Data Quality Assurance in Immunization Information Systems: Incoming Data

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

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About MIROW data quality assurance project

The Modeling of Immunization Registry Operations Workgroup (MIROW) of the American Immunization Registry Association (AIRA) was formed to develop a topic-by-topic Best Practice guidebook for various aspects of immunization information systems (IIS) functionality. The MIROW Steering Committee conducted an assessment in April 2005 within the IIS community to learn which functional components were problematic to deploy and could benefit from a collective guidance.

The ***first topic*** selected for analysis and development of best practice recommendations was the management of the "Moved or Gone Elsewhere (MOGE) Status of Patients and Other Patient Designations". Recommendations were developed during 2005, and the final guidance chapter is available at the AIRA web site at http://www.immregistries.org/docs/MIROW_MOGE_Chapter_Final_122005_rev1.doc . The best practice recommendations were presented at the 40th National Immunization Conference (March 6–9, 2006, Atlanta, GA). Slides and the recorded presentation are available at http://cdc.confex.com/cdc/nic2006/techprogram/P10124.HTM.

The ***second topic*** selected for analysis and development of best practice recommendations was the vaccination level deduplication in IIS. Recommendations were developed during 2006, and the final guidance chapter is available at the AIRA web site at http://www.immregistries.org/pdf/AIRA_BP_guide_Vaccine_DeDup_120706.pdf . The best practice recommendations were presented at the 41st National Immunization Conference (March 5–8, 2007, Kansas City, MO). Slides and the recorded presentation are available at http://cdc.confex.com/cdc/nic2007/techprogram/P12532.HTM .

The current report represents MIROW efforts to develop best practice recommendations for the ***third topic*** chosen, data quality assurance in IIS. The development process consisted of a preliminary phase (web-based teleconferences, June–August 2007), face-to-face meeting (August 21–23, 2007, Atlanta, GA), and subsequent post-meeting work on finalizing emerging recommendations.

The National Vaccine Advisory Committee has included a recommendation to "Promote the adoption of a guidebook and best practices for IIS as started by the CDC/NIP and AIRA/MIROW workgroup to adopt consistent operational guidance and quality control procedures that ensure good data quality." This guide is one example of addressing this recommendation on data quality validations.

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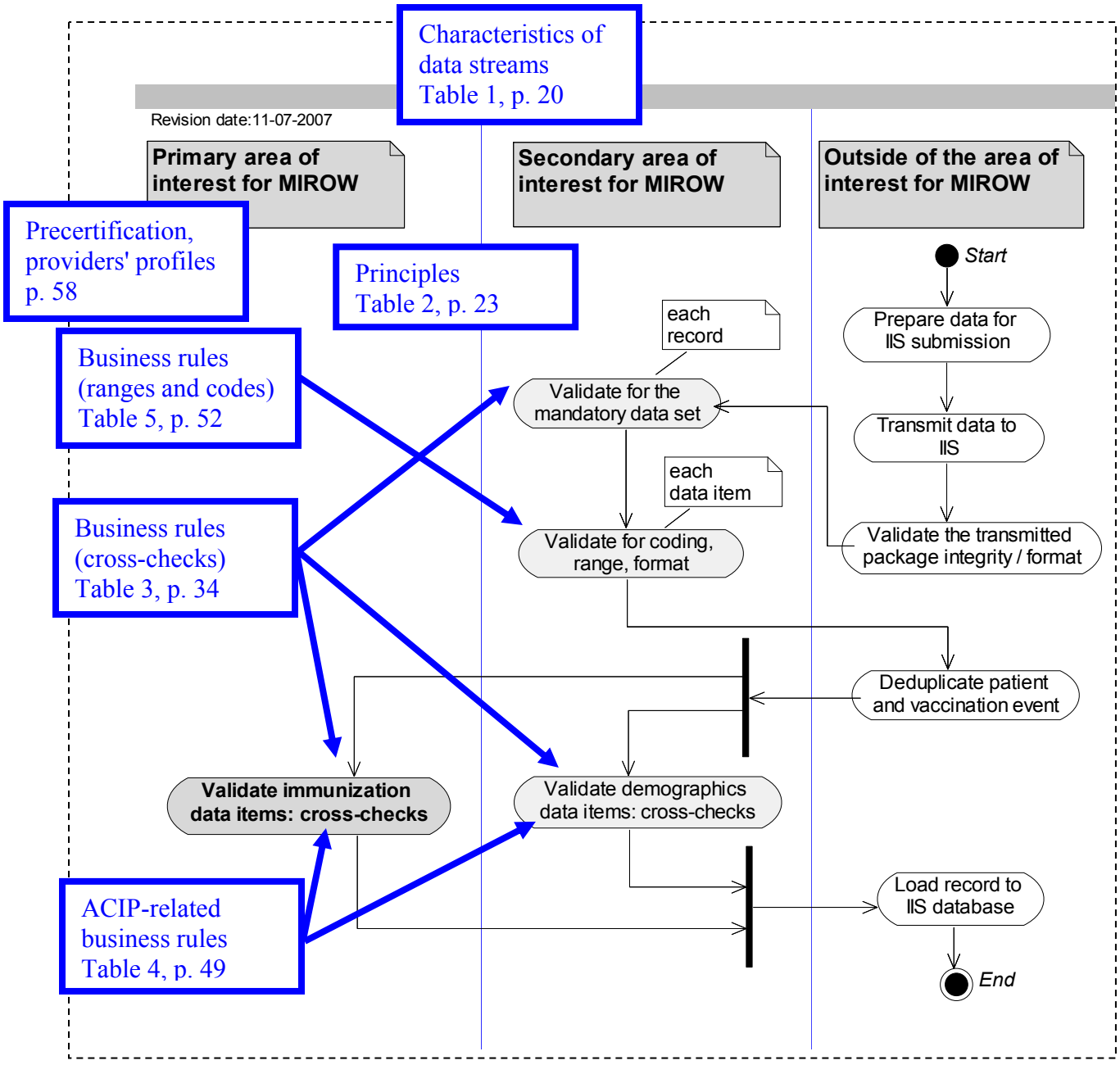


Introduction

Why data quality assurance is important?
Immunization Information Systems (IIS) were developed to improve healthcare delivery by moving immunization histories from paper medical records into electronic files. The advantages of maintaining immunization data in an electronic format are tremendous. It allows practices to print immunization histories without pulling medical charts; allows automated calculation of "immunizations due" based on the child's age, history, and the Advisory Committee on Immunization Practices (ACIP) schedule; makes immunization histories transportable if the patient seeks care elsewhere; and makes it possible for medical practices to assess immunization coverage and generate recall notices at the practice level.

However, all these benefits depend on the quality of the information in the IIS. The information in the IIS should be a true reflection of what has actually transpired in the medical practice. For the IIS to be useful to providers, providers must be able to have confidence in the data it contains.

The accuracy of immunization records is a decisive factor in improving the health of patients, the operation of healthcare clinics, and public health decision making. Immunization records lacking quality may result in increased morbidity and mortality among the population. It is the responsibility of the IIS and the submitters to ensure the reliability of data held in the IIS. Data are loaded into the IIS from variety of external sources, and at this loading point it is especially critical to establish standards for validating incoming data. This document discusses best practices for maintaining data quality by focusing on validation checks that can be applied before data get into the IIS. It reflects a belief that establishing generally accepted consistent approaches for data quality is especially important as the IIS community moves toward data sharing across systems and across states.

Accurate, complete, and timely data in IIS promote participation among healthcare providers, insurance companies, and others. Higher participation results in more complete records for patients. Following are some of the benefits of higher data quality:

- Increased provider trust
- Increased use of the data
- Improvements in clinical practices
- Improved the health of the patient
- Improved public health

Poor data quality results in a loss of confidence in the IIS and has been shown to lead to a decrease in registry use and further incomplete data. The consequences of poor data quality include the following:

- Incomplete picture of a patient's immunizations, and possible erroneous recommendations
- Incomplete and inaccurate data on patients
- Loss of provider participation
- Public policy decisions skewed by inaccurate summary data

It is critical that registries adopt a consistent approach to data quality as the IIS community moves towards increased data sharing. This guide can help the IIS look for common errors using standardized rules for validation checks. These rules can be applied in all IIS environments nationwide in an effective, consistent approach at critical points in the process, such as precertification and pre-load validation.

A proactive approach for continuous quality improvement is also fundamental. It includes the following steps:

- Inform submitters regarding data needed to properly carry out IIS functions.
- Interact with submitters to correct data that fail quality checks.
- Provide submitters with ongoing picture of quality indicators from the data.

Expected benefits

Best practices guidelines on data quality assurance will positively affect immunization registries by providing the following benefits:

- Encourage common data validation practices, thereby improving overall data quality and usefulness of registry information.
- Serve as a technology-neutral requirement guideline for information technology projects.
- Foster collaboration and aid in communication among IIS professionals.

Scope: data quality assurance in IIS

The main focus of this project is incoming data quality assurance in IIS. This includes development of validation rules and procedures for incoming IIS data feeds, such as Vital Records, provider health records, and electronic Medicaid or other billing data (**Fig. 1**). Not included in the scope of this project are data quality assurance procedures and checks for the existing data in the IIS or for data provided from an IIS to analysts. At the same time discovered contradictions between incoming and existing data that could result in changes for data in the IIS database are in the scope. Also not included are issues such as data reporting structures (e.g., HL7, Flat file, XML, X-12n).

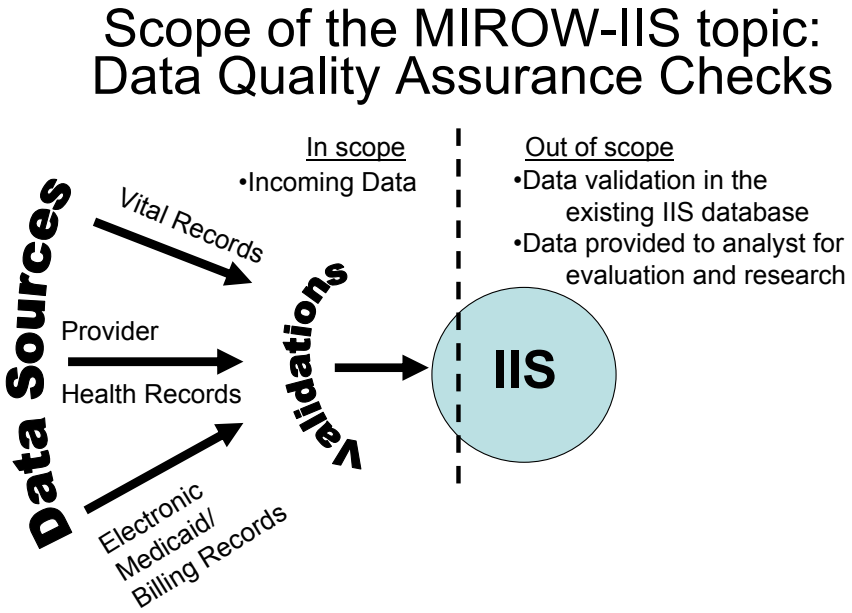


Figure 1. Illustration of the scope of the Data Quality Assurance topic

The context diagram (**Fig. 2)** illustrates types of data quality validations for incoming data to IIS: precertification, pre-load, and existing data validations. ***Precertification*** is the process of evaluating the incoming data quality of new submitters before allowing them to regularly add data to the IIS in order to ensure that the data sent are correctly formatted and complete. This can help identify systemic data errors prior to data imports. Issues related to the precertification process are addressed in the Chapter 6 "Pre-Certification and Providers' Profiles". ***Pre-load*** validation consists of inspecting the data reported by certified submitters prior to loading that data to the IIS. The core recommendations for the pre-load validations are located in the Chapter 4 "Principles" and in the Chapter 5 "Business rules" of this guide. Validation of ***existing*** data can reveal additional data quality issues after data have been loaded and allow them to be addressed.

The pre-load validation process is a main area of best practice development efforts. Validations are conducted at the file level, record level (cross-checks between data items), and data item level (range/code checks). Validation of the existing data inside the IIS database is considered to be within the scope of this project within first 30 days from the date loaded.

Data sources' profiles can help to identify systematic problems and patterns. For example, each provider 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 data source type, the IIS can maintain an idealized profile, and compare incoming data for conformity to that profile.

The further details of the scope are presented on the process overview/project scope details diagram (**Fig. 3**) in the Process Overview section of this document.

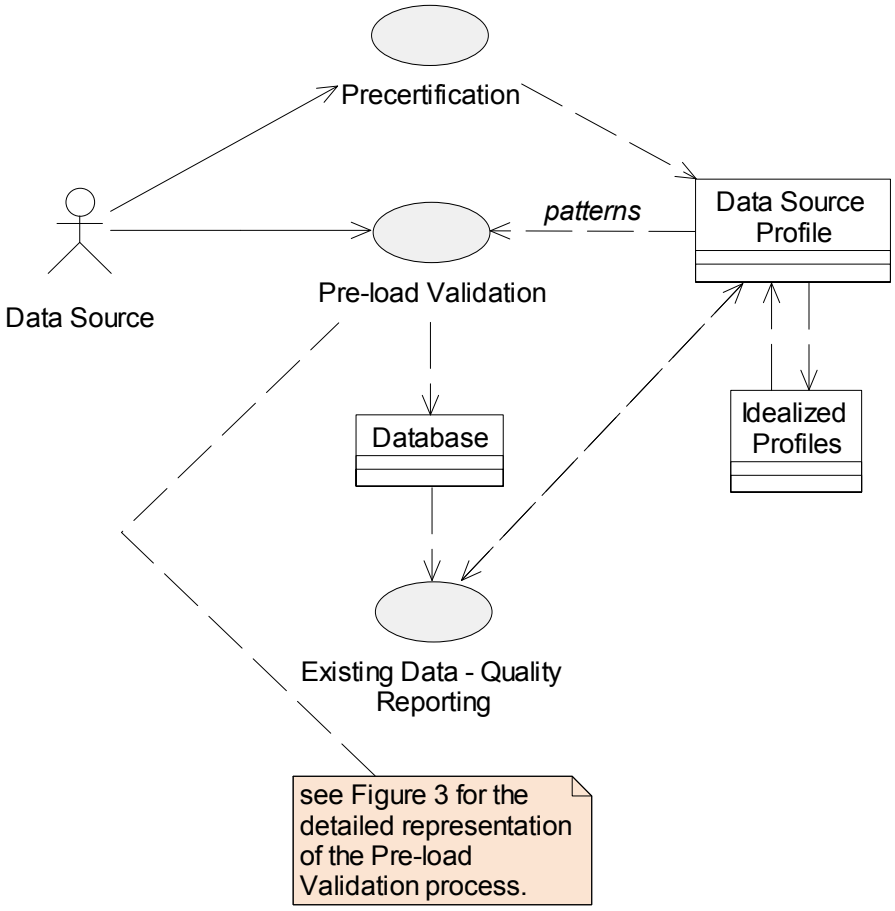


Figure 2. Types of data quality validations for incoming data

Intended audience
This guide is designed to be read by both programmatic, technical and operational personnel involved in creating or maintaining an IIS. The guide intends to bridge the gap between technical and program staff so they can have a mutual understanding of the issue of data quality assurance, and target actions to address these recommendations.

Intended use
This guide contains a set of recommended operational best practices (including a set of principles and business rules to follow) that are intended for use as a basis for requirements in incoming data quality assurance in IIS. Additionally, this guide can be used by IIS for staff training, operational documentation, and communication purposes.

Validation rules presented here were deemed those most valuable in improving data quality, but the intent is not to limit IIS data validation to this set of rules alone. The workgroup recognizes that special situations in some registries may require validation techniques beyond what are included here. As a result, registries may have additional requirements that address their individual situation. For example, in the matter of minimal set of recommended data items the workgroup realizes that there will be other variables needed due to state requirements, especially in the Vital Records feed, so the set of mandatory data items in this guide represent a minimalist approach.

The specific implementations of data validation rules could vary according to the vendors' technology, application architecture, and specifics of a particular IIS.

The utilized approach and presented results are relevant for and can be used beyond immunization information systems, e.g., for developing and documenting best practices and operational requirements for domain-specific data validation applications in public health, health care, and other areas.

Implementation independence
The IIS best practice recommendations are intended to be directed toward the business/operational level and, as a result, are independent from particular IIS implementations and technology solutions. This intention reflects the industry-wide strategic approach to capture and maintain business knowledge, requirements, and policies/constraints independently of implementation architecture and technical solutions. As a result, the best practice recommendations will be able to support the wide variety of IIS implementations strategies on different technological platforms.

The direct implications of this approach can be illustrated with the example of provider health records submissions to an IIS. Regardless of how vaccinations are reported to an IIS—electronic non-interactive transmission (batch), paper-based reporting, or interactive transmission such as direct entry via the user interface —the data go through the same set of recommended best practice validation checks. In the case of direct data entry, validation checks that are impossible to implement due to constraints of the real-time environment are implemented after the direct entry session is concluded.

In other words, ***conditions (criteria)*** for data items that IIS validates should be the same regardless of how these data items have been reported to IIS; ***actions*** resulting from evaluating these validation conditions (e.g., accept, reject, research) could differ depending on the specific method of reporting (e.g., direct user entry versus batch reporting).

Workgroup approach

This section contains a brief description of the methodology and process used by MIROW; see Appendix C for the expanded description of the workgroup approach.

The workgroup used business engineering and facilitation techniques to analyze immunization registration processes and develop recommendations. The group used a pragmatic results-oriented approach that has been effective for modeling of immunization registration and cancer registration operations. Initial ***preparatory off-line work*** (assembling pertinent materials, producing preparatory notes, analysis of processes and development of preliminary drafts) was performed by a group of business analysts and subject matter experts (SMEs). During a subsequent ***face-to-face facilitated modeling session*** in Atlanta, GA (August 21–23, 2007) a full (large) workgroup of SMEs used preparatory materials as a framing/scoping resource and began development and formulation of consensus-based recommendations. The ***post-session work*** has been aimed at finalizing the development of recommendations. The workgroup was divided into two small groups of SMEs, each addressing a set of remaining tasks during a series of teleconferences. Additional teleconferences were dedicated to reviews of the progress of small groups by the full group of SMEs.

The workgroup used the following definition of a consensus among SMEs regarding the best practice recommendations developed, which did not reflect 100% agreement, but rather meant **"*I can live with that and support it.*"**

Chapter 1: Executive Summary

The Modeling of Immunization Registry Operations Workgroup (MIROW) was formed by the American Immunization Registry Association (AIRA) in partnership with Centers for Disease Control and Prevention / National Center for Immunization and Respiratory Diseases (CDC/NCIRD) to develop a Best Practice guidebook for immunization information systems (IIS). The National Vaccine Advisory Committee has included a recommendation to "Promote the adoption of a guidebook and best practices for IIS as started by the CDC/NIP and AIRA/MIROW workgroup to adopt consistent operational guidance and quality control procedures that ensure good data quality." This guide is one example of addressing this recommendation on data quality validations.

This guide's topic—incoming data quality assurance—was selected on the basis of a survey conducted by the MIROW Steering Committee within the IIS community. The workgroup, using modern business modeling and facilitation techniques, conducted a 2-and-a-half-day meeting in Atlanta, GA (August 21–23, 2007), as well as multiple pre- and post-meeting teleconferences to analyze existing practices and to formulate consensus-based recommendations. These recommendations are presented as a part of the emerging Best Practice guidebook in a section titled “Data Quality Assurance in Immunization Information Systems: Incoming Data.”

Major ***accomplishments*** of the workgroup are listed below:

- Developed principles on which to base the incoming data quality assurance process, business rules to follow, and specific scenarios that illustrate application of principles and business rules.
- Developed and re-confirmed key definitions for data quality assurance.
- Described healthcare providers' precertification as a process of evaluating the incoming data quality of new submitters, prior to allowing them to regularly add data to IIS in order to ensure that the data sent are correctly formatted and complete, thereby helping to identify systemic data errors prior to data imports.
- Recommended that there should be a general source profile for each kind of provider (e.g., pediatric, geriatric) that the IIS should maintain to identify expected distributions of vaccinations.
- Reached consensus among subject matter experts, demonstrating that despite differences in immunization registry programs and a variety of perspectives among software vendors, common approaches through consensus can be developed and agreed upon with use of business modeling and facilitation techniques.

