DATA VALIDATION GUIDE

For the IIS Onboarding Process

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Executive Summary

In the current environment of interoperability among health care information systems, it has become increasingly important for immunization information systems (IIS) to control the quality of data in their systems. The growing number of health care providers who submit data via Health Level 7 (HL7) interfaces has created a need for IIS to evaluate data in new ways – before permitting the submission of data into their production systems. To build on the work already done in this area and reduce further duplication of effort among IIS, **the American Immunization Registry Association (AIRA) initiated a project in 2016 to research, review, and make recommendations for onboarding processes and practices specific to data validation**.

This guide was developed to provide practical guidance on data quality measures to implement in an IIS during the onboarding process. The audience includes IIS managers and other IIS staff members, Immunization Program managers, IIS and AIRA partners, and electronic health record (EHR) vendors. The guide builds on business rules developed in earlier documents such as the MIROW Best Practices Guides on Data Quality Assurance. It identifies and highlights proven practices used in the IIS community and gives IIS a resource for building or expanding their own onboarding data validation processes.

Topics covered in the guide include:

- **Source of data for the validation process**
- **Parameters for the test data load**
- **Accuracy and completeness measures with suggested thresholds**
- **Methodology approaches - aggregate data review and individual patient record review**
- **Roles of IIS, provider organization and electronic health record (EHR) staff**
- **Helpful hints for successful implementation**
- **Preparations to Go Live**
- **Short term data validation after Go Live**
- **Sample data quality reports from IIS**

This guide was developed in expectation that each IIS program will adjust the implementation of the recommended business rules and practices to their own specific needs and unique implementation concerns. The recommendations and examples represent an attempt to balance ideal practices with pragmatic considerations of what is possible within the IIS.

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Background

Over the past 20 years, the nation's immunization information systems (IIS) have become increasingly integrated into the immunization programs they support. IIS also have gained respect in the health care provider community as a valued resource and multi-faceted tool in the provision of immunization services. IIS functionality now usually includes consolidating immunization-related patient information, clinical decision support, aggregate data reporting, vaccine inventory ordering and accountability, and many other tools.

The introduction of Meaningful Use (MU) in 2011 by the Centers for Medicare and Medicaid Services created an additional demand on IIS programs.[1] This demand resulted from a MU requirement that provider organizations exchange data electronically with certain public health systems, including IIS, in order to be eligible for the Meaningful Use Incentive Program.[2] IIS began receiving a high volume of requests from electronic health record (EHR) vendors wanting to test and prove their products' abilities to exchange data electronically, and from provider organizations who wanted to establish electronic data exchange (EDE) in order to receive funds through the Incentive Program.

MU and the associated national movement toward electronic data exchange (EDE) present both challenges and opportunities for IIS. Challenges occur especially in the area of having adequate resources to meet national standards that are evolving and changing, and the high level of demand from provider organizations. Opportunities for IIS lie with the significant potential to receive more timely and more complete data than ever before. These opportunities also create a responsibility for IIS to reevaluate best ways to assess, monitor, and improve or maintain the quality of data.

Purpose

The purpose of this guide is to provide practical guidelines that IIS can use to ensure the quality of their data during the onboarding process. Also known as precertification,[3] onboarding is the process of connecting, validating, and approving a new EDE source - from the moment of first contact with the provider organization to the go live approval. This guide focuses on one aspect of onboarding - the data validation process. The data validation process assesses new sources of data for accuracy and completeness in a designated pre-production environment before allowing data into the IIS production system. **High quality data in an IIS is important for the purposes of person matching and deduplication, immunization deduplication, accurate vaccine forecasting, and inventory management.** To build on the work already done in this area and further reduce duplication of effort among IIS, the American Immunization Registry Association (AIRA) initiated this project in 2016 to research, review, and make recommendations for onboarding processes and practices specific to data validation.

This guide identifies and highlights proven practices used in the IIS community and gives IIS a resource to build or expand their onboarding data validation processes.

[1] EHR Incentives and Certifications: Meaningful Use Definition and Objectives. Available at HealthIT.gov website: *https://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives*
[2] EHR Incentives and Certifications: EHR Incentive Programs. Available at HealthIT.gov website: *https://www.healthit.gov/providers-professionals/ehr-incentive-programs*
[3] The term "precertification" was used in the MIROW Chapter 3: Data Quality Assurance in Immunization Information Systems: Incoming Data.

Audience

This document has been developed for IIS managers seeking guidance on data quality measures to implement for quality assurance/control in their IIS during the onboarding process. The document may also be valuable to the Centers for Disease Control and Prevention (CDC), National Center for Immunizations and Respiratory Diseases (NCIRD), Immunization Program Managers, IIS staff members, IIS vendors, EHR vendors, jurisdiction-specific information technology staff, national organizations supporting IIS, and other partner/policy makers.

Methodology

To create this guide, AIRA assembled a workgroup that consisted of subject matter experts (SMEs) from the IIS community, CDC partners, public health consultants, and AIRA staff (see list of participants in Acknowledgements section). During the initial phase of the project, existing IIS materials were gathered and reviewed to identify the relevant onboarding data validation practices. The materials included AIRA's Modeling of Immunization Registry Operations Workgroup (MIROW) best practice guidelines on data quality, CDC Health Level 7 (HL7) implementation guides, and documents gathered directly from IIS programs. With support from a public health consultant and an AIRA project manager, the workgroup met via telephone once or twice a month from April through August of 2016. The workgroup reviewed materials and developed recommendations for the onboarding data validation guide. The consultant drafted and revised the guidelines based on input and feedback from the workgroup and others. Finally, the document was reviewed by AIRA staff, AIRA Board of Directors, and the IIS community, with the final version completed in August 2016.

Scope of Work

Onboarding of an EDE includes many steps - from the initial contact with a provider organization all the way to "go live" submission of data into the IIS production environment. While the focus of this guide is EDE with health care provider organizations, the highlighted processes can also apply to other data sources such as state vital statistics offices, health plans, and Medicaid. This guide focuses on the data validation process for provider organizations.

To set the context for data validation, Section 2 gives an overview of the major steps in the onboarding process. The remainder of the document covers activities that should occur only after data sources have received a test account, established connectivity to the IIS test environment, and received approval to begin testing. This guide will offer platform-neutral suggestions for data validation processes.

The workgroup specifically deemed the following topics out of scope for this document:

- The ongoing monitoring of incoming data and existing data
- Processes for engagement with provider organizations, EHRs), and health information exchanges (HIEs)
- Query/response messaging
- Structure and format of HL7 messages

PRIMARY RESOURCE MATERIALS

- ✔ **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]
- ✔ **IIS-specific data quality protocols and resources listed in Appendix B**

[4] Available on the AIRA website:
http://www.immregistries.org/resources/aira-mirow
[5] Available at the CDC website:
http://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html

Onboarding Overview

Many IIS have a step-by-step process in place for getting a provider organization ready to send patient data from an EHR to the IIS. The nomenclature for these steps varies from IIS to IIS. The precise processes covered under each step may also vary. The following description is intended to provide a general overview of the onboarding process and Figure 1 provides a flow chart of the steps.

Onboarding starts with a process sometimes called **DISCOVERY** or **PREPARATION** where initial information about the provider organization is gathered to assess readiness in moving forward with the interface project. This may often be preceded by a formal registration process in which provider organizations have to officially register for onboarding. The next step usually involves **PLANNING** where information is shared to understand interface configuration needs and any modifications required in the EHR, the provider organization's business practice, or its clinical workflow. During planning, the provider organization or EHR representative should provide a CVX-to-vaccine mapping table that includes all vaccine types in use within the EHR at present as well as in the past. The IIS program should give the provider organization and/or the EHR vendor all documents needed for implementation of the interface, including the data validation process and criteria for data acceptance. A third step is **DEVELOPMENT** and **TESTING** where initial interface configuration is completed on both the IIS side and the provider organization side based on information gathered during the planning stage. The EHR's CVX code table is examined by the IIS program to ensure its accuracy and completeness. Other coding elements may also be reviewed such as manufacturer, route, and site. Connectivity testing usually occurs at this time. Technical message review also occurs: HL7 messaging syntax and formatting requirements are evaluated to test the structural validity of the HL7 message and ensure the required elements are present. This can be an automated process to decrease the impact on IIS staff resources. Testing tools developed by the National Institute for Standards and Technology (NIST)[6] are also available for IIS to use to validate vocabulary for valid HL7 field values. In fact, the IIS may require the EHR vendor and/or Provider Organization to pre-validate their message format with NIST. After messages pass the HL7 requirements, the IIS may perform additional content validation for each segment and subcomponent, as needed. Next, the **DATA VALIDATION** phase occurs. At this point, the EHR vendor and/or the provider organization will have demonstrated that they are capable of formatting a message correctly and that they will be submitting the proper data elements. Real patient data is submitted to the IIS test environment and reviewed by IIS staff to ensure quality standards are met. When the data has met the IIS program's quality criteria, the IIS program makes the decision to **GO LIVE**. Final changes to the configuration are made to allow provider organization data to pass to the IIS production system. Although provider organization data now flows to the IIS production environment, data quality processes continue. An IIS interface requires ongoing, often daily, monitoring by the IIS and the provider organization. Although not covered in this guide, it is important to have processes in place for a continuous data quality improvement process.[7]

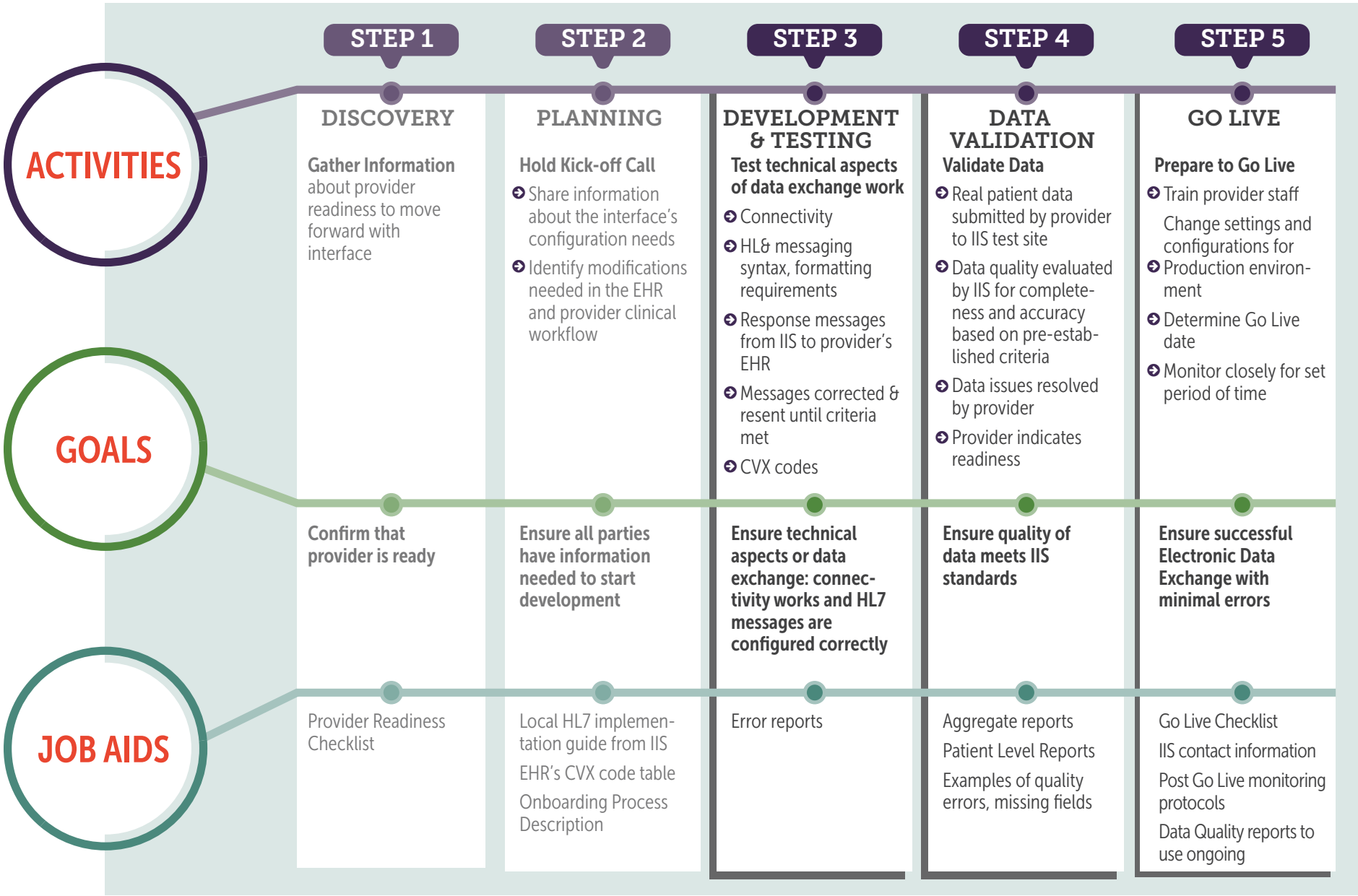
Caveats: The steps listed above are neither all-inclusive nor mutually exclusive. The terminology for each step is not prescriptive and an IIS may use different terms for the steps. An IIS may have additional steps, different terms, and a different order of events for the overall onboarding process and that is perfectly acceptable.

