AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

HL7 FAQ

Frequently Asked Questions Series
Reviewed and Approved by AIRA and CDC Staff

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Organization of this Document

This document is organized by topics, which are listed on the next page 2. The topics are followed by the list of questions which link to the full question and answer.

Implementation Resources

The current HL7 2.5.1 Rel. 1.5 IG is here:

https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf

The addendum is here:

https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf

A consolidated version of the HL7 2.5.1 Rel. 1.5 IG with the Addendum applied:

http://repository.immregistries.org/files/resources/5bef530428317/hl7_2_5_1_release_1_5__2018_update.pdf

Testing tool to ensure the messages are meeting the HL7 standard including some test cases:

https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/home

Contents

1. Data Types

1.1 What is a data type flavor?

A standard set of restrictions on a standard data type. When HL7 v2.x implementation guides are developed, data types often are (and should be) constrained to suit a particular use for a message element. Therefore, multiple specializations of a data type are required that necessitates a distinct specification and identifier. Each specialization becomes a data type flavor. However, HL7 datatype should never be transmitted in an HL7 message.

Data type flavors are not indicated directly in HL7 messages, rather they are a concept that is used in implementation guides to indicate how data should be structured in an HL7 message. When a guide specific flavor is specified, OBX-2 of the message should be populated with the base HL7 data type for that flavor. For example, if DT_IZ01 is used to for OBX-5, then the data type in OBX-2 will be DT. For OBX messages, where the data type used in OBX-5 is indicated in OBX-2, the data type is used and not the data type flavor. For example, if an implementation guide specifies that DT_IZ01 should be used for a specific OBX-5 then the value of DT should be placed in OBX-2, not DT_IZ01. The data type flavor is an artefact for use in the guide and is never referred to directly in the HL7 message.

1.2 What is an HD (Hierarchic Designator) datatype?

The HD data type is one of the most complex and confusing data types in HL7 version 2. Keep in mind the HD data type is sometimes used for fields (e.g., MSH-4) and other times used for components (e.g., CX.4 as used in PID-3). In the examples below, we demonstrate HD usage using component-based scenarios, but the same suggestions and rules apply for field level HD usage as well.

The HD data type is divided into 3 elements:

- The Namespace
- The Universal ID
- The Universal ID Type

The last two elements work together to define an ID along with the appropriate ID Type and the Release 1.5 IG constrains the Universal ID to be an OID and constrains the Universal ID Type to the value "ISO". The Namespace and the OID should be synonyms for each other. That is, the HD element should NOT be populated such that the Namespace is a value in the value set specified by the OID.

The Release 1.5 IG allows for 3 valid "flavors" of the HD data:

- Namespace&& (ideally without the trailing ampersands)
- Namespace&<OID>&ISO
- &<OID>&ISO

The Name space is widely used today; and support for sending and receiving the Namespace is highly encouraged for all vendors. The OID can be used in addition to the Namespace, but we do not encourage replacing the Namespace with the OID. That is, while the third flavor above is valid, we don't endorse the use of it due to the current extensive use of Namespace. Future releases of the IG may tighten the Usage of the Namespace to Required (R) while still supporting the use of OIDs.

1.3 How should I implement the TS (Time Stamp) data type?

For data elements where the time component is optional, the receiving system may decide to support using the time or not. If the receiving system chooses not to use the time, and if it is formatted correctly, an error/warning should not be returned for sending a time.

1.4 How should I implement the XTN (Extended Telecommunications Number) data type?

Currently when sending a phone number, the Area/City Code (XTN.6) has a usage of RE while the Local Number (XTN.7) has a usage of "R".

- Legacy data in the IIS (or EHR) may exist without an area code. The ability to still message this data is needed, which is why the area code is "RE".
- IIS can further constrain the usage of the area code if local needs require it.
- Future releases of the IG will maintain the current usages.

1.5 What are the possible variations in XTN fields?

The large number of Conditional Usages makes the XTN data type a complex one. It can be used to send either phone numbers or email addresses, but each of those looks quite different.

- A maximally populated phone number looks like this:
  - ^PRN^CP^^^406^5557896
- As noted above, it is also valid to send a phone number without an area code, when the area code is not known:
  - ^PRN^PH^^^^5552236
- An email address looks like this:
  - ^NET^^warren.jackson@example.com
- When populating a field with both phone numbers and an email address, they are separated by the repetition (~) delimiter. For example, the PID-14 value for a patient with a home phone, cell phone and email address would look like this:
  - ^PRN^CP^^^406^5557896~^PRN^PH^^^^5552236~^NET^^warren.jackson@example.com

1.6 What HL7 field (XPN-6 Degree or XPN-14 Professional Suffix) is used for Vaccine Administering Provider Suffix and does it use free-text?

Professional suffix can be sent is RXA-10 “Administering Provider”, which has a data type of XCN. Within XCN, XCN-21 contains information on professional suffix and is a string field. Therefore, there are no associated codes with this field.

There are many caveats to receiving professional suffix information from EHRs. First, RXA-10 “Administering Provider” is a RE field and may be empty for completed or partially administered non-historical doses. Second, even if RXA-10 is received, XCN-21 is an optional field. Thus, most EHRs are not certified to indicate professional suffix information and the information is not likely to be populated in messages.

2. Value Sets

2.1 What is the future of the NIP004 (Serological Evidence) value set that was part of the HL7 v2.3.1 IG?

In the HL7 2.3.1 IG, the NIP004 value set was designed to document Vaccination contraindications/precautions (LOINC code 30945-0). Values included allergies, medical observations (pregnancy, fever, chronic illness, etc.) and immunities. Because the newer v2.5.1 IG no longer uses NIP004, that value set is not being maintained.

The HL7 2.5.1 IG Rel. 1.5 uses the PHVS_VaccinationContraindication_IIS value set for contraindications/precautions and documents different LOINC codes for Presumed Immunity (59784-9) and Serological Immunity (75505-8) with their own value sets of PHVS_EvidenceOfImmunity_IIS and PHVS_SerologicalEvidenceOfImmunity_IIS respectively. The NIP004 value set is not part of the HL7 2.5.1 messaging standard. However, if a system is not using the most recent v2.5.1, then IG needs to exchange concepts not included in NIP004, and local codes may be added to expand the NIP004 value set.

