on the appropriate response. Like any IIS program policy, violation actions for business rules should be communicated clearly to IIS-AOs.

The initial step is evaluating the business rule to help inform which violation action might be most effective and appropriate. Some questions to help with the evaluation:

- How common is violation of this business rule?
- Where is this error originating? At what point in the submission process is the error most commonly occurring? Is there one IIS-AO or EHR vendor causing most violations, or is it a widespread issue?
- Could this be addressed during the onboarding process?
- Have there been past attempts to improve this issue? What was the impact of those attempts?
- How significant is the impact of this issue on medical or public health purposes, IIS technical processes, or vaccine accountability?

The following decision tree can be used when considering a potential violation action:



Q.1 Should the business rule have a violation action?

As previously mentioned, not all business rules in this guide need a violation action. Some business rules also could potentially have a violation action but not be high priority for an IIS program relative to other business rules. For example, improving the validity of vaccination event dosage (BR127) might not be a high priority for an IIS program compared to more urgent data quality priorities. IIS programs should attempt to implement all business rules in this guide over time; however, it is reasonable to strategically focus on implementing violation actions for certain business rules before others.

- If yes, proceed to Q.2.
- If no, document the decision for no violation action (A.1).

Q.2 Should the violation action be a technical solution?

Violation of certain business rules can be identified only by analyzing data at rest because a comprehensive assessment of the data over time is required. Violation of these rules cannot be managed via rejecting data or sending an automated message during submission. As an example, IIS program staff would need to analyze data at rest to determine whether an IIS-AO has significant deviations in the number of historical submissions over time (BR167). For violations that cannot be identified during submission, programmatic options such as communication, education, and outreach are often more appropriate actions. Training IIS-AO staff to utilize automated reports in the IIS can be helpful in encouraging IIS-AOs to take ownership of their data quality.

- If yes, proceed to Q.3.
- If no, implement the decision to accept/keep data and use a programmatic solution (A.2).
  - Document, communicate, and implement the decision.

Q.3 Is the violation of the business rule impossible?

"Impossible errors" are situations in which the data submitted cannot possibly be correct in any circumstance due to the laws of time and nature. For example, a vaccine dose administered before the patient's date of birth (BR111) is impossible.

"Possible errors" are errors that could occur in the process of administering a vaccination event. The submission describes a vaccination event that does not meet a clinical best practice (e.g., a dose administered after the lot number expiration date) or common practice (e.g., providing a vaccine outside of the recommended age range) but could have happened as described. A vaccination event submission should accurately reflect the vaccination event that actually occurred (even if it does not meet clinical best or common practices), so the data should not be rejected (P10).

- If yes, proceed to Q.4.
- If no, implement the decision to accept/keep data and return an automated message communicating the issue (A.3).
  - Document, communicate, and implement the decision.
  - If this type of issue is found to be common for a specific IIS-AO, IIS program staff also should consider additional outreach to determine the source of the issue and resolve it.

Q.4 Should any data be rejected?

When determining whether data should be rejected, it is helpful to balance the costs and benefits of accepting versus rejecting the data. In the simplest situation, a submission should be rejected if it is missing data elements needed for basic functions of the IIS (e.g., date of birth for forecasting and deduplication). BR001 includes the data elements that the subject matter experts identified as the minimum/mandatory data elements needed for the basic functions of the IIS. Many other business rules are more complex, and there are strong reasons to support accepting or rejecting data. When potentially invalid data are added to an IIS, the usefulness of the data in the IIS can be reduced along with the trust that partners have in the IIS. When data are rejected from an IIS, the goal is for the IIS-AO to correct and resubmit the data. If the data are fixed and resubmitted, the completeness and validity of data in the IIS is improved. Unfortunately, there are situations in which an IIS-AO might not resubmit data or might resubmit inaccurate data to avoid rejection (e.g., submitting a generic first name when the first name is unknown). When IIS-AOs do not accurately resubmit data, completeness and accuracy suffer.

IIS programs often determine whether to reject data based on the impact to the IIS of accepting the data, whether the IIS program has the resources to follow up on potentially invalid data once accepted into the IIS via programmatic approaches when technical approaches are not practicable, and the likelihood that data will be corrected and resubmitted. An additional factor to consider is how easy it would be for the IIS or IIS program to correct the problem caused by the violation (e.g., low-quality data in the IIS). For example, if the IIS merges all patients and deletes data, unmerging can be very difficult. In this case, a bad date of birth or truncated name could have major consequences that are hard to remedy. If, on the other hand, an IIS has a more sophisticated merging process that preserves previous information and allows for data to be more easily unmerged—especially when recognized early—then the IIS can be more open to accepting the chance of getting some bad data in order to accept good data.[101]

- If yes, proceed to Q.5.
- If no, use A.3 described above.

[101] As previously noted, deduplication and consolidation are out of scope for this document; however, the specific algorithm and process of deduplication and consolidation in an IIS may impact the types of violation actions that are appropriate for implementation for the IIS program.

Q.5 Should the entire submission be rejected?

Rejecting the entire submission means to reject all submissions related to the patient in the submission (i.e., the demographic submission and all vaccination event submissions). The entire submission should be considered for rejection if it has a missing or invalid data element needed for the basic functions of the IIS. For example, if a submission does not include a patient first name, the IIS would reject the entire submission (BR001).

- If yes, implement the decision to reject the entire submission and return an automated message communicating the issue (A.5a).
  - Document, communicate, and implement the decision.
  - IIS program staff also should review reports to identify concerning trends related to rejection of submissions (either for a specific IIS-AO or across all IIS-AOs). IIS program staff should work with IIS-AO staff to fix data quality issues. Step 4.2 in the Chapter 4: Incoming Data Submission describes the process of reviewing reports to identify issues with submissions.
- If no, implement the decision to reject specific erroneous data and return an automated message communicating the issue (A5.b).
  - Document, communicate, and implement the decision.
  - As in the previous step, IIS program staff should review reports to identify concerning trends related to rejection of data (either for a specific IIS-AO or across all IIS-AOs). IIS program staff should work with IIS-AO staff to fix important data quality issues.

This decision tree can be used to evaluate each business rule the IIS program is planning to implement. The IIS program should regularly assess and evaluate the status of data quality in the IIS and consider whether violation actions should be adjusted over time to better address issues.

INVALID VS. UNRECOGNIZED

One challenge for IIS programs and IIS-AOs is that data can be viewed as "invalid" when it is not recognized by the IIS, which can happen when code sets are inaccurate or outdated. For example, an NDC could be valid, but the IIS might not have the NDC in its tables or might have the NDC incorrectly documented in a table. When implementing violation actions, it may be beneficial to consider the impact of rejecting unrecognized versus invalid values.

- An unrecognized value is a coded value that is not known by the IIS (e.g., not in the table). The value could potentially be valid, but the IIS is not aware of it.
- An invalid value is a coded value that is known by the IIS and is previously known to be invalid (e.g., BR121). In practice, there are very few truly invalid codes by this logic.

Chapter 9: Implementation Considerations contains additional information about code sets.

9

IMPLEMENTATION CONSIDERATIONS

9 IMPLEMENTATION CONSIDERATIONS

There are several significant implementation considerations to examine as an IIS program adopts the best practices in this guide.

This chapter covers high-level implementation considerations:

- HL7 standards
- Vaccine code sets
- ACK messages
- Action codes (RXA-21)
- Mandating data elements
- IIS-AO responsibility for data quality
- IIS-AO training and education
- Staff time and resources

HL7 STANDARDS

Not all IIS implement the HL7 specifications in the same way, which can lead to data quality issues. To minimize variation across jurisdictions, especially when there is changing vaccine guidance (e.g., new vaccines, new birth doses), it is important to support and promote the current standards endorsed by the CDC and Office of the National Coordinator for Health Information Technology for HL7 messaging and transport for IIS interfaces (P20). The Aggregate Analysis Reporting Tool (AART)[102] is an application specifically developed to visualize and compile results and information on community-driven measures and tests related to the IIS Functional Standards.[103]

When HL7 specifications[104] are reviewed and updated, it often takes time for the IIS community to catch up with those changes. It is important that an IIS program review the current business logic for data fields, compare it with the updated HL7 specifications, and then address any differences. Equally important is for IIS programs to communicate with IIS-AOs and other partners about plans and schedules to update these specifications.

[102] https://www.immregistries.org/aggregate-analysis-reporting-tool
[103] https://www.cdc.gov/vaccines/programs/iis/func-stds.html
[104] https://repository.immregistries.org/resource/hl7-version-2-5-1-implementation-guide-for-immunization-messaging-release-1-5-1/

HL7 STANDARDS VS. DATA QUALITY OPERATIONAL BEST PRACTICES

It is possible for a message to meet HL7 standards while having low data quality. Likewise, it is possible for a message to have high data quality without fully meeting HL7 standards. IIS programs should educate IIS-AOs on how to successfully implement the technical goals of HL7 standardization as well as on high data quality for the operational requirements of the IIS.

VACCINE CODE SETS

When new values are updated or added to a vaccine code table (e.g., CVX, MVX, NDC), there can be a lag time between their release and when EHRs and IIS implement them.

New values can impact both new and historical vaccination event submissions. EHRs might not reference the same vaccine code tables as those recognized by an IIS; therefore, data are either rejected, omitted, or incorrectly translated because invalid or missing code values were sent. This can lead to mismatched or omitted data in the IIS. To properly evaluate historical vaccination event submissions and successfully support data at rest activities, it is also important to maintain old codes as they change over time. CDC maintains comprehensive lists of code sets,[105] and more information can be found in *Vaccine Code Set Considerations*.[106] Keeping up with changing code sets is a challenge in the IIS community, and there is a need for a standardized approach to updating vaccine code sets to allow both IIS and EHRs to integrate them into their systems. IIS programs should communicate to IIS-AOs the process and resources used to update tables.

[105] Data Code Sets (https://www.cdc.gov/vaccines/programs/iis/code-sets.html)
[106] https://repository.immregistries.org/resource/vaccine-code-set-considerations/

ACK MESSAGES

Data exchange between a sending system and a receiving system consists of a message and a response.[107]

Every time an IIS receives a Vaccination Record Update (VXU) message, it is expected to return an ACK message back to the sending application. ACK messages can be used to identify when a message has been accepted, when it has warnings, when it has errors, and what errors were detected. These messages are a crucial means for IIS to provide feedback to IIS-AOs so they can easily identify data quality issues (P12) and correct them. IIS should return ACK messages for all submissions, including those without issues. If a submission includes an error, the ACK message should provide clear information about the errors for staff at IIS-AOs to review and act on.[108]

There is a need for further standardization of ACK errors and error messaging across all IIS. The IIS community should develop additional guidance on how to standardize error identification and messaging across jurisdictions. Not all EHRs and submitting organizations consistently review ACK messages, and some IIS-AOs do not have easy access to them. Even IIS-AOs that do have access to ACK messages might not be aware of how to find or interpret them. When end users at an IIS-AO do not have access to ACK messages, one strategy is for the IIS program to grant limited access to the IIS to view ACK messages or reports that offer the same information.

[107] Guidance for HL7 ACK Messages to Support Interoperability (https://repository.immregistries.org/files/resources/5835adc2add61/guidance_for_hl7_acknowledgement_messages_to_support_interoperability_.pdf)

[108] Aggregate Immunization Acknowledgment Message Reports Guidance White Paper (https://www.himss.org/resources/aggregate-immunization-acknowledgment-message-reports-guidance-white-paper) provides guidance for clinical software, IIS, and third-party system developers who want to support better access and usage of ACK message data.

ACTION CODES (RXA-21)

If a submission requires correction on the part of the IIS-AO, corrected data may be resubmitted.

If the IIS program notifies the IIS-AO or EHRs that a message should be resubmitted, the vendor should resend the message with the HL7 field RXA-21 indicating what action needs to be taken. This field tells the receiving system what the sending system expects to occur with that vaccination event.[109] The value codes for this field are add ("A"), update ("U"), or delete ("D"), and the field is required for all vaccinations (BR108). However, not all EHRs and IIS are able to send/receive multiple types of action codes. Some EHRs can send only one code (often the add "A" code), and some IIS must delete, then add, in order to update. In some cases, incorrect information needs to be corrected manually in both the EHR and IIS, which is why preventing errors at the time of data entry is important. More on action code concepts and best practices can be found in Chapter 7: Implementation Considerations of the guide *Consolidating Demographic Records and Vaccination Event Records*.[110] IIS should develop protocols to identify when a corrected message has been resubmitted by the IIS-AO.

