IIS DATA QUALITY PRACTICES

Monitoring and Evaluating Data Submissions



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EXECUTIVE SUMMARY

Immunization information systems (IIS) rely on complete, accurate, and timely immunization reporting to support clinical and public health immunization practices. Without quality data, the ability of IIS to provide a diverse array of functions, such as clinical decision support (CDS), vaccine inventory management and accountability, reminder/recall, and coverage assessment reporting, is severely limited.

Ongoing monitoring and evaluation of data submissions, a constantly evolving process, helps to ensure high-quality data. **This document offers IIS practical guidance on real-world data monitoring and evaluation practices in place today.** Specifically, this guide is intended to assist IIS in identifying and addressing data quality issues in data submissions to help ensure that IIS data can be used for its intended purposes. This guide also offers recommendations on how to conduct outreach and education to data submitters regarding data quality issues.

Topics covered in this document include:

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

The primary audience for this guide includes IIS managers and IIS staff with responsibility for ensuring and overseeing IIS data quality. Staff involved in the onboarding process and staff involved in the technical maintenance and development of IIS functionality may also benefit from the content shared in this guide.

The information presented in this guide is aimed at helping IIS programs expand their efforts to monitor and analyze incoming data and to address data quality issues.

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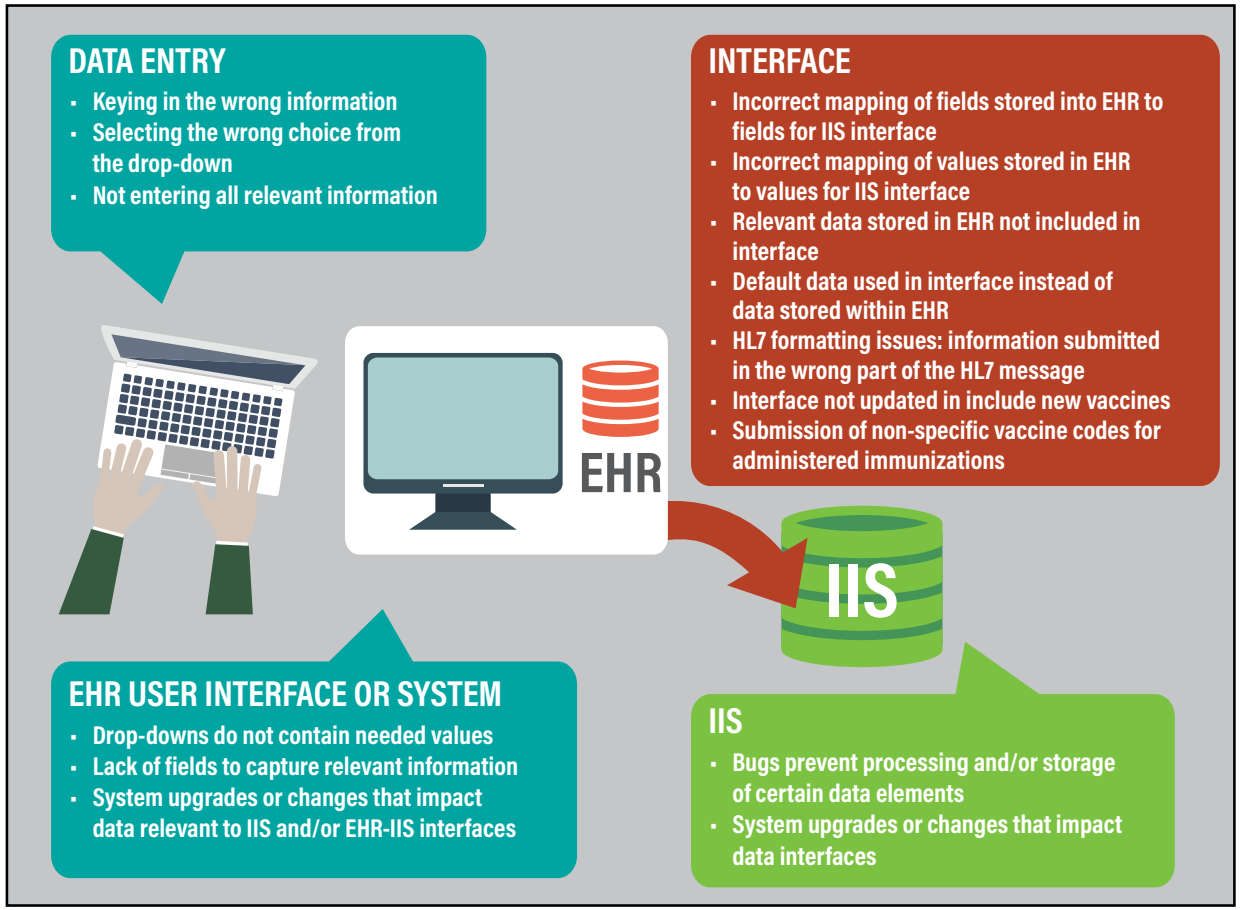
INTRODUCTION

Background

Immunization information systems (IIS) are electronic population-based health information systems that record all vaccination doses for patients in each geopolitical area. For the past 20 years, IIS have consolidated patient and immunization records from multiple sources (e.g., immunization providers, vital statistics, etc.). IIS also provide a diverse array of functions, such as clinical decision support (CDS) for immunizations, vaccine inventory management and accountability, reminder/recall tools, and coverage assessment reports for providers and public health agencies. Historically, immunization data have been entered manually into the IIS by clinicians, but during more recent years, IIS have adopted real-time electronic data exchanges (EDE) between IIS and electronic health record (EHR) systems, which allows for a more automated and streamlined process.

The rapid growth of EDE has created new challenges in maintaining high levels of data quality within the IIS. There are numerous potential causes of data quality issues in electronic data submissions from provider organizations. These range from data entry errors in the EHR user interface to problems stemming from the electronic interface between the EHR and IIS. In some instances, problems with the IIS may also cause data quality concerns. These potential sources of data quality issues are illustrated in Figure 1.

Figure 1. Potential Causes of Data Quality Issues in Provider Data Submissions to IIS



To address the challenges, IIS aim to ensure high-quality data entry into the IIS by performing data validation during the onboarding process before allowing providers to submit data to the IIS production environment. Once an interface is "live," IIS monitor and evaluate the incoming data, as the quality may change over time. Staff turnover, changes in clinical workflows around immunization administration and/or documentation, and EHR or IIS system changes can all impact the usability of data submitted to the IIS. Furthermore, the introduction of new vaccines and changes to immunization recommendations over time warrant ongoing review of incoming data.

Ideally, all IIS programs have policies and procedures in place to continually monitor and evaluate incoming data to ensure that it is accurate, timely, and complete and to ensure that providers are following proper clinical immunization practices.

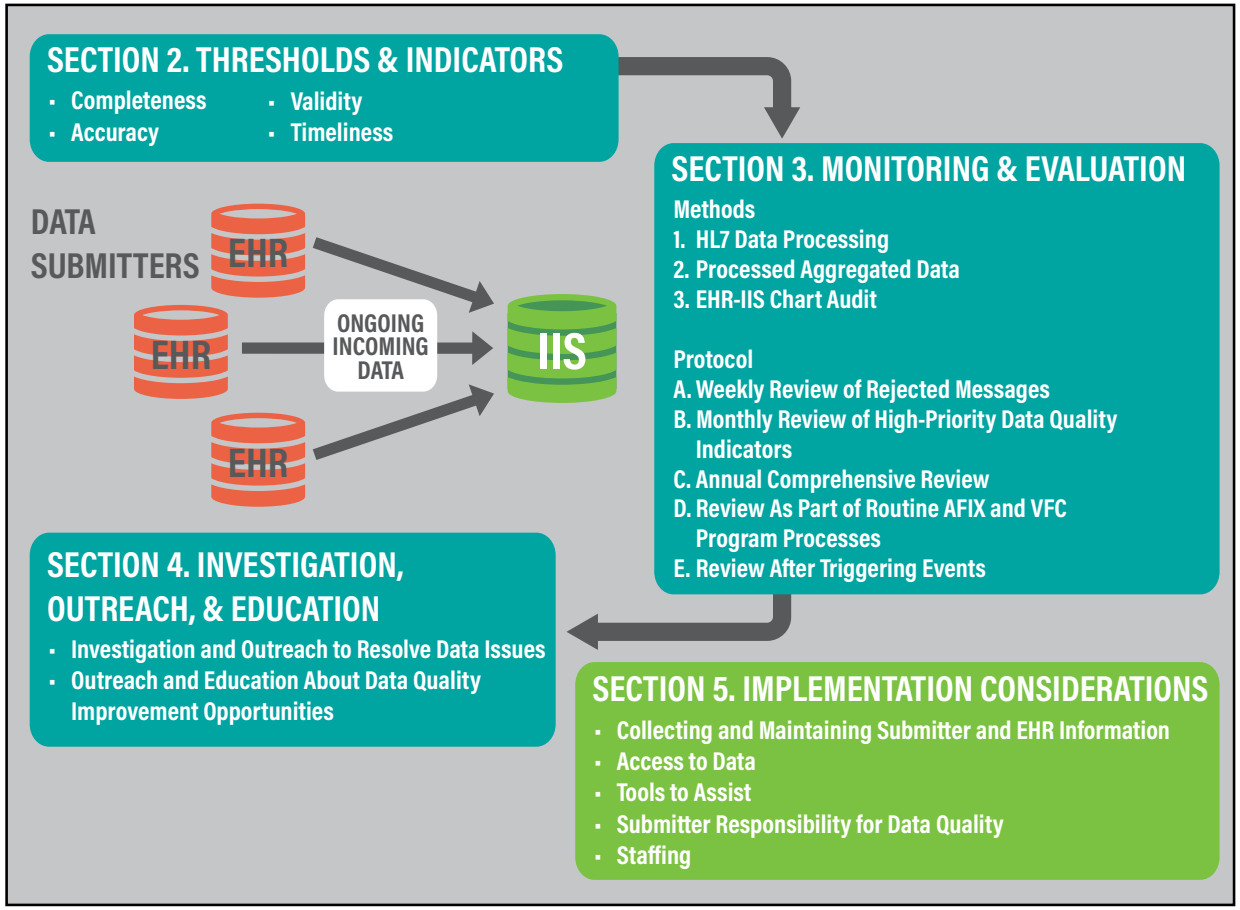
Purpose

The purpose of this guide is to provide practical guidance on techniques, methodologies, and processes for IIS to monitor and evaluate the quality of ongoing data submissions. This guide also offers recommendations on how to conduct outreach and education to data submitters regarding data quality issues. **There are many different data quality indicators and practices that can be used to assess ongoing data submissions. This guide is designed to present these options for consideration to assist IIS in identifying and addressing data quality issues. This guide is not intended to describe a one-size-fits-all approach.** Topics covered in this document include:

- An overview of thresholds and indicators to assess data quality across several dimensions
- A discussion of methods for monitoring and evaluating incoming data, including a sample monitoring and evaluation protocol
- An overview of practices for outreach and education around data quality issues
- A discussion of implementation considerations and strategies for programs looking to begin or enhance their monitoring and evaluation practices
- Several sample reports used by IIS programs to monitor and evaluate data submissions

A visual depicting how the information in this guide fits together is presented in Figure 2.

Figure 2. Provider Data Monitoring and Evaluation Guide Topics



Scope

This guide focuses on IIS practices related to the routine monitoring and evaluation of ongoing incoming data submissions. For simplicity, this document will largely reference data submissions with the understanding that many parties may be involved in the transmission of data from a health care provider organization to the IIS. The review process begins immediately after a provider organization has passed the onboarding phase[1] and has been approved to submit data to the production environment. This process continues for as long as the provider organization submits data to this environment.

Many data quality practices are conducted by IIS and immunization programs in the administration of federal programs, such as Assessment, Feedback, Incentives, and Exchange (AFIX) and Vaccines for Children (VFC). While this guide does not include a detailed discussion of these program-specific practices, it does include general discussions on how data quality review should be incorporated into the implementation of these programs.

IIS data processing functionality and deduplication algorithms play a significant role in helping to maintain and ensure quality data in an IIS. These are especially important considering the volume of data processed electronically and the need for IIS data to be available in a timely manner. Data processing functionality and deduplication algorithms that are not sufficient can lead to incomplete and inaccurate data in the IIS.

Although discussion of these functionalities and manual deduplication is out of the scope of this guide, the data monitoring and evaluation practices described can help IIS programs identify where functionality and algorithm changes may be advantageous. Programs can refer to several resources for guidance around deduplication in an IIS.[2]

Audience

The primary audience for this guide includes IIS managers and IIS staff with primary responsibility for ensuring and overseeing IIS data quality. In some programs, this may include individuals with various roles, including: data quality specialists, data exchange staff, and/or interoperability or interface coordinators. Staff involved in the onboarding process and staff involved in the technical maintenance and development of IIS functionality may also benefit from the content shared in this guide.

Methodology of Guide Development

This guide began with a draft outline of the scope based on initial conceptualization from the Assessment Steering Committee (ASC). IIS were asked to submit information on their practices for monitoring and evaluating ongoing incoming data submissions. This information was used to refine the focus of this guide on the review of HL7 data processing and aggregate data.

Interviews were conducted with programs that submitted sample reports and indicated a willingness to be involved in the project. Additional programs were selected for interviews based on the review of materials.

IIS PROGRAM INTERVIEWEES

- Colorado
- Nebraska
- North Dakota
- Oregon
- Tennessee

Interviews were conducted with staff from Colorado, Nebraska, North Dakota, Oregon, and Tennessee.

1 See the Data Validation Guide for the IIS Onboarding Process for a complete discussion on this topic: http://www.immregistries.org/resources/data/AIRA_Data_Validation_Guide.pdf.

2 See IIS deduplication resources from the CDC at https://www.cdc.gov/vaccines/programs/iis/technical-guidance/deduplication.html, the Unique Records Profile: A guide to resolving duplicate records in health information systems from the Public Health Informatics Institute at http://www.phii.org/resources/view/4380/unique-records-portfolio-guide-resolving-duplicate-records-health-information, and the MIROW guide on Vaccine Level Deduplication in IIS at http://www.immregistries.org/resources/aira-mirow. An additional MIROW guide on record consolidation is also forthcoming.

The content of the guide is based on the materials submitted by IIS, the interviews conducted with the select programs listed, and a review of existing materials relevant to the topic. Interviewees were invited to review draft content prior to publication.

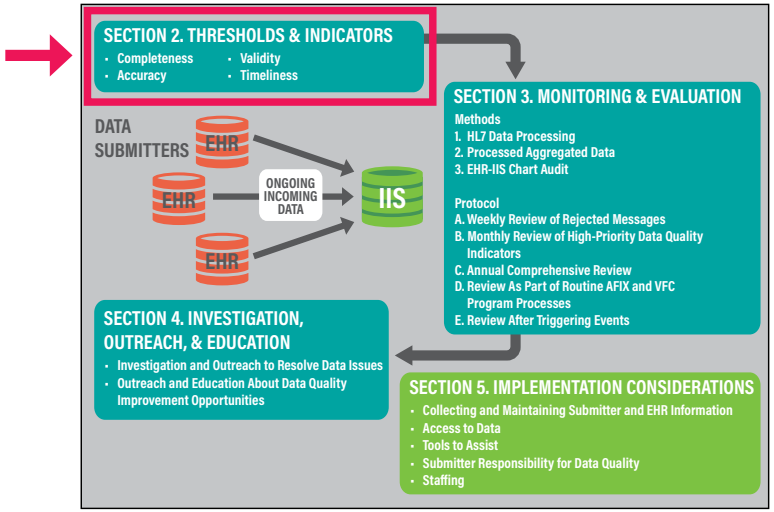
PRIMARY RESOURCE MATERIALS REVIEWED FOR THIS TOPIC:

- ✔ **AIRA Data Validation Guide for the IIS Onboarding Process, February 2017**[3]
- ✔ **AIRA Modeling of Immunization Registry Operations Workgroup Best Practices Guides**[4]
  - ☐ Data Quality Assurance in Immunization Information Systems: Incoming Data, February 2008
  - ☐ Data Quality Assurance in Immunization Information Systems: Selected Aspects, May 2013
  - ☐ Decrementing Inventory via Electronic Data Exchange, April 2015
- ✔ **HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, v 1.5 (Published and Posted Nov. 5, 2014, by Centers for Disease Control and Prevention, and Addendum, Published July 2015)**[5]
- ✔ **CDC's 2013-2017 IIS Functional Standards, Core Data Elements**[6]

3 Data Validation Guide for the IIS Onboarding Process (2017, AIRA). http://www.immregistries.org/resources/data/AIRA_Data_Validation_Guide.pdf.
4 Available on the AIRA website: http://www.immregistries.org/resources/aira-mirow.
5 Available on the CDC website: https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html.
6 Available on the CDC website: https://www.cdc.gov/vaccines/programs/iis/func-stds.html.

THRESHOLDS AND INDICATORS

Completeness, accuracy, and timeliness are the most frequently described data attributes in assessing the quality of IIS data[7] and other public health data sets.[8] IIS want data submissions to be complete and timely, with reporting that is an accurate and precise reflection of what occurred in a clinical visit. An additional relevant dimension of data quality is validity. Validity checks can be used to help uncover issues that may stem from inaccurate EHR documentation, inaccurate data reporting, or improper immunization practice.



DATA ATTRIBUTE DEFINITIONS

- **Completeness:** The degree to which full information about a data set, record, or individual data element is captured in the IIS. For this guide, completeness of the data set reported is within scope (reporting of all immunizations to all patients served) as is completeness of records and data elements submitted.
- **Accuracy:** The degree to which the IIS data reflect reality (i.e., what occurred in a clinical visit). The gold standard of assessing accuracy is a chart audit to compare EHR and IIS data.
- **Timeliness:** The amount of time between an event of interest and when those data were captured in the IIS. The data should be captured in the IIS within recommended limits.
- **Validity:** The degree to which IIS data conform to rules of what is accepted or expected by the IIS. Can be applied to a record and individual data element. Some measures of validity may be used as proxies for assessing accuracy outside of conducting chart audits; others may be used to identify vaccine administration errors.

Indicators and thresholds used to evaluate data submissions in each of these areas are presented below. These were gathered from MIROW documents,[9] the Data Validation in Onboarding Guide,[10] and IIS practice.

7 The 2008 MIROW Guide, Data Quality Assurance in Immunization Information Systems, discusses accuracy, completeness, and timeliness. See pp. 86-88. http://www.immregistries.org/resources/aira-mirow
8 Chen, H., Hailey, D., Wang, N. and Ping, Y. "A Review of Data Quality Assessment Methods for Public Health Information Systems," International Journal of Environmental Research and Public Health, 11(5): 5170-5207.
9 See the 2008, 2013, and 2015 MIROW Guides. http://www.immregistries.org/resources/aira-mirow
10 This guidance document was produced through the participation of subject matter experts from the IIS community, CDC partners, public health consultants, and AIRA staff.

CONSIDERATIONS

While it may not be feasible to implement routine monitoring and evaluation of all indicators, IIS should use the following information as a reference to help develop a data quality protocol for ongoing review of provider data. Some indicators may be selected for routine analysis, and others may be used in ad hoc analysis. IIS may also customize indicators and thresholds utilized based on provider organization type and known capabilities of various EHR systems and/or sending organizations. While this section is meant to provide a comprehensive list of indicators for use in data quality analysis, additional indicators may exist.

Another consideration is where to monitor and evaluate for these indicators—in the provider's original data submission to the IIS and/or in the processed, aggregated provider data stored in the IIS. Analysis in each area may produce different results depending on IIS data processing business rules. Application of these quality measures is also discussed further in Section 3.

Completeness

IIS are often valued as a resource for complete, consolidated immunization information. The completeness of the IIS data is important, as it impacts the accuracy of IIS functionality and reports based on the data, such as patient immunization forecasts, immunization coverage assessments, and reminder/recall functionality. Ultimately this can impact a clinician's immunization practice and the ability of public health to prevent and respond to vaccine-preventable disease threats. While data completeness at the jurisdiction level is out of scope for this guide (e.g., evaluation of whether all providers in the jurisdiction are reporting), data completeness for reporting providers can be assessed.

If an organization has reported to the IIS, the completeness of its data submission can be evaluated. This evaluation can look at whether the submitted data include all relevant immunization events and all patients served. It can also look at the completeness of individual data elements related to the immunizations and patients.

Completeness of individual data elements has implications for data use. For example, in the event of a vaccine recall, complete immunization reporting with populated vaccine lot numbers and populated client demographic information allows health care providers and public health to quickly identify individuals at risk for vaccine-preventable disease.

Completeness Thresholds and Indicators

Data Set Completeness: Methods to assess completeness vary depending on what aspect is being measured. To assess completeness of a data set from an individual data submitter, IIS can look for indicators that might be a sign of a data completeness issue. For example, if a data submission includes only administered vaccinations, the historical vaccinations recorded in their system may not be included in the interface to the IIS.

Other indicators to assess completeness involve comparing a data submission against what could likely be expected from that provider organization. This could be done using the provider profile concept discussed in the MIROW Data Quality guides.[11,12] This involves comparing a summary of submissions to a generic profile of what the IIS could expect from the type of organization the submitter represents (e.g., pediatric clinic, travel clinic, etc.). Another method involves comparing a summary of submissions to the submitter's own profile documented during the onboarding process. The summary of submissions could also be compared to the provider's data submission patterns and historical norms or against its vaccine ordering history.

A listing of the completeness indicators an IIS may use in an assessment of data submissions is included in Table 1. Specific thresholds for identifying when follow-up is needed based on these indicators are not presented, as these need to be based on each IIS's review of the data and capacity for follow-up. These indications are based on the MIROW provider profiling concept as well as IIS practice, per interviews with program SMEs.

11 See 2008 MIROW Guide (Chapter 3), pp. 59-60 and pp. 98-99, "Appendix F. A possible statistical approach to an automated methodology for utilization of providers' profiles for analysis of reported data quality."
12 See 2013 MIROW Guide (Chapter 7), p. 77.

Table 1. Indicators of Potentially Incomplete Reporting by Provider Organizations

No.	Indicators of Potentially Incomplete Reporting	Notes
1	**Historical immunizations** are not represented or are not represented in the proportion consistent with program expectations or previously noted patterns.	This may indicate that historical immunizations are being left out of the data submission to the IIS.
2	The **frequency** of data submissions is not consistent with program expectations or previously noted patterns from that submitter.	Review may determine that a large submitter that normally sends real-time messages, for example, sends nothing for a given day. This may be indicative of a data completeness issue for that day's worth of data. If the data are eventually reported, timeliness is impacted. Frequency for intermittent vaccinators or low-volume submitters may be too variable to follow predictive patterns.
3	The **number of rejected** messages in data processing is not consistent with program expectations or previously noted patterns.	Review may determine that more messages from a submitter are being rejected over a given time period than seen previously. Or a review may flag all submitters exceeding a certain rejected message rate for a given time period. For example, increases in rejected records across multiple submitters may indicate an issue with a vendor hub and/or IIS processing.
4	The **volume** of messages and/or immunizations submitted and/or processed is not consistent with program expectations or previously noted patterns.	For example, review may determine that a submitter that normally reports at least 500 vaccinations in a given time period has reported only 100 vaccinations over the same period of time. Volume can be influenced by several factors, including flu season, news of a vaccine-preventable disease cases and/or outbreak, back-to-school periods, and vaccine shortages. Decreased volume across multiple submitters may indicate an issue with a vendor hub and/or IIS processing.
5	All **patient ages represented** in the practice are not represented in the submitter data.	Review may determine that a family practice clinic is not submitting immunizations for the adults it serves to the IIS. May be based on review of aggregated submitted data or chart audit.
6	All **vaccines administered** in the practice are not represented in the submitter data.	May be identified through review of CVX codes submitted compared to a provider profile, review of vaccines ordered compared to vaccines reported, and/or an EHR chart audit. Lower than expected IIS-based coverage rates may also indicate incomplete data reporting. Introduction of new vaccines and vaccine codes warrant additional attention to ensure submission.

Individual Data Element Completeness: Assessment of the completeness of individual data elements is relatively straightforward. This involves assessing the percent completeness of key data elements reported in a submission to the IIS. The completeness of individual data element reporting by a submitter can have implications for how their HL7 messages are processed, for IIS deduplication processes, and for IIS data use. For an overview of data elements by data use, see Appendix A.

Table 2 includes a listing of patient demographic data elements, and Table 3 includes a listing of vaccine-related data elements to consider evaluating for recommended completeness levels. These are summarized from MIROW Guides,[13] the Data Validation Guide for the IIS Onboarding Process,[14] and the IIS Core Data Elements, referenced in the IIS Functional Standards.[15]

IIS can use Appendix A and Table 2 and Table 3 to identify priority data elements for IIS deduplication algorithms and planned data use and then follow up with data submitters falling below minimum thresholds. Note: the recommended thresholds are presented as a guide for IIS programs; each program should determine appropriate thresholds based on individual IIS processing algorithms and planned data use.

NOTE

Analysis results may differ depending on where these data elements are assessed—in the providers' original HL7 data submission or in the processed, aggregated data stored in the IIS due to IIS data processing business rules.

13 See 2008 MIROW Guide (Chapter 3), pp. 34-51 and 2013 MIROW Guide (Chapter 7), pp. 70-87, for complete list of Business Rules.

14 Data Validation Guide for the IIS Onboarding Process. Available at: *http://www.immregistries.org/resources/data/AIRA_Data_Validation_Guide.pdf*. Last Updated: November 2016.

15 Core Data Elements are derived from Immunization Information Systems (IIS) Functional Standards, 2013-2017. Centers for Disease Control and Prevention. Available at: *http://www.cdc.gov/vaccines/programs/iis/func-stds.html*. Last updated: Dec. 18, 2012.

Table 2. Patient Demographic Data Element Completeness Recommendations

No.	Data Element	Recommended Level	Reference	Notes
1	Patient Clinic ID	100%*	DV Guide	• Used to attribute a patient to a clinic • May be used in client deduplication
2	Patient Name: First, Middle, Last	100%*	MIROW BR105	• Used in client deduplication
3	Patient Date of Birth	100%*	MIROW BR105	• Used in client deduplication
4	Patient Gender	95-100%	DV Guide	• May be used in: client deduplication; accuracy crosschecks of gender-specific vaccine recommendations; and examination of vaccination rates by gender
5	Patient Address: Street, City, State, County, ZIP	95-100%	DV Guide	• May be used in: client deduplication; reminder/recall; examination of vaccination rates by county, ZIP code or other geographic analysis
6	Patient Race	95-100%	Core Data Element	• May be used to examine vaccination rates by race. Analysis may not be relevant for IIS that utilize race information from vital records and disregard race in submission
7	Patient Ethnicity	95-100%	Core Data Element	• May be used to examine vaccination rates by ethnicity. Analysis may not be relevant for IIS that utilize ethnicity information from vital records and disregard ethnicity in submission
8	Patient Phone	90-95%	DV Guide	• May be used in: client deduplication and reminder/recall
9	Patient Phone Type	90%**	Core Data Element	• IIS and immunization programs vary in terms of expectations for submitter to report this data. May be used for reminder/recall
10	Patient Email Address	90%**	Core Data Element	
11	Patient Primary Language	90%**	Core Data Element	
12	Mother's Maiden Name	90%***	Core Data Element	• Used in client deduplication
13	Mother's Name: First, Middle, Last	90%***	Core Data Element	• May be used in reminder/recall for minors and for client deduplication

* This information is crucial for an IIS. The current HL7 2.5.1 Implementation Guide[16] and corresponding Addendum[17] recognize this and designate this field as required. Absence of this data element in a data submission would result in a fatal processing error and rejection of the message. See Appendix B.

** If the program intends to use these data elements in reminder/recall activities.

*** Applies only to submission of information about a minor.

16 HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5). November 5, 2014. Available at https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html.

17 HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5) Addendum. July 2015. Available at https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html.