It is also noteworthy that for many IIS the data quality checks occur simultaneously with the HL7 Development and Testing Phase. Appendix C contains examples of onboarding processes and checklists. Figure 1 depicts the steps described above. Steps 1 and 2 are out-of-scope for this guide. Step 3 includes **some** processes that are in scope and some that are not. Step 4 — Data Validation — is the primary focus of this guide. Step 5 includes important actions to take after data quality is approved and before data is allowed into the IIS production system.

[6] NIST Immunization Test Suite: *https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/home*
[7] See *Appendix C-2* for a fuller description of possible steps in the onboarding process.

Onboarding Process Steps for HL7 Electronic Data Exchange

Figure 1. Onboarding Process Steps for HL7 Electronic Data Exchange (Steps 3- 5 are in scope for this guide)



Source of Data for Validation Process

While "fake" or "test" data may have been used in the development and testing phase (e.g., in the HL7 message validation process), such data does not allow the IIS to accurately assess an organization's readiness to go live. **Real patient data from the provider organization's production EHR should be used during the validation phase.** The IIS should hold the data separate from their production database, usually in a test or pre-production site. Validation should be done for each provider organization separately, even those with the same EHR system, since implementation of an EHR may differ from one organization to another. Even within an organization, it is best to get data from each facility or physical site as usage of the EHR may vary. There may be some exceptions to this site-level requirement if all sites use the same version of the EHR or submit data through a common EHR-vendor hub. The need for site-level review may be reduced if the hub normalizes the data to meet IIS requirements. Still, if IIS resources allow, it is recommended to test each site's data separately: how the EHR is actually used may vary from site to site.

Parameters for Data Set

The minimum data load required for a meaningful assessment depends on the size of the practice and the number of immunizations administered on a regular basis. The data should include the full set of vaccines administered across the age range covered by the practice and represent typical messaging at the provider organization's office on a daily or weekly basis. While some IIS have determined that 250-1000 HL7 messages are needed for a thorough testing process, others have found that 50-100 patient records with vaccinations can provide a good idea of data quality.[8]

For smaller practices administering a low volume of vaccines, a numerical requirement may be unrealistic. Reviewing records over a period of time may work better than an absolute numerical requirement, with the advantage that the period of time can be adjusted according to the volume of vaccines administered. Real-time submission over a two- to four-week period usually provides enough data. If not, it may be more practical to ask for a historical data load covering a longer time period — such as the last quarter or year. For the smallest provider organizations, or those that only give the occasional vaccine, another option is for the IIS to give the provider organization a suite of test cases for entry into their EHR and subsequent submission to the IIS.

Whichever method the IIS chooses, it is essential that the sample data represent the provider organization's vaccination practice, covering the full age range accepted by the IIS. Historical as well as administered vaccine doses should be sent for validation. **Test messages should be submitted to the IIS until all vaccine and demographic data issues have been resolved, the proportion of vaccines sent to the IIS is appropriate for the practice, and all vaccines administered are represented in the provider organization's data received by the IIS.**

[8] It may be advisable to exclude influenza messages from the count, especially during flu season. You may easily reach the numerical goal with an overabundance of flu vaccine data and an inadequate representation of the full panel of vaccines. Flu messages are still reviewed, just not counted toward the minimum number of records (if a minimum number has been established).

Data Quality Components

The three components of data quality are accuracy,[9] completeness, and timeliness. During the onboarding process, accuracy and completeness of data are the primary concerns. Timeliness can best be evaluated later during ongoing data monitoring in the production environment. Accuracy assessment in the onboarding data validation phase is a search for suspect data, often revealed by cross-checking data elements for consistency and appropriateness, and by comparison to the originating medical record. Completeness in this context refers to the complete recording of all data elements for a particular patient and immunization event. Certain recommended fields may be important enough for an IIS to establish completeness thresholds before allowing a provider organization's data into the IIS production environment. Completeness also refers to the capture of all expected immunizations based on the providers' profile (i.e., not just sending pediatric doses but all doses administered).

Selecting Metrics and Thresholds

The metrics and thresholds selected will vary by provider organization type, capabilities of the EHR, IIS-specific needs, and other circumstances and local needs. In practice, some IIS have made their own determinations of which among the required fields are critical enough to cause automatic rejection of a message. Common must-have elements include first and last name, client ID (or medical record number), date of birth, vaccine type (CVX/NDC codes), and vaccination encounter date. Other fields that are important but not always required at the 100% level are gender and address. An IIS may want to set expected thresholds for other important data elements at a high level of completeness — perhaps 90-95% — before the interface is approved for production.

Determining the threshold of data completeness for non-required fields is somewhat arbitrary as there are no national standards in place. If the IIS program sets the threshold too high for non-critical fields, they run the risk of holding up progress to production indefinitely. If they do not set an expectation at all, they may never get the fields they want. As an overall rule of thumb, if an EHR captures a data element that has a corresponding field in the IIS, the IIS should encourage the provider organization to submit it, regardless of its priority.

In determining thresholds of data quality, each IIS program should examine the importance of each specific field to their own system and immunization program needs to determine when a data source is approved to go to production.

Accuracy Measures

The MIROW documents, referenced in the Introduction section, provide a solid foundation of best practices for incoming data quality. The 2008 MIROW guide "Data Quality Assurance in Immunization Information Systems: Incoming Data," hereinafter referred to as the 2008 MIROW guide, contains a comprehensive description of relevant principles and business rules. The 2013 MIROW guide "Data Quality Assurance in Immunization Information Systems: Selected Aspects," hereinafter referred to as the 2013 MIROW guide, updates, clarifies, and deletes some of the 2008 business rules. These best practice guidelines can be used by IIS to develop rules, protocols, and procedures that ensure the quality of data in the IIS. The business rules for "cross-check data validations" from these two documents are especially relevant to this guide and can assist with measurement of accuracy.

Cross-checks can be used to examine conflicts within a specific vaccine event, such as vaccine administration date preceding birth date, submission date preceding administration date, and consistency of manufacturer and CVX code within an event. See **Appendix D-1** for a list of Selected Data Checks from the 2008 MIROW guide. In addition, comparing age at time of vaccination to the Advisory Committee on

[9] See more detailed definitions of accuracy, completeness, and timeliness in the MIROW Guide: Data Quality Assurance in Immunization Information Systems: Incoming Data. pp 86-88. *http://www.immregistries.org/resources/aira-mirow*

Immunization Practices (ACIP) recommended schedule can reveal inconsistencies and potential inaccuracies related to minimum and maximum age for vaccines (including those due to actual clinical practice).[10] In addition to cross-check validations, accuracy for certain individual fields can be reviewed for common data flaws. For example, screening for names of "unknown, "test," or "baby," should be performed at some point in the data quality review.

Table 1 lists a subset of the 2008 and 2013 business rules, which were prioritized in the original MIROW documents, and reviewed, prioritized, and slightly modified by this guide's workgroup. It may be very helpful for the reader to review the original MIROW documents for complete information on these and other business rules and data quality processes.[11] Lower ranking business rules are not included in the table, but might be of higher priority to some IIS.

A total of 13 of the MIROW business rules received a high or medium priority rating by the workgroup.[12] The nine high priority rules are listed in the first part of **Table 1** (in business rule number order, not priority order). The four medium priority rules are at the bottom of the table.

It is recommended that each IIS review the Principles and Business Rules found in the two MIROW data quality guides and determine which are most valuable for their own unique state specific needs and available resources.

[10] See *http://www.cdc.gov/vaccines/acip/recs/* for up-to-date ACIP Recommendations on Immunizations.
[11] See 2008 MIROW Guide, pp.34-51 and 2013 MIROW Guide, pp. 70-87, for complete list of Business Rules.
[12] Note that BR 105 covers minimum/mandatory dataset. The elements listed there are superseded by the more up-to-date and comprehensive listing of required fields in HL7 Version 2.5.1 Implementation Guide, release 1.5. For details on the BR 105 dataset, see *Appendix D-4*.

Table 1. Business Rules for Accuracy Validation

Data Validation Check Description	Source of Rule	Rationale	Comments
HIGH PRIORITY			
Vaccination Encounter Date must not be before Patient Date of Birth	BR 101	Indicates major data quality issue	**Possible interpretations**: • Either the Vaccination Encounter Date or Patient Date of Birth is incorrect (or both) • Patient identification is incorrect (e.g., could be a sibling)
Vaccination Encounter Date must be less than or equal to (before or the same as) the Submission Date	BR 103	Indicates major data quality issue	**Possible interpretations:** • Vaccination Encounter Date is incorrect and EHR allows recording of encounter date in the future
Every administered vaccine should be recorded as a single Vaccination Event (e.g., combo vaccine should be recorded as 1 event rather than separate events for each component)	BR 107	Indicates data quality or clinical quality issues Is a requirement for VFC accountability – affects inventory if using IIS for tracking	**Possible interpretations:** • Data entry error • Provider organization's EHR may not be updated with the correct combo vaccine choice **Example:** Pentacel®, which contains DTaP, IPV, and Hib, should be submitted as one CVX code (one Vaccination Event) rather than one Vaccination Event for DTaP, one for IPV, and one for Hib (three Vaccination Events)
Vaccination Encounter Date should not be the same as the Patient Date of Birth unless it is on the list of vaccines recommended for administration on the date of birth, e.g., HepB	BR 114	Indicates major data quality issue with date of birth, vaccine administration date, or vaccine code, or clinical practice issue	**Note:** At this time, only HepB is recommended before 1 month of age **Possible interpretations:** • Clinical practice error • Professional decision which differs from common practice • Date entry error with Vaccination Encounter Date, or Date of Birth • Provider organization's EHR may not support data validation for these fields
Manufacturer and CVX Code should not contradict one another	BR 116	Indicates a significant data quality issue – potential that wrong vaccine code has been entered, which may affect the decrementing of inventory If using IIS for vaccine accountability and inventory, this validation check is necessary	**Possible interpretations:** • Data entry error • Code translation (or other) error in software • Provider organization's EHR system may not be up-to-date and may include incomplete or invalid values/choices • CVX code preferred (CPT code may be used if necessary). Vaccine type and Trade Name are not contained in HL7; vaccine type is determined by CVX and MVX (manufacturer) values within the message • NDC will be used in future and could be substituted for the CVX in this cross validation business rule

Data Validation Check Description	Source of Rule	Rationale	Comments
Vaccination Encounter Date should not be after the lot number expiration date	BR 118	Indicates data quality issue with dates or lot numbers, or clinical practice	**Possible interpretations**: • Expired vaccine was used • Data entry error
Administered vaccinations coded with an "unspecified" CVX code (should have specific Vaccine Types, e.g., Hib PRP-OMP; unspecified vaccine types, e.g., Hib, unspecified formulation)	BR 121	Vaccine accountability/inventory may be affected if type is "unspecified" Not specific enough to enable IIS forecaster to predict the next scheduled immunization correctly, possibly resulting in incorrect vaccination	**Note:** IIS should strongly encourage recording a specific vaccine type **Possible interpretations:** • The submitting system does not support the specific code so the recorder was forced to select the unspecified type • The recorder did not know what specific vaccine was given • The submitting system incorrectly reports the vaccine type • The vaccine should have been recorded as historical rather than administered • Clinical trials of new vaccines should be considered
Doses should not be recorded as given before the minimum patient age or after the maximum patient age for that particular vaccine	BR 130	Significant number of doses given too early or too late may be a data quality issue or clinical practice issue	**Possible interpretations:** • May indicate clinical practice issues, including off-label use • May indicate data entry or coding issues **Implementation options** – an IIS may use its forecaster/clinical decision support tool to find "invalid" doses, or may develop separate queries to produce ongoing reports. See Appendix D-1 for implementation examples
MEDIUM PRIORITY			
Use of a Provider Organization Profile: If the Facility is a specific type of practice (e.g., pediatric), the currently administered vaccinations should match a pattern in similar practices, and/or should match a state-supplied vaccine list, especially in universal vaccine states for pediatric patients	BR 113	Can be a very useful tool in data quality review once developed and automated	**Notes:** See Section 4 and Appendix D-2 for more information on developing provider organizations' profiles Requires a fair amount of work to implement but payoff may be worth it if automated reports can be created In universal vaccine states, where the state immunization program purchases vaccine for all childhood vaccines, the vaccines available to providers are predetermined by the state immunization program. Therefore, a profile can be created for the under 19 years of age population and applied to all providers serving children and enrolled in the state-supplied program. If vaccines are documented as administered that do not fall within this predetermined list an IIS can flag it as incorrect. **Possible interpretations:** Variance from the expected profile could reflect actual clinical activity (e.g., inventory shortage) or manual coding errors