MANDATING DATA ELEMENTS

A submission should contain the minimum/mandatory set of data elements to meet the basic operational needs of an IIS (P05).

BR001: Minimum/mandatory data elements provides a table with the specific minimum/mandatory data elements, organized by submission type. Unlike other business rules in this guide, there are specific violation actions associated with the data elements in BR001. If BR001 is violated, the violation action options are to reject either:

- The entire submission for the patient if the missing data element impacts the entire submission for the patient
- The specific vaccination event submission if the missing data element impacts only the vaccination event

[109] *HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 2018 Update* (https://repository.immregistries.org/resource/hl7-version-2-5-1-implementation-guide-for-immunization-messaging-release-1-5-1/)
[110] https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/

Mandating a data element is a technical approach (i.e., automatic rejection) to ensure the completeness of a set of data elements in the IIS (e.g., that all accepted submissions will contain a date of birth).

Appendix J: Implementation of BR001 includes specific details on the implementation of the violation action for BR001, including visuals and scenarios.

Minimum/mandatory data elements reflect the absolute minimum amount of information needed to support the operational needs of an IIS. However, the minimum/mandatory data elements do not capture all data elements that may be needed to meet HL7 requirements or jurisdictional and federal policy requirements. Therefore, IIS-AOs should capture and submit all relevant data on patients and their vaccination events (P08) rather than solely meeting the minimum. By providing comprehensive submissions rather than just the minimum/mandatory data elements, IIS-AOs improve the functionality of the IIS, which enables more meaningful usage of IIS data to support medical and public health needs.

Mandating a data element can be an effective method for ensuring completeness of a data element in an IIS; however, there are certain risks associated with this approach.

By emphasizing the value of completeness within the IIS for a single data element, there are potential negative impacts on other data quality characteristics.[111] The risks associated with mandating a data element can be reduced if the IIS program has the resources to alert and prepare IIS-AOs to submit that data element, thus reducing the risk of submissions being rejected. There are also alternative programmatic and technical methods to improve the completeness of a data element without mandating that it be submitted.

[111] Chapter 2: Fundamental Concepts includes more information about the balance between data quality characteristics.

Some programmatic and technical methods of increasing completeness include but are not limited to:

- Immunization Quality Improvement for Providers[112] and VFC programs supporting data quality in the IIS
- Partnerships with medical organizations (e.g., state level chapters of the American Academy of Pediatrics) that can push their members to report complete data elements
- Strong relationships between an IIS program and EHRs
- ACK messaging that provides IIS-AOs with detailed message submission information
- Utilizing two-dimensional (2D) vaccine barcoding to replace manual entry of vaccine information
- Peer pressure within and between IIS-AOs (i.e., bad data in an IIS is a disadvantage to all IIS-AOs)
- Appealing IIS features that incentivize providers to send complete data (e.g., inventory management, reports)

LOT NUMBER

In *Data Quality Assurance in Immunization Information Systems: Selected Aspects,* lot number was added to the list of minimum/mandatory data elements. The current group of data quality subject matter experts determined that lot number should not be included in the list. Appendix K: Lot Number Data Quality contains the details that led to their decision.

IIS-AO RESPONSIBILITY FOR DATA QUALITY

One of the most important and effective strategies IIS can use to ensure the quality of incoming data is to involve the IIS-AOs.

IIS should clearly communicate data quality expectations and refer to these expectations in data use agreements, the onboarding process, and routine program interactions with submitters (e.g., Immunization Quality Improvement for Providers and VFC communications). *IIS Data Quality Practice: Monitoring and Evaluating Data Submissions* provides a list of suggested expectations for ensuring data quality that the IIS program can share with IIS-AOs.[113]

[112] https://www.cdc.gov/vaccines/programs/iqip/
[113] https://repository.immregistries.org/resource/iis-data-quality-practices-monitoring-and-evaluating-data-submissions/

Representatives of the EHR, the IIS-AO, and the IIS program all should participate in the onboarding process, and roles should be clearly defined early in the process. It is crucial to have the participation of clinical staff at the IIS-AO to address workflow issues and handle data quality reviews as they arise. Because IIS-AOs may have different system configurations at each site, it is important to treat each site's data separately and to have representatives from each site participating in the data review. In some situations, separate staff may be available for each function. In others, one person might be responsible for most or all the onboarding and data validation processes. Regular feedback for IIS-AOs is one way to reinforce the virtuous cycle of data use. Another is to share with IIS-AOs how their data compare to established data quality targets.

IIS-AO TRAINING AND EDUCATION

The training and education of IIS-AO staff is fundamental to high-quality IIS data.

It is important that the IIS program implements the appropriate tools and/or reports (P13) for monitoring interface performance and reviewing/troubleshooting error messages. Training for IIS-AO staff can go beyond basic interface training to involve general IIS training and/or specialized training related to HL7 messaging or other technical specifications. IIS-AOs that use the IIS to manage their vaccine inventory will need to reconcile their inventory, which could require additional training.

IIS-AO education should cover some of the data quality characteristics at a high level, but it should also focus on specific data elements, such as proper use of medical record numbers (BR159), how to report combination vaccines (BR120), or proper field structure (BR129).

Education and communication should go both ways between the IIS-AO and the IIS program to allow for continual collaboration and data stewardship.

It is important that IIS program staff and IIS-AO staff remain flexible and keep informed of new technologies and changing priorities to ensure the highest level of data quality.

STAFF TIME AND RESOURCES

Maintaining high data quality can be a time- and resource-intensive process for both IIS-AOs and IIS programs.

It is important to note that specific roles, job titles, and organizational structures vary by IIS program. Relationships among the IIS program and, in some cases, a separate information technology department can inform how certain roles are broken out. In some IIS programs, data quality practices and tasks are split among multiple staff (e.g., one staff person responsible for monitoring HL7 processing and another staff person responsible for data quality outreach). In others, multiple staff share joint responsibility for the data quality practices related to ongoing data submissions, or one staff person leads all the various data quality tasks. IIS programs can refer to the IIS sample role descriptions from the Public Health Informatics Institute[114] for guidance on staffing roles and responsibilities within an IIS program. Additionally, some common IIS, IIS-AO, and EHR job titles and roles are summarized in *Data Validation Guide for the IIS Onboarding Process*.[115]

To implement a successful data quality plan, an IIS needs both funding and IIS functionality.

IIS programs should ensure there is funding to support the long-term infrastructure (e.g., staff to provide education and outreach). Functionality will need to be created in the IIS to run data quality reports and internal tools.[116] This requires the appropriate resources (i.e., funding and staffing) to design, develop, and test the new functionality, as well as to implement a training curriculum for both IIS staff and IIS-AOs.

[114] IIS Workforce Classifications (http://www.phii.org/resources/view/9398/iis-workforce-classifications)
[115] https://repository.immregistries.org/resource/data-validation-guide-for-the-iis-onboarding-process/
[116] Appendix E contains information about a data quality analysis overview report.

APPENDICES

APPENDIX A SCOPE

The scope for the MIROW data quality topic includes recommendations for IIS to ensure high-quality data submitted by IIS-AOs.

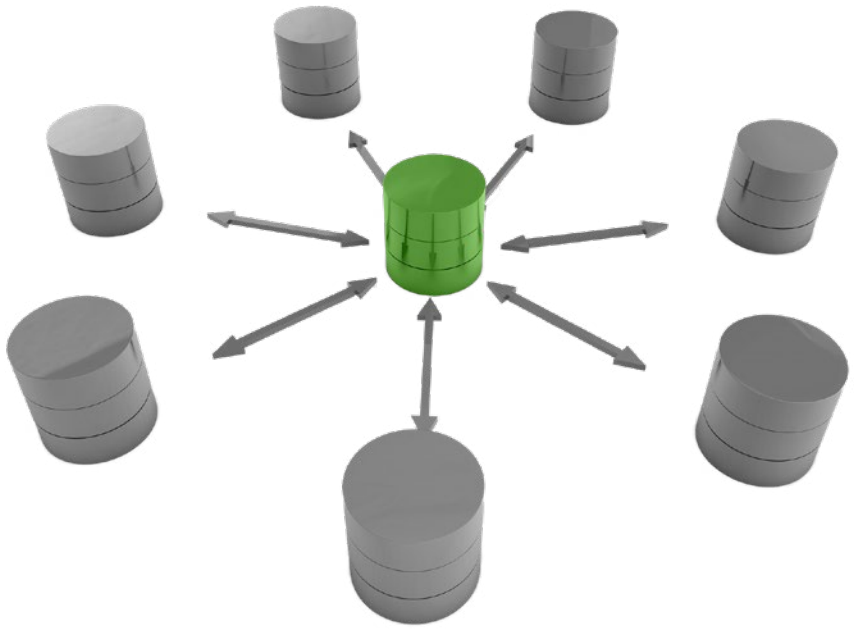
The guide formulates operational best practices for the capture of data that can be used for data analysis, such as immunization coverage assessments and programmatic decision making. The intent is to publish one guide, whose scope includes the following:

- The repackaging and updating of two previous MIROW guides related to data quality:
  - *Data Quality Assurance in Immunization Information Systems: Selected Aspects,* issued May 17, 2013
  - *Data Quality Assurance in Immunization Information Systems: Incoming Data,* issued February 11, 2008
- The inclusion of *Lot Number Validation Best Practices* (a MIROW micro-guide), issued May 8, 2014
- The review, cataloging, and extraction of some business rules based on other resources related to data quality that exist in the IIS community
- A special emphasis on CDC's Immunization Information Systems (IIS) Data Quality Blueprint[117] as resource that informs the actions of the IIS community

FOCUS STATEMENT

Development of a comprehensive overview of consensus-based best practice recommendations for an IIS to address data quality issues related to onboarding, incoming data, and data at rest analysis.

[117] https://www.cdc.gov/vaccines/programs/iis/about.html



INCLUDING

1. Documentation of onboarding and incoming data submission processes with a focus on activities related to data quality
2. Data validation rules for incoming data
3. Aspects of provider organization management, including:
   - Verification of an IIS-AO
   - Rules for the roles of a vaccinating organization, a recording organization, and a submitting organization
   - Rules for deauthorization
4. Monitoring quality assessments of incoming submissions and data at rest that lead to sustainable practices that support data quality
5. Best practices for improving the data quality characteristics of accuracy, availability, completeness, consistency, timeliness, uniqueness, and validity[118] and following CDC's Immunization Information Systems (IIS) Data Quality Blueprint[119]