IISs that have not yet updated to HL7 2.5.1 IG should consider pre-adopting newer code sets to support current HL7 messaging standards.

2.2 How are LOINC codes described in NIP003 supposed to be used with respect to individual profiles?

AIRA has published Guidance on Detailed Message Structure and Use of Specific LOINC Codes describing in more detail the message structure of VXU and RSP messages including guidance on LOINC codes which are appropriate to use in different sections of the message.

2.3 Does the CVX value set include a code for animal Rabies vaccines?

The CVX value set only covers human vaccines.

2.4 How should non-US vaccines be handled?

CVX codes exist for several vaccines which are not available in the United States but may be part of a patient's history. Receiving systems should be prepared to support receipt of these non-US vaccines given to a patient, regardless of where they might have received them as they may be included in messages as part of a patient's immunization record. IISs are responsible for collecting complete immunization histories, including doses that may not count towards immunity in the US.

- Pentavalente is a vaccine available in Mexico. In 2007, the formulation of the vaccine changed from DTP/HEP B/Hib to DTaP/Polio/Hib (Pentavalente Acellular). Separate CVX codes exist for each formulation (102 and 170 respectively).
- Hep A, live attenuated vaccine (CVX code 169) is never recommended by ACIP and does not count towards Hep A completion. IIS should record this but not count it as a valid dose.
- Two versions of a killed, oral cholera vaccine now have CVX codes (172 and 173).
- PCV10 (CVX code 177) is valid but recommendations are that all patients have at least one dose of PCV13.
- Several new CVX codes (178 and 179) have been created for bivalent and monovalent OPV vaccines. The trivalent formation is no longer available as of April 2016. Bivalent and monovalent OPV vaccines do not count towards polio completion.

2.5 Can an IIS code values in their system from one inactive to code to the proper active code?

IISs are responsible for storing and reporting vaccinations under the CVX code that best represents the concept. An IIS has the freedom to update the codes in their database to reflect the correct representation of what really happened.

2.6 In the HL7 2.5.1 Rel. 1.5 IG there are 6 concept codes for Serologic Evidence of Immunity. Are there concept codes for any additional diseases, specifically Polio, Hib and Tetanus?

Concept codes for these three diseases do not exist because ACIP does not recognize evidence of immunity for these diseases. If a provider claimed these, there would be no effect on the recommendations. The patient would still need to be vaccinated if they haven't been.

2.7 How can serologic evidence of immunity be messaged?

Serologic evidence of immunity is messaged using an OBX segment using the value of "75505" for OBX-3.1. Values for OBX-5 can be found in the "PHVS_SerologicalEvidenceOfImmunity_IIS" value set. Example OBX segment:

OBX|1|CE|75505-8^Disease with serological evidence of immunity^LN|3|76902006^Tetanus^SCT|||||F|||20201027

Please be aware of nuances of using values for diseases not included in the "PHVS_SerologicalEvidenceOfImmunity_IIS" value set, as it may not be proven that there is serological evidence of immunity for the disease.

2.8 How should an IIS process NDC and CVX when they don't match?

The HL7 2.5.1 Rel. 1.5 IG does not give direction on which code to give priority or whether the IIS should accept this data or not. The order of the codes in the CE data type do not signify which concept should be given priority. They should be describing the same concept, although one code might be more specific than the other and thus carry more detail. The receiver of the data can read either code to understand the concept. Two community guides give further guidance on processing this data in an IIS:

- https://repository.immregistries.org/resource/iis-functional-guide/
- https://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/

2.9 What is the correct Concept Code for Mumps (Finding)?

Value Set Error Corrections in HL7 2.5.1 Release 1.5

- Value Set Name – Serological Evidence of Immunity - IIS

- Concept Code 341112003 (Mumps Finding) should be 371112003

2.10 How should doses administered with a needle-free method be coded?

Existing route codes should cover non-needle administrations and, depending on the mechanism, valid options could include percutaneous, subcutaneous, etc. For a full list of route-of-administration codes, please see "HL7-defined Table 0162 - Route of administration" in the 2.5.1 IG.

2.11 Why does the IG not support a full list of HL7 route codes?

The IG constrains the base standard to only those route codes that would be used in an immunization context. EHR and IIS should and do implement these constraints. Please see "HL7-defined Table 0162 - Route of administration" for the list of constrained codes.

2.12 What to do with Gender X?

Non-binary gender has been discussed at HL7 and SISC (for more information see https://confluence.hl7.org/display/VOC/The+Gender+Harmony+Project) and in response, HL7 has added “X” as a value to table 0001 (Administrative Sex) to represent non-binary gender.

For immunizations, the value of “X” has not been added to the 2.5.1, as of now. This does not preclude two organizations agreeing to extend the values in HL7001 table to include “X” and messaging the value of “X” when appropriate. However, please note, that it can cause issues for other organizations outside of the agreement that have not extended the value set of HL7001, as there is no current guidance on what HL7001 values to message instead of “X” when one organization cannot receive “X”.

2.14 What to do with NDCs that are not on the CDC website?

The preferred NDC is the Unit of Use. If an NDC is listed on manufacturer's website but is not showing on the CDC code set resources, then the CDC Code Set project should be contacted at iisinfo@cdc.gov.

CDC works to release NDC codes as soon as they receive information from proper sources. Please contact iisinfo@cdc.gov, if you see NDCs used for vaccines that are not on the current lists.

Additional Resources:

IIS | Code Sets | NDC | Vaccines | CDC

IIS | NDC Table Access | Code Sets | HL7 Data | Vaccines | CDC

IIS | NDC Crosswalk tables | Code Sets | HL7 Data | Vaccines | CDC

2.15 How should an IIS map two values, "sublingual" and "intranasal", that an EHR vendor is sending?

Because there is a larger value set for route of administration, IISs may receive values that are not included in the 2.5.1 IG. As such values can be mapped to the value in the 2.5.1 IG that is the closest approximation of the value sent by the EHR. For example, "intranasal" could be mapped to "nasal" and "sublingual" could be mapped to "oral".

2.16 We have got the NDC codes for COVID vaccines, e.g., Pfizer-BioNTech: 59267-1000-01. Are these codes valid/accepted as CDC Immunization Administered Code"?

NDC and CVX are both acceptable for the date range for which they are applicable.