Data Validation Check Description	Source of Rule	Rationale	Comments
The same patient should not receive the same antigen more than once in a single day	BR 117	Indicates possible clinical or data entry issues	**Possible interpretations**: • Partial dose given first time — e.g., injection interrupted and not completed, and 2nd dose given in same visit • Two separate pediatric doses to comprise one adult dose and given to an adult • Poor clinical practice (Pediarix and IPV both given) • Data is from different patients
Route and Site should not contradict each other for a given Vaccine Type and Patient's age	BR 119	Indicates possible clinical or data entry issues	**Possible interpretations:** • Data entry error • Systematic code translation (or other) error in software • Clinical error • Provider organization's EHR system may not be a current version and may be incomplete or include invalid values/choices • Provider organization's EHR may not support data validation for these fields
Vaccination Encounter Date should be within the Vaccine Product License Date range — after the Vaccine Product License Begin Date and before the Vaccine Product License End Date	BR 120	Doses should not be recorded as given before or after U.S. licensure-very likely coding or data entry error	**Notes:** Apply this rule to administered vaccines only, not historical **Possible interpretations:** • Incorrect coding • Data entry error • Unexpired vaccine used after Product License End Date. • Expired vaccine was used • Vaccine may have been given in another country with different availability, e.g., DTaP-Hib-IPV licensed in Canada and Mexico but not in USA at this point • Experimental/investigational drug trial • Vaccine code has been changed (re-used) **Challenge:** There is no single, authoritative source for many Vaccine Product License Dates. It may be necessary to compile the list from a variety of sources. One good place to start is the vaccine status table in the Red Book.[13]

[13] 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.

Completeness Measures

An important measurement in data validation is completeness at the field level. Having complete demographic and immunization records ensures the adequacy of information needed to match patient records in the IIS. It also ensures that adequate data is available in the IIS for clinical-decision making by providers to determine which vaccines a patient may need. **In addition, high quality complete data allows the IIS to be used for public health and population-level analyses. Increasingly, IIS are filling an important role in vaccine accountability and reporting, as well as monitoring vaccine uptake during outbreaks. These IIS roles and functions require specific data elements to meet federal standards.**

The business rules defined in the 2008 and 2013 MIROW guides, explicitly and implicitly, describe some of the individual fields/data elements that are deemed necessary for a high quality record submission. Explicitly, business rules 104 and 105 list the minimum/mandatory required data items (e.g., name, date of birth, vaccination encounter date, vaccine type)[14]. Other MIROW business rules implicitly recommend the inclusion of specific fields in order to evaluate data accuracy through the cross-checking of data elements (e.g., lot number, manufacturer, route of administration).

In addition to the MIROW guides, two other documents provide valuable information when developing data element requirements, and were used to develop **Table 2**:

- CDC's 2013-2017 IIS Functional Standards, Core Data Elements[15]
- HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, and Addendum, which defines the "usage" of each data element, segment, and message, in terms of whether or not they are required, conditional, or optional[16]

Ultimately, the IIS may want to include in the analysis all Core Data Elements and all data elements defined as "Required" in the HL7 guide. Practically, however, most IIS will need to take an incremental approach to their ultimate goals, and start with those fields most important to achieving their data quality priorities. In determining completeness levels, each IIS program should examine the importance of each field to their own system and immunization program. Inability of a provider organization to meet a specific threshold need not prohibit permission to go live. That decision is made by the IIS program — the completeness levels listed in **Table 2** are general recommendations, not absolutes.

Completeness demonstrates the percent of submitted records that contain data in various data fields/elements. For the purposes of **Table 2**, the completeness percentage is calculated by dividing the number of data fields/elements present (per data field/element) by the total number of demographic records or vaccination events (depending on data field/element) submitted. For example, if 100 vaccination events are submitted by a provider and 90 of those contain a CVX or NDC code, then the vaccine administered product type field has a completeness rate of 90% (90 complete divided by 100 total). Based on the threshold for this field in the table, that data source will not be allowed to go to production until the percentage reaches 100% (i.e., all vaccination events contain a CVX or NDC code). Note that the recommended completeness levels in **Table 2** have been developed only in relation to the onboarding data validation process. Some, but not all, may apply to ongoing data quality monitoring. Additional recommendations will be developed in the future specific to ongoing data quality monitoring.

[14] See *Appendix D-4* for details of minimum/mandatory data in Business Rule 105.
[15] Core Data Elements can be found in *Appendix E* and are derived from Immunization Information Systems (IIS) Functional Standards, 2013-2017. Centers for Disease Control and Prevention. Also, available at: *http://www.cdc.gov/vaccines/programs/iis/func-stds.html*. Last updated: December 18, 2012.
[16] HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5) November 5, 2014.

Table 2. Recommendations for Completeness Measure Thresholds[17]

Field/Element	Recommended Completeness Level[18]	Location in HL7 Messaging	Designation Usage in HL7	Source of Rule (other than HL7)	Rationale for Requiring High Completeness Level
Medical Record Number (AKA Client ID)	100%	PID-3	Required (R)	Workgroup	• Unique identifier of patient at provider organization level • Deduplication — matching to existing patient • May be leveraged by provider's EHR in query messaging
Patient Name (Last, First)	100%	PID-5	Required (R)	BR 105	• Component of minimum/mandatory dataset — see details in Appendix D-4
Mother's Maiden Name	90% (if the patient is a minor)	PID-6	Required but can be empty (RE)	Workgroup	• Deduplication for childhood population • 90% is gold standard level. Though currently difficult to achieve this mark, highly recommended as a goal because of its deduplication value
Patient Date of Birth	100%	PID-7	Required (R)	BR 105	• Component of minimum/mandatory dataset — see details in Appendix D-4
Patient Gender	95-100%	PID-8	Required (R)	Workgroup	• Deduplication • Possibility of future gender-specific vaccine recommendations **Note:** This changed from RE to R in the HL7 Addendum
Address	95-100%	PID-11	Required but can be empty (RE)	Workgroup	• Deduplication • Reminder-recall at IIS level • Coverage assessments at geographic level
Phone	90-95%	PID-13	Required but can be empty (RE)	Workgroup	• Deduplication • Reminder/recall — for IIS that use auto-dialers and potential text message reminders

[17] Note: when the IIS is used to meet the CDC vaccine tracking and accountability requirements, certain data elements must be present. Table 2 notes those elements required for VFC accountability. For more information, see the MIROW document, Decrementing Inventory via Electronic Data Exchange. April 2015. Available at the AIRA website: *http://www.immregistries.org/resources/aira-mirow*

[18] Note that the HL7 Implementation Guide describes actions to take at the message level when fields are not present or empty but the recommended completeness level described here is the recommended threshold of completeness before allowing data source to go to production.

Field/Element	Recommended Completeness Level[18]	Location in HL7 Messaging	Designation Usage inHL7	Source of Rule (other than HL7)	Rationale for Requiring High Completeness Level
Mother/Father/ Guardian (Next of Kin)	90-100% (if the patient is a minor)	NK1-2	If NK1 segment is present, then NK1-2 segment is Required (R)	Workgroup	• Deduplication
Vaccination Encounter Date	100%	RXA-3	Required (R)	BR 105	• Component of minimum/mandatory dataset – see details in Appendix D-4
Vaccine Administered Product Type (CVX or NDC Code)	100%	RXA-5	Required (R)	BR 105	• Component of minimum/mandatory dataset – see details in Appendix D-4
Dosage (Administered Amount)	90%	RXA-6	Required (R)	Workgroup	• Accuracy cross-checks • Clinical practice review • VFC requirement
Administered/ Historical Indicator	100% for administered doses *See note below	RXA-9	Required (R) *See note below	BR 105	• Component of minimum/mandatory dataset – see details in Appendix D-4
Administering Provider Name	90% for administered doses *See note below	RXA-10	If dose is administered, then field is Required but can be empty (RE); otherwise it is Optional (O)	Workgroup	• May be VFC requirement in some states
Lot Numbers	100% for administered doses and if managing vaccine accountability and inventory in IIS *See note below	RXA-15	If dose is administered, then field is Required (R); otherwise it is Optional (O)	BR 105	• Component of minimum/mandatory dataset – see details in Appendix D-4 • Tracking doses back to patient when lot recall occurs so patients can be notified and revaccinated if required • Managing inventory • Cross-checking accuracy of vaccine type • VFC Requirement

Field/Element	Recommended Completeness Level[18]	Location in HL7 Messaging	Designation Usage in HL7	Source of Rule (other than HL7)	Rationale for Requiring High Completeness Level
Vaccine Lot Expiration Date	90% for administered doses. *See note below	RXA-16	If dose is administered, then field is Required but can be empty (RE); otherwise it is Optional (O)	BR-118 cross-check	• Useful for data quality checks within a practice, accuracy cross-checks, and clinical practice review • VFC requirement
Manufacturer	95-100% for administered doses and if managing vaccine accountability/ inventory in IIS. *See note below	RXA-17	If dose is administered, then field is Required (R); otherwise it is Optional (O)	BR 116 cross-check IIS may be able to validate accuracy of data by cross checking manufacturer against vaccine type (CVX) or lot number	• Tracking doses back to patient when lot recall occurs • If using IIS for vaccine accountability with the VFC program • Managing inventory • Cross-checking accuracy of vaccine type
Route	90%	RXR-1	Required (R) if RXR segment is sent	BR 119 cross-check	• Accuracy cross-checks • Clinical practice review
Body Site	90%	RXR-2	Required but can be empty (RE)	BR 119 cross-check	• Accuracy cross-checks • Clinical practice review **Note:** This field does not have a standard code value for Oral or Nasal Vaccines so this should be factored in when examining completeness for this field
VFC Eligibility (if practice is participating in the VFC program) Note: The HL7 guide refers to this data element as the Vaccine Funding Program Eligibility	90%	OBX -3 LOINC Code 64994-7	If OBX segment is present and if dose is administered, then field is Required but can be empty (RE)	BR 122 A patient's eligibility for a public program (e.g., VFC program, state program) should be consistent with the administered vaccine dose's designation for a stock type (e.g., public, private).	• Enables immunization program to determine amount of vaccine supply needed to immunize the under 19 years-old population • This a state-specific business rule — some states allow this; some do not • This BR is more about program's policy, and less about data quality • State-supplied vaccine (such as VFC vaccine) should be given to eligible children; this is specific to the vaccine

Field/Element	Recommended Completeness Level[18]	Location in HL7 Messaging	Designation Usage in HL7	Source of Rule (other than HL7)	Rationale for Requiring High Completeness Level
Vaccine Funding Source	90%	OBX-3 LOINC Code 30963-3	Optional	Workgroup	• If vaccine for the immunization comes from the VFC program, it is a VFC requirement to document the funding source • Can be used when reviewing inventory borrowing logs
VIS-related: • VIS vaccine type • VIS publication date • VIS presentation date (date VIS form provided to patient)	90%	OBX-3 LOINC Codes VIS vaccine type: 30956-7 VIS publication date: 29768-9 Presentation date: 29769-7	If this is an administered vaccine, then VIS information is required (R). See CDC HL7 implementation guide for more details[19]	Federal law requires the provision of the Vaccine Information Statement for most childhood vaccines	Federal requirement to record VIS publication date and date document provided to patient/parent. If not recorded in the IIS, must be present in some form of permanent medical record maintained by the provider

* Note: The administered/historical indicator (RXA-9) is required except when the dose is refused or not administered. If the vaccine was refused or not administered, it is optional.

[19] See HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5, 10/2014, pp 96-97.

Methodology

Aggregate data review

Early in the data validation process, an IIS may choose to run some basic metric queries on counts of vaccines administered by age, and by time period such as week, month, or year. A count and percentage of invalid doses will also be helpful. Such broad reports can give an early indication of egregious problems that can be corrected before getting into the more time-intensive data quality processes. For example, low numbers of expected vaccine types could be an indication of coding issues in the EHR or consistent data entry selection errors. It is worth noting an initial data validation step that an IIS can choose to perform even before the HL7 technical message review occurs. In this very early step, the provider organization submits a large extract file in the format preferred by the IIS - at this point it could be in flat file or HL7 format. A review of the data can help uncover and resolve basic and widespread data quality issues before proceeding to the subsequent onboarding validation. See **Appendix F-5** for more information.