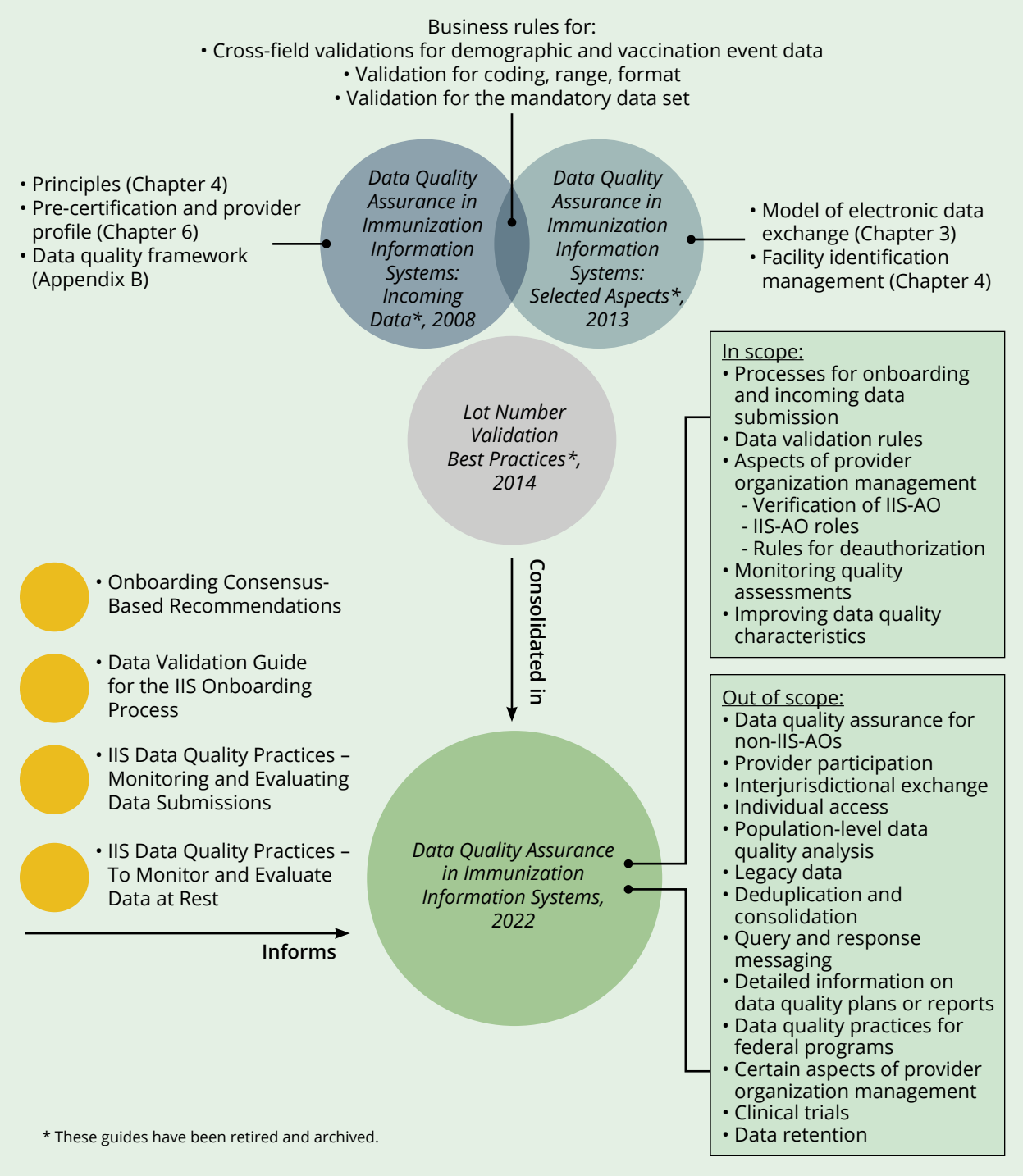
[118] The Immunization Information Systems (IIS) Data Quality Blueprint lists the characteristics starting with "available," since data should be available to answer public health questions. The order of characteristics following "available" is complete, timely, valid, accurate, consistent, and unique.
[119] https://www.cdc.gov/vaccines/programs/iis/about.html

EXCLUDING

1. Data quality assurance for non-IIS-AOs
2. The process of increasing the proportion of provider organizations that submit data to the IIS (i.e., provider participation)
3. Data quality issues related to interjurisdictional exchange or similar processes
4. Individual (person) access/submissions to IIS (e.g., by a patient, guardian)
5. Population-level data quality analysis (e.g., comparisons of IIS population to census data)
6. Importing legacy data (e.g., data collected before the provider organization was connected to the IIS) into IIS to improve data saturation[120]
7. Processes to support deduplication and consolidation of records[121]
8. Data quality topics related to query/response messaging
9. Detailed information about developing and implementing a data quality plan or a data at rest quality analysis plan
10. Detailed information on reports that can be developed to support data quality assurance
11. Specific data quality practices conducted by IIS and immunization programs in the administration of federal programs, such as Immunization Quality Improvement for Providers and VFC
12. Aspects of provider organization management, including:
    a. Standardization for identification of provider organizations
    b. Perspectives beyond that of data quality assurance (e.g., vaccine management, VFC, EHR vendors, providers)
13. Clinical trial considerations
14. Policy recommendations related to data retention

[120] For information on legacy data, see *Importing Legacy Data to Improve IIS Saturation* (https://repository.immregistries.org/resource/importing-legacy-data-to-improve-iis-saturation/).
[121] The Scope in Chapter 1: Introduction references several resources for deduplication and consolidation.

Figure 11 | *Topics included and excluded from the scope*



DOCUMENTS USED IN DEVELOPMENT OF THIS GUIDE

DOCUMENT NAME	RELATIONSHIP WITH THIS GUIDE
Data Quality Assurance in Immunization Information Systems: Selected Aspects	Replaced by this guide and retired[122]
Data Quality Assurance in Immunization Information Systems: Incoming Data	
Lot Number Validation Best Practices	
Onboarding Consensus-Based Recommendations[123]	Informs this guide
Data Validation Guide for the IIS Onboarding Process[124]	
IIS Data Quality Practices – Monitoring and Evaluating Data Submission[125]	
IIS Data Quality Practices – To Monitor and Evaluate Data at Rest[126]	

[122] Please email info@immregistries.org to receive copies the three archived MIROW documents.
[123] https://repository.immregistries.org/resource/onboarding-consensus-based-recommendations/
[124] https://repository.immregistries.org/resource/data-validation-guide-for-the-iis-onboarding-process/
[125] https://repository.immregistries.org/resource/iis-data-quality-practices-monitoring-and-evaluating-data-submissions/
[126] https://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/

APPENDIX B SUMMARIZED AIRA DATA QUALITY RESOURCES

The following guides produced by AIRA contain helpful guidance, recommendations, and tools for improving data quality in IIS.

ONBOARDING CONSENSUS-BASED RECOMMENDATIONS (2018)[127]

The *Onboarding Consensus-Based Recommendations guide* was developed to improve and standardize onboarding across jurisdictions. In addition to drawing on existing AIRA resources, subject matter experts from IIS programs, EHR vendors, IIS vendors, and the American Academy of Pediatrics all contributed feedback from their respective viewpoints. This ensures that the guide addresses onboarding from all relevant perspectives. The guide contains two primary sections: (1) Process – Improvements and Recommendations and (2) Implementation – Considerations and Recommendations.

Topics covered in the guide include:

- Onboarding prerequisites
- Roles and responsibilities of onboarding stakeholders
- Improvements and recommendations for each step of the onboarding process
- Data quality testing and validation during the onboarding process
- Implementation considerations and recommendations
- Ways to streamline the onboarding process and reduce the backlog of providers waiting to onboard

Appendix B of the guide contains information on key resources used to develop it and useful additional guidance and tools, including HL7 specifications and sample onboarding materials from IIS programs. Appendix D provides specific recommendations that support process improvements and implementation.

[127] https://repository.immregistries.org/resource/onboarding-consensus-based-recommendations/

DATA VALIDATION GUIDE FOR THE IIS ONBOARDING PROCESS (2017)[128]

The *Data Validation Guide for the IIS Onboarding Process* focuses on the data validation aspect of onboarding. It covers activities that occur after a data source receives a test account, establishes connectivity to the IIS test environment, and receives approval to begin testing. The guide builds on prior IIS community resources. Primary source materials are listed on page three of the guide and include references to MIROW guides, CDC's HL7 Implementation Guide and Addendum, and onboarding materials furnished by IIS.

The guide was developed in expectation that each IIS program will adjust implementation to its own specific needs and concerns. The list of recommendations is not exhaustive. Individual IIS programs may choose to implement additional rules and processes based on their requirements. The recommendations and examples represent an attempt to balance ideal practices with pragmatic considerations of what is possible within an IIS.

Topics covered in the guide include:

- Source of data for the validation process
- Parameters for the test data load
- Accuracy and completeness measures with suggested thresholds
- Methodology approaches for aggregate data review and individual patient record review
- Roles of IIS program, IIS-AO, and EHR staff
- Guidance for successful implementation
- Preparations for Go Live
- Short-term data validation after Go Live

Table 1 contains a prioritized list of data quality business rules that ensure data accuracy. Table 2 provides a list of data elements with recommended completeness thresholds. Appendix D contains information on the development and use of provider profiles and a list of selected data checks in Table D-1. Appendix F gives examples of data quality reports using aggregate data analysis.

[128] https://repository.immregistries.org/resource/data-validation-guide-for-the-iis-onboarding-process/

IIS DATA QUALITY PRACTICES – MONITORING AND EVALUATING DATA SUBMISSIONS (2017)[129]

The *IIS Data Quality Practices – Monitoring and Evaluating Data Submissions* guide offers IIS practical guidance on real-world data monitoring and evaluation practices of incoming data. It is intended to assist IIS in identifying and addressing data quality issues in data submissions to help ensure that IIS data can be used as intended. The guide focuses on the process that begins immediately after a provider has passed the onboarding phase and been approved to submit data to the production environment. The guide also offers recommendations on how to conduct outreach and education to data submitters regarding data quality issues.

Topics covered in the guide include:

- A review of data quality indicators
- Methodologies for data quality review
- Sample data quality monitoring and evaluation protocol
- Strategies for outreach and education regarding data quality
- Implementation considerations
- Sample data monitoring and evaluation reports from IIS
- Review of open-source tools for monitoring and evaluating data submissions

Appendix A contains a list of data elements cross-referenced by use to assist IIS in prioritizing data elements for data quality evaluation and monitoring. Appendix C contains sample data evaluation and monitoring reports from a variety of IIS.

[129] https://repository.immregistries.org/resource/iis-data-quality-practices-monitoring-and-evaluating-data-submissions/

IIS DATA QUALITY PRACTICES – TO MONITOR AND EVALUATE DATA AT REST (2018)[130]

The *IIS Data Quality Practices – To Monitor and Evaluate Data at Rest* guide provides guidance to IIS program staff for assessing and improving the quality of data at rest within the IIS. It discusses techniques, methodologies, and processes for ensuring that the live production data within the IIS is trustworthy and useful. This includes both demographic and immunization record information.

Topics covered in the guide include:

- A description and prioritization of data quality measures
- Systemic data issues related to address accuracy and special deduplication and record merge situations
- General implementation and process considerations
- A step-by-step guide to developing a data quality plan for data at rest
- Sample reports used by IIS programs to monitor and evaluate data at rest

Tables 1 and 2 provide completeness recommendations for demographic and vaccination elements, along with priority assignments. Appendix C provides additional information on patient-level and vaccination-level deduplication. Appendix F has examples of address cleansing projects completed by IIS programs to improve data quality specific to patient addresses. Examples of data quality reports that focus on data at rest can be found in Appendix G.

[130] https://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/

APPENDIX C READING PATHS

The following reading paths represent a minimalistic approach. A curious reader interested in detailed understanding of the "who, what, why, where, when" aspects of data quality assurance should read the entire document.

A reader new to using MIROW documents is encouraged to read *MIROW and the Best Practice Development Process*[131] and Appendix D: Acronyms, Abbreviations, Vocabulary, and Domain Diagram. Those unclear about the scope for this guide should read Appendix A: Scope.