Best practices guidelines on data quality assurance will positively affect immunization registries by providing the following ***expected benefits***:

- Encourage common data quality assurance practices, thereby improving overall data quality and usefulness of registry information.
- Serve as a technology-neutral requirement guideline for information technology projects.
- Foster collaboration and aid in communication among IIS professionals.

The results of this project are intended to support a consistent alignment of the data quality assurance processes in immunization registries according to recommended guidelines.

Chapter 2: Process Overview

The diagram in **Fig. 3** places best practice recommendations developed by the MIROW in a context of the process of getting data from a submitter to an IIS.

Before allowing new submitters to regularly add data to an IIS they have to go through a precertification process of evaluating the incoming data quality (see Chapter 6 of this guide). Precertification provides value by ensuring that the data sent are complete and by helping to identify systemic data errors.

The process (**Fig. 3**) starts with a submitter (see **Table 1**) preparing data for a submission. Prepared data are then transferred to the IIS (a transmitted package may contain one or more Vaccination Event Submissions). At the IIS, the overall file is first checked for integrity and format. Then each record is validated for a mandatory data set and each data item is validated for a proper coding, range, and format. The identification of the patient and vaccination event (vaccination level deduplication) should then be completed before the data quality cross-checks. Validation cross-checks include: inter-item, inter-record, and inter-database checks, and checks for data patterns in particular sources. After completion of all validation checks, reported data are loaded to the IIS. On every validation step, decisions to accept, reject, conduct research (can include a chart audit at the provider's office), or perform additional actions (that can result in correction/editing of certain field value) are made.

According to the diagram in **Fig. 3**:
1) The ***primary area of interest*** for MIROW includes ***immunization-related data items*** validations related to inter-item (within a record), inter-record, and inter-database cross-checks and checks for data patterns in particular sources.
2) The ***secondary area of interest*** for MIROW includes ***demographics-related data items*** validations related to inter-item (within a record), inter-record, and inter-database cross-checks as well as validations of all data items (demographics and immunization) for coding, range, and format and validation of the reported records for the mandatory/minimal data set.
3) ***Outside of the area of interest*** for MIROW are issues related to data preparation for IIS submission, data transmission to IIS, and validation of the transmitted packages for the integrity/format.

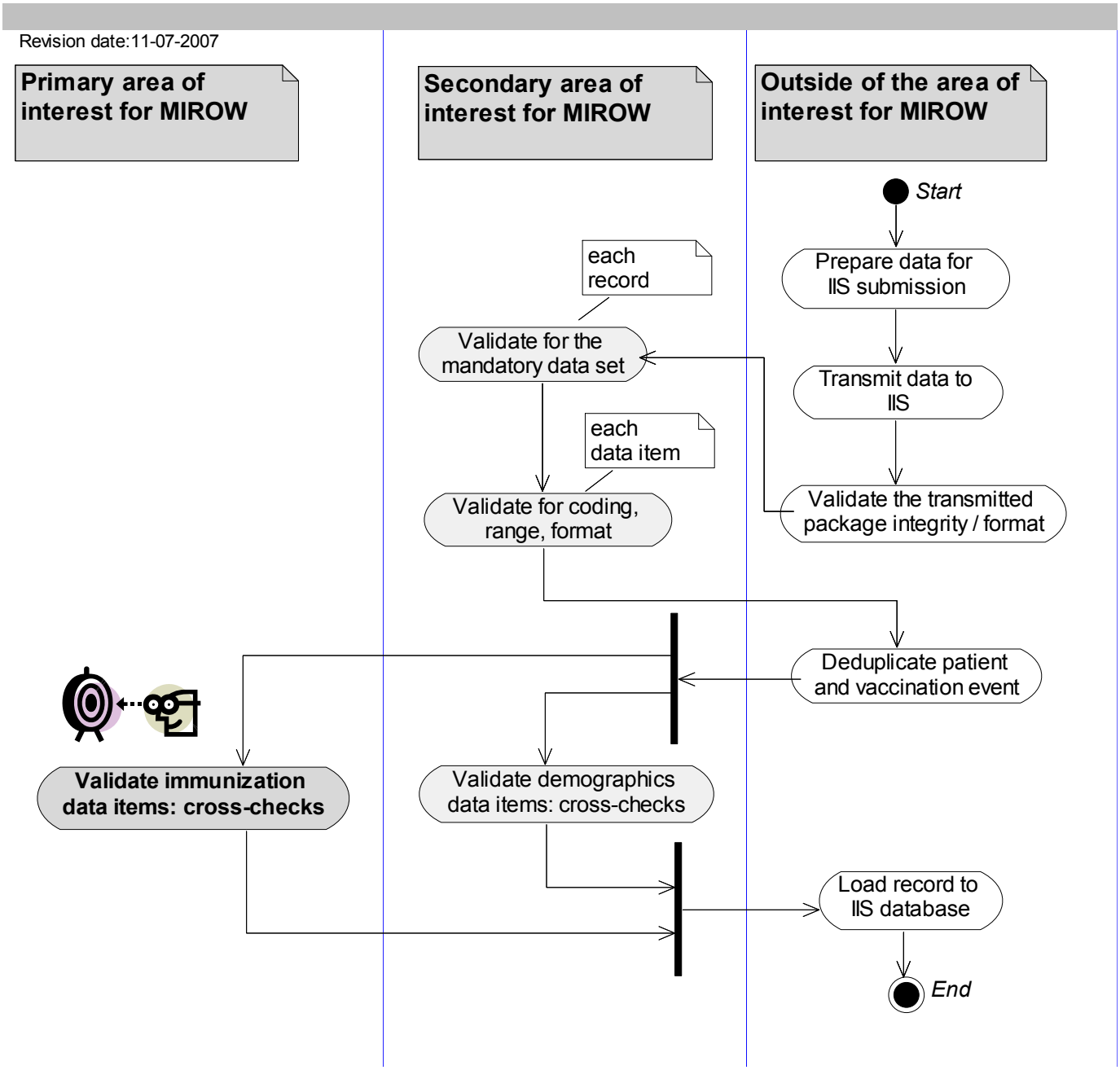


Figure 3. Process overview / Project scope details

Table 1. Comparative characteristics of validated data streams.

Characteristic	Vital Records	Provider Health Records	Electronic Medicaid/ Billing Records
Source	Office/Bureau of Vital Statistics.	Healthcare provider.	Medicaid, HMO, healthcare provider (billing).
Purpose of reporting	To provide denominator of the population of interest. Voluntary or statutory/regulatory requirement.	To provide immunization data for clinical decisions, population assessments, historical immunizations. This type of reporting adds new residents to the denominator (people that were not born in the area covered by IIS).	To provide administrative and financial information.
Data quality/ reliability and trustworthiness	Definitive source of the birth dates.	Definitive source of the immunization data. Provide updates for the demographic information (e.g., address).	Inferior/secondary source of immunization and demographic data.
Submission/report types	Births, deaths, corrections, adoptions, legal name changes. (Can also include reports on HepB given at birth).	Report on a single immunization. Immunization history for a patient. Report of client conditions related to immunization (comments or reactions).	Insurance/group plan information.
Methods of reporting/access	Batch file—electronically or on physical media (e.g., tape).	Direct entry to IIS. Batch file—electronically or on physical media (e.g., tape); includes real-time HL7 exchange.	Batch file—electronically or on physical media (e.g., tape).
Issues and barriers affecting data quality	In practice it is possible that wrong birth date comes from Vital Records, but those are rare occasions; see principle P07 below.	Duplicate records. Software may not support latest vaccines and may not include all data fields of interest (e.g., manufacturer and lot number). Users' data entry errors.	Duplicate records. Data not recorded and used for clinical decision support are not reviewed by clinicians. Billing data are designed to generate revenue, not to treat patients. Accuracy may be compromised when clinical practice is coded for reimbursement purposes only.

Chapter 3: ACIP Recommendations Considerations

There is a clear intersection between the Advisory Committee on Immunization Practices (ACIP) guidelines on vaccine administration and the data quality validation rules the MIROW was charged to create. However, data that violate ACIP recommendations can and do arrive for import into IIS, and should not be excluded on that basis alone. The ACIP guidelines prescribe clinical standards for which immunizations should be given. The data in an IIS should show what actually happened in the medical encounter, even if that conflicts with the ACIP recommendations. This guide does not intend to document all of the algorithmic decisions based on the ACIP schedule. For example, rules involving valid immunization intervals developed by ACIP were not taken into debate by MIROW. A variety of principles and business rules were defined and agreed upon to support this positioning of MIROW recommendations regarding ACIP rules (see, for example principle P10).

All the incoming data should be checked against the ACIP recommendations. Overall, use of ACIP recommendations helps to improve the integrity of the data collected through the IIS. The workgroup has developed business rules for validations checks to be consistent with ACIP recommendations. Additionally a subset of ACIP recommendations has been specifically mentioned because the workgroup believed that it will provide the most value in identifying potential data quality problems from submitting sources. Certain clinical validation checks were also examined and presented as business rules throughout the document, e.g., consistency between the route of administration and site of administration. It is important to periodically examine and review ACIP recommendations and other clinical guidance because the recommended schedules and the other clinical decision guidelines change.

All the incoming data should be checked against the ACIP recommendations. Overall, use of ACIP recommendations helps to improve the integrity of the data collected through the IIS. The workgroup has developed business rules for validations checks to be consistent with ACIP validations. Additionally a subset of ACIP recommendations have been specifically mentioned because the workgroup believed that they will provide the most value in identifying potential data quality problems from submitting sources. Certain clinical validations checks (that are not related to ACIP recommendations) were also examined and presented as business rules throughout the document, e.g., consistency between the route of administration and site of administration. It is important to periodically examine and review ACIP recommendations and other clinical guidance because the recommended schedules and the other clinical decision guidelines change.

The illustration in **Fig. 4** represents scenarios that can lead to ACIP recommendations violations. Reports inconsistent with ACIP recommendations, may indicate

- Actual clinical practices (judgments, errors, …) or
- Data quality problems (documentation error, data entry, IIS errors, …)

In many cases, it is not possible to distinguish between these two situations without further investigation. It is worth noting that even if ACIP guidelines are not violated, this does not necessarily mean that there are no data quality problems.

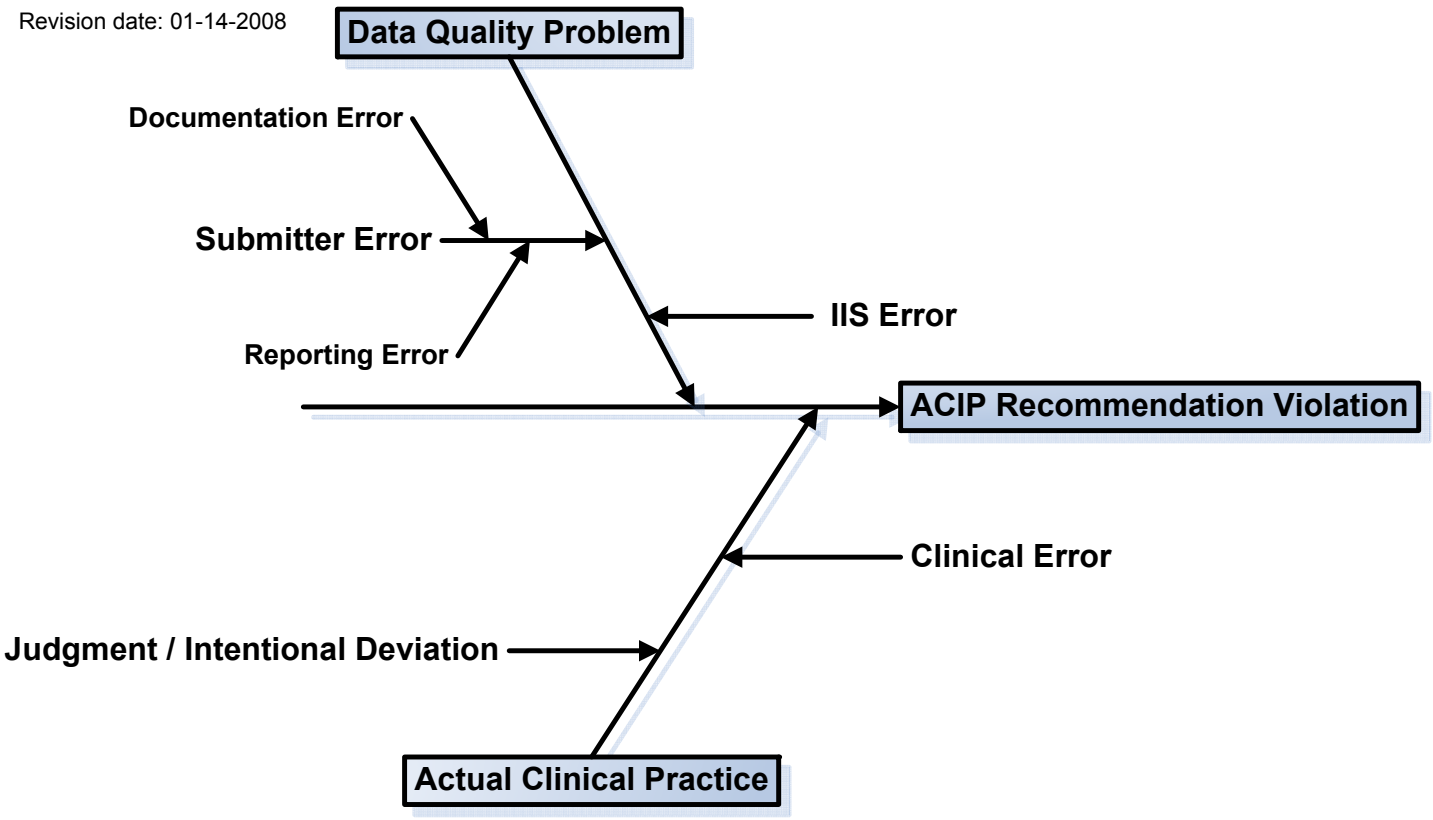


Figure 4. Types of ACIP recommendations violations: cause and effect diagram

Chapter 4: Principles

A principle reflects business guidelines, practices or norms that the workgroup recommends to follow. It is a high-level direction that guides the development of more specific business rules (see Chapter 5).

Table 2. **Principles of incoming data quality assurance in IIS**

#	Principle Statement	Comments
P01	Consistency principle: The conditions (criteria) for validating data items should be the same regardless of how these data items have been reported to an IIS.	Regardless of a data item's source and the way the data have been reported (e.g., direct user entry versus batch reporting), the data item should go through the same set of data validation checks (conditions/criteria). Note: Business Rules encompass both conditions (criteria) and actions to be taken (see Chapter 5). Related Business Rules: all.
P02	Variable outcomes principle: When conditions (criteria) of a validation check are not satisfied, the resulting actions (e.g., accept, reject, research) may vary depending on the data item's source and the way data were reported.	For example, interactive exchange/method (user interface - UI) versus non–interactive exchange/method (batch reporting): If users fails to complete a non-mandatory field, they may be asked if they intended leave the field blank, though in a non-interactive mode, the fact that the field is missing might be ignored and no action taken. Note: Business Rules encompass both conditions (criteria) and actions (see Chapter 5). Related Business Rules: BR101, BR102, BR114, BR118, BR119, BR120, BR122, BR126, BR128. ***Definition of "UI"*** (user interface) method of submission: interactive session when a Submitter conducts a direct data entry in the IIS. ***Definition of "Batch"*** method of submission: automated non-interactive transmission of data to the IIS; could include data on multiple vaccination events or on a single vaccination event.
P03	Rejected data principle: When information is rejected by the IIS, the following actions should be taken: • If batch, then log the error and notify Submitter. • If UI, then display an error message and offer the opportunity to correct.	These are both notifications with the intent of correcting the error (resubmit, edit) Example: when information is not accepted it still can be held (in some buffer zone) for a further research or rejected outright. Related Business Rules: BR101, BR102, BR103, BR104, BR105, BR106, BR110, BR112, BR116, BR125.

#	Principle Statement	Comments
		General recommendation: with a batch submission the IIS should be able to stop processing and reverse previously processed transactions within the batch. It is a good practice to process vaccination events within a batch one by one and then decide what part of the batch submission to load (load the whole batch, or reject the whole batch, or load the part of it), rather than load individual vaccination events one by one immediately as they processed.
P04	Internal consistency principle: Characteristics of the vaccination history should not contradict one another. This includes reported data as well as data already in the IIS.	This principle is a basis for all cross-check validations. This principle covers cross-validations between characteristics of multiple vaccination events that comprise immunization history, as well as cross-validations between characteristics of individual vaccination events. Vaccination history includes demographics, information on all recorded vaccination events, and client conditions (e.g., allergy). Example: vaccine type should match administration route. Also, vaccine type should be paired with the licensed vaccine manufacturer. Related Business Rules: BR101, BR102, BR103, BR110, BR114, BR115, BR116, BR118, BR119, BR120, BR122, BR126.
P05	Accuracy principle: The data recorded in the IIS should match exactly what happens in a clinical encounter, whether or not it is clinically appropriate.	When reported data contradict clinical guidelines, it might be because of data entry error or IIS processing error, not necessarily because of the actual clinical actions (see "ACIP Recommendations Considerations" above). Actions for business rules should be formulated in such a way to allow recording of the actual clinical activity. See P03 for a clarification mechanism—go back to sender and investigate. Some usual business rule actions will have to be overridden when deviation of the recommended clinical practice is confirmed. • Example: An individual goes to 2 different flu clinics on the same day • Example: Pediarix® along with polio or HepB or DTaP (i.e., one of the Pediarix components) given on

#	Principle Statement	Comments
		the same day Registries should periodically audit a random sample of incoming data to verify that it matches clinical records. Submitters should periodically audit a random sample of data to verify that it is correctly stored in IIS. Related Business Rules: BR112, BR113, BR114, BR117, BR118, BR119, BR120, BR122, BR124, BR126, BR128, BR129, BR130, BR131, BR132.
P06	Appropriate vaccination principle: The vaccinations reported by a provider should be appropriate for the population served at the clinic.	In a pediatric practice, certain types of vaccines are used in a certain proportion, e.g., a certain percentage of DTaP, polio, Hib, and MMR is to be expected. Related Business Rules: BR113.
P07	Vital Records principle: Vital Records is the definitive source for • Date of Birth • Date of Death	In practice it is possible that a wrong birth date or death date comes from vital records, but those are rare occasions. There are other sources of the birth date beyond vital records, e.g., patient from another city. Currently approximately 50%–80% of birth dates come from vital statistics. Death dates can be accepted from providers as well, but Vital records would be a definitive source of this information. Related Business Rules: (none).
P08	Validation priority principle: The importance of validating a data item is related to the data item's significance in clinical decision making, public health assessments, and research.	This principle provides priorities for the validation of a data item. ***The critical data items (have to be validated as a high priority) are:*** • ***Vaccine Type*** • ***Vaccination Encounter Date*** • ***Patient Date of Birth*** Additional data items could be important, e.g., for epidemiologic surveys, school assessments. Related Business Rules: (none). Classification of Business Rules in Chapter 5 is based on this principle.

#	Principle Statement	Comments
P09	Maintain data integrity principle: Any modification of the data in the IIS should not violate the integrity of the existing data.	Scenario: Billing data in the registry, new record from provider arrives. IIS updates data in the registry, changing, for example, Date of Birth. As a result, some dates for vaccinations that are already in the registry might come before the Date of Birth. So the change in the Date of Birth would be wrong and should not be processed. Another scenario: a modification to the vaccination encounter date should not result in a future date. Related Business Rules: (none).
P10	ACIP recommendations principle: Deviations from ACIP recommendations and US licensure may indicate data quality problems.	See Chapter 3 "ACIP Recommendations Considerations", Table 4 "ACIP Recommendations-related business rules", and Appendix D "ACIP Recommendations-related rules: implementation examples". In general, doses should be valid per all of the ACIP recommendations (intervals, ages, dose sizes, inter-group conflicts). When ACIP recommendations are violated, records should be investigated (flagged and researched). This is a way to "fish" - *meaning an examination that ... hopes to discover information for a later proceeding (Webster dictionary).* Related Business Rules: BR114, BR117, BR128, BR129, BR130, BR131, BR132.
P11	Timeliness principle: Data should be timely. Data should be reported and recorded in the IIS, as well as be available to users in a timely manner.	In order to be useful for clinical decision support and for health policymaking, immunization data should appear in the registry soon after the clinical event occurs. Business rules may include specific standards. See P05 for the accuracy principle. See [1]: the Immunization Registry Minimum Functional Standards, standard #4. Related Business Rules: BR108, BR115, BR123, BR127.
P12	Completeness principle: The information submitted to the IIS must contain the minimum/mandatory set of data items in order to be accepted by an IIS.	The minimum/mandatory set of data is necessary to support the functionality of an IIS. Additional relevant data, if available, are valuable when they improve the functionality of IIS (we do not want minimum data, we want good data). Additional data items could be important, e.g., for epidemiologic surveys and school assessments. The goal is to capture all relevant data on patients and their vaccination events.