Aggregate data review via reports, queries and other analysis functionality provides an efficient way to examine large volumes of data for potential errors. Aggregated data analysis can identify error trends and patterns and assist in the correction of systemic problems.

Some IIS have automated reports that can be run at the provider organization or site level by IIS staff. These reports can aid in the discovery of data anomalies or errors and can reduce the burden on IIS staff resources. Reports that break down vaccines administered by age and dose allow the reviewer to identify patterns of error related to vaccine type and age appropriateness. This could include a summary of vaccinations given outside of the recommended schedule, such as those given too soon, too young, or too old, missing and over- or under-represented vaccine types, vaccine types that have an incorrect manufacturer, and vaccine types that are "unspecified." It is important that reports passed on to the provider organizations include examples of data issues at the patient level so the clinic can investigate.

The clinic may find they need to change their workflow, data entry protocols, clinical practices, or ask the EHR vendor to make changes. If feasible, making these reports accessible for provider organizations to run themselves can help with clinical staff investment in the process.

Examples from IIS of processes for aggregate reports:

In Missouri, after a provider organization has successfully sent data to test for a period of time (without errors identified in the HL7 review process), IIS staff run a series of Statistical Analysis System (SAS) programs to cross-check the data and produce reports. These programs check that all standard codes are valid and calculate completeness rates of specific demographic and immunization data elements. The programs also cross-check CVX vaccine codes with manufacturers, vaccine codes with ACIP minimum and maximum ages, and appropriate route/body site for the vaccine type.[20]

In Minnesota, the validation process involves creating two extract files (one client and one immunization) and importing the data into an Access database quality assessment tool. A series of queries are run based on the imported data: count of shots, review of CVX codes, quality checks related to ACIP inconsistencies, and others. Additionally, a random sample of patients is created for auditing against the medical record (see next section).[21]

In Massachusetts, a quality metric tool is used early in the testing process. This tool is an SQL based query that can be run on the database to measure overall validity of the data: counts of vaccine types

[20] Missouri Immunization Interoperability Interface via HL7. Internal process document provided via email on 4/18/16 by Damon Ferlazzo, Immunization Information Systems Coordinator, Bureau of Immunizations, Missouri Department of Health and Senior Services.
[21] Email from Monica Hemming, MIIC Data Quality Analyst, Minnesota Department of Health, 4/20/16.

administered by age, counts of vaccines administered by year, and the count of invalid/valid doses with certain thresholds. In addition, a data quality overview report has been developed which provides a summary of the incoming data. The counts and percentages provide information on potential red flags in the overall data.[22] An example of the overview report is included in **Appendix F-1**.

Appendix F contains a sample of data quality reports used by different IIS.

Individual Patient Record Review

Some IIS choose to compare IIS data to the originating medical record in order to complete the data validation process. If time and resources are available, this can be an excellent data quality strategy. Most commonly, patients are selected for individual review based on identified errors or suspicious data. In addition, some IIS do a random selection of patients, with the number and age cohort varying by IIS, but usually in the 20-40 range. **Although quite time-consuming, manual review of patient records can be valuable in revealing problems that are not obvious in an aggregate review.** Working with a provider organization's clinical staff will help identify the source of problems, whether data entry error, incorrect mapping, or actual clinical practice. In addition, clinical staff may identify other data problems not visible by a review of the HL7 messages or aggregate reports. Engaging clinic staff in the review process will also help train them for ongoing data quality monitoring as they will ultimately 'own' that responsibility.

The number of records reviewed and the process for doing so depends on the IIS' available resources. One method involves requesting the clinic staff to print out copies of specific patient records from their EHR, and submit them to immunization program staff for comparison. Another method, less resource-intensive on the IIS, has the IIS provide the clinic with the list of patient records, and ask the clinic staff to do the review between the two systems. In doing the comparison record review, the IIS program may choose to review all data elements available, or in the interest of time and efficiency, choose to select a subset of the elements deemed most important to the IIS.

The following list provides an example of data elements to review when comparing medical records to IIS data:[23]

- Client ID
- Patient's first and last name
- Patient's gender
- Patient's date of birth
- Patient's address and phone number
- Patient's parent/guardian name (if the patient is a minor)
- Vaccination administration dates
- Vaccine names
- CVX codes
- Vaccine lot numbers (if administered by site)
- Expiration Dates
- Vaccine dosage mL (if administered by site)
- Manufacturer's code or Trade name (if administered by site)
- Administered route and site (if administered by site)
- Name of administering clinic/hospital
- Vaccine Eligibility (for state supplied vaccine programs such as VFC)
- Vaccine Funding Source
- Vaccine Information Statement (VIS) Edition Date and Date it was Given

[22] Email from Kimberly Lay, Data Quality Coordinator, Massachusetts Immunization Information System (MIIS), Massachusetts Department of Public Health, 4/15/16.
[23] CIIS Immunization Interface Process, Colorado Department of Public Health and Environment, December 1, 2015. Provided by Vanessa Willis, Colorado IIS Immunization Branch.

Use of Provider Organization Profiles

Each provider organization practice, depending on the age and type of population served, is expected to administer a certain range of vaccine types in specific proportions. The IIS can maintain typical profiles for different types of practices – such as pediatric, adult, OB-GYN – and assign a profile type to each practice. The provider organization profile then can be compared to incoming data files for discrepancies. When the two do not match, problems likely exist, including miscoding issues, missing vaccine codes, and systematic data entry errors (e.g., entering a pneumococcal polysaccharide instead of a conjugate vaccine). This comparison will also detect unusual but accurate patterns of administration due to temporary vaccine shortages, a shift in the provider organization population or unusual clinical practice.[24] Profiles can be developed in different ways. **The 2008 MIROW guide provides the following suggestions, with more details available in Appendix D-2:**

1. **Statistically develop provider organization profiles by averaging data in the IIS from all provider organizations of the same type, and compare a specific provider organization's vaccine distribution to that of the average distribution for that type of provider organization. Large deviations from the average profile may indicate problems, particularly errors or omissions in vaccine codes.[25]**
2. **Develop distributions based on the "ideal" vaccination pattern, i.e., if the population in question receives all recommended immunizations, and compare each provider organization's pattern to that "ideal" distribution.**
3. **Establish a provider organization-specific vaccine distribution profile. In this approach, each provider organization would have its own distribution, which would be developed with IIS staff. It would involve working with each provider organization to understand and quantify their clinical practice and establish a provider organization-specific profile. Every data file would be compared to that distribution to ensure that no deviations are observed.**

A provider organization-specific profile as described in #3 can be developed for VFC provider organizations, especially in a universal distribution state. In this case, the IIS (or the immunization program) has access to the provider organization's ordering and usage information which can form the basis for the profile. This will be easiest to accomplish for provider organizations that have a history of using the IIS to manage their vaccines. It may be a process that is more suited to the ongoing monitoring of data quality rather than the initial data validation process described here.

Roles

Defining the role of each entity/stakeholder should occur in the Discovery or Planning stage of the onboarding process. Representatives of the EHR vendor, the provider organization, and the IIS should all participate. On the provider organization side, it is crucial to have the participation of clinical staff to address workflow issues and handle data quality reviews. Since provider organizations may have different system configurations at each site, it is important to treat each site's data separately and usually to have representatives from each site participating in the data review. In some situations, there may be separate staff available for each function. In others, one person may be responsible for most or even all of the onboarding and data validation processes.

Within the IIS program, specific designation of roles and job titles vary from state to state, from program to program. Organizational structures vary and relationships among the Immunization Program, the IIS, and, in some cases, a separate information technology (IT) department, will inform how roles are broken out. In addition, the IIS vendor may take responsibility for some or all of the onboarding process.

[24] 2008 MIROW Guide, pp 59-60.
[25] For more details on this approach, see 2008 MIROW Guide, p. 98-99, "Appendix F. A possible statistical approach to an automated methodology for utilization of providers' profiles for analysis of reported data quality."

Here is a breakdown of the most common job categories/titles along with their major tasks:

IIS Roles:

- Project manager/data exchange coordinator — oversight and coordination of each interface
- Technical team member, interface coordinator — connectivity and configuration of each interface, testing HL7 messages[26]
- Data exchange analyst/data quality analyst - data validation assessment and follow-up with provider organization — could be a shared responsibility between technical team and program team[27]
- Immunization Program — input on VFC requirements as needed

Provider Organization Roles:

- Clinical information or health information analyst — (mostly found in larger provider organizations) — development of interface on the EHR side
- Clinical staff — data quality review, verification that patient and vaccination information is complete and accurate, educating all clinic staff in the proper use of the EHR and its role in data quality
- Clinical champion — (could be clinical staff or MU-dedicated staff member) - responsible for keeping the process moving forward on the provider organization side

EHR Roles:

- Project manager/implementation manager — liaison with EHR technical team. Assurance that all coding and development within the EHR database and application are correct for the interface (These EHR roles may be filled by the provider organization — see first bullet above under Provider Organization Roles)

HELPFUL HINTS
for Successful Implementation of Data Validation Processes:

- Start incrementally if new to an onboarding data validation process, first establishing a base level of data validation, then adding to it as capacity allows.
- Adhere as closely as possible to national specifications for incoming messages (VXUs) as well as outgoing messages (ACKs).
- Have at least one team member who is fluent in HL7 messaging.
- Provide a local specification guide distilled to local variations as a companion to the national HL7 implementation guide.
- Have a clear policy statement on data quality requirements, and provide a data quality best practices guide to EHR vendors and provider organizations.
- Meet a national or vendor-accepted standard for transport.
- Document internal data validation processes.
- Automate data quality reports in the pre-production environment to save IIS staff time.
- Provide reports to provider organizations throughout the testing process.
- Engage clinic staff to help with review of data and patient records.
- Make data quality reports available to provider organizations to run through a user interface as feasible, with priority on availability in the production system and availability in pre-production as possible.
- Understand how your programmatic requirements may impact how you handle eventual production data.
- Take into account differences among EHR capabilities and what can be realistically required — striking a balance of not requiring so much that nobody can do it, but also getting what is really needed for program operations.

[26] Also see IIS Interface Analyst Sample Role Description, Public Health Informatics Institute, March 2016. http://www.immregistries.org/resources/iis-workforce
[27] Also see IIS Data Quality Analyst Sample Role Description, Public Health Informatics Institute, March 2016. http://www.immregistries.org/resources/iis-workforce

Other Issues

Manual triggers to submit data: In the discovery and planning phases, IIS staff should clarify how HL7 messaging is triggered. It may come to light that the EHR system requires manual action to send an HL7 message to the IIS. Most systems now have automated processes, but some do not and require human intervention to trigger the "send." During the testing and validation phases, IIS staff should confirm the mode of message initiation. Where a manual trigger is needed, the IIS should require that the provider organizations have a written policy and staff training protocols addressing this subject. IIS staff should pay close attention to frequency of data submission in the first few weeks after going live.

Automatic triggers that submit administered vaccine erroneously: In some systems, an automatic trigger sends a vaccination event that is planned, but the actual administration does not occur due to deferral or refusal. If the submission date and vaccination date are the same, this may not be easily identified by the IIS. It is important to identify this possible scenario in the discovery phase of onboarding.

Adding additional sites: Multi-site organizations may want to add new facilities to an existing approved interface. In many cases, it is advisable to require each site or facility to go through a data validation process before approving the move to the production system. The new site should complete the same testing protocols as other sites within the organization, submitting enough data to have a meaningful data quality assessment. Staff at the new facility may also need training specific to the IIS. In cases of very large provider organizations that manage their own EHR systems internally, that have staff dedicated to oversight and training of personnel, it may be unnecessary to require a separate validation process for each site.

Working with a third party entity such as a Health Information Exchange (HIE) or an EHR hub presents its own challenges and processes relevant to data validation. Some third parties function as a simple pass-through from provider organization to IIS and back, without touching the data. Others transform the data through a program or script that assures it matches submission requirements for the IIS. The important thing is to have good and clear communication so that all parties, including provider organizations, know who is responsible for each function. It is especially vital to clarify and document who is responsible for the data quality checks and for follow-up with provider organizations.

Preparations to Go Live

It may be helpful to use a Go Live checklist as you near the final stages of onboarding. The checklist can include final steps to get ready for moving to Production as well as a plan for the organization to follow after going live.

See Appendix C-3 for example of a Go Live checklist.

