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### Background and Context

The consolidation of immunization records from multiple sources is a primary function of immunization information systems (IIS). To ensure complete, accurate, and timely consolidated records, IIS must receive data from a high proportion of immunizers within their catchment area through standardized reporting channels. Messaging standards have been present across the IIS community for more than 20 years and have increasingly gained importance as electronic health record (EHR)-IIS interoperability has grown in necessity across health care. The primary standard for IIS messaging is the HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5. Additional electronic interfaces (e.g., flat file, Vital Records, Medicaid) also provide data for IIS. Finally, IIS still collect data through the IIS user interface. Once consolidated, the data reside in the IIS database for use by public health programs as well as for clinical encounters. The data residing in an IIS database are often referred to as data at rest (DAR).

In 2016, AIRA convened the Measurement for Assessment and Certification Advisory Workgroup (MACAW) to develop and propose measures for IIS Assessment.<sup>3</sup> The DAR content area within the Measurement and Improvement (M&I) Initiative focuses on the data residing in an IIS database.<sup>4</sup> Measures and tests are shared with the AIRA board of directors and the full IIS community to ensure broad community input and agreement.

### Assessment Stage Details

MACAW defined the scope, measures, tests, outcomes, and testing methods for measuring data quality of the data at rest within an IIS. This work has its foundations in the Functional Standards document and <u>IIS Data Quality Practices – To Monitor and Evaluate Data at Rest.</u><sup>5</sup>

#### Functional standards

The importance of data quality is evident in the <u>IIS Functional Standards v4.1</u>.<sup>6</sup> The revised IIS Functional Standards were developed by the CDC Immunization Information Systems Support Branch (IISSB) through a consensus-based process involving input from a variety

<sup>&</sup>lt;sup>1</sup> http://www.cdc.gov/vaccines/programs/iis/about.html

<sup>&</sup>lt;sup>2</sup> http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf

<sup>&</sup>lt;sup>3</sup> https://www.immregistries.org/measurement-for-assessment-certification-advisory-workgroup

<sup>&</sup>lt;sup>4</sup> https://www.immregistries.org/measurement-improvement

<sup>&</sup>lt;sup>5</sup> https://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/

<sup>&</sup>lt;sup>6</sup> https://www.cdc.gov/vaccines/programs/iis/functional-standards/func-stds-v4-1.html

of IIS managers and technical experts from across the United States. They are intended to reflect the functionality an IIS should strive to attain to fully support program and stakeholder immunization-related goals. The following overarching principle in the Functional Standards best describes the importance of data quality to the IIS.

As an IIS matures, the importance of data quality becomes more pronounced. Data quality is the cornerstone of successfully reaching all immunization-related goals. IIS Functional Standards related to data quality are woven into the Essential Infrastructure Functional Standards and are reflected in multiple goals in this document. This underscores the importance of thinking about and applying data quality in all aspects of access and use of IIS data and functionality.

### Scope

#### In scope

- Data quality of patient-level data elements which were extracted from an IIS database
- Data quality of vaccine-level data elements which were extracted from an IIS database

#### Out of scope

- Data quality of actual HL7 messages (although the in-scope extracted data could have been submitted to the IIS via HL7)
- Data quality of provider-level data elements
- Coverage reports
- Inventory management

#### Measures

The measures comprise three categories—completeness, validity, and timeliness—and are described in greater detail below.

#### Completeness measures

Completeness is the degree to which full information about a data set, record, or individual data element is captured in the IIS, i.e., the proportion of stored data measured against the potential of "100% complete." The following list measures the percentage of patient or vaccination records in which the data element was present (e.g., had a value). Completeness strictly measures how often an element is populated with a value regardless

of how valid or timely the data are. Validity and Timeliness are distinct measures.

Patient completeness measures

- 1.1 Patient first name is present.
- 1.2 Patient middle name is present.

<sup>&</sup>lt;sup>7</sup> https://repository.immregistries.org/files/resources/5c002cbde216d/aira\_dq\_guide\_data\_at\_rest\_-final.pdf

- 1.3 Patient last name is present.
- 1.4 Patient birth date is present.
- 1.5 Patient gender is present.
- 1.6 Patient address street is present.
- 1.7 Patient address city is present.
- 1.8 Patient address state is present.
- 1.9 Patient address ZIP code is present.
- 1.10 Patient complete address is present.
- 1.11 Patient race is present.
- 1.12 Patient ethnicity is present.
- 1.13 Patient phone number is present.
- 1.14 Patient email is present.
- 1.15 Mother's maiden name is present.
- 1.16 Responsible person first name is present.
- 1.17 Responsible person last name is present.