PROGRAM MANAGERS

- Executive Summary
- Chapter 2: Fundamental Concepts
- Chapter 7: Principles
- Chapter 8: Business Rules
- Chapter 9: Implementation Considerations

IMMUNIZATION PROGRAM STAFF

- Executive Summary
- Chapter 2: Fundamental Concepts
- Chapter 3: Onboarding Provider Organizations
- Chapter 4: Incoming Data Submission
- Chapter 5: Data at Rest
- Chapter 6: Provider Organization Management
- Chapter 7: Principles
- Chapter 8: Business Rules
- Chapter 9: Implementation Considerations

[131] https://repository.immregistries.org/resource/mirow-and-the-best-practice-development-process/

DATA QUALITY COORDINATORS

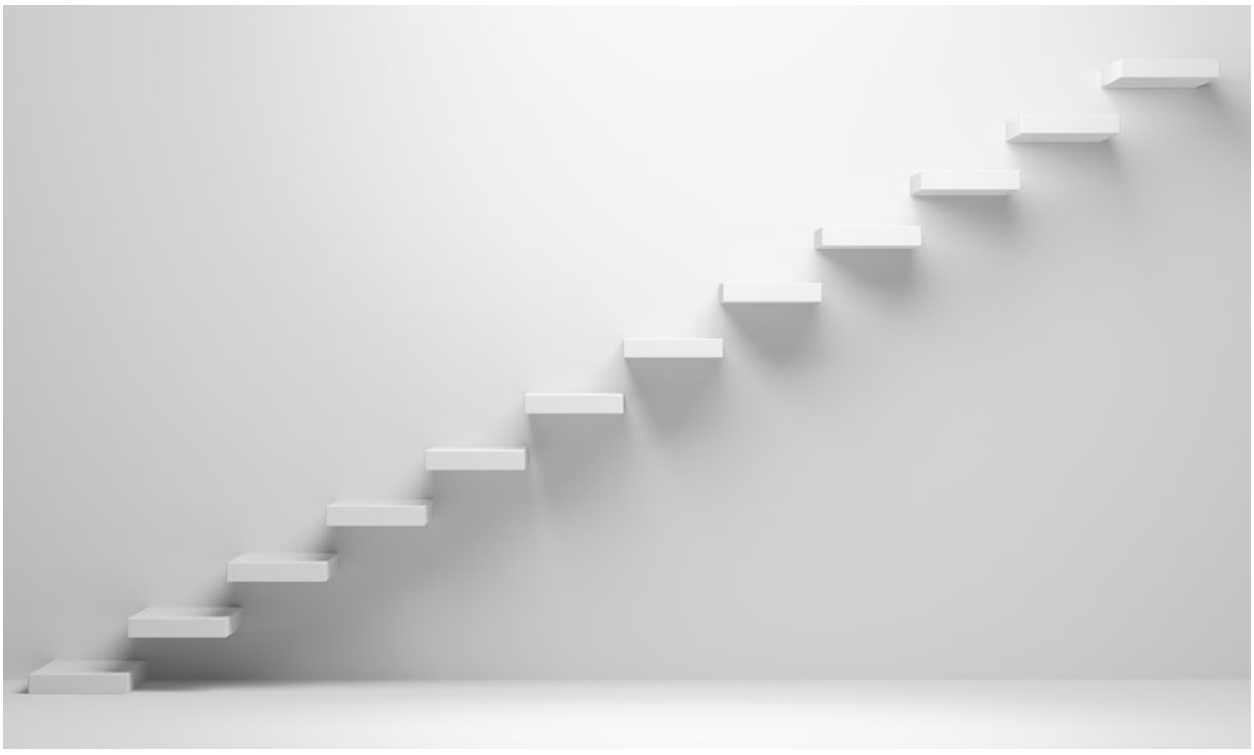
- Executive Summary
- Chapter 2: Fundamental Concepts
- Chapter 3: Onboarding Provider Organizations
- Chapter 4: Incoming Data Submission
- Chapter 5: Data at Rest
- Chapter 6: Provider Organization Management
- Chapter 7: Principles
- Chapter 8: Business Rules
- Chapter 9: Implementation Considerations
- Appendix B: Summarized AIRA Data Quality Resources
- Appendix E: Data Quality Analysis Overview Report
- Appendix F: Patient Record Review
- Appendix G: Inputs and Outputs in Incoming Data Submission
- Appendix H: Provider Organization Management: Out-of-Scope Rules
- Appendix I: HL7 Considerations for IIS-AO Roles
- Appendix J: Implementation of BR001
- Appendix K: Lot Number Data Quality

HL7 IMPLEMENTATION SPECIALISTS

- Executive Summary
- Chapter 2: Fundamental Concepts
- Chapter 3: Onboarding Provider Organizations
- Chapter 4: Incoming Data Submission
- Chapter 5: Data at Rest
- Chapter 6: Provider Organization Management
- Chapter 7: Principles
- Chapter 8: Business Rules
- Chapter 9: Implementation Considerations
- Appendix B: Summarized AIRA Data Quality Resources
- Appendix E: Data Quality Analysis Overview Report
- Appendix F: Patient Record Review
- Appendix G: Inputs and Outputs in Incoming Data Submission
- Appendix H: Provider Organization Management: Out-of-Scope Rules
- Appendix I: HL7 Considerations for IIS-AO Roles
- Appendix J: Implementation of BR001
- Appendix K: Lot Number Data Quality

TECHNICAL DEVELOPERS

- Chapter 7: Principles
- Chapter 8: Business Rules
- Chapter 9: Implementation Considerations
- Appendix D: Acronyms, Abbreviations, Vocabulary, and Domain Diagram
- Appendix I: HL7 Considerations for IIS-AO Roles
- Appendix J: Implementation of BR001
- Appendix K: Lot Number Data Quality



APPENDIX D ACRONYMS, ABBREVIATIONS, VOCABULARY, AND DOMAIN DIAGRAM

This appendix contains vocabulary specific to data quality. For a listing of the full vocabulary from all MIROW guides, see MIROW Common Vocabulary.[132]

ACRONYMS AND ABBREVIATIONS

This section contains a list of acronyms and abbreviations used throughout the document.

ABBREVIATION	
ACK	Health Level Seven code for Acknowledgment
ADT	Health Level Seven code for Admit, Discharge, and Transfer
AIRA	American Immunization Registry Association
BR	Business rule
CDC	Centers for Disease Control and Prevention
CPT code	Current Procedural Terminology code
CVX	Health Level Seven code for Vaccine Administered
EHR	Electronic health record
HIE	Health information exchange
HL7	Health Level Seven International
IIS	Immunization information system
IIS-AO	IIS-authorized organization
MIROW	Modeling of Immunization Registry Operations Work Group
MSH	Health Level Seven code for Message Header
MVX	Health Level Seven code for Vaccine Manufacturer
NDC	National Drug Code
P	Principle (high-level business rule)
RXA	Health Level Seven code for Pharmacy Administration Segment
VFC	Vaccines for Children
VXU message	Health Level Seven code for Vaccination Record Update

[132] https://www.immregistries.org/mirow-common-vocabulary

VOCABULARY AND DOMAIN DIAGRAM

This section contains a vocabulary (i.e., agreed upon terms and definitions) and domain diagrams.

VOCABULARY

TERM	DEFINITION	COMMENT
Action Code	a value submitted on a vaccination event submission (via the HL7 message) that indicates the desired action to be taken on a vaccination event	Examples: "A" (add), "D" (delete), "U" (update).
Address	the place where a party is located or may be reached	A party may be a patient or an organization.
Administered/ Historical Indicator	the type of a submission based on whether submitted by the vaccinating organization ("administered") or by a third party ("historical")	Values for the indicator are administered or historical. • **Administered** means that the provider organization recorded and/or submitted its own vaccination event (i.e., attests that it conducted the vaccination event). • **Historical** means that the provider organization submitted a vaccination event conducted by a different provider organization (i.e., states that it did not conduct the vaccination event).
Antigen	a foreign (non-self) substance found in the body that produces an immune response	Vaccinations allow the immune system to develop a defense against antigens. Every vaccine relates to one or more antigens. Vaccines are designed to confer immunity against specific disease antigens or toxins, like measles, polio and diphtheria. One or more doses of a vaccine, administered over a period of time, may be required to produce long-lasting immunity.
Birth Certificate Number	a registration number for an official document of a patient's date and place of birth and parentage	An example of an alternate patient ID.
Birth Facility	a physical location where a patient is born	Examples: hospital, home.
Cohort	a group of people who share a common characteristic such as age	Typically, the cohort is a population of interest.

TERM	DEFINITION	COMMENT
CVX Code	a numerical identifier used to identify a vaccine type	CVX codes are assigned by CDC.
Data Consumer	an IIS-AO that has access to patient immunization history	
Data Enterer	a person who works for a recording organization and enters submission data	
Data Quality	the degree to which data meets requirements	
Data Quality Assurance	the planning, implementation and control activities that apply quality management techniques to data, in order to assure it is fit for consumption and meets the needs of data consumers	
Date of Birth (DOB)	the date of the patient's birth	
Date of Death (DOD)	the date of the patient's death	
Demographic Data Element	a part of a demographic record	For further information, see tables A-4 and A-6 in *Consolidating Demographic Records and Vaccination Event Records*.[133] Examples: IIS patient ID (unique identifier assigned by IIS to each patient), patient first name, patient last name, date of birth, gender.
Demographic Record	a collection of demographic data elements pertaining to a patient	
Demographic Submission	a submission regarding a patient's demographic information	
Dose-Level Eligibility	a patient's eligibility for a funding program as determined for each administered dose of vaccine	

[133] https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/

TERM	DEFINITION	COMMENT
Dose-Level Public/ Private Indicator	an indicator of the source of funding that paid for a vaccine	Funding source in HL7 specification is the equivalent of the private/public indicator. Lot level public/private indicator is part of the vaccine inventory and discussed in *Immunization Information System Inventory Management Operations*[134] and *Decrementing Inventory via Electronic Data Exchange*.[135] Examples: • Two stock – public, private • Three stock – public VFC, public non-VFC, private
Electronic Data Exchange	an interface in which data can be communicated electronically between an IIS and another system, such as an electronic health record system	
HL7 (Health Level Seven International)	global authority on standards for interoperability of health information technology	
IIS Data Quality	the degree to which data sent to or stored in an IIS meet current standards, support clinical decision-making needs, and are available to answer key public health questions with high confidence	
IIS Patient ID	a unique identifier assigned to a patient by an IIS	
IIS Program	the staff and/or activities that focus primarily on maintaining and operating the IIS in support of immunization program activities	
IIS-AO Common Name	a familiar name by which an IIS-AO is known in the community	This is a public-facing name used by the organization.
IIS-AO ID	a unique identifier assigned by an IIS to represent an IIS-AO	
IIS-AO Legal Name	a name by which an IIS-AO is legally known	

[134] https://repository.immregistries.org/resource/immunization-information-system-inventory-management-operations/
[135] https://repository.immregistries.org/resource/decrementing-inventory-via-electronic-data-exchange-1/

TERM	DEFINITION	COMMENT
IIS-Authorized Organization (IIS-AO)	an organization that has an agreement with an IIS that allows for the submittal and/or retrieval of IIS information	Examples: Provider organization, vital records office, hospitals, schools.
Immunization History	a collection of information detailing vaccination events for a patient	
Immunization Information System (IIS)	a confidential, population-based, computerized database for recording information, including immunization history and vaccine doses given by participating health care providers	
Immunization Program	a public health organization that coordinates public health activities related to immunization for a geographic jurisdiction	
Inventory	a collection of inventory items	
Lot Number	an identifier assigned by a manufacturer to a specific batch of vaccine product type	
Lot Number Expiration Date	the date after which the vaccine is no longer considered potent	
Manufacturer	an organization that produces a vaccine product type	Example: Sanofi Pasteur.
Medicaid Number	a unique identifier assigned to a person for the purposes of receiving medical services financed by Medicaid	An example of an alternate patient ID.
Medical Record Number	an identifier assigned to a patient by the provider organization	
Mother's Maiden Name	the last name under which the patient's mother was born	
MVX Code	an identifier established and maintained by CDC that describes a manufacturer	A re-labeler may also have an MVX code as a distributer but not a manufacturer. Example: Manufacturer Sanofi Pasteur has MVX Code "PMC."

TERM	DEFINITION	COMMENT
NDC	an identifier assigned to a vaccine product type identifying the manufacturer/labeler, product, and presentation	The National Drug Code[136] (NDC) is assigned by the Food and Drug Administration and the manufacturer. There are different NDCs on the outer packaging (or unit of sale, "UoS") and the unit of use (UoU) for the same vaccine product type.[137]
Organization	a party that is a body of people with a particular purpose	
Party	a person or organization	
Patient	a person who is the actual or potential recipient of a vaccine	
Patient Ethnicity	ethnicity of the patient	
Patient First Name	the patient's first name	
Patient Gender	the patient's gender	
Patient Last Name	the patient's last name(s)	
Patient Middle Name	the patient's middle name(s)	
Patient Name	a word or phrase that constitutes the distinctive designation of a patient	
Patient Phone Number	the patient's phone number	
Patient Race	the patient's race	
Patient Record	a record of information for a patient including both demographic record and vaccination event records for that patient	
Person	a human being	
Provider (Provider Individual)	a person who is a medical professional or clinician who works for a provider organization	
Provider Identifier	a unique identifier that labels and establishes the identify of a provider	

[136] https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory
[137] CDC's *Updated Guidance for Documenting Vaccine National Drug Codes (NDCs) and Lot Numbers in IISs and EHRs* (https://www.cdc.gov/vaccines/programs/iis/2d-barcodes/downloads/guidance-documenting-ndc.pdf) provides additional input on this topic.