3. Scope Definition

3.1 Are TB test results in scope?

The Immunization Guide does not cover TB test results. At one time a CVX code was created for PPD because it is injected like vaccinations, but the use case of reporting this via VXU is not supported by the current guide. Similarly, PPD is not a vaccine and not supported for sending to IIS.

3.2 When should a submitting system trigger a VXU message?

See the HL7 2.5.1 Rel 1.5 IG for information on trigger events.

3.3 When will v2.8.2 roll out?

The updated CDC HL7 resources page (https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html) discusses the v2.8.2 IG being reserved for future release, with there being no current release date.

4. Populating a Message

4.1 What should a sending system do if a message triggering event is hit but the system does not have enough data to build a fully conformant message?

If key data elements such are vaccine type, administration date and a link to a patient are available, it is permissible to send the message and let the receiving system determine if it is willing to accept a non-conformant message. The sending system may still populate MSH-21 with the profile ID they are intending to meet even if the message itself is not conformant with the profile.

In general, the following principles should be followed:

- Non-conformance should not stop the exchange of usable data.
- Local business rules still determine if the data is usable.
- It is OK to put a profile in MSH-21 even if the sending system knows the message is not conformant.

4.2 Is it reasonable to expect a submitting EHR to populate PID-3 with a State Registry Number (with PID-3.5 equal to SR)?

While this method would be supported by the guide, it is not specifically defined in the HL7 2.5.1 Rel. 1.5 IG and EHR certification is not testing EHR systems for the ability to behave in this way. In addition, certification does not require EHR systems to be able to store or report the state registry ID. Many IISs require the Medical Record Number to be sent in PID-3 and most (if not all) EHR systems are able to do this.

4.3 Is a patient's Social Security Number (SSN) an acceptable patient identifier to use?

The answer depends on local regulations, laws, and policies. Perhaps some IISs collect SSN and use it for patient matching, but there is at least one IIS that forbids EHR's from sending SSN. The HL7 2.5.1 Rel 1.5 IG does not require that SSN specifically be used as a patient identifier, certification does not require EHRs to send SSN when known, and IIS validation does not expect IISs to be able to receive or store SSN. In general, IISs have or are moving away from using SSN for patient identification.

4.4 What is the meaning of a Completion Status (RXA-20) of PA (Partially Administered)?

A Partially Administered status, or PA, is used to indicate when less than a fully potent dose of vaccine was administered. It could mean that less than the full volume of a potent dose was administered (e.g., the patient moved unexpectedly and only a portion of the dose was actually administered) or it could mean that the dose was sub-potent (e.g., there was a manufacturing issue or a cold-chain break). Different IISs have different requirements for sending partial administrations, therefore it is critical to talk to your trading partner to determine their expectations. Regardless, it is important to include partially administered doses in any testing workflows to ensure that both systems deal with the PA completion status appropriately. It is important that partially administered doses do NOT get counted as full and valid doses. This applies to both VXU and RSP messages. This topic will be elaborated on more fully in future versions of the implementation guide.

4.5 When submitting an NDC code or lot number, should the VXU message contain the Unit of Sale (package) or Unit of Use (vial/syringe) value?

The HL7 IG is silent on this topic, but the CDC has indicated that a provider may capture the NDC or lot number on the Unit of Use OR Unit of Sale, depending on the established clinical workflow. Note that "recording" and "sending" are different; a provider could record the Unit of Use in the EHR and send the Unit of Sale if the sending system maintains a mapping. The IIS should be prepared to receive either Unit of Use or Unit of Sale value.

Many IISs need the Unit of Sale for inventory reconciliation purposes; however, it is not always possible to derive the Unit of Sale from the Unit of Use (some vaccines such as Prevnar 13 use the same Unit of Use NDC for different packaging). Therefore, if the Unit of Sale is not sent, all IIS functionality may not be available to the EHR users. We recommend, when documenting administered vaccines requiring reconstitution, that the sending system record and send the NDC from the lyophilized vaccine even when the vaccine contains an antigen containing diluent (such as Menveo or Pentacel).

For EHR certification, all possible NDC codes for a vaccine are considered valid. Note that for a Vaqta and Engerix-B certification, limited it to NDCs for pediatric formulations because of the age of the patient. Guidance clarifying these points was sent by the CDC in June, 2017 and can be found in the AIRA repository.

4.6 When sending multiple immunities (either presumed or serological) in a single message, how should they be grouped underneath the ORC/RXA segments? Does there need to be a separate ORC/RXA pair of segments for each immunity or can multiple immunity OBX segments be grouped under a single ORC/RXA pair?

The use of ORC/RXA segments to encapsulate patient-level OBX observations has no semantic meaning and are only present to conform to HL7 message structure expectations. Senders can group all patient-level observations under a single ORC/RXA pair, receivers should process patient-level observations grouped under one or more ORC/RXA pair without distinction.

4.7 How should free text comments be messaged?

First, it is important to note only clinically relevant comments which can't be discretely messaged elsewhere should be included as part of the HL7 message. For example, don't send patient immunity data as a free text comment, rather send it as an observation using the appropriate LOINC code. Release 1.5 indicates that free text comments can be sent as an occurrence of RXA-9 (Administration Notes), however, because this field is also used to transmit the Information Source (i.e., new or historical vaccination event), the SISC has reconsidered this approach and will make recommendations concerning this topic in future versions of the implementation guide to send free text comments in an OBX segment using LOINC code 48767-8 (Annotation Comment).

Lastly, EHR systems have not been certified to send notes and IISs are not expected to process them. It is expected, in many situations, that these notes will be ignored. Sending and accepting notes would be a locally negotiated functionality.

4.8 How should a baby with no first name be recorded?

When patient really has no first name, the recommendation is to give the patient the first name of "Baby" as this would be a signal to the underlying matching system that this patient did not have a real first name.

Additional Resources:

https://www.cdc.gov/vaccines/programs/iis/activities/downloads/TAD-MIROW-Interactive-Workshop-2016.pdf

https://repository.immregistries.org/files/resources/59d677eb1b908/aira_mirow_consolidating_demographic_rec_updated.pdf

4.9 How should I implement time zone in MSH-7?

Sending systems can express time in any time zone

- Not required that sending system use correct time zone
- Offset indicates difference from UTC

Receiving system

- Must read time zone offset when reading/understanding time
- Should not require a time zone to be used
- IIS may require that messages should be created in the future

Consider having some leeway to account for

- Minor differences in exact time set (at least 1 minute?)
- Mistakes in using time zone (at least 65 minutes?)