#### Vaccination event completeness measures

- 1.18 Vaccine administration code is present.
- 1.19 Vaccine administration date is present.
- 1.20 Vaccine information source (e.g., Admin/Historical Indicator) is present.
- 1.21 Vaccine lot number is present.
- 1.22 Vaccine lot expiration date is present.
- 1.23 Vaccine eligibility code is present.
- 1.24 Vaccine funding source is present.

#### Validity measures

Validity is the degree to which the data conform to the syntax (i.e., format, type, range) of its definitions, (e.g., to the rules of what is accepted or expected by the IIS).<sup>8</sup>

#### Patient validity measures

- 2.1 Patients born on the first of the month do not exceed normal distribution of birth dates.
- 2.2 Patients born on the 15th of the month do not exceed normal distribution of birth dates.
- 2.3 Patients born on the last day of the month do not exceed normal distribution of birth dates.
- 2.4 Patient has more vaccinations than expected.

#### Vaccination event validity measures

- 2.5 Vaccine administration date is after vaccine lot expiration date.
- 2.6 Vaccine administration date is before birth date.

<sup>8</sup> https://repository.immregistries.org/files/resources/5c002cbde216d/aira\_dq\_guide\_data\_at\_rest\_final.pdf

- 2.7 Vaccine administration dates on the first day of the month do not exceed normal distribution of administration dates.
- 2.8 Vaccine administration dates on the 15th of the month do not exceed normal distribution of administration dates.
- 2.9 Vaccine administration dates on the last day of the month do not exceed normal distribution of administration dates.
- 2.10 Vaccine administration code was administered at an improbable age.
- 2.11 Vaccine administration code is not specific for administered vaccination event.
- 2.12 Vaccine lot number has an invalid prefix.
- 2.13 Vaccine lot number has an invalid infix.
- 2.14 Vaccine lot number has an invalid suffix.
- 2.15 Vaccine lot number contains at least one invalid character.
- 2.16 Vaccine lot number is too short.
- 2.17 Vaccine administration code is unrecognized.
- 2.18 Vaccine manufacturer is unrecognized.
- 2.19 Vaccine administration route is unrecognized.
- 2.20 Vaccine body site is unrecognized.

#### Timeliness measures

Timeliness is the amount of time between the occurrence of the real-world event and its documentation in the IIS, (i.e., the time lag between the date of vaccination and the date the record is received by the IIS).<sup>9</sup>

#### Vaccination event timeliness measures

3.1 Administered vaccination events are entered into the IIS within one (1) clinical day from administration date.

#### Measure outcomes

Each measure has a defined expectation. The expectations are used during testing to determine how well an IIS aligns with the published national standards. Once each test case is executed against an IIS, the IIS is slotted into one of the following categories:

**Meets:** The IIS meets the expectation.

**Does not meet:** The IIS does not meet the expectation.

**Not measured:** The IIS is unable to be measured at this time.

<sup>&</sup>lt;sup>9</sup> https://repository.immregistries.org/files/resources/5c002cbde216d/aira\_dq\_guide\_data\_at\_rest\_-\_final.pdf

### **Testing Method**

Data at Rest (DAR) measures the quality of data in IIS production systems using a series of steps.

#### **Data Extraction**

- •IIS extract all children residing in their jurisdiction born in the two most recent calendar years
- Includes tab-separated patient and immunization files

#### **Data Transformation**

- •IIS configure and run an AIRA-supplied command line tool against the extracted patient and immunization file
- The tool analyzes the data for completeness, validity, and timeliness measures
- •The tool produces an Aggregate Detection File (ADF) containing counts of the data quality detections

#### **Data Loading**

•IIS upload the ADF into AART for further analysis

# Completeness Measures

All completeness measure expectations have been set based on the <u>IIS Data Quality Practices: To Monitor and Evaluate Data at Rest</u> document developed by the Assessment Steering Committee (ASC).

## Patient completeness

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 1.1	Patient first name is present.	Total number of patient records with a first name present	Total number of patient records extracted	> 99.0%
Measure 1.2	Patient middle name is present.	Total number of patient records with a middle name present	Total number of patient records extracted	> 75.0%
Measure 1.3	Patient last name is present.	Total number of patient records with a last name present	Total number of patient records extracted	> 99.0%
Measure 1.4	Patient birth date is present.	Total number of patient records with a birth date present	Total number of patient records extracted	> 99.0%
Measure 1.5	Patient gender is present.	Total number of patient records with a gender present	Total number of patient records extracted	> 99.0%
Measure 1.6	Patient address street is present.	Total number of patient records with the street component (e.g., address line 1) of an address present	Total number of patient records extracted	> 85.0%
Measure 1.7	Patient address city is present.	Total number of patient records with the city component of an address present	Total number of patient records extracted	> 85.0%
Measure 1.8	Patient address state is present.	Total number of patient records with the state component of an address present	Total number of patient records extracted	> 85.0%
Measure 1.9	Patient address ZIP code is present.	Total number of patient records with the ZIP code component of an address present	Total number of patient records extracted	> 85.0%