Final preparations prior to the interface going live should include training of the provider organization staff. Training can include general IIS training if needed, as well as specialized training related to HL7 messaging, error reports, and ongoing data validation. Final instructions on connecting to the IIS production environment should be provided to the provider organization and/or EHR representative. A go live date and time should be selected when provider organization and IIS staff are available to monitor and trouble-shoot any issues that arise. Final changes to the configuration are made to allow provider organization data to pass to the IIS production system.

Short Term Data Quality Review after Go Live

The IIS program should establish a protocol for close review of data for a period of time (often 30-60 days) after go live. The IIS can monitor by looking at a sampling of messages periodically and by using data quality metric tools and reports. Provider organizations can monitor by assigning staff to review IIS response messages (ACKs) that indicate errors and rejections. They should also log into the IIS regularly to compare data between the IIS and EHR. IIS data quality reports that can be run by provider organization staff are especially helpful. A list of provider organization expectations should include:

- Consistently reviewing the warning/error report and promptly fixing any issues
- Resending any failed messages after correcting the problem with the message (in response to ACK notifications)
- Keeping the EHR application up-to-date and notifying IIS of any upgrades or system changes (which can occasionally create unexpected problems)
- Ensuring CVX, NDC, and MVX code tables and VIS publication dates are current with CDC-provided updates
- Ensuring the interface continues to run at all times (especially after a power outage, or after installing or upgrading servers and software

An example of a "report card" approach is included in *Appendix F-2*. Use of a report card or other data quality reports during this time period identifies: transmission, mapping and/or coding issues that were overlooked during onboarding, and use of vaccine that is unexpected or inappropriate. This approach is most successful for improving data quality when there is provider organization office staff buy-in.

See Appendix F-2 for an example of a report card.

This guide has focused on one aspect of onboarding – the data validation process. Validating data during the period of onboarding offers an opportunity to scrutinize the data at a level impractical during ongoing data processing. Issues that are otherwise difficult to identify can be isolated and addressed during this testing period. This will help ensure a high quality of data, once approved and allowed into the IIS production environment. Cleaning erroneous data from the production system is difficult and resource intensive; it is preferable to not allow these data to be accepted in the first place.

The guide has included practical recommendations for the implementation of data quality protocols. Recommendations range from the importance of using real patient data in the validation process, to accuracy assessments through data cross-checks, and to completeness assessments at the field level. Business rules and data elements have been prioritized to assist IIS programs in the selection of data quality metrics and criteria. Examples of approaches taken by various IIS around the country are included, and sample data quality reports can be found in **Appendix F**.

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

Appendix A–1: Abbreviations

ACRONYMS	
ACIP	Advisory Committee on Immunization Practices
AIRA	American Immunization Registry Association
BR	Business Rule
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
CPT code	Current Procedural Terminology code
EMR/EHR	Electronic Medical Record/Electronic Health Record)
DOB	Date of Birth
EDE	Electronic Data Exchange
EHR	Electronic Health Record
HIE	Health Information Exchange
HL7	Health Level Seven International
IIS	Immunization Information System
IIS-AO	IIS-Authorized Organization
LOINC	Logical Observation Identifiers Names and Codes
MIROW	Modeling of Immunization Registry Operations Work Group (AIRA section)
NCIRD	National Center for Immunizations and Respiratory Diseases
NDC	National Drug Code
SME	Subject Matter Expert
UI	User Interface
VFC	Vaccines for Children
VIS	Vaccine Information Statement

Appendix A–2: Definitions of Terms

CPT – A numerical string that describes the procedure (a billable service) of administering a vaccine. Current Procedural Terminology codes are developed by the American Medical Association to bill for medical or psychiatric procedures performed by health care practitioners. See http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt

CVX – A numerical code that describes a Vaccine Type. CVX codes are assigned by CDC to support electronic messaging of immunization histories via HL7. See http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx. Vaccine Type maps to a CVX code. There is normally one CVX code per one Vaccine Type.

EHR System – Electronic health records system utilized by the provider organization. There is no commonly understood distinction between the concepts of an electronic health record and an electronic medical record, and no such distinction has been made uniformly in the literature. For the purposes of this project, the term "EHR system" or simply "EHR" will be used to refer to both EHR and EMR systems.

HL7 Specification – Health Level Seven (HL7) is a nationally recognized standard for electronic data exchange between systems housing health care data. See description in Appendix A–3 for more details.

IIS-Authorized Organization – An organization that has an agreement with the IIS which allows submittal and/or retrieval of the IIS data.

LOINC – Provides a universal standard for identifying laboratory observations within an OBX segment in an HL7-based data exchange.

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 is the organization that manufactures a specific vaccine. vaccines. MVX is the code used in an HL7 message that identifies the manufacturer.

Meaningful Use – Meaningful use is using certified electronic health record (EHR) technology to: Improve quality, safety, efficiency, and reduce health disparities, engage patients and family, improve care coordination, and population and public health, 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.

OBX – In HL7 the OBX is used to transmit a single observation or observation fragment.

Onboarding – Process of bringing a new data exchange source from first contact to going live with the exchange.

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.

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 Product Type – A category of the vaccine product that is ordered, shipped, administered, etc. Vaccine Product Type, for inventory tracking/ management purposes, is characterized by the NDC code. Vaccine Product Type, for immunization tracking purposes, is characterized by the Vaccine Type (or CVX code, or CPT code), Manufacturer (MVX code), and Trade Name.

Vaccine Type – The Vaccine Type is defined as a category of Vaccine. A single Vaccine Type may be associated with many Vaccine Product Types (i.e., different manufacturers, different packaging).

Appendix A–3: Health Level 7 (HL7) Description

Health Level Seven (HL7)[28] is a nationally recognized standard for electronic data exchange between systems housing health care data. In a collaborative effort between the Centers for Disease Control & Prevention (CDC) and AIRA, an HL7 implementation guide (based on HL7 Version 2.5.1) has been developed, maintained, and updated to facilitate the exchange of immunization records between different systems. According to the HL7 Version 2.5.1 Implementation Guide, "the HL7 standard is a key factor that supports this two–way exchange of information because it defines a syntax or grammar for formulating the messages that carry this information. It further describes a standard vocabulary that is used in these messages. It does not depend on specific software, that is, it is platform independent."[29] In a collaborative effort between the Centers for Disease Control & Prevention (CDC) and AIRA, an HL7 implementation guide has been developed, maintained, and updated to facilitate the exchange of immunization records between different systems.

The scope of the HL7 guide includes:[30]

- Sending and receiving immunization histories events for individuals
- Requesting immunization histories for individuals
- Requesting an evaluated history and forecast for individuals
- Responding to requests for complete immunization histories by returning immunization histories
- Responding to requests for evaluated history and forecast
- Acknowledging receipt of immunization histories and requests for immunization histories
- Reporting errors in the messaging process
- Sending observations about an immunization event (this may include patient eligibility for a funding program, reactions, forecasts, and evaluations)

[28] See *www.HL7.org* for more information about Health Level Seven.
[29] HL7 Version 2.5.1 Implementation Guide for: Immunization Messaging, Release 1.5. 11/5/14. Published by CDC, 10/1/2014, p. 2.
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Appendix C-1: Sample of Onboarding Readiness Checklist for Provider Organizations[31]

- ☐ Provider Organization is active in the IIS and has recently submitted all documents required to begin work on an HL7 interface.
- ☐ Technical support is available to the Provider Organization and includes in-depth knowledge of translating and correcting HL7 message errors. This support could be from internal staff, the EHR vendor, or a third party.
- ☐ EHR vendor has a history of supporting the Provider Organization when technical assistance is needed regarding their product.
- ☐ EHR system has been in use at the Provider Organization for at least x months.
- ☐ EHR system is able to send and receive electronic data using HL7 version 2.5.1 messages.
- ☐ EHR system is capable of sending valid codes in accordance with the CDC Implementation Guide and local state requirements.
- ☐ EHR system is capable of capturing and sending IIS expected data fields. Expected data fields include all data elements listed in the local state requirements.
- ☐ Provider Organization is committed to an ongoing quality data exchange and will provide staff time and other resources necessary for efforts to develop, test, implement, and maintain an interface for interoperability with the IIS.
- ☐ Provider Organization understands that data needs may change, and request to adapt content and processes in the future may be made by the IIS Team as data requirements change.

[31] Adapted from WyIR Provider Onboarding Readiness Checklist, Wyoming Immunization Registry, December 2015. Retrieved on June 25, 2016 from: *https://health.wyo.gov/publichealth/immunization/wyir-wyoming-immunization-registry/*

Appendix C-2: Sample Onboarding Process Document

This document describes in detail the various stages involved when developing an interface with the IIS.[32]

NOTE: The steps outlined below must be completed for each individual site regardless of the status of another site within the same Provider Organization. For large organizations, there may be a point person for the organization as a whole, and it is important to involve Site-specific personnel at the appropriate time.

1. DISCOVERY/PREPARATION – Initial information about the Provider Organization and its Sites is gathered to assess readiness in moving forward with the interface project.

1.1. The Provider Organization and/or Site complete the IIS Provider Organization Onboarding Readiness Checklist, sent by the IIS Team. Based on the results, the Site will:

- Determine it is ready to move forward with the project, and notify IIS team to continue to Step 1.2.
- Determine it is not yet ready to move forward with the project. The Site, in conjunction with the IIS Team and the EHR Vendor as necessary, will discuss barriers and develop a readiness action plan.

1.2. The IIS Team will:

- Contact the Site to discuss moving the project forward to the Planning stage, which includes discussing the IIS Provider Organization Onboarding Readiness Checklist, planning a kick-off call and EHR demonstration.
- Provide the Site with a copy of the IIS HL7 Implementation Guide and other relevant documents such as data validation and data quality requirements and criteria.
- Verify that the Provider Organization and/or Site have an up-to-date IIS Provider Organization Enrollment Agreement in place.

2. PLANNING – Information is gathered to understand the interface's individual configuration needs and any modifications required in the EHR, in the Site's business practice, or in the Site's staff workflow or training. Steps 2.1 and 2.2 may be combined if it is more convenient for all parties involved. The EHR Vendor is typically not involved at this stage, but may be included at the request of the Site.

2.1. A kick-off call is held between the IIS Team, the Provider Organization/Site Contact, technology or project management staff from the Provider Organization and/or Site, and appropriate relevant clinical staff that oversee or use the EHR for vaccination data entry. During the call:

- The group discusses the project timeline, including ongoing meetings, roles, communications, milestones, and file frequency.
- The Site Contact completes the IIS HL7 Site Profile, used by the IIS Team to track details such as the Site's interface configuration, training needs, or issues/opportunities identified during the kick-off call. Site staff should begin filling out the profile prior to the kick-off call, which will assist Site staff in understanding the type of information discussed on the call and will help ensure the correct Site staff members are present for the call.
- The IIS Team provides IIS-related education to the Site staff present.
- The IIS Team reviews the IIS Data Reporting Guidelines.

2.2. At least one Site staff member familiar with the day-to-day use of the EHR (multiple if different EHR modules are handled by different staff), demonstrates to the IIS Team how it is utilized on a daily basis (using a remote web-based meeting tool). In order to clarify any ambiguities

[32] This sample document is adapted from two sources: Wyoming Department of Health, WYIR Interface Project States, 11/2015; and Arkansas Department of Health, Immunization Registry, Process Overview for Electronic Data Exchange to the Registry, Arkansas WebIZ. Retrieved from: http://www.health.wyo.gov/familyhealth/immunization/WyIROnboarding.html http://www.healthy.arkansas.gov/programsServices/MeaningfulUse/Documents/Process-OverviewDataImmunizations.pdf

documented in the IIS HL7 Site Profile, the IIS Team may request to see the following:

- Both demographic and vaccination data entry workflows, and any alternative workflow methods, including the following:
  - How a patient is added or updated
  - How a next of kin and next of kin's relationship to the patient is added or updated
  - How an administered vaccine is documented
  - How a historical vaccine is documented
  - How a contraindication is documented
  - How a vaccine refusal is documented
- A comparison between the functionality present in the Site's EHR and the IIS for the following functionalities:
  - Forecasting recommended vaccinations for patients
  - Contacting patients that are due recommended vaccinations
  - Managing vaccine inventory

2.3. The Site and IIS Team ensure that all remaining questions or concerns documented in the IIS HL7 Site Profile are researched and documented.

3. DEVELOPMENT/INITIAL TESTING – Initial interface configuration is completed on both the IIS side and the Site side based on information gathered during the Planning stage, and is modified as needed until the Go Live stage. Exact steps during the Development stage may vary depending on what was found during previous stages. HL7 messages are tested for adherence and compliance with HL7 Implementation Guide.