4.10 How to message alias information in HL7?

It was permissible to only message first or last name if it is all that is known. IISs may, or may not accept this data, but should process the remainder of the message normally regardless.

Additional Resource:

https://repository.immregistries.org/files/resources/59d677eb1b908/aira_mirow_consolidating_demographic_rec_updated.pdf

4.11 Where should patient's county of residence be populated in the PID segment? PID-11.9 or PID-12?

EHRs are not required to submit patient's county of residence, however, if they collect and send a patient's county of residence, PID-11.9 should be populated. When submitting county of residence, the five-digit FIPS county code is preferred (FIPS codes https://www.census.gov/geographies/reference-files/2019/demo/popest/2019-fips.html)

IISs are highly encouraged to use address standardization software to derive the county of residence for a patient's address. More information can be found in the *IIS Functional Guide, vol. 2*

(*https://repository.immregistries.org/files/resources/5a83216a1d369/aira_functional_guide_vol2_final.pdf*)

4.12 To report adverse effect, is it necessary to first have a record for vaccination already reported (via RXA) for the vaccine receiver? As we understand adverse event needs to be mandatorily reported with RXA segment.

The CDC IG 1.5 does not require an adverse event to be associated with a vaccination given, nor is it a requirement that the vaccination must be reported to the IIS first before reporting the adverse event. Reporting could be associated to only the fact an adverse event occurred, and no vaccination. (See Appendix B excerpt above.) With or without a vaccination it does have to be messaged under an RXA. This is because there is no other way to message an OBX without sending it under an RXA in this version of the standard. So, if this is not associated with a vaccination event, a "dummy" RXA should be sent with the value in RXA-5 being "998^No vaccine administered^CVX" as in the example from the guide above.

4.13 What resources are available to check if a message to report adverse effect is correct?

You should always verify all examples pass with the NIST tooling.

4.14 If adverse event is reported directly with RXA segment, then will the vaccination record be created along with the adverse effect record, if one does not exist?

An adverse event can be reported separately or with an administered vaccination. The IIS will only record a vaccination record if it is submitted to the IIS. It will not assume an administration from a reported adverse event. There may be some confusion as an adverse event can only be transmitted if sent after an ORC/RXA segment. If this adverse event is related to a known vaccination, then that vaccination event can be reported in ORC/RXA with the adverse event in the OBX segment(s). Otherwise, the ORC/RXA segment should indicate that no vaccine was given with CVX 998 in RXA-5.

4.15 How do we send immunization records to the CDC?

IISs are operated by states and local jurisdictions. Providers using the software should contact their local jurisdiction about steps in integrating software. CDC does not normally accept immunization records directly. They first go to the local IIS.

4.16 What should IISs do when multiple refusals are received for the same event? What about if a refusal is deleted in an EHR?

Currently, there is no national guidance on how IISs should process multiple or deleted refusals, and it is unlikely that most IISs merge or delete refusals. Some IISs may not store refusals at all. If an EHR would like to reverse a reported refusal, they should reach out to the IIS to discuss how to handle the reversal.

4.17 If a patient does not consent to share their immunization data, what should be sent to the IIS? Should a message still be sent with PD1-12 populated to indicate that the patient data should be protected, or should a message not be sent at all?

The appropriate course of action depends on local policy and regulations. Some jurisdictions accept messages with PD1-12 populated appropriately, while others may request that messages be suppressed in this scenario. Be sure to discuss this topic with your trading partners in order to understand the local requirements.

4.18 How do I populate an HL7 message to indicate that a particular dose needs privacy protection?

The HL7 2.5.1 Rel. 1.5 IG describes how to use PD1-12 to send a Protection Indicator to message the patient's privacy preference (to share data or not). The IG does not indicate how to override the patient level Protection Indicator for specific doses of vaccine. For example, a teen may wish to apply privacy protection to a dose of HPV. While several options exist, there is not currently any community agreement on how to message this.

4.19 How widespread is the usage of ORC-14 (Provider Call Back Phone Number) by IIS?

In most cases, this field is completely ignored. There may be some IISs that store this data, but we are not aware of any IIS that expects data to be sent. To date, there has been no discussions related to this data by IISs, and the current national IG only mentions the field without providing an additional description (which is done for all fields IIS normally care about.) So, there is little evidence this field is used by any IIS today.

4.20 Is it possible to send both CVX and NDC codes in RXA-5 (Administered Code)?

RXA-5 has 2 triplets of components. RXA-5.1 is one code, RXA-5.4 can be another code. The codes must be essentially equivalent, so you can send CVX in one and NDC in the other. Each triplet consists of a code, free text, and a code system identifier. If the code is populated, you must indicate the code system. The national IG does not have preference for the order in which the codes are sent. Receiving systems should rely on the code system (in RXA-5.3 and RXA-5.6) to determine the nature of the code and not assume that code types will always appear in a consistent order.

4.21 When and how should RXA-18 (Substance/ Treatment Refusal Reason) be populated?

If RXA-20 (Completion Status) is indicated as “RE”, then RXA-18 is required. Use table NIP002 as the value set.

4.22 Do we need to accept and store all refusal reasons listed in the value set?

You do not need to store all refusal reasons listed in the value set. IISs should ignore any refusal reason they will not store, but still process the rest of the message normally.

IISs can constrain, but not add to, any value set listed in the IG. However, before constraining any value set, the IIS should evaluate whether the values might be useful for any purpose in the future.

4.23 If an EHR sends our IIS a value for Substance Refusal Reason that we do not accept, should we send an error back?

If your IIS does not accept a substance refusal reason, then an error of warning ("W") or informational ("I") should be sent back in the ACK message to the EHR. The information in the error segment will provide the EHR information for which the value is not accepted.

4.24 When should OBXs containing VIS data be included in a VXU message?

There is a conformance statement (IZ-24) and value set (in appendix A), which indicates that if the CVX code in RXA-5 is in the PHVS_VISVaccine_IIS value set, then VIS OBX segments are required. This means submitting systems must include VIS information for all vaccines typically administered in the US for healthy children and adults. Administered vaccines submitted without VIS information are technically in violation of the current guidance.