# Patient completeness cont.

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 1.10	Patient complete address is present.	Total number of patient records with a complete address present. Complete address is defined as a record where street (e.g., address line 1), city, state, and ZIP code are all present	Total number of patient records extracted	> 85.0%
Measure 1.11	Patient race is present.	Total number of patient records with a race present	Total number of patient records extracted	> 95.0%
Measure 1.12	Patient ethnicity is present.	Total number of patient records with an ethnicity present	Total number of patient records extracted	> 95.0%
Measure 1.13	Patient phone number is present.	Total number of patient records with a phone number present	Total number of patient records extracted	> 90.0%
Measure 1.14	Patient email is present.	Total number of patient records with an email present	Total number of patient records extracted	> 90.0%
Measure 1.15	Mother's maiden name is present.	Total number of patient records with a mother's maiden name present	Total number of patient records extracted	> 90.0%
Measure 1.16	Responsible person first name is present.	Total number of patient records with a responsible person first name present	Total number of patient records extracted	> 90.0%
Measure 1.17	Responsible person last name is present.	Total number of patient records with a responsible person last name present	Total number of patient records extracted	> 90.0%

# Vaccination event completeness

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 1.18	Vaccine administration code is present.	Total number of vaccination event records with a vaccine administration code present	Total number of vaccination event records extracted	> 99.0%
Measure 1.19	Vaccine administration date is present.	Total number of vaccination event records with a vaccine administration date present	Total number of vaccination event records extracted	> 99.0%
Measure 1.20	Vaccine information source (e.g., Admin/Historical Indicator) is present.	Total number of vaccination event records with a vaccine information source (e.g., Admin/Historical Indicator) present	Total number of vaccination event records extracted	> 99.0%
Measure 1.21	Vaccine lot number is present.	Total number of administered (i.e., 00) vaccination event records with a vaccine lot number present	Total number of administered (i.e., 00) vaccination event records extracted	> 99.0%
Measure 1.22	Vaccine lot expiration date is present.	Total number of administered (i.e., 00) vaccination event records with a vaccine lot expiration date present	Total number of administered (i.e., 00) vaccination event records extracted	> 99.0%
Measure 1.23	Vaccine eligibility code is present.	Total number of administered (i.e., 00) vaccination event records with a vaccine eligibility code present	Total number of administered (i.e., 00) vaccination event records extracted	> 99.0%
Measure 1.24	Vaccine funding source is present.	Total number of administered (i.e., 00) vaccination event records with a vaccine funding source present	Total number of administered (i.e., 00) vaccination event records extracted	> 99.0%

## Validity Measures

All validity measure expectations have been set based on the <u>IIS Data Quality Practices: To Monitor and Evaluate Data at Rest</u> document developed by the Assessment Steering Committee (ASC).

## Patient validity

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 2.1	Patients born on the first of the month do not exceed normal distribution of birth dates.	Total number of patient records with a birth date on the first of the month	Total number of patient records extracted	< 4.0%  For any given calendar year, there are 12 "first days of a month." 12 days/365 days per year represents 3.3% of the days in a calendar year. IIS with more than 4.0% of birth dates falling on the first of the month may have data validity issues.
Measure 2.2	Patients born on the 15th of the month do not exceed normal distribution of birth dates.	Total number of patient records with a birth date on the 15th of the month	Total number of patient records extracted	< 4.0%  For any given calendar year, there are 12 "15th of a month" dates. 12 days/365 days per year represents 3.3% of the days in a calendar year. IIS with more than 4.0% of birth dates falling on the 15th of the month may have data validity issues.
Measure 2.3	Patients born on the last day of the month do not exceed normal distribution of birth dates.	Total number of patient records with a birth date on the last day of the month	Total number of patient records extracted	< 4.0%  For any given calendar year, there are 12 "last days of a month." 12 days/365 days per year represents 3.3% of the days in a calendar year. IIS with more than 4.0% of birth dates falling on the last day of the month may have data validity issues.

# Patient validity cont.

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 2.4	Patient has more vaccinations than expected.	<ul> <li>Total number of patient records with at least one of the following:</li> <li>More than 20 vaccination events before 6 months of age</li> <li>More than 30 vaccination events before 2 years of age</li> </ul>	Total number of patient records extracted	< 1.0%

# Vaccination event validity

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 2.5	Vaccine administration date is after vaccine lot expiration date.	Total number of vaccination event records where the administration date is after the vaccine lot expiration date	Total number of vaccination event records extracted where both administration date and vaccine lot expiration date are present	< 1.0%
Measure 2.6	Vaccine administration date is before birth date.	Total number of vaccination event records where the administration date is before the patient's birth date	Total number of vaccination event records extracted where both administration date and patient birth date are present	< 1.0%