TERM	DEFINITION	COMMENT
Provider Organization	an organization that has any combination of the following characteristics: • Provides vaccination services • Responsible for an entity that provides vaccination services • Manages inventory for an entity that provides vaccination services	
Provider Organization Profile	a representation of the characteristics associated with a provider organization and its submissions to an IIS	
Provider Organization Type (PO Type/Sub-Type)	a classification system for provider organizations based on a combination of services provided and the cohort served	Examples: obstetrician-gynecologist, pediatrician.
Recording Organization (Recorder)	an IIS-AO that records information for submission to an IIS	
Responsible Party	a person responsible for a patient	Examples: parent, mother, father, guardian.
Submission	a collection of information sent from an IIS-AO to an IIS	
Submission Date	the date a submission is received by an IIS	
Submission Error	the type of error that occurs in the receipt and attempted acceptance of a submission	
Submission Status	the state of a submission upon submission to an IIS	
Submitting Organization (Submitter)	an IIS-AO that submits information to an IIS or to an intermediary submitter with an IIS as the destination	
Time Frame	a period of time, especially with respect to some action or project	

TERM	DEFINITION	COMMENT
Trade Name	the manufacturer's proprietary name for a vaccine type	Some trade names include the intended use in the name, such as adults, pediatrics. The term "trade name" is equivalent to the term "product name" in CDC code sets. Examples: ACTHIB, Comvax, EngerixB-Peds, EngerixB-Adult.
Vaccinating Organization (Vaccinator)	an IIS-AO that vaccinates a patient	
Vaccination Encounter	an opportunity for one or more vaccination events to occur	Vaccination encounter represents an interaction (e.g., office visit) between a patient and a provider organization during which zero, one, or more vaccination events occur. In some cases, no vaccination events take place at a vaccination encounter (e.g., a patient refuses vaccinations).
Vaccination Encounter Date	the date of a vaccination encounter	
Vaccination Encounter Type	a kind of vaccination encounter	Used to indicate if the vaccination encounter was the result of a special event, such as a mass vaccination, or not. Examples: office visit, mass vaccination clinic.
Vaccination Event	a medical occurrence of administering one vaccine to a patient	Vaccination event does not include refusals or contraindications. These are reported as part of the vaccination encounter. Several vaccination events can happen within one vaccination encounter.
Vaccination Event Data Element	a part of a vaccination event record	For further information, see tables A-5 and A-6 in *Consolidating Demographic Records and Vaccination Event Records*.[138] Examples: vaccine product type, manufacturer, lot number.
Vaccination Event Date	the date of the vaccination event	
Vaccination Event Dosage	the measurement of how much vaccine was administered during a vaccination event	Examples: 1 mL, 0.5 mL.
Vaccination Event Record	a collection of related vaccination event data elements pertaining to a vaccination event	

[138] https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/

TERM	DEFINITION	COMMENT
Vaccination Event Submission	a submission regarding a vaccination event(s)	
Vaccination Forecast	the result of applying rules to determine dates for the next vaccine(s) to be administered to a patient	
Vaccine (Vaccine Dose)	a dose of substance administered during a vaccination event	Vaccine is a classification of a vaccine product type that is described by a lot number and other elements. The lot number is not a unique identifier; rather, it identifies a group of vaccines. Example: • Vaccine Type = HepB CVX Code = 8 • Vaccine Product Type: NDC = 58160-0820-11 Manufacturer/MVX code = SKB Trade Name = ENGERIX B-PEDS • Vaccine: Lot Number = ABCD Lot Number Expiration Date = MM/DD/YYYY
Vaccine Product License Begin Date	the date a product license began	
Vaccine Product License End Date	the date a product license ended	
Vaccine Product Type	a classification that describes the manufacturer and presentation of a vaccine type	The vaccine product type is related to the vaccine type, which is a broader grouping, as well as the vaccine, which has a specific value. Examples of vaccine product types that belong to the same vaccine type of HepB, CVX Code = 8, but have different NDC codes: • Vaccine Product Type 1 NDC = 58160-0820-11 Manufacturer/MVX code = SKB Trade Name = ENGERIX B-PEDS • Vaccine Product Type 2 NDC = 00006-4981-00 Manufacturer/MVX code = MSD Trade Name = RECOMBIVAX-PEDS

TERM	DEFINITION	COMMENT
Vaccine Route of Administration	the method of administration for a vaccine	Examples: Intramuscular, intranasal, oral.
Vaccine Site of Administration	the anatomical location where a vaccine is administered	Examples: Arm, thigh, nasal passage.
Vaccine Type	a classification of vaccines that describes the disease to which it provides immunity	The vaccine type is related to: • One or more vaccine product type(s), which includes NDC • The vaccine which is a specific dose Examples: MMR, Hib-HepB, HepB-Peds.

DOMAIN DIAGRAM

How to read a data quality assurance domain diagram

A domain diagram is a high-level representation of the main "things" (terms/concepts), including a description of how these "things" (terms/concepts) are related. It is important to note that the domain diagram is not a technical specification. Instead, the domain diagram provides the foundation (in the form of a vocabulary) for other modeling diagrams and materials.

Relationships between terms are visualized by connecting lines. Names associated with these lines describe the types of relationships between terms and should reflect how the business talks about itself.

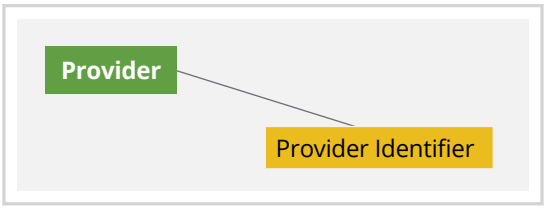
Read the relationships in the direction of the arrow. For example, a **birth facility** *is located at* an **address**:

Birth facility and address are both defined in the term report that is included with the domain diagrams.

An entity (term) may also be acting in a role. For example, an **IIS-Authorized Organization** that *submits* for an **IIS-Authorized Organization** is acting in the role of **Submitting Organization**—the term in [ ] on the diagram.

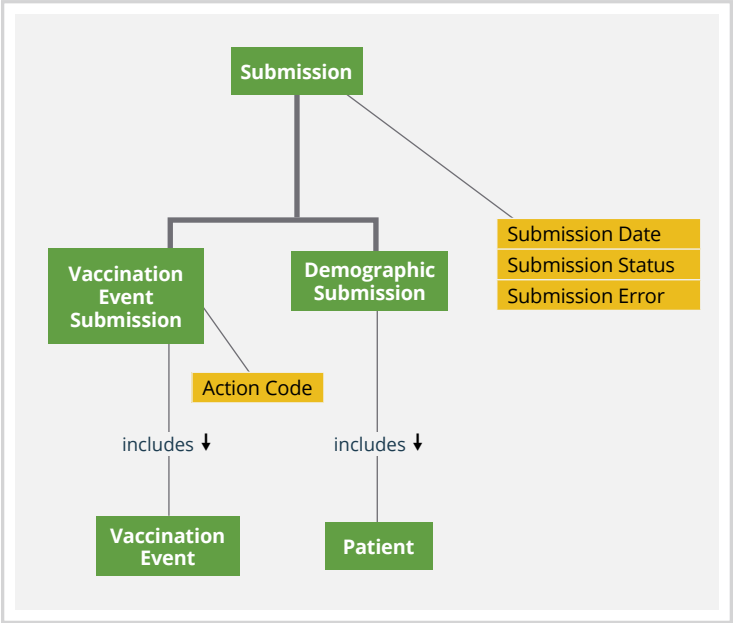
This allows us to use the term **Submitting Organization** in a rule statement and know that it is an **IIS-Authorized Organization** submitting information that is being referenced.

Provider Identifier is an attribute of **Provider**. It has a very close relationship with the term, and the relationship when written out is **Provider** *has* a **Provider Identifier**. Rules will describe the circumstances under which a **Provider** should have a **Provider Identifier**. You may have a Provider without a **Provider Identifier**, but you should not have a **Provider Identifier** without a **Provider**.

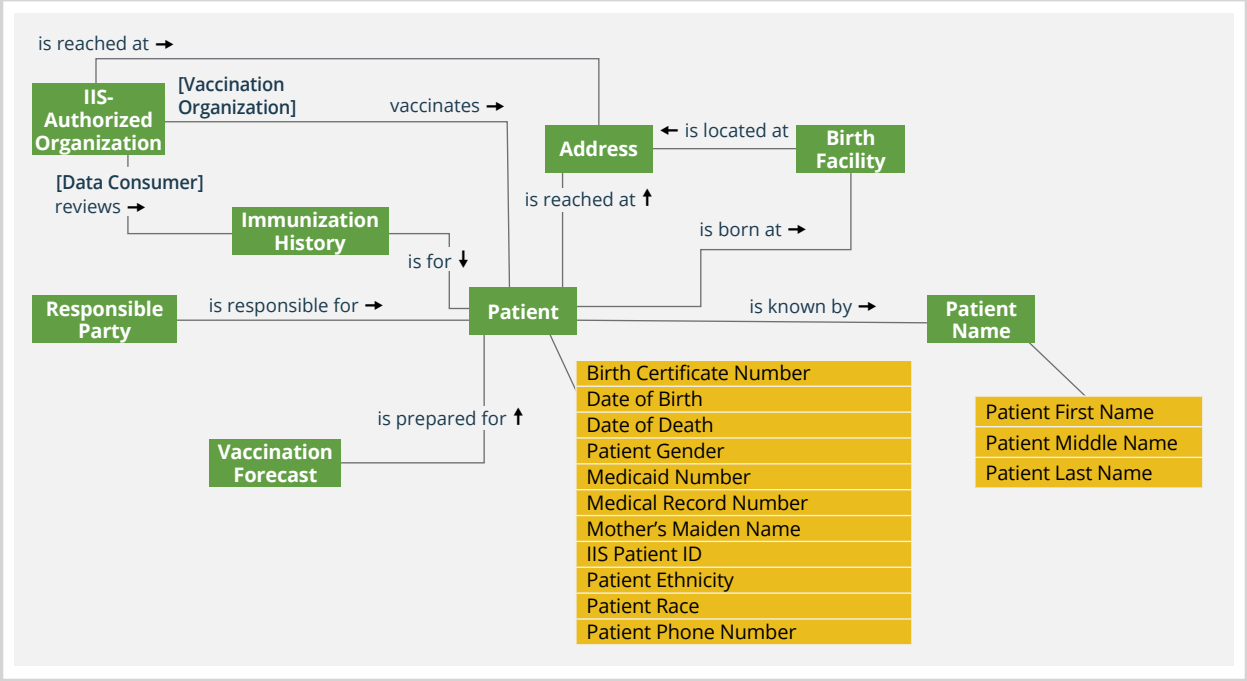


Additional information is provided using categorization schemes. As an example, the following diagram shows that **Vaccination Event Submission** and **Demographic Submission** are types of **Submission**.