#	Principle Statement	Comments
		Minimum data are needed to accurately identify a person and vaccine. See AIRA/MIROW deduplication recommendations: AIRA Modeling of Immunization Registry Operations Workgroup (eds). Vaccination level deduplication in Immunization Information Systems. Atlanta, GA: American Immunization Registry Association. December, 2006. http://www.immregistries.org/pdf/AIRA_BP_guide_Vaccine_DeDup_120706.pdf NVAC recommends a core data set, but IIS can accept a set of data (record) less than NVAC recommends. See P05 for the accuracy principle. Related Business Rules: BR104, BR105, BR106.
P13	Supremacy of medical records principle: Medical records are a more reliable source of immunization data than billing records.	Clinical data are better (more reliable and accurate) than billing data. Typically, CPT codes are used with billing data, and CVX or CPT codes in clinical data. IIS most likely will get lot number with clinical information. Medical records will be more likely reviewed and corrected as necessary, whereas billing data are not (unless rejected for payment). A distinction is made between billing data extracted from a clinical practice management system, and billing data from a system which is solely used for billing; clinic-based data are more accurate. Medicaid/Billing records are sometimes inaccurate, particularly the Vaccine Encounter Date, as some billing systems will incorrectly report the date billed as the date of the Vaccination Encounter. This problem may go undetected for some time since the date billed is the same or close to the Vaccine Encounter Date. Note: Some health provider systems will export data for a registry from their "billing interface," but this does not mean that their data fall into this billing records category. This business rule is for reports from systems that are primarily for billing purposes. Some health provider systems (PMS) can only export using a "billing interface" but the data represent accurate patient health records. Related Business Rules: (none).

Chapter 5: Business Rules

A Business Rules approach
Business rules represent specific requirements regarding how the business should operate based on the laws, policies, regulations, and chosen business/operational style.

The following notes reflect the MIROW approach to the development of business rules and associated best practices:

- The developed business rules and associated best practices will need to change and evolve over time as business requirements change.
- The focus was on those business rules that have the greatest potential for providing data quality value and use across all registries.
- The rules represent an attempt to balance "ideal" possible practices with "pragmatic" considerations of what will be possible to implement in the registries.
- The assumption for a business rule: If you have the data, you should use the validation check.
- Each state will "tweak" the implementation of business rules (and associated best practices) based on their needs and unique implementation concerns.
- The highest prioritized business rules should be implemented first as resources become available to the registry
- The list of rules presented here is not exhaustive. Individual IIS may choose to implement additional rules based on their unique requirements and insights.

A Business Rule as a set of conditions and actions
A business rule includes conditions (criteria) that have to be evaluated and actions initiated depending on evaluation results. In other words, ***Business Rule = Conditions (Criteria) + Actions***.

The condition (criteria) stated in the business rule is not a 'make or break' requirement for accepting data in the registry. The reader should refer to the action associated with the business rule to see the consequences of the condition not being met. Figure 5 illustrates actions taken in batch and UI settings when conditions of a business rule are violated. The major difference between these two settings is that in the UI case the IIS can prompt a submitter to correct a questionable or inappropriate entry right away. The action resulted in a business rule implementation for data quality assurance in IIS could be one of these:

1) If no problems: ***"Accept"***. Proceed with loading to the registry.

2) If some problems exist that are tolerable:
    a) For batch: ***"Accept and investigate"***. Flag for investigation/follow-up and proceed with loading to the registry.
    b) For UI - issue a warning to give submitter an opportunity to fix the problem
        b1) if submitter corrects the problem - ***"Accept".*** Proceed with loading to the registry;
        b2) if submitter does not correct the problem - ***"Accept"*** anyway. Proceed with loading to the registry.

3) If some borderline problems exist (between "accept for investigation" and "reject") that prevent loading to the registry:

a) For batch: ***"Hold and investigate".*** Flag for investigation/follow-up and proceed with the investigation.

b) For UI - issue a warning to give submitter an opportunity to fix the problem;

b1) if submitter corrects the problem - ***"Accept".*** Proceed with loading to the registry;

b2) if submitter does not correct the problem - ***"Reject" (complete or partial).*** Log the error and notify Sender.

4) If some problems that are intolerable:

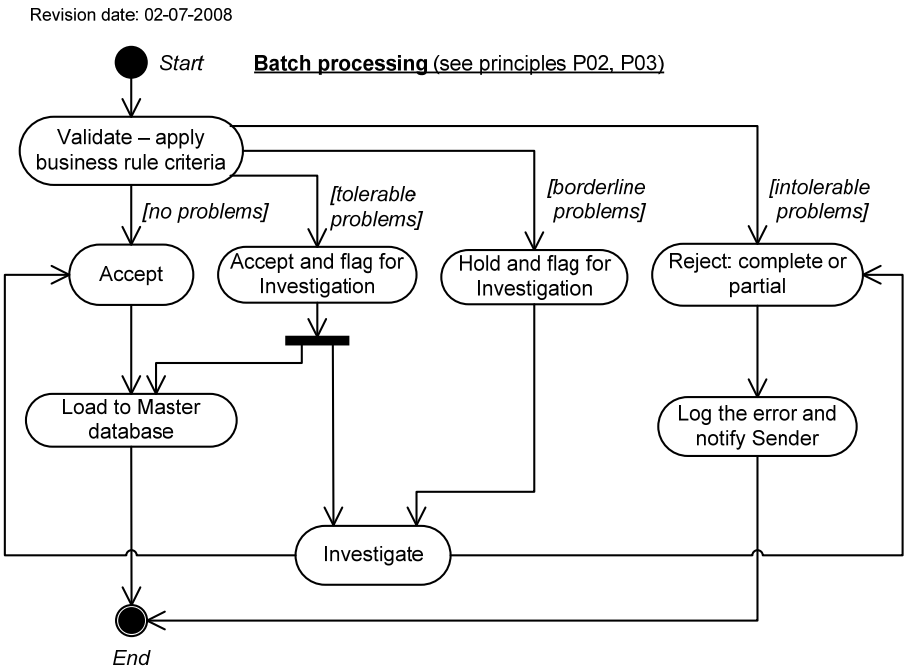
a) For batch - ***"Reject" (complete or partial).*** Log the error and notify Sender;

b) For UI - issue a warning to give submitter an opportunity to fix the problem;

b1) if submitter corrects the problem - ***"Accept".*** Proceed with loading to the registry;

b2) if submitter does not correct the problem - ***"Reject" (complete or partial).*** Log the error and notify Sender.

Decisions to reject the submitted vaccination information completely or partially require a certain degree of flexibility in the IIS processing. With a batch submission the IIS should be able to stop processing and reverse transactions within the batch that already happened. It is a good practice to process vaccination events within a batch one by one and then decide what part of the batch submission to load (load the whole batch, or reject the whole batch, or load the part of it), rather than load individual vaccination events one by one immediately as they processed.



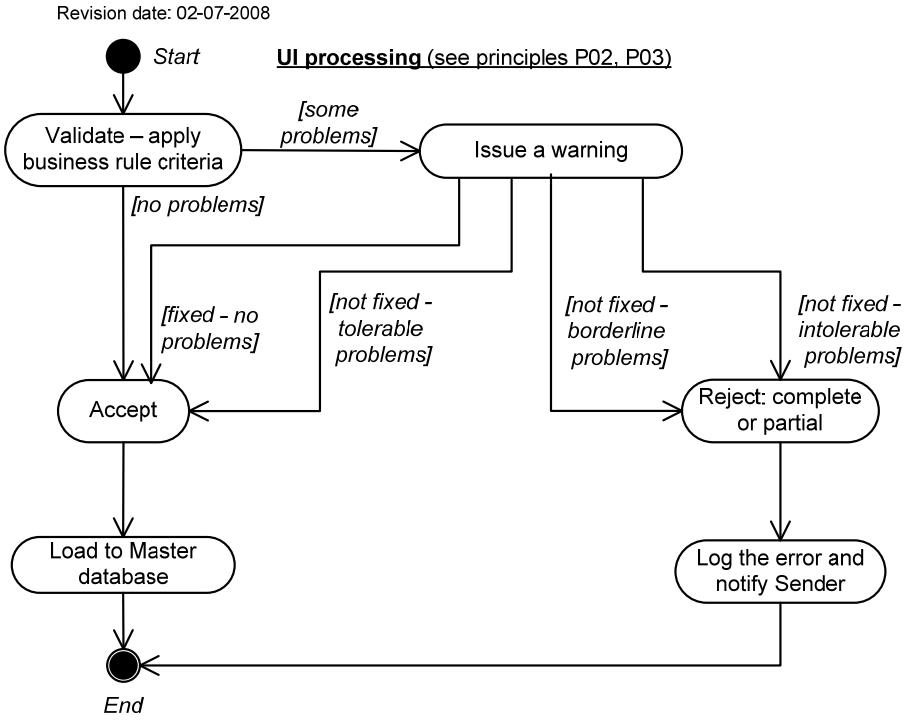


Figure 5. Actions taken in batch and UI settings

Business rules classification and presentation
Table 3 and **Table 4** below contain business rules for cross-check validations. Each business rule has been given:

- A unique ***identifier*** for reference, e.g., BR101, BR102.
- A ***priority***. The prioritization scheme was defined as follows:
    - **A =** Biggest impact, most practical and the most widespread
    - **B =** Experts were split between A and C
    - **C =** Lower impact, not as doable, impacts a small group
- A ***category***. See Figure 6 and the discussion of the business rules classification scheme below.

Figure 6 describes the classification scheme for ***categories*** of business rules. This scheme roughly follows the domain diagram. It is built around major entities/attributes that characterize the immunization registration domain (see Appendix A and principle P08): Patient (Date of Birth), Vaccination Event (Encounter Date), and Vaccine (Type). Also, Vaccination Event Submission and Provider entities from the domain model are incorporated into the classification scheme to cover additional bases. The codes shown on Figure 6 (P, VE, P-VE, etc) are used in the business rules table to indicate the areas/groupings covered by a particular business rule. For example, code P indicates that a business rule is related to the Patient (Date of Birth) entity of the domain model (single group), and P-VE code indicates that a business rule is related to both Patient (Date of Birth) and Vaccination Event (Encounter Date) entities (across groups).

This classification scheme is used in Table 3 and Table 4 below. Additionally, in Table 3, the business rules are color-coded to emphasize associations with three major data items (see principle P08): Vaccine Type (highlighted in beige), Vaccination Encounter Date, and Patient Date of Birth (highlighted in blue); the rest of the business rules in Table 3 are highlighted in green.

Figure 7 presents key data validation dates that are referenced in business rules.

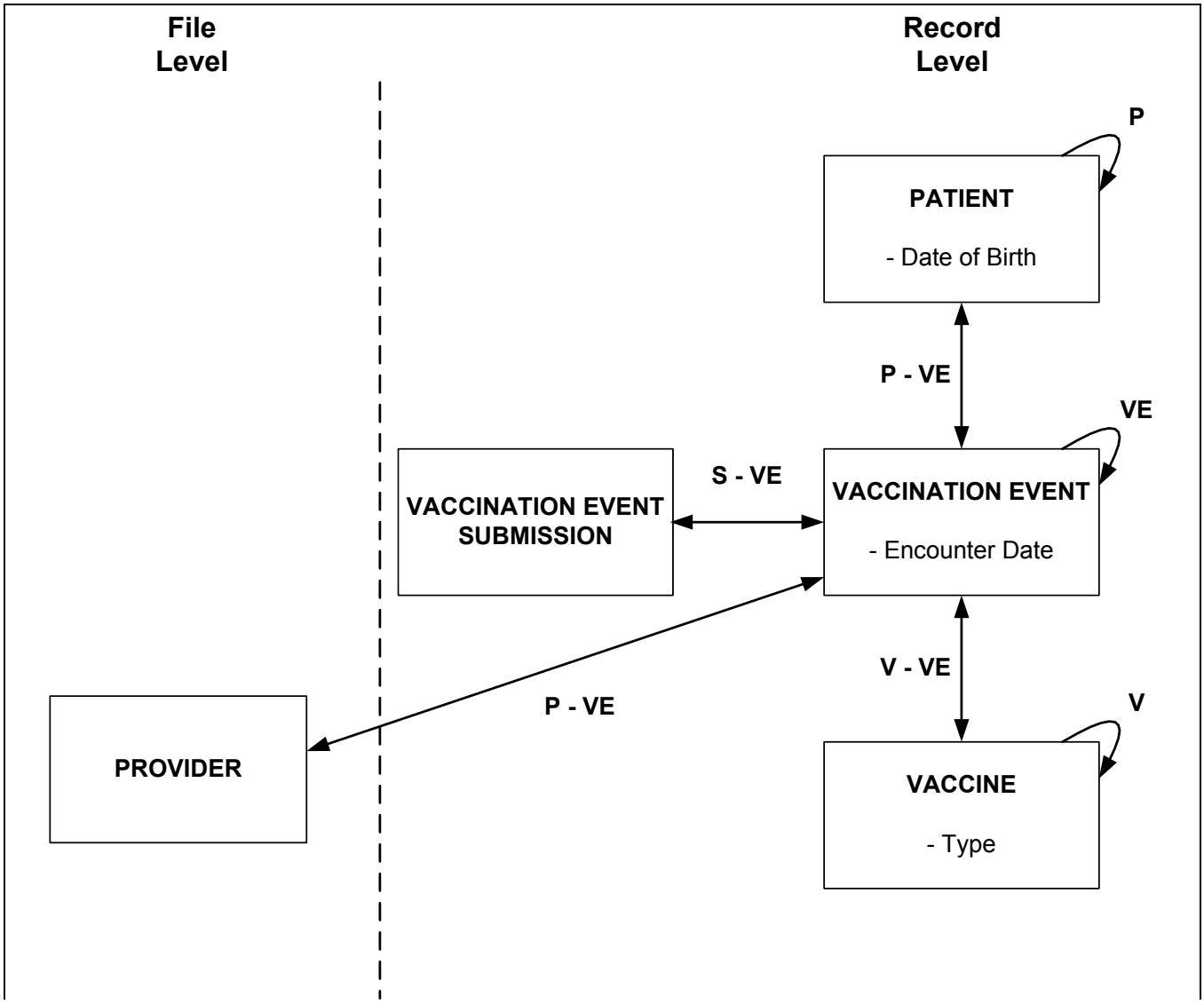


Figure 6. Classification scheme for categories of business rules

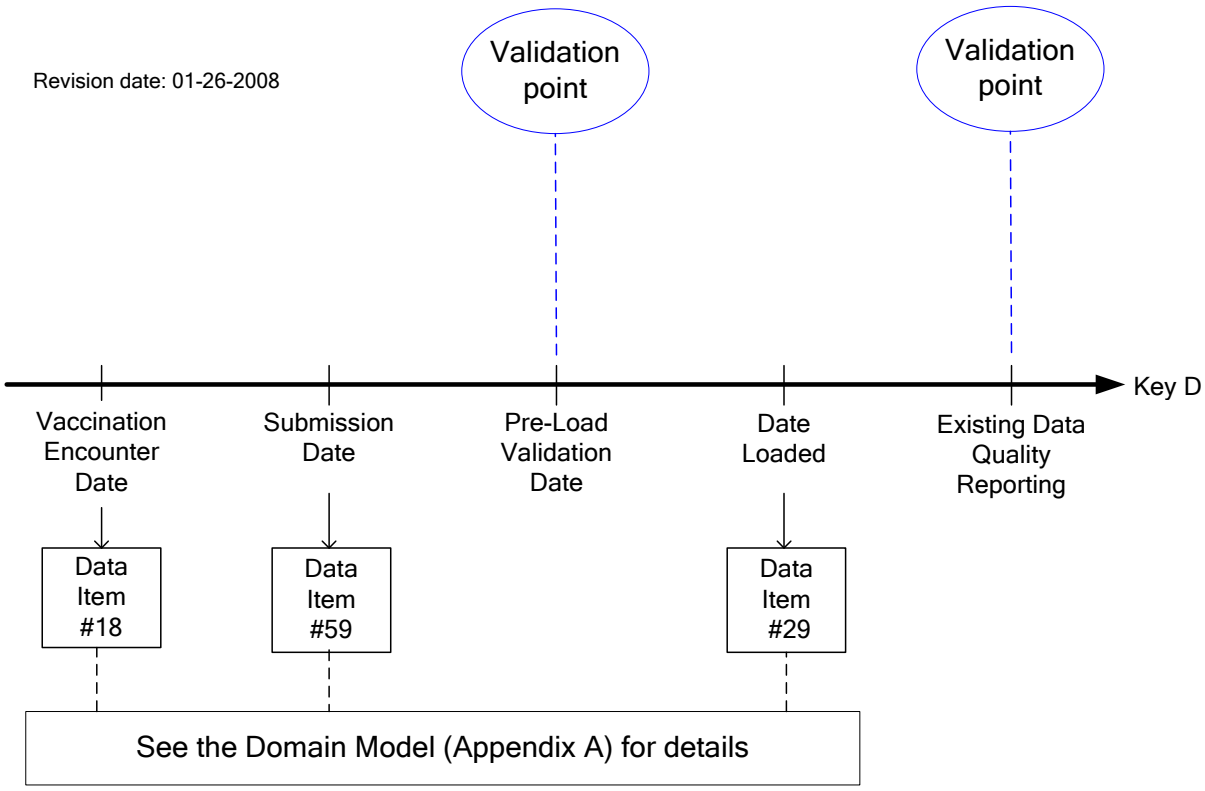


Figure 7. Key data validation dates

Table 3. Business Rules
(See Table 4 for ACIP-related business rules; Abbreviations: Pri = Priority, Cat = Category.)