However, in most situations IISs are not required to collect VIS information; so in practice, this requirement is not enforced. Senders should send this information when it's available. Regardless, the administered information should still be submitted to the IIS without VIS information.

4.25 RXA-20 (Completion Status) has a usage of RE. What happens if a VXU message does not include a value for this data element?

Sending systems must indicate this and an IIS may reject data that it is not properly designated as complete. Conversely, IISs may accept this data while assuming it's a complete and finished immunization to support legacy systems that are not yet compliant with the latest guide.

4.26 How should non-standard dose amounts be recorded in the IIS?

Technically speaking, an IIS should be able to store any valid mL amount. While 0.7 mL might not be the correct amount for a vaccination, the amount given is the amount that should be recorded in the IIS.

4.27 We would expect to see the maiden name in the last name of the XPN field, since patient's maiden name is a repetition coming in PID-5 if two values are sent anyway, as in the PID message fragment below:

PID|1||1129949^^^^MR||TEST^PATIENT^^^^^L~MaidenName^First name of patient^^^^^M|

If only one last name is sent, I would assume just take that as the maiden name.

This question refers to a **patient's** maiden name; and should not be confused with the **mother's** maiden name (PID-6). The guide requires the patient's legal name to be sent in the first repetition of PID-5, subsequently allowing for a list of other possible names for the patient; to include the patient's maiden name. This is not a data element recognized by the CDC and it's unclear how many IISs potentially accept this name. Still, it can be messaged in the current standards and might be useful for improving matches.

While the data type does require the first name, a sending system may decide to only send the last name. As long as the EHR indicates "M" for Maiden in PID-5.7, then the IIS may read PID-5.1 as being the patient's maiden last name; and without regard to whether other fields, such as patient's maiden first name, are completed.

4.28 Can the date of eligibility (OBX-14) be different than the immunization administration date (RXA-3)?

Depending on the workflow of the clinic, the date of eligibility (OBX-14) could be different than the administration date (RXA-3).

Additional Resource:

Information about populating OBX-14, please see:

https://repository.immregistries.org/files/resources/5d782f0f88b83/observation_date-time_guidance_document_v1_0.pdf

5. Demographics Only

5.1 What is the right way to transmit demographic data about a patient when there is no associated immunization event?

The HL7 2.5.1 Rel. 1.5 IG includes demographics-only messages as a use case while not fully elaborating on how to accomplish the use case. One option is to send a VXU message without an Order Group (the Order group has a cardinality of [0..*] which indicates that it is valid to send a VXU message without any ORC/RXA/RXR/OBX segments). Alternatively, in other interoperability domains, ADT messages are typically used to transmit patient demographic data. Based on discussions by SISC, future versions of the implementation guide will provide guidance on using an ADT message in this use case. In the meantime, be sure to discuss this use case with your trading partners to decide on a message format and the events which trigger a demographics-only message.

5.2 How should IISs handle multiple reported races?

Since PID-10 field is repeatable, IISs should accept all races sent.

6. Query/Response

6.1 What data should be used to populate patient demographics in an RSP response message?

When generating an RSP message, the IIS should echo back the QPD segment received in the QBP query message. This is the patient demographic data sent by the querying system, and it should be returned as it was sent. Other segments in the RSP (PID, PD1, NK1) should be populated with data from the responding system's database. Querying systems may use this data to validate patient selection. Demographic data sent by the querying system in the QPD segment should not be used to populate the PID, PD1 or NK1 segments. The patient ID in QPD-3 should echo what was submitted in the query, but PID-3 can repeat so it can be populated with more than one identifier including:

- The querying system's MR for the patient.
- The IIS ID using a value of "SR" in PID-3.5

6.2 Is it permitted to send an ERR segment and an MSA-1 value of AE within a Z31, Z32 or Z42 message?

The IG lists the usage of ERR as RE (required but may be empty) in all profiles, including the Z42 profile required by Meaningful Use. This is at odds with Figures 41 and 44 in the national IG, which appear to constrain MSA-1 to AA in the absence of serious errors. The figures were not meant to indicate message constraints (although that is not clear from the figures) and we feel it's acceptable for Z31, Z32 and Z42 messages to support both the AE and the AA values in MSA-1. One could conceive of a situation where a trivial error would not prevent a response but could warrant an error message along with a value of AE in MSA-1. We suspect that this would be relatively rare and unimportant. We do agree that a usage of RE in the Z31, Z32 and Z42 profiles is probably more than we need and may change the usage in future releases to O (Optional). Until then, the ERR segment should be supported in all profiles.

Additional Resource:

AIRA has published a new guidance document providing more detail about allowed values for MSA-1, QAK-2 and ERR-4. Please consult this document for additional guidance.

6.3 The RSP message only allows for a single ERR segment. What should I do if more than one error is generated?

The HL7 base standard only allows a single ERR segment in an RSP^K11 message. We have worked with HL7 to submit a proposal to allow ERR to repeat, however, this will not be available in the base standard until version 2.9. At this time, we don't have required guidance on how to prioritize errors, but strongly recommend that your local business rules prioritize errors according to severity and return the most severe error found.

Additional Resource:
guidance_for_hl7_acknowledgement_messages_to_support_interoperability_.pdf (immregistries.org)

6.4 How should ORC-3 (Filler Order Number) be populated in the RSP message?

For a given dose, there are really three types of "immunizations IDs" an IIS might know about for a particular immunization:

- **Querying System Immunization ID**
  - This is the ID sent in the VXU (if the querying system has sent a message for dose) and is the unique identifier for the dose from the system querying the IIS.
- **Other External System Immunization ID**
  - This is the ID sent in the VXU but was from a different provider. That is, this immunization was reported by someone other than the system who is doing the query.
- **IIS Immunization ID**
  - This is the IIS internal ID (usually automatically assigned upon insert into the DB (e.g., the primary key)

When replying to a query:

- ORC-3 should be the Querying System Immunization ID when known
  - This ID may not be known with UI entry or in the case where the immunization was submitted by someone other than the querying system.
  - Otherwise the IIS Immunization ID
- ORC-3 should not be the Other External System Immunization ID
- e.g., The IIS wouldn't return Dr. Alpha's Immunization ID in Dr. Beta's RSP.