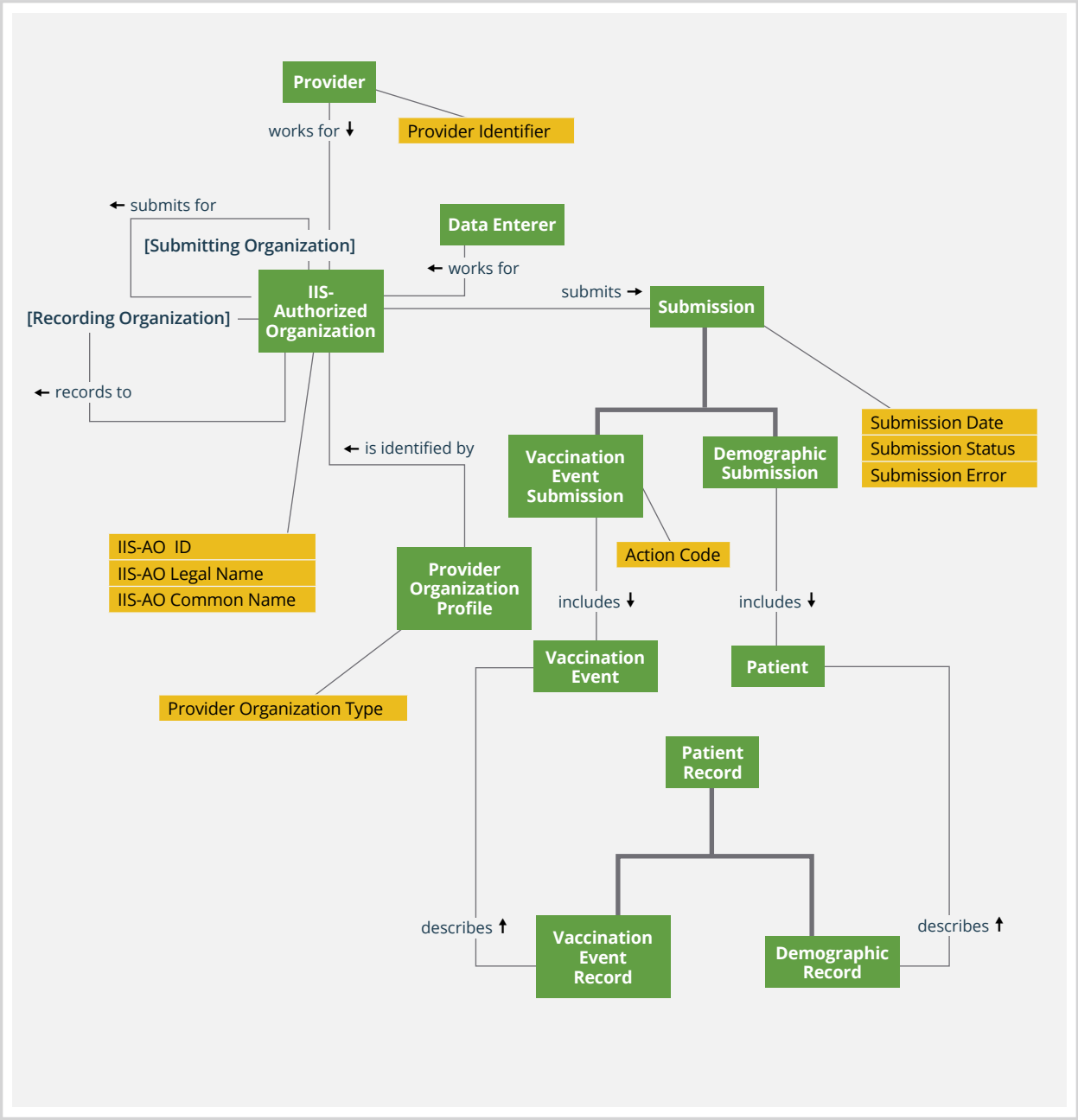
The two terms all share the same characteristics of **Submission** (known as inheritance), such as **Submission Status** and **Submission Date**, etc. Each term will also have information that is specific to it. For example, a **Demographic Submission** *includes* a **Patient**, whereas a **Vaccination Event Submission** *includes* a **Vaccination Event**.



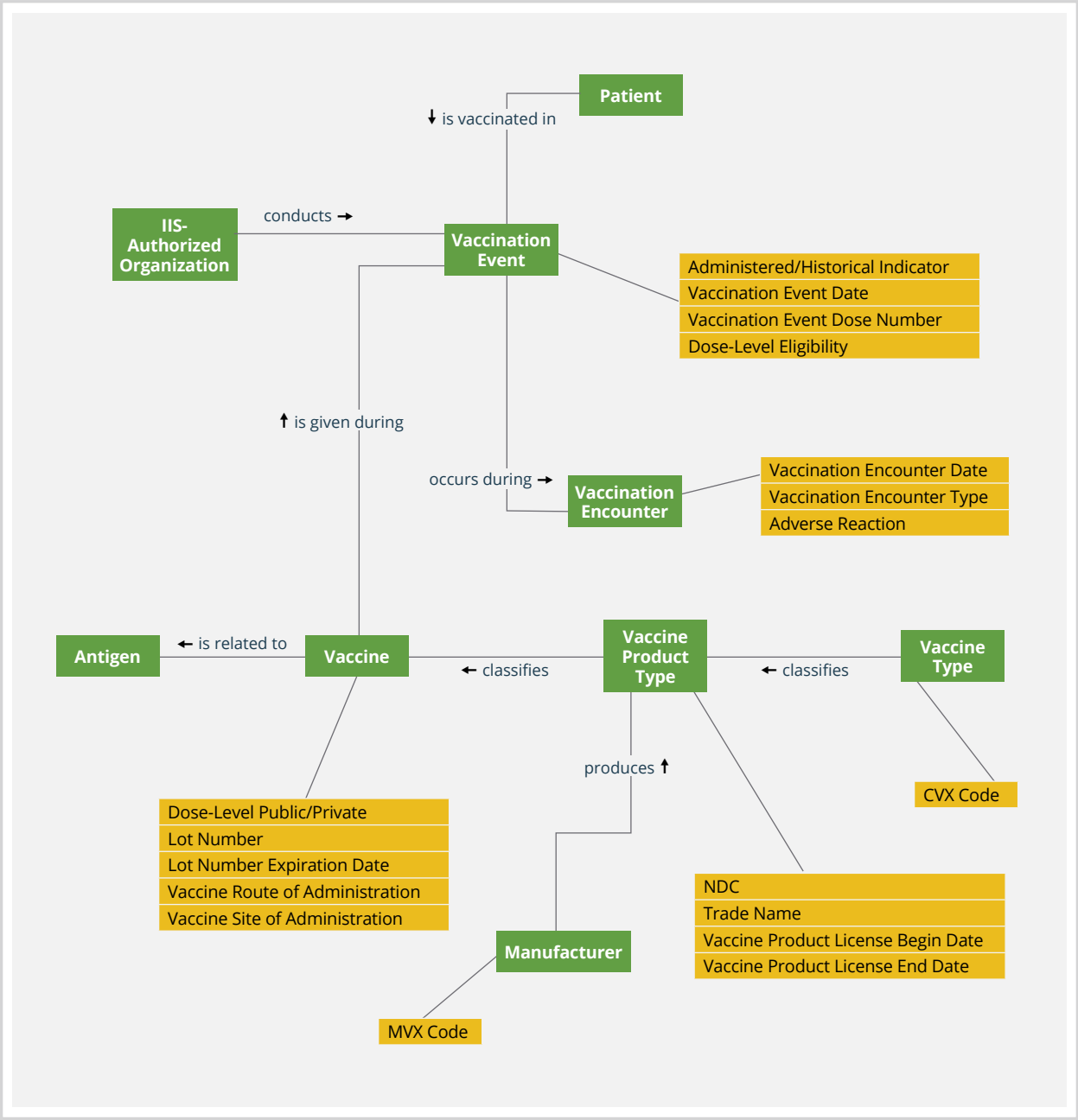
PATIENT



SUBMISSION


Provider
works for
Provider Identifier
submits for
[Submitting Organization]
Data Enterer
works for
[Recording Organization]
IIS-Authorized Organization
submits
Submission
records to
is identified by
Submission Date
Submission Status
Submission Error
Vaccination Event Submission
Demographic Submission
IIS-AO ID
IIS-AO Legal Name
IIS-AO Common Name
Provider Organization Profile
Action Code
includes
includes
Vaccination Event
Patient
Provider Organization Type
Patient Record
describes
Vaccination Event Record
Demographic Record
describes

VACCINATION EVENT



APPENDIX E DATA QUALITY ANALYSIS OVERVIEW REPORT

Any data quality analysis overview report should contain high-level summary metrics of the data received to explain what the data represent (i.e., sample of data versus complete legacy load).

The data would be submitted to a test environment that contains a copy of the production data, when possible, to provide context of how many new records or duplicate records it will create.[139] Summary metric data could include:

- Name and identification number of sending facility
- Report date that analysis was completed
- Dates that summarize data (e.g., submission dates, range for dates of births included)
- Total number of patients, both the number contained in the submissions and a breakdown of how many were created as new patients into the IIS (i.e., how many patients did the IIS not already have)
- Total number of immunizations, both the number contained in the submissions and a breakdown of how many were created as new immunizations into the IIS (i.e., how many immunizations did the IIS not already have)
- Number of potential patient and vaccination event duplicates created
- Number of vaccination events recorded as administered versus historical
- Summary data that can be used for comparison of Vaccines for Children (VFC) program data and provider profile, such as doses administered per age ranges or vaccine eligibility

[139] All appropriate steps should be taken to ensure the test environment is secure to protect patient data.

Each data quality analysis overview report should contain an analysis and breakdown of the completeness of key data elements for both patient and immunization records. Each IIS will need to develop thresholds to help prepare providers on expectations of data quality. A list of these completeness metrics and thresholds can be found in Table 2 in *Data Validation Guide for the Onboarding Process*.[140] Other metrics that may be included are known data quality issues, such as first/last name fields containing "test" or non-typical characters (BR145). Other sections of the reports should include validity metrics to identify records that go against known vaccine practices or patterns (BR143, BR144, BR142). For more information see:

- Chapter 8: Business Rules for applicable business rules
- Appendix D-1 2 (a selected data checks table) and Appendix F (sample reports) in *Data Validation Guide for the Onboarding Process*.[141]

[140] https://repository.immregistries.org/resource/data-validation-guide-for-the-iis-onboarding-process/
[141] https://repository.immregistries.org/resource/data-validation-guide-for-the-iis-onboarding-process/

APPENDIX F PATIENT RECORD REVIEW

In addition to aggregate data review, individual patient record review can be a useful data quality strategy.

Although it is time-consuming and resource-intensive, manual review of patient records can be valuable in revealing problems that are not obvious in an aggregate data review.

A patient record review, or chart review, ensures that data not only "look right" (validity) but actually are right (accuracy). This type of quality assurance involves taking a random sample of patients from the incoming file and comparing all reported data elements to the patient's chart to assess accuracy and completeness. Steps taken could include:

1. Selecting a random sample of records from an incoming file
2. Sending a list of patients to the IIS-AO to pull patients' charts
3. During a site visit, validating each data element from the file against the data in the patient's chart (i.e., a chart audit) by comparing it to what is in the IIS
4. Comparing every element in the file for validation in the chart and, for the encounter dates reported in the file, examining the chart for additional vaccination events that may have occurred at the visit but were not reported in the file
5. Reporting errors/omissions back to the IIS-AO for correction
6. Repeating the process until the IIS is satisfied with the quality of data in the file

This stage involves significant burden to IIS staff as well as IIS-AO staff, and not all IIS-AOs may be willing to provide the time and staff necessary to complete this stage.

Engaging IIS-AO staff in the review process also helps train them for ongoing data quality monitoring processes and encourages them to own the responsibility for high-quality data being sent to the IIS. By promoting ownership of the data, the IIS program can build a partnership among all stakeholders to take responsibility for ensuring that the data in the IIS is of sufficiently high quality to support clinical decision-making and answer key public health questions.

APPENDIX G INPUTS AND OUTPUTS IN INCOMING DATA SUBMISSION

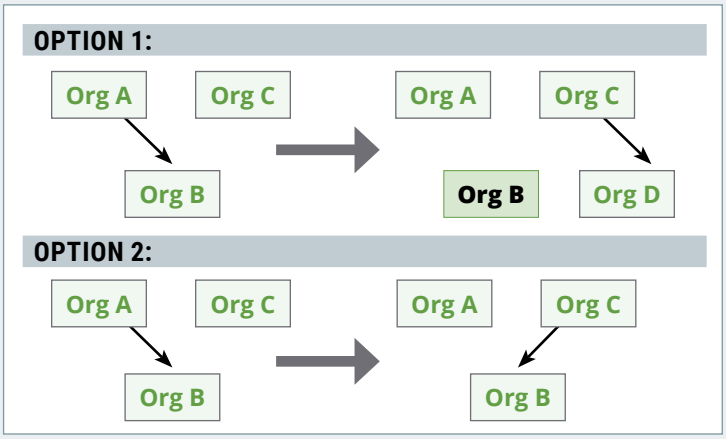
The following table lists the inputs and outputs for each step in the incoming data submission process.