Pri	#	Business Rule		Comments	Cat
		Condition	**Recommended Action**		
A	BR101	Vaccination Encounter Date must not be before Patient Date of Birth. Data items: • Vaccination Encounter Date • Patient Date of Birth	• Batch: Reject the patient and all related vaccination event submissions (new/incoming) • UI: Reject the vaccination event *See note 1 at the end of this table for explanations.*	• Implementation Example o Iterate through each vaccination event in the record being validated; reject if any Encounter Date precedes Date of Birth • Possible interpretations: o Vaccination Encounter Date is incorrect o Patient Date of Birth is incorrect o Patient Date of Birth and Vaccination Encounter Date are incorrect o Patient identification is incorrect (e.g., could be a sibling) • Research may include: o Check existing patient for high confidence date of birth • Principle(s): P01, P02, P03, P04.	P-VE
A	BR102	Vaccination Encounter Date should not be after the Patient Date of Death. Data items: • Vaccination Encounter Date • Patient Date of Death	• Batch: Reject the patient and all related vaccination event submissions (new/incoming) • UI: Reject the vaccination event	• Implementation Example: Check: o If Vaccination Encounter Date is after Date of Death o If Date of Death is after Vaccination Encounter o Iterate through each vaccination event in the record being validated; reject if any Encounter Date is later than the Date of Death. • Possible interpretations: o Date of Death is recorded incorrectly or patient is not actually deceased o Vaccination Encounter Date is incorrect	P-VE

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
				○ Error in software used to report encounter to IIS ○ Two distinct patients are reported (one who received the vaccination and one who is deceased) • Research may include: ○ Determine if the patient is deceased and the correct date of death ○ Determine if the patient identification (match) is correct • Principle(s): P01, P02, P03, P04. • Other: This is rare.	
A	BR103	Vaccination Encounter Date must be less than or equal to (before or the same as) the Report Submission Date. Data items: • Report Submission Date • Vaccination Encounter Date	• Reject the vaccination event submission	• Principle(s): P01, P03, P04 • Other: ○ If the system does not capture the submission date, the default should be system's date at the time of validation.	S-VE
A	BR104	The minimum/mandatory set of data items for the Vital Records includes: • Patient Date of Birth, • Patient Name, First • Patient Name, Last • Birth Certificate Number • Birth Facility (name , address, county) – could be in home birth	• Reject the Patient's record (complete rejection of submitted information)	• Implementation Example ○ This set of variables related to the Birth record. Different / additional variables might be needed for other types of Vital Records, such as Death Record, Adoption Record, and Correction. • Additional state-specific items can be added to the set. • Principle(s): P01, P03, P12.	Misc

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
		• Gender • Mother's Name, First, Last, and Maiden			
A	BR105	The minimum/mandatory set of data items for the Provider Health Records must include: • Provider Organization Name/ID • Patient Name, First • Patient Name, Last • Patient Date of Birth • Vaccine Encounter Date • Vaccine Type	• If the demographic data items are incomplete (patient can't be identified): Reject the Patient's record (complete rejection of submitted information) • If the demographic data items are complete (patient can be identified): Reject those vaccination events that are incomplete (partial rejection of submitted information)	• Principle(s): P01, P03, P12. • Other**:** o Should Include: ▪ Patient Gender ▪ Medical Record Number ▪ Parent information ▪ Other identifiers • Additional state-specific items can be added to the set.	Misc
A	BR106	The minimum/mandatory set of data items for the Electronic Medicaid/Billing Records must include: • Provider Organization Name/ID • Patient Name, First • Patient Name, Last • Patient Date of Birth • Vaccine Encounter Date • Vaccine Type	• If the demographic data items are incomplete (patient can't be identified): Reject the Patient's record (complete rejection of submitted information) • If the demographic data items are complete (patient can be identified): Reject those vaccination events that	• Principle(s): P01, P03, P12 • Other: note – see P13 • Additional state-specific items can be added to the set.	Misc

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
			are incomplete (partial rejection of submitted information)		
A	BR107	Every administered vaccine should be recorded as a single vaccination event. Data items: • Vaccination Event Submission - Administered/ Historical Indicator	• Accept and flag for investigation (to follow up with submitter)	e.g., COMVAX®, which contains HepB and Hib would be recorded as one vaccination event rather than two vaccination events. See the domain model in Appendix A. Principles: Principle(s): P01, P05.	Misc

A	BR108	Vaccinations should appear in the registry within 2 business days of the Report Submission Date.
		
		Data items:
		• Report Submission Date
		• Vaccination Event Submission Date Loaded
			• Examine the process and determine the cause	• Principle(s): P01, P11
				• Other:
				  ○ Monitoring should be done.
				  ○ The error message should include how long it will take for the data to appear.
				  ○ This is to maintain the confidence of our providers.
				  ○ This has a direct effect on data completeness.
				  ○ Notification types: an error message, a phone call
					S-VE

B	BR109	Vaccination Event reported by Provider assumed to be "Historical" until attested or proven otherwise. Data items: • Vaccination Event Submission - Administered/ Historical Indicator	• When value is missing, Accept and set Administered/ Historical Indicator to "Historical"	• "Administered/Historical Indicator" information should be reported explicitly or derived implicitly. • Individual IIS should establish a criterion of sufficient proof to count a shot as "Administered", e.g., presence of specific information, such as lot number, manufacturer, expiration date, site, or a time period of less than 30 days between vaccination date and submission date.	Misc

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
B	BR110	VFC-eligible children should have the manufacturer and lot number reported with vaccination event. Data items: • Vaccination Encounter Date • VFC Eligibility – Start Date • VFC Eligibility – End Date • Vaccine Manufacturer • Vaccine Lot Number	• Reject the vaccination event submission This applies to administered immunizations only.	This information is needed for inventory management and vaccine accountability. The IIS may choose to relax this requirement for some submitters who are unable to provide the data items. In the future this requirement most likely will be more restrictive. Principle(s): P01, P03, P04	Misc
B	BR111	Adverse reactions reported on administered vaccines should be identified for tracking and following up. Data items: • Vaccination Event - Adverse Reaction • Vaccination Event Submission - Administered / Historical Indicator	• Accept • Flag for tracking	See Vaccine Safety Registry Committee (VASREC) document on the AIRA web page: http://www.immregistries.org/docs/IISVAERS_Collaboration_final_VASRECWG_042005.doc Principle(s): (none).	Misc
B	BR112	The percentage of Vaccination Event Submissions from the Vital Records with hepatitis B birth doses should be within an expected threshold level (to be determined by each IIS). Data items: • Vaccine Type • Submitter Type	• If threshold is deviated by 10%, then immediately follow up with vital records department.	Principle(s): P01, P05.	Misc

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
B	BR113 generic	If the provider 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. <u>Data Items:</u> • Vaccine Type • Date of Birth • Vaccination Encounter Date	• Accept and flag for investigation (initiate research of provider's records)	• See section " Precertification and Providers' Profiles" and Appendices E and F for specific distributions for various practices and for possible approaches to utilize providers' profiles. • Research may include: o Dialog with provider to determine if the reported percentages reflect actual clinical activity (e.g., inventory shortage or manual coding errors). o Audit automated data processes for systematic omission of data or faulty code translation. • Principle(s): P01, P05, P06.	Pr-VE
B	BR114	Vaccination Encounter Date should not be on the Patient Date of Birth unless it is on the list of vaccines recommended on the date of birth, e.g. HepB. <u>Data items:</u> • Vaccination Encounter Date • Patient Date of Birth • Vaccine Type (or CVX, …)	• Batch: Accept and flag for investigation • UI: Accept (after issuing a warning)	• Possible interpretations: o Clinical error o Professional decision which differs from common practice o The current date accidentally typed in the Encounter Date field (instead of a date few days ago when vaccination was given) o Other typographical error • Research may include: o Provider reviewing patient chart o Provider contacting patient or other source to validate Date of Birth • Principle(s): P01, P02, P04, P05, P10. • Other: o Closely related to BR101	P-VE

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
				○ There may be exceptions to this rule (typically old rules that no longer apply, other countries, etc) ○ This is related to ACIP	
B	BR115	For administered vaccinations, Report Submission Date should be within 30 days of Vaccination Encounter Date. Data Items: • Report Submission Date • Vaccination Encounter Date	• Accept and flag for investigation This is applicable only to batch submissions.	• Principle(s): P01, P04, P11. • Other: ○ See NVAC recommendations ○ Keep in the source profile the average time until submission. ○ This is an issue for investigation and training	S-VE
B	BR116	Trade Name, Manufacturer, CVX Code, CPT Code and Vaccine Type should not contradict one another. Data items: • Trade Name • Manufacturer (MVX Code) • CVX Code • CPT Code • Vaccine Type {Hib – PRP-OMP}	• Reject the vaccination event submission.	• Possible interpretations: ○ Typographical error. ○ Code translation (or other) error in software. • Research may include: ○ Review of source document(s). ○ Review of all submissions from provider to detect systematic errors. • Principle(s): P01, P04, P13 (CVX codes are preferred over CPT codes). • Other: ○ We need to know the vaccination type. ○ Not all data items are available all the time. ○ Multiple CPT codes can map to the same CVX code.	V

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
B	BR117	The same patient should not receive the same antigen more than once in single day. Data Items: • Vaccination Encounter Date • Vaccine Type (in order to derive the antigen)	• Follow best practice recommendations in the MIROW deduplication materials. (This is not the Accept/Reject situation)	• Implementation Example See the following MIROW publication: AIRA Modeling of Immunization Registry Operations Workgroup (eds). Vaccination level deduplication in Immunization Information Systems. Atlanta, GA: American Immunization Registry Association. December, 2006, p. 21. Available at: http://www.immregistries.org/pdf/AIRA_BP_guide_Vaccine_DeDup_120706.pdf • Possible interpretations: o Incorrect or incomplete vaccination deduplication o Invalid dose or incomplete immunization o Two separate pediatric doses on the same date to an adult o Poor clinical practice (Pediarix and IPV) • Principle(s): P01, P05, P10. • Other: o Deduplication may remove some or all of this. The match needs to be made at the antigen level, so the antigen needs to be determined from the vaccine type that is reported.	VE-V
B	BR118	Vaccination Encounter Date should not be after the lot number expiration date. Data items: • Vaccination Encounter Date • Lot Number Expiration Date	• Batch: Accept and flag for investigation • UI: Accept (after issuing a warning)	• Possible interpretations: o Expired vaccine was used o Typographical error • Principle(s): P01, P02, P04, P05.	VE-V

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
B	BR119	Route and Site should be consistent with the vaccine type. Data items: • Vaccine Type • Route • Site	• If batch – accept and flag for investigation • If UI – Accept (after issuing a warning)	• Implementation Example HepB site reported as subcutaneous, , not intramuscular. • Possible interpretations: o Typographical error. o Systematic code translation (or other) error in software. o Clinical error. • Research may include: o Reference to source document(s). o Review of all submissions from provider to detect systematic errors. • Principle(s): P01, P02, P04, P05. • Other: o See appendix G for Vaccine Site/Route Guide (adapted from the 2003 Red Book and ACIP General Recommendations (MMWR 2006:51 [No.RR-2]:15–18.).	V-VE
B	BR120	Vaccination Encounter Date should be within the Vaccine Product License Date range. Data items: • Vaccination Encounter Date • Vaccine Product License Begin Date • Vaccine Product License End Date	• Batch: Accept and flag for investigation • UI: Accept (after issuing a warning)	• Implementation Example CVX code = 51 (HepB-Hib) recorded as given in 1957(it was implemented in USA around 1989) • Possible interpretations: o Incorrect coding. o Typographical error. o Unexpired vaccine used after Product License End Date. o Expired vaccine was used. o It could be a vaccine given in another. country: DTaP-Hib-IPV licensed in Canada	V-VE

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
				and Mexico but not in USA at this point. o Experimental drug trial. o CPT code has been changed (re-used). o Research may include: o Reference to source documents. • Principle(s): P01, P02, P04, P05. • Other: o The vaccine should be given within the period when the vaccine is in use. o There is no single, authoritative source for many Vaccine Product License Dates. o There may be different operational ways to implement this rule. o This is for administered vaccines only, not historical. o There are instances when investigational vaccines are used outside of the range. Doses should not be recorded as given before or after US licensure. Red Book® Online Table – Status of Licensure and Recommendations for New Vaccines http://aapredbook.aappublications.org/news/vaccstatus.shtml.	

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		

B	BR121	Administered vaccinations should have specific Vaccine Types, e.g., Hib PRP-OMP;
		unspecified vaccine types, e.g., Hib, NOS, are less desirable.
		
		<u>Data items:</u>
		• Administered/Historical Indicator
		• Vaccine Type
			• Accept – during production;
			• Investigate - during precertification.
				• Implementation example
				  ○ Vaccine Type is Hib, NOS, and Administered/Historical Indicator is Administered. The vaccinator would have known which Hib was given and this should have been reported.
				• 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 was not administered, but instead was copied from a historical source. It is being incorrectly reported as administered.
				• Research may include:
				  ○ Contacting submitter to examine recording process and determine at which step the vaccine event become unspecified.
				• Principle(s): P01.
				• Other:
				  ○ Vaccine type cannot be unspecified if you are recording vaccine information from vaccination inventory module.
				  ○ HIB PRP-OMP: OMP = meningococcal outer membrane protein complex.
				
				  ○ HIB, NOS: NOS = not otherwise specified.
					V-VE

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
				• Encourage recording a specific vaccine type.	
C	BR122	A patient's VFC eligibility should be consistent with the funding source of the vaccine administered. Data items: • VFC Eligibility • Vaccine Funding Source	• Batch: Accept and flag for investigation • UI: Accept (after issuing a warning)	• This is a state-specific business rule – some states allow this, some don't. • This BR is more about program's policy, and less about data quality. • VFC vaccines should be given to VFC eligible children; this is specific to the vaccine. • Principle(s): P01, P02, P04, P05.	Misc
C	BR123	The volume of reporting from the Vital Records feed should be within an expected threshold level (to be determined by each IIS) . Data items: • Report Submission Date	• If the rate of reporting significantly deviates from the threshold, follow up with Vital Records department. • This is not an Accept/Reject situation.	See also BR112. Principle(s): P01, P11.	Misc
C	BR124	The percentage of vaccination events in which the responsible party name is the same as the patient name should be within an expected threshold level (to be determined by each IIS).	• If threshold is exceeded significantly, initiate investigation. • This is not an Accept/Reject situation.	When importing incoming data into parent or guardian fields in an IIS, first identify the actual data definitions and usage of similar fields (guardian, responsible party, parent, payer) by the source agency. This rule is especially useful during the precertification process. Principle(s): P01, P05.	Misc

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
C	BR125	The percentage of rejected vaccination events submissions in a report should be within an expected threshold level. <u>Data items:</u> • Vaccination Event Submission - Accepted/Rejected	• This is not an Accept/Reject situation. Precertification: • If more than 10% of the vaccination event submissions are rejected for errors, initiate an investigation. Post-certification: • If a batch contains at least 50 vaccination event submissions and more than 10% are rejected for errors, stop processing and investigate.	During precertification is the time to determine the quality of the existing data and the extract and formatting process. (Note that 10% is an arbitrary number) Rejection of records because they already exist should not be considered in this rate. The process of extracting and formatting data is fraught with risk. One way to find systematic errors is to look for unusual rates of bad data. Precertification evaluation for unacceptable rates of rejected records is one measure that can be used. While records may be rejected because they are unacceptable in format or content, this may reflect accurately the data in the source record. However, if the rate of errors is high enough, our confidence in the process to produce the data is challenged. There is no best level to use for record rejection rate. It is obvious that a batch of 10 records with 2 rejected records is probably not the same concern as 10,000 records with 20% rejection rate. It might be interesting to consider weekly rejection rates for each data source. Principle(s): P01.	Misc

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
C	BR126	An administered vaccine should not have a medical contraindication for a patient. Data Items: • Vaccination Event Submission - Administered/Historical Indicator • Vaccine Type • Exemption / Contraindication	• Batch: Accept and flag for investigation • UI: Accept (after issuing a warning)	Applicable to all vaccines. Principle(s): P01, P02, P04, P05.	V-P
C	BR127	Hepatitis B birth doses from the Vital Records feed should be reported within an agreed-upon timeframe. Data items: • Vaccine Type • Submitter Type • Vaccination Encounter Date • Report Submission Date	• This is not an Accept/Reject situation • If vital records feed is not reported with 3 business days of agreed upon timeframe, then follow up immediately with vital records department	Principle(s): P01, P11.	V-VE

Note for Table 3:

1) For BR101.Vaccination date should never be before birth date. There are two acceptable responses to receipt of records with this characteristic: reject the entire record, or reject only the offending immunization record. A number of factors suggest which response

to use. When data are being entered via a user interface, the immunization record may be rejected and the user notified. The user may then immediately determine the corrections necessary to enter the record. In the case of automated data entry, such as via HL7 message, the user may not immediately respond. This means that the response must be handled by the receiving system. Various factors may determine the response in this case.

1. During precertification, we presume that no data are loaded. At this stage, we take before-birth immunizations as an indicator of potentially problematic data extraction. This warrants further investigation to determine the frequency and the cause.
2. During exchange of data with regular certified provider, the decision to reject the entire incoming record may vary.
    a. Incoming record does not match an existing record in the system. The incoming record contains a before-birth immunization. This is the strongest situation for rejecting the entire record. However, a case may be made for accepting the record and rejecting the immunization record.
    b. Incoming record matches an existing record in the system. The birth dates of the incoming and existing records match. The incoming record contains a before-birth immunization. This is a good candidate for rejecting the incoming, before-birth immunization.
    c. Incoming record matches an existing record in the system. The birth date of the incoming record does not match the existing record. The incoming has a before-birth immunization. There are two issues here. If rules for birth date allow change of existing birth date, consider rejecting immunization record. However there are two conflicting data elements, suggesting increased likelihood of problem data.

In either case, we must balance the need to get data into the system and the need for accepting only valid data. We must determine if a before-birth vaccination date is sufficient evidence of bad data to reject data that are associated, but do not have apparent problems—and must balance the willingness to risk bad data with the willingness to have less data.

Table 4. ACIP Recommendations -related business rules
(See Table 3 above for other business rules.)
(See Table D-1 in Appendix D for specific ACIP recommendations-related rules from the Minnesota Immunization Information Connection [MIIC]).

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
B	BR128	A patient should not have more than: • 50 vaccinations before 5 years of age • 35 vaccinations before 2 years of age • 70 vaccinations regardless of age <u>Data Items:</u> • Date of Birth • Vaccination Encounter Date	• Batch: Accept and flag for investigation • UI: Accept (after issuing a warning)	• Possible interpretations: o Might be two patients reported as one • Principle(s): P01, P02, P05, P10. • Other: o This should be completed after the patient information has been de-duplicated. o There is a trend to recommend the flu vaccination more often, so these numbers could be increased in the future. o See appendix D for implementation examples. If this condition is violated strictly from incoming source data, the source is notified. If this condition is violated from a combination of incoming source data and existing data, it should be flagged for research because it is not known which data are problematic.	P-VE

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
B	BR129 generic	A patient should not have more than 7 DTaP vaccinations by age 7. (Additional rules should be developed for other types of vaccinations.) <u>Data Items:</u> • Date of Birth • Vaccination Encounter Date • Vaccine Type	• Accept and flag for investigation	• Principle(s): P01, P10	P-VE
B	BR130 generic	Doses should not be recorded as given before the minimum patient age or after the maximum patient age for that particular vaccine. <u>Data Items:</u> • Date of Birth • Vaccination Encounter Date • Vaccine Type	• Accept and flag for investigation	• Principle(s): P01, P10 • Other: o This is a way to fish. o This is based on the current ACIP recommendations in effect at the time of the evaluation. o See appendix D for implementation examples.	P-VE

Pri	#	Business Rule		Comments	Cat
		Condition	Recommended Action		
B	BR131	Doses should not be recorded as given before the minimum interval has been met. Data Items: • Vaccination Encounter Date	• Accept and flag for investigation	Research provider's records Principle(s): P01, P10 • Other: ○ See appendix D for implementation examples.	VE
C	BR132	A patient should not have more than 10 vaccinations per visit. Data Items: • Vaccination Encounter Date	• Accept and flag for investigation	• 7–9 vaccinations could be given per visit (if needed)– per ACIP recommendations / Pink Book • Principle(s): P01, P10 If this rule is violated strictly from incoming source data, the source is notified. If this rule is violated from a combination of incoming source data and existing data, it should be flagged for research because it is not known which data are problematic.	VE

Table 5. Business rules: ranges and codes for selected individual data items
(See Table A-1 in appendix A for description of data items; use numbers in the left column for navigation in Table A-1.)