6.5 How should ORC-17 (Entering Organization) be populated if the administration was entered into the IIS by IIS staff from a paper record? Should it reflect the organization who submitted the paper record or the IIS who entered it?

The HL7 base standard defines ORC-17 as "This field identifies the organization that the enterer belonged to at the time he/she enters/maintains the order, such as medical group or department."

This could refer to any number of organizations, such as: the one that gave the dose, the one that reported it electronically to the IIS (which may not be the one that gave it), the one that reported it via paper to the IIS or the IIS itself if they are the first to electronically capture the data.

6.6 Which of the three different LOINC codes for "vaccine type" (30956-7, Vaccine Type; 30979-9, Vaccines Due Next; or 38890-0, Component Vaccine Type) should be used when constructing an RSP message?

The HL7 2.5.1 Rel. 1.5 IG notes that 30956-7 is preferred over 38890-0. 30956-7 is used in 2015 EHR certification testing. To ensure consistency, we recommend using 30956-7 over both 38890-0 and 30979-9. Future versions of the implementation guide will provide additional guidance on which LOINC codes are appropriate in a given context.

6.7 When transmitting a recommendation, should the RSP contain the CVX code for the vaccine group or for a specific vaccine?

This is an area where "just enough Information" is likely better than prescriptive "give exactly this product". That said, sometimes giving more information is warranted because the ACIP schedule dictates a specific vaccine should be given based on previous administrations. In those cases, you may want to get more prescriptive. From a conformance perspective, any CVX is technically legal. In most cases, the CVX for the vaccine group is usually the most appropriate, whereas recommendations for specific vaccines are only appropriate for a few cases. However, this is managed by the CDS engine that produces the recommendation and is not constrained by the messaging standard which allows for any CVX. The message should accurately reflect the vaccine the CDS engine is recommending. Please see the CDSi project for more information on how CDS engines should properly generate recommendations.

6.8 What is the best way to handle a scenario where the database does not contain discrete or parseable Administered Amount data with which to populate RXA-6 and RXA-7?

While dealing with older data, or data being submitted by organizations which do not adhere to HL7 2.5.1. Rel 1.5 IG requirements for VXU messages, it is possible to have data that can't be used to populate the administered amount (RXA-6) and units (RXA-7) in a reliable manner. In this case, rather than sending questionable data in the RSP message, we recommend that RXA-6 be populated with 999 and RXA-7 be left blank. This is how these fields will be populated for historical vaccination events. We do not believe a lack of data in these fields will be a serious impediment to quality patient care on the part of the clinician receiving the RSP message.

6.9 How many patients can be returned in a query response?

In response to a Z34 query, if the jurisdiction is allowed by local regulation, law, and policy to indicate that multiple patients were found, the maximum number allowed to be returned using the Z31 profile is the lower of the maximum number requested (via RCP-2 in the query message) and the maximum number that the receiving system is capable of returning.

In response to a Z44 query only a single patient may be returned using the Z42 response profile because RCP-2 is fixed to a value of 1 record. If multiple matching patients are found, the Z33 profile is used to indicate that a single high threshold match was not found.

6.10 Should a responding system ever filter the doses returned in a query response? Should the IIS filter administrations returned as part of a query response such that doses contributed by the querying system are not returned?

Some providers are reporting problems with reconciling administered doses since the IIS query response includes doses already included in the provider's EHR system. In some cases, the EHR is not able to filter doses appropriately in the display, consequently creating duplicates.

We strongly recommend that IISs do NOT filter the query response in any way.

6.11 Should the IIS filter administrations returned as part of a query response such that for protected patients only doses submitted by the querying system are returned?

We strongly recommend that IISs do NOT filter the query response in any way. Returning a partial history for a patient is problematic for many reasons. Special care should be taken if local policy requires any kind of filtering of immunization history.

6.12 When would a refusal be sent in an RSP message?

Refusals can be returned in an RSP message. However, consideration of the following is recommended:

- CDS engines should not consider refusals
- Doses due will continue to be forecasted regardless of previous refusals
- IIS should work closely with trading partners to ensure that, if sent, refusals will be handled appropriately by the receiving system

6.13 How should I submit a re-query after Z31 RSP?

When a provider queries for a patient, the IIS might return a Z31 (Return Candidate Clients) if the IIS is unsure exactly who the provider is looking for. Note: Not all jurisdictional policies allow for multiple patients to be returned.

The provider selects the proper patient from the Z31 and issues a re-query to the IIS:

- The EHR should re-query with data found in Z31 RSP, NOT with data from EHR
- IIS should leverage the SR ID to improve the matching score

NOTE: This is NOT a patient matching problem where the provider believes the IIS hasn't properly merged. The two or more records presented to the provider are indeed unique people.

Additional Resource:
Further guidance on queries and managing multiple matches can be found in the IIS Functional Guide, Vol.1: Query and Response.

6.14 How do I indicate disease with presumed immunity when full observation date is not known

Sending on OBX with history of disease (LOINC 59784-9) OBX-14 is required when the date of the observation is known. A recent decision by SISC clarifies this as "If the appropriate value is not known, OBX-14 should remain empty – it is an RE field and is not required in every message instance." If the sender does not know the full date, and only knows the year and month, there are two options:

1. Do not send a value in OBX-14, leave it blank
2. Send only the YYYYMM in OBX-14

Option #2 is technically a conformance violation, but may be done if the submitter wishes to allow systems capable of accepting a partial data to receive this information. Receiving systems that cannot accept this value should continue to process the message as OBX-14 is an RE field. A conformance issue here should cause that system to treat this field as a blank.

6.15 Why is dose validity not required for all vaccinations?

Dose validity may not be applicable to all vaccinations, therefore it can't be required. However, IISs should send dose validity for all vaccinations that are evaluated.

6.16 Why are error segments in the RSP only 0..1?

This is a limitation of the base HL7 standard with guidance on how to pick the one error to return when multiple errors might exist.

Additional Resource:

guidance_for_hl7_acknowledgement_messages_to_support_interoperability_.pdf (immregistries.org)

6.17 What to send back when there is an error in a query.

An RSP^Z33 should be used instead of an RSP^Z23.

6.18 What is the best approach for returning the information to the requestor when presented with a query request (QBP) for vaccine history, given the requesting facility was the one who administered the vaccine or even the one who reported it?

