

Appendix B – Guidance on Usage and Example Messages

Double line Boxed comments will be removed in final document.

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DRAFT

Immunization History Definition

An immunization history consists of the following components:		
Data Element	NVAC ¹ Core Data Element ²	HL7 Message Location
Client identifiers ID ³ Name Mother's maiden name	Optional Required Required	PID-3 PID-5 PID-6
Client demographics Race Ethnicity Gender Birth date Death date Birth order Multiple Birth Indicator Birth State Birth facility	Required Required Required Required Required Required Required Optional	PID-10 PID-22 PID-8 PID-7 PID-29 PID-24 PID-25 PID-11
Client locators address phone (and email)	Optional Optional	PID-11 PID-13
Client IIS status (MOGE)	Optional	PD1-16
Client eligibility for vaccine funding (VFC)	Optional	PV1-20
Client primary language	Optional	PID-15
Client privacy request (protection of information)		PD1-12
Client desires on being contacted for reminders		PD1-11
Next of kin name, address and phone number	Optional	NK1 Segment
History of vaccine preventable disease such as Varicella	Optional	OBX segment

¹ National Vaccine Advisory Committee

² Required means that a system must be able to store if known. Optional means that a system should be able to store if known.

³ ID is a list of all important identifiers like IIS id, medical record number, birth registration number and SSN.

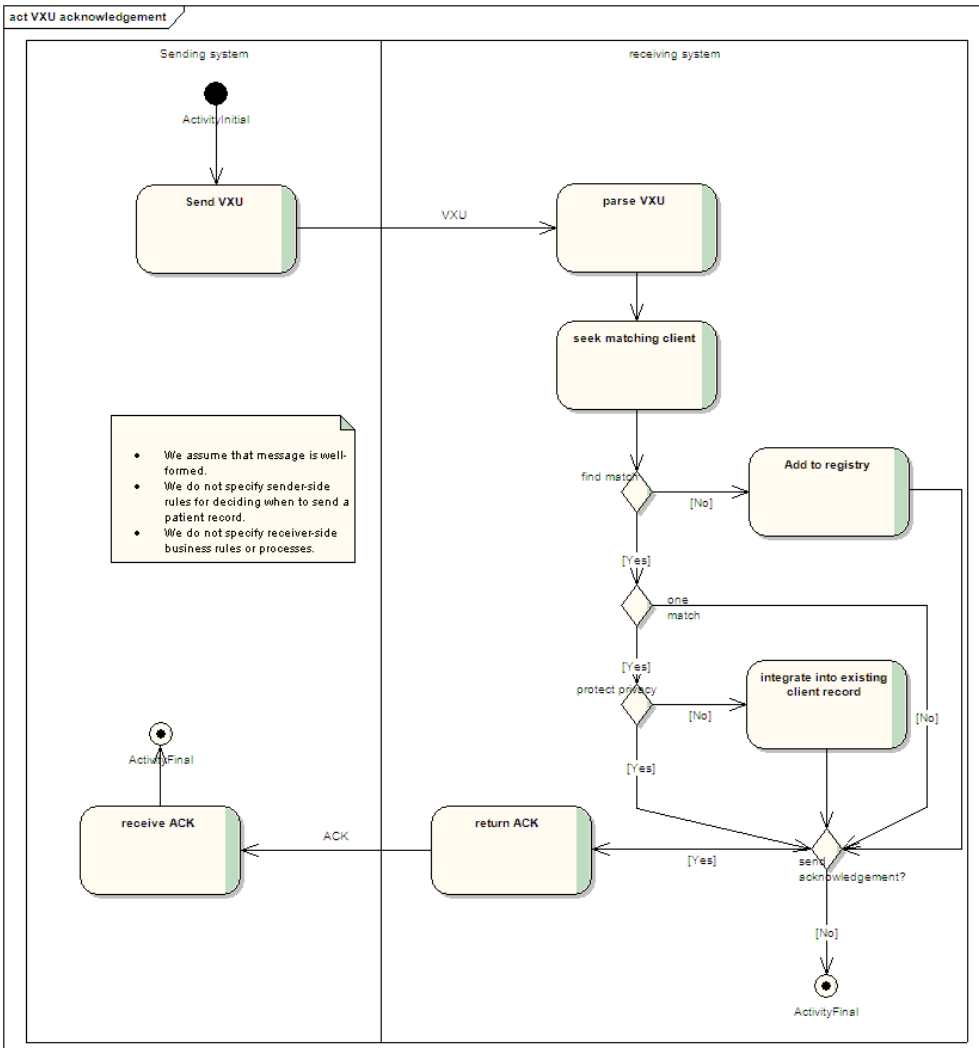
An immunization history consists of the following components:		
Data Element	NVAC ¹ Core Data Element ²	HL7 Message Location
Immunization records		RXA segment
Vaccine	Required	RXA-5
Vaccine lot	Required	RXA-15
Vaccination date	Required	RXA-4
Quantity		RXA-6 and RXA-7
Vaccine provider Administering Organization	Optional	RXA-10
Ordering clinician		ORC-12
Clinic site of administration		RXA-11
Manufacturer	Required	RXA-17
Vaccine information sheet date		OBX segment
Injection site	Optional	RXR-2
Administration route		RXR-1
Vaccine Expiration Date	Optional	RXA-16
Funding source		OBX segment
Record source (historical indicator)	Optional	RXA-9
Reactions to vaccination		OBX segment
Refusal of vaccination		RXA-18 and RXA-20
Client conditions that impact forecasting and dose validation		OBX Segment
Next dose forecast		OBX Segment
Validation of recorded dose based on schedule recommendations		OBX Segment