Table 3. Vaccine Data Element Completeness Recommendations

No.	Data Element	Recommended Level	Reference	Notes
1	Vaccine Administration Date	100%*	MIROW BR105	• Used in vaccine deduplication
2	Vaccine Product Type	100%*	MIROW BR105	• Analysis of HL7 data submissions may include review of CVX and/or NDC codes • Used in vaccine deduplication
3	Vaccine Event Information Source	100%	MIROW BR105	• ay be used in quality crosschecks
4	Vaccine Manufacturer	100%**	MIROW BR116	• May be used in quality crosschecks, vaccine deduplication
5	Vaccine Lot Number	100%**	MIROW BR105	• Used in dose-decrementing from inventory. May be used in vaccine recalls, vaccine deduplication
6	Vaccine Expiration Date	90%**	MIROW BR118	• May be used in validity checks related to vaccine administration. See Table 5, item 1
7	Vaccine Dose Volume and Unit	90%**	DV Workgroup	• May be used in clinical decision support to determine validity of dose
8	Vaccine Site of Administration	90%**	MIROW BR119	• May be used in accuracy and validity crosschecks. See Table 5, items 10 and 11
9	Vaccine Route of Administration	90%**	MIROW BR119	• May be used in accuracy and validity crosschecks. See Table 4, item 6 and Table 5, items 10 and 11.
10	Vaccine Administering Provider: Name, Suffix	90%**	DV Guide	• May be used to assess administration patterns across clinicians and/or to facilitate clinical follow-up
11	Vaccine Eligibility at Dose Level	100% among VFC providers, otherwise N/A	DV Guide	• Applies to providers participating in VFC and other state-supplied vaccine programs • Some IIS also request submission of funding source (aka dose-level public/ private indicator) to help with dose-decrementing from inventory and for vaccine accountability purposes; however, this data item is not currently stored in or received from the majority of EHR systems[18]
12	VIS Information: Type, Publication Date, Date Given to Patient	90%***	Core Data Element	• IIS and immunization programs vary in terms of their expectations for providers to report this information. Programs that expect reporting to the IIS perform data validation checks to help ensure VIS information is shared with patients

* This information is crucial for an IIS. The current HL7 2.5.1 Implementation Guide[19] and corresponding Addendum recognize this and designate this field as required. Absence of this data element in a data submission would result in a fatal processing error and rejection of the message.

** Applies to administered immunizations only.

*** If program intends to review this information to help ensure that VIS information is shared with patients.

18 See discussion of funding source in the 2016 MIROW Guide on Decrementing Inventory via Electronic Data Exchange. http://www.immregistries.org/resources/aira-mirow/AIRA_MIROW_DI-v-EDE_Guide_Final_010417.pdf

19 HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5). Nov. 5, 2014. Available at https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html.

Some data elements, such as patient name, date of birth, vaccination type, and vaccination date, represent high-value information that is critical in a data submission. These fields are needed to properly attribute the information to the correct record in the IIS and to process meaningful immunization data. This is acknowledged in the HL7 2.5.1 Implementation Guide, which labels these fields as required (R). If the IIS HL7 processing requirements match the HL7 2.5.1 Implementation Guide, the IIS should expect 100% completeness in the stored IIS data for these elements.

Required, or "R," fields are treated differently than "RE" fields in HL7 processing. If an IIS processes any of these data elements as RE, the data value may be empty and still be accepted by the IIS. Being aware of how an IIS processes these data elements can help programs troubleshoot and investigate rejected messages and data element completeness issues.

If indicators signal incomplete reporting, IIS may also need to assess IIS acceptance and storage of these data, as sometimes issues with IIS processing can impact completeness of data submissions. Note: many of the data elements listed in Table 2 and Table 3 can be reviewed for accuracy in addition to completeness.

In addition to using the completeness indicators and assessing the completeness of individual data elements in the IIS, IIS programs may conduct chart audits to help assess IIS completeness. Comparing the IIS data against EHR data can provide verification of completeness and accuracy in reporting.

Accuracy

Accuracy refers to the degree to which the IIS data reflect reality (i.e., what occurred in a clinical visit). The accuracy of data submissions impacts the accuracy of the IIS functionality and reports that are relied on by clinicians, public health, and other stakeholders. Ensuring that submissions are a true reflection of the vaccination encounters helps IIS and immunization programs uncover clinical practice issues. This may include improper dosing, improper administration, use of expired vaccine, and other problems that could impact vaccine efficacy and protection from disease.

Accuracy Thresholds and Indicators

As mentioned previously, chart audits can be used to verify the accuracy of data submissions. If discrepancies are noted, the root cause of the problem should be addressed to ensure accurate submission of data going forward. Once this is done, any inaccurate data in the IIS should be corrected. Although chart audits may provide a gold standard for comparison for accuracy, they are also expensive and time consuming.

Improbable Scenarios: Outside of chart audits, IIS programs can also use some measures of validity as proxy measures for accuracy. In some cases, the validity violations are indicative of improbable scenarios (and therefore inaccurate data reporting by the submitter). This includes submission of a vaccination date before the patient date of birth and a vaccination date that is in the future (after the submission date). Table 4 lists these improbable scenarios. Note: many IIS have business rules that prevent processing and storage of these data in the IIS. IIS can assess whether data stored in their systems meet these criteria and determine if implementation of business rules is warranted.

Table 4. Indicators of Inaccurate Data – Improbable Scenarios

No.	Indicator	Notes
1	Vaccination date is before patient date of birth	• May be flagged in HL7 processing depending on implementation of local business rules. Both dates should be investigated to determine which date is in error
2	Vaccination date is after the submission date (i.e., vaccination date is in the future)	• May be flagged in HL7 processing depending on implementation of local business rules
3	Birth date is after the submission date (i.e., birth event is in the future)	• May be flagged in HL7 processing depending on implementation of local business rules
4	Manufacturer and vaccine product contradict one another	• Crosschecks can be completed to check for inconsistencies in manufacturers and vaccine products for submitted immunizations. Note: the manufacturer for a specific vaccine may change over time due to organizational mergers, acquisitions, etc.
5	Submitted vaccine descriptions and/or codes contradict one another	• Example: CVX code 144 and the vaccine name Pediarix® submitted for one immunization event. CVX code 144 represents a seasonal, intradermal, preservative-free influenza vaccine, and Pediarix® is a DTaP-Polio-HepB combination vaccine • Another example is a contradiction between CVX and NDC codes submitted for the same vaccination
6	Vaccine administration route of oral along with an administrative site indicating submission via another route	• Example: a vaccination administered orally cannot be administered with a site of left thigh or right arm
7	Vaccine administered is not yet available to clinicians	• Example: a new flu vaccine becomes available on 07/31/2017, however a record is received indicating administration on 06/02/2017 • See the Current HL7 Code Set[20] for a current list of pending vaccines
8	Vaccine reported as administered in U.S. has never been available for administration in U.S. or is not yet available for administration	• See the Current HL7 Code Set for a current list of non-U.S. vaccines. Also, refer to U.S. vaccine licensure dates. The Red Book includes information on licensure of new vaccines[21]
9	Vaccine administered is not a vaccine that was ever available and is not in the pipeline of new vaccines	• See the Current HL7 Code Set for a current list of never active vaccines

20 Current HL7 Standard Code Set: CVX – Vaccines Administered. CDC. https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx. The status column indicates if the vaccine is currently available in the United States. Sign up to receive email updates when this information is changed.

21 Red Book® Online Table – Status of Licensure and Recommendations for New Vaccines: Report of the Committee on Infectious Diseases, American Academy of Pediatrics, Elk Grove, Illinois. 2015. Available at: http://aapredbook.aappublications.org/news/vaccstatus.shtml. Note: subscription required to access the table.

If analysis of IIS data reveals instances of these improbable scenarios, the IIS can follow up with submitters to determine the root cause of the error, such as inaccurate data capture in an EHR or an inaccuracy in the mapping of EHR data in the interface. In some instances, IIS data processing changes that result in errors may be uncovered. Whatever the root cause, these issues may require updates, either to a data feed and/or to existing data in the IIS.

Validity

A few other validity measures may be used to identify *potential* inaccuracies in the IIS data. Presence of these indicators may be due to inaccurate data submissions, or they may in fact represent a clinical encounter that violates clinical practice or vaccine management expectations. For example, a provider may report administration of a vaccine from a vaccine lot that is past expiration date. Follow-up is needed to determine if an expired vaccine was in fact administered or if a non-expired vaccine dose was administered and there was a problem with submission of that information to the IIS.

While expired vaccine should never be administered, clinicians sometimes administer vaccines outside of immunization recommendations. IIS programs can look to patterns in the data and the volume of validity violations to help discern when the violations represent inaccuracies or improper clinical practices. Additional examples of these types of validity violations are provided in Table 5.

Validity Violations

Many of the validity violations listed include specific examples based on current immunization recommendations. IIS forecasting based on CDC CDSi logic guidance[22] will invalidate doses outside of minimum and maximum age recommendations and those not meeting min/max intervals between doses. However, CDSi logic does not cover all these validity violations. IIS must continually review validity scenarios used in data quality checks to ensure concordance with current immunization practice recommendations, vaccine-licensing guidelines, and vaccine availability information. There is currently no national resource that consolidates and maintains this information. This is an area for potential IIS community collaboration.

22 The CDC CDSi Logic Specification and Supporting Data are available at https://www.cdc.gov/vaccines/programs/iis/cdsi.html.

Table 5. Immunization Validity Violations That May Indicate Inaccurate Data or Potential Improper Clinical Practices

No.	Indicator (all apply to administered immunizations)	Notes
1	Vaccination administration date is after the vaccine expiration date for the corresponding vaccine lot	• Expired vaccine product should not be used
2	Proportions of values for reported vaccines administered violate expectations	• Example: a report displaying proportions of vaccines processed by the IIS over a period of time may show that certain vaccines are lower or higher than expected (or show that certain vaccines are missing). Expected proportions may be based on information learned about the submitter during the onboarding process and/or based on information previously submitted to the IIS. Proportions may also be based on generic provider profiles • Violations may indicate issues with how vaccines are mapped from the EHR to the electronic interface
3	Lack of submission of common combination vaccines	• Example: one IIS reported that a provider submitted a single antigen followed by the combination vaccine code. In this case, the IIS failed to process because two or more vaccines in the submitted message were duplicates • May indicate EHR data entry issue and/or electronic interface mapping issue that prevents submission of combination vaccines to the IIS
4	Vaccination other than hepatitis B at birth, vaccination other than hepatitis B before 1 month of age	• Hepatitis B is currently the only vaccine recommended at birth and the only vaccine recommended prior to 1 month of age. To apply the 1 month rule, use the patient's date of birth + 28 days • Infants born to mothers with hepatitis B virus infections are recommended to receive hepatitis B immune globulin (HBIG) soon after birth.[23] HBIG is represented in HL7 messaging as CVX 30
5	Vaccination minimum interval violations	• Certain minimum intervals must be followed between vaccine doses.

23 See viral hepatitis B information from CDC at https://www.cdc.gov/hepatitis/hbv/perinatalxmtn.htm.

6	Vaccine reported as administered was at one point available but is no longer in distribution	• Example: while oral polio vaccine is still used in some parts of the world, it has not been available in the U.S. since 2000.[24] It may be submitted as a historical vaccine, but it is not expected to be submitted as an administered vaccine • A more recent example is Cervarix®. GSK, the vaccine manufacturer, announced in August 2016 that it is no longer distributing this vaccine in the United States. The final lots shipped had an expiration date of Nov. 29, 2016[25] • IIS should consider lot expiration dates when assessing this indicator, as providers may have lingering stock that may be used until the product is expired
7	Vaccination before the minimum patient age or after the maximum patient age for a particular vaccine group or product: • Hepatitis A < 6 months (see note) • Hib-containing vaccine < 6 weeks • HPV < 9 years • Influenza < 6 months • MMR < 6 months (see note) • PCV < 6 weeks • PPSV23 < 2 years (see note) • Td, Tdap < 7 years • Varicella < 1 year • Zoster < 50 years • DT, DTaP ≥ 7 years • First dose HPV ≥ 27 years • Rotavirus ≥ 8 months, 1 day • Various influenza products administered outside of product age indications[26]	• Must be based on current vaccine recommendations. IIS may want to focus on identification of scenarios that would warrant re-vaccination to ensure proper protection from disease. These are generally scenarios that look at vaccination before minimum age requirements • ACIP allows for a four-day grace period for immunization recommendations • One dose of MMR and one dose of Hepatitis A is currently indicated for infants aged 6 through 11 months before international travel[27] • A large volume of PPSV23 administered at less than two years of age is usually indicative of a coding error. PCV13 is currently a routinely recommended vaccination for infants and children; PPSV23 is recommended for children with certain high-risk conditions

24 Polio Vaccination. CDC. Last Reviewed 2014. https://www.cdc.gov/vaccines/vpd/polio/index.html

25 GlaxoSmithKline letter to customers regarding Cervarix® vaccine distribution in the United States. Aug. 18, 2016. Available at https://www.gskdirect.com/medias/GSKDirect-Cervarix-Tip-Lok-Syringe-Discontinuation-8.18.2016.pdf?context=bWFzdGVyfHJvb3R8OTg1NDB8YXBwbGljYXRpb24vcGRmfGhmMi9oYTUvODg0MTAyNTM4O-DU3NC5wZGZ8NmE4NzUzYWUwMzYwMTE0Mjg2NmRhMmMwODQwOTY1YTA1ZDQ3YjliMGZlODY2ZmY-wOGE5ZmU3YmEyODQxOTFjOA.

26 An example of this is the Influenza Vaccine Products for the 2016-2017 Influenza Season resource from the Immunization Action Coalition, available at http://www.immunize.org/catg.d/p4072.pdf.

27 Recommended Immunization Schedule for Persons Aged 0 through 18 Years, United States, 2016. CDC. https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html.

8	Administered hepatitis vaccine product formulation and patient age contradictory: • Pediatric Engerix-B administered to adults >19 years • Adult Engerix-B administered to a child <11 years	• Must be based on current FDA licensure • Pediatric Engerix®-B is approved for use only in children and adolescents younger than 20 years of age. Adult Engerix®-B is approved for use only in adolescents (>10 years) and adults[28]
9	A patient receiving the same antigen more than once in a single day	• IIS deduplication functionality may not accept this information. This may be clinically valid in certain circumstances (e.g., administering an adult two 0.25 ml doses of influenza vaccine [to make a 0.5 ml dose])
10	Route and/or site contradictory for a given vaccine:[29] • DTaP, DT, Tdap, Td, Hib, Hep A, Hep B, HPV, MCV4, MenB, PCV administered any route besides IM • MMR, MMRV, MPSV, Varicella, Zoster administered any route besides SC • Intradermal flu administered any route besides intradermal • Any vaccine other than intradermal flu administered intradermal • Rotavirus administered any route besides orally • Any vaccines other than rotavirus or typhoid administered orally	• Vaccines should always be administered by the route recommended to preserve efficacy. Refer to current vaccine licensing and immunization recommendations • Vaccines that can be administered IM or SC: o PPSV o IPV
11	Administered vaccine route and/or site contradictory for given patient's age:[30] • Neonates (first 28 days) receiving vaccine any route besides IM and site other than anterolateral thigh	• Age and site(s) for intramuscular vaccines: o Neonates (first 28 days): anterolateral thigh o Patients <12 months: anterolateral thigh preferred o Patients 12 months-2 years: anterolateral thigh preferred; deltoid may be used o Patients 3+: deltoid muscle preferred, anterolateral thigh may also be used • Age and sites for subcutaneous vaccines: o Patients <12 months: usually thigh; triceps if necessary o Patients ≥12 months: usually upper-outer triceps area

28 Discussed on p. 159 (Chapter 10) of the Pink Book, Epidemiology and Prevention of Vaccine-Preventable Diseases. 13th Ed. See https://www.cdc.gov/vaccines/pubs/pinkbook/hepb.html.

29 These must be based on current immunization recommendations. The scenarios provided are based on information in the Immunization Action Coalition's resource on Administering Vaccines: Dose, Route, Site, and Needle Size, dated June 2016. http://www.immunize.org/catg.d/p3085.pdf

30 These must be based on current immunization recommendations. The scenarios provided are based on information in the Immunization Action Coalition's Administering Vaccines Ask the Experts resource, updated August 2016. http://www.immunize.org/askexperts/administering-vaccines.asp

12	Vaccination with vaccine formulations that are no longer available for patient administration	• See the Current HL7 Code Set[31] for a current list of Inactive vaccines; these may be submitted as historical immunizations but should not be reported as administered. Note: the HL7 Code Set does not include vaccine licensure date ranges. See number 15 below.
13	Vaccination date is outside of the U.S. licensure date range for the product (i.e., vaccination before licensure or vaccination after licensure end date)	• See also Table 4, item 8, which refers to vaccines that are not at all available in the U.S.; this indicator refers to vaccines that were available at some point in the U.S.
14	Vaccine funding source and client VFC eligibility contradict one another	• E.g., private vaccine given to VFC-eligible child, state-supplied vaccine given to non-VFC eligible individual
15	Patients with an unexpected total number of immunizations given their age For example: • 20+ immunizations before age 6 months • 30+ immunizations before age 2 years	• More than likely indicates issues with IIS patient or vaccine deduplication; however, over-vaccination can and does occur • IIS must account for the potential for annual influenza vaccination in total vaccine counts • Examples from the Kansas Data Quality Report. See Appendix C-4
16	Discrepancies between data stored in the EHR and data stored in the IIS	• As identified through a chart audit process. May be due to an interface issue or an issue with IIS processing. See Figure 1 for potential causes of interface and IIS processing issues

Based on the indicator and the volume of the validity violations seen in the data, further investigation and follow-up with a submitter may be warranted. If the submissions are found to be accurate, they may reflect clinical practice errors, professional decisions that deviate from common and recommended practices, or off-label use of vaccine. If the submissions are found to be in error, this may be because of an EHR data entry error, EHR data entry limitation, and/or a coding or mapping error. IIS should work with the submitter to make changes to prevent future occurrences of the problem and then correct data in the IIS.

Poor Data Recording/Capture or Data Submission Practices

Indications of poor data entry and/or submission practices include submission of placeholder values such as 000-000-0000 for a patient phone number or submission of "unknown" for the manufacturer of an administered vaccine. IIS need to verify with the submitter if the data were entered into the EHR or if default or placeholder data are being used in the interface. A list of indicators of inaccurate data submissions is presented in Table 6.

Depending on local HL7 processing, some IIS may completely reject messages that lack specificity in key fields, such as name and vaccine. In these cases, messages submitted with a generic name, such as "Baby" or an unknown vaccination (CVX '999'), are rejected. These efforts must be constantly evolving, as methods for bypassing IIS processing rules are ever changing (e.g., rejection of "baby boy" leads to submission of "babyboy1"). IIS acceptance of certain placeholder data may lead to mis-merges or duplicate records, and acceptance of unknown values may lead to loss of previously stored, more detailed values.

31 Current HL7 Standard Code Set: CVX – Vaccines Administered. CDC. *https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx*. The status column indicates if the vaccine is currently available in the United States. Sign up to receive email updates when this information is changed.

Table 6. Indicators of Poor Data Recording/Capture or Data Submission Practices

No.	Indicator	Notes
1	Proportions of expected values for a given demographic field (e.g., race, ethnicity, gender, etc.) violate expectations	E.g., submission of all patients with race equal to "Asian." This is an example from an IIS that found that this field was set to default to "Asian" in the electronic interface.
2	Administered vaccinations submitted with unspecified CVX codes	Use of unspecified CVX codes should be limited to historical vaccinations
3	Submission of an unknown vaccination (CVX code '999')	May be flagged in HL7 processing depending on implementation of local business rules
4	Submission of invalid client demographic data Examples: • Name: submission of generic name such as 'Baby,' 'Mickey Mouse,' 'Donald Duck,' 'Patient,' 'Test,' etc. • Social Security number: format other than XXX-XX-XXXX or XXXXXXXXX; starting with '9'; starting with '666'; all 0s in any group • Email: does not contain '@'; does not contain a period • Phone: area code does not contain three digits; local number does not contain seven digits	May be flagged in HL7 processing depending on implementation of local business rules. Submission of invalid patient demographic data impacts client deduplication
5	Submission of "unknown" for various fields for an administered immunization (i.e., manufacturer, patient race, patient street address, etc.)	A submission of "unknown" for a particular value may be a complete submission to the IIS, but it is not precise and it can have implications for data quality checks and data use. IIS may want to check local processing of unknown data values to ensure that an unknown value does not overwrite an existing, more precise value
6	High volume of immunizations with administration date of 01/01/YYYY or MM/01/YYYY	The first month of the year and/or the first day of the month may be used as a stand-in date when the precise immunization date is not known.
7	Submission of placeholder data for numeric fields such as phone number, patient ID values, lot number, etc. (e.g., submission of 999-999-9999 or 123-456-7890 for phone number)	Repeated or consecutive numbers are often indicators of placeholder numeric data
8	Historical immunizations have lot number information or are received within 24 hours of administration	This might indicate an error with the administered/historical indicator

9	Lot numbers that violate validity expectations	Examples: • Numbers that start or end with certain combinations of characters, such as: MED, SKB, LOT, PENT, DTAP, etc. • Inclusion of characters other than a dash (lot numbers should be represented only by combinations of letter(s), number(s), and/or dash(s) • Presence of preceding spaces or spaces within the number See MIROW Lot Number Validation Best Practices[32] and Lot Number Patterns by Manufacturer and Vaccine Table[33] for additional examples and discussion of this topic
10	National Provider Identifier (NPI) numbers that violate validity expectations	NPI numbers must be 10 characters, consist of all numbers, and begin with a 1 or 2. The number also contains a check digit that can be used in validation[34]

Timeliness

Timeliness refers to whether the time between vaccination and when the data were available in the IIS was within recommended limits. In the case of data submitted to IIS, timeliness generally refers to the time between when an immunization is recorded in the EHR and when that immunization is processed and available in the IIS.

In some IIS, submission to the IIS is simultaneous with processing and availability of that data; in others, there is a lag between submission and IIS processing. IIS should be cognizant of the potential for timeliness measures to be influenced by IIS processing lags. If timeliness measures are used to assess data submissions, they should reflect the time between an immunization administration and when that information was submitted to the IIS.

Timely reporting of immunization data helps ensure completeness of IIS data and accuracy of IIS functionality. When there is a delay between when an immunization event occurs in a clinical setting and when that immunization is recorded in the IIS, IIS CDS will not be accurate, IIS coverage assessment data will underestimate coverage, and IIS reminder/recall functionality may target individuals who are up to date on their immunizations. Timeliness has the potential to impact patient care, documentation, and reporting to meet childcare or school reporting requirements; additionally, over-vaccination and vaccine wastage may occur. Furthermore, the IIS inventory for that provider will not be reflective of its actual inventory for IIS that perform dose-decrementing based on reported immunizations. This could present problems for dose accountability and vaccine ordering.

If timeliness measures are used to assess provider data submissions, they should reflect the time between an immunization administration and when that information was submitted to the IIS.

32 Lot Number Validation Best Practices, Revision 1.1, June 2015. AIRA. http://www.immregistries.org/resources/AIRA-MIROW_Lot_Numbers_Validation_Best_Practices_Micro-Guide_-Final-.pdf

33 Lot Number Patterns by Manufacturer and Vaccine Table, Updated May 2016. AIRA. http://www.immregistries.org/resources/aira-mirow/AIRA_MIROW_Microguide_-_2015_Lot_Number_Patterns_v2.0.pdf

34 See Requirements for National Provider Identifier (NPI) at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProvIdentStand/Downloads/NPIcheckdigit.pdf.

The use of SOAP web services and other transport protocols that support real-time transfer of data from EHR systems to IIS have no doubt increased the timeliness of data submissions to IIS. Real-time data transfer is ideal, as this allows clinicians to take advantage of IIS CDS and allows IIS to receive timely updates.

Timeliness Thresholds and Indicators

The current IIS Functional Standards do not offer specific timeliness targets for data submissions. Likewise, while the MIROW data quality guides call for timely submission of data to the IIS, this is not further defined.

Many IIS expect real-time submissions that are technologically capable. Although real-time data transfers usually occur within seconds, timeliness measures generally assess the proportion of data submitted within one day of when the vaccination information was recorded in the EHR. For submitters that are not capable of real-time data exchange, many IIS expect submission within one week of the vaccination event. Some timeliness reporting expectations may also be explicitly documented in statute, rule, or policy within a given jurisdiction.

Some IIS routinely monitor timeliness of data submissions by assessing the time between dose administration and entry into the IIS. Based on feedback received as part of an AIRA information request on the subject, one program reported requiring that 90% of administered immunizations be reported within one day and 100% be reported within three business days. Providers must meet this threshold as part of the onboarding process, and these timeliness measures are assessed weekly for production submitters. Another IIS monitors timeliness on a quarterly basis, along with other data quality statistics. The program uses a quarterly report that includes information on the average number of days between dose administration and entry into the IIS, by month and for the quarter. This program requires that all doses administered to persons younger than 18 years old be reported to the IIS within four weeks.

In these measures of timeliness, IIS must consider what data to analyze at what point in time. For example, allowing for a period of time to pass allows for capture and analysis of doses reported weeks or months after actual administration.

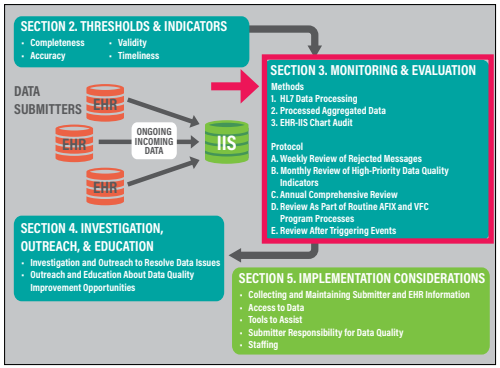
Other IIS programs reported monitoring for gaps or unexpected changes in reporting patterns as an indicator for potential issues with completeness and timeliness. Programs reported looking at whether real-time reporters submitted data for a given day and/or week and looking for submitters that did not send any data over a longer period of time, such as a month or four weeks.

Overall, practices to monitor or assess timeliness are used to help verify that electronic data interfaces are working as they should, especially for real-time submitters. Providers that routinely submit less timely data usually have barriers to more frequent data submission. While IIS programs want data submitted sooner rather than later, there may be appropriate occasions when it is acceptable to have slight delays in timeliness for the sake of accuracy and completeness of data submissions.

MONITORING AND EVALUATION

This section reviews methods to conduct ongoing monitoring and evaluation of data submissions as well as a recommended protocol for this practice. Methods for an IIS to evaluate data quality include:

- Analysis of HL7 data processing
- Analysis of processed aggregated data
- Comparing EHR and IIS data



Data review in each of these areas allows an IIS to look for different quality indicators; employing all three methods helps ensure a comprehensive data quality review.

A recommended protocol for continual monitoring and evaluation of data submissions should include both:

- A review of high-priority data indicators across submitters to identify those with critical issues needing follow-up
- A routine data review with submitters to review quality metrics and identify improvement opportunities.

CONSIDERATIONS

The following methods and practices discussed are intended to be recommendations for IIS to consider implementing to help ensure the quality of data submitted by providers. An IIS may go above and beyond these recommendations or may implement different aspects of these recommendations at different points in time. IIS should consider their data quality priorities and resources and pursue an approach that best fits their needs.

Methods

HL7 Data Processing

Analyzing HL7 data processing information is one method to review the quality of data submitted to the IIS. This includes analysis of message processing outcomes, such as rejected messages and other errors, volume of data processed, and frequency of data submission. Frequent review of HL7 data processing can:

- Alert IIS to issues that may not be as clear from review of aggregate data
- Alert IIS to technical issues with interfaces and/or with IIS HL7 processing functionality
- Allow for the quick identification and correction of issues

SECTION 3. MONITORING & EVALUATION

Methods
1. HL7 Data Processing
2. Processed Aggregated Data
3. EHR-IIS Chart Audit

Protocol
A. Weekly Review of Rejected Messages
B. Monthly Review of High-Priority Data Quality Indicators
C. Annual Comprehensive Review
D. Review As Part of Routine AFIX and VFC Program Processes
E. Review After Triggering Events

For example, an IIS may see a significant number of messages being rejected. If this is not discovered as part of the review of HL7 processing, it might not be discovered until there is investigation of lower than expected coverage rates in the IIS. Review of HL7 data processing can also alert IIS to EHR system upgrades and other changes that are not communicated to the IIS. These changes can result in data submissions that stop, submissions that include improperly attributed data, or submissions that result in an increased number of processing errors. Finally, review of HL7 data processing can alert IIS staff to processing issues that usually impact all submissions. As one SME reported, she could tell when her IIS HL7 processer was going to go down due to the issues she saw in her weekly review of all HL7 data processed.