#	Data Item (Entity/Attribute)	Range / Codes	Comments
04	CPT Code	Should be chosen from the standard table of billing codes.	See Appendix A, Table A-1, item 3 for a link to the CPT codes reference source.
05	CPT Code – Inception Date	Dates should represent valid calendar dates.	
06	CPT Code – End Date	Dates should represent valid calendar dates.	
08-1	Patient Name, First	Should not contain invalid name characters such as []{}0123456789~!@#$%^&*\, as well semantically invalid names, e.g., "daughter."	May want to warn if name length equals 1. The mean length of patient first and last names should be around 5–7 characters, while the maximum length should be somewhat higher, with nearly all lengths being less than the maximum length for first or last name. Suspected batch should be reviewed for possible data truncation. The length of patient names tends to be evenly distributed around the median value with the maximum length being an atypical length. If the maximum length is common to a large fraction of all name lengths, this may indicate a data truncation error. (e.g., “JOHNSON,” “THIBODEAUX” and “JONES” are sent as “JOHNSO,” “THIBOD” and “JONES.”) This rule is to be used in precertification. Number of characters could vary from region to region: the mean of the population as a whole should

#	Data Item (Entity/Attribute)	Range / Codes	Comments
			be taken into consideration.
08-02	Patient Name, Middle	Should not contain invalid name characters such as []{}0123456789~!@#$%^&*\	
08-03	Patient Name, Last	Should not contain invalid name characters such as []{}0123456789~!@#$%^&*\	May want to warn if name length equals 1. See also comments for Patient Name First above.
09	Patient Date of Birth	Dates should represent valid calendar dates.	Related cross-check business rules: BR101, BR104, BR105, BR106, BR113, BR114, BR128, BR129, BR130
09-1	Patient Date of Death	Dates should represent valid calendar dates.	Related cross-check business rules: BR102
10	Patient Gender	Should be chosen from the standard table of codes for gender.	See HL7 implementation guidelines.
10-01	Mother's Name, Maiden	Should not contain invalid name characters such as []{}0123456789~!@#$%^&*\	
10-3	SSN	The SSN is divided into area code, group code, and serial numbers (AAA-GG-SSSS) for each part the following rules apply: ● Total SSN length = 9 ● '000' < Area Code <= '772' AND Area Code <> '666' ● Group Code <> '000' ● Serial Numbers <> '0000' ● SSN <> '987-65-4320' AND SSN <> '987-65-4329' In addition, there are some correct SSNs that are commonly reported but should be rejected: ● '123-45-6789' ● 'NNN-NN-NNNN' where N is same number	An SSN is made up of numbers and optional dashes. Dashes should be removed for validation. See Wikipedia article for more information: http://en.wikipedia.org/wiki/Social_Security_number

#	Data Item (Entity/Attribute)	Range / Codes	Comments
18	Vaccination Encounter Date	Dates should represent valid calendar dates.	When vaccination encounter date is on a date when vaccinations are not expected to be given (e.g., January 1), the report has to be accepted and researched. This approach is most appropriate during the precertification stage. There are two kinds of encounter dates that may be considered invalid: ● Holiday: Recognized, national holidays (e.g., Thanksgiving) when regular clinics are not open. ● Place holder: A date, such as January 1, that is not only a holiday but is sometimes used to indicate a date of "unknown." There are situations when vaccines are given on these dates (e.g., hospital nurseries will administer shots on January 1). There are more dates that may be suspect, e.g., lots of incoming records with the 1st, 15th, or 31st of the month. These might also be placeholder dates, or used when only a month and year were recorded. Related cross-check business rules: BR101, BR102, BR103, BR105, BR106, BR110, BR113, BR114, BR115, BR117, BR118, BR120, BR121, BR127, BR128, BR129, BR130, BR131, BR132

#	Data Item (Entity/Attribute)	Range / Codes	Comments
20	Vaccination Event – Site	Should be chosen from the standard table of vaccination sites and routes.	CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book) Appendix D: Vaccine Administration, page 5: Administering Vaccines—Dose, Route, Site, and Needle Size Related cross-check business rules: BR119
21	Vaccination Event – Route	Should be chosen from the standard table of vaccination sites and routes.	Pink Book: Appendix D: Vaccine Administration Guidelines, page 5: Administering Vaccines—Dose, Route, Site, and Needle Size Related cross-check business rules: BR119
22	Vaccination Event– Dosage	Includes 1) value and 2) unit of measurement; both have to be captured or known (e.g., presumed to be in mL) Value has to be a positive number. Unit of measurement, e.g., mL.	Value should be numeric. Value should not be negative. If value is zero, the presumption is that field was not filled. Unit of measurement should be agreed upon between the reporting parties. The group recommends a consistent approach in which volumes are reported – mL are preferred (not in terms of full dose, half dose, etc. This year's dose might not be the same as next year's dose.)
29	Vaccination Event Submission –Date Loaded	Dates should represent valid calendar dates.	Related cross-check business rules: BR108
36	Vaccine – Type	Should be chosen from the standard table of vaccine nomenclature.	See CVX or CPT codes. Related cross-check business rules: BR112, BR113, BR117, BR119, BR121, BR126, BR127

#	Data Item (Entity/Attribute)	Range / Codes	Comments
36-1	Vaccine – Product License Begin Date	Dates should represent valid calendar dates.	Related cross-check business rules: BR120
36-2	Vaccine – Product License End Date	Dates should represent valid calendar dates.	Related cross-check business rules: BR120
37	Vaccine – Lot Number	Typically, an alpha-numeric field. No established standard exists.	BR110
38	Vaccine – Lot Number Expiration Date	Dates should represent valid calendar dates.	Related cross-check business rules: BR118
39	Vaccine – CVX Code	Should be chosen from the standard table of CVX codes.	http://www.cdc.gov/vaccines/programs/iis/stds/cvx.htm
41	Vaccine – Manufacturer	Should be chosen from the standard table of MVX codes.	http://www.cdc.gov/vaccines/programs/iis/stds/mvx.htm Related cross-check business rules: BR110, BR116
47	State/Province	• If country code is specified as 'US' (or not indicated and assumed to be 'US'), state code should be drawn from the USPS state codes list. This list should also include the Federal District (DC), insular areas, Freely Associated States, and Armed Forces codes. • State/Province designations for other country codes may or may not be validated. If they are validated they should match what is required by the postal authority for that country for mailing purposes.	
48	ZIP Codes	• For addresses with a US country code (or a blank US country code that is assumed to be US): ZIP codes may be either 5 or 9 digits in length (ZIP+4)	

#	Data Item (Entity/Attribute)	Range / Codes	Comments
		and with a dash appearing after the first 5 digits. This dash should be optional and either removed or added as needed by the registry. ● Non-US ZIP codes should follow the postal code regulations of that country's postal authority. Registries may choose whether or not to validate non-US postal codes.	
56	Vaccine Information Statement – Date of Issue	Dates should represent valid calendar dates.	
59	Report Submission Date	Dates should represent valid calendar dates.	Related cross-check business rules: BR103, BR108, BR115, BR123, BR127

Notes:

1) Only complete dates are acceptable (best practice), but if day is not available, then 15th of the month can be put in and accepted. Such "guesses" should be flagged appropriately. Month or year can not be guessed. Having just month and a year happens often for the chicken pox history of disease.

2) The use of native HL7 codes in the IIS should be encouraged. Consistent use of code sets positively affects the data quality. First data quality is improved through the clear definition of the data items received; the use of HL7 messaging and recommended code sets are a way to get clearly defined data items. Second, there are quality implications in converting from one code set to another. Having consistent codes sets in the registry and in the messaging removes ambiguity, sources of systematic error, and improves data quality.

Chapter 6: Precertification and Providers' Profiles

The Provider Precertification Process

Before loading data to the IIS, every provider's data files must go through the process of precertification. During precertification, source data are examined carefully for format, accuracy and completeness. If possible, it is advisable to compare data with the chart to validate content. Only when accuracy of data is established, should data be processed in production from that provider. Every IIS should have this process in place. This will ensure that the quality of data loaded to the IIS and will provide the opportunity to correct errors before loading. Cleaning erroneous data from an IIS is difficult and resource intensive; it is much preferable to not allow these data to be loaded in the first place.

During precertification, a data source gets a great deal of "individualized" attention, and many otherwise difficult to identify issues can be isolated and addressed. The level of examination that occurs in precertification is in-depth; it is generally impractical to have this process in place during normal data processing.

Certification of data should occur not only when a new data source joins the IIS, but also when electronic or billing systems are changed or modified, when the patient population for a provider changes, when new vaccines are introduced and when the IIS's data structure changes. In addition, IISs should periodically recertify providers to ensure ongoing good data quality.

To have an efficient and good precertification process, an IIS needs to have a test environment where it can process data for precertification.

All electronic data streams (Vital Records, Medicaid/billing data files, EHR files) should be precertified. This process is very important as provider organizations increasingly use their own software systems to track immunizations within their clinics and generally prefer to send batch files rather than enter immunizations to the IIS directly.

Stage 1: Preliminary Test File Check for Format Compliance

The IIS may accept various formats for the data, often including a "flat file format" or an HL7 format. After a provider chooses the format, the IIS can then send appropriate specifications to the provider, including any codes that need to be used. A test file of real data is then produced by the provider and sent to the IIS in a secure manner in the chosen format. It is best to choose a time period over which a good sampling of vaccine types would be included in the file. For example, a large clinic could send all vaccinations entered for one week. A smaller clinic might have to include a longer period of time if the vaccinations are infrequent. The submitted data should be checked for appropriate format and then imported into a test database.

Stage 2: In-Depth Test File Checks
The next step in the process is to perform checks on the data to make sure that expected data are included. In addition to the field level and record level checks that are also performed on every file that is processed through the IIS, additional checks should be done that include file level checks. These would include a tabulation of all data values in the file to make sure that appropriate codes are being used and that vaccinations match with appropriate age groups, as well as examination for conformity to the vaccine distribution that is appropriate for this provider type. The following are examples of checks that should be performed in the precertification process:

A. Field-level and inter-field checks should be done as described in the business rules. Assessments of plausibility of vaccine types relative to age of patient: (MMR, varicella prior to age 1 year, PCV7 and Hib after 5 years of age, Td before 7 years of age, etc.) can be made. If too many of these errors are seen, there may be a mis-coding issue. Please refer to the business rules, and the end of this chapter for a comprehensive list of business rules.
B. Whole file checks involve examination of the whole file for identification of data anomalies such as "abnormal" data uniformities, and assessment of plausibility of the data. The simplest way to perform this is to do a frequency distribution of values of all fields: Are all DOBs in the file the same, are too many "John's" in the file? One of the most important file level checks is examination of the vaccine types in the file, described in detail in the next section.

Vaccine distribution based on provider profile
This is one of the most important checks that occur in precertification. Each provider 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 population, or unusual clinical practice.

The most useful types of provider 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 profiles by averaging data in the IIS from all providers of the same type, and compare a specific provider's vaccine distribution to that of the average distribution for that type of provider. 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's pattern to that "ideal" distribution. See Appendix E for examples of such distributions.
3. Establish a provider-specific vaccine distribution profile. In this approach, each provider would have its own distribution, which would be developed with IIS staff. It would involve working with each and every provider to understand and quantify their clinical practice and establish a provider-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 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.

Stage 3: Chart Audit

Once a file passes the in-depth file checks (Stage 2), the best practice is to also conduct a chart review to ensure that data do not only "look right" but they actually are right. This type of quality assurance would involve taking a random sample of patients from the incoming file, and comparing all reported data elements to the patient's chart for accuracy and completeness. The following steps would be involved:

A. Select a random sample of records from incoming file: N=100.
B. Send list of patients to the provider to do a chart pull.
C. IIS prints a copy of all data found in the file for each patient in the sample,
D. Validate each data element from the file against the data in the chart (chart audit).
E. Compare every element in the batch file for validation in the chart. In addition, for the encounter dates reported in the file, examine the chart for additional immunization events that may have occurred at the visit and were not reported in the file.
F. Report errors/omissions back to the facility for corrections.
G. Repeat process until IIS is satisfied with quality of data in the file.

Note that this stage does involve significant burden to the provider, and not all providers may be willing to provide the time and staff necessary to complete this stage.

Existing AFIX (http://www.cdc.gov/vaccines/programs/afix/default.htm) activities (if they are taking place) can be leveraged.

Stage 4: Periodic In-Depth Data Checks

- Checks similar to Stage 2 are periodically run on a current subset of the IIS database to identify patterns that indicate either systematic and widespread coding problems or actual immunization practice problems. For example, a monthly report can be produced examining all vaccinations input during the last month. Rules are applied and errors are sent to the submitting providers along with details on who entered the vaccination data.

- Invalid doses and other special reports can also highlight systematic data quality issues that can be corrected by the source, as well as practice issues to address through education.
- Recall notices sent out by clinics, public health departments, or the region can highlight missing or erroneous data, which should then be fixed as close to the source as possible.

Table 6 contains 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).

Table 6. Selected data checks that can be included in the precertification process

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

Data Checks	Type of check	BR#	When
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 yrs	Within record check/ ACIP	BR130	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
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 pt	File level checks	BR117	Pre-, and ongoing
Compare to ideal distribution for type of practice	File level checks	BR113	Pre- and Periodic
More than50 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

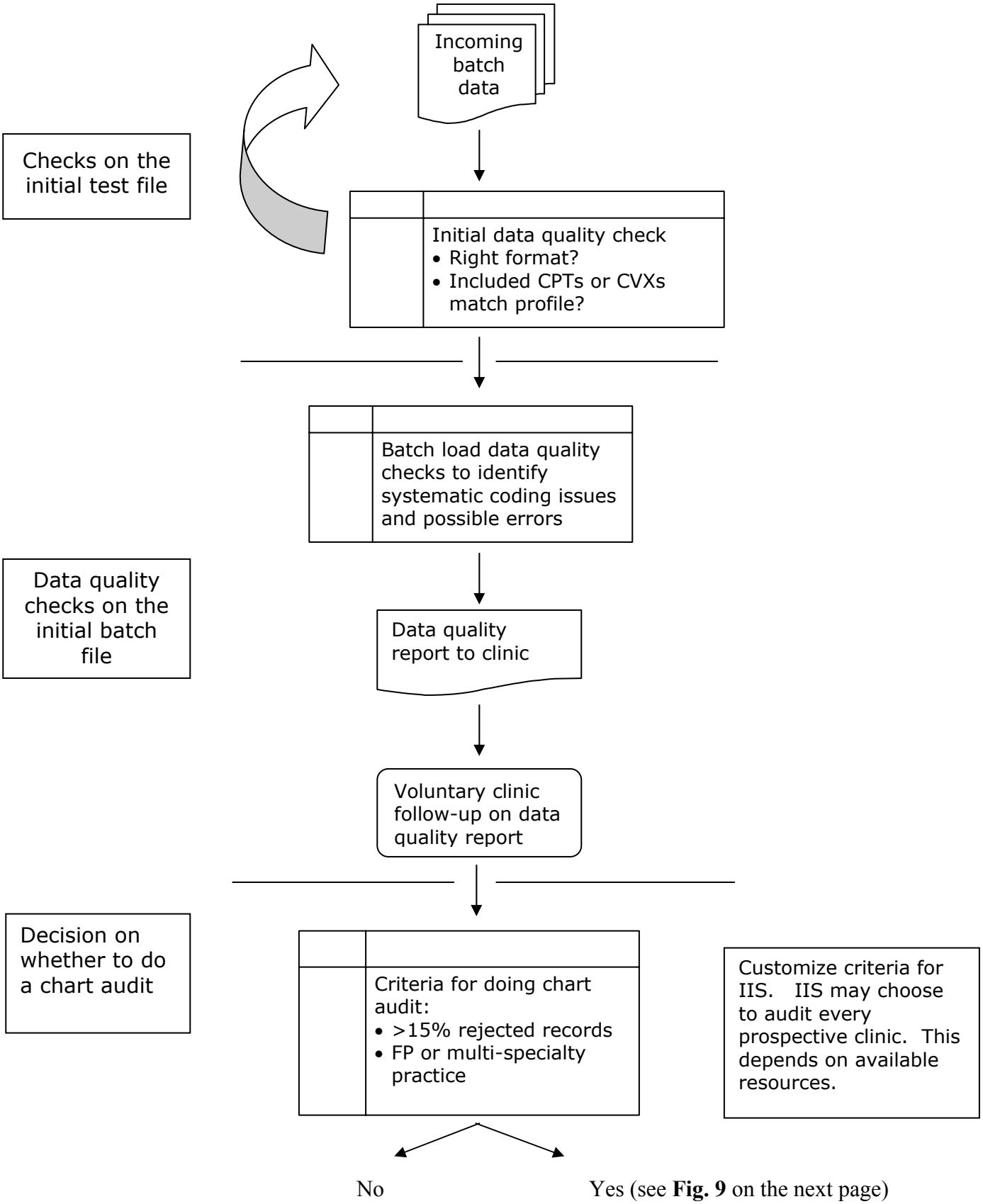


Figure 8. Data quality process for batch data loaded into IIS

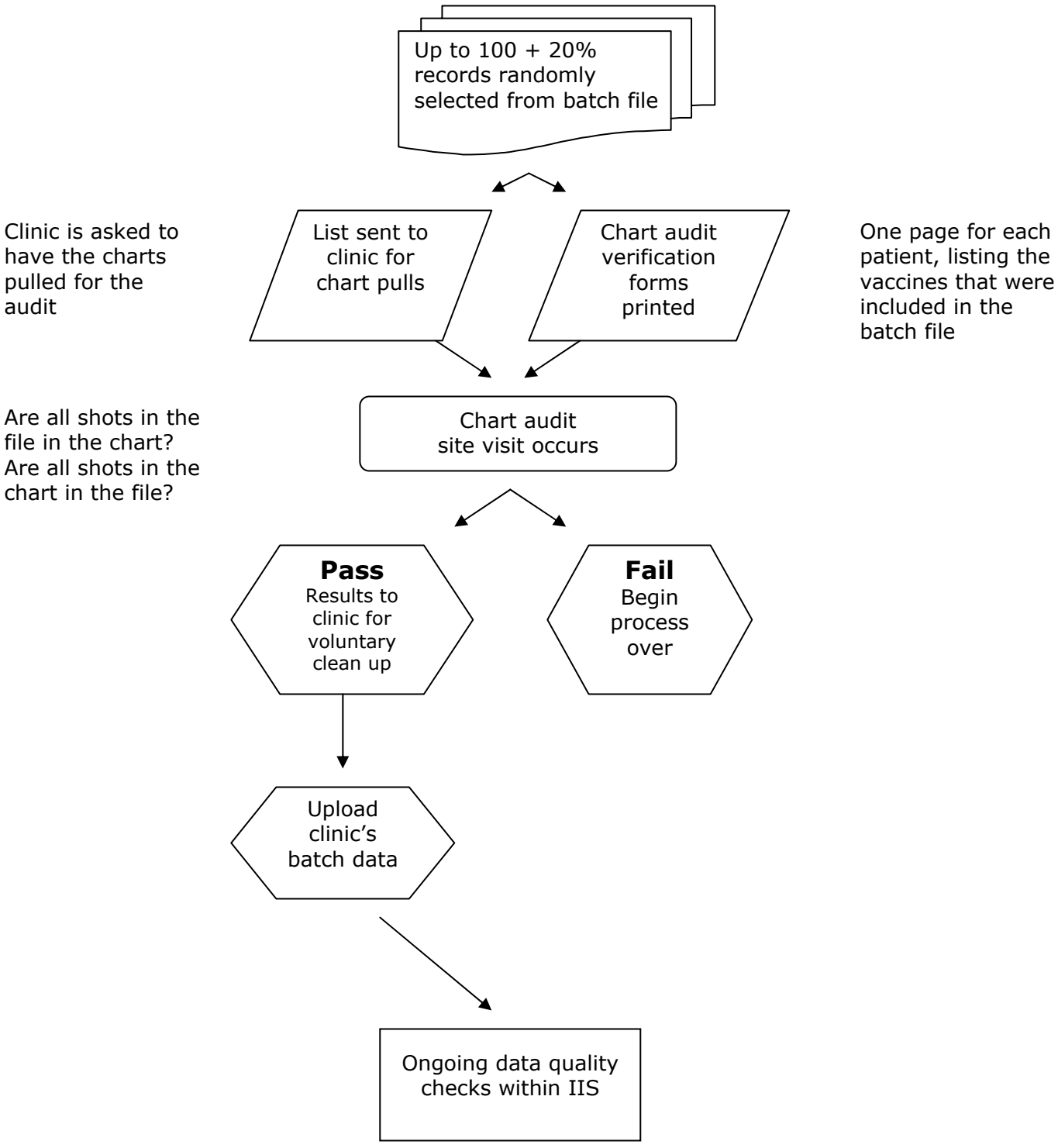


Figure 9. Process for conducting a chart audit

Chapter 7: Barriers to implementations

Barriers to implementation of the data quality assurance business rules occur at both the IIS and data source/submitter. The following are barriers to implementation:

IIS

- Limited resources and competing priorities for those limited resources
- Underlying data structure does not support the data quality assurance business rules
- Import process modifications are necessary
- Lack of training

Data source/submitter

- Limited resources and competing priorities for those limited resources
- No perceived benefits to the data source/submitter for fixing the data
- Source may have a problem, e.g., some temporary inability to process data properly
- Low level of commitment to quality reporting to the IIS
- Lack of training

Conclusions

Consistent use and implementation of these guidelines will help improve data quality assurance practices in immunization information systems. The following summary is a brief description of the key outcomes and accomplishments of the MIROW workgroup.