3.1. The IIS Team provides the Site ID to the Site Contact, which is needed to ensure the proper mapping of the messages in the IIS.

3.2. EHR vendor successfully installs interface in Site's local environment(s) (may not be applicable for all EHR vendors). The Site modifies the interface, business processes, and/or staff training.

3.3. The EHR Vendor offers support as changes are made. The scope of changes involving the EHR Vendor can affect the project timeline. (For example: if the Site's current EHR version is not able to collect data as documented in the implementation guide, the Site might need to upgrade to a version that does collect the required data elements.)

3.4. All parties ensure that all known interface deficits, concerns, and issues are resolved.

3.5. Connectivity testing ensures the interface's ability to securely send HL7 messages to the IIS.

- The Site staff or the EHR Vendor should inform the IIS Team if the EHR can create but cannot securely send HL7 messages so the IIS Team can provide tools to assist.

3.6. Messages are tested for adherence to HL7 standards.

- EHR vendor or provider organization generates HL7 test message from provider organization's local environment and sends to IIS for formatting review. This step can be done with fake data and will only test the structural validity of the HL7 message and ensure the required elements are present. The provider organization/EHR will need to repeat this step until deemed successful by the IIS team.

4. DATA VALIDATION – Real patient data is submitted from the Site's Production EHR to the IIS Test environment and reviewed by the IIS Team to ensure quality standards are being met.

4.1. Data validation testing reviews messages for completeness and accuracy, and may reveal previously unknown interface, EHR, workflow, data entry, or other issues needing additional attention. The data quality assurance testing process will appear as follows:

- The Site generates HL7 messages using real patient data and sends to the IIS over the established interface connection.
- IIS staff analyzes the information sent across the interface connection and provides the Site and/or EHR vendor with results.

4.2. The IIS Team reviews the accumulated messages and provides feedback to the Site regarding data quality. The IIS Team will ensure that

the interface meets all IIS requirements in accordance with the IIS HL7 V251 Specification Guide. The Site may share the feedback with their EHR Vendor at their discretion.

- Feedback to the Site will be in the form of aggregate reports and/or patient record-specific reports. The IIS Team may hold a call with the Site contact to discuss how to interpret the report and to discuss projected steps the Site must take to correct errors identified and to improve data quality.
- In some cases, the IIS team will ask the Site to pull specific requested hard-copy patient records and submit to IIS for comparison and data validation.
- In some cases, the IIS team will ask Site to compare specific records in the IIS to the EHR to determine source of issues. Provider organization works with IIS staff to resolve issues.
- The IIS may require records be submitted over a certain period of time or that a certain number of records be submitted.
- The IIS may also require that submissions reach a certain threshold for completeness and accuracy before the Site is allowed to go live.
- This process may need to be repeated for several cycles until quality data is achieved.

5. GO LIVE – Final preparations are completed prior to the interface going live and submitting real-time data to the IIS Production system.

5.1. The IIS Team provides IIS-related training to the Site staff. This training includes:

- Any general IIS training required to meet the needs of the Site.
- Specialized training related to HL7 messaging, the interface, etc., including but not limited to Correct Lot Decrementing training.

5.2. The IIS Team will ensure that the Site Contact has all contact information needed to address any issues or concerns as they arise post-go live.

5.3. If the Site is using the IIS to manage their vaccine inventory, the Site's inventory in the IIS will be reconciled by the Site staff.

- This includes all Sites receiving state supplied vaccines, but can also include those using only private vaccine stock if the Site uses the IIS to manage their private vaccine inventory.

5.4. Any deficiencies in the interface and any resulting required interventions or additional responsibilities of the Site are discussed and agreed upon by the IIS Team and the Site.

- This includes special arrangements based upon unique functions or limitations of the Site's EHR. For example: if a vaccine is deleted from the Site's EHR and the interface cannot send an HL7 message that designates the vaccine as such, the Site would be required to manually delete the corresponding information from the IIS to ensure quality patient care.
- These agreements vary greatly depending on the Site's EHR and other factors.

5.6. Settings and configurations are checked and any changes needed are completed.

5.7. The process is monitored closely by all parties for a period of time determined by the IIS (usually 2-8 weeks).

- IIS staff verify the receipt of enhanced data files submitted to the IIS on go live date.
- Provider organization sends ongoing data files to the IIS.
- Provider organization and/or EHR technical contact monitor and promptly correct any and all errors represented in the HL7 management logs.

Note on working with EHR vendors: In some cases, the IIS may have already worked with specific EHR vendors whose products are used by provider organizations in the IIS' jurisdiction. Initial testing with the EHR vendors can help in making sure their products can meet the HL7 formatting requirement. If so, testing still should occur at each provider organization with real patient data sent from the provider's own local EHR environment.

Appendix C-3: Sample Go Live Checklist[33]

For (Insert Clinic's Name) _____

Below are steps we need to discuss prior to going live. Please review the list and provide me with the relevant information:

1. Proposed go live date: _____
2. Please provide the name and contact info of the person for failed messages and when web service is unavailable. Establish process/ resending contingencies.
3. Please provide the name and contact info of the individual (or individuals) who will be responsible for ensuring data quality, reviewing the response files, fixing issues identified in the response files including training staff if necessary. We require both a technical contact and an onsite contact at the provider organization. The provider organization will need to put together a process for how they will monitor inventory issues. How this is done is up to the facility but it is very important that someone review the response files daily to resolve the issues. A plan must be sent for IDPH's review and approval before the provider organization can go live.

   Technical Contact (Name, email address, phone number):

   _____

   _____

   Onsite Contact (Name, email address, phone number):

   _____

   _____

Ensure that the person(s) listed have access to IIS.

Some provider organizations can get a consolidated report created by their vendor so that they can easily view the data in the response files instead of reviewing every response file for each job via the user interface.

4. What is the time frame in which error messages from the IIS response files will be resolved?
5. Does your EMR have the ability to re-send updated messages to the IIS? If no, users must re-enter the correct information in both the EMR and in the IIS.
6. Does your EMR have the ability to send deletion messages to IRIS? If no, if a user deletes an immunization in their EMR, they need to log in to the IIS and delete the immunization there as well.
7. Is the lot number typed for each immunization given or is there a dropdown list where the lot number is selected? When lot numbers are mistyped in the EMR, IRIS will not deduct inventory.
8. Confirm provider organization will be using the same certificates in the production environment. If needed, you can submit a new CSR for your production server.
9. Establish a process to communicate or provide training for the staff if needed to correct issues with data entries.
10. Communicate go live date to staff and when they can stop manually updating patient info in IRIS.
11. HP will provide the production URL and password prior to go live.
12. Eve of go live date: Validate inventory is still accurate in IRIS.

[33] This sample document is adapted from the Iowa Go Live Checklist, Iowa Department of Public Health, Bureau of Immunization and TB. Provided by Kim Tichy, IRIS Coordinator, June 2, 2016.

Appendix D-1: Selected Data Checks table from MIROW Data Quality Guide[34]

Below is a list of data checks that can be included in the precertification process. Some checks can be done at all levels of data processing (precertification, ongoing, and periodic). Others are more appropriate for precertification because they require more effort. Some checks are more appropriate as database checks because they examine the whole record of a patient, i.e., different submissions have to all merge together and the record is examined as a whole (e.g., x number of immunizations prior to 6 months of age).

DATA CHECKS	TYPE OF CHECK	BR#	WHEN
Minimum data set is present	Within record check	BR105, BR106	Pre-, and ongoing
DOB <= encounter date	Within record check	BR101	Pre-, and ongoing
All vax except HepB should be > DOB+28 days	Within record check	BR114	Pre-, and ongoing
Vax name consistent with CPT or CVX code	Within record check	BR116	Pre-, and ongoing
Historical indicator/vax type contradiction (e.g.,NOS with "administered" indicator)	Within record check	BR121	Precertification
Vax type consistent with route and site	Within record check	BR119	Precertification
Encounter date < lot expiration date	Within record check	BR118	Pre-, and ongoing
Encounter date within license date of product	Within record check	BR120	Pre-, and ongoing
MMR < 361 days	Within record check/ ACIP	BR130	Pre- and periodic
Varicella < 361 days	Within record check/ ACIP	BR130	Pre- and periodic
PCV < 6 weeks	Within record check/ ACIP	BR130	Pre- and periodic
Hib < 6 weeks	Within record check/ ACIP	BR130	Pre- and periodic
Td to child <7 years of age	Within record check/ ACIP	BR130	Pre- and periodic
DT, DTaP to child >7 years of age	Within record check/ ACIP	BR130	Pre- and periodic
Hib-containing vax to child >5 years of age	Within record check/ ACIP	BR130	Pre- and periodic
PCV to child >5 years of age	Within record check/ ACIP	BR130	Pre- and periodic
PPV23 to child <2 years of age	Within record check/ ACIP		Pre- and periodic
All vaccines are the same	File level checks		Pre-, and ongoing
All DOBs are the same	File level checks		Pre-, and ongoing
All vaccine dates are the same	File level checks		Pre-, and ongoing

[34] 2008 MIROW Data Quality guide, Table 6, pp 61-62.

DATA CHECKS	TYPE OF CHECK	BR#	WHEN
All names, etc. are the same	File level checks	BR124	Pre-, and ongoing
Same antigen containing vaccine given more than once on the same day to the same patient	File level checks	BR117	Pre-, and ongoing
Compare to ideal distribution for type of practice	File level checks	BR113	Pre- and periodic
More than 50 vax for child <5 years	Database / ACIP	BR128	Periodic
More than 35 vax for child < 2 years	Database / ACIP	BR128	Periodic
More than 70 vax lifetime	Database / ACIP	BR128	Periodic
More than 3 doses Hib/PCV7/DTaP at 6 months	Database / ACIP	BR129	Periodic
Minimum interval violations	Database / ACIP	BR131	Periodic
Additional ACIP type rules	Database / ACIP	BR129	Periodic

Note: The above vaccine schedule related examples are subject to change based on ACIP recommendations, and therefore need to be periodically reviewed.

Appendix D-2: Provider Organization Profile Information[35]

Note: References to Appendices E and F in content below refer to those found in the 2008 MIROW Data Quality guide.

Vaccine distribution based on provider organization profile

This is one of the most important checks that occur in precertification. Each provider organization practice, depending on the age and type of population served, is expected to administer a certain range of vaccine types, and in specific proportions. For each practice type, the IIS can maintain such a profile, and compare incoming data files for conformity to that profile.

This method can identify systemic problems such as:

- miscoding issues (crosswalk errors)
- missing vaccine codes – usually those that have been recently introduced
- systematic data entry error (e.g., entering a pneumococcal polysaccharide instead of a conjugate vaccine)

This method can also identify unusual but accurate patterns that are due to temporary shortages, a shift in the provider organization population, or unusual clinical practice. The most useful types of provider organization profiles are for pediatric practices, or clinics that see all age groups. Profiles can be developed in different ways. Here are some suggestions:

1. Statistically develop provider organization profiles by averaging data in the IIS from all provider organizations of the same type, and compare a specific provider organization's vaccine distribution to that of the average distribution for that type of provider organization. Large deviations from the average profile may indicate problems, particularly errors or omissions in vaccine codes. See detailed explanation in Appendix F.

2. Develop distributions based on the "ideal" vaccination pattern, i.e., if the population in question receives all recommended immunizations, and compare each provider organization's pattern to that "ideal" distribution. See Appendix E for examples of such distributions.

3. Establish a provider organization-specific vaccine distribution profile. In this approach, each provider organization would have its own distribution, which would be developed with IIS staff. It would involve

[35] 2008 MIROW Data Quality guide, pp 59-60.

working with each and every provider organization to understand and quantify their clinical practice and establish a provider organization-specific profile. Every data file would be compared to that distribution to ensure that no deviations are observed.

The IIS can choose one or more of these methods to establish provider organization profiles depending on resources available. Method 2 is somewhat "quick and dirty" because it establishes the profile based on the recommendation schedule, which is not necessarily what the actual practice may be. However, it is the easiest method, and for all practical purposes it will identify most systematic level errors in incoming data.