Processed Aggregated Data

Analysis of processed aggregated data is another method for data quality review. Review of this data allows an IIS to assess completeness of individual data elements, accuracy and validity, and timeliness of submissions. Even with vigorous data validation practices in the onboarding process and monitoring of ongoing HL7 data processing, many IIS find data quality issues after looking at the data in aggregate form.

For example, one SME reported that evaluation of aggregate data revealed that all records had been submitted with the same race. The code was valid, so it was not flagged in the HL7 data processing. Investigation determined that the interface was set to send in a default race code, regardless of the patient race stored in the EHR. Review of processed aggregated data also allows IIS to evaluate data quality attributes discussed in this guide, including data element completeness (Table 2 and Table 3), assessment of improbable scenarios (Table 4), assessment of immunization validity (Table 5), and assessment of poor data submission practices (Table 6).

EHR-IIS Chart Audit

A third method for IIS to evaluate the quality of ongoing incoming data is to compare IIS data to the data documented in the originating medical record (i.e., paper charts or EHR charts). This practice is usually employed in the investigation of issues noted in analysis of HL7 data processing and/or analysis of processed aggregated data, as this provides verification of the accuracy of data reported to the IIS. The number of patient records reviewed often depends on the issue noted and when verification of an issue (and/or a correction of an issue) can be confirmed.

35 See MIROW Chapter 3, Stage 3: Chart Audits, http://www.immregistries.org/resources/aira-mirow.
36 http://www.immregistries.org/resources/data/AIRA_Data_Validation_Guide.pdf

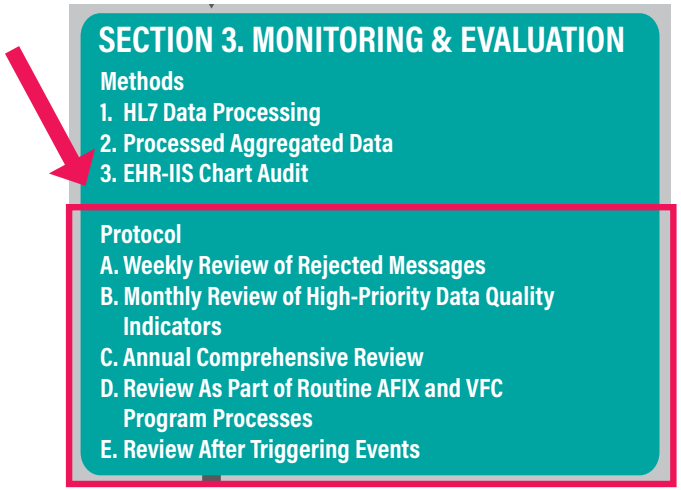
A more formal chart-audit process can also be employed as a complementary strategy for evaluating ongoing data submissions to an IIS. Chart audits usually involve comparing a set number of patient records in the IIS to records in the EHR to look for discrepancies in documentation in these systems for specific data elements. The review may be comprehensive and look at all data elements available or may focus on a subset of the elements deemed highest priority by the IIS.

Both the 2008 MIROW Guide[35] and the *Data Validation Guide for the IIS Onboarding Process*[36] include additional information about conducting a chart audit. Colorado and Massachusetts also offer examples of chart audits conducted as part of their data quality practices for ongoing data submissions. The Colorado program reviews approximately 50 patients, and the completeness and accuracy findings are translated into a Data Quality Report that is reviewed with the provider (see Appendix C-6 for additional detail). The Massachusetts program puts the onus of conducting a chart audit on the provider. Providers are expected to compare five to 10 records between their EHR and the IIS and submit their findings to the IIS program using an Excel template.[37]

Although individual patient record review and chart audits can be time consuming, comparison of patient records across systems can reveal data quality issues not evident through other means.

Protocol

IIS must consider the various data quality indicators and data quality review methods discussed and determine what indicators and practices are most applicable to their programs. This requires periodic review of the various data quality indicators and continual adjustments to how these are applied in routine data quality practices. Selection of indicators and thresholds and application to monitoring and evaluation practices must be based on individual IIS data needs, data analysis findings (and data quality issues of concern), and program capacity to implement.



Although application of these indicators and practices can vary across IIS, a recommended data quality protocol is offered. This protocol is intended to provide a framework for IIS to assess their own data quality practices or to help build a more comprehensive program. Programs may choose to implement this protocol with different frequencies and data indicators and by targeting specific providers for various aspects of monitoring and evaluation. Data use priorities and staffing will largely drive these decisions.

A comprehensive protocol for IIS monitoring and evaluation of data includes practices to identify and follow up on critical data issues in a timely manner as well as practices to more comprehensively assess data to identify general improvement opportunities.

Implemented together, these practices can help IIS ensure a well-rounded approach to ongoing monitoring of the quality of incoming data. Specific indicators and methods for each component of the recommended protocol are offered.

37 See Massachusetts 2016 AIRA National Meeting presentation on their data quality protocols and tools, at *http://www.immregistries.org/resources/iis-meetings/The_Quest_for_the_Best_Establishing_a_Data_Quality_Protocol_and_Tools_for_Incoming_Data.pdf*.

An IIS data quality protocol to review ongoing incoming data should include:

A. Weekly review of rejected message rates across submitters to identify those with high rates needing follow-up

B. Monthly review of data set completeness and accuracy indicators to identify those needing follow-up

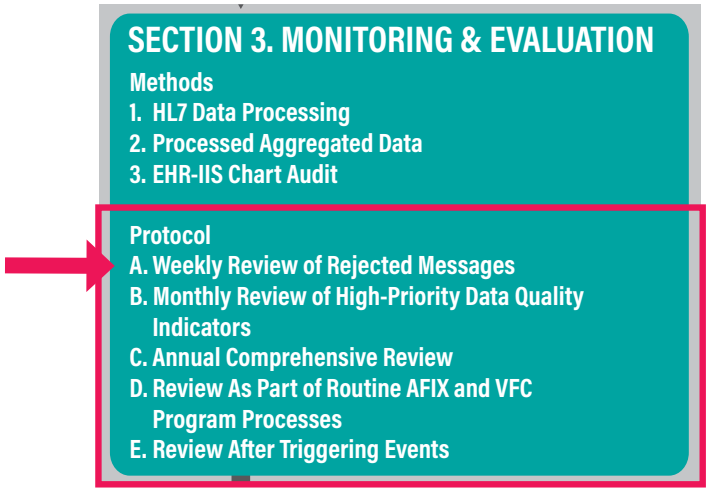
C. Annual comprehensive data quality review for each submitter, including comparison of EHR and IIS data

D. Review of select data quality indicators for individual providers as part of AFIX and VFC program practices

E. Ad hoc review after introduction of new vaccines, vaccine codes, immunization recommendations, and requirements

A. Weekly Review of Rejected Messages

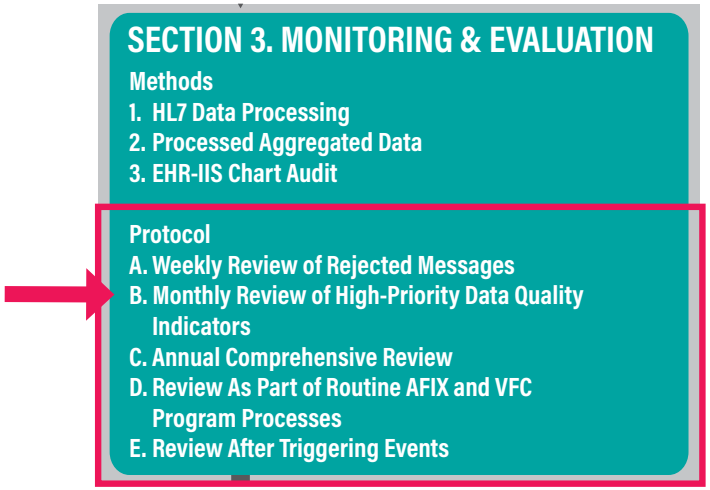
Frequent review of rejected message rates can alert IIS to problems stemming from interface changes that can negatively impact completeness and timeliness. Weekly identification of submitters with rejected message rates exceeding thresholds can allow an IIS to limit the impact of these lost data and quickly work with the submitter on a resolution strategy.



Tennessee and Nebraska each review rejected message rates across their submitter organizations on a weekly basis. The Tennessee Weekly Frequency of HL7 Imports Report (Appendix C-1) and the Nebraska Weekly HL7 Report (Appendix C-2), are both Microsoft Excel reports that list submitters in the jurisdiction and information on: total messages received in a given week, total rejected messages, and rejected message rates. Submitters with comparatively high rejected message rates are singled out for follow-up. These reports also contain additional information that help these programs further investigate HL7 data processing requiring follow-up.

B. Monthly Review of High-Priority Data Quality Indicators

In addition to rejected message rates, additional high-priority data indicators should be reviewed across submitters with relative frequency. Monthly review is suggested to allow for analyzing patterns within this timespan and to allow for time to complete follow-up with submitter organizations not meeting expectations.



Substantial variances in frequency and/or volume of reporting are both flags of incomplete reporting. Presence of an appropriate organization-identifying code in HL7 messages is another high-priority point of analysis for some IIS. Also, indications of potentially invalid immunizations should also be prioritized. Investigation can determine if these data are inaccurate or if they are accurate but violate validity expectations.

High-priority indicators to review monthly include:

- Substantial variance in frequency and volume of reporting (that is less than what is expected) [Completeness]
- Review of organization-identifying codes in HL7 messages [Accuracy]
- Indications of invalid submissions [Accuracy and Validity]

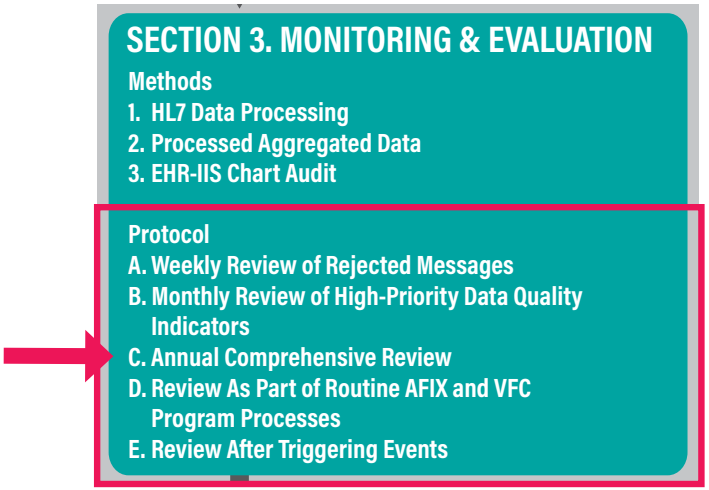
Sample IIS reports from Tennessee and Nebraska demonstrate analysis of data set completeness. The Tennessee Weekly Frequency of HL7 Imports Report (Appendix C-1) allows for analysis of HL7 message counts by week for the past four weeks as well as the date that non-submitting providers last submitted data. The Nebraska Weekly HL7 Report (Appendix C-2) allows for analysis of total immunizations and total records updated; Nebraska also reviews a Monthly Immunizations Report (Appendix C-2) that allows for comparison of total immunizations processed by each submitter. Both Tennessee and Nebraska also look at missing or mis-mapped organization identifying codes in messages with relative frequency.

The North Dakota Monthly VFC Provider Error Report (Appendix C-3) is an example of how one IIS implemented monthly data accuracy and validity analysis across its submitters. The North Dakota analysis looks at 25 different error scenarios that could potentially be indicators of inaccurate data or vaccine administration and vaccine management practices that do not follow expectations.

C. Annual Comprehensive Review

A comprehensive data quality protocol should also include a thorough review of a submitter's data completeness, accuracy, and timeliness on at least an annual basis.

The analysis is done based on processed, aggregated data from the submitter and may be presented in a Data Quality Report Card format.



Comparison of EHR and IIS data is also recommended, as this offers the opportunity to identify issues that may otherwise go unnoticed and provide verification of IIS data analysis findings. This in-depth review can occur on an anniversary date of onboarding or otherwise be completed on a rolling basis. The purpose of this review is to better understand the quality of an individual submitter's data submissions to an IIS and identify areas for improvement.

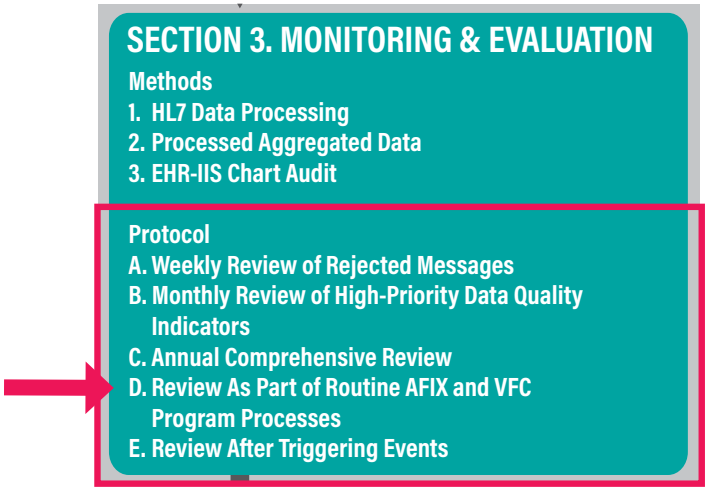
An annual comprehensive review of data from a submitter should include analysis of:

- Data completeness for key data elements
- Data timeliness
- Data accuracy

Sample reports from North Dakota, Kansas, Wisconsin, and Colorado demonstrate in-depth data quality reviews (Appendix C-3, C-4, and C-5, respectively). Each of these reports allows for review of a variety of indicators, including completeness rates for patient and immunization data elements, timeliness measures, and indications of inaccurate data submission. In Colorado, where data quality is graded on a Data Quality Report Card (Appendix C-6) per submitter, a portion of the grade is determined by the number of discrepancies found in a comparison of EHR and IIS data.

D. Review As Part of Routine AFIX and VFC Program Practices

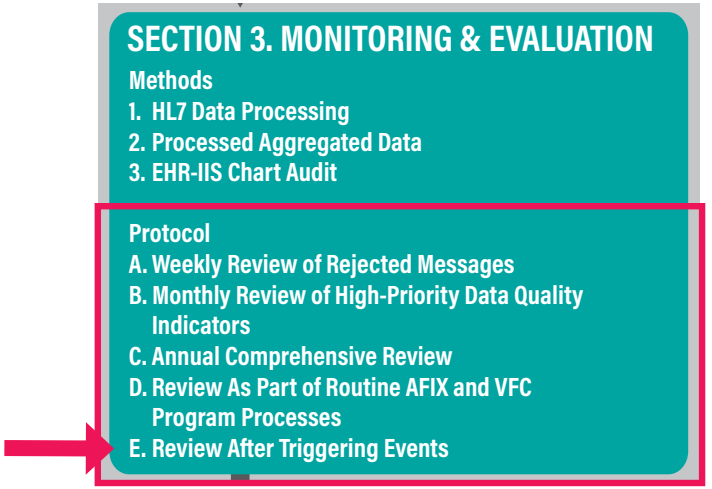
IIS data is being increasingly used to support immunization program activities such as Assessment Feedback Incentives Exchange (AFIX) assessments for immunizers as well as Vaccines for Children (VFC) vaccine ordering and accountability practices. IIS should enlist AFIX and VFC staff in the ongoing review of the quality of submitters' data submissions. Both the AFIX and VFC programs offer opportunities to discuss IIS data quality with submitters and tie that discussion to tangible data use implications.



AFIX and VFC staff may find an in-depth Data Quality Report Card informative, and they may also conduct additional data reviews at specific points in time. For example, an AFIX visit process may include an EHR-IIS chart audit component or a review of the distribution of vaccines reported to the IIS over a period of time. A chart audit would find discrepancies between EHR and IIS data, and a review of the distribution of vaccines reported could indicate potential issues with unreported or mis-mapped vaccine codes. These reviews (and any subsequent resolution) help ensure that the IIS-based AFIX coverage rates are an accurate reflection of the immunization status of the submitters' patient population. Similarly, "just in time" reviews of indicators related to immunization administration and vaccine management practices may be used in the VFC vaccine ordering process.

E. Review After Triggering Events

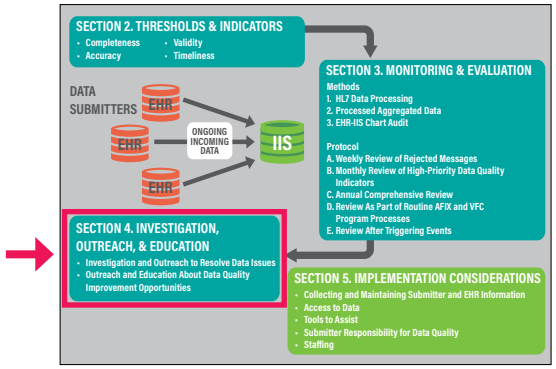
In addition to these routine data quality review practices, IIS should also conduct ad hoc reviews across submitting organizations after certain triggering events. This can include the introduction of new vaccines, new vaccine codes, and changes in federal immunization requirements. Another example would be a change in vaccine licensure and/or distribution that could affect vaccine practice. Cervarix® provides a relatively recent example. GlaxoSmithKline, the manufacturer of this human papillomavirus vaccine, announced in August 2016 that it would cease distribution of the vaccine in the United States.[38] The last shipment date occurred Aug. 31, 2016, for vaccine expiring Nov. 29, 2016. This product discontinuation offers an opportunity for IIS to evaluate whether any provider reported administration of Cervarix® after the expiration date.



38 GlaxoSmithKline letter to customers regarding Cervarix® vaccine distribution in the United States. Aug. 18, 2016. Available at https://www.gskdirect.com/medias/GSKDirect-Cervarix-Tip-Lok-Syringe-Discontinuation-8.18.2016.pdf?context=bWFzdGVyfHJvb3R8OTg1NDB8YXBwbGljYXRpb24vcGRmfGhmMi9oYTUvODg0MTAyNTM4O-DU3NC5wZGZ8NmE4NzUzYWUwMzYwMTE0Mjg2NmRhMmMwODQwOTY1YTA1ZDQ3YjliMGZlODY2ZmY-wOGE5ZmU3YmEyODQxOTFjOA.

INVESTIGATION, OUTREACH AND EDUCATION

This section reviews practices for follow-up and outreach with submitters, both when a critical data issue is identified that needs action and when the outreach is intended to be more informative or educational.



Investigation and Outreach to Resolve Data Issues

Monitoring data quality indicators across submitters allows IIS to identify those not meeting IIS quality expectations. Once these organizations are identified, IIS must prioritize submitters for additional investigation and outreach if necessary. IIS should evaluate metrics across all submitters to understand baselines and help set

thresholds for identification of submitters needing follow-up action. The baseline data and use of thresholds allows IIS to monitor the number of submitters needing follow-up over time. It also allows IIS to communicate data quality expectations and protocols to submitters. IIS programs may want to consider various factors when determining thresholds for submitter follow-up: quantity of messages received, quantity of immunizations administered, submitter type (e.g., pharmacy, pediatric clinic, etc.), and/or participation in the VFC program.

For example, Tennessee uses 5% as a threshold for rejected messages each week. Note: this includes fully rejected messages that are not processed by the IIS. Submitters exceeding this threshold are singled out for additional investigation and follow-up. Tennessee SMEs reported that they hope to see fewer submitters exceeding this threshold over time due to their continued attention to this data quality indicator. Similarly, North Dakota uses specific thresholds to quickly identify VFC providers needing follow-up due to errors seen on their Monthly VFC Provider Error Report (Appendix C-3). In North Dakota, these thresholds are set based on submitter size in terms of number of doses ordered. Programs may also want to prioritize based on submitter type and population served.

Depending on the data quality evaluation findings, IIS may perform additional investigation to verify or better understand what may be the cause the data issue(s) noted. Nebraska and Tennessee review a sample of individual HL7 messages identified in their evaluations as having high rates of rejected messages. Oftentimes, IIS staff identify the cause and can pass this along in their outreach to the submitter. North Dakota does additional investigation into the errors noted on its monthly report if it sees something particularly unexpected and/or surprising. This also prepares staff to discuss the findings with a submitter.

Communication to a submitter about a data issue should be targeted to the contacts that can help resolve the problem(s). The message should include a clear request for the submitter to follow up on the issue(s) noted within a specific time frame. Contacts to consider for outreach include individuals from a corporate health system, the clinic, and the EHR vendor group or another IT group, depending

on the submitter and how its data interface is set up. SMEs reported relying on existing relationships established through the submitter onboarding process or through other IIS or immunization program activities to conduct this outreach.

Tennessee and Nebraska reported doing quick phone calls or brief emails to submitter contacts about high rejected-message rates. These communications were conversational in tone and included a description of the problem (including potential causes that the IIS can see in the data) and proposed steps for resolution. In North Dakota, VFC staff conducts outreach to submitters exceeding monthly error thresholds. A secure email to these submitters describes the issues found, a spreadsheet containing the specific records needing review, and a deadline for follow-up.

Note: It is imperative for IIS programs to maintain data security and confidentiality while working with submitters to investigate, resolve, or discuss data quality issues. Oftentimes, IIS data quality investigations include review of specific client records. IIS should ensure that communications with submitter staff regarding these clients and their client records are handled in a secure manner.

Communications should be handled through phone conversations and/or through secure email systems and be limited to staff that have a role in investigating and/or resolving a data issue. Secure email systems use additional protections such as encryption and user login/message retrieval features to maintain security of the information being shared. Additionally, IIS can refer to client IDs rather than client names and other readily identifiable information in communications with submitters.

Resolution Process

Once the initial outreach to a submitter about a data issue has been completed, IIS should take steps to ensure that follow-up action occurs within the time period expected. This involves tracking the data issue and performing ongoing outreach as needed until the IIS can verify that the issue(s) has been resolved. Verification may include review of the submitter's HL7 data processing, review of the submitter's processed aggregated data, and/or comparison of EHR and IIS records. If data quality issues are numerous and/or significant enough, an IIS may have the submitter go through the full onboarding data validation process again. The selection of verification methods should depend on the original issue(s) uncovered.

Throughout the outreach process, IIS staff should serve as a resource for the submitter to make sure they understand the problem and uncover and address the root cause. Oftentimes working with a submitter on a data issue involves facilitating conversations between a submitter's clinical staff and their EHR or IT support contacts. It can also involve conversations with additional stakeholders, such as VFC or other immunization program staff when immunization administration and/or vaccine management practices are being investigated.

In Nebraska and Tennessee, their routine HL7 data processing reports allow them to monitor rejected message rates and other data processing indicators to see if follow-up action has occurred. While they reported that most submitters respond to their outreach quickly, some are identified as needing outreach week after week or month after month. They reported that factors influencing how quickly data issues are addressed include the contacts involved in the outreach, the EHR or IT vendor, and the relationship between the submitter and their EHR or IT support. SMEs noted that, in some cases, changes needed to address a data issue are entered into a queue for the vendor or technical contact to address.

In North Dakota, VFC providers are expected to address the data issues noted on their emailed Error Reports within one month. North Dakota staff re-runs the report for these providers to see if there is a change in the total number of errors in the IIS data.

In the event of inaccurate documentation or interface issues, resolution involves not only correcting the issue for future submissions but also correcting inaccurate or incomplete data from previous submissions. While a submitter must be responsible for submitting data to address completeness concerns, correcting inaccuracies in existing IIS data can be done by either the submitter or the IIS. Often, this depends on the scope of the problem and the submitter's capability to submit corrections. In North Dakota, submitters are responsible for making corrections for errors noted on their Monthly VFC Error Report. SMEs also reported willingness to do mass cleanups of data when investigation reveals an inaccuracy that spans a greater period of time and/or impacts a greater volume of records.

If a submitter is non-responsive to repeated outreach regarding a data quality concern, IIS should leverage any state or federal reporting requirements/programs and the VFC program to motivate them to action. For example, submitters participating in Meaningful Use programs are generally expected to be responsive to public health agencies; lack of responsiveness could potentially impact their program attestation and/or audit results.[39] VFC programs can also be used as leverage, as lack of response on IIS data quality concerns could translate to site visits or impact their ability to order vaccine.

SMEs noted these strategies were generally a last resort due to lack of response from a submitter's EHR/IT contacts (rather than unwillingness on the part of the submitter to resolve the issue). However, IIS that referenced immunization reporting requirements in the Meaningful Use program in their outreach to submitters found that it was an effective strategy to garner a quick response. Very few of the SMEs interviewed reported getting to the point of either threatening to turn off or disconnecting a production interface due to lack of responsiveness regarding data issues. If this strategy was pursued, it was in consultation with submitter contacts to gain the attention of EHR/IT staff or to address significant data issues.

Outreach and Education About Data Quality Improvement Opportunities

In addition to conducting outreach with submitters not meeting data quality expectations, IIS should also aim to conduct outreach based on an Annual Comprehensive Review for all submitters in the jurisdiction. This reinforces IIS data quality expectations and provides an opportunity to make data improvement suggestions. While largely meant to be educational and informative, these reviews ensure that data issues that need timely correction or follow-up do not otherwise get missed.

Outreach and Education Tips:

- Offer a summary so the submitter can quickly see at a glance how it is doing in terms of the quality of data submissions and opportunities for improvement.
- Remind submitters of the connection between IIS data quality and data use—not only by the submitter but also by all IIS users.

39 The Centers for Medicare and Medicaid Services EHR Incentive Programs Modified Stage 2 and Stage 3 Final Rule includes a discussion of the "active engagement" providers must exhibit in working with public health agencies. See pp. 62818-62819, https://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25595.pdf.

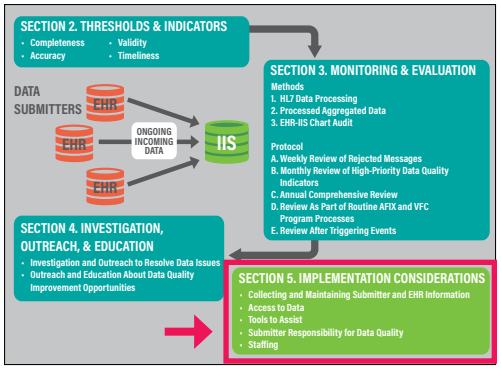
- Consider sharing information on how the submitter's data quality compares to others in the jurisdiction to increase interest in and investment in these analyses.
- The data quality review should be shared with staff that are responsible for addressing areas for improvement. Provider organization Meaningful Use contacts and senior leadership may also benefit from receiving IIS data quality updates.
- Determine the best method for sharing information, either via email or through scheduled conference calls, for example. This may depend on the results of an analysis and whether there were any critical findings needing more timely investigation and/or follow-up.

The concepts described in this chapter are demonstrated in sample reports from Colorado, Wisconsin, and North Dakota. Colorado lists a prominent grade on its *Data Quality Report Card* (Appendix C-6). An "A" grade on the report is considered passing, and no additional follow-up action is requested. A grade of "B" or "C" is used to indicate that work is needed to improve the quality of data submissions. The Wisconsin *Data Quality Report* (Appendix C-5) offers an upfront summary of findings, followed by customized and specific suggestions for data improvement. Finally, the North Dakota *Quarterly Interoperability Report* (Appendix C-3) includes data allowing for comparison to other specific submitters within the jurisdiction and includes several explanatory footnotes that help a submitter interpret the data.