We know of no requirement for which an IIS should report "00" administered vaccinations as being administered. The use of this field is primarily to support EHR reporting to the IIS and to differentiate the vaccinations that might need to be decremented and represent a primary source of the record. I think many IISs return the information source flag as sent in. However, this is changing because IISs are now reporting to other IISs; and the current recommendation for those entities is for the IIS to report and receive all vaccinations from other IISs as being "historical".

Getting into more details I would say the following is correct:

- An IIS can represent administered vaccinations as either administered or historical. There is no general guidance that the IIS must do one or the other.

- An IIS should send all the information it has (unless prevented by policy or law). So, send the administered amount when known.

- Any information you might send with an administered vaccination can also be sent with a historical record. You do not have to limit the information of an administered dose if you represent it as a historical.

- You could look at reporting a different information source code such as 08, but we have not seen anyone do this and it will likely lead to confusion and problems for others.

Having a policy of simply always reporting the vaccinations as historical seems to be a very practical solution, unless you can find a good business reason why your partners need to know the distinction.

Additional Resource:
https://repository.immregistries.org/files/resources/5a83216a1d369/aira_functionalguidevol1_final.pdf

6.19 Should patient first name, last name or DOB be a hard rejection (AR) and the message rejected completely since these are crucial data elements?

No, these should be "AE". HL7 V2 (the base international standard) is very specific that "AR" – unfortunately – can only be used in very limited situations. See the ACK Guidance document for discussion/definition on this. These examples would be "AE" with a Severity of "E".

Historically, some IISs define a concept of "hard rejection" and use "AR" to signal this. However, this is not a concept defined in the IG, and the use of "AR" this way is not consistent with the current guide or recent ACK Guidance. The correct response should be "AE" to indicate the data needs to be corrected and resubmitted. Application reject (AR) can only be used in very limited situations. See the ACK Guidance document for discussion/definition on this.

Additional Resource:
IIS Health Level 7 (HL7) Implementation | CDC

6.20 We don't really reject any message if RXA is missing required fields that we deem need to be there. However, we would want to send back an AE and error warning severity of W so the provider would fix the transaction since there is a loss of information.

If the message doesn't justify the provider (or EHR) to take action and resubmit, the ACK would contain either "AA" (with no err segments), "AA" with only "I" level severity, or "AE" with "W" level ERR segments. No "E" level ERR segments here.

If important information has been lost, and you would like to request the submitter to fix and resend, then you must indicate this with a warning severity of "E". You are still free to process as much or as little of the message as your business rules allow. For example, you could process the other vaccinations while indicating one of them has a problem and requires resubmission of the entire message.

Additional Resource:
https://repository.immregistries.org/resource/guidance-for-hl7-acknowledgement-messages-to-support-interoperability/

6.21 We will not store a vaccination with a bad date but we may still accept the patient information on the same message. Should we indicate this as AE or AW at the error level?

In this situation, you can still store any information in the message that is good, while still rejecting the message for correction and resubmission. That is, you can map the patient and issue an AE + E for the RXA errors. An AE + E is an indication to the EHR that errors must be corrected and resubmitted. Of course, on resubmission you'll get the patient again, but this approach allows you to store as much good data as possible while the IIS should be deduplicating duplicate reports anyhow. For example, if a message contained five vaccination events with four of them being good and one of them being bad, you can store the patient in order to maintain the four good immunizations; and reject the bad with an AE + E for correction and resubmission. The EHR might resubmit the entire five vaccination events again, but that shouldn't be a problem for the IIS.

Additional Resource:

American Immunization Registry Association | Resource Repository (immregistries.org)

6.22 Anything that would be error warning of severity of I would be an AA response.

This is correct, provided there are no "W" or "E" severity errors.

6.23 One jurisdiction has not allowed insurance companies to use QBP/RSP on the MIIS due to state legislation. Should insurance companies be allowed to query the registry like normal providers or should we set up a specific specification for insurance companies?

This inquiry is a policy question. The IG defines a QBP/RSP mechanism but does not define who the IIS may authorize to use the functionality. There is nothing technically preventing you from using the same QBP/RSP. However, are there demographics or other data that you return to providers which wouldn't be able to be returned to insurance companies? If so, then you probably have a couple options.

6.24 Is it appropriate for an IIS to return an invalid code in an RSP, if it was in the original VXU message that was sent? Should the IIS only include valid HL7 codes in the RSP or is it appropriate to return whatever is in the patient record (valid or invalid)?

We recommend not returning invalid codes. The system that sent the data may be able to understand it (since they sent it), but many other receiving systems may struggle to understand the code; and this could have unintended consequences. This approach would work for many fields, but not all fields; especially for those fields with are considered more critical which can potentially change the meaning of the overall data.

6.25 While reactions go with the vaccine, should there be a RXA with 998 (no vaccine), followed by comment OBXs? This is how we are sending it the in Z22 message.

If the IIS decides to report this back out on a query, then they would report it as you have shown below, under a CVX 998 code. This is the same location to which CDS recommendations are sent. There is no need to put this contraindication under its own RXA/ORC. It can be placed with other "patient level" observations. Other than being used to indicate that the following OBX segments don't apply to a specific vaccination (therefore being at the patient level), there is no meaning assigned to the ORC/RXA segment when CVX 998 is sent.

Additional Resource:

https://repository.immregistries.org/files/resources/5938386822754/message_structure_guidance_document_v1_1__formatted.pdf

6.26 For the LOINC codes 30956-7 Vaccine Type and 38890-0 Component type we are sending the CVX for "unspecified formula". For COVID, we would like to use the specific vaccine CVX (currently 207 and 208) and not use 213.

- Evaluation should always use the unspecified code. The specifics of the vaccine type administered are found in the RXA segment.
- Forecasting should use the unspecified code until the IIS knows dose one. Given current ACIP recommendations, it then seems logical (and recommended by ACIP and documented in CDSi) to forecast a specific second dose. Obviously, this can/will change as ACIP recommendations change, so it should be configurable to plan for the future. This does happen occasionally in other cases (e.g., MenB), though rare and almost never (that I can think of) happening prior to the first dose. In general, using the Unspecified code is preferred so as not to cause confusion (e.g., recombivax is forecasted, but the provider doesn't have that in stock, Can they use another product?).

6.27 How can we retrieve complete immunization history of the same record we just inserted? The QPD segment, does not seem to have any unique identifier.