INPUT	ACTION	OUTPUT
Task 1: Collect and Submit Data		
• Patient information	B1.1 Record Patient Encounter	• Validated demographic information
• Patient is due for one or more vaccinations	B1.2 Administer Vaccine	• Vaccination event
• Vaccination event	B1.3 Record Vaccination Event	• Recorded vaccination event
• Verified demographic information • Recorded vaccination event	B1.4 Submit Submission	• Submission of data to the IIS
Task 2: Validate Submission		
• IIS-AO information • Submission of a message	B2.1 Perform IIS-AO Verification	• Verified IIS-AO ID • Verification that the message is a current HL7 version supported by the IIS and meets the technical requirements of the IIS
• Verified IIS-AO ID • Verification that the message is a current HL7 version supported by the IIS and meets the technical requirements of the IIS	B2.2 Validate Submission	• Validated patient record • ACK message
Task 3: Correct Errors		
• ACK messages	B3.1 Correct Errors	• Updated submission file (if needed)
Task 4: Review Submission Reports		
• Reports that provide information on submission and data element rejection rates • Reports that provide information on the timeliness of submissions • Ad hoc reports as needed	B4.1 Review IIS Submission Reports	• Important issues communicated to the IIS-AO • Updates to education/training material
• Submission Reports	B4.2 Review IIS-AO Submission Reports	• Correction of submission issues

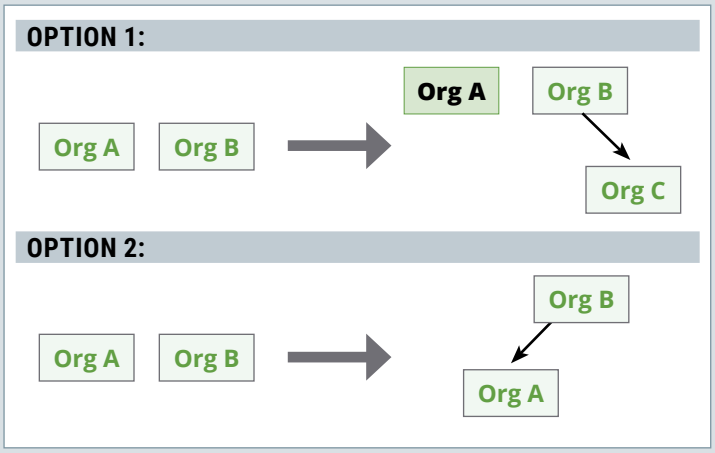
APPENDIX H PROVIDER ORGANIZATION MANAGEMENT: OUT-OF-SCOPE RULES

Provider organization management has become a broad and multifaceted topic over the past decade. The subject matter experts for this guide were specialists in data quality and did not represent the full breadth of expertise needed to comprehensively address provider organization management.

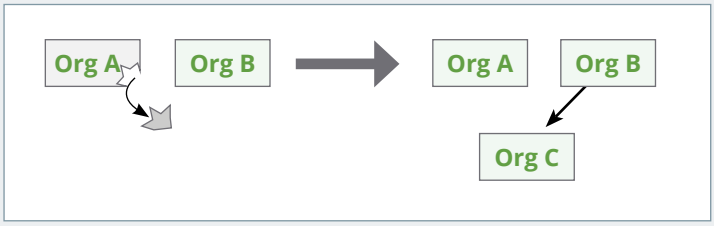
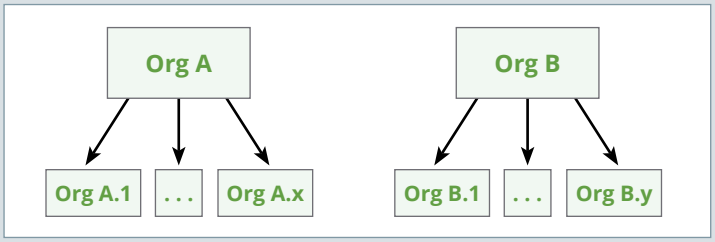
For that reason, this guide is specifically focused on best practices for provider organization management from the perspective of data quality. MIROW recommends that a separate project address the broader challenges of provider organization management. Six business rules from *Data Quality Assurance in Immunization Information Systems: Selected Aspects*[142] were out of scope for this guide and would be better addressed in a future guide. The original language for the six rules is provided below.

RULE	STATEMENT	REMARKS
BR818 – Org B is a part of Org A, is acquired intact by Org C	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: • Option 1: Deauthorize acquired IIS-AO (Org B) and create a new IIS-AO (Org D) with a new IIS-AO ID, and associate it with the acquiring IIS-AO (Org C). • Option 2: Update the structural hierarchy of the acquired (Org B) and acquiring (Org C) IIS-AOs and maintain the acquired IIS-AO ID.	For example:  Consideration needs to be given to the impact on the master/patient index, as well as to other concerns (e.g., patient's consent to share, primary care physician, reminder/recall, medical record number)

[142] Please email info@immregistries.org to receive the archived MIROW guide.

RULE	STATEMENT	REMARKS
BR819 – Stand-alone Org A is "acquired" as an intact sub-unit by another Org	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: • Option 1: Deauthorize 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). • 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:  Consideration needs to be given to the nature of the structural change and applicable jurisdictional rules, etc., to ensure integrity of the patient's association with the appropriate IIS-AO.
BR820 – Org A and Org B merge to form one new organization	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 deauthorized and a new IIS-AO (Org C) should be created with a new IIS-AO ID.	For example: 

RULE	STATEMENT	REMARKS
BR821 – Org B is part of Org A and becomes a new stand-alone entity	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: • Option 1: Deauthorize the original sub-unit (Org B) and create a new IIS-AO (Org C) with a new IIS-AO ID. • Option 2: Remove the structural linkage between the 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.	For example: **OPTION 1:** Org A → Org B Org A, Org C, Org B **OPTION 2:** Org A → Org B Org A, Org B Note: Option 2 will maintain association of IIS data with original IIS- AO. Option 1 might not.

RULE	STATEMENT	REMARKS
BR822 – Portion of Org A is acquired by and becomes a sub-unit of another Org	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): • 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:  Note: This is not the same as providers (i.e., persons) from one organization leaving one IIS-AO and joining another IIS-AO (no changes to be made in this case). In this scenario, providers will no longer be associated with data related to the original IIS-AO.
BR823 – Org A and Org B, containing sub-org units, merge to form one new organization	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:  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.

APPENDIX I HL7 CONSIDERATIONS FOR IIS-AO ROLES

This section provides guidance on how to implement the IIS-AO roles described in Chapter 6: Provider Organization Management using the HL7 messaging standard.

The association between key terms related to provider organization management and the HL7 standard are presented below. As mentioned, MIROW recommends that an additional project address the complexities of provider organization management in greater breadth and depth. Given the quickly changing environment in which IIS are exchanging data, there are many new considerations about how IIS-AOs are tracked. The addition of HIEs and the IZ Gateway to the IIS community has led to many interesting questions about tracking roles. Given the expertise of the subject matter experts and the time available, this section will not attempt to address HIEs or the IZ Gateway.

ORGANIZATION ROLE INFORMATION	HL7 HOME	DEFINITION FROM THE HL7 VERSION 2.5.1 IMPLEMENTATION GUIDE FOR IMMUNIZATION MESSAGING[143]	NOTES
Vaccinating Organization IIS-AO ID	RXA-11 (Administered at Location)	The name and address of the facility that administered the immunization[144]	For an administered vaccination event submission, this IIS-AO ID should be the same as the IIS-AO ID reported for the entering organization (ORC-17). For a historical vaccination event submission, this field may be blank, since the vaccinating organization could be unknown.

[143] https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf

[144] Note that the components listed for use are "Component 4 (the facility name/identifier), Subcomponent 1 (identifier), Subcomponent 2 (Universal ID – This shall be an OID, if populated. Note that this should not be a local code but, rather, a universal ID code), Subcomponent 3 (Universal ID type [specify which universal ID type]), Component 9-15 (Facility address)." In practice, only the "Subcomponent 1 (identifier)" is used.

ORGANIZATION ROLE INFORMATION	HL7 HOME	DEFINITION FROM THE HL7 VERSION 2.5.1 IMPLEMENTATION GUIDE FOR IMMUNIZATION MESSAGING[143]	NOTES
Recording Organization IIS-AO ID	ORC-17 (Entering Organization)	This field identifies the organization that the enterer belonged to at the time he/she enters/maintains the order,[145] such as medical group or department.	For an administered vaccination event submission, this IIS-AO ID should be the same IIS-AO ID reported as the vaccinating organization (RXA-11). For a historical vaccination event submission, this IIS-AO ID should be different from the IIS-AO ID reported as the vaccinating organization (RXA-11).[146] For a historical vaccination event submission, RXA-11 may be blank, since the vaccinating organization could be unknown.
Submitting Organization IIS-AO ID	MSH-22 (Responsible Sending Organization)	Business organization that originated and is accountable for the content of the message.	MSH-22 indicates the organization responsible for the content.
Submitting Organization IIS-AO ID	MSH-4 (Sending Facility)	This field identifies the organization responsible for the operations of the sending application.	MSH-4 indicates the organization responsible for the message at the "application" level.

[145] The provider's vaccination order.

[146] In some cases, an IIS-AO submits an administered vaccination event but does not have all expected information for the expanded set of data items (e.g., legacy immunizations, limited EHR capacity, hepatitis B birth doses). For more information about current methodologies for the collection of legacy data, please see *Importing Legacy Data to Improve IIS Saturation* (https://repository.immregistries.org/resource/importing-legacy-data-to-improve-iis-saturation/).

INDIVIDUAL PERSON INFORMATION	HL7 HOME	DEFINITION FROM THE HL7 VERSION 2.5.1 IMPLEMENTATION GUIDE FOR IMMUNIZATION MESSAGING[147]
Vaccine Prescriber – Provider Identifier	ORC-12 (Ordering Provider)	This field contains the identity of the person who is responsible for creating the request[148] (i.e., ordering physician).[149] In the case where this segment is associated with a historic immunization record and the ordering provider is not known, then this field should not be populated.[150]
Vaccine Administrator – Provider Identifier	RXA-10 (Administering Provider)	This field is intended to contain the name and provider ID of the person physically administering the pharmaceutical.
Data Enterer Identifier	ORC-10 (Entered By)	This identifies the individual that entered this particular order.[151] It may be used in conjunction with an RXA to indicate who recorded a particular immunization.

[147] https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf
[148] The provider's vaccination order.
[149] The National Provider Identifier is one way to identify an individual provider.
[150] Remark: In the case where this segment is associated with a historical immunization record and the administering provider is not known, then this field should not be populated.
[151] The provider's vaccination order.

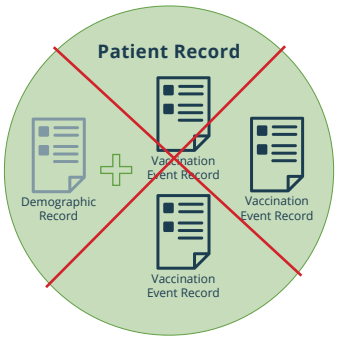
APPENDIX J IMPLEMENTATION OF BR001

This section provides guidance on the violation actions for BR001: Minimum/ mandatory data elements. The section also includes details on four scenarios that highlight the violation actions associated with the rule.

BR001 VIOLATION ACTIONS

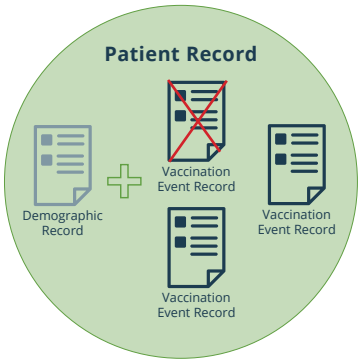
If BR001 is violated, the violation actions should be to reject:

- The entire submission for the patient if the missing data element impacts the entire submission for the patient



or

- The specific vaccination event submission if the missing data element impacts only the vaccination event



SUBMISSION
A submission includes a demographic submission and zero or more vaccination event submissions.