IMPLEMENTATION CONSIDERATIONS

This section of the guide is intended to review general implementation considerations and strategies to help programs looking to begin or enhance their data monitoring and/or evaluation practices. Major topics discussed include:

- Collecting and Maintaining Submitter and EHR Information
- Access to Data
- Tools to Assist
- Submitter Responsibility for Data Quality
- Staffing



Monitoring and evaluating incoming data is an ongoing task that requires dedicated resources. This involves establishing, maintaining and/or enhancing data quality monitoring and evaluation tools or reports, conducting the analysis, and completing ongoing outreach to resolve data issues and provide education around data quality, all potentially time- and resource-intensive activities. These implementation considerations and strategies are aimed at helping programs make informed decisions about the design of data monitoring and evaluation protocols that support efficient use of time in implementation of these activities.

Collecting and Maintaining Submitter and EHR Vendor Information

Maintaining information about submitters is critical for IIS to understand what data to expect, how to interpret data submitted, and whom to follow up with regarding data issues.

These data can be cross-referenced in ongoing data quality checks to assess data submissions. For example, Oregon is planning to add a field to its provider management system to capture expected frequency of data submissions. Storing this data will allow it to cross-reference with frequency seen in data submissions to the IIS and quickly flag those needing follow-up.

In addition to serving as reference for that individual submitter, this information can help IIS build generic profiles of certain submitter types that can be used in the data quality analysis process (i.e., if a submitter is a certain type, its administered vaccinations should match a pattern in similar practices and/or should match a state-supplied vaccine list). Developing automated profile checks such as this can help IIS quickly identify variance from expected patterns that may reflect actual clinical activity or potential vaccine coding errors. The Data Validation Guide[40] and the 2008 MIROW Guide[41] offer additional detail on use of provider profiles in data quality review.

Finally, while some data issues are submitter-specific, some can span otherwise unrelated organizations that share the same EHR platform. Multiple SMEs indicated that maintaining a log of EHR platform and/or vendor issues was particularly helpful.

40 See Section 4. Provider Organization Profiles in the AIRA Data Validation Guide: http://www.immregistries.org/resources/data/AIRA_Data_Validation_Guide.pdf.

41 See Chapter 3. Data Quality Assurance in IIS: Incoming Data: http://www.immregistries.org/resources/aira-mirow.

Submitter information for IIS to collect and maintain may include:

- Organizational affiliation(s)
- Organization type
- Population served
- Vaccinations administered, including types and volume
- Provider contacts:
  - Nurse clinic managers
  - VFC contact(s)
  - EHR/IT technical contact(s)
  - Quality improvement contact(s)
  - Reporting program (e.g., Meaningful Use) contact(s)
- Interface details:
  - Previous onboarding go-live date(s)
  - Format used
  - Transport used
  - Expected frequency
  - Expected volume of messages
  - EHR platform
  - HIE(s) used
- Information about IIS data quality findings and/or investigations

Access to Data

Programs must consider access to data for data quality monitoring and evaluation activities. Data to query and potentially track over time include: original data submissions, data related to HL7 processing (e.g., errors generated), submitters' processed data, and data quality metrics generated through monitoring and evaluation reports.

While access to submitters' processed data in the IIS generally isn't a problem, programs may need to consider how to access original data submissions and HL7 processing information, both to troubleshoot and investigate data issues and to allow querying for patterns. Sometimes these data are saved and/or readily accessible for only a short period of time. Because of this, one program that was interviewed copied HL7 processing data from its IIS on a weekly basis and saved this information in an Access database to facilitate analysis.

Similarly, IIS need to consider data processing capacity and data storage needs for executing data quality queries and storing results from these analyses. For example, the Wisconsin IIS program noted that it must run its data quality report card queries during off-hours to prevent the system from slowing down for its users. It also reported that the report card results and outputs take up a significant amount of space.[42] Finally, programs should consider whether and how to track data quality progress over time. Tracking over time requires storage of data quality query findings to allow for this information to be accessed later for comparison purposes.

Tools to Assist

Performing ongoing data quality monitoring and evaluation is a resource-intensive task. IIS programs should consider what tools are available to support staff with this work—including those currently available within their IIS or department and those in use in other IIS programs.

42 Petit, A. Wisconsin Immunization Registry Report Cards: IIS Data Quality Feedback to Providers. Presentation at the 2016 AIRA National Meeting. Slides available at http://www.immregistries.org/resources/iis-meetings/Wisconsin_Immunization_Registry_Report_Cards_Providing_IIS_Data%20Quality_Feedback_to_Providers.pdf.

Other strategies to ensure quick access to monitoring and evaluation data include:

- Automating the generation of routine data quality queries
- Setting up queries to flag or otherwise highlight indications where data submissions do not meet expectations
- Using report outputs that allow review of data at multiple levels of submitter organization hierarchy

For example, the Nebraska weekly and monthly data reports (Appendix C-2) present results at the parent organization level; staff can click a drop-down button within the report to quickly see the data for all submitters affiliated with the parent organization. These can help IIS spend additional time on conducting outreach and data improvement instead of on report generation and review.

Designing and enhancing data quality reports can be time- and resource-intensive for both IIS program and IT staff. IIS may want to consider joint development opportunities and/or use of shared services or products for data quality monitoring tools and reports. Joint development may include any collaborative development of standards, business requirements, functional or system requirements, design specifications, or production of actual software tools or applications by two or more IIS.[43] Products of joint development work may be deployed by individual programs or collectively as an open source or other shared resource.

Programs may also consider use of currently available open source tools to aid in the work of monitoring and evaluating incoming data. This includes the IIS Data Quality Assurance (DQA) tool and HLN's Quality Assurance (QA) tool. The DQA tool is a product designed to assist IIS in monitoring and analyzing the quality of data submissions. It allows for analysis of HL7 data processing outcomes as well as review of aggregate data in the IIS.[44] Another open source tool available to programs is the QA tool. This tool allows IIS to easily review a body of processed HL7 messages and drill down to review errors and warnings recorded by the IIS HL7 message processor.[45] More information about both tools, including sample screens/reports, a list of current users, and references to learn more, is available in Appendix D.

Data quality assurance in an IIS is an ongoing need. Regardless of a program size, IIS should ensure resources are dedicated to efforts to monitor and improve the quality of data submitted to the IIS.

In addition to data quality tools and reports, IIS should also consider contact management systems and issue tracking systems. These systems can track submitter contacts and previous and current data quality investigations and follow-up actions. This helps ensure visibility into current and previous data quality issues.

Submitter Responsibility for Data Quality

One of the most important strategies for IIS to ensure the quality of ongoing incoming data is to enlist data submitters in this work. IIS should clearly communicate submitter data quality expectations and

refer to these expectations in data use agreements, in the onboarding process, and in routine program interactions with submitters (e.g., AFIX and VFC). Published expectations around ensuring data quality should include:

- A description of what it means to submit complete, accurate, and timely data

43 Immunization Information Systems Joint Development: Practical Guidance for Collaborative IIS Projects. http://www.immregistries.org/resources/Joint_Development_Report-_Final.pdf

44 See http://openimmunizationsoftware.net/dataQuality/dataQuality.html.

45 Noam Arzt communication with AIRA staff.

- Expectations for maintenance of data interfaces, including: ensuring CVX, NDC, and MVX code tables and VIS publication dates are current with CDC-provided updates; ensuring that data are submitted to the IIS if an interface is interrupted by a power outage or installation or upgrade of servers or software
- Expectations for designating individual(s) responsible for IIS data investigation and resolution
- Expectations for submitter responsibilities for ongoing monitoring and evaluation of data quality, including: monitoring and handling ACK messages, resending any failed messages after correcting the problem with the message (in response to ACK notifications), consistent generation and review of any reports available in the IIS for the submitter to conduct a self-assessment of its data quality, and participation in EHR-IIS chart audits, as necessary
- Expectations for maintaining ongoing communication with the IIS around changes that may impact data submissions, including: notification of EHR upgrades and/or changes, changes related to submitter organization ownership or management (change in affiliation, mergers, closures, etc.); submitters should also proactively notify IIS in the event of staffing changes related to data quality contacts
- Expectations for responding to IIS data inquiries or data concerns in a timely manner

IIS can also encourage submitter responsibility for data quality by:

- Highlighting or otherwise championing submitters with high data quality
- Sharing information on how submitter organizations compare to their peers in data quality metrics, to motivate improvement
- Offering guidance and training on how submitters can monitor, assess, and improve their IIS data quality (This should be done as part of the onboarding process and as part of routine interactions with the provider on AFIX and VFC matters. IIS can also integrate training opportunities into Help Desk interactions. Training should cover: how to monitor and respond to ACK messages and how to run, interpret, and use reports available to them in the IIS that can help them monitor and improve data quality.)
- Communicating data quality indicators and monitoring/evaluation protocols used by the IIS so submitters are aware of what will be assessed and when outreach around data quality issues may occur
- Encouraging submitter use of IIS data and functionality, including CDS, assessment reports to monitor rates (outside of formal AFIX visits), and reminder/recall functionality; submitters that use these data and tools are more likely to be invested in them and motivated to ensure high-quality data submissions

Finally, in interactions with submitters, IIS should continually emphasize the importance of data quality in terms of its impact on data use—for the individual provider and for all users of the system. The data quality practices are meant to ensure that all IIS users have complete, accurate, and timely information to support clinical and public health actions.

Staffing

Another consideration for IIS in implementing the data quality practices is the variability in how this work can be staffed within a program. SMEs interviewed held a variety of positions within their respective programs: epidemiologist, help desk and data exchange coordinator, and data quality specialist, for example. In some cases, the data quality practices were split among multiple staff (e.g., one staff person responsible for monitoring HL7 processing and another staff person responsible for data quality outreach). In other cases, multiple staff shared joint responsibility for the data quality practices related to ongoing data submissions, or one staff person led all the various data quality tasks.

IIS can refer to the IIS sample role descriptions from the Public Health Informatics Institute[46] for guidance on staffing roles and responsibilities within an IIS program. Job roles especially relevant to the data quality practices outlined in this guide include: data quality analyst, interface analyst, data extract analyst, and data entry deduplication specialist.

Regardless of the staffing model, IIS should ensure that responsibilities are clearly delineated and that resources are dedicated to the highest-priority data quality tasks. Data quality responsibilities can also be embedded within multiple IIS and immunization program positions, as IIS data quality is an integral part of numerous immunization program activities.

46 IIS Workforce Classifications, available at http://www.phii.org/resources/view/9398/iis-workforce-classifications.

CONCLUSION

Conducting ongoing monitoring and review of incoming data can uncover a myriad of data issues, from improper vaccine administration to poor quality documentation. Ultimately, these issues can impact IIS usability and hamper clinical and public health efforts to protect individuals and the community from disease.

Ensuring the quality of incoming data to an IIS is no small task. It is an ongoing need that involves data monitoring and analysis, outreach, and working with submitting organizations to address data issues. Data validation in the onboarding process is an important tool to establish high-quality data interfaces. However, this is not a guaranteed constant. Many factors can influence the quality of data submitted to an IIS production environment, including: technological changes such as system upgrades or EHR changes, submitter changes such as buyouts and mergers, staffing changes, and changes in vaccine products and recommendations. In addition to reviewing data for documentation errors, IIS and immunization programs also have an interest in identifying potential vaccine management and administration practices that fall outside of requirements and/or recommendations.

IIS programs can analyze a variety of data quality indicators to review incoming data. This guide presented a summary of these indicators for consideration. Determining what to monitor and assess and thresholds to use in this practice are decisions that should be based on consideration of multiple factors, including: data quality concerns and/or priorities, current and planned data use, and program capacity. This guide reviews sample practices of two aspects of data monitoring and analysis: monitoring HL7 data processing outcomes and reviewing submitters' aggregate data in the IIS. This guide also offers a review of methodologies used in select programs, including an overview of the tools and reports utilized for data quality monitoring and evaluation. The information presented is aimed at helping IIS programs expand their efforts to monitor and analyze incoming data and take steps to address data quality issues.

These actions help ensure that IIS users have access to complete, accurate, and timely data to support clinical decision making and public health immunization assurance activities.

APPENDIX A: DATA ELEMENTS BY DATA USE

Completeness and accuracy of certain data elements in submissions have implications for IIS processes and/or data use practices. The following table offers a list of these data elements cross-referenced by data use. IIS can use this information in determining priority data elements to monitor and evaluate.

CONSIDERATIONS

IIS should review local IIS processing algorithms and planned data use to confirm elements utilized. Additionally, deduplication processes can place higher emphasis on certain data elements to aid in the deduplication of records.

Table 7. Data Elements Included in Provider Submissions by Data Use

	Patient-Level De-Duplication[47]	Vaccine-Level De-Duplication[48]	Quality Checks[49]	Dose Decrementing from Inventory[50]	Reminder/ Recall[51]	Coverage Assessment[52]
Patient Demographic Data Elements						
Patient Clinic ID	X			X	X	X
Patient Name	X				X	
Patient DOB	X		X		X	X
Patient Gender	X		X		X	X
Patient Address	X				X	X
Patient Race	X					X
Patient Ethnicity	X					X
Patient Phone	X				X	
Patient Phone Type					X	
Patient Email Address					X	
Patient Primary Language					X	
Mother's Maiden Name	X					

47 See also *Immunization Information Systems Patient Level De-Duplication Best Practices*. Section 3.6 includes a review of identifiers. Available at https://www.cdc.gov/vaccines/programs/iis/interop-proj/downloads/de-duplication.pdf.

48 See the 2006 MIROW Guide on *Vaccine Level Deduplication in IIS* for a discussion of this topic. Available at http://www.immregistries.org/resources/AIRA-BP_guide_Vaccine_DeDup_120706.pdf.

49 Data quality crosschecks are discussed in the 2008 and 2013 MIROW Guides on Data Quality (Chapters 3 and 7). These are available at http://www.immregistries.org/resources/aira-mirow.

50 See the 2016 MIROW Guide on *Decrementing Inventory via Electronic Data Exchange* for a discussion of key data elements used in this process. Pp. 90-91. Available at http://www.immregistries.org/resources/aira-mirow/AIRA_MIROW_Decrementing_Inventory_via_Electronic_Data_Exchange_Guide.pdf.

51 See the 2009 MIROW Guide on *Reminder/Recall in IIS* for a discussion of this topic. Available at http://www.immregistries.org/resources/AIRA-MIROW_RR_041009.pdf.

52 See the 2015 *Analytic Guide for Assessing Vaccination Coverage Using an IIS* for a discussion of this topic. Available at http://www.immregistries.org/resources/other-aira-resources/Analytic_Guide_for_Assessing_Vaccination_Coverage_Using_an_IIS.pdf.

Table 7, continued. Data Elements Included in Provider Submissions by Data Use

	Patient-Level De-Duplication[47]	Vaccine-Level De-Duplication[48]	Quality Checks[49]	Dose Decrementing from Inventory[50]	Reminder/ Recall[51]	Coverage Assessment[52]
Patient Demographic Data Elements						
Mother's Name: First, Middle, Last	X				X	
Vaccine Data Elements						
Vaccine Administration Date		X		X		
Vaccination Product Type		X	X	X		
Vaccine Event Information Source			X			
Vaccine Manufacturer			X			
Vaccine Lot Number				X	X	
Vaccine Expiration Date			X	X		
Vaccine Dose Volume and Unit			X			
Vaccine Site of Administration			X			
Vaccine Route of Administration			X			
Vaccine Administering Provider: Name, Suffix			X			
Vaccine Eligibility at Dose Level				X		
VIS Information: Type, Publication Date, Date Given to Patient			X			

APPENDIX B: REQUIRED SEGMENTS & DATA FIELDS FOR HL7 SUBMISSION MESSAGING

The current HL7 Implementation Guide[53] and corresponding Addendum[54] indicate usage guidelines for message segments and elements within segments. If an IIS conforms to the guide regarding treatment of the required segments and elements, lack of submission of these required or conditionally required segments and/or fields in a VXU message would result in fatal processing and rejection of the message.

In addition to these requirements, IIS may further constrain local implementation specifications to require additional information in VXU messages.[55] For example, some IIS require inclusion of MSH-4 in messages even though the current Implementation Guide lists this field as required, though it may be empty (R instead of RE). IIS should review their HL7 processing functionality and their local specifications to confirm scenarios that may cause rejections.

Use of required fields in HL7 processing should always be based on business need. Programs must balance the need for certain data with the potential that the requirements may result in increased rejected messages and loss of data.

53 HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5). Nov. 5, 2014. Available at https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html.

54 HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5) Addendum. July 2015. Available at https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html.

55 Additional information about constraining the IG for local needs is available in the AIRA/CDC HL7 FAQ document: http://www.immregistries.org/resources/technical-assistance/HL7_FAQ_December_2016.pdf.

APPENDIX C: SAMPLE DATA MONITORING AND EVALUATION REPORTS FROM IIS PROGRAMS

IIS methods for ongoing monitoring and evaluation of data submissions are continually evolving. The samples shared in this appendix offer a snapshot of the tools and reports used by select IIS in this process at one point in time. These samples were shared in response to AIRA information requests or in AIRA meeting presentations for the benefit of the IIS community.

Appendix C-1. Tennessee

Tennessee Weekly Frequency of HL7 Imports Report[56]

Background

Report is used by staff to review HL7 message processing. It identifies submitters with a >5% error rate for a given week and is used to identify submitters that have not submitted data in the given time period. Key data fields include:

- Organization name and organization IDs
- HL7 message data by week for each of the past four weeks: the sum of HL7 messages received, the sum of HL7 messages resulting in an error, the sum of HL7 messages resulting in an error due to an internal system issue
- A message error rate for the past week (rate of >5% flagged for follow-up)
- Reason for error
- Date last message was received (among non-submitting organizations)

Note: Approximately 488 organizations are represented on the report. These organizations may represent multiple individual facilities. On average about 20 organizations exceed the 5% error threshold for a given week.

Report Generation

Tennessee generates a daily report showing the same information; the daily report displays information for each day for the last seven days. The daily report is used to investigate issues seen on the weekly report, e.g., to pinpoint the start of a problem. Both the daily and the weekly report are auto-generated using SAS. SAS queries are set up to access the IIS data tables to pull in the necessary data. SAS generates an XML file with the results. Staff open the XML file in MS Excel for review.

56 Information based on interview with Tennessee IIS staff and material submitted to AIRA in response to information request on this subject.

Sample Report Images

Figure 3. Tennessee Weekly Frequency of HL7 Imports Report

Example *Weekly Frequency of HL7 Imports by Organization Report*

Weekly Number of HL7 Imports by Org.
09/11/16 through 10/08/16

Organization Name	IRMS Number	PHC-Hub Profile ID	Yr_2016_Wk_37_Num_All	Yr_2016_Wk_37_Num_Err	Yr_2016_Wk_37_Num_Inf_Err	Yr_2016_Wk_38_Num_All	Yr_2016_Wk_38_Num_Err	Yr_2016_Wk_38_Num_Inf_Err	Yr_2016_Wk_39_Num_All	Yr_2016_Wk_39_Num_Err	Yr_2016_Wk_39_Num_Inf_Err	Yr_2016_Wk_40_Num_All	Yr_2016_Wk_40_Num_Err
Organization A	2863	17011	173	0	0	9	0	0	52	0	0	0	0
Organization B	21905	2326	99	0	0	162	1	0	127	0	0	123	0
Organization C	21823	1957	0	0	0	0	0	0	0	0	0	0	0
Organization D	3488	1952	7	0	0	13	0	0	14	0	0	18	0
Organization E	3999	2325	0	0	0	0	0	0	0	0	0	0	0
Organization F	5004	2008	0	0	0	0	0	0	0				
Organization G	3486	1544	293	5	0	145	1	0	252				
Organization H	112	1242	110	1	0	46	0	0	0				
Organization I	1884	1541	0	0	0	0	0	0	0				
Organization J	10244	765	151	0	0	353	0	0	193				
Organization K	21916	1951	0	0	0	0	0	0	0				
Organization L	4599	848	88	0	0	78	0	0	83	0	0	100	0
Organization M	3791	931	10336	0	0	0	0	0	0	0	0	0	0
Organization N	10257	849	0	0	0	0	0	0	0	0	0	0	0
Organization O	3800	1782	0	0	0	0	0	0	0	0	0	0	0
Organization P	1352	2346	13	0	0	1,586	1	0	9	0	0	146	0
Organization Q	21727	1951	9	0	0	12	0	0	31	0	0	4	0
Organization R	1878	2884	0	0	0	7	0	0	3	0	0	55	0
Organization S	21935	1975	0	0	0	0	0	0	0	0	0	0	0
Organization T	21976	2427	0	0	0	0	0	0	0	0	0	0	0
Organization U	1465	716	0	0	0	13	0	0	15	1	0	12	0
Organization V	10248	717	2552	111	0	2542	0	0	3288	0	0	2258	0
Organization W	1381	844	252	2	0	401	2	1	397	7	0	484	6

SUM OF HL7 IMPORTS BY PROVIDER AND BY WEEK

Gray rows: No HL7 messages have been received by the organization in the reported timeframe

Example *Weekly Frequency of HL7 Imports by Organization Report*: Organizations with >5% of Messages Error the Previous Week

Weekly Number of HL7 Imports by Org.
09/11/16 through 10/08/16

Organization Name	IRMS Number	PHC-Hub Profile ID	Yr_2016_Wk_40_Num_All	Yr_2016_Wk_40_Num_Err	Percent	Reason_for_Error (select organization only)
ORGANIZATION A	1342	758	1	1	100	Invalid vaccination date
ORGANIZATION B	1656	1790	30	30	100	Invalid vaccination date
ORGANIZATION C	10331	686	7	2	28.57142857	No vaccination date
ORGANIZATION D	21706	1325	5302	1504	28.36665409	
ORGANIZATION E	950	472	77	20	25.97402597	
ORGANIZATION F	21842	1765	97	15	15.46391753	
ORGANIZATION G	3463	1223	446	68	15.24663677	
ORGANIZATION H	652	1766	66	10	15.15151515	Missing patient address
ORGANIZATION I	750	1641	91	12	13.18681319	Sending in NF as the CVX code for Gardasil 9; this is unrecognized
ORGANIZATION J	10332	702	18	2	11.11111111	No immunization date

PROVIDERS WITH >5% ERROR RATE IN A GIVEN WEEK

Date Non-Submitting Orgs Last Submitted as of 10/08/16

Organization Name	IRMS Number	PHC-Hub Profile ID	Year	Month	Day
ORGANIZATION A	2841	1448	2016	8	29
ORGANIZATION B	2532	1321	2016	8	23
ORGANIZATION C	21669	1927	.	.	.
ORGANIZATION D	889	507	2016	6	24
ORGANIZATION E	21539	760			
ORGANIZATION F	10156	509			
ORGANIZATION G	10158	511	.	.	.
ORGANIZATION H	10154	508	2016	8	16
ORGANIZATION I	1964	1561	2015	11	24
ORGANIZATION J	3702	1743	2016	8	18
ORGANIZATION K	21521	741	2016	4	27
ORGANIZATION L	2734	1189	2016	7	19
ORGANIZATION M	1988	1644	2016	4	14
ORGANIZATION N	21919	1953	.	.	.
ORGANIZATION O	21636	1190	2016	1	14
ORGANIZATION P	3707	1401	.	.	.

LIST OF NON-SUBMITTING PROVIDERS, WITH DATE OF LAST SUBMISSION

If year, month, and day are missing, then the organization has never submitted data to TennIIS

Appendix C-2. Nebraska

Nebraska Weekly HL7 Summary and Detailed Reports[57]

Background

The reports are used by staff to identify submitters with failed jobs and/or a high number of rejected messages for a given week. The program looks for submitters with greater than a 20% rejected-record rate for a given week and submitters with no jobs processed. The report is also used to identify the cause of the rejections. Key data fields include:

- Organization name and organization IDs; can also be viewed by parent organization and/or the vendor submitting the data
- Summary HL7 data for the week of interest:
  - Jobs: count of completed, count of failed, total, and percent completed rate
  - Records: count of processed, count of rejected, and percent rejected rate
  - Immunizations: count of new immunizations
- Detailed HL7 data for the week of interest: reasons for rejected messages (count by reason)
- Watch reports:
  - Organizations with 20% or more rejected records
  - RXA-5 rejection reasons
  - Non-submitting organizations

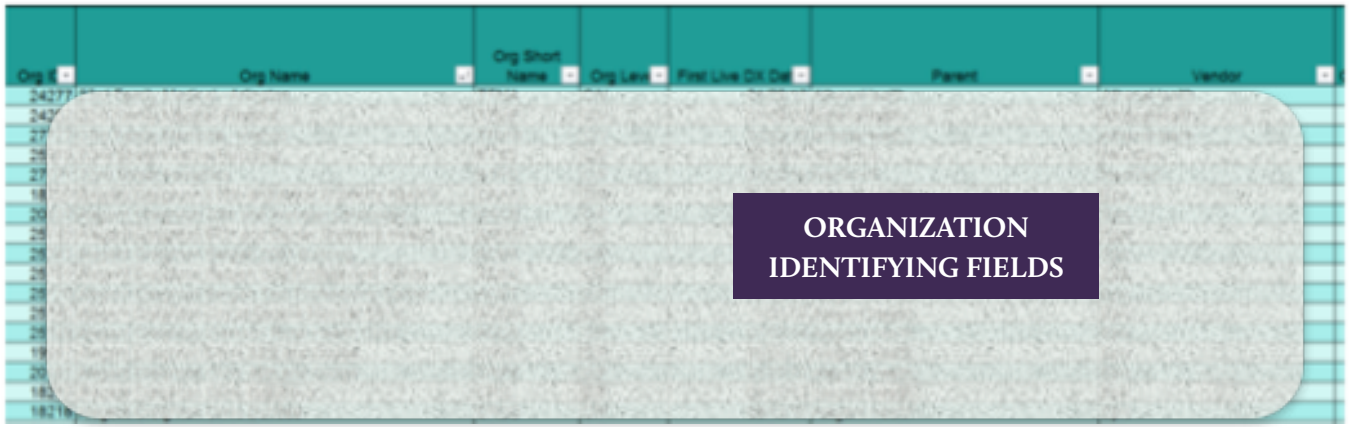
Report Generation

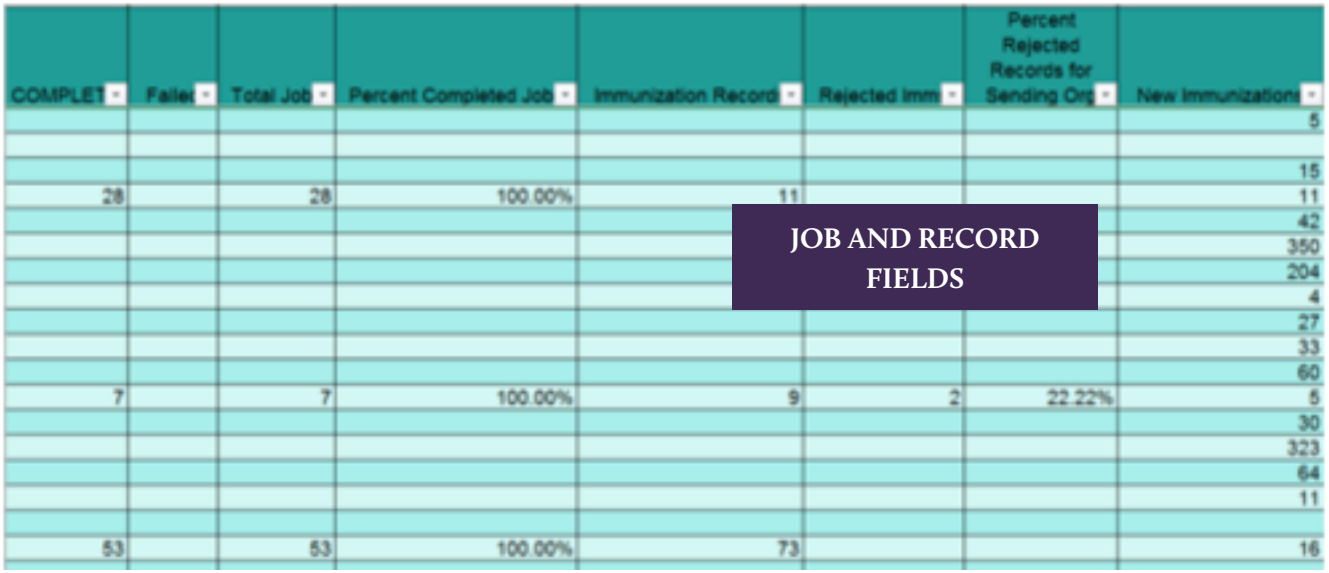
The program uses automated scripts to pull data from the IIS data tables and put this data in an email that goes to a staff person. The staff person imports the data into MS Access, where the data are manipulated and tallied. Data from Access are presented in a MS Excel file that goes out to internal staff for review. Note: use of Access also facilitates tracking over time.