QPD-3 PatientList is equivalent to the PID-3 Patient Identifier List. You should put your MRN in this field, just as you would in PID-3. Most IISs require this field to be populated and use your MRN as a strong indicator of which patient to return.

6.28 Is it permitted to respond with a Z42 message in response to either a Z34 or Z44 query and let the Provider decide whether to consume the forecast or not?

This approach isn't standard per the HL7 2.5.1 Rel 1.5 IG. The IG defines a set of transactions related (see tables 7-2 and 11-2). Responding with a Z32 message upon receiving a Z42 message is inconsistent with the national IG and should be avoided. Because the national IG does not exclude particular LOINC codes from a given profile, a forecast may be included in both Z32 and Z42 messages so they – in essence – overlap, but each meet the requirements of their respective profiles. For MU3, EHRs will be required to consume and display a Z42 response. The IIS will need to declare readiness for returning a Z42.

7. Transport

7.1 With the CDC WSDL, should the same endpoint be used for both VXU/ACK and QBP/RSP messages or should there be two separate end points?

The HL7 2.5.1 Rel. 1.5 IG is silent on the transport mechanism, but we recommend implementing the CDC WSDL. Currently, a single endpoint is the arrangement used by all known IISs. Requiring partners to use two separate URLs will likely cause interoperability headaches and barriers.

7.2 Which webservice protocol is recommended, REST or SOAP?

In 2011, a panel of industry experts concluded that SOAP Web Services was the best fit for meeting the needs of transmitting immunization data via HL7 messaging. The experts also defined a WSDL for all trading partners to implement, with the goal that all trading partners implement at least the nationally specified WSDL. This doesn't preclude IISs and others from supporting additional transport layers.

It's important to note that the top priority for transport is to support sending of HL7 messages. Any transport protocol that the sender and submitter can each support is acceptable for sending immunization data in production system. The SOAP standard is recommended by the community and has been widely adopted by nearly every IIS. Systems that can support this protocol have at least one common transport mechanism that will work seamlessly with most/all IISs and EHR systems working in the immunization space.

Additional Resources:

- https://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/services.html
- Transport 101
- SOAP WSDL 101

8. Constraining Local Profiles

8.1 Where can I find guidance for local guide authors about how R, RE, O, and X usages can be changed in a local IG?

Some basic rules for constraining the national IG are documented in the conformance chapter (Chapter 2B starting in version 2.6) of the HL7 base standard. While Chapter 2B makes its first appearance in version 2.6, the content is applicable to all versions of HL7. We recommend examining the most recent version (2.8.2) of the base HL7 standard when reading Chapter 2B. In general, a local IG is only allowed to add constraints to the national IG, not loosen them. For example, an RE (required but allowed to be empty) usage can be tightened to be R (Required) but cannot be loosened to O (Optional).

When expanding value sets used in a local IG, consider the following:

- Where possible be very specific about which values in a value set you require to be supported by a trading partner.
- Consider any functional implications for the new value(s). Some new values may impose a new requirement for functionality or workflow in the trading partner system.
- If the concept being added to the value set is already represented by a permitted value in the value set that permitted value must be used.
- A local code cannot be added to an open value set to represent an explicitly excluded concept already listed in the value set.
- Once a value is included in a value set, it cannot be redefined. For instance, once B is defined as Blue, it cannot be redefined as Baby Blue. A new code must be created for the new concept.

8.2 Can a derived specification use data elements with an Optionality of B (backwards compatible) or W (withdrawn)?

Per Chapter 2b (Conformance) of the base standards, derived specifications can still use Backwards Compatible data elements (they can be assigned a Usage of R, RE, O or C (a/b)).

Elements in the base standards with an Optionality of W (withdrawn) can only be given a Usage of X in a derived specification.

8.3 Profile Z31 in the HL7 2.5.1 Rel 1.5 IG provides information about what needs to be done in case there are a list of potential matches for a query. Is there any standard for the threshold of the maximum number of potential matches that an IIS sends?

No, the IIS maximum is a local policy decision. Keep in mind the sending system also uses RCP-2 to set an upper limit on the number of candidates it will accept in response to a query. It expects that a responding system will send no more candidates than this number. The maximum number of candidate patients should be no more than the lower of these two numbers.

9. Evaluating Conformance

9.1 When should the receiving system apply Conformance Statements and other requirements from the HL7 2.5.1 Rel. 1.5 IG?

Receiving systems should apply business rule checks that align with IIS policies for quality of incoming data and only verify conformance statements supporting those IIS policies. IISs are not required to verify HL7 conformance for every received message, and if they do, they should indicate the severity of violations consistent with IIS policy. IISs should focus on receiving good data, not on enforcing every conformance rule.

10. Emergency Response

10.1 During emergency responses, it may be important to track and share vaccination information for priority groups, such as those in with particular risk factors or those in a specific line of work. Is there a way of doing so?

Yes, AIRA has been working on guidance for reporting information on specific population groups and tiers (see: https://repository.immregistries.org/resource/priority-group-preliminary-guidance/) for HL7 messaging. Population groups could be categorized based on: occupation, risk factors, or other information about the person; and in accordance with CDC or local guidance.

This information would then be messaged in an OBX segment at either the patient or vaccination level:

> OBX|2|CE|95715-9^ Population group^LN |1| COVID-01^Deployed \T\ mission essential personnel^999|||||F|||20200654

10.2 Is there any additional information on documenting COVID OBXs specifically eligibility and funding codes at this time?

COVID OBXs were discussed on the October 2020 SISC call. Most participants on the call thought the proposed solution of coding funding source as Public (VXC50) and Eligibility as Not VFC Elig (V01) would be workable.

This solution is workable for now, and when it is no longer federally funded, the COVID vaccines should be coded as appropriate.

10.3 Regarding the CVRS, where should providers place VTrckS Provider PIN in their HL7 messages to IISs?

EHR providers are not being asked to put VTrckS pin anywhere, not even RXA-11.4.2. That might be something for reporting to CVRS, but it's not directly related to what EHR's are sending to IISs. EHR systems should follow and meet the requirements of the current guide whereas IISs are responsible for meeting the additional reporting requirements that CVRS maintains.

Questions about this FAQ?
Contact the AIRA Technical Assistance Team
Using either this weblink, or email info@immregistries.org.