IMPLEMENTATION BY DATA ELEMENT

	SUBMISSION			
	Demographic-Only	Administered Vaccination Event + Demographic	Historical Vaccination Event + Demographic	Demographic from Vital Records
Vaccinating Organization		X		
Recording Organization			X	
Submitting Organization	X	X	X	X
Patient First Name	X	X	X	X
Patient Last Name	X	X	X	X
Date of Birth	X	X	X	X
Birth Certificate Number				X
Birth Facility				X
Patient Gender				X
Vaccination Event Date		X	X	
Vaccine Type		X	X	
Administered/Historical Indicator		Administered	Historical	

LEGEND

Reject entire submission for the patient (i.e., demographic submission and all related vaccination event submissions)	
Reject the specific vaccination event submission with the missing data element	

SCENARIOS FOR BR001

Scenario 1: The submission for a patient named Maxwell Portland includes a demographic submission and one administered vaccination event.

MINIMUM/MANDATORY DATA ELEMENTS	DATA IN THE SUBMISSION
Vaccinating Organization	Clinic A
Recording Organization	
Submitting Organization	Clinic A
Patient First Name	Maxwell
Patient Last Name	Portland
Date of Birth	01/02/2003
Vaccination Event Date	2/16/2022
Vaccine Type	Influenza (CVX: 205)
Administered/Historical Indicator	Administered

Resolution: This submission contains all minimum/mandatory data elements and meets the requirements of BR001. Unless there are other significant issues, this entire submission (i.e., demographic submission and vaccination event submission) should be accepted.

Scenario 2: The submission for a patient named Ashley Laurel includes one demographic submission and one historical vaccination event.

MINIMUM/MANDATORY DATA ELEMENTS	DATA IN THE SUBMISSION
Vaccinating Organization	
Recording Organization	Clinic B
Submitting Organization	Clinic B
Patient First Name	Ashley
Patient Last Name	Laurel
Date of Birth	[Not included]
Vaccination Event Date	2/16/2022
Vaccine Type	Influenza (CVX: 205)
Administered/Historical Indicator	Historical

Resolution: This submission is missing the birth date. Since the birth date impacts the entire submission for the patient, the entire submission (i.e., demographic submission and vaccination event submission) should be rejected.

SCENARIOS FOR BR001

Scenario 3: The submission for a patient named Layla Ashland includes one demographic submission and three administered vaccination events.

MINIMUM/MANDATORY DATA ELEMENTS	DATA IN THE SUBMISSION		
Vaccinating Organization	Clinic C	Clinic C	Clinic C
Recording Organization			
Submitting Organization	Clinic C		
Patient First Name	Layla		
Patient Last Name	Ashland		
Date of Birth	2/01/2021		
Vaccination Event Date	2/07/2022	2/07/2022	2/07/2022
Vaccine Type	Hep A (CVX: 83)	Hep A (CVX: 83)	Hep A (CVX: 83)
Administered/Historical Indicator	Administered	Administered	Administered

Resolution: This submission is missing the vaccination event date for the third vaccination event submission. Since the vaccination event date impacts only the specific vaccination event, the third vaccination event should be rejected. Unless there are other significant issues, the demographic submission and remaining two vaccination event submissions should be accepted.

Scenario 4: The submission for a patient named Jack Dayton includes one demographic submission, one administered vaccination event, and one historical vaccination event.

MINIMUM/MANDATORY DATA ELEMENTS	DATA IN THE SUBMISSION	
Vaccinating Organization	Clinic D	
Recording Organization		Clinic D
Submitting Organization	Clinic D	
Patient First Name	Jack	
Patient Last Name	Dayton	
Date of Birth	12/19/1972	
Vaccination Event Date	2/16/2022	2/16/2022
Vaccine Type	COVID-19 (CVX: 208)	COVID-19 (CVX: 208)
Administered/Historical Indicator	Administered	Administered

Resolution: This submission contains all minimum/mandatory data elements and meets the requirements of BR001. Unless there are other significant issues, this entire submission (i.e., demographic submission and vaccination event submission) should be accepted.

APPENDIX K LOT NUMBER DATA QUALITY

Lot numbers are important for several reasons, including supporting deduplication of vaccination events, recall of vaccine, and inventory management. In 2014, MIROW created a micro-guide, *Lot Number Validation Best Practices*, to address validation of lot numbers. The content from the micro-guide has been incorporated into this guide, and the micro-guide has been retired.

This appendix highlights topics related to data quality for lot numbers:

- Principles and business rules related to lot numbers
- Background information about the decision not to include lot number in the minimum/mandatory data elements

PRINCIPLES AND BUSINESS RULES RELATED TO LOT NUMBERS

PRINCIPLES

The lot number principles in this guide focus on validating lot numbers in submissions against known lot numbers (P23), referencing a directory of manufacturer-specific coding schemes (P24), and maintaining the directories so they remain relevant (P25).

A lot number directory should include two components:

- Lot numbers from the inventory module (e.g., from shipping logs), which apply to publicly purchased vaccine doses
- Previously validated and confirmed lot numbers, which apply to privately and publicly purchased vaccine doses

Several challenges are associated with the development and management of a lot number directory. Manufacturers may be reluctant to share specific lot numbers or broader lot number coding patterns due to concerns about counterfeiting. In addition, a manufacturer's lot number formats can vary by vaccine due to the use of different systems in different production facilities.

There is also a concern about which organization(s) could manage lot number directories. Based on ongoing discussions, there are concerns about managing a directory at a national level. Individual IIS do not wish to manage directories due to the resources required and concerns about replicating the work at every IIS. At the same time, lot number directories would be beneficial for IIS, and the principles are included here to demonstrate the value in overcoming present obstacles.

BUSINESS RULES

The business rules focus on what is possible to achieve within the current environment (i.e., no reference directories available for validation). The business rules emphasize the value of submitting lot numbers (BR131), describe what characters should be included in a lot number (BR129), and clarify what information should not be included in a lot number (BR130, BR132). Supporting information for BR132 and illustrative examples for BR130 and BR132 are included below.

Supporting information for BR132

Lot numbers should not include extraneous character strings (BR132). IIS-AOs have historically added characters into the lot number data element to communicate information unrelated to the lot number. For example, "(P)" was submitted to provide a value for the public/private indicator designation. The illustrative examples for BR130 and BR132 include several instances of extraneous character strings included with a lot number. Each IIS will have to modify and expand currently identified cases to reflect its own specifics. In some cases, there are leading/trailing spaces in lot number data items that come from HL7 transmissions.

Illustrative examples for BR130 and BR132

The following table shows lot numbers with extraneous character strings (Before column) and how they would look once cleaned by the IIS to contain only lot number information (After column) (BR130).

BEFORE	AFTER	REMARKS
(P)123AA	123AA	Removed prefix (P) indicating public/private.
123AA-P	123AA	Removed appendix -P.
123AA – Note	123AA	Removed appendix – Note.
P123AA	123AA	Removed prefix P.
123AAIC3ZXY	123AA	Lot number should not be followed by "IC3" and additional text.

BEFORE	AFTER	REMARKS
123AA/456BB	123AA 456BB	Two records are identified.
12AB,34BC,56CD	12AB 34BC 56CD	Three records are identified.
C1426AA C1894BB	C1426AA C1894BB	Two records are identified.
123AAAHBV789	123AA AHBV789	Two records are identified.
123AA PENTACEL	123AA	Vaccine name, together with preceding space removed.
123(AA):	123AA	Characters "(", ")", and ":" are removed.
U44889AA (36 MO+)	U44889AA	(36 MO+) is removed.
UT2176KA- PF .25	UT2176KA	-PF .25 is removed.
U3174CA P-FREE	U3174CA	P-FREE is removed.
12345AB PRIVATE	12345AB	PRIVATE is removed.
1329Y STATE	1329Y	STATE is removed.
U4488EA (6-35)	U4488EA	(6-35) is removed.
1206901	1206901	Removed * at beginning and * at end.
AVEN T0533-2	T0533-2	Removed AVEN.
U3872CA(*)	U3872CA	Removed (*).
S/K ENG 1374A1	1374A1	Removed S/K ENG.
1292Y-(2DOSE)	1292Y	Removed –(2DOSE).
VFC MERCK-1297Y	1297Y	Removed VFC MERCK-.
(PRT) VFC U1188A	U1188A	Removed (PRT) VFC.
P-V WYETH F51336	F51336	Removed P-V WYETH.
ST 0611N	0611N	Removed ST.
M12028 (OVER19)	M12028	Removed (OVER19).
UH899AB(ST>6MO)	UH899AB	Removed (ST>6MO).
UT3575DA PREFLD	UT3575DA	Removed PREFLD.
X12025/A12025	X12025 A12025	Removed /; two lot numbers are identified.
U1830AA INFT PVT	U1830AA	Removed INFT PVT.

DECISION NOT TO INCLUDE LOT NUMBER IN THE MINIMUM/MANDATORY DATA ELEMENTS

Lot number was one of the data elements considered for inclusion as a minimum/ mandatory data element for administered vaccination event submissions. The subject matter experts emphasized the value of having lot number included for every administered vaccination event because lot numbers support vaccine management, vaccine accountability, and recall efforts if there are issues with a vaccine. At the same time, many subject matter experts expressed concerns that mandating lot number could cause some IIS-AOs to submit inaccurate lot numbers to avoid rejection. An additional concern was that rejected vaccination event submissions might not be resubmitted to the IIS.

BACKGROUND

- 2008 – *Data Quality Assurance in Immunization Information Systems: Incoming Data:* Lot number was not included as a mandatory data item.
- 2013 – *Data Quality Assurance in Immunization Information Systems: Selected Aspects:* Lot number was added to the list of mandatory data items with the following explanation:

  At the time the MIROW Work Group made these recommendations, not all sending systems, either 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.
- 2021 – The MIROW Small Group reviewed available data and found that many IIS have a high level of completeness for lot number and that none of the IIS reviewed through the AIRA Measurement and Improvement Initiative mandated receipt of lot number.

Analysis

Mandating a data element is one method of ensuring its completeness. Mandating a data element can be useful and necessary if basic functions of the IIS cannot be completed without that specific element. However, the act of mandating a data element risks losing vaccination event submissions that do not include the mandated data element. Mandating data elements in Chapter 9 includes information about alternative options for improving completeness of data elements.

Impact of mandating submission of lot number on selected[152] data quality characteristics

CHARACTERISTIC	BENEFIT	RISK
Accuracy/ Validity	If IIS-AOs prioritize submitting lot numbers, they may improve the accuracy/validity of the lot numbers they are submitting.	Lot number may be falsified or poorly entered in order to get the record accepted.
Availability	Lot number data is available for inquiries into vaccine distribution, inventory, and administrations.	Potential decrease in availability for vaccination event data if some vaccination events are rejected and not resubmitted with lot number.
Completeness	100% completeness for the lot number data element.	Potential decrease in completeness for vaccination events if some vaccination events are rejected and not resubmitted with lot number.
Timeliness	No specific benefit determined.	When lot number is initially mandated, more vaccination event records may be rejected and require resubmission, thereby reducing the timeliness of data.

Summary

Lot number is an important data element to be included regularly in vaccination event submissions. Many IIS have achieved a high level of completeness for lot number via programmatic initiatives (using both incentives and disincentives) rather than mandating submission. The risks associated with mandating submission of lot numbers should be assessed and mitigated by the individual IIS program.

[152] There is not expected to be a major impact on the characteristics of consistency and uniqueness.

APPENDIX L SELECTED REFERENCES

This appendix contains references to general materials that discuss aspects of data quality assurance.

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2022 DATA QUALITY GUIDE

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PAST MIROW DATA QUALITY GUIDES[153]

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MICRO-GUIDE: LOT NUMBER VALIDATION BEST PRACTICES

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