57 Information based on interview with Nebraska IIS staff and material submitted to AIRA in response to information request on this subject.

Sample Report Images

Figure 4. Nebraska Weekly HL7 Summary and Detail Reports





57 Information based on interview with Nebraska IIS staff and material submitted to AIRA in response to information request on this subject.

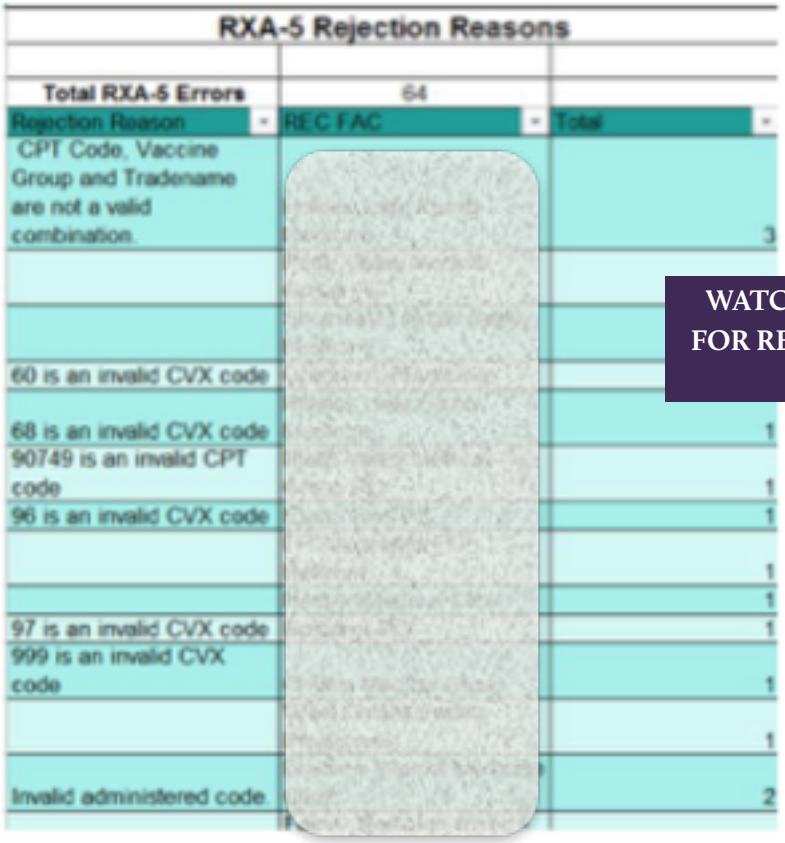
Total Sampled Record	RXA-5	RXA-6	PID-3	RXA-2	MSH-9	ORC-3	PID-7	DUP	Non-consent	Unidentified	Other	MSH-4
1	1											
2			2									
23		23										
2	2											

COUNT OF DATA ISSUES BY LOCATION IN MESSAGE

Organizations with 20% or more Rejected Records

Count of Orgs	9																	
High Rejection Totals						343	251	13	1	0	7	2	1	0	2	0	0	0	0
Parent	Name	Vendor	Level	% Rejects	Imm Records	# Rejects	Sampled	RXA5	RXA6	PID6	RXA3	ORC3	PID7	DUP	Non-Consent	MSH8	Other	Unidentified
Independent				22.22%	9	2	1	1							0			
Independent				36.51%	63	23	2								0			
Independent				50.00%	22	11	3								0			
Independent				100.00%	1	1	1								0			
Independent				76.92%	26	20	2								0			
Independent				32.26%	31	10	2								0			
Independent				41.67%	12	5	2								0			
Health Services				100.00%	179	179	0								0			
Health Services																		

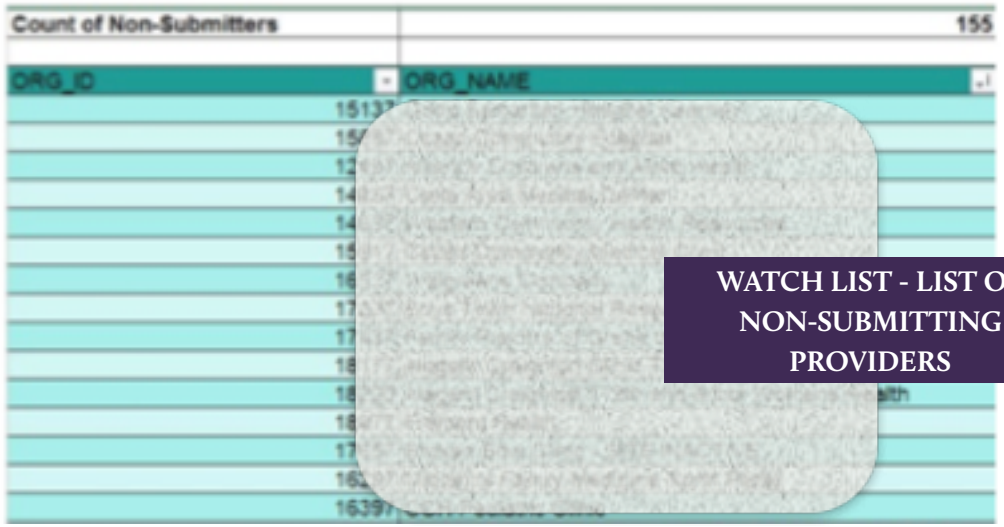
WATCH LIST - PROVIDERS ≥20% REJECTED RECORDS



RXA-5 Rejection Reasons

Total RXA-5 Errors	64	
Rejection Reason	REC FAC	Total
CPT Code, Vaccine Group and Tradename are not a valid combination		3
60 is an invalid CVX code		
68 is an invalid CVX code		1
90749 is an invalid CPT code		1
96 is an invalid CVX code		1
		1
		1
97 is an invalid CVX code		1
999 is an invalid CVX code		1
		1
Invalid administered code		2

WATCH LIST - REASONS FOR REJECTED MESSAGES IN RXA-5



Count of Non-Submitters	155
ORG_ID	ORG_NAME
1513	
15	
12	
14	
14	
15	
16	
17	
17	
18	
18	
18	
17	
16	
1639	

WATCH LIST - LIST OF NON-SUBMITTING PROVIDERS

Nebraska Monthly Immunizations Summary and Detailed Reports[58]

Background

Used by staff to analyze monthly patterns in volume of immunizations submitted by submitters. Key data fields and indicators include:

- Organization name and organization IDs; can also be viewed by parent organization and/or the vendor submitting the data
- Information about the interface: go-live date, HL7 version, and transport protocol
- Variations in immunizations processed over time for each submitter (and overall); the sum of immunizations processed by the IIS in a given month is displayed, along with the sum from previous months to facilitate this review
- Dose-level eligibility reporting data (lack of data and/or incorrect eligibility data)
- To Watch report:
    - Rate of change in immunization reporting volume from month to month
    - Lack of immunization reporting

Report Generation

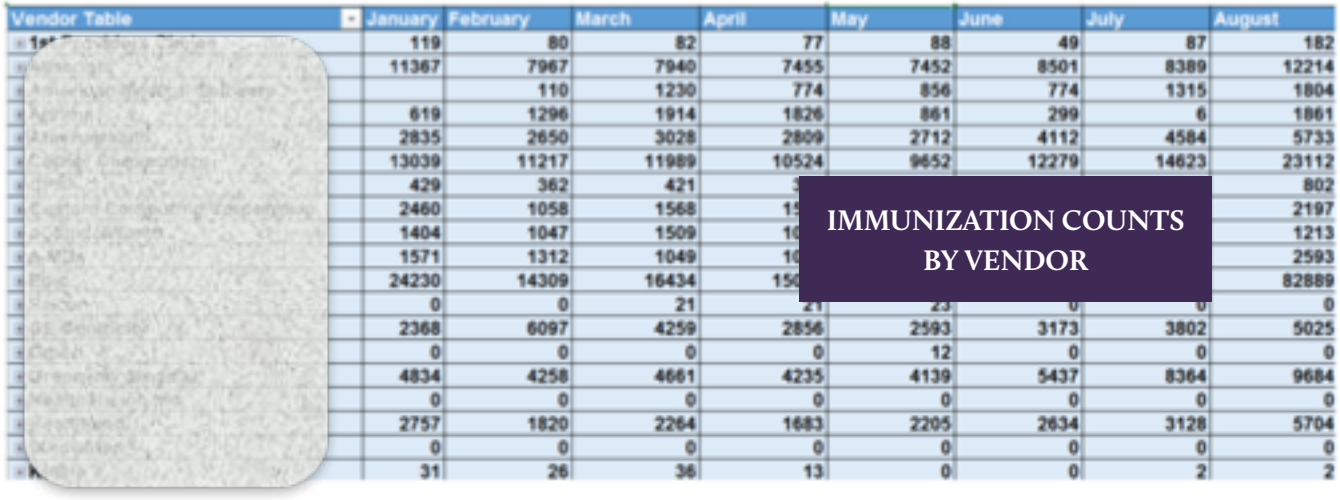
The program uses automated scripts to pull data from the IIS and generate an email to staff with this information. These data are imported into MS Access for manipulation and tallying by organization, parent, and vendor and for storage to facilitate tracking over time.

58 Information based on interview with Nebraska IIS staff and material submitted to AIRA in response to information request on this subject.

Sample Report Images

Figure 5. Nebraska Monthly Immunization Summary and Detail Reports

Continued, monthly immunization counts by vendor:



Vendor Table	January	February	March	April	May	June	July	August
1st	119	80	82	77	88	49	87	182
	11367	7967	7940	7455	7452	8501	8389	12214
		110	1230	774	856	774	1315	1804
	619	1296	1914	1826	861	299	6	1861
	2835	2650	3028	2809	2712	4112	4584	5733
	13039	11217	11989	10524	9652	12279	14623	23112
	429	362	421					802
	2460	1058	1568	1				2197
	1404	1047	1509	1				1213
	1571	1312	1049	1				2593
	24230	14309	16434	15				82889
	0	0	21	21	23	0	0	0
	2368	6097	4259	2856	2593	3173	3802	5025
	0	0	0	0	12	0	0	0
	4834	4258	4661	4235	4139	5437	8364	9684
	0	0	0	0	0	0	0	0
	2757	1820	2264	1683	2205	2634	3128	5704
	0	0	0	0	0	0	0	0
	31	26	36	13	0	0	2	2

58 Information based on interview with Nebraska IIS staff and material submitted to AIRA in response to information request on this subject.

Continued, monthly immunization counts, drill-down view:

Vendor Table	January	February	March	April	May	June	July	August
[redacted]	119	80	82	77	88	49	87	182
	11367	7967	7940	7455	7452	8501	8389	12214
	1177	844	665	884	953	948	825	1385
	1167	842	665	882	951	948	825	1385
	10						0	0
	2684						58	2424
	0						0	0
	198						0	0
	302						66	0
	0	0	0	0	0	0	0	0
	220	147	211	112	182	342	401	615
	248	228	209	192	232	299	229	652
	153	88	117	160	213	224	125	243
	1563	951	724	645	528	516	437	914
	6977	4803	4950	4505	4564	5337	5623	7340
	100	90	86	115	142	45	0	0
	6	6	3	6	3	5	0	0
	81	32	25	11	1	3	12	1
	0	0	0	0	0	0	0	0
[redacted]	702	459	457	474	395	719	704	1044

IMMUNIZATION COUNTS BY VENDOR, WITH DRILL-DOWN BY PROVIDER

Org Name	Org ID	New Imms With No El	100% Null Elig	Children with Adult El	Adults with Child Eli
[redacted]					1
		65	65		
		897			
		7			
		38			
		106	106		
		1	1		
		8	8		
		24	24		
		34			2
		163			
		14	14		
		140			
		127	127		

COUNTS OF VFC ELIGIBILITY DATA ISSUES BY PROVIDER

Org Name	Org ID	Januar	Februar	March	April	May	June	July	August
[redacted]		2	52	33	33	32	20	22	35
		105	686	355	329	428	538	872	904
		11					1		
		4				4	11		

TOTAL VFC ELIGIBILITY DATA ISSUES BY MONTH OVER TIME

Org Name	Org ID	January Immunization	January Eligibili	January Ratio
[redacted]	[redacted]	0		
		278		
		8		
		2	2	100.00%
		171	105	61.40%
		0		
		0		
		2		
		76	11	14.47%

RATE OF VFC ELIGIBILITY DATA ISSUES BY PROVIDER

	NESIIS Overall Deltas	-16565	-16210	-16.59%
687				

		December to January		January to February	
Org ID	Org Name	Dec to Jan Chang	Dec to Jan Rate of chang	Jan to Feb Chang	Jan to Feb Rate of Chang
[redacted]		0		0	
		-143	-33.97%	-121	-43.53%
		4	100.00%	-4	-50.00%
		-421	-71.11%	1057	618.13%
		0			
		0			
		0			
		0			
		2			
		20	35.71%		
		-2	-100.00%		
		-16	-80.00%		
		0		0	
		0		0	
		-19	-51.35%	-18	-100.00%

WATCH LIST – RATE OF CHANGE FROM ONE MONTH TO NEXT, BY PROVIDER

Count 132

Org ID	Org Name	rg L	Date Adc	rst Live DX	7 Ve	nsaction	Parent	Vendor	Stati	Dec-1	Jan-1	Feb-1	Mar-1	Apr-1
[redacted]		C/V	24-Nov-14	01/28/2013	2.5.1	PHINI	[redacted]		Active	0	0	0	0	0
		D/P	01-Jan-12	01/27/2012	2.5.1	SOAP			Active	0	0	0	0	0
		D/P	01-Jan-12	05/06/2011	2.5.1	SOAP			Active	0				
		D/P	09-Jul-14	07/02/2014	2.5.1	SOAP			Active	0				
		D/P	01-Dec-13	12/01/2013	2.5.1	SOAP			Active	0				
		D/P	01-Dec-13	12/01/2013	2.5.1	SOAP			Active	2	0	0	0	0
		C/P	01-Jan-12	05/06/2011	2.5.1	SOAP			Active	0	0	0	0	0

WATCH LIST – LIST OF NON-SUBMITTING PROVIDERS

Appendix C-3. North Dakota

North Dakota Monthly VFC Provider Error Report Queries[59]

Background

These are used by staff to look for 25 scenarios in IIS data that may be indicators of vaccine accountability, data entry, or data administration errors. Certain errors always warrant follow-up; others warrant follow-up if a certain threshold has been met for a certain practice size. Provider size is determined by the number of doses ordered during the previous calendar year. This is calculated once per year at the beginning of the year.

Report Generation

This report is generated monthly using SAS. Data on doses administered from the previous month are analyzed. Counts of errors for each of the scenarios are generated. The data are generated by IIS staff and sent to VFC staff for review and follow-up.

59 Information based on interview with North Dakota IIS staff and material submitted to AIRA in response to information request on this subject.

Indicators and Thresholds

Figure 6. North Dakota Monthly VFC Provider Error Report Indicators

Errors:

1. State supplied vaccine administered to "NOT ELIGIBLE" child 0-18 years
2. State supplied PCV13/Zoster/Varicella/Influenza/MMRV administered to adult 19 and older
3. Private supplied vaccine administered to VFC eligible child 0-18 years
4. State supplied HPV/Tdap/MCV4/MMR/PPV23/HBV/HAV to "NOT ELIGIBLE" adult 19 and older
5. Dummy doses (i.e. lot number is missing) entered for VFC eligible record
6. Minimum interval violation
7. Minimum interval violation between live virus vaccines
8. Minimum age violation
9. Administered expired vaccine
10. DTaP administered after age 6 years
11. Hepatitis A administered before age 1 year
12. Hib administered after age 5 years
13. HPV administered before age 9 years
14. HPV administered after age 26 years
15. MMR administered before age 1 year
16. MCV4 administered before age 9 months
17. PPV23 administered before age 2 years
18. Td administered before age 7 years
19. Tdap administered before age 7 years
20. Varicella administered before age 1 year
21. Zoster administered before age 50 years
22. Rotavirus administered after age 8 months
23. Dose administration date equals birthdate (except Hep B)
24. Vaccine no longer available in U.S.
25. HPV2 administered to males

INDICATORS FOR MONTHLY ERROR REPORT

Figure 7. North Dakota Monthly VFC Provider Error Report Thresholds

Error	Extra Small Providers	Small Providers	Medium Providers	Large Providers	Extra Large Providers
State-supplied to NE child	>5	>5	>10	>15	>15
State-supplied PCV13/PPV23 VAR/INFL/MMRV to 19+	>5	>5	>5	>5	>5
State Supplied HPV/TDAP/MCV4/MMR//HBV/HAV/Td to NE 19 years or older	>5	>5	>10	>15	>15
Minimum age/interval violations	>5	>5	>10	>15	>15
Expiration date exceeded	>5	>5	>5	>5	>5
Dummy doses to VFC-eligible	>5	>5	>10	>10	>10
Vaccine Specific Violations	>5	>5	>5	>5	>5

Provider Classification	Number of Doses Ordered in the Previous Calendar Year
Extra small	0 – 100
Small	101 – 200
Medium	201 – 750
Large	751 – 3,500
Extra large	Over 3,500

PROVIDER SIZE CLASSIFICATION

North Dakota Interoperability Quarterly Report Card[60]

Background

This report is for submitters to review information about the data interface between the IIS and a health system. Summary data is presented for an entire health system. Comparative data for other health systems is also provided. Detailed information for individual facilities within the health system is also presented. Includes information about HL7 data processing and about data at rest in IIS.

This is currently sent to 11 organizations, representing about 365 individual facilities. The report is customized based on the submitter type. For example, the report generated for an adult provider does not include the infant immunization rate.

Report Generation

North Dakota staff generate these reports the first week following the end of the calendar quarter. The technical lead queries the system for the messaging statistics (number of VXQ and VXU messages, error rate), and the interoperability coordinator uses SAS to analyze IIS data at rest. SAS generates the reports in PDF format.

60 Information based on interview with North Dakota IIS staff and material submitted to AIRA in response to information request on this subject.

Sample Report Images

Figure 8. North Dakota Quarterly Interoperability Report

Q2 2016 Interoperability Report Card

Provider: SAMPLE Health System
Reporting Period: April 1, 2016 to June 30, 2016
Report Data Generated: 7/14/2016

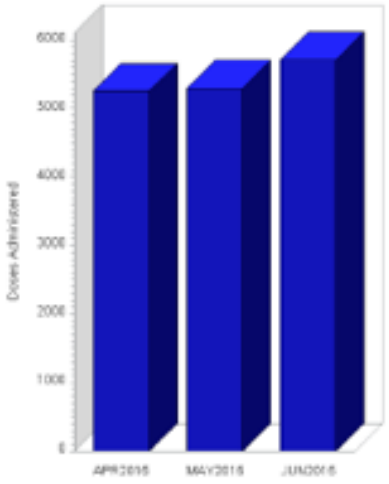
Summary

Number of VXQ (query) Messages Submitted to NDIIS	516,824
Number of VXU (immunization administration) Messages Submitted to NDIIS	26,527
Number of Error Messages Sent from NDIIS*	1.7%
Infant Immunization Rate‡	74%
Adolescent Immunization Rate¥	74%
Adult (18 and older) Tdap Rate	68%
Adult Immunization Rate†	29%

*Error messages are due to incorrect or missing data required in the VXU messages, including invalid newborn names, sent to the NDIIS.
‡Infant rate is for kids 19-35 months of age who were up-to-date with 4 dtap, 3 hib, 1 MMR, 3 polio, 3 hepatitis B and 1 varicella vaccine as of the last day of the quarter.
¥Adolescent rate includes teens 13-15 years of age who were up-to-date with 1 MCV4 and 1 Tdap by the last day of the quarter.
†Adult rate includes adults 65 years of age and older who have received 1 valid dose of PPV23 and Zoster vaccine by the last day of the quarter.

1) Doses Administered Per Month at SAMPLE Health System*

COVER PAGE



*When interpreting this graph it must be taken into account that the number of doses administered fluctuates throughout the year, with a high number of doses administered around school entry and during flu season.

2) Average Number of Days Between Dose Administration and Entry into the NDIIS

	Average Number of Days Between Dose Administration and Entry into the NDIIS			
Health System	APR2016	MAY2016	JUN2016	Average Dose Entry Time
Health Groups	6.3	5.2	3.5	4.9
Health System 1	0.3	0.3	0.1	0.2
Health System 2	0.5	0.4	0.3	0.4
Health System 3	0.3	0.2	0.2	0.2
Health System 4	0.6	0		0.6
Health System 5	0.3	0		0.3
Interoperable LPHU	1.0	1		0.9
Interoperable Pharmacies	1.6	1.1	2.7	2.0
Non Interoperable Providers	3.7	2.1	1.1	2.4
Other Interoperable Providers	1.0	0.6	0.3	0.6
Provider Clinic Group	0.2	0.0	0.0	0.1

TIMELINESS OF DATA SUBMISSION, BY HEALTH SYSTEM

3) Number of Duplicates Added by Health System

Health System	APR2016	MAY2016	JUN2016
Health System 1	14	19	12
Health System 2	13	12	21
Health System 3	12	18	49
Health System 4			
Health System 5	2	1	4
Hospital Group	1	.	3
Interoperable LPHU	2	3	4
Interoperable Pharmacies	.	.	4
Non Interoperable Providers	6	11	24
Other Interoperable Providers	13	2	1
Provider Clinic Group	4	2	4

NUMBER OF DUPLICATES ADDED, BY HEALTH SYSTEM

4) Number of Newborns Added to the NDIIS with an Invalid First Name*

Health System	APR2016	MAY2016
Health System 1	.	2
Health System 3	.	
Health System 5	1	
Hospital Group	1	1

NUMBER OF INVALID FIRST NAME SUBMISSIONS FOR NEWBORNS, BY HEALTH SYSTEM

*A first name is considered invalid if it was entered using a standard newborn naming convention such as Baby Girl or BoyA.

5) Percent of Dose Data Elements Complete for SAMPLE Health System

NDIIS Dose Fields	APR2016	MAY2016	JUN2016	Average Complete
Lot Number*	74%	75%		
Manufacturer‡	80%	81%		
VFC Complete	100%	100%		
Valid Doses	100%	100%	100%	100%

PERCENT VACCINE DATA ELEMENT FIELD COMPLETENESS

Goal for all dose data elements is 100%.
*Lot number completeness does not include dummy doses. A dummy dose is when the vaccine abbreviation is entered in place of the administered lot number. When the lot number and funding source data sent in the HL7 message do not match an existing lot in the NDIIS, a dummy dose is added.
‡An UNKNOWN Manufacturer value is not considered complete.

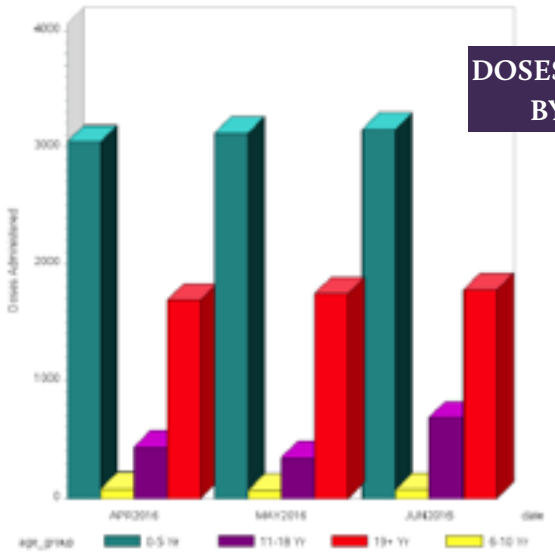
6) Client Demographic Data Elements Filled for SAMPLE Health System‡

NDIIS Client Fields	APR2016	MAY2016	JUN2016	Average Complete
Address	100%	100%	100%	100%
Birth State	35%	34%	35%	35%
City	100%	100%	100%	100%
Ethnicity	63%	63%	63%	63%
First Name	100%			
Home Phone	58%			
Last Name	100%			
Middle Name	84%			
Mother's First Name	42%	48%	47%	46%
Mother's Last Name	41%	47%	46%	45%
Mother's Maiden Name*	27%	31%	30%	29%
Race	84%	85%	84%	84%
Sex	92%	93%	93%	93%
State	100%	100%	100%	100%
Zip Code	100%	100%	100%	100%

PERCENT DEMOGRAPHIC DATA ELEMENT FIELD COMPLETENESS

Goal for all required client data elements is 100%.
*Not an NDIIS required field.
‡Name fields with an NA or UNKNOWN value are not considered complete.

7) Doses Administered Per Month by Age Group at SAMPLE Health System



DOSES ADMINISTERED BY AGE GROUP

*When interpreting this graph it must be taken into account that the number of doses administered fluctuates throughout the year, with a high number of doses administered around school entry and during flu season.
‡Kids 6-10 years of age should be up-to-date with their childhood immunizations and will not be due for adolescent immunizations until age 11, so the number of doses administered to this age group will always be much smaller than for those in the other age groups.

THE FOLLOWING COMPONENTS OF THE INTEROPERABILITY REPORT PROVIDE INFORMATION ON INDIVIDUAL PROVIDERS (FACILITIES) WITHIN THE SELECTED HEALTH SYSTEM.

Individual Providers of SAMPLE Health System

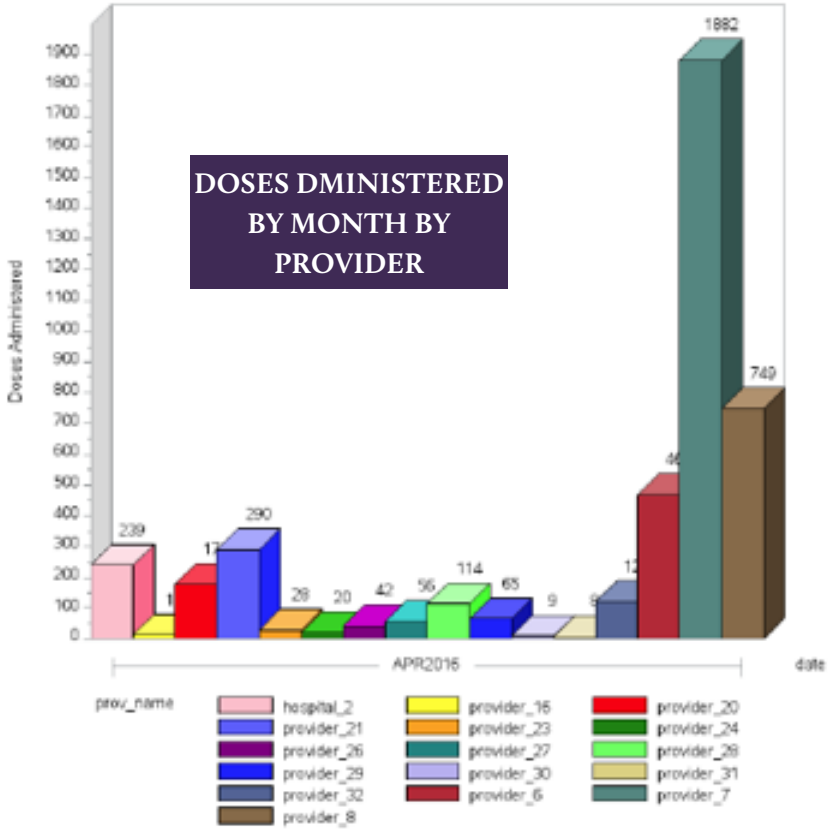
8) Average Number of Days Between Dose Administration and Entry into the NDIIS by Provider

		Average Time from Administration to Dose Entry into NDIIS			
Provider ID	Provider Name	APR2016	MAY2016	JUN2	Average Dose Entry
01101	hospital_1	0.0	0.0		
01181	hospital_2	1.9	0.9		
01321	hospital_3	0.0	0.0	0.0	0.0
01341	hospital_4	0.0	4.8	0.0	1.7
01351	hospital_5	15.6	0.0	0.1	4.7

TIMELINESS OF DATA SUBMISSION, BY PROVIDER

9) Doses Administered Per Month By Provider

DOSES DMINISTERED BY MONTH BY PROVIDER



Note: Similar graphs provided for each month of the quarter but not shown.

