

Data is the lifeblood of an immunization information system (IIS). It comes from several different sources—Vital Records, providers, Medicaid, and other electronic billing systems—and supports and informs all activities around patient and public immunization. For this reason, IIS programs strive to ensure that only high-quality data enters the IIS. The result of high-quality data? Increased provider trust and use of IIS data, improved clinical immunization practices, better individual and public health, and well-informed public policy decisions.

To help immunization practitioners improve the quality of IIS data, a national group of immunization subject matter experts convened to develop best practice guidelines for validating data before it enters the IIS. The group used a consensus-based process to craft the guidelines, which are detailed in *Data Quality Assurance in Immunization Information Systems: Incoming Data*. When immunization programs apply these generally accepted and consistent best practice guidelines, not only will IIS data quality improve significantly, but the IIS will be better prepared to share data across systems and states—an expectation of the IIS community that continues to grow.

This mini-guide summarizes the original best practice guidelines and describes immediate actions an IIS can take to improve data quality.

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Immunization Information Systems for a New Era

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Sample Business Rules for Quality of Individual Data Items

This section presents a sample of some additional Business Rules included in the original guidelines. These additional Business Rules address validating immunization—and demographics—related data items for coding, range, and format, and for the mandatory data set that must be included in reported records.

CPT Code: Should be chosen from the standard table of billing codes.

Patient Name-First: Should not contain invalid name characters such as [] {} 0123456789~!@#\$\$%^&*^, as well semantically invalid names; for example, “daughter.”

Patient Date of Birth: Dates should represent valid calendar dates.

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.

Practical Implications

Each IIS and submitter of immunization data may experience challenges to implementing the best practices included in this mini-guide and outlined in the original guidelines. For example, the IIS and submitter may have limited resources, competing priorities, a lack of training or technical expertise, or data structures or processes that do not fully support the recommendations. However, these best practices serve as a valuable foundation for improving data quality, with each IIS adding, modifying, or removing recommendations as their unique regulations, needs, and realities require. In addition, by providing a mutual understanding of the issue of data quality assurance in the IIS, this guide and the original best practice guidelines bridge the gap between technical and program staff, while also helping these groups target actions to implement the best practices guidelines. It is also a useful training resource and reference document for IIS staff and others with a vested interest in improving performance and usefulness of the IIS. The overarching goal of the best practices is to improve overall data quality within the IIS.

Learn More About Ensuring IIS Data Quality

The usefulness of an IIS and its ability to improve patient and population health relate directly to the quality of the data in the system. This mini-guide provides practical guidelines that most IIS practitioners can apply to validate and improve the quality of data entering the IIS. For more in-depth, technical information related to these best practices, download the original best practice guidelines, *Data Quality Assurance in Immunization Information Systems: Incoming Data*, from the AIRA web site: http://www.immregistries.org/pdf/AIRA_MIROW_Chap3_DQA_02112008.pdf.



Improving the Quality of Data Entering the IIS



Critical Activities to Ensure High Data Quality

SUBMITTER PRE-CERTIFICATION: evaluating the format and completeness of incoming data from new submitters before allowing them to regularly add data into the IIS.

PRE-LOAD VALIDATION: inspecting incoming data reported by certified submitters to ensure high quality before loading it into the system.

Let In Only Good Data

Inaccurate or incomplete data is difficult and resource-intensive to clean once entered into the IIS. For this reason each IIS must verify that a potential submitter’s data file is in a format accepted by the IIS, and the data it contains is complete and accurate—a process called *submitter pre-certification*. They must also carefully examine data before loading it into the IIS— a separate process called *pre-load validation*. These two processes are key steps any IIS can take to greatly improve IIS data quality.

Pre-certifying a Submitter

The process of pre-certifying a submitter should be fairly systematic. The IIS lets potential submitters know what data file formats the system accepts and provides the submitter with the data codes they must use. The submitter then provides a sample file with real patient data to the IIS, which the IIS examines for completeness and accuracy. When possible, an IIS staff person manually validates the data, checking patient records against the patient’s medical chart for data entry errors or other data quality issues. When the submitter’s sample file meets the IIS criteria, the submitter can regularly add data to the IIS.

To ensure ongoing data quality, the IIS should plan to periodically re-certify all submitters. They should also re-certify submitters when changes occur that might cause format or data issues; for example, when new vaccines are introduced, the submitter’s patient population changes, the submitter upgrades or replaces its billing or electronic records system, or the IIS data structure changes.

Steps for Pre-Certifying Submitters

Take the following steps to ensure the IIS only accepts data files that are properly formatted, accurate, and complete:

STEP 1: Submitter Produces a Sample File

The submitter selects a file format supported by the IIS—for example, a flat file or HL7 format file. The IIS then sends the submitter the appropriate specifications for the chosen format, including required codes. Based on the specifications, the submitter produces and securely sends the IIS a sample data file populated with real data.

STEP 2: IIS Examines the Sample File

The IIS reviews the file for required data and conducts the standard field and record level checks done on regularly submitted data. The IIS also conducts file-level checks to ensure:

- Use of appropriate codes by tabulating data values
- Vaccinations match with appropriate age groups
- Vaccine distribution is appropriate for the provider type

The last two items are critical because each provider practice has a “provider profile”—the range and proportions of vaccine types it is expected to administer based on the age and population the practice serves. The IIS compares the profile against incoming data files; when the two do not match problems likely exist, including miscoding issues, missing vaccine codes, and systematic data entry errors. This comparison also detects unusual but accurate patterns due to temporary vaccine shortages, a shift in the provider population, or unusual clinical practice.