Appendix D-3: Provider Organization Profiles – BR113 from 2013 MIROW Data Quality Guide[36]

Table 3. Provider Organization Profile Business Rule

BR #	Condition	Recommended Action	Comments
BR113	If the IIS-AO (Vaccinator) is a "specific," (e.g., pediatric) practice, the currently administered vaccinations should match a pattern in similar practices Note: This could apply to many practices. A practice includes a unique combination of various groups of the population. Data items: • Vaccine Type • Date of Birth • Vaccination Encounter Date • IIS-AO Type/Sub-Type • Administered/Historical Indicator	Accept and flag for investigation (initiate research of provider organization's records)	See section "Precertification and Providers' Profiles" and Appendices E and F in 2008 MIROW Guide for specific distributions for various practices and for possible approaches to utilize provider organizations' profiles • Possible approaches may include: 1. Dialogue with IIS-AO (Vaccinator) to determine if the reported percentages reflect actual clinical activity (e.g., inventory shortage or manual coding errors) 2. Review data exchange logs for error messages (application errors, system outages) on IIS side and IIS-AO side 3. Funding and staffing restrictions should be taken under consideration. NYC experience of communicating with IIS-AO regarding their profiles should be considered • Principle(s): P01, P05, P06

[36] 2013 MIROW Data Quality guide, p 77.

Appendix D-4: Minimum/Mandatory Dataset from BR 105, 2013 MIROW Guide[37]

Table 4. MIROW BR 105 Details

BUSINESS RULE 105		
Condition	**Recommended Action**	**Comments**
The minimum/mandatory set of data items for the "administered" Vaccination Event submission must include: • IIS-AO ID (Vaccinator/Recorder) • Patient Name, First • Patient Name, Last • Patient Date of Birth • Vaccination Encounter Date • Vaccine Type • Administered/Historical Indicator = "Administered" • Lot Number **BR105R2** The minimum/mandatory set of data items for the "historical" Vaccination Event submission must include: • Patient Name, First • Patient Name, Last • Patient Date of Birth • Vaccination Encounter Date • Vaccine Type • Administered/Historical Indicator = "Historical"	When less than minimum/mandatory set is received, the whole submission should always be rejected	• For a recommended (not minimum) set of data items, refer to the list of core data elements [2.1], HL7 standard (IG Implementation Guide) [2.5], local manuals, and other materials. • See the section "Administered/Historical Indicator" in chapter 3 for a discussion (page 27). 1. Rules for accepting or rejecting "Administered" Vaccination Event Submissions with less than the expanded data set should be the same for Electronic Data Exchange and Direct User Interface submissions. Note: Typically, when a provider organization first adopts an electronic health record "administered" vaccines from the past do not have lot number data entered into them. For on-boarding purposes a distinction may need to be made between newly administered vaccines and legacy doses of administered vaccines since there are different data quality expectations. 2. When a reduced set of data items is reported for the "Administered" Vaccination Event, an error message should always be sent or displayed in the UI. Also, other methods of communicating data quality problems should be employed, i.e., monthly reports. • Vaccine Type can be expressed as a CVX code (preferably) or can be derived from NDC code. (Truncated – see original MIROW document for complete information.)

[37] AIRA Modeling of Immunization Registry Operations Work Group (eds.). *Data Quality Assurance in Immunization Information Systems: Selected Aspects*. Atlanta, GA: American Immunization Registry Association. 2013, pp. 72-74.

Appendix E - Core Data Elements

This appendix lists each of the core data elements that an IIS will be required to store and/or produce per CDC Functional Requirement 3.4 within the 2013-2017 timeframe. This is not a comprehensive list of all items that external information systems such as EHRs, vital records, practice management, or billing systems are expected to store and send; that will likely be included in a future work effort. Where appropriate, the IIS may infer or auto populate distinct values; actual architectural solutions will differ among systems.[38]

Patient ID	Patient Primary Language
Patient Name: First	Patient Telephone Number
Patient Name: Middle	Patient Telephone Type (e.g., home, cell)
Patient Name: Last	Patient E-mail address
Patient Alias Name: First	Patient Status Indicator – Provider facility level
Patient Alias Name: Middle	Patient Status Indicator – IIS level
Patient Alias Name: Last	Vaccine Product Type Administered
Patient Date of Birth	Vaccination Administration Date
Patient Gender	Vaccine Manufacture Name
Patient Multiple Birth Indicator	Vaccine Lot Number
Patient Birth Order	Vaccine Expiration Date
Responsible Person Name: First	Vaccine Dose Volume and Unit
Responsible Person Name: Middle	Vaccine Site of Administration
Responsible Person Name: Last	Vaccine Route of Administration
Responsible Person Name: Relationship to Patient	Vaccine Ordering Provider Name
Mother's Name: First	Vaccine Administrating Provider Name
Mother's Name: Middle	Vaccine Administering Provider Suffix (e.g., MD, RN, LPN)
Mother's Name: Last	Vaccine Event Information Source (administered or historical)
Mother's Name: Maiden Last	VFC/grantee program vaccine eligibility at dose level
Patient Address: Street	VIS Type and Publication Date
Patient Address: City	VIS Date given to patient
Patient Address: State	Contraindication(s)/Precaution(s)
Patient Address: Country	Contraindication(s)/Precaution(s) Observation Date(s)
Patient Address: Zip code	Exemption(s)/Parent Refusal of Vaccine
Patient Address: County of Residence	Date of Exemption/Parent Refusal of Vaccine
Race	Vaccine Reaction(s)
Ethnicity	History of vaccine preventable disease (e.g., varicella)
Birthing Facility Name	Date of History of Vaccine Preventable Disease
Patient Birth State	

[38] 2013-2017 Immunization Information System (IIS) Functional Standards Immunization Information Systems (IIS) Functional Standards, Appendix B — IIS Core Data Elements.

Appendix F-1. Reports from Massachusetts IIS[39]

Figure 2. Data Quality Input Screen (from Massachusetts IIS)

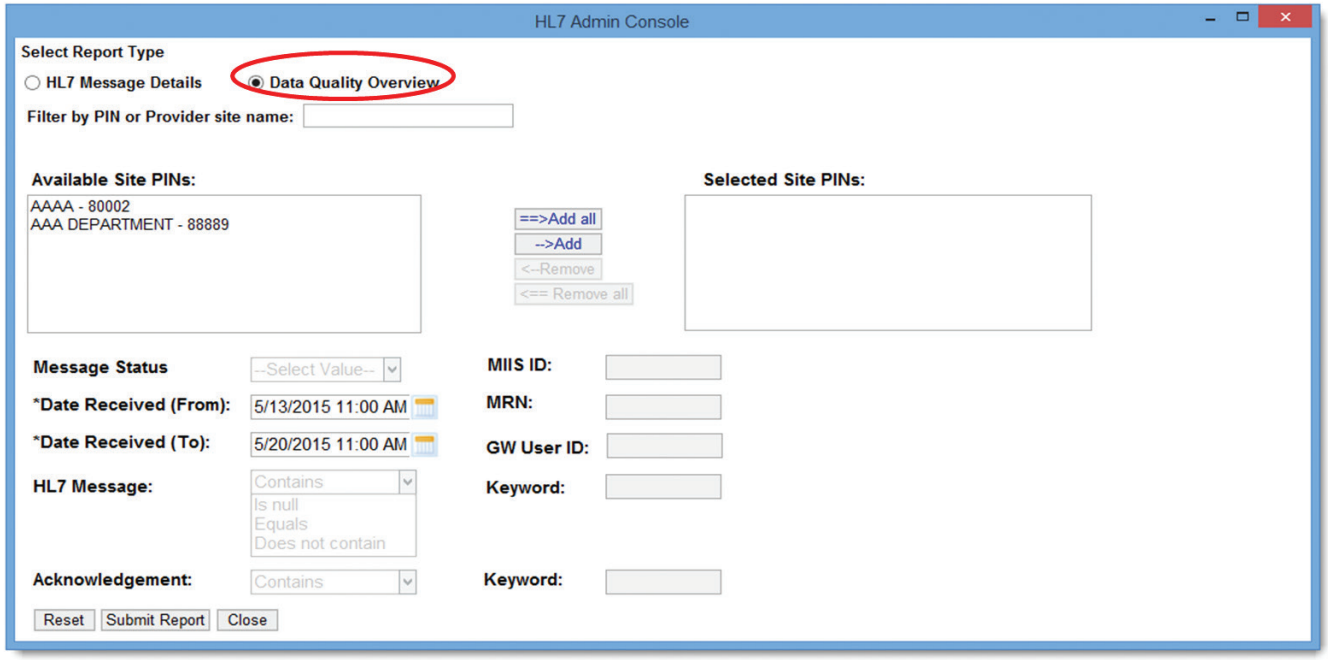


Figure 3. Data Quality Output – Overview Report (from Massachusetts IIS)

Massachusetts Immunization Information System

Data Quality Overview

Selected Site PIN: 11398
Date Received From: 04/28/2016 01:50 PM **Date Received To:** 05/05/2016 01:50 PM

Total HL7 Messages: 147

Description	Value
Number of Administered Immunizations given to patients >= 19	25
Number of Historical Immunizations given to patients >= 19	53
Number of Administered Immunizations given to patients < 19	29
Number of Historical Immunizations given to patients < 19	40
Total Immunizations	147
Percentage of Administered Immunizations given to Patients < 19 with VFC eligibility at the Shot Level	100%
Percentage of Administered Immunizations with lot number	98%
Percentage of Administered Immunizations with vaccine manufacturer	100%
Percentage of Administered Immunizations with Route of Administration	98%
Percentage of Administered Immunizations with Site of Administration	74%
Percentage of Administered Immunizations with Missing Units or Units Not Equal to ML	0%
Percentage of Administered Immunizations missing dose size	6%
Total # of Administered Immunizations for each CVX code	
DTaP,5 pertussis antigens (106)	7 (13%)
DTaP-Hib-IPV (120)	1 (1.9%)
Flu-IIV3(TIV), p-free (140)	3 (5.6%)
HepA-Adult (52)	2 (3.7%)
HepA-Peds 2 Dose (83)	5 (9.3%)
HepB Adult (43)	9 (16.7%)
Hib-OMP (49)	5 (9.3%)
Hib-PRP-T (48)	3 (5.6%)
HPV4 (62)	2 (3.7%)
HPV9 (165)	4 (7.4%)
Invalid CVX Code	2 (3.7%)
IPV (10)	5 (9.3%)
MCV4-D (Menactra) (114)	9 (16.7%)
MMR (3)	4 (7.4%)
PCV13 (133)	19 (35.2%)
PPSV23 (33)	11 (20.4%)
Rotavirus, pentavalent (116)	4 (7.4%)
Td (9)	1 (1.9%)
Td-preservative free (113)	5 (9.3%)
Tdap (115)	40 (74.1%)
Varicella (21)	4 (7.4%)
Zoster (Shingles) (121)	2 (3.7%)

This report was printed by Alice Stecko at DPH-Immunization Program from the MIIS on May 05, 2016 at 01:50 PM. Page 1 of 1

Appendix F-2. Reports from Wisconsin IIS[40]

Figure 4. Report Card – Completeness of Demographic Data (from Wisconsin IIS)

Data Completeness (Patients)

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

Clients updated during assessment period: **216**

Data Field	Count	Percentage
Patient Name: Last	216	100.00%
Patient Name: First	216	100.00%
Patient Name: Middle	135	62.50%
Mother's Maiden Last Name	109	50.46%
Mother's First Name	119	55.09%
SSN	161	74.54%
Gender	216	100.00%
Birth Date	216	100.00%
County	209	96.76%
Country of Birth	216	100.00%
Chart Number	35	16.20%
Ethnicity	198	91.67%
Race	177	81.94%
Provider-PCP	6	2.78%
Responsible Person: Primary Designated *	18	8.33%
Responsible Person: Last Name	207	95.83%
Responsible Person: First Name	206	95.37%
Responsible Person: Middle Name	98	45.37%
Responsible Person: Phone	192	88.89%
Responsible Person: E-mail	18	8.33%
Responsible Person: Address/P.O. Box	210	97.22%
Responsible Person: City	211	97.69%

* 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

[40] Petit, A. Wisconsin Immunization Registry Report Cards: IIS Data Quality Feedback to Providers.