10) Number of Dummy Doses Entered into NDIIS Client Records by Provider*

"DUMMY DOSES" ENTERED BY PROVIDER

Provider ID	Provider Name			16	Total Dummy Doses	Total Doses	% Dummy Doses
01101	hospital_1	1	8	8	17	17	100%
01181	hospital_2	83	105	150	338	781	43%
01321	hospital_3	2	2	6	10	10	100%
01341	hospital_4	5	6	6	17	26	65%
01351	hospital_5	11	7	19	37	37	100%

*A dummy dose is when the vaccine abbreviation is entered instead of a lot number. When the lot number and funding source data sent in the HL7 message do not match an existing lot in the NDIIS, a dummy dose is added in place of the actual lot administered.

11) Number of Dummy Doses Entered for VFC Eligible Kids into the NDIIS by Provider*

Provider ID	Provider Name	APR2016	MAY2016	JUN2016	Total
01181	hospital_2	.	.		
01341	hospital_4	1	.		
01351	hospital_5	.	.	4	4

"DUMMY" DOSES ENTERED FOR VFC ELIGIBLE

*A dummy dose is when the vaccine abbreviation is entered instead of a lot number. It is a requirement of the VFC program that all doses of publicly funded vaccine be documented with the correct lot number.

12) Number of Privately Purchased Vaccine Doses Given to VFC Eligible Kids by Provider*

Provider ID	Provider Name	APR2016	MAY2016	JUN2016	Total
01181	hospital_2	0	0	0	0
01341	hospital_4	.	0		
01501	hospital_7	0	0		
04855	provider_3	0	0	0	0

PRIVATE DOSES ADMINISTERED TO VFC ELIGIBLE

*This creates a borrowed dose of private vaccine that then needs to be paid back using state supplied vaccine.

13) Number of State Supplied Vaccine Doses Given to Kids Not Eligible for VFC Vaccine by Provider*

Provider ID	Provider Name	APR2016	MAY2016	JUN2016	Total
01181	hospital_2	20	26		
01341	hospital_4	.	0		
01501	hospital_7	0	0		
04855	provider_3	0	0	0	0

STATE-SUPPLIED DOSES ADMINISTERED TO POPULATIONS NOT VFC ELIGIBLE

*This creates a borrowed dose of state vaccine that then needs to be paid back using privately purchased vaccine.

14) Dose Data Elements Filled by Provider*

Provider ID	Provider Name	NDIIS Dose Fields	APR2016	MAY2016	JUN2016	Average Complete
01101	hospital_1	Lot Number	0%	0%	0%	0%
		Manufacturer	100%	100%	88%	96%
01181	hospital_2	Lot Number	65%	61%		
		Manufacturer	72%	75%		
01321	hospital_3	Lot Number	0%	0%		
		Manufacturer	50%	50%	17%	39%
01341	hospital_4	Lot Number	0%	33%	50%	28%
		Manufacturer	20%	33%	58%	37%
		Valid Doses	100%	89%	100%	96%

PERCENT VACCINE DATA ELEMENT FIELD COMPLETENESS

*This table only shows those providers with less than 90% completeness for one or more data elements during at least one month during the quarter.

15) Client Level Demographic Data Elements by Provider*

Provider ID	Provider Name	NDIIS Client Fields	APR2016	MAY2016	JUN2016	Average Complete
01101	hospital_1	Address	100%	100%	88%	96%
		Birth State	100%	38%	25%	54%
		City	100%	100%	88%	96%
		Ethnicity	100%	88%	63%	83%
		Home Phone	100%	63%	75%	79%
		Middle Name	100%	100%	88%	96%
		Mother's First Name	0%	13%		
		Mother's Last Name	0%	13%		
		Mother's Maiden Name	0%	0%		
		Race	100%	88%	75%	88%
		Sex	100%	88%	100%	96%
		State	100%	100%	88%	96%
		Zip Code	100%	100%	88%	96%
01181	hospital_2	Birth State	41%	32%	28%	34%
		Ethnicity	48%	50%	58%	52%

PERCENT DEMOGRAPHIC DATA ELEMENT FIELD COMPLETENESS

*This table only shows those providers with less than 90% completeness for one or more data elements during at least one month during the quarter.

Appendix C-4. Kansas

Kansas Data Quality Tool and Reports

Background

Kansas uses a data quality tool and reports available within its IIS. IIS staff and submitters can generate these reports. The report can be used to analyze a complete IIS dataset or data for a one-month time frame (by patient date of birth or vaccination date).

Screen Shots and Sample Reports

Figure 9. Kansas Data Quality Tool Screen Shot

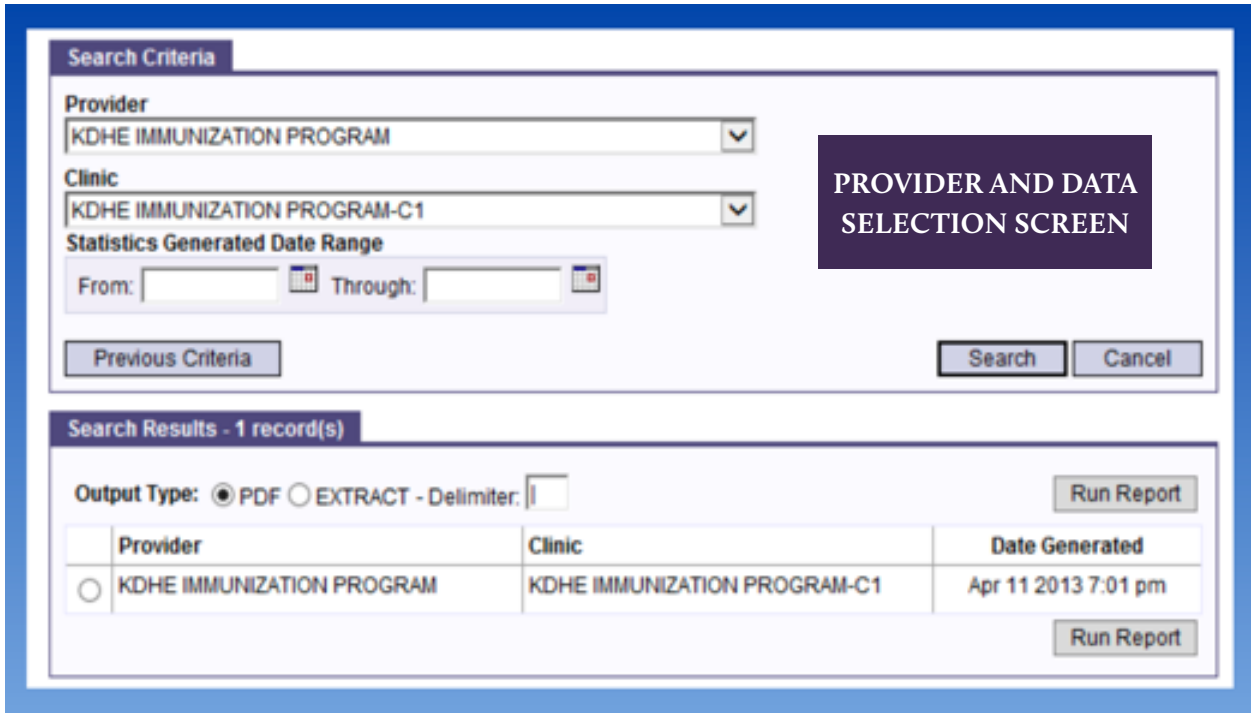
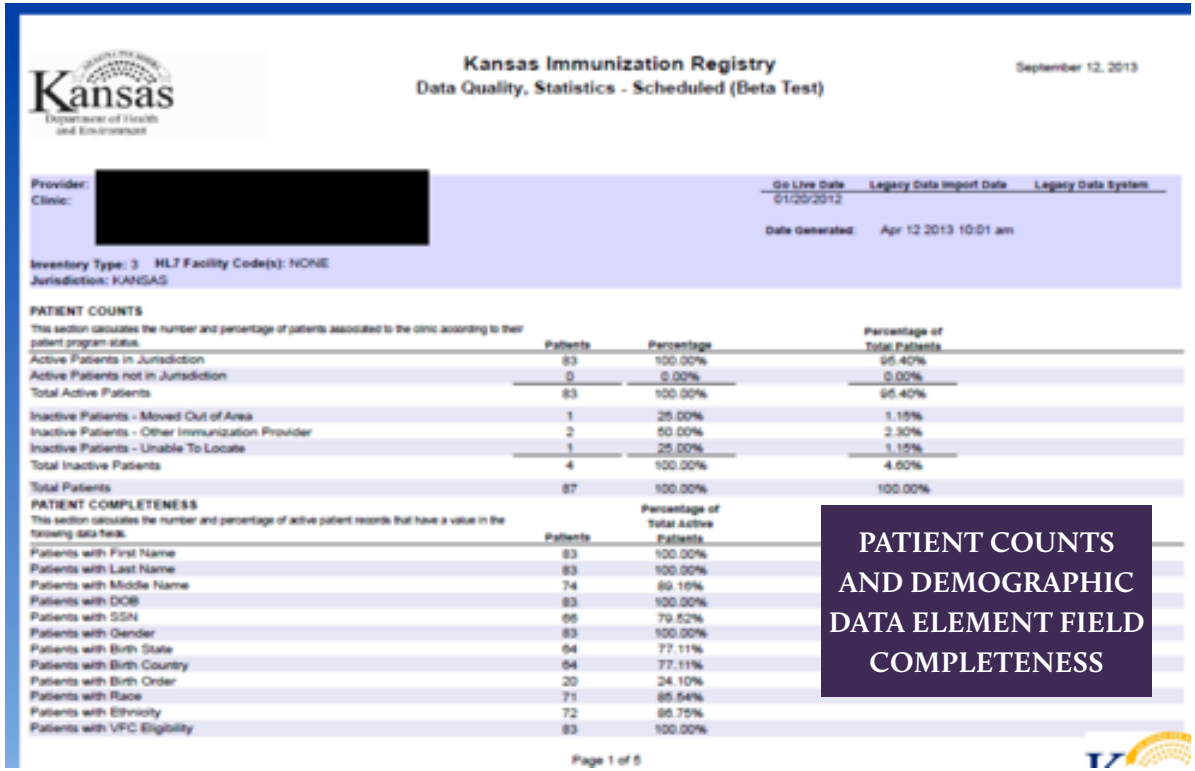


Figure 10. Kansas Data Quality Report



Kansas Department of Health and Environment

Kansas Immunization Registry
Data Quality, Statistics - Scheduled (Beta Test)

September 12, 2013

Provider: [redacted]
Clinic:

Go Live Date	Legacy Data Import Date	Legacy Data System
01/20/2012		

Date Generated: Apr 12 2013 10:01 am

Inventory Type: 3 HL7 Facility Code(s): NONE
Jurisdiction: KANSAS

PATIENT COUNTS

This section calculates the number and percentage of patients associated to the clinic according to their patient program status.

	Patients	Percentage	Percentage of Total Patients
Active Patients in Jurisdiction	83	100.00%	95.40%
Active Patients not in Jurisdiction	0	0.00%	0.00%
Total Active Patients	83	100.00%	95.40%
Inactive Patients - Moved Out of Area	1	25.00%	1.15%
Inactive Patients - Other Immunization Provider	2	50.00%	2.30%
Inactive Patients - Unable To Locate	1	25.00%	1.15%
Total Inactive Patients	4	100.00%	4.60%
Total Patients	87	100.00%	100.00%

PATIENT COMPLETENESS

This section calculates the number and percentage of active patient records that have a value in the following data fields.

	Patients	Percentage of Total Active Patients
Patients with First Name	83	100.00%
Patients with Last Name	83	100.00%
Patients with Middle Name	74	89.16%
Patients with DOB	83	100.00%
Patients with SSN	66	79.52%
Patients with Gender	83	100.00%
Patients with Birth State	64	77.11%
Patients with Birth Country	64	77.11%
Patients with Birth Order	20	24.10%
Patients with Race	71	85.54%
Patients with Ethnicity	72	86.75%
Patients with VFC Eligibility	83	100.00%

Page 1 of 5

PATIENT COUNTS AND DEMOGRAPHIC DATA ELEMENT FIELD COMPLETENESS

Provider: [redacted]
Clinic:

Date Generated: Apr 12 2013 10:01 am

Patients with Mother's First Name	66	79.52%
Patients with Mother's Middle Name	30	36.14%
Patients with Mother's Maiden Name	66	79.52%
Patients with Mother's Last Name	63	75.90%
Patients with Street Name or PO Box	83	100.00%
Patients with City	83	100.00%
Patients with County	80	96.39%
Patients with State	83	100.00%
Patients with Zip Code	83	100.00%
Patients with Home Phone Number	58	69.88%
Patients with Cell Phone Number	0	0.00%
Patients with Email Address	0	0.00%
Patients with History of Varicella Disease	3	3.61%
Patients with Date of Varicella Disease	3	3.61%
Patients created by Vital Statistics Import	0	0.00%

DEMOGRAPHIC DATA ELEMENT FIELD COMPLETENESS (CONTINUED)

VACCINATION COMPLETENESS

This section calculates the number and percentage of vaccination events (for those active patients associated to the selected clinic) that have a value in the following data fields for each category.

	All Vaccinations	Percentage of All Vaccinations	All Non-Historical Vaccinations	Percentage of All Non-Historical Vaccinations	Clinic Non-Historical Vaccinations	Percentage of Clinic Non-Historical Vaccinations
Total Vaccinations	1,549	100.00%	483	100.00%	241	100.00%
Vaccinations Added but not Administered	0	0.00%	0	0.00%	0	0.00%
Vaccinations with Vaccination Date	1,549	100.00%	483	100.00%	241	100.00%
Vaccinations with Manufacturer	616	39.77%	427	88.41%	241	100.00%
Vaccinations with Lot Number	507	32.73%	422	87.37%	241	100.00%
Vaccinations with Expiration Date	499	32.21%	422	87.37%	241	100.00%
Vaccinations with NDC	158	10.20%	158	32.71%	136	56.43%
Vaccinations with Funding Source	376	24.27%	374	77.43%	241	100.00%
Vaccinations with Site	361	23.31%	343	71.01%	241	100.00%
Vaccinations with Route	357	23.60%	343	71.01%	241	100.00%
Vaccinations with Administered By	344	22.21%	343	71.01%	241	100.00%
Non-Historical Vaccinations with VIS Date Given	297	61.49%	297	61.49%	214	88.80%
Non-Historical Vaccinations with VIS Effective Date	297	61.49%	297	61.49%	214	88.80%
Unspecified Formulation (UF) entered as Non-Historical Vaccines	4	0.83%	4	0.83%	0	0.00%

VACCINE DATA ELEMENT FIELD COMPLETENESS

Kansas

Provider: [redacted]
Clinic:

Date Generated: Apr 12 2013 10:01 am

ACCURACY, VACCINATION GIVEN AT INVALID AGE

This section calculates the number and percentage of vaccination events and the patients impacted (for patients associated to the clinic) that were given any single immunization outside of ACIP age recommendations or vaccine label guidelines for each category.

	All Vaccinations	Percentage of All Vaccinations	Number of Patients Impacted	Clinic Vaccinations	Percentage of Clinic Vaccinations	Number of Patients Impacted
Total Vaccinations	1,549	100.00%	83	246	100.00%	76
DTaP / TD / TDAP Vaccinations before 6 weeks of age	0	0.00%	0	0	0.00%	0
DT / DTP / DTaP Vaccinations after 7 years (2557 days) of age	3	0.19%	3			
Td / Tdap Vaccinations before 7 years (2553 days) of age	0	0.00%	0			
Kinrix (DTaP-IPV) Vaccinations before 4 years (1457 days) of age	1	0.06%	1			
Polio Vaccinations before 6 weeks of age	0	0.00%	0			
MMR Vaccinations before 1 year (361 days) of age	3	0.19%	3	0	0.00%	0
Hib Vaccinations before 6 weeks of age	1	0.06%	1	0	0.00%	0
Hib Vaccinations after 6 years (2190 days) of age	0	0.00%	0	0	0.00%	0
Varicella (CPOX) Vaccinations before 1 year (361 days) of age	2	0.13%	2	0	0.00%	0
Pneumococcal Vaccinations before 6 weeks of age	0	0.00%	0	0	0.00%	0
PPV23 Vaccinations before 2 years (726 days) of age	0	0.00%	0	0	0.00%	0
HPV Vaccinations before 9 years (3283 days) of age	0	0.00%	0	0	0.00%	0
HPV Vaccinations after 28 years (10226 days) of age	0	0.00%	0	0	0.00%	0
Cervarix Vaccinations and a gender of Male	0	0.00%	0	0	0.00%	0
Hep A Vaccinations before 1 year (361 days) of age	1	0.06%	1	0	0.00%	0
Meningococcal Vaccinations before 11 years of age	0	0.00%	0	0	0.00%	0
Influenza Vaccinations before 6 months of age	0	0.00%	0	0	0.00%	0
Rotavirus Vaccinations before 6 weeks of age	0	0.00%	0	0	0.00%	0
First dose of Rotavirus after 12 weeks of age	5	0.32%	5	1	0.41%	1
Rotavirus Vaccinations after 32 weeks of age	0	0.00%	0	0	0.00%	0
Non-Hep B Vaccinations before 4 weeks of age	1	0.06%	1	0	0.00%	0
Zoster Vaccinations before 50 years (18258 days) of age	0	0.00%	0	0	0.00%	0
Vaccinations before their DOB	0	0.00%	0	0	0.00%	0
Vaccinations after the Expiration Date	8	0.52%	5	0	0.00%	0
Vaccinations in the future	0	0.00%	0	0	0.00%	0

VALIDITY VIOLATIONS

Provider: [redacted]
Clinic:

Date Generated: Apr 12 2013 10:01 am

ACCURACY, VACCINATION COUNTS INCONSISTENT WITH PATIENT'S AGE

This section calculates the number and percentage of active patient records (associated to the clinic) that have a total number of vaccinations that is more than what is appropriate for their age.

	Patients	Percentage of Active Patients
Patients with more than 2 DTaP Vaccinations before 4 months of age	0	0.00%
Patients with more than 3 DTaP Vaccinations before 6 months of age	0	0.00%
Patients with more than 4 DTaP Vaccinations before 1 year of age	0	0.00%
Patients with more than 6 DTaP Vaccinations before 7 years of age	0	0.00%
Patients with more than 2 Polio Vaccinations before 4 months of age	0	0.00%
Patients with more than 2 HIB Vaccinations before 4 months of age	1	1.20%
Patients with more than 3 HIB Vaccinations before 6 months of age	0	0.00%
Patients with more than 4 HIB Vaccinations before 1 year of age	0	0.00%
Patients with more than 2 PCV Vaccinations before 4 months of age	0	0.00%
Patients with more than 3 PCV Vaccinations before 6 months of age	0	0.00%
Patients with more than 4 PCV Vaccinations before 1 year of age	0	0.00%
Patients with more than 2 HepA Vaccinations	2	2.41%
Patients with more than 4 HepB Vaccinations	2	2.41%
Patients with more than 4 HIB Vaccinations	2	2.41%
Patients with more than 3 HPV Vaccinations	0	0.00%
Patients with more than 3 Meningococcal Vaccinations	0	0.00%
Patients with more than 2 MMR Vaccinations	3	3.61%
Patients with more than 4 PCV Vaccinations	2	2.41%
Patients with more than 3 Rotavirus Vaccinations	0	0.00%
Patients with more than 1 Tdap Vaccinations	1	1.20%
Patients with more than 2 Varicella Vaccinations	1	1.20%
Patients with 10 or more Vaccinations on the same date	0	0.00%
Patients with 20 or more Vaccinations before 6 months of age	0	0.00%
Patients with 30 or more Vaccinations before 2 years of age	0	0.00%
Patients with 40 or more Vaccinations before 5 years of age	0	0.00%
Patients with 70 or more Vaccinations	0	0.00%

VALIDITY VIOLATIONS, CONTINUED

TIMELINESS

This section calculates the number and percentage of vaccinations events where the amount of time elapsed between the date of vaccination and the date it was created in the IIS is within the indicated timeframes for each category.

	All Vaccinations	Percentage of All Vaccinations	Clinic Vaccinations	Percentage of Clinic Vaccinations
Total Vaccinations	1,549	100.00%	246	100.00%
Vaccinations entered < 1 day of Administration	317	20.46%	165	67.07%
Vaccinations entered in at least 1 day and < 2 days of Administration	49	3.16%	39	15.85%
Vaccinations entered in at least 2 days and < 7 days of Administration	59	3.81%	19	7.72%
Vaccinations entered in at least 7 day and < 14 days of Administration	19	1.23%	9	3.66%
Vaccinations entered in at least 14 day and < 30 days of Administration	31	2.00%	13	5.28%
Vaccinations entered in 30 days or more of Administration	1,074	69.34%	1	0.41%

Page 4 of 5

Provider: [redacted]
Clinic:

Date Generated: Apr 12 2013 10:01 am

INVENTORY MANAGEMENT

This section summarizes several key inventory elements for full inventory (type 3) providers.

	Count
Number of Active Inventory Locations	1
Number of Closed Reconciliations within the last 12 months	9
Total Number of Closed Reconciliations	11
Number of Expired Inventory Line Items with Quantity > 0	2
Total Number of Doses Wasted or Expired in the last 12 months	87

VACCINE INVENTORY INFORMATION

Appendix C-5. Wisconsin

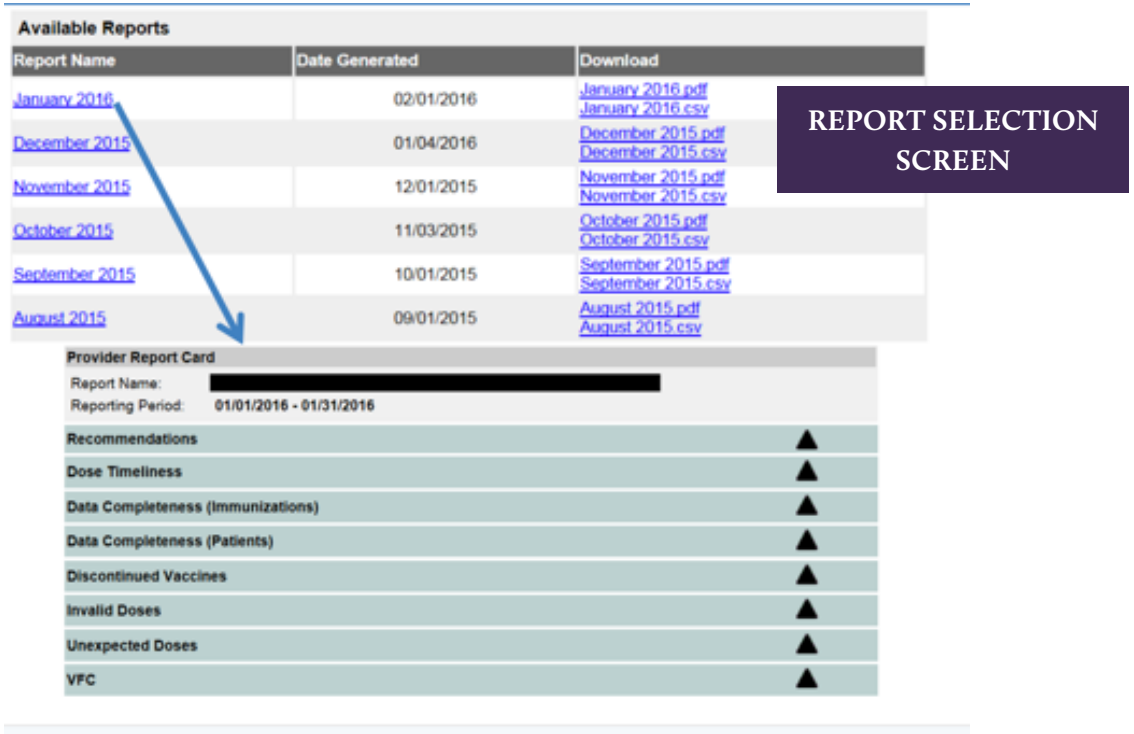
Wisconsin Data Quality Report Card[61]

Background

Wisconsin built queries to generate data quality report cards for its submitters. After IIS staff generates these reports, they are available in the IIS for staff review. One use of the reports is in the immediate post-onboarding period. IIS staff emails these reports monthly in the three months following onboarding go-live.

Screen Shots and Sample Report

Figure 11. Wisconsin Provider Data Quality Report Card Screen Shot



61 Petit, A. Wisconsin Immunization Registry Report Cards: IIS Data Quality Feedback to Providers. Presentation at 2016 AIRA National Meeting. Slides available at http://www.immregistries.org/resources/iis-meetings/Wisconsin_Immunization_Registry_Report_Cards_Providing_IIS_Data%20Quality_Feedback_to_Providers.pdf.

Figure 12. Wisconsin Data Quality Report Card

Recommendations

Based on the information in this report, WIR recommends this organization focus on improving the following fields:

Report Card	Field	Percentage	Goal
Data Completeness (Immunizations)	Vaccine Administering Provider Title/Suffix	0.00%	80.00%
Data Completeness (Patients)	Mother's First Name		
Data Completeness (Patients)	Mother's Maiden Last Name		
Data Completeness (Patients)	SSN		

RECOMMENDATIONS FOR DATA QUALITY PRIORITIES

Dose Timeliness

Indicates the delay between the date an immunization was given and when it was added to WIR.

Immunizations given during assessment period: **757**

Timeframe Received	Count	Percentage
Within 1 day	750	99.08%
2-7 days	3	0.40%
8-14 days	0	0.00%
15-30 days	3	0.40%
31+ days	1	0.13%

TIMELINESS

Data Completeness (Immunizations)

Indicates the data included with each immunization record aded to WIR.

Immunizations given during assessment period: **757**

Data Field	Count	Percentage
Vaccine Product Type Administered	757	100.00%
Vaccine Administration Date	757	100.00%
Vaccine Manufacturer Name	753	99.47%
Vaccine Trade Name	755	99.74%
Vaccine Lot Number	755	99.74%
Vaccine Expiration Date *	579	76.49%
Vaccine Dosage	754	99.60%
Vaccine Site of Administration	712	94.06%
Vaccine Route of Administration	736	97.23%
Vaccine Ordering Provider Name	751	99.21%
Vaccine Administering Provider Name	752	99.34%
Vaccine Administering Provider Title/Suffix	0	0.00%
Dose Level Eligibility	744	98.28%

* Only immunizations entered using the WIR Inventory Module retain this data.

VACCINE DATA ELEMENT FIELD COMPLETENESS

Data Completeness (Patients)

Indicates the data currently available on each patient updated during the assessment period.

Clients updated during assessment period: **420**

Data Field	Count	Percentage
Patient Name: Last	420	100.00%
Patient Name: First	420	100.00%
Patient Name: Middle	408	97.14%
Mother's Maiden Last Name	206	49.05%
Mother's First Name	200	47.62%
SSN	278	66.19%
Gender	420	100.00%
Birth Date	420	100.00%
County	418	99.52%
Country of Birth	420	100.00%
Chart Number	413	98.33%
Ethnicity	403	95.95%
Race	380	90.48%
Provider-PCP	24	5.71%
Responsible Person: Primary Designated *	6	1.43%
Responsible Person: Last Name	414	98.57%
Responsible Person: First Name	414	98.57%
Responsible Person: Middle Name	393	93.57%
Responsible Person: Phone	400	95.24%
Responsible Person: E-mail	52	12.38%
Responsible Person: Address/P.O. Box	415	98.81%
Responsible Person: City	415	98.81%

* WIR uses the address of the primary responsible person for each patient as the contact address for that patient. If no primary responsible person is designated, WIR selects one using the best information available

DEMOGRAPHIC DATA ELEMENT FIELD COMPLETENESS

Discontinued Vaccines

Indicates counts of immunizations administered during the reporting period that have been discontinued.