Send Immunization History (VXU)

Business Process

The following activity diagram illustrates the process of sending and receiving an immunization history. It is meant to be illustrative and not prescriptive. With the exception of the HL7 message structure processing and the return of an

acknowledgement, the activities are based on local business rules. These rules must be documented for smooth interoperability. HL7 only addresses the messages, VXU and ACK.



1. The process for sending a VXU (Immunization history) begins with the sending system building the VXU message.
2. The sending system connects to the receiving system and sends the VXU.
3. The receiving system accepts the message.
4. The receiving system parses the message and validates.
 - a. Determine if message meets HL7 rules

- b. Validate based on local business rules⁴
- 5. Seek matching client in receiver data base
 - a. No match is found⁵
 - i. Add the client to the receiver database.
 - ii. Send acknowledgement message⁶
 - b. Exactly one match found
 - i. Determine if client in receiver data base has indicated that his/her data is to be protected (protection indicator = Y)⁷
 - ii. Protection indicator = Y
 - 1. Do not integrate record into receiver data base
 - 2. Send acknowledgement⁸
 - iii. Protection indicator = N
 - 1. Based on local business rules, integrate incoming record into receiver data base.
 - 2. Send acknowledgement
 - c. More than one match found
 - i. Send acknowledgement⁹
- 6. Send acknowledgment to sending system
- 7. Sending system accepts acknowledgement message.¹⁰

Note that sending system may indicate that it does not accept acknowledgement messages. In this case, no acknowledgement is returned. This is not recommended.

It is expected that a client's immunization is the complete history known to the sending system, and not just updates on new information in the sending system. This has important implications for processing those incoming records. At the same time, the

⁴ See Send Error in ACK for dealing with errors if either of these two tasks identifies problems.

⁵ Local business rules determine what happens next, but we assume that it is a simple insert of the client record. The receiving system may require review and confirmation prior to insertion. Other systems may choose to require human review before adding to data base.

⁶ See Send Acknowledgement with no error.

⁷ Locally, this may be known as the sharing indicator. In this case, the equivalent value is sharing = N.

⁸ Local business rules may vary. In general, the acknowledgement may reject the client record, but not indicate the existence of the client record in the receiver system.

⁹ Local business rules will determine how the multiple matches are to be handled. The record could be put into a pending state, rejected outright, loaded in as a new record for clean up later.

¹⁰ The sending system response to an acknowledgement message (ACK) is locally determined. Good practice would be to have a way to use the ACK to alert user to outcome and to allow trouble-shooting of problem messages.

sending system may not know of all immunizations, so receiving system must have a process for integrating the received data into an existing record. The Modeling Immunization Registry Operations Workgroup (MIROW) has produced a chapter of best practices on this process. This is available on the American Immunization Registry Association web site (www.immregistries.org).

The following example messages represent straightforward immunization history messages. They do not illustrate dealing with specific use cases, such as messaging reactions, client specific conditions or vaccine forecasts. Clearly, these may be components of a VXU, but will be addressed separately to simplify the messages.

It is important to reiterate here that conformant systems should be able to successfully populate and process the VXU message segments and fields identified as Required or Required but may be empty. They should be able to populate and process conditional items when the predicate conditions are met. If segments or fields are optionally repeating, they should be able to gracefully handle the repetitions. Systems that do not conform to these expectations risk missed data.