Figure 5. Report Card – Completeness of Immunization Data (from Wisconsin IIS)

Data Completeness (Immunizations)

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

Immunizations given during assessment period: **181**

Data Field	Count	Percentage
Vaccine Product Type Administered	181	100.00%
Vaccine Administration Date	181	100.00%
Vaccine Manufacturer Name	174	96.13%
Vaccine Trade Name	174	96.13%
Vaccine Lot Number	174	96.13%
Vaccine Expiration Date *	174	96.13%
Vaccine Dosage	174	96.13%
Vaccine Site of Administration	154	85.08%
Vaccine Route of Administration	170	93.92%
Vaccine Ordering Provider Name	174	96.13%
Vaccine Administering Provider Name	170	93.92%
Vaccine Administering Provider Title/Suffix	167	92.27%
Dose Level Eligibility	174	96.13%

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

Figure 6. Report Card – Invalid, Discontinued, and Unexpected Vaccine Dose (from Wisconsin IIS)

Discontinued Vaccines

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

Vaccine	Count

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
HepB	1	1	0	0	0	2	22	9.09%

Unexpected Doses

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

Case	Count	Total	Percentage

Figure 7. Report Card – VFC Related Data Quality (from Wisconsin IIS)

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: **82**

Eligibility	Count	Percentage
Not Determined/Unknown	3	3.66%
Insured	8	9.76%
No Insurance	34	41.46%
Native American/Alaskan Native	0	0.00%
Badger Care	8	9.76%
Medicare	0	0.00%
Medical Assistance	31	37.80%
Insurance, No vaccine	3	3.66%

Figure 8. Report Card – Recommendations based on Provider Organization's Performance (from Wisconsin IIS)

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	47.62%	50.00%
Data Completeness (Patients)	Mother's Maiden Last Name	49.05%	75.00%
Data Completeness (Patients)	SSN	66.19%	90.00%

Figure 8 Note: The percentage column reflects the provider organization's performance for the specific fields. The goal column reflects the IIS goal. Report Card – Invalid, Discontinued, and Unexpected Vaccine Dose (from Wisconsin IIS).

Appendix F-3. Reports from Colorado IIS

CO CIIS Data Validation Finding Reports

A sample size of 40 patients (minimum) are randomly selected from the provider organization's test file. Patient IDs are given to the provider organization or site which then sends the chart records back to the IIS for comparison to what the IIS received.

"The data validation findings report records the discrepancies that were discovered during the data validation review. The comparison is used to calculate an accuracy rate which is based on the number of discrepancies relative to the total number of reported data on the patient records. Hospitals/Clinics must achieve at least a 95% accuracy rate before they can go live with CIIS."[41]

A summary report produces the total number of discrepancies, broken down into categories as seen in the first report below. A detailed report displays discrepancycategories, issue descriptions, specific examples, issue details, and corrective actions.

[41] Colorado Department of Public Health and Environment, CIIS Data Validation Procedure Manual.

Figure 9. CIIS Data Validation Findings Report (from Colorado IIS)

COLORADO
Disease Control & Environmental Epidemiology Division
Department of Public Health & Environment

CIIS Data Validation Findings

Site Reviewed: Test Site

Site Code

Batch ID(s)

Date of Review

Ratings Page:

Discrepancy Found	NUMBER FOUND
Incorrect CVX Code	
Missing Parent/Guardian Name	

Data Validation RATING: B (87%)

Next Steps

If Rating is:	
A (95%)	CIIS is ready to take your site live
B	Please complete the following: □ Review report and specific issues of concern □ Review this information with EHR vendor if needed □ Please resolve issues and apply corrections to EHR and Interface (consult EHR vendor if needed) □ Please provide staff training if needed □ Please complete 'Responses/Resolution' field for each example □ Return Report to CIIS □ CIIS will complete Data Quality Review to verify corrections □ Once corrections are verified site will Go Live
C	Please complete the following: □ Complete steps above □A second Data Validation Review will be performed

Figure 10. CIIS Data Validation Findings Report – Summary (from Colorado IIS)

COLORADO

CIIS Data Validation Findings

Summary Page:

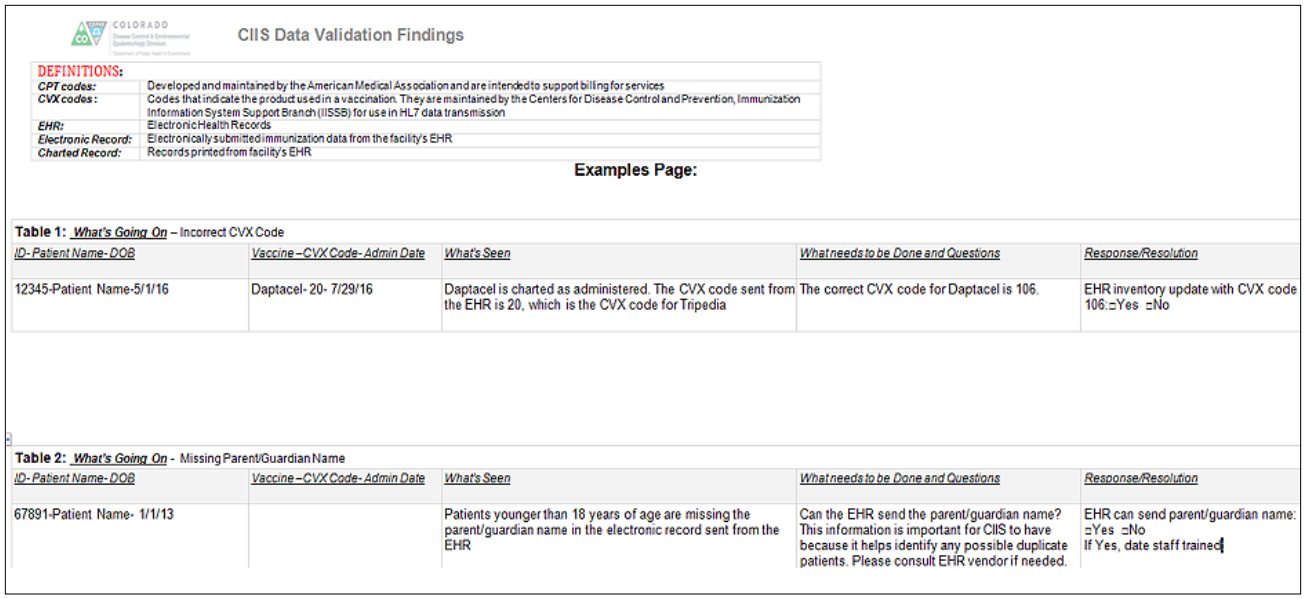
DATA REVIEWED: The following data elements were reviewed to check the accuracy and completeness of what is coming across in the interface compared to what the site entered into their EHR. Immunization records are checked for appropriate usage of vaccine based on vaccine manufacturer guidelines for licensure dates and the age of the patient at the time of the vaccination. The coding of each immunization is also checked to ensure that is makes sense from a clinical perspective

Data Elements Requested and Reviewed	Passed for Accuracy and Completeness
Patient's first and last name	✓
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	

Data Validation Review Summary

What's Going On:	What's Seen:	What Needs To Be Done:	See Table:
Incorrect CVX Code	Daptacel : CVX 20	Correct Code: 106	1
Missing parent's name	Missing in electronic record	Workflow/training	2

Figure 11. Data Validation Findings Report - Patient Specific Review (from Colorado IIS)



COLORADO

CIIS Data Validation Findings

DEFINITIONS:	
CPT codes:	Developed and maintained by the American Medical Association and are intended to support billing for services
CVX codes:	Codes that indicate the product used in a vaccination. They are maintained by the Centers for Disease Control and Prevention, Immunization Information System Support Branch (IISSB) for use in HL7 data transmission
EHR:	Electronic Health Records
Electronic Record:	Electronically submitted immunization data from the facility's EHR
Charted Record:	Records printed from facility's EHR

Examples Page:

Table 1: *What's Going On* – Incorrect CVX Code

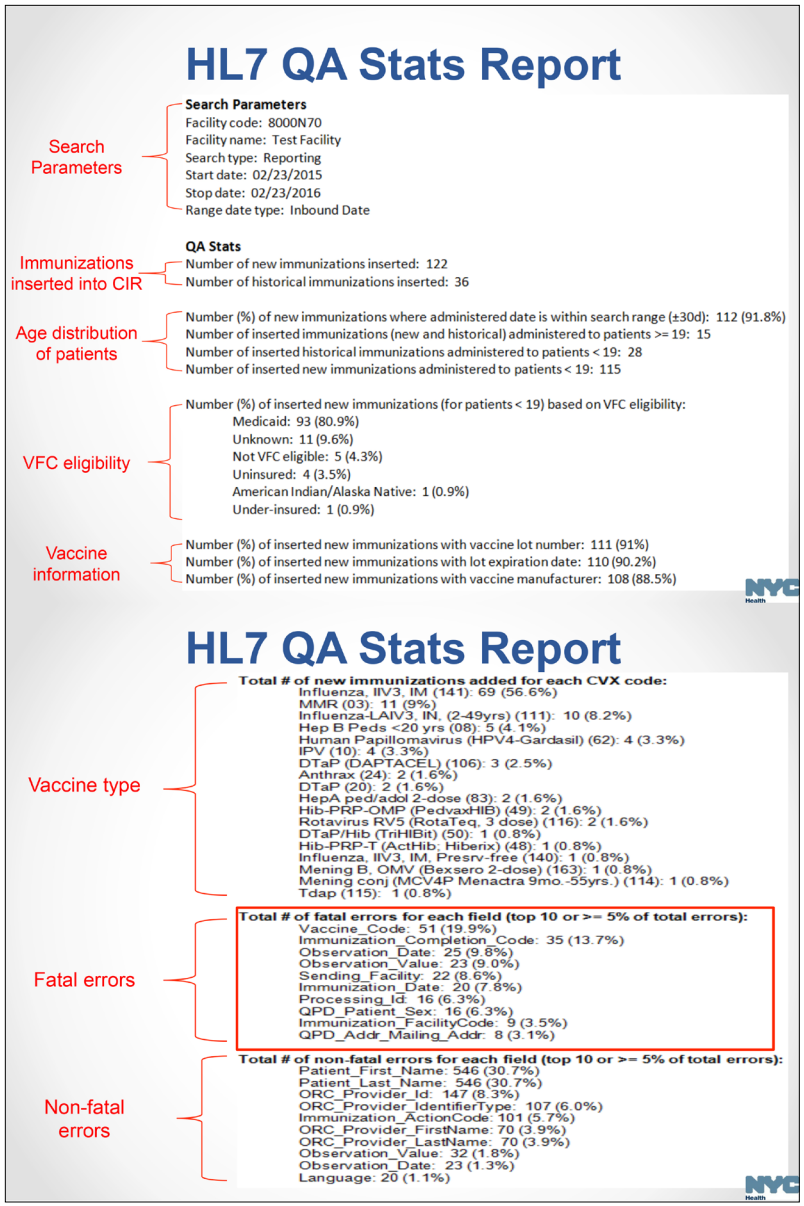
ID- Patient Name- DOB	*Vaccine – CVX Code- Admin Date*	*What's Seen*	*What needs to be Done and Questions*	*Response/Resolution*
12345-Patient Name-5/1/16	Daptacel- 20- 7/29/16	Daptacel is charted as administered. The CVX code sent from the EHR is 20, which is the CVX code for Tripedia	The correct CVX code for Daptacel is 106.	EHR inventory update with CVX code 106:□Yes □No

Table 2: *What's Going On* - Missing Parent/Guardian Name

ID- Patient Name- DOB	*Vaccine – CVX Code- Admin Date*	*What's Seen*	*What needs to be Done and Questions*	*Response/Resolution*
67891-Patient Name- 1/1/13		Patients younger than 18 years of age are missing the parent/guardian name in the electronic record sent from the EHR	Can the EHR send the parent/guardian name? This information is important for CIIS to have because it helps identify any possible duplicate patients. Please consult EHR vendor if needed.	EHR can send parent/guardian name: □Yes □No If Yes, date staff trained

Appendix F-4. Reports from NYC Citywide Immunization Registry[42]

Figure 12. HL7 QA Stats Report (from New York City IIS)



[42] DeMeo E, Perri B, et al. Onboarding Providers to the NYC IIS HL7 Web Service.

Appendix F-5. Pre-HL7 Message Review Process Description – from Missouri[43]

Data Extracts

A data quality assessment will be conducted of the provider organization's data prior to moving the organization into the message validation stage. The organization submits a CVX code table listing, and also submits 500-1000 patient and immunization records to DHSS in non-HL7 format. This patient/immunization data will consist of two separate spreadsheets (patient data, immunization data for the same patients). This data should be a real representation of what the organization will actually be sending, and the file can be submitted via secure email or dropped into the SFTP site. If the latter, we give them login credentials to the SFTP site.

Examples of what we will be looking for to correct when reviewing the sample data:

- Dates (dates of birth, immunization dates, etc.) are valid; no future dates
- No test data in a file that is supposed to have been production data; example- Joe Test, Test Address, Test State, etc.
- First and Last name in their respective fields, not just the First Name field
- City, State and Zip in their respective fields, not in one address space
- Code identification has been represented correctly, for example (1) if the patient identifier is labeled DCN, the identifier should be a DCN, not an internal organization ID or SSN, or (2) checking for the proper use of codes to represent race and ethnicity in accordance with HL7 standards
- CVX codes are valid

Once the provider fixes any issues they might have with their spreadsheet data their messages can be validated.

[43] Missouri Department of Health and Senior Services. Missouri Immunization Interoperability Interface via HL7.