Major consensus-based accomplishments of the workgroup:

- Developed principles on which to base the data quality assurance process, business rules to follow, and specific scenarios that illustrate application of principles and business rules.
- Developed and reconfirmed key definitions for data quality assurance.
- Described healthcare provider precertification as a process of evaluating the incoming data quality of new submitters before allowing them to regularly add data to IIS in order to ensure that the data sent are correctly formatted and complete and thereby helping to identify systemic data errors prior to data imports.
- Recommended that there be a general source profile for each kind of provider (e.g., pediatric, geriatric) that the IIS should maintain to identify expected distributions of vaccinations.
- Reached consensus among subject matter experts, demonstrating that despite differences in immunization registry programs, common approaches through consensus can be developed and agreed upon with business modeling and facilitation techniques.

Primary process acknowledgments from the workgroup's activities:

- In spite of differences in immunization registry programs, common approaches can be discovered and agreed upon.
- Business modeling initiative provides an efficient way for collaboration and exchange of ideas among peers.
- Business modeling and facilitation techniques help to reach a consensus and document agreed-upon approaches.
- Facilitated sessions promote and organize brainstorming and allow groups to achieve results.
- Business modeling promotes and organizes the analysis and improvement of immunization operations.

The approach and results presented are relevant for and can be used beyond immunization information systems—for developing and documenting best practices and operational requirements for domain-specific data quality assurance applications in public health, healthcare, and other areas.

The results of this project are intended to support a consistent alignment of the data quality assurance processes in immunization registries according to recommended guidelines.
The National Vaccine Advisory Committee has included a recommendation to "Promote the adoption of a guidebook and best practices for IIS as started by the CDC/NIP and AIRA/MIROW workgroup to adopt consistent operational guidance and quality control procedures that ensure good data quality." This guide is one example of addressing this recommendation on data quality validations.

Selected References

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Appendix A. Domain Model

Background
In developing the domain model presented in this section, the MIROW intended to define a set of terms and definitions identifying concepts and data elements relevant for the data quality assurance topic. The resulting set of terms and definitions, captured in the domain model, provides a vocabulary for consensus-based best practice recommendations formulated by the group. The MIROW took as a starting point an existing model constructed for the topic of vaccination level deduplication (available for the download at http://www.immregistries.org/pdf/AIRA_BP_guide_Vaccine_DeDup_120706.pdf) and expanded/modified that model to fit the needs of the data quality assurance topic. The model was developed during the preliminary phase of this project, in a series of web-based teleconferences among MIROW experts, and was finalized during the face-to-face meeting.

Domain model purpose and explanation
A domain is an area of knowledge or activity characterized by a set of concepts and terminology understood by the business practitioners in the area.

A domain model captures a business vocabulary—terms and definitions. It ensures that all terminology and concepts that will appear in the process description and business rules are known and understood by the domain practitioners (agreed-upon definitions and meaning).
A domain model includes:

- A domain diagram that shows major business entities, their relationships and responsibilities (**Figure A-1**).
- A table of entities and attributes that provides the full descriptive details of the components represented on the diagram (**Table A-1**)

Entities and attributes shown on Figure A-1 are numbered; these numbers correspond to numbering of rows in Table A-1, where entities and attributes are described.

Unlike a data model diagram, which depicts storage of information, or a workflow/process diagram, which depicts the sequence of steps in a process, a domain diagram is a high-level static representation of the main "things" (entities) involved in the immunization process, including a description of how these "things" (entities) are related. It is important to note that the domain diagram is not a technical specification. Instead, the domain diagram provides the foundation for other modeling diagrams and materials.

How to read and interpret the domain diagram:

- Relationships between entities are visualized by connecting lines.

- Names associated with these lines describe the type of the relationship between entities. Example: a relationship between *Vaccination Event Submission* and *Vaccination Event* is shown as a connecting line with the word (label) "describes". Such a relationship should be read as "*Vaccination Event Submission describes Vaccination Event*".

- The general convention for interpretation of relationships between entities is to construct such a description by reading clockwise, starting from the first entity name (*Vaccination Event Submission*), then relationship name—*describes* (note that the name is shown on the top of the line, supporting a clockwise reading), then the second entity name (*Vaccination Event*).

- If we need to read the same description in the opposite direction, from *Vaccination Event* to *Vaccination Event Submission*, we would have to place a second name—"is described" — below the line. In this case, using the clockwise reading rule, a description would be "*Vaccination Event is described* in *Vaccination Event Submission."* In most cases just one name for a relationship is employed (like "*describes*" in the example just considered), assuming that it should be sufficient for a proper interpretation of a relationship in both directions.

Description of the domain diagram
The entities and their characteristics (attributes) presented on the domain diagram **(Figure A-1)** describe a limited fragment of the immunization domain related to the IIS data quality assurance topic. Key entities are: Patient, Vaccination Event, Vaccine, Vaccination Event Submission, and Submitter (the source of information about a vaccination event); details on all of these and other entities are presented in the **Table A-1**.

Patient is getting vaccinated as a result of the ***Vaccination Event***. More than one Vaccination Event can happen during the ***Vaccination Encounter*** (office visit). In other words, Patient can receive several vaccine shots during a single office visit; each shot would be represented by a dedicated vaccination event. Accordingly, the relationship between Vaccination Event and Vaccination Encounter is labeled with "1" for the Vaccination Encounter and "1…n" (meaning one or many) for the Vaccination Event.

Vaccine refers to a product that produces an immune response in a patient and is administered during the Vaccination Event. It is described by a set of characteristics (attributes), such as vaccine type, CVX code, trade name, lot number, etc. A single Vaccine can be related to multiple ***Families/Groups.*** Vaccine that belongs to multiple vaccine Families/Groups is referred to as a "combination" or "combo" vaccine. A single Vaccine can contain multiple ***Antigens***, such as tetanus, diphtheria, and pertussis.

Information about the Vaccination Event comes to a registry from a ***Submitter*** **(**also known as a Source) in the form of a ***Report*** that contains several ***Vaccination Event Submissions.*** Typical Submitters would be a vaccination ***Provider Organization*** and medical insurance company. Characteristics (attributes) of the Submitter and the Vaccination Event Submissions are important in evaluating vaccination data for data quality assurance purposes: there are different levels of confidence in different sources and ways they report. For example, Documentation Type and Method of submission affects the level of confidence in the immunization data (e.g., direct entry to the registry vs. electronic feed).

Vaccination Event Record (not shown on the domain diagram) includes information about the vaccination event from all domain entities.

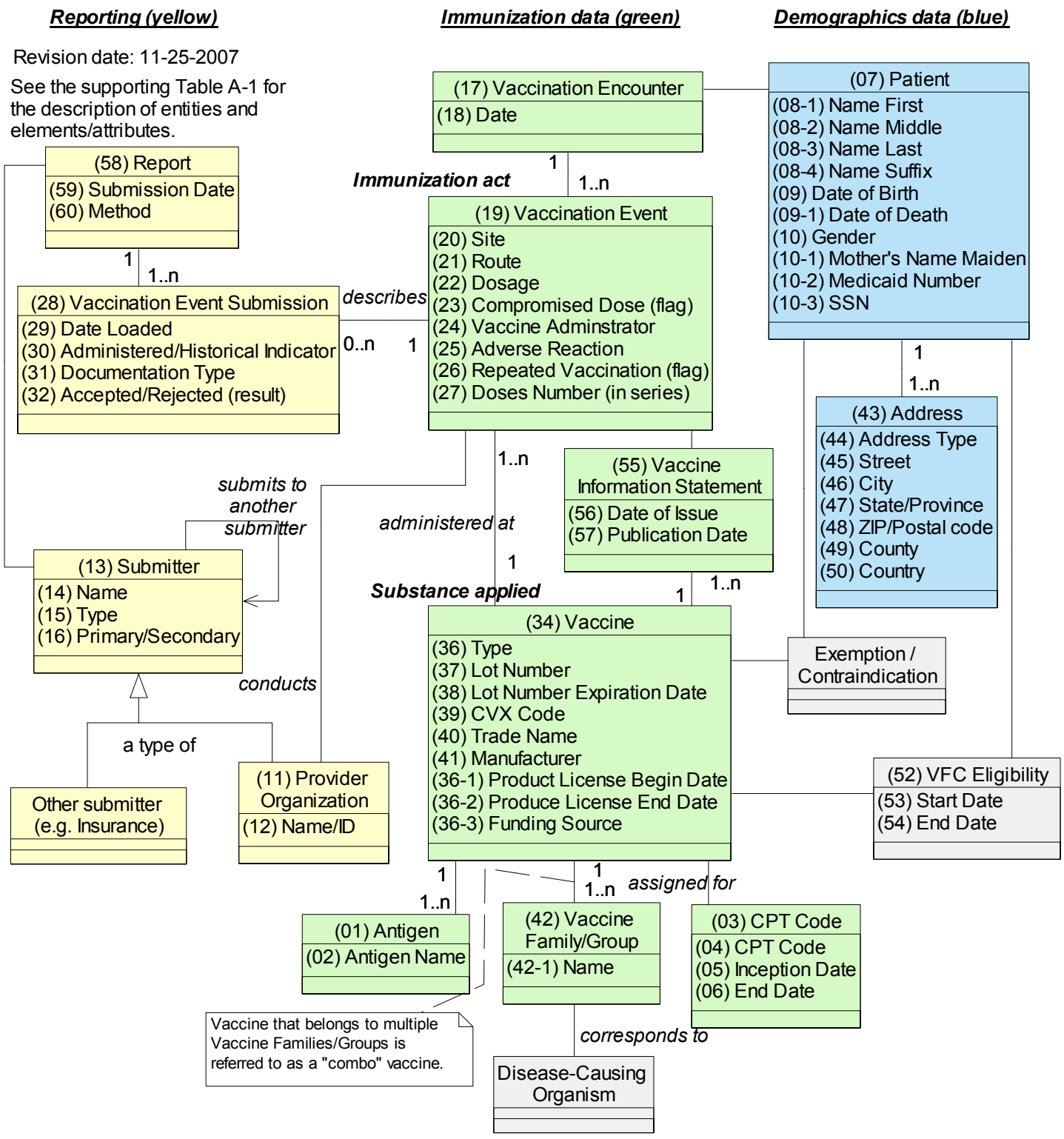


Figure A-1. Domain diagram

Table A-1. Entities and attributes (terms and definitions).

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
01	**Antigen** [2]		Antigen: a foreign (non-self) substance found in the body that can be either live (such as viruses and bacteria) or inactivated proteins and polysaccarides. Vaccinations allow the immune system to develop a defense against antigens. Every vaccine relates to one or more antigens.	See CDC *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 10th edition, Jan. 2007, Chapter 1, Principles of Vaccination. Also known as the "Pink Book" Vaccines are designed to confer immunity against specific disease antigens or toxins, like measles, polio and diphtheria. One or more doses of a vaccine, administered over a period of time, may be required to produce long-lasting immunity. Information about antigens usually derived from other immunization information, e.g. vaccine type, trade name.
02	Antigen	Name		Examples: diphtheria, tetanus, pertussis Usually derived from other immunization information, e.g. vaccine type, trade name HL7: n/a CDC Core Data Set: N
03	**CPT Code**		Procedure Code related to the vaccine.	These are billing codes. Used along with CVX codes (see below). Some CPT Codes have been re-used. There are vaccines that do not have CPT codes. CPT™ codes from the "Immune Globulins and Vaccines, Toxoids" sections of the American Medical Association's Current Procedural Terminology (CPT) 2006 http://www.cdc.gov/vaccines/programs/iis/stds/cpt.htm

[1] Formatting : a) for HL7: <name>(table/item number); b) for CDC Core Data Set: Y <name> – in data set, N – not in data set, N/A – not applicable.
[2] Rows related to Entities are shaded, rows related to Attributes of these Entities are not shaded.

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
04	CPT Code	CPT Code	CPT: Stands for Current Procedural Terminology. Codes developed by the American Medical Association that stand for medical or psychiatric procedures performed by healthcare practitioners.	Example: 90700 – DTaP AMA: http://www.ama-assn.org/ama/pub/category/3113.html HL7: Administered Code (0292/00347) CDC Core Data Set: N
05	CPT Code	Inception Date	The inception date is the published date when the CPT code is allowed to be used. The inception date may not be the date of licensure of the vaccine.	HL7: n/a CDC Core Data Set: N
06	CPT Code	End Date	The end date is when the published CPT code is not allowed to be used for that vaccine.	HL7: n/a CDC Core Data Set: N CPT codes are typically valid for certain periods; therefore, dates can be used to assess validity.
07	**Patient**			Just a few attributes for the Patient that are relevant to the topic of data quality assurance are present in this domain model.
08-1	Patient	Name First		HL7: Name Type (0200 /00108) CDC Core Data Set: Y (Patient name: first, middle, last)
08-2	Patient	Name Middle		HL7: Name Type (0200 /00108) CDC Core Data Set: Y (Patient name: first, middle, last)
08-3	Patient	Name Last		HL7: Name Type (0200 /00108) CDC Core Data Set: Y (Patient name: first, middle, last)
08-4	Patient	Name Suffix		HL7: Name Type (0200 /00108) CDC Core Data Set: Y (Patient name: first, middle, last)
09	Patient	Date of Birth	The patient's date of birth, either stated or reported on the patient's birth certificate.	Used for data validation, e.g., vaccinations given before birth date are invalid. HL7: Date of Birth (00110) CDC Core Data Set: Y (Patient birth date)

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
09-1	Patient	Date of Death	The date of death.	Used for data validation
10	Patient	Gender	This is the observed or reported patient's Sex.	One vaccine at this time is gender specific—HPV for females. HL7: Sex (0001/00111) CDC Core Data Set: Y (Patient sex)
10-1	Patient	Mother's Name Maiden		Unreliable data field in patient's record—missing often, misunderstood, stores other data fields (next appt. date, etc.). Also, people often do not like to give it out (sensitive data). Very helpful to match records when accurate.
10-2	Patient	Medicaid Number		Can be validated with external systems.
10-3	Patient	SSN		While online verification of Social Security Numbers is possible through the SSA, it will probably be impossible for Health Departments to gain access to this service since they have no legitimate right to ask for the SSN in the first place. Most newborns today receive SSNs automatically through a request on their birth certificate work sheet. When this happens, SSA responds electronically with the assigned number to the VR agency. Therefore, a newborn SSN from VR can be presumed to be valid. CA, MI, are not storing it. VT does not collect it. GA, MN – store it, but cannot show it.
11	**Provider Organization**		A provider organization is a collection of related providers (clinicians) that are treated as an entity that administered immunizations. Provider Organization "owns" the immunization.	The provider organization of the vaccination event may be unknown. In some instances it could be difficult to identify a Provider Organization. For instance, an IPA (Independent Practice Association) submits data on multiple clinics which are not related in a sense of owning a vaccine. Provider's profile should have information on how to route follow-up requests.

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
12	Provider Organization	Name/ID	This name can be a corporate name and may include a number of different provider offices/sites and physician groups.	Example: Dr. Smith Associates HL7: Administered-at location (0292/00353) CDC Core Data Set: Y (Vaccine provider)
13	**Submitter**		Entity that submits immunization data to the registry. The "Submitter" is the organization that reports a Vaccination Event	Also known as source; indicates where the information came from. Provider's profile should have information on how to route follow-up requests.
14	Submitter	Name	Name of the organization that submits a report regarding the vaccination event.	HL7: n/a CDC Core Data Set: N
15	Submitter	Type	Can include all types of providers and organizations submitting data to the registry: Values can include but are not limited to: o Public and private healthcare providers (administering vaccines) o Public and private healthcare providers–" Other" (entering historical shot information) o Health plans – Third-party provider or HMO o Public and private schools (administering vaccines and/or entering historical shot information) o Other registries—by electronic interfaces or batches o WIC (entering historical information) o Head Start centers and child care providers o Medicaid (billing batches)	Insurance is one type of submitter. See also Primary/Secondary for Vaccination Event Submission. HL7: see table NIP007 CDC Core Data Set: N

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
16	Submitter	Primary/ Secondary	The "primary submitter" is the PROVIDER ORGANIZATION that submits a VACCINATION EVENT SUBMISSION and claims that it conducted the VACCINATION EVENT (administered the VACCINE). The "secondary submitter" is a SUBMITTER that submits a VACCINATION EVENT SUBMISSION and is not the PROVIDER ORGANIZATION that conducted the VACCINATION EVENT.	Secondary submitter data can be differentiated from the primary submitter if the administering provider name is included in the data for each vaccine dose. Submitters will in most cases be the Provider Organization where the vaccine is administered, but may be a secondary entity that collects reports from multiple sources (for example, a regional immunization registry passing reports to a state registry), or one that receives and transcribes reports of historical vaccine events (such as a school record or an immunization card carried by the patient). HL7: Sending Facility (00004) Administration Notes (NIP001/00351) indicates whether the vaccine event information is from the vaccine provider, or other source. CDC Core Data Set: N
17	**Vaccination Encounter**		The visit data	Several vaccination events can happen within one vaccination encounter.
18	Vaccination Encounter	Date	Date of the vaccination. The date that the patient received dose(s) of the vaccine(s).	HL7: Date/time start of administration (0292/00345) or Date/time end of administration (0292/00346). CDC Core Data Set: Y (Vaccination date).
19	**Vaccination Event**		Administration of one Vaccine to a Patient. Several vaccination events can happen during one vaccination encounter.	Example: a "needle stick", a tablet. The presence or absence of some of these items may inform the decision to determine the best immunization from a match.
20	Vaccination Event	Site	Anatomical site where immunization was administered.	CDC Pink Book: Appendix D: Vaccine Administration Guidelines, page 5:Administering Vaccines—Dose, Route, Site, and Needle Size. HL7: Administrative site (0163/00310) CDC Core Data Set: Y (Vaccine injection site)

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
21	Vaccination Event	Route	The method of administration. Includes injection, intranasal or oral.	HL7: Administrative Route (0162/00309) CDC Core Data Set: N
22	Vaccination Event	Dosage	The measurement of how much vaccine was administered.	HL7: Administered Amount (0292/00348), Administered Units (0292/00349) CDC Core Data Set: N Examples: 1 mL, .5 mL, 1 microgram, … Examples: 1 dose, 2 doses, 0.5 doses, …
23	Vaccination Event	Compro-mised Dose (flag/indi-cator)	A flag indicating that a dose of vaccine should not considered when evaluating the immunization history. A "compromised" indicator. Indicates that a dose administered to a patient is considered substandard and therefore not a valid dose. ***Out of scope for the DQA topic***	There are a number of reasons that a dose of vaccine is not considered when evaluating the immunization history. These include: -immunization with product that has been compromised (too old, overheated, or expired), -uncertain quantity of vaccine has been administered (e.g., the child jerked away during administration and some of the vaccine was spilled). Recording them in the registry is important for several reasons including: - maintaining accurate inventory - noting lots used (in case of recall) - Indicator of need for a repeat dose (sometimes given immediately) Deduplication algorithms should not identify these as duplicate records, but rather duplicate vaccines of which the second dose is the valid (kept) dose. HL7: Completion Status (0322/01223) and OBX notes CDC Core Data Set: N

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
24	Vaccination Event	Vaccine Adminis-trator	The person who gave the vaccination (as opposed to the Provider Organization above).	Example: Dr. Smith HL7: Administering Provider (0292/00352) CDC Core Data Set: n/a
25	Vaccination Event	Adverse Reaction	Used to indicate if an adverse event (AE) is associated with a vaccination event. A vaccine adverse event can include any adverse reaction that the patient experiences after receiving a dose of vaccine.	See http://www.vaers.hhs.gov/reportable.htm HL7: n/a CDC Core Data Set: N
26	Vaccination Event	Repeated Vaccina-tion (flag)	A flag indicating that a dose of vaccine has been administered as a remedy to a compromised dose (see above).	A single flag (this one or Compromised Dose flag) would be sufficient for implementation purposes. HL7: n/a CDC Core Data Set: N
27	Vaccination Event	Dose Number (in series)	A specification of which dose in the series. A sequential number.	HL7: n/a CDC Core Data Set: Y (Vaccine dose number) Examples: 1 of 3, 2 of 3, …
28	**Vaccination Event Submission**		A report regarding the vaccination event.	A submission could be sent twice (or more), once by provider organization and once by other source. Vaccination Event Submission is a part of the Report (see item 58).
29	Vaccination Event Submission	Date Loaded	The date that the vaccine event data were loaded into the registry (usually from a batch file). This is the completion of the data submission.	These data may not be visible to the user from the GUI (graphic user interface) and therefore may not be available. Also, this date should not be confused with the vaccine event date. This is not necessarily the date that the report was sent. This is not necessarily the date the report was received. HL7: n/a; Internal variable used to monitor when data is ready to take action. CDC Core Data Set: N