Supported Message Segments

The following table lists the segments and their usage.

Segment	Cardinality	Usage¹¹	Notes
MSH	[1..1]	R	Every message begins with an MSH
PID	[1..1]	R	Every VXU requires one PID
PD1	[0..1]	RE	
NK1	[0..*]	RE	NK1 may repeat and may include the client with a relationship of self.
PV1	[0..1]	RE	
IN1	[0..1]	O	IN1-3 are not specified in this guide.
IN2	[0..1]	O	
IN3	[0..1]	O	
All of the following segments are part of the ORDER group. A VXU does not require an ORC group, allowing update of patient/client related data in the absence of updated RXA data. Each RXA does require an ORC.			

¹¹ R means it is required. RE means it is required if known/available. X means not supported in this Guide. O means optional.

ORC	[0..*]	RE	
RXA	[1..1] ¹²	R	Each RXA is the child of on ORC
RXR	[0..1]	RE	Each RXR is the child of one RXA
OBX	[0..*]	RE	Each OBX is the child of one RXA. Each RXA may have more than one OBX segment.
NTE	[0..1]	RE	Each NTE is the child of one OBX

Example VXU # 1-Basic message:

Storyboard:

Johnny New Patient (male), born 4/14/09 has had 1 dose of Hep B on 4/15/09, according to the record brought in by Mom (Sally Patient). They live at 123 Any Street, Somewhere, Wisconsin 54000. Nurse Sticker at Dalittle Clinic (DCS_DC), administers the following shots on 5/31/09:

- DTAP-Hep B-IPV (Pediatrix) lot # xy3939 IM
- HIB (ActHIB) lot # 33k2a IM

They were all ordered by Dr Mary Pediatric who belongs to Dabig Clinical System (DCS). Mom acknowledged that his data may be shared with other providers. Johnny is eligible for Medicaid. His medical record number in Dabig Clinical System is 432155. Myron Clerk entered the information into the EHRs (MYEHR).

The information was sent from Dabig Clinical System to the State IIS

Note that we will indicate the end of each segment with a <CR>. Segments may wrap around in this document. We will insert a blank line between each segment for increased readability.

```
MSH|^~\&|MYEHR|DCS|||20090531145259||VXU^V04^VXU_V04|3533469|P|2.5.1
||AL <CR>
```

```
PID|1||432155^^^DCS^MR||Patient^Johnny^New^^^L||20090414150308|M||
123 Any St^^Somewhere^WI^54000^^L<CR>
```

```
PD1|||||||||N|20090531<CR>
```

```
NK1|1|Patient^Sally|MTH|123 Any St^^Somewhere^WI^54000^^L<CR>
```

¹² Each ORC must have 1 RXA and each RXA belongs to exactly 1 ORC.

```

PV1|1|R|||||||||||||V02^20090531151344<CR>
ORC|RE||197023^DCS|||||^Clerk^Myron||^L||||DCS^Dabig
Clinical System^StateIIS<CR>
RXA|0|1|20090415132511|20090415132511|31^Hep B Peds
NOS^CVX|999|||01^historical record^NIP0001||||| <CR>
ORC|RE||197027^DCS|||||^Clerk^Myron||^Pediatric^MARY^^^^^^L^^^^^^
^^^^^MD<CR>
RXA|0|1|20090531132511|20090531132511|48^HIB PRP-
T^CVX|999|||^Sticker^Nurse|^DCS_DC|||33k2a||PMC^sanofi^MVX<CR>
RXR|IM^IM^HL70396<CR>
ORC|RE||197028^DCS|||||^Clerk^Myron||^Pediatric^MARY^^^^^^L^^^^^^
^^^^^MD<CR>
RXA|0|1|20090531132511|20090531132511|110^DTAP-Hep B-
IPV^CVX|999|||^Sticker^Nurse|^DCS_DC|||xy3939||SKB^GSK^MVX<CR>
RXR|IM^IM^HL70396<CR>

```

Example VXU #2 - Indicate vaccine funding source and client eligibility status:

Immunization messages must be able to convey the eligibility status of a recipient when they received immunizations. In addition, these messages must be able to include information on the funding source for an immunization. While these are related, they are separate concepts.

Eligibility status:

The PV1 segment shall be used to convey eligibility status, as it has in the past. The PV1-20, Financial Class, is a repeating field of FC data type. This data type is composed of two components. The first is financial class code (data type IS) and points to a user defined table (0064). The second component is Effective Date and in our case indicates when the financial class was determined. The format is displayed below.