Vaccine	Count
Pnu-Imune 23	1

ADMINISTRATION OF DISCONTINUED VACCINES

Other Examples:

- Prevnar 7
- Acel-Imune
- H1N1
- RotaShield
- Orimune
- Certiva
- Fluogen
- Flu Shield
- ProHIBIT
- Tetramune

Invalid Doses

Indicates doses administered outside of schedule recommendations during the assessment period. Unless otherwise determined, clients follow the ACIP schedule. A single dose that is invalid for multiple reasons will only count once under the 'total' column.

Vaccine Group	Age	Interval	Group	Size	Other	Total	Count	Percentage
DTP/aP	4	6	0	0	0	6	77	7.79%
Influenza	0	1	0	0	0	1	221	0.45%
HepA	0	8	0	0	0	8	49	16.33%
HepB	21	4				22	59	37.29%
Meningo	0	2				2	15	13.33%
MMR	0	4				4	23	17.39%
Pneumococcal	0	3	0	0	0	3	63	4.76%
Polio	1	3	0	0	0	3	62	4.84%
Rotavirus	0	1	0	0	0	1	32	3.13%
Varicella	0	4	0	0	0	4	23	17.39%
Pneumo-Poly	3	17	1	0	0	18	111	16.22%
HPV	0	4	0	0	0	4	42	9.52%

VALIDITY VIOLATIONS

Schedule: Doses at 0, 1-2, and 6 months after initiation.
Age Range: 9-30 years
Minimum Intervals: Dose 1 to 2=28 days, Dose 2 to 3=84 days, Dose 1 to 3 = 16 weeks
Notes: HPV Bivalent (Cervarix) is invalid for males

Unexpected Doses

Indicates specific immunization cases which may be valid, but should not occur frequently.

Case	Count	Total	Percentage
DTaP Over 7 Years	4	121	3.31%
Pediarix as 4th/5th Dose DTaP	1	31	3.23%

Other Examples:

- Over age MMRV
- Under age Kinrix
- Under age Menactra
- Under age Menveo

VALID BUT UNEXPECTED DOSES

VFC

Indicates counts of patients eligible for VFC (Vaccines for Children) and other programs. Individual patients may have more than one eligibility.

Patients aged 18 years or younger during assessment period: **218**

Eligibility	Count	Percentage
Not Determined/Unknown	12	5.50%
Insured	76	34.86%
No Insurance	9	4.13%
Native American/Alaskan Native	0	0.00%
Badger Care	0	0.00%
Medicare	0	0.00%
Medical Assistance	123	56.42%
Insurance, No vaccine	3	1.38%

PATIENT COUNT BY VFC ELIGIBILITY CATEGORY

Appendix C-6. Colorado

CIIS Post-Production Ongoing Data Quality Report Card[62]

Background

This will be used to assess accuracy and completeness of submitters IIS data six months post go-live and will also be used to assess ongoing production submitters on an annual basis.

Approximately 20 data fields are reviewed for accuracy and completeness in the IIS as compared to what is stored in the EHR. Colorado uses a formula that applies different weights to issues found to generate an overall data quality grade of A, B, or C. Issues that affect the accuracy of CDS are weighted more heavily than others. For example, an inaccuracy in the reporting of an antigen to the IIS is more heavily weighted than some of the completeness issues, such as VIS edition date.

Note: The Colorado report previously gave submitters a percentage rating rather than a grade. Colorado found that submitters were fixated on addressing the issues most likely to raise their percentage instead of addressing all issues noted. With the letter grade Colorado found that submitters are more likely to address all the issues.

Report Generation

IIS and EHR records for about 50 patients are compared. A data validation web application (external to the IIS) is used to assess the data quality and generate the report. SQL statements are used to pull IIS data.

61 Information based on interview with Colorado IIS staff and material submitted to AIRA in response to information request on this subject.

Sample Report Images

Figure 13. Colorado Post-Production Ongoing Data Quality Report Card

COLORADO

CIIS Post Production On-Going Data Quality Report Card

Post Production Data Quality Report Card: The following data elements were reviewed to check the accuracy and completeness of data elements sent in the electronic record

Accuracy: Electronic immunization records are checked for appropriate usage of vaccine based on vaccine manufacturer guidelines for licensure dates and the age of the patient at the time of the vaccination. The coding of each immunization is also checked

Completeness: The Completeness values are reviewed to help gauge how often meaningful values are found in the electronic data sent from the EHR are included.

Data Elements Reviewed	Passed for Accuracy and Completeness	Post Production Data Quality Rating*
Patient's first and last name	✓	A
Patient's Gender	✓	
Patient's DOB	✓	
Patient's Address	✓	
Patient's Phone Number	✓	
Parent/Guardian Name		
Vaccination Admin Date	✓	
Vaccine Name	✓	
Vaccine Lot ID #	✓	
Vaccine Dosage (mL)	✓	
Manufacturer/Trade Name	✓	
Administered Route	✓	
Administered Body Site	✓	
Vaccine Expiration Date	✓	
Administered By	✓	
VIS Edition Date		
Date the VIS Sheet was Given		
VFC Eligibility	✓	
Funding Source	✓	
Administering Clinic/Hospital	✓	
CVX/CPT code	✓	

COVER PAGE

*Ratings that are below an A rating:

Data elements that did not pass for accuracy and completeness will be listed with specific examples in the attached report for review and resolution.

APPENDIX D: OPEN SOURCE TOOLS

Appendix D-1. Open Immunization Software Data Quality Assurance (DQA) Tool[63, 64]

Background

Dandelion Software originally developed the DQA tool in 2011, in collaboration with the Texas IIS program. This tool was designed to allow IIS staff to monitor and review the quality of HL7 data submissions. AIRA also funded enhancements to this tool to facilitate analysis of the quality of data at rest in an IIS. This work was part of an AIRA Assessment Steering Committee (ASC) pilot project designed to assess how well the DQA tool would meet IIS community needs for addressing data quality.

The pilot found that, although the tool largely covered data quality indicators and metrics of interest, there were barriers for IIS programs to deploy and maintain this tool locally. Namely, IIS programs reported challenges in being able to implement this outside software in state/program public health IT networks. Another challenge was the lack of dedicated resources to support maintenance and development of this tool.

The DQA tool offers IIS programs the ability to assess the quality of a batch of submitted HL7 messages and the ability to assess the quality of data at rest in an IIS. The report is highly customizable and flexible, giving IIS the opportunity to apply different weights to different data quality indicators and customize the report scoring, and so on.

The Data Quality Report output from the tool includes: a scoring summary, message processing information, information on HL7 message quality, completeness information (for information about patients and vaccines), and timeliness information.

The Michigan IIS program currently utilizes the DQA tool.

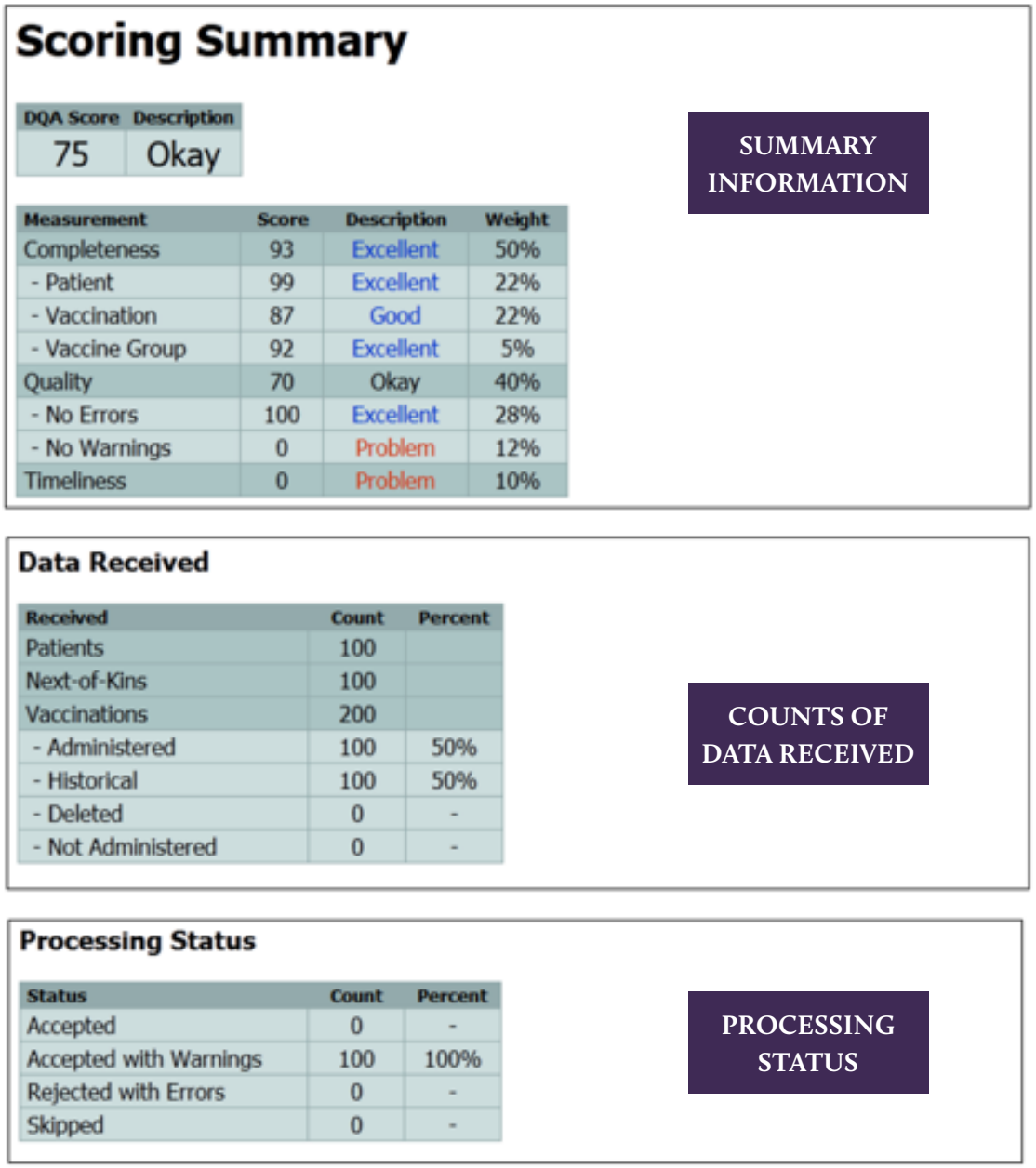
Sample Report Images

On the following pages are samples of select portions of the DQA report. For a complete overview of the report, including detailed descriptions of each section, please see: http://openimmunizationsoftware.net/dataQuality/dqaReport.html.

63 AIRA. Open Source Resources. Data Quality Assurance Tool. *http://www.immregistries.org/resources/open-source*

64 Open Immunization Software. Data Quality. *http://openimmunizationsoftware.net/dataQuality/dataQuality.html*

Figure 14. Open Immunization Software Data Quality Assurance Report



Scoring Summary

DQA Score	Description
75	Okay

Measurement	Score	Description	Weight
Completeness	93	Excellent	50%
- Patient	99	Excellent	22%
- Vaccination	87	Good	22%
- Vaccine Group	92	Excellent	5%
Quality	70	Okay	40%
- No Errors	100	Excellent	28%
- No Warnings	0	Problem	12%
Timeliness	0	Problem	10%

SUMMARY INFORMATION

Data Received

Received	Count	Percent
Patients	100	
Next-of-Kins	100	
Vaccinations	200	
- Administered	100	50%
- Historical	100	50%
- Deleted	0	-
- Not Administered	0	-

COUNTS OF DATA RECEIVED

Processing Status

Status	Count	Percent
Accepted	0	-
Accepted with Warnings	100	100%
Rejected with Errors	0	-
Skipped	0	-

PROCESSING STATUS

Codes Received

Codes Received

ADDRESS CODES RECEIVED

Address Country

Value	Label	Mapped To	Status	Count
USA		USA	Valid	100

Address State

Value	Label	Mapped To	Status	Count
MI		MI	Valid	100

Quality

Quality measures the number of errors and warnings that are encountered during processing. Total errors registry must account for less than one percent of total number of patients and vaccinations. Total warnings registered are expected to account for less than ten percent of the total patients and vaccinations.

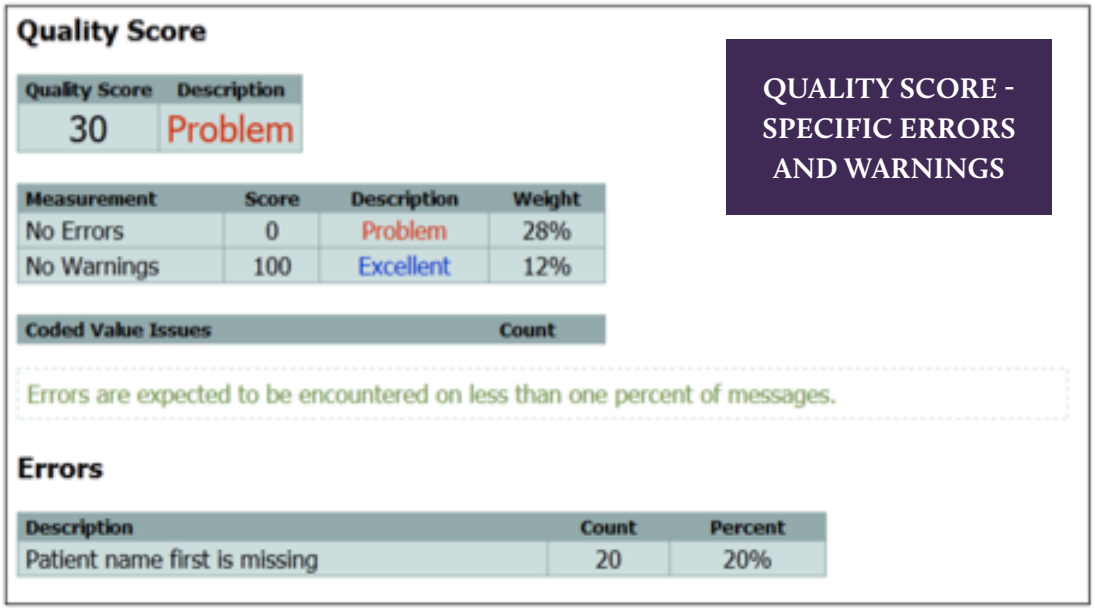
Quality Score

Quality Score	Description
70	Okay

QUALITY SCORE BASED ON PROCESSING ERRORS AND WARNINGS

Measurement	Score	Description	Weight
No Errors	100	Excellent	28%
No Warnings	0	Problem	12%

Quality Score with Errors



Quality Score

Quality Score	Description
30	Problem

Measurement	Score	Description	Weight
No Errors	0	Problem	28%
No Warnings	100	Excellent	12%

Coded Value Issues	Count

Errors are expected to be encountered on less than one percent of messages.

Errors

Description	Count	Percent
Patient name first is missing	20	20%

QUALITY SCORE - SPECIFIC ERRORS AND WARNINGS

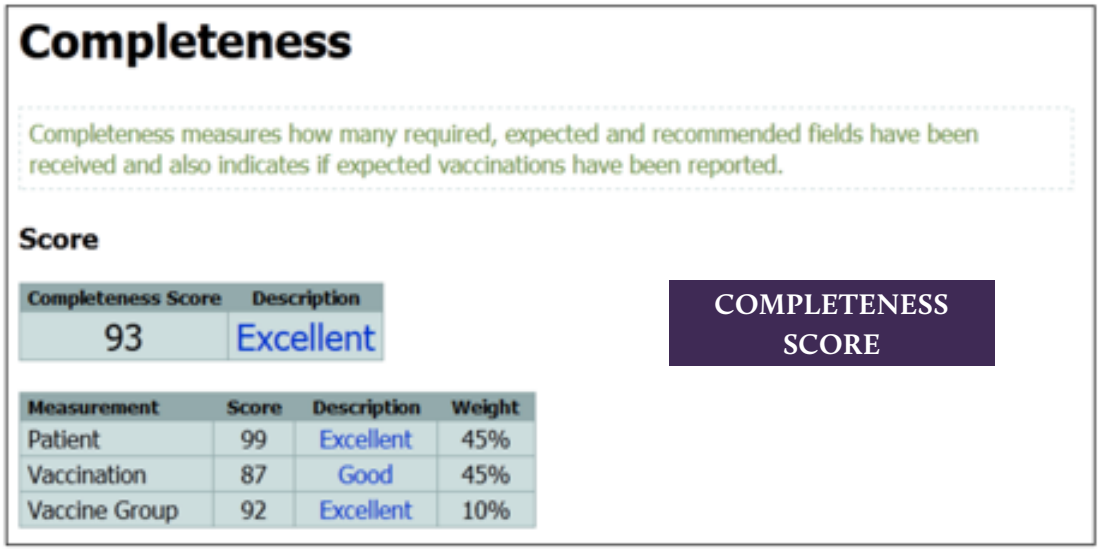
Warnings

Warning to message size rate is expected to be less than ten percen

Warnings

Description	Count	Percent
Vaccination financial eligibility code is missing	100	100%

QUALITY SCORE, CONTINUED



Completeness

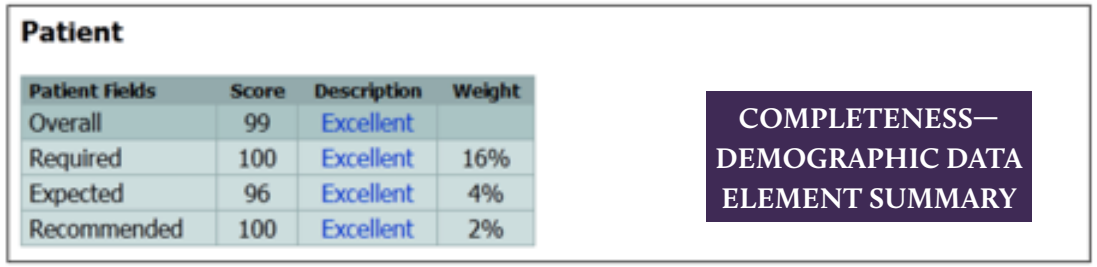
Completeness measures how many required, expected and recommended fields have been received and also indicates if expected vaccinations have been reported.

Score

Completeness Score	Description
93	Excellent

Measurement	Score	Description	Weight
Patient	99	Excellent	45%
Vaccination	87	Good	45%
Vaccine Group	92	Excellent	10%

COMPLETENESS SCORE



Patient

Patient Fields	Score	Description	Weight
Overall	99	Excellent	
Required	100	Excellent	16%
Expected	96	Excellent	4%
Recommended	100	Excellent	2%

COMPLETENESS—DEMOGRAPHIC DATA ELEMENT SUMMARY

Patient Completeness Required

Required	HL7	Count	Percent	Description	Weight
Patient Id	PID-3	100	100%	Excellent	3.5%
First Name	PID-5.2	100	100%	Excellent	1.7%
Last Name	PID-5.1	100	100%	Excellent	1.7%
Birth Date	PID-7	100	100%	Excellent	3.5%
Sex	PID-8	100	100%	Excellent	1.7%
Address	PID-11	100	100%	Excellent	0.7%
- Street	PID-11	100	100%	Excellent	1.7%
- City	PID-11	100	100%	Excellent	0.4%
- State	PID-11	100	100%	Excellent	0.4%
- Zip	PID-11	100	100%	Excellent	0.4%

COMPLETENESS—DEMOGRAPHIC DATA ELEMENT DETAIL

Patient Completeness Expected

Expected	HL7	Count	Percent	Description	Weight
Middle Name	PID-5.3	88	88%	Good	1.5%
Phone	PID-13	100	100%	Excellent	1.5%
Mother's Maiden	PID-6	100	100%	Excellent	1.5%

COMPLETENESS—DEMOGRAPHIC DATA ELEMENT DETAIL

Patient Completeness Recommended

Recommended	HL7	Count	Percent	Description	Weight
Ethnicity	PID-22	100	100%	Excellent	0.7%
Race	PID-10	100	100%	Excellent	0.7%
Responsible Party	NK1	100	100%	Excellent	0.1%
- First Name	NK1	100	100%	Excellent	0.3%
- Last Name	NK1	100	100%	Excellent	0.3%
- Relationship	NK1	100	100%	Excellent	0.1%

COMPLETENESS—DEMOGRAPHIC DATA ELEMENT DETAIL

Patient Completeness Optional

Optional	HL7	Count	Percent
Resp Party Address	NK1-4	100	100%

COMPLETENESS—DEMOGRAPHIC DATA ELEMENT DETAIL

Vaccination Completeness

Vaccination

Vaccination Fields	Score	Description	Weight
Overall	87	Good	
Required	86	Good	16%
Expected	100	Excellent	4%
Recommended	70	Okay	2%

COMPLETENESS—VACCINE DATA ELEMENT SUMMARY

Vaccination Completeness Required

Required	HL7	Count	Percent	Description	Weight
Vaccination Date	RXA-3	200	100%	Excellent	4.5%
Vaccination Code	RXA-5	200	100%	Excellent	4.5%
Information Source	RXA-9	200	100%	Excellent	4.5%
VFC Status	OBX-5	0	-	Problem	2.2%

COMPLETENESS—VACCINE DATA ELEMENT SUMMARY

Vaccination Completeness Expected

Expected	HL7	Count	Percent	Description	Weight
CVX Code	RXA-5	200	100%	Excellent	1.5%
Lot Number	RXA-15	100	100%	Excellent	1.5%
Manufacturer	RXA-17	100	100%	Excellent	1.5%

COMPLETENESS—VACCINE DATA ELEMENT DETAIL

Vaccination Completeness Recommended

Recommended	HL7	Count	Percent	Description	Weight
Admin Amount	RXA-6	100	100%	Excellent	1.6%
Completion Status	RXA-20	0	-	Problem	0.7%

COMPLETENESS—VACCINE DATA ELEMENT DETAIL

Vaccination Completeness Optional

Optional	HL7	Count	Percent
Action Code	RXA-21	200	100%
Refusal Reason	RXA-18	200	100%
Vaccination Id	ORC-3	200	100%

COMPLETENESS—VACCINE DATA ELEMENT DETAIL

Vaccine Group Expected

Vaccine Group

Expected	CVX	Label	Count	Percent
DTaP	20	DTaP	10	10%
Hep B	Problem: no vaccines received for this group			
Polio	10	IPV	12	12%
Hib	49	Hib (PRP-OMP)	5	5%
	48	Hib (PRP-T)	14	14%
Influenza	141	Influenza, seasonal, injectable	11	11%
	140	Influenza, seasonal, injectable, preservative free	10	10%
MMR	94	MMRV	2	2%
Varicella	94	MMRV	2	2%
	21	varicella	2	2%
Pneumococcal	133	Pneumococcal conjugate PCV 13	9	9%

Vaccine Group Recommended

Recommended	CVX	Label	Count	Percent
HPV	118	HPV, bivalent	2	2%
	62	HPV, quadrivalent	1	1%
Rotavirus	116	rotavirus, pentavalent	6	6%
Tdap	115	Tdap	10	10%
Hep A	83	Hep A, ped/adol, 2 dose	6	6%

COMPLETENESS—VACCINE GROUPS

Timeliness

Timeliness measures the number of days between the date a message was received and the most recent administered vaccination indicated in that message. Submitters should send administered vaccinations as soon as possible after administration, normally once a week.

Timeliness Score

Timeliness Score	Description
100	Excellent

TIMELINESS SCORE

Timeliness Measures

Measurement	Score	Description	Weight
Early	100	Excellent	10%

Vaccination Received	Count	Percent
Early	100	100%

Timeliness of Vaccination Update	
Vaccination Admininistered	Tue, Dec 20, 2011
Batch Received	Tue, Dec 20, 2011
Average Elapsed Days	0.0

TIMELINESS - DETAIL

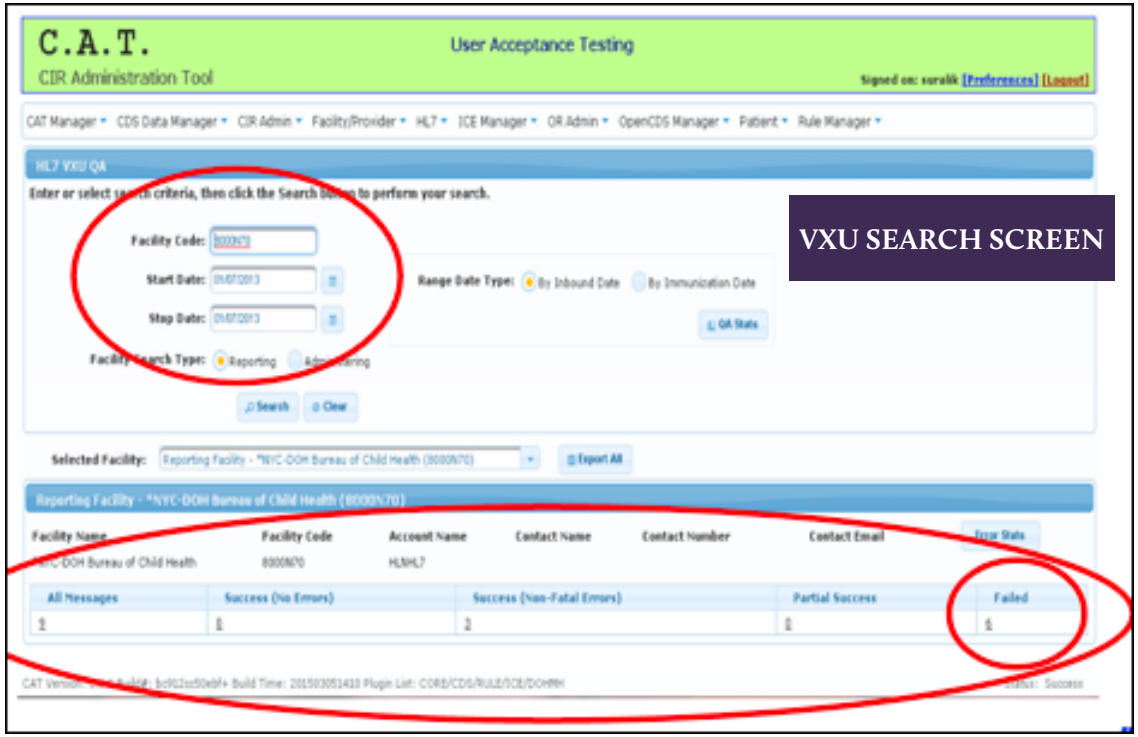
Appendix D-2. HLN Quality Assurance (QA) Tool[65]

Background

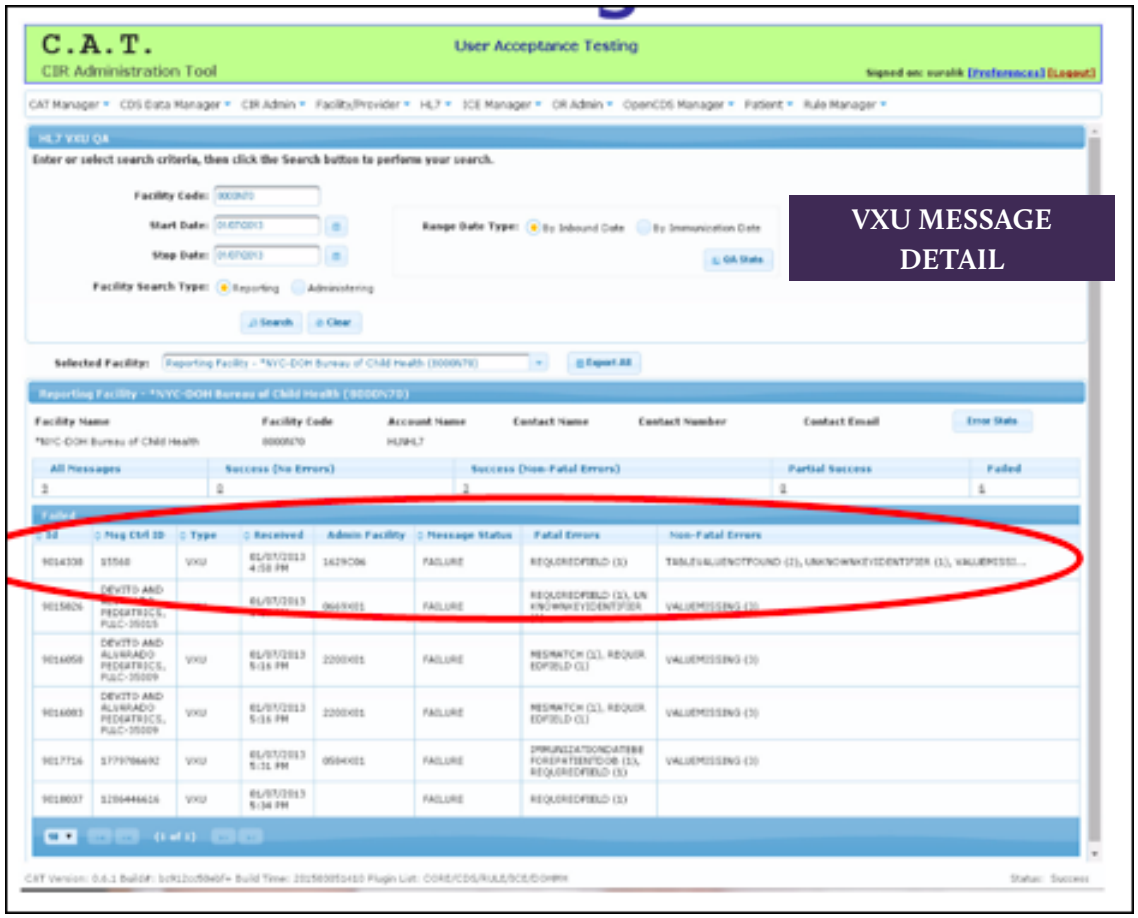
The Quality Assurance tool was developed by HLN in collaboration with the New York City IIS program. The QA tool allows for IIS staff to search for HL7 messages (using basic parameters or advanced search options), review summary information about messages submitted, and investigate data issues.