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
30	Vaccination Event Submission	Adminis-tered/ Historical Indicator Formerly, Record Source Type	Values: Administered or Historical. "Administered" means that submitter attests that they gave this shot (administered the vaccination event). All other cases are considered to be "Historical."	"Historical" is another provider's data. "Historical" can come only from Secondary submitter; also, "Transcribed" (see below) can come only from Secondary submitter. "Administered" can come only from Primary submitter. Possible situation: more than one submitter claims the shot. HL7: NIP 001 Immunization Information source? or Source of comment (0105/ 00097) ? CDC Core Data Set: N
31	Vaccination Event Submission	Documentation Type	Values: o Billing/Claim o Clinical o Transcribed Transcribed describes information received from a "secondary submitter," e.g., second-hand information.	Example: one doctor called another doctor for the information. HL7: n/a CDC Core Data Set: N
32	Vaccination Event Submission	Accepted/ Rejected (the result)	An accepted vaccine event submission means that the data conformed to the data guidelines and were or will be uploaded into the registry. A rejected vaccine event submission means that the vaccine event data did not conform to the data submission guidelines of the registry and were or would not be uploaded into the registry.	HL7: n/a CDC Core Data Set: N

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
34	**Vaccine**		A vaccine is a product that is intended to produce an immune response(s) in a patient. The product that is given; the VACCINE that was administered at the vaccination event.	Vaccines can be identified generically or by brand name (or both) in a registry. Some registries identify equivalent vaccines. Issue: Antiviral (?) Example: The specific package in the refrigerator. Absence/presence of vaccine data items is a criterion when evaluating which record is best.
35			Reserved (see item 42 for the former item 35)	
36	Vaccine	Type	The vaccine type is the specific kind of vaccine given during the vaccination event. It is the formulation – the "the kind of stuff in the bottle."	Examples: Hib-HbOC, HepB-Hib. This should map to CVX. There is normally one CVX Code per one vaccine type. There are vaccine types that do not have a CVX code. The vaccine type can include single types of vaccines as well as combination vaccines, e.g., IPV, or IPV, DTaP, HepB. Also the vaccine type data may indicate a generic or specific type of vaccine: e.g., pneumo or PCV7 or PPV23. HL7: Administered Code (0292/00347). This is CVX code CDC Core Data Set: Y (Vaccine type)
36-1	Vaccine	Product License Begin Date	When the trade name or product license began.	
36-2	Vaccine	Produce License End Date	When the trade name or product license ended.	
36-3	Vaccine	Funding Source		Can be used in conjunction with VFC eligibility.

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
37	Vaccine	Lot Number	The lot number is the number assigned by the manufacturer for a specific batch of vaccine developed and distributed. This is the tracking number of the administered vaccine.	HL7: Substance Lot Number (0292/01129) CDC Core Data Set: Y (Vaccine lot number)
38	Vaccine	Lot Number Expiration Date	Manufacturers are required to assign a lot number expiration date to each batch of vaccine.	Note: This is important to some registries to provide reasons why a record was not loaded (not all registries have business rules associated with this). HL7: Substance Expiration Date (0292/01130) CDC Core Data Set: Vaccine expiration date

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
39	Vaccine	CVX Code	The typical representation of the vaccine type reflected as a CVX code. There is generally one CVX code per one vaccine type, which may include one or more vaccines. This is a standard set by CDC.	Example: 47 – Hib-HbOC CDC assigns specific CVX codes to each vaccine or combination of vaccines. Note: there are CVX codes for vaccines that do not exist. Those codes are considered placeholders. There have been issues in the past when some have been reassigned, but generally this is not supposed to happen. There are vaccine types that do not have a CVX code. It was intended that a CVX code would be paired with the code for Manufacturer (s) (code = MVX) and this pair would indicate a specific vaccine, e.g., brand name. VR agencies typically capture only the vaccine trade name, not CVX. HL7: Administered Code (0292/00347) CDC Core Data Set: Y (Vaccine type)
40	Vaccine	Trade Name	The Trade Name is the name under which the manufacturer copyrights the vaccine(s). Trade name is synonymous with the Brand name. A trade name usually assigned by manufacturer to identify vaccine type.	Example: ACTHIB®, COMVAX® (HepB-Hib) CDC Pink Book, Appendix B, U.S. Vaccines If Trade Name is not actively collected by a particular IIS, it can be derived from other variables, e.g., Vaccine Type and Manufacturer Name. HL7: n/a CDC Core Data Set: N

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
41	Vaccine	Manufacturer	Organization that manufactured a vaccine. The manufacturer refers to the company that develops and distributes vaccine(s). There may be several manufacturers of a particular vaccine family/group and/or vaccine type.	CDC assigns an MVX code to specific vaccine manufacturers. Issue: The manufacturer can change when a brand is sold to a different manufacturer. http://www.cdc.gov/vaccines/pubs/pinkbook/pink-appendx.htm It was intended that a MVX code would be paired with the code for vaccine (code = CVX) and this pair would indicate a specific vaccine, e.g., brand name. HL7: Substance manufacturer name (0227/01131) CDC Core Data Set: Y (Vaccine Manufacturer) HL7: n/a CDC Core Data Set: N VR agencies typically capture only the manufacturer name, not MVX.

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
42	**Vaccine Family/ Group**		The ACIP Immunization Schedule describes several categories, which in general correspond to individual antigens, and sets forth, for each one, the number of immunization doses that will be required to produce complete immunity, based on immunological research and clinical trials. These categories will be referred to as immunization series (*Families/Groups*). http://www.cdc.gov/vaccines/programs/iis/pubs/prog-eval-guide.htm.	ACIP classification of the Vaccine Family/Group Name should be followed as the standard. It may be extended as necessary Example: Hib, HepB, IPV Examples are: The DTP family can include DT, DTaP, Tdap, Td, DTP. Although immunization series (Family/Group) in the ACIP Schedule generally correspond to single antigens, this is not always so: DTP (diphtheria-tetanus-pertussis) and MMR (measles-mumps-rubella) are regarded as series (Family/Group), even though they each refer to multiple antigens. It would be more to the point to say that immunization series (Family/Group) correspond to vaccines, rather than antigens, since both DTP and MMR are vaccine products. http://www.cdc.gov/vaccines/programs/iis/pubs/prog-eval-guide.htm Is crucial in the first step of finding pairs for deduplication to consider. HL7: n/a CDC Core Data Set: n/a
42-1	Vaccine Family/ Group	Name	The Vaccine Family/Group Name is a broad category of vaccines that are related by vaccine type. There is not necessarily a one-to-one relationship between Family/Group Name and Type. There may be multiple family/group names for one vaccine.	Family/Group name usually derived from other information, e.g., trade name, CVX code.
43	**Address**			There are maybe multiple addresses per patient HL7: 00114
44	Address	Address Type		
45	Address	Street		

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
46	Address	City		
47	Address	State/ Province		
48	Address	ZIP/ Postal code		
49	Address	County		
50	Address	Country		
51			Reserved	
52	**VFC Eligibility**			At the shot level; patient can be eligible for one vaccine but not eligible for another vaccine. HL7 does not support shot-level VFC eligibility.
53	VFC Eligibility	Start Date		
54	VFC Eligibility	End Date		
55	**Vaccine Information Statement**		Vaccine Information Statements (VISs) are information sheets produced by CDC that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Federal law requires that VISs be handed out whenever (before each dose) certain vaccinations are given.	
56	Vaccine Information Statement	Date of Issue		
57	Vaccine Information Statement	Publication Date	Defines a revision/version.	

	Name		Description	Remarks & Relationship to other standards (HL7) [1]
58	**Report**		Collection of vaccination events that have been submitted, e.g., a batch file with thousands of patients and shots or a single electronic message. Includes one or more Vaccination Event Submissions (see item 28).	
59	Report	Submission Date	Is the date that the data were received, but not necessarily loaded by IIS.	
60	Report	Method	This has nothing to do with the information content; it is strictly how the information was submitted (the medium). Values o Electronic Interface (HL7 or other) o Registry Specific User Interface	User interface is an opportunity to seek human evaluation and decision. Some registries may use this information to direct them how to evaluate duplicates. They may trust data via the user interface more than electronic or batch data. User interface, although not entirely error-free, is an opportunity for human evaluation and decision. HL7: n/a CDC Core Data Set: N

Appendix B. Data Quality Framework—Completeness, Accuracy, and Timeliness

Accuracy is the extent to which the data recorded in the IIS match what happens in a clinical encounter, whether or not the information is clinically appropriate (***concordance***).

In other words, accuracy is the degree to which the registry data reflect what occurred in the visit. Accuracy of incoming data is hard to determine without comparing to the medical record, which is a proxy for the visit.

There are two types of metrics for accuracy:

1) A good, but not always practical standard
In many cases the data in the IIS look okay, but they may not be. More precise accuracy measures are done by comparing data elements in incoming data with the same data in the medical record. In precertification, and periodically, a random sample of records (patients with their immunizations) can be selected from the incoming data and compared to the medical record or AFIX data. Metrics include:

- % of DOBs that match
- % of vaccine types (e.g., CVX codes) that match
- % of vaccine dates that match
- % of manufacturers that match
- % of names that match
- % of addresses that match

The IIS can use the elements it considers important to do this analysis.

2) A more practical approach
There are high-level (gross) accuracy measures that can indicate whether the data "look" accurate—without referring to the chart. For example:

- % of patients with an unreasonable number of vaccination events in an encounter
- % of immunization types in each file. Are some missing, over- or underrepresented?
- % of records with DOB prior to immunization date
- % of records with DOB or immunization date in the future
- % of vaccine administered before the vaccine license date

A high percentage of errors would definitely indicate poor quality of incoming data. However, a low percentage of these errors does not necessarily indicate high-quality data.

Completeness refers to the recording of full information on cases/events. There are two types of completeness:

- Comprehensive reporting of **all vaccination events** that encompasses all vaccinations for all patients from all providers
- Complete recording of **all data elements** for a particular event. This characteristic is often monitored by tabulating the use of "unknown" and other non-specific codes.

There are 5 levels of metrics for completeness:

1) All individuals within the targeted age range are reported (everybody, i.e., from vital statistics and only immunized, from health care providers, insurance plans, etc.). To determine completeness at this level, one has to do a comparison to the provider's population. One way to do this is to define a specific day or a specific week and generate a list of all patients that were vaccinated during that week according to the IIS. Ask the provider to generate a list of all patients who were vaccinated that week and compare the two lists. Determine

- % of individuals vaccinated in the clinic not reported to the IIS
- % of individuals not vaccinated in the clinic reported to the IIS (That would be an accuracy issue)

2) All providers that administer immunizations in a jurisdiction report to the IIS

3) All immunization events that are reflected in providers' records are reported to the IIS

This can be examined at the gross level to see if the files "look okay": Vaccine distribution at the file level: Are there types of vaccines characteristic of the particular practice type that are missing? Are all of these vaccines represented in the transfers in the appropriate proportions? This analysis would identify systematic errors due to miscoding or consistent data entry errors.

More subtle analysis would involve comparing records in the data file submitted with those in the chart. For example, select a random sample of individuals in the file, and then compare to the chart:

- % of immunizations found in the chart not reported to the IIS

Note that in the case 1 above all the people might be there but their events might not be. In this case, all the events might be there, but people without events could be missing.

4) All elements of the immunization event are transferred to IIS:

Frequency analysis of the elements an IIS considers important will determine each element's completeness in the IIS

% of records with immunization date
% of records with CVX code
% of records with manufacturer
% of records with lot number
% of records with administering provider

Important distinction here is that this does not imply that all events are recorded (as in the case 3 above). In this case it just addresses the completeness of all events that happen to be found.

5) All elements of the demographic part of the immunization record present

Timeliness reflects the degree to which the time between an event of interest to IIS and the recording of this event in the IIS falls within recommended limits; this also applies to the time between any intermediate events/stages of this process.

Delays may be introduced at several different points from the moment a vaccine is administered to the point when it appears in the IIS. The IIS can have overall metrics (for overall timeliness), and also have more specific metrics that measure specific delays in the journey of the immunization record. All these metrics can be represented in terms of percentage of immunizations in specific time ranges (% within 1 week, 1–4 weeks, >4 weeks, etc.)

- Number of days from DOB to when record appears in IIS—for Vital Records
- Number of days from vaccine administration to when it appears in the IIS
- Number of days from when record is submitted by the provider to when it appears in IIS
- Number of days from when a record is rejected to when the provider is notified
- Number of days from when a provider is notified to when a correction is reported

Appendix C. Workgroup Approach

Process

The process used for a development of best practices is presented on the **Figure C-1**. This process includes six steps described below. Responsibilities of parties involved in the best practices development effort are described in **Table C-1**.

Step 1. Topic selection is performed by the Steering Committee.

Step 2. Selection of subject matter experts (SMEs) is performed by the Steering Committee based on recommendations from the public health community.

Step 3. Preliminary work is performed by a small group of business Analysts and subject matter experts (SMEs). This work includes gathering and analyzing current practices for the selected topic. A goal is to develop materials that will serve as a basis for a productive face-to-face meeting. Common products of this step include development of a domain model and related glossary of common terms and definitions. Also, major areas of the collaborative work are defined during this step, including modeling instruments and templates used to elicit and capture information during the face-to-face session.

Step 4. The ***face-to face session*** is a culmination of best practice development efforts. It involves a multidisciplinary team of experts, business analysts, facilitators, observers, administrative staff, and sponsors (see **Figure C-2**). During the modeling session experts, acting in a focused, structured, and facilitated environment, analyze existing "as-is" practices, brainstorm solutions, and reach consensus regarding recommended best practices captured in the form of a "to-be" model.

Step 5. The post-meeting phase is designated to finalize recommendations developed during the face-to-face sessions. The major modes of collaboration during this phase are teleconferences and e-mails. The duration of this step varies from a few weeks to a few months depending on the amount and significance of remaining issues. Editors and external reviewers are involved in the creation of a resulting best practices recommendations document.

Step 6. During the implementation phase, a survey instrument is used to conduct targeted evaluation of IIS operations improvements resulting from utilization of the developed best practices and, later, targeted efforts are initiated to promote and encourage compliance as standards of excellence. Feedback from implementation efforts is analyzed, and best practice guidance recommendations are updated accordingly.

Methods and techniques

- Business modeling techniques are employed to analyze IIS processes and to develop the best practice recommendations.
- Facilitation and web-based teleconferencing techniques are used during the face-to-face meeting session and conference call meetings.
- Standard Unified Modeling Language (UML) notation is the notation of choice for this project. Subject matter experts do not need to have prior knowledge of this form of

notation. It is intuitive and easily interpreted by either technical or non-technical professionals. Necessary explanations of the UML notation will be provided during the face-to-face modeling sessions.

- The definition of a consensus among subject matter experts regarding developed best practice recommendations does not reflect an absolute 100% agreement, but rather it means "*I can live with that and support it.*"
- Best Practice Recommendations. Definition: A best practice is "a superior method or innovative approach that consistently exceeds the standard level of performance as determined by expert review, evidence of significant improvement vs. the standard approach, consistently superior results, or agreement of multiple sources."
  Yasnoff WA, Overhage JM, Humphreys BL, LaVenture M. A national agenda for public health informatics: summarized recommendations from the 2001 AMIA Spring Congress. J Am Med Inform Assoc 2001; 8(6):535–45.
  Simply speaking, a best practice for IIS is the agreed-upon "most superior way" to perform a particular routine operation(s).

Expected Products

Results of the analysis and the incremental, consensus-based recommendations development process are captured in the following business modeling artifacts:

- textual descriptions of restrictions, rules, and operational policies (***business rules*** modeling)
- diagrams of the processes and process-related collaborations among parties (UML ***activity diagrams***)
- diagrams of entities involved in the processes and their relationships (UML ***domain diagrams***)
- other products in tabular and textual formats, as well as supporting sketches and illustrations.

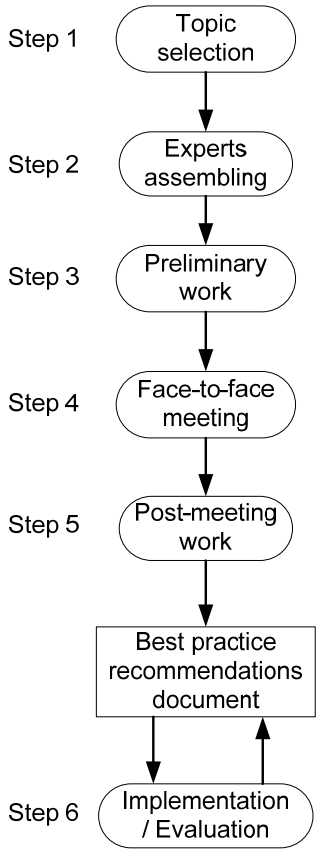


Figure C-1. The process of developing best practice recommendations

Table C-1. Process steps and participants responsibilities

	Steering Committee	Panel of Experts	Analysis Team	Facilitation Team	External Reviewers	Editorial Team
Step 1: Select the topic						
Step 2: Assemble experts						
Step 3: Preliminary work						
Step 4: Face-to-face meeting						
Step 5: Post-meeting work						
Step 6: Implementation						

Heavily involved Somehow involved Not involved

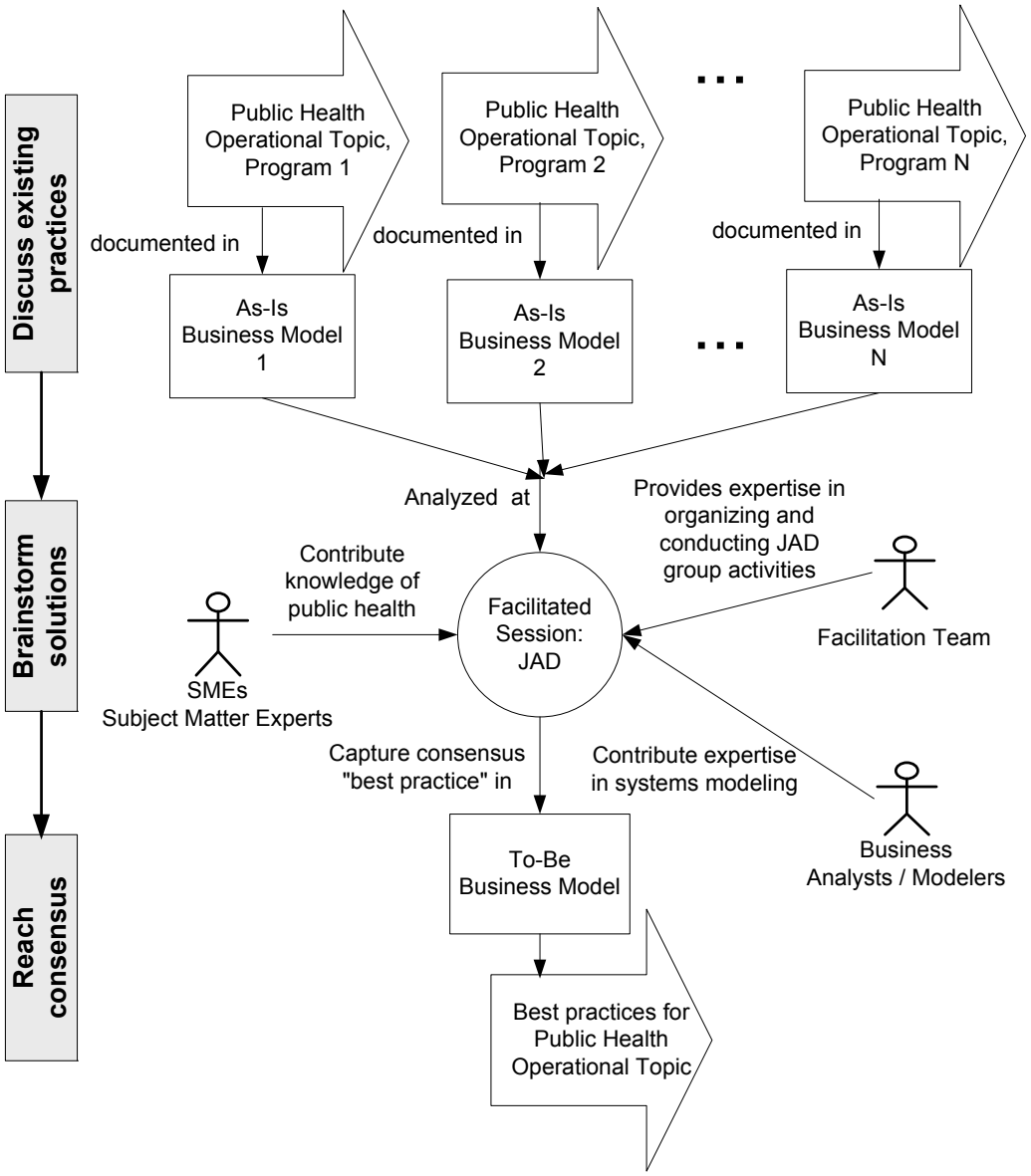


Figure C-2. Facilitated modeling session

Appendix D. ACIP Recommendations-Related Rules: Implementation Examples

Table D-1. ACIP Recommendations-related rules: implementation examples
(The following are examples of ACIP derived rules and are not an exhaustive list. These rules are subject to change based on ACIP recommendations, and therefore need to be periodically reviewed.)