/Financial class^Effective date/

A repetition is indicated by the repetition symbol, ~. The repetition follows the ~. If a list of eligibility is sent, the repetitions should be unique on financial class and effective date. That is, two different financial classes may have the same effective date. Similarly, two different effective dates may have the same financial class.

Only the current eligibility needs to be sent in a message, but the history of eligibility should be stored. Receiving systems should be able to accept either current eligibility or complete history of eligibility.

Eligibility status is a key data element for creating the Vaccines for Children (VFC) report on vaccine usage. Support for this report requires that systems store a history of eligibility statuses and assessment dates. In the past, some systems have only kept the most current status. This prevents accurate reporting.

Sending One Financial Class With Date:

The following example shows the PV1 segment with one financial class and effective date.

MSH... .

PID...

PV1|1|R|||||||||||||||V02^20090531151344<CR>

Sending Two Financial Classes With Dates:

The following example shows the PV1 segment with two different financial classes and their effective dates. The first financial class is from the standard VFC classes and the second is a hypothetical financial class. Both were evaluated on the same day.

MSH... .

PV1|1|R|||||||||||||||V02^20090531151344~IHS02^20090531151344<CR>

If repetition is used and indicates 2 financial classes on the same date, they should not be mutually exclusive. (i.e. Medicaid and not eligible for VFC)

Documentation of local usage will greatly facilitate interoperability. This documentation should include both local values in table 0064 and business rules for processing.

Funding Source:

The funding source of a vaccination indicates who paid for a given immunization. Table xxx lists the categories. Local systems may support additional values, but must document them.

Comment [RS1]: We still need a LOINC code as well. So the codes in the examples are stand-ins.

We still need a LOINC code as well. So the codes in the examples are stand-ins.

The following table lists the value set.

Value	Label	Definition
PVF	Private funds	Immunization was funded by private funds, including insurance.
FDF	Federal funds	Immunization was funded with public funds from the federal government.
STF	State funds	Immunization was funded with public funds from a state.
MLF	Military funds	Immunization was paid for with military funds.
TRF	Tribal funds	Immunization was paid for with tribal funds.
OTH	Other	Immunization was paid for by funding not listed above.
UNS	Unspecified	Funding source for immunization is not specified.

The funding source may be linked to each immunization record, using an OBX segment. (See note below for the supporting infrastructure on the system side.)

Note that the order of OBX segments is not specified. They may appear in any order. So one immunization may have an OBX listing funding source, followed by an OBX indicating an adverse reaction. The order may be reversed and receiving system should gracefully handle them in either case.

The following example shows an immunization record with one funding source and a second, historical record of an immunization without a funding source.

MSH...

```
ORC|RE|197027^DCS|1970237^DCS|||||^Clerk^Myron|^Pediatric^MARY^^^
^^^L^MD<CR>
```

```
RXA|0|1|20090531132511|20090531132511|48^HIB PRP-
T^CVX|999|^Sticker^Nurse|^DCS_DC|||33k2a|PMC^sanofi^MVX<CR>
```

```
OBX|1|CE|11111-1^funding source for immunization^LN|1|PVF^Privately
funded^table source||||F|||20090415132511<CR>
```

```
RXR|IM^IM^HL70396<CR>
```

Comment [RS2]: This needs to be fixed when codes are determined.

```
ORC|RE|197023^DCS|197023^DCS|||||^Clerk^Myron||^L||||DCS^
Dabig Clinical System^StateIIS<CR>

RXA|0|1|20090415132511|20090415132511|31^Hep B Peds
NOS^CVX|999|||||||<CR>
```

In the example above, we see that the first immunization in the message was funded by Private funding. The second immunization in the message does not have funding source included, probably because it is not able to be determined, since it is a historic record of an immunization.

Supporting infrastructure:
In order to support this level of detail, the funding source for each dose of vaccine given must be recorded. There are a number of potential solutions, but one logical one is to build on existing inventory management capabilities. If each immunization is pulled from a specific lot of vaccine and that lot has a funding source associated, then the funding source may be determined. This would require that the inventory management system would need to separate vaccine lots with the same lot number, but different funding.

Example VXU #3 - Include immunization history evaluation and forecast in VXU

Comment [RS3]: The LOINC codes and value sets are still in the process of development. The basic concepts should not change.