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 2.7	Vaccine administration dates on the first day of the month do not exceed normal distribution of administrations dates.	Total number of vaccination event records with an administration date on the first day of the month	Total number of vaccination event records extracted	< 4.0%  For each calendar year, there are 12  "first days of a month." 12 days/365  days per year represents 3.3% of the days in a calendar year. IIS with more than 4.0% of administration dates falling on the first of the month may have data validity issues.
Measure 2.8	Vaccine administration dates on the 15th of the month do not exceed normal distribution of administration dates.	Total number of vaccination event records with an administration date on the 15th of the month	Total number of vaccination event records extracted	< 4.0%  For each calendar year, there are 12 "15th of a month" dates. 12 days/365 days per year represents 3.3% of the days in a calendar year. IIS with more than 4.0% of administration dates falling on the 15th of the month may have data validity issues.
Measure 2.9	Vaccine administration dates on the last day of the month do not exceed normal distribution of administration dates.	Total number of vaccination event records with an administration date on the last day of the month	Total number of vaccination event records extracted	< 4.0%  For each calendar year, there are 12 "last days of a month." 12 days/365 days per year represents 3.3% of the days in a calendar year. IIS with more than 4.0% of administration dates falling on the last day of the month may have data validity issues.

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 2.10	Vaccine administration code was administered at an improbable age.	Total number of vaccination event records with an improbable administration code based on the patient's age at the time of the vaccination event  Examples:  Adult HepB to an infant Rotavirus to a 2-year-old	Total number of vaccination event records extracted	< 1.0%
Measure 2.11	Vaccine administration code is not specific for administered vaccination event.	Total number of administered (i.e., 00) vaccination event records with an unspecified administration code	Total number of administered (i.e., 00) vaccination event records extracted	< 1.0%
Measure 2.12	Vaccine lot number has an invalid prefix.	Total number of administered (i.e., 00) vaccination event records where vaccine lot number is present but with an invalid value at the beginning of the lot number Invalid prefix examples: LOT, (P), MED, SKB, PUB	Total number of administered (i.e., 00) vaccination event records extracted where lot number is present	< 1.0%
Measure 2.13	Vaccine lot number has an invalid infix.	Total number of administered (i.e., 00) vaccination event records where vaccine lot number is present but with an invalid value in the middle of the lot number  Invalid prefix examples:  LOT, (P), MED, SKB, PUB	Total number of administered (i.e., 00) vaccination event records extracted where lot number is present	< 1.0%

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 2.14	Vaccine lot number has an invalid suffix.	Total number of administered (i.e., 00) vaccination event records where vaccine lot number is present but with an invalid value at the end of the lot number  Invalid prefix examples:  LOT, (P), MED, SKB, PUB	Total number of administered (i.e., 00) vaccination event records extracted where lot number is present	< 1.0%
Measure 2.15	Vaccine lot number contains at least one invalid character.	Total number of administered (i.e., 00) vaccination event records where vaccine lot number is present but contains an invalid character  Valid characters include: 0-9, a-z, A-Z, or "-"	Total number of administered (i.e., 00) vaccination event records extracted where lot number is present	< 1.0%
Measure 2.16	Vaccine lot number is too short.	Total number of administered (i.e., 00) vaccination event records where lot number is present but less than five (5) characters long	Total number of administered (i.e., 00) vaccination event records extracted where lot number is present	< 1.0%
Measure 2.17	Vaccine administration code is unrecognized.	Total number of vaccination event records where vaccine administration code (CVX) is present but is not a value on CDC's CVX code set list	Total number of vaccination event records where vaccine administration code is present	< 1.0%
Measure 2.18	Vaccine manufacturer is unrecognized.	Total number of vaccination event records where manufacturer code (MVX) is present but is not a value on CDC's MVX code set list	Total number of vaccination event records where manufacturer code is present	< 1.0%

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 2.19	Vaccine administration route is unrecognized.	Total number of vaccination event records where administration route is present but is not a valid value per HL7 National IG release 1.5	Total number of vaccination event records where administration route is present	< 1.0%
Measure 2.20	Vaccine body site is unrecognized.	Total number of vaccination event records where body site is present but is not a valid value per HL7 National IG release 1.5	Total number of vaccination event records where body site is present	< 1.0%

## Timeliness Measures

The timeliness measure expectation has been set based on the <u>IIS Data Quality Blueprint</u> developed by the CDC.

### Vaccination event timeliness

Measure #	Measure Name	Numerator	Denominator	Expectation
Measure 3.1	Administered vaccination events are entered into the IIS within one calendar day from administration date.	Total number of administered (i.e., 00) vaccination event records where vaccine administration date and system entry date into the IIS are less than or equal to one day of each other	Total number of administered (i.e., 00) vaccination event records	> 95.0%