Conditions (Criteria) for Business Rules	BR #	Comments
Rules pertaining to min/max age		
Any shot other than HepB given before 1 month of age	BR130	
DTP/aP, DT, Hib, Polio, PCV given at < 6 weeks of age	BR130	
3rd HepB given at < 6 months of age		
MMR given at < 1 year of age	BR130	
Varicella given at < 1 year of age	BR130	
PPV23 given at < 2 years of age	BR130	
Td given at < 7 years of age	BR130	
Hib containing vaccine given at ≥ 5 years of age	BR130	
PCV at ≥ 5 years of age	BR130	
DTP/aP, DT given at ≥ 7 years of age	BR130	
Tdap • ADACEL® given <11 years or ≥65 years • BOOSTRIX® given <10 years or ≥19 years	BR130	
A measles, mumps, rubella-containing vaccine given to an individual born before 1957	BR130	
Rules pertaining to minimum intervals between doses		
DTP/aP, DT, Hib, Polio, HepB, PCV: Minimum interval between doses 1-2 < 28 days	BR131	
DTP/aP, DT, Hib, Polio, PCV: Minimum interval between doses 2-3 < 28 days	BR131	
Minimum interval between 2 live vaccines (e.g., MMR and Var) < 4 weeks	BR131	
Rules pertaining to general ACIP schedule		
More than 2 doses of DTP/aP/Polio/Hib/PCV given < 4 months	BR128	
More than 3 doses of DTP/aP/Polio/Hib/PCV given < 6 months	BR128	
More than 14 total shots given < 6 months	BR128	
More than 4 doses of DTP/aP/Hib/PCV given < 12 months	BR128	
More than 3 shots of Polio given before 24 months	BR128	
More than 20 shots given before 24 months	BR128	
More than 5 shots of the same vaccine given before 6 years	BR128	

Appendix E. Examples: Utilization of Providers' Profiles for Analysis of Reported Data Quality

This method compares the proportion of vaccines in the prospective clinic with the proportion of vaccines in the ideal distribution (see section " Precertification and Providers' Profiles" of this guide).

In a case study of a pediatric practice (**Figure E-1**), the ideal distribution is based on the recommended childhood schedule. The actual percentages are compared with the ideal percentages for each series. Because several vaccines are given in combination, all components have to be broken down and added to the appropriate series: e.g., the number of Pediarix's® has to be added to the number of DTaPs to come up with the total number of DTaPs given for the DTP series.

The example of application of the same approach to the adolescent practice is presented on **Figure E-2.** The comparison between the actual and ideal distributions does not work as well as with children in this case. Part of the reason may be that many of the recommendations for adolescents are new and often not adopted as readily as childhood recommendations.

VACCINE_NAME	Frequency	Percent
Adeno T7	1	0
DT-Peds	20	0.06
DTAP/Polio/Hep B	3779	10.62
DTaP	2458	6.91
FLU 6-35 Months	271	0.76
FLU >= 3 Years	2926	8.22
FLU p-free 6-35 months	1666	4.68
FLU-Nasal	13	0.04
HPV quadrivalent	31	0.09
HepA-Adult	186	0.52
HepA-Ped 2 Dose	6840	19.23
HepA-Unspecified	1	0
HepB adolescent- 2 dose	3	0.01
HepB-Hib	7	0.02
HepB-Peds	267	0.75
HepB-Unspecified	1	0
Hib-HbOC	3733	10.49
Hib-OMP	4	0.01
Hib-PRP-D	3	0.01
Hib-PRP-T	12	0.03
Hib-Unspecified	2	0.01
Ig	10	0.03
Lyme	2	0.01
MCV4 (Meninge conjugate)	1	0
MMR	1250	3.51
MMRV	1247	3.5
MPSV4 (Meninge poly)	3	0.01
Mumps	1	0
Pneumo-PCV7	4801	13.49
Pneumo-PPV23	48	0.13
Polio-Inject	1244	3.5
RIg	18	0.05
RSV-IgIM	16	0.04
Rabies-IM	37	0.1
Rotavirus	2337	6.57
Td	80	0.22
Tetanus	2	0.01
Typhoid-Oral	1	0
Typhoid-ViCPs	15	0.04
Varicella	2241	6.3
Total	35578	99.97

1

"idealized" pediatric practice vax distribution for children < 6 years of age

Series	count	% IDEAL
HepB	3	8.8
Rotavirus	3	8.8
DTP	5	14.7
Hib	4	11.8
PCV	4	11.8
IPV	4	11.8
Influenza	5	14.7
MMR	2	5.9
Varicella	2	5.9
HepA	2	5.9
TOTAL	34	100.0

2

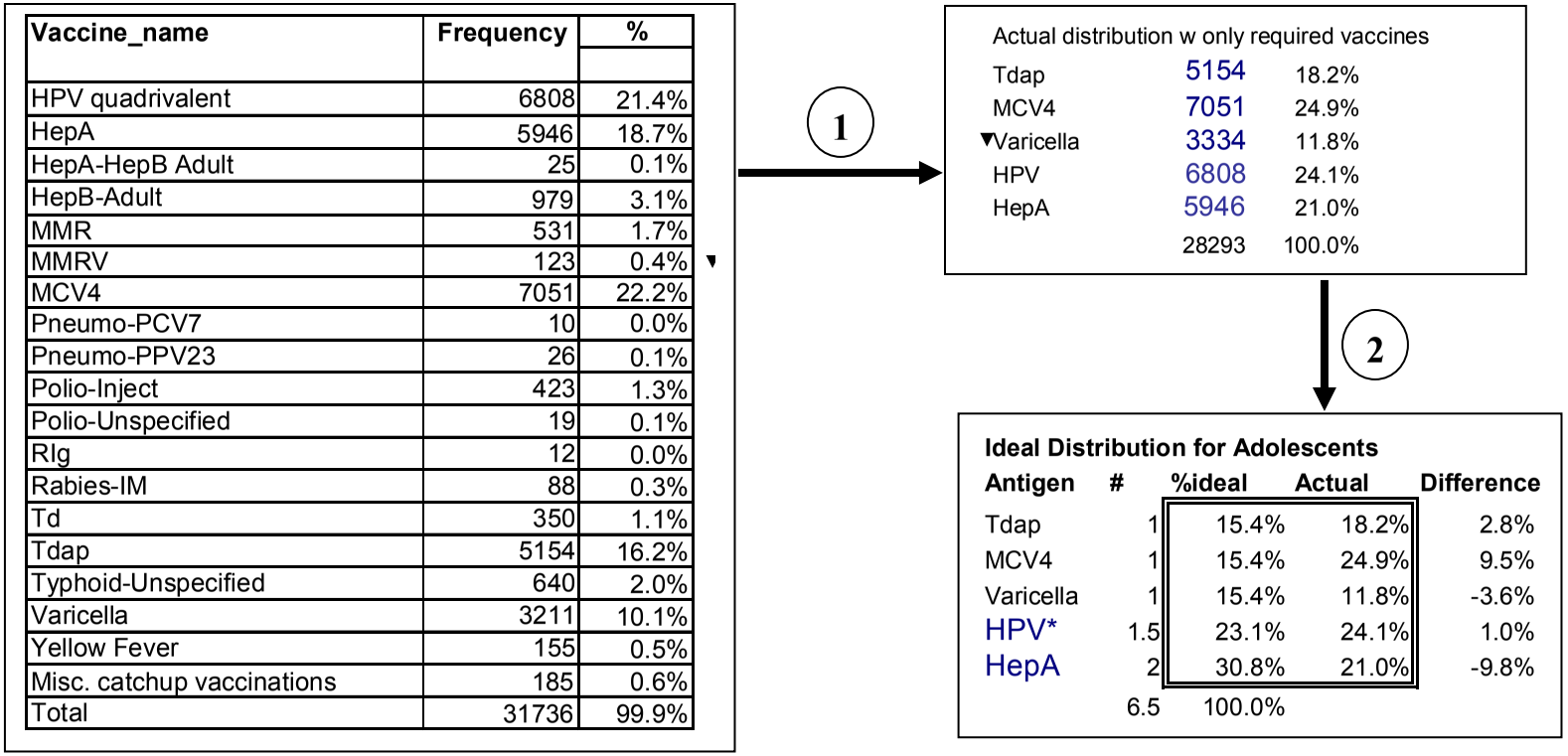
CLINIC DATA	COUNT	%	% IDEAL	Difference
HepB	4054	9.2	8.8	0.4
Rota	2337	5.3	8.8	-3.5
DTP	6257	14.2	14.7	-0.5
Hib	4029	9.1	11.8	-2.6
PCV	4801	10.9	11.8	-0.9
IPV	5023	11.4	11.8	-0.4
Influenza	4863	11.0	14.7	-3.7
MMR	2497	5.7	5.9	-0.2
Varicella	3488	7.9	5.9	2.0
HepA	6840	15.5	5.9	9.6
TOTAL	44189			

3

HepA seems higher than expected… why?

Outbreaks of hepatitis A in this IIS area had prompted increased recommendations for hepatitis A vaccination

Figure E-1. Example: All Shots Given at a Certain Facility to Children <6 years of age, 01/01/2007–11/07/2007



Vaccine_name	Frequency	%
HPV quadrivalent	6808	21.4%
HepA	5946	18.7%
HepA-HepB Adult	25	0.1%
HepB-Adult	979	3.1%
MMR	531	1.7%
MMRV	123	0.4%
MCV4	7051	22.2%
Pneumo-PCV7	10	0.0%
Pneumo-PPV23	26	0.1%
Polio-Inject	423	1.3%
Polio-Unspecified	19	0.1%
RIg	12	0.0%
Rabies-IM	88	0.3%
Td	350	1.1%
Tdap	5154	16.2%
Typhoid-Unspecified	640	2.0%
Varicella	3211	10.1%
Yellow Fever	155	0.5%
Misc. catchup vaccinations	185	0.6%
Total	31736	99.9%

Note: The comparison between the actual and ideal distributions does not work as well as with children in this case. Part of the reason may be that many of the recommendations for adolescents are new and often not adopted as readily as childhood recommendations.

Figure E-2. Example: All Shots Given at a Certain Facility to Adolescent Patients, 01/01/2007–11/07/2007

Appendix F. A possible statistical approach to an automated methodology for utilization of providers' profiles for analysis of reported data quality

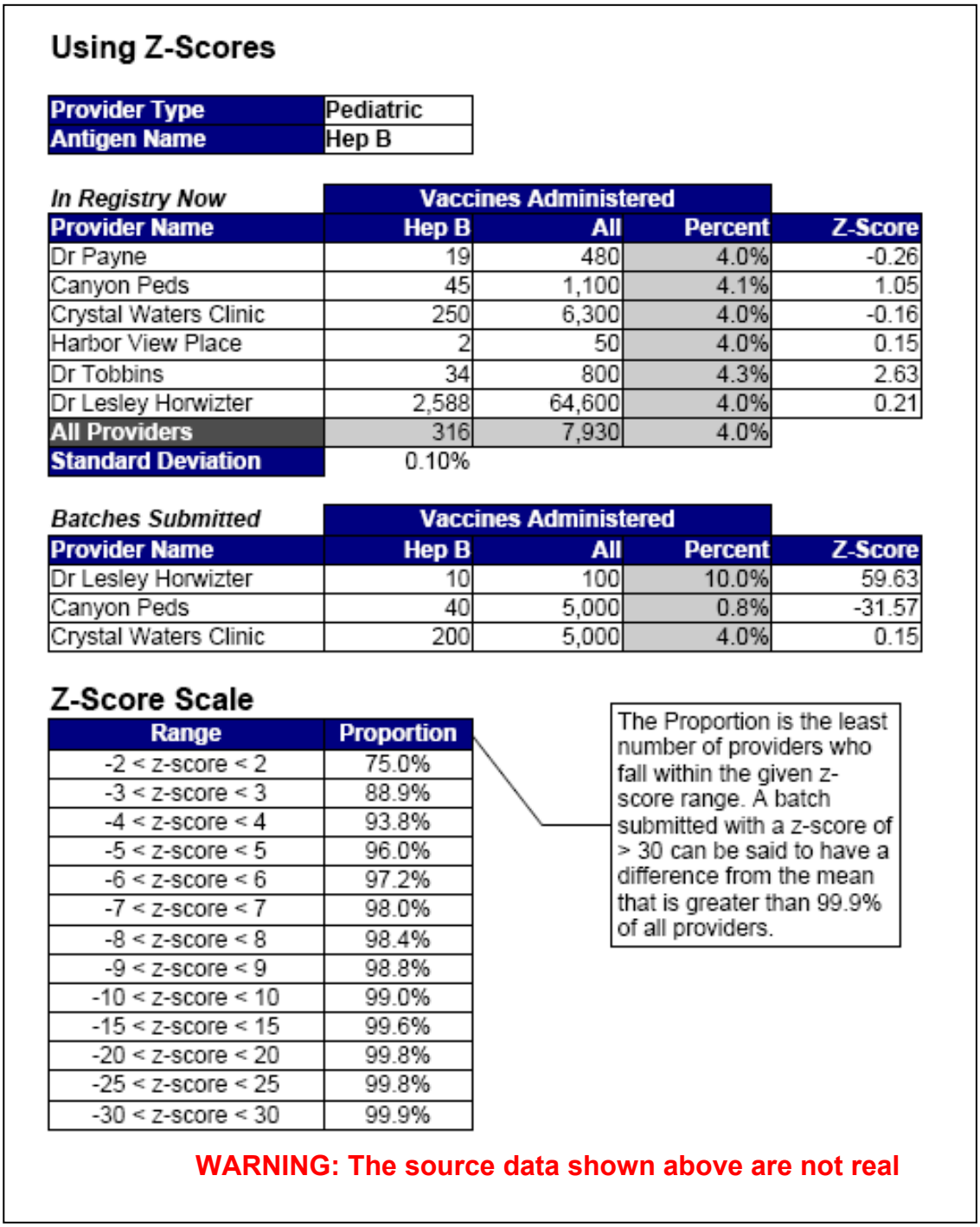
Note: see Chapter 6 " Precertification and Providers' Profiles" of this document.

The IIS needs to be able to flag batches of data (incoming, precertification, or post-import processing) that have administered vaccines that do not match what is expected for that kind of practice. A possible solution is to use standard deviation and z-scores to determine batches that fall outside the norm. Following is how that could be done:

1. First the registry categorizes their current providers into different groups based on what type of population they are serving. These will be called PROVIDER GROUPS.
2. A set of antigens will be identified for each PROVIDER GROUP.
3. Queries are run on the registry's current production environment to determine the percentage of administered vaccines with the indicated antigen. For each provider this percentage will be termed the " Provider Percent." An average score for all the groups will also be determined using the same method and will be called "Mean Percent ."
4. Using these values, a standard deviation will be determined for the percents in this group. Standard Deviation = SQRT(SUM((Provider Percent - Mean Percent) ^ 2 / (Number of Providers)).
5. Using this standard deviation a Z-score can be given to each provider's batch for each antigen. Z-score = (Provider Percent - Mean Percent) / Standard Deviation (**Figure F-1**)
6. When -1 < Z-score < 1 is true for a given provider, it can be said that that provider's reporting of a particular antigen is within one standard deviation of the norm.

Using the standard deviations is then possible to focus on batches of data that fall outside the norm. Batches that fall outside the norm should be reviewed. It may be that the provider does not belong to the PROVIDER GROUP it was assigned to, providers may not be reporting data as they should, or the deviation may represent a new practice that is not yet widespread.

This process assumes that the registry data is already accurate and is a good model in of itself.



Using Z-Scores

Provider Type	Pediatric
Antigen Name	Hep B

In Registry Now

	Vaccines Administered			
Provider Name	**Hep B**	**All**	**Percent**	**Z-Score**
Dr Payne	19	480	4.0%	-0.26
Canyon Peds	45	1,100	4.1%	1.05
Crystal Waters Clinic	250	6,300	4.0%	-0.16
Harbor View Place	2	50	4.0%	0.15
Dr Tobbins	34	800	4.3%	2.63
Dr Lesley Horwizter	2,588	64,600	4.0%	0.21
All Providers	316	7,930	4.0%	
Standard Deviation	0.10%			

Batches Submitted

	Vaccines Administered			
Provider Name	**Hep B**	**All**	**Percent**	**Z-Score**
Dr Lesley Horwizter	10	100	10.0%	59.63
Canyon Peds	40	5,000	0.8%	-31.57
Crystal Waters Clinic	200	5,000	4.0%	0.15

Z-Score Scale

Range	Proportion
-2 < z-score < 2	75.0%
-3 < z-score < 3	88.9%
-4 < z-score < 4	93.8%
-5 < z-score < 5	96.0%
-6 < z-score < 6	97.2%
-7 < z-score < 7	98.0%
-8 < z-score < 8	98.4%
-9 < z-score < 9	98.8%
-10 < z-score < 10	99.0%
-15 < z-score < 15	99.6%
-20 < z-score < 20	99.8%
-25 < z-score < 25	99.8%
-30 < z-score < 30	99.9%

The Proportion is the least number of providers who fall within the given z-score range. A batch submitted with a z-score of > 30 can be said to have a difference from the mean that is greater than 99.9% of all providers.

WARNING: The source data shown above are not real

Figure F-1. Z-Scores Illustration

Appendix G. Vaccine Site/Route Guide

Adapted from the 2003 Red Book and ACIP General Recommendations (MMWR 2006:51 [No.RR-2]:15–18

Vaccine	Route	Site
DTaP	IM	L/R Anterolateral Thigh or Deltoid
Td	IM	L/R Anterolateral Thigh or Deltoid
DT	IM	L/R Anterolateral Thigh or Deltoid
Hib	IM	L/R Anterolateral Thigh or Deltoid
HepB	IM	L/R Anterolateral Thigh or Deltoid
HepA	IM	L/R Anterolateral Thigh or Deltoid
Influenza	IM	L/R Anterolateral Thigh or Deltoid
Pneumococcal Conj (PCV7)	IM	L/R Anterolateral Thigh or Deltoid
Pneumococcal Poly (Pneumo23)	IM or SC	L/R Anterolateral Thigh or Deltoid
IPV	IM or SC	L/R Anterolateral Thigh or Deltoid
MMR	SC	L/R Anterolateral Thigh or Deltoid
Varicella	SC	L/R Anterolateral Thigh or Deltoid

Combinations:

DTaP-HepB-IPV	IM	L/R Anterolateral Thigh or Deltoid
HepB-Hib	IM	L/R Anterolateral Thigh or Deltoid
HepA-HepB	IM	L/R Deltoid