STEP 3: IIS Staff Person Compares Sample File to Medical Chart

Once the sample file passes the checks outlined in Step 2, an IIS staff person should verify the accuracy of data in the sample by manually comparing a random sample of

patients from the incoming electronic file to each patient’s medical chart. The IIS staff person will need to request and receive the medical charts for the sample records from the submitting practitioner to complete this step.

STEP 4: IIS Periodically Examines a Subset of IIS Data

Finally, the IIS should periodically conduct the data checks in Step 2 on a subset of the IIS database to identify patterns that indicate systematic and widespread coding problems or actual immunization practice problems.

Validating Incoming Immunization Data

Pre-load validation is a series of recommended data validation actions the IIS should take to ensure data quality. This section of the mini-guide highlights best practices outlined in the original guidelines for validating immunization data, and to a lesser degree, demographics data, within a single individual’s record, between records, and between IIS databases. These best practices are presented as *Principles* and *Business Rules*.

Principles for Data Quality

A Principle reflects a recommended business practice. For example, the Vital Records principle states “Vital Records is the definitive source for Date of Birth and Date of Death data.” Principles often provide high-level direction for the development of more specific Business Rules.

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| 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. |
| 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. |
| 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. |
| 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. |
| 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. |
| P06 | Appropriate vaccination principle: The vaccinations reported by a provider should be appropriate for the population served at the clinic. |
| P07 | Vital Records principle: Vital Records is the definitive source for Date of Birth and Date of Death. |
| 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. |
| P09 | Maintain data integrity principle: Any modification of the data in the IIS should not violate the integrity of the existing data. |
| P10 | ACIP recommendations principle: Deviations from ACIP recommendations and US licensure may indicate data quality problems. |
| 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. |
| 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. |
| P13 | Supremacy of medical records principle: Medical records are a more reliable source of immunization data than billing records. |

ACIP Recommendations

A Note About ACIP Recommendations

Guidelines from the Advisory Committee on Immunization Practices (ACIP) improve the integrity of data collected through the IIS, and all incoming data should be checked against them. The Business Rules presented in this mini-guide and also noted in the original best practice guidelines ensure that validations are consistent with ACIP recommendations. Those Business Rules with the greatest potential for identifying data quality problems from submitting sources have been specifically included. However, data in the IIS should reflect what actually happened in the medical encounter, even if the data violates ACIP recommendations.

Business Rules for Data Quality

A Business Rule describes an expected condition. For example Business Rule BR101 states that the “Vaccination Encounter Date must not be before Patient Date of Birth.” Although this mini-guide includes only the Business Rule conditions, you can see recommended actions in the original best practice guidelines this mini-guide was based on.

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| BR101 | Vaccination Encounter Date must not be before Patient Date of Birth. |
| BR102 | Vaccination Encounter Date should not be after the Patient Date of Death. |
| BR103 | Vaccination Encounter Date must be less than or equal to (before or the same as) the Report Submission Date. |
| 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, Gender, Mother’s Name, First, Last, and Maiden. |
| 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. |
| 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. |
| BR107 | Every administered vaccine should be recorded as a single vaccination event. |
| BR108 | Vaccinations should appear in the registry within 2 business days of the Report Submission Date. |
| BR109 | Vaccination Event reported by Provider assumed to be “Historical” until attested or proven otherwise.* |
| BR110 | VFC-eligible children should have the manufacturer and lot number reported with vaccination event. |
| BR111 | Adverse reactions reported on administered vaccines should be identified for tracking and following up. |
| 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). |
| BR113 | 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. |
| 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. |
| BR115 | For administered vaccinations, Report Submission Date should be within 30 days of Vaccination Encounter Date. |
| BR116 | Trade Name, Manufacturer, CVX Code, CPT Code and Vaccine Type should not contradict one another. |
| BR117 | The same patient should not receive the same antigen more than once in single day. |
| BR118 | Vaccination Encounter Date should not be after the lot number expiration date. |
| BR119 | Route and Site should be consistent with the vaccine type. |
| BR120 | Vaccination Encounter Date should be within the Vaccine Product License Date range. |
| BR121 | Administered vaccinations should have specific Vaccine Types, e.g., Hib PRP-OMP; unspecified vaccine types, e.g., Hib, NOS, are less desirable. |
| BR122 | A patient’s VFC eligibility should be consistent with the funding source of the vaccine administered. |
| BR123 | The volume of reporting from the Vital Records feed should be within an expected threshold level (to be determined by each IIS). |
| 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). |
| BR125 | The percentage of rejected vaccination events submissions in a report should be within an expected threshold level. |
| BR126 | An administered vaccine should not have a medical contraindication for a patient. |
| BR127 | Hepatitis B birth doses from the Vital Records feed should be reported within an agreed-upon timeframe. |
| 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. |
| BR129 | A patient should not have more than 7 DTaP vaccinations by age 7. (Additional rules should be developed for other types of vaccinations.) |
| BR130 | Doses should not be recorded as given before the minimum patient age or after the maximum patient age for that particular vaccine. |
| BR131 | Doses should not be recorded as given before the minimum interval has been met. |
| BR132 | A patient should not have more than 10 vaccinations per visit. |

* Providers may report vaccines they administered at their practice. Providers may also report vaccines another provider administered (historical), submitting a record that documents a patient’s immunization status by listing the vaccine along with date and location of the vaccine’s administration.