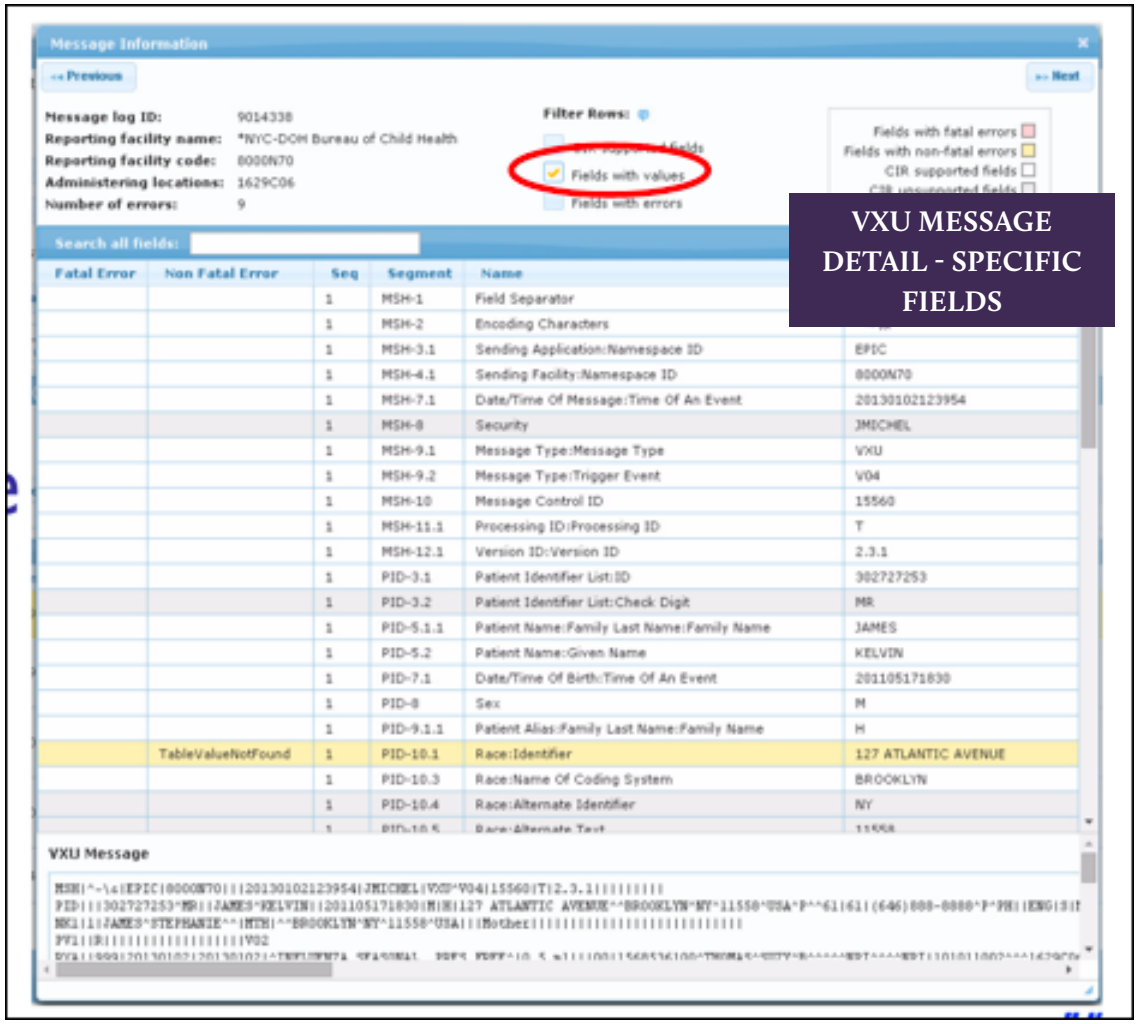
Sample Screens and Report Images

Figure 15. HLN QA Tool, Message Review



65 DeMeo, E. Using Quality Assurance Tools to Improve HL7 Reporting to NYC's Citywide Immunization Registry. Presentation at the 2016 AIRA National Meeting. Slides available at http://www.immregistries.org/resources/iis-meetings/Using_Quality_Assurance_Tools_to_Improve_HL7_Reporting_to_NYC%E2%80%99s_Citywide_Immunization_Registry.pdf.


C.A.T.
CDR Administration Tool
User Acceptance Testing
VXU MESSAGE DETAIL



VXU MESSAGE DETAIL - SPECIFIC FIELDS

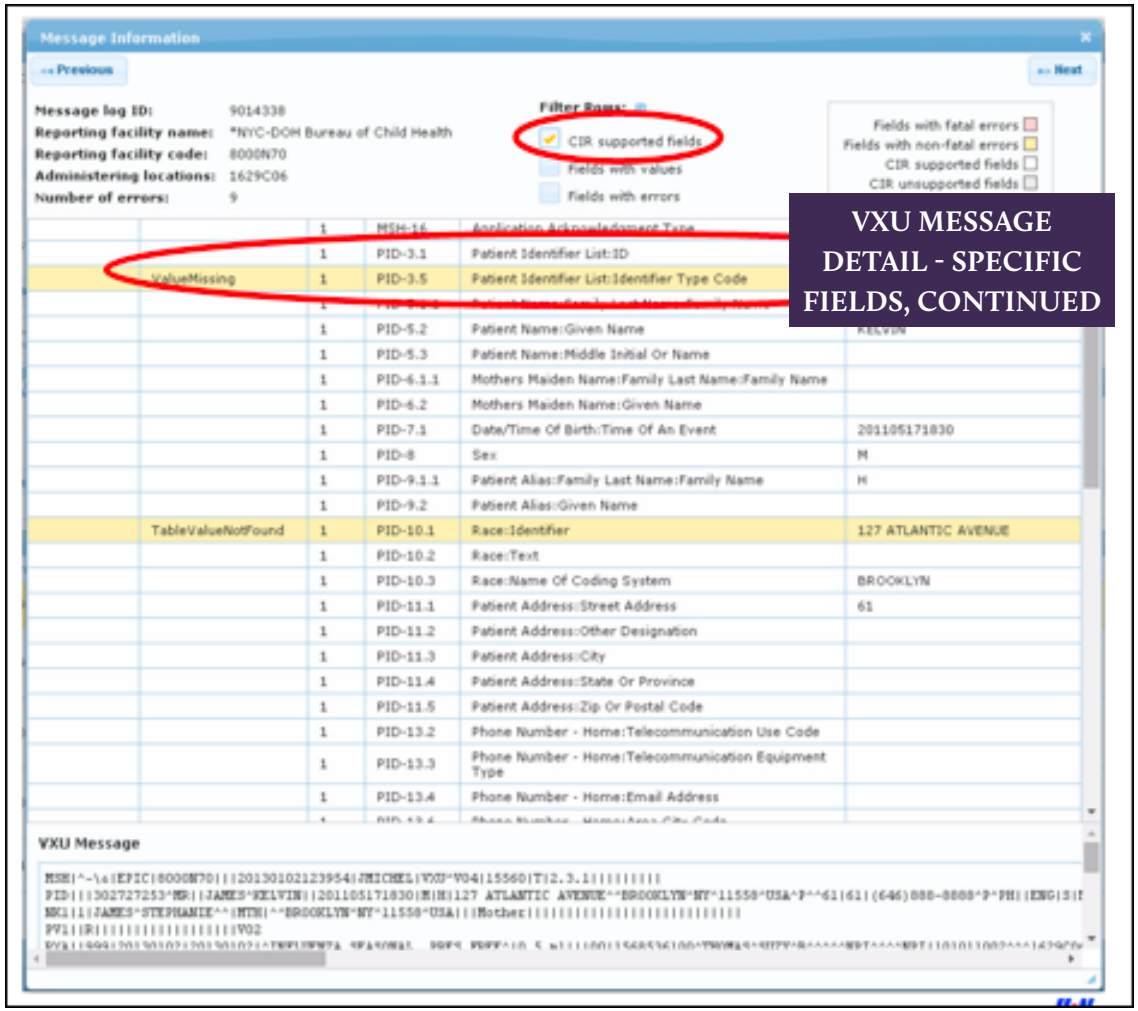
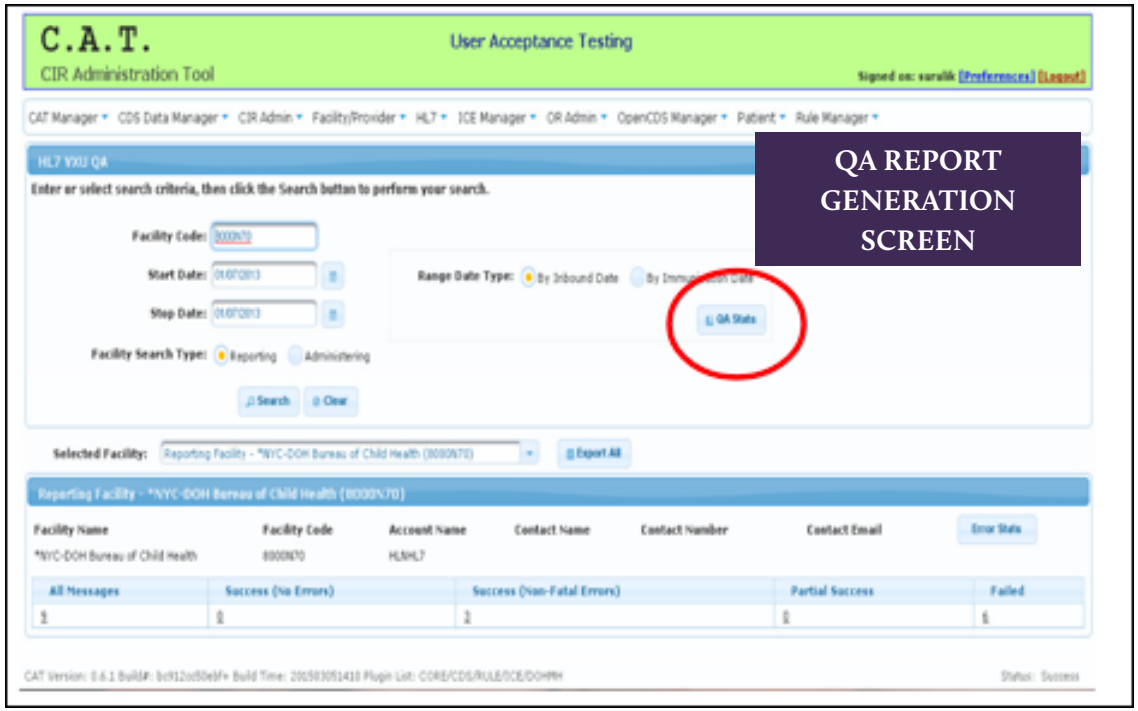
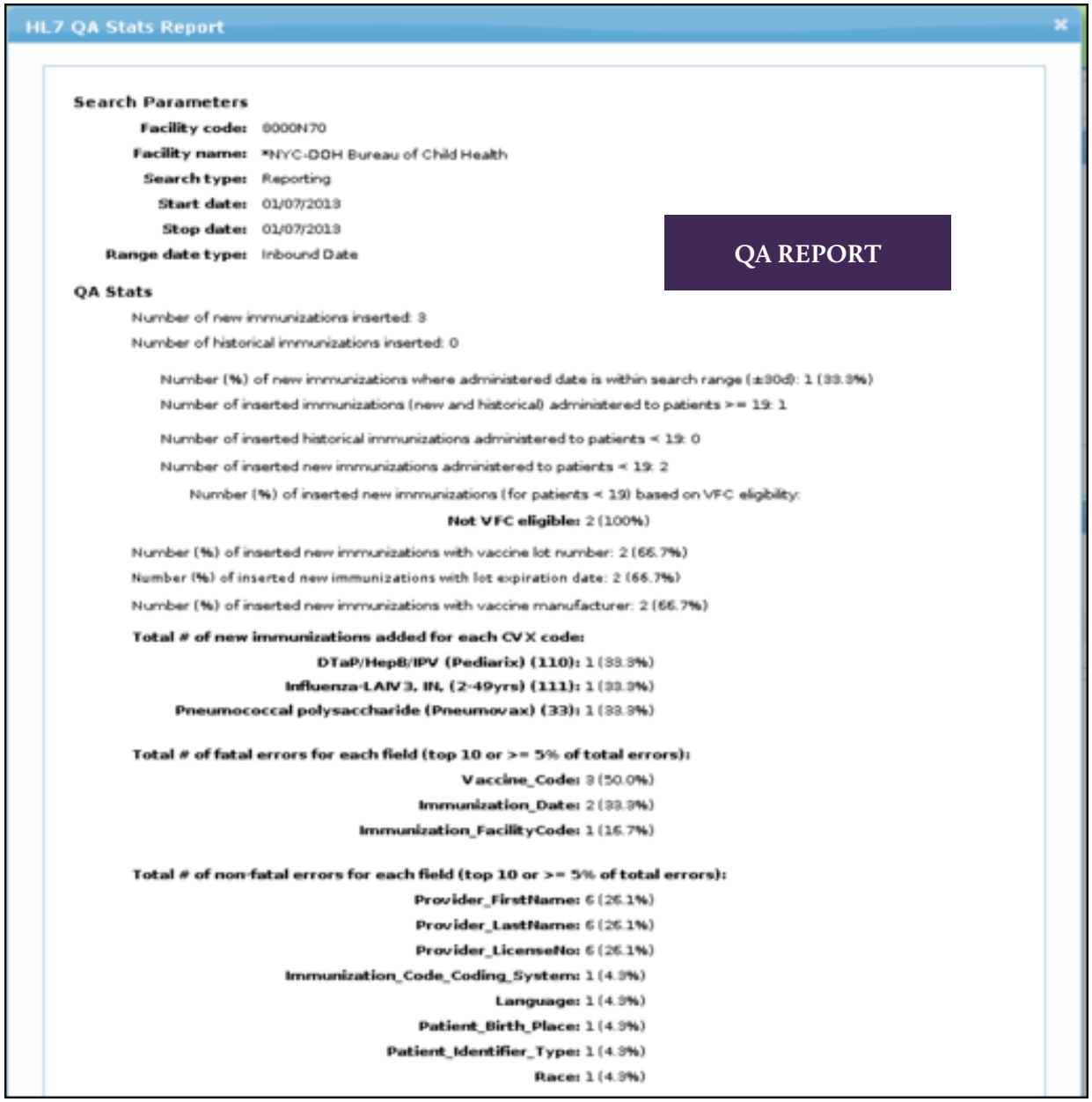

Message Information
Previous
Next
Message log ID: 9014338
Reporting facility name: *NYC-DOH Bureau of Child Health
Reporting facility code: 8000N70
Administering locations: 1629C06
Number of errors: 9
Filter Rows:
CIR supported fields
Fields with values
Fields with errors
Fields with fatal errors
Fields with non-fatal errors
CIR supported fields
CIR unsupported fields
VXU MESSAGE DETAIL - SPECIFIC FIELDS, CONTINUED
ValueMissing
TableValueNotFound
VXU Message

Figure 16. HLN QA Tool, QA Statistics





HL7 QA Stats Report

Search Parameters

Facility code: 8000N70
Facility name: *NYC-DOH Bureau of Child Health
Search type: Reporting
Start date: 01/07/2013
Stop date: 01/07/2013
Range date type: Inbound Date

QA REPORT

QA Stats

Number of new immunizations inserted: 3
Number of historical immunizations inserted: 0

Number (%) of new immunizations where administered date is within search range (±30d): 1 (33.3%)
Number of inserted immunizations (new and historical) administered to patients >= 19: 1

Number of inserted historical immunizations administered to patients < 19: 0
Number of inserted new immunizations administered to patients < 19: 2

Number (%) of inserted new immunizations (for patients < 19) based on VFC eligibility:
Not VFC eligible: 2 (100%)

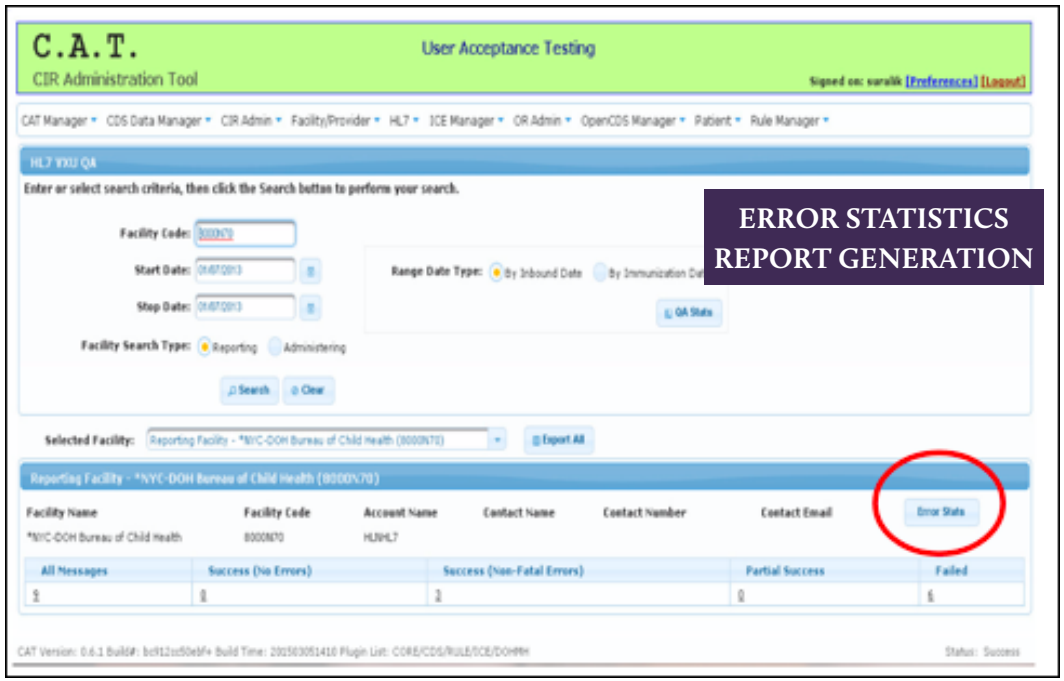
Number (%) of inserted new immunizations with vaccine lot number: 2 (66.7%)
Number (%) of inserted new immunizations with lot expiration date: 2 (66.7%)
Number (%) of inserted new immunizations with vaccine manufacturer: 2 (66.7%)

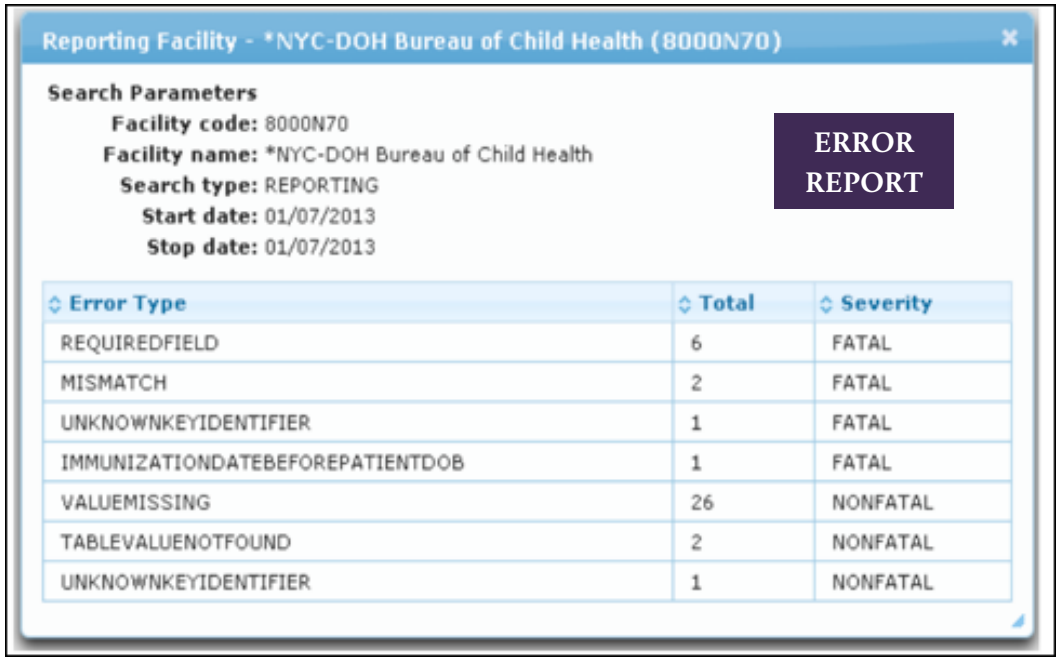
Total # of new immunizations added for each CVX code:
DTaP/HepB/IPV (Pediarix) (110): 1 (33.3%)
Influenza-LAIV 3, IN, (2-49yrs) (111): 1 (33.3%)
Pneumococcal polysaccharide (Pneumovax) (33): 1 (33.3%)

Total # of fatal errors for each field (top 10 or >= 5% of total errors):
Vaccine_Code: 3 (50.0%)
Immunization_Date: 2 (33.3%)
Immunization_FacilityCode: 1 (16.7%)

Total # of non-fatal errors for each field (top 10 or >= 5% of total errors):
Provider_FirstName: 6 (26.1%)
Provider_LastName: 6 (26.1%)
Provider_LicenseNo: 6 (26.1%)
Immunization_Code_Coding_System: 1 (4.3%)
Language: 1 (4.3%)
Patient_Birth_Place: 1 (4.3%)
Patient_Identifier_Type: 1 (4.3%)
Race: 1 (4.3%)

Figure 17. HLN QA Tool, Error Statistics





Appendix E-1. Abbreviations

Table 8. Acronyms

ACRONYMS	
ACIP	Advisory Committee on Immunization Practices
AFIX	Assessment, Feedback, Incentives and Exchange
AIRA	American Immunization Registry Association
ASC	Assessment Steering Committee
BR	Business Rule
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CDSi	CDC Clinical Decision Support Logic
CVX	Codes for Vaccine Administered
DOB	Date of Birth
DQA	Data Quality Assurance
DV Guide	Data Validation Guide
DXC	DXC Technology
EDE	Electronic Data Exchange
EHR	Electronic Health Record
HBIG	Hepatitis B Immune Globulin
HIE	Health Information Exchange
HL7	Health Level Seven International
HPE	Hewlett Packard Enterprise
IIS	Immunization Information System
MIROW	Modeling of Immunization Registry Operations Workgroup
MVX	Manufacturers of Vaccines
NDC	National Drug Code
NPI	National Provider Identifier
SME	Subject Matter Expert
VFC	Vaccines for Children
VIS	Vaccine Information Statement

Appendix E-2. Definition of Terms

Accuracy – A dimension of data quality; refers to the degree to which the data reflect reality. In the case of immunization data submitted, accuracy refers to the degree to which the data match the clinical encounter.

Clinical decision support (CDS) – An automated process that determines the recommended immunizations needed for a patient and delivers these recommendations to the health care provider.[66]

Code for Vaccine Administered (CVX code) – A numerical code that describes a vaccine type. CVX codes are assigned by CDC to support electronic messaging of immunization histories via HL7.

Completeness – A dimension of data quality; refers to the degree to which full information about a data set or an individual data element is captured in the IIS. In the case of data submissions to an IIS, completeness refers to the submission of all relevant data from the submitters and to the completeness of individual data elements of interest.

Electronic health records (EHR) – System utilized by the provider organization. EHR generally refers to the technology and all the software of an electronic recordkeeping system used in health care. Electronic medical record refers to the medical records maintained in an EHR system.

Health Level Seven (HL7) – A nationally recognized standard for electronic data exchange between systems housing health care data.

Interface – The electronic connection between EHR and IIS for electronic data exchange between these systems.

Lot number – The number assigned by the manufacturer to a specific batch of vaccine product type. Lot number can be used by IIS to track administered vaccines.

Lot number expiration date – This is the expiration date assigned to each lot of vaccine by the manufacturer. Beyond this date, the vaccine should no longer be administered.

Manufacturer (MVX code) – Manufacturer refers to the organization that manufactures a specific vaccine. MVX is the code used in an HL7 message that identifies the manufacturer.

Meaningful use – Meaningful use is using certified EHR technology to: improve quality, safety, and efficiency; reduce health disparities; engage patients and family; improve care coordination and population and public health; and maintain privacy and security of patient health information. See https://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives.

National drug code (NDC) – NDC is defined as a unique numeric identifier of the vaccine product type. Each drug product is assigned a unique three-segment number. This number, known as the NDC, identifies the labeler (manufacturer or distributor), product, and trade name.

National provider identifier – NPI is a unique numeric identifier issued by the Centers for Medicare and Medicaid Services used to identify health care providers.

Onboarding – Process of bringing a new data exchange source from first contact to going live with the exchange. Can also apply to the process of enhancing or changing an existing data interface.

Provider organization – An organization that provides vaccination services or is accountable for an entity that provides vaccination services. A provider organization can be a solo practice with one clinical site or can contain a collection of related providers (e.g., clinicians, physicians, nurses) with multiple sites.

66 The CDC CDSi Logic Specification and Supporting Data are available at *https://www.cdc.gov/vaccines/programs/iis/cdsi.html*.

Timeliness – A dimension of data quality; refers to whether the time between an event of interest (e.g., vaccination) and when that data was captured in the IIS occurred within recommended limits.

Trade name – Indicates the manufacturer's proprietary name for a product, and in some cases, its intended use (e.g., adults, pediatrics) is included in the name.

Vaccination encounter date – Synonymous with vaccination administration date.

Vaccine expiration date – This is the expiration date assigned to each lot of vaccine by the manufacturer. Beyond this date, the vaccine should no longer be administered.

Validity – A dimension of data quality; refers to the degree to which the data conform to rules of what is accepted or expected by the IIS.

Appendix F. References

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