The LOINC codes and value sets are still in the process of development. The basic concepts should not change.

Evaluating an immunization history, based on the recommendations of the ACIP schedule or other schedule is an important function provided by many IIS. Based on this evaluation and other factors, recommendations may be made for next doses due. Some of their trading partners would like to receive the outcome of this evaluation. The previous implementation guide included a method for accomplishing this using OBX segments. This document illustrates how this is done and expands on the types of information that may be messaged.

This document does not describe nor specify the functionality or accuracy of the forecasting service. The focus is only on the content of the messages. Implementations should publish documentation on local specifics.

This document is not meant to support a call to a forecasting and evaluation service. It is meant to support existing applications that message vaccine forecasts and evaluation as a part of a complete immunization history.

When a clinician evaluates a person’s immunization history and makes recommendations, she/he must use a standard (schedule). Traditionally, clinicians have evaluated based on vaccine groups or families. The schedule has one or more sets of immunization events that can be satisfied to indicate protection against the diseases of the vaccine group of interest. These constitute a series.

The following table lays out the information needed to convey an evaluation and forecast.

Data element	Use	Current status in HL7 VXU	Optionality for meaningful evaluation and forecast¹³.
Schedule	Identifies the standards used. ACIP is the prototypical example.	Not available	Required
Vaccine group/family	Identifies which diseases are expected to be prevented by completion of series.	Can be accomplished using vaccine, NOS, CVX codes. Combination vaccines require special OBX segment.	Required
Series name	Name of the specific set of doses and recommendations that were used to evaluate this dose and make recommendations.	Not available	Optional
Ordinal position in primary	Indicates which dose in a series this given immunization	Use LOINC 30973-2	Required

¹³ This does not mean that every message must have one of the required OBX. It just means that this concept needs to be known to put the evaluation and forecast in context.

¹⁴ Note that we are talking about primary series and not the booster doses that may follow completion of a primary series. For example, Td has a series of closely spaced doses in the primary series, followed by intermittent doses that are recommended 5-10 years after completion of the primary series. In the cases of ordinal position and number of doses in series, we are only considering those in the primary series.

¹⁵ Need to deal with boosters.

Data element	Use	Current status in HL7 VXU	Optionality for meaningful evaluation and forecast ¹³ .
series ¹⁴	fulfills. ¹⁵		
Dose Validity ¹⁶	Indicates if this dose was given appropriately for this series in this schedule.	Not available	Optional
Number of doses in primary Series	Indicates how many appropriately given doses are required to meet the goals of this series. Note that in the case where there are doses that may be skipped, due to the age of the client/patient, the number shall reflect the adjusted number of doses.	Not available	Optional
Series Status	This indicates the status of the client's progress toward meeting the goals of the series selected. This could be complete, overdue, in progress, etc.	Not available	optional
Next dose forecast	Can indicate earliest, recommended and latest due dates for next dose. Need to add overdue date and latest date	LOINC 30979-9&30980-7 – Date vaccine due 30979-9&30973-2 -- Vaccine due next dose number 30979-9&30981-5 – Earliest date to give	Required for forecast

¹⁶ This might be redefined to include incomplete dose and impotent dose.

Data element	Use	Current status in HL7 VXU	Optionality for meaningful evaluation and forecast ¹³ .
	permissible.	need new LOINC codes for overdue date and latest date permissible.	
Non-potent dose received	This indicates that the client received a dose of vaccine that was not potent. That is, it was out of date or mishandled. It can also indicate that the client did not receive a complete dose because they jumped during injection.	Not available	Optional
Reason code	This can indicate why a dose is not valid or that the recommendation was changed because of a special circumstance.	LOINC 30982-3	Optional

It is important to note that evaluation relates to doses received, but recommendations relate to doses not yet given. Each will be addressed separately. Evaluation will be associated with an immunization received. Recommendations will be associated with future events. That is they will be associated with an RXA that indicates that no dose was given. They will not be associated with existing immunization records (RXA). This means that if a person has received one hep B dose (valid). The evaluation will be associated with the first RXA indicating that she/he received the dose. The OBX following this will indicate the evaluation. The recommendations for the next dose due will be associated with a second RXA.

There are other factors relating to forecasting, such as exemption and previous immunity. These are dealt with in the client specific conditions impacting forecasting.

When a given dose is evaluated against a schedule, we can make a number of observations about it. Each dose of vaccine recorded is transmitted in an RXA segment. Each RXA segment may have one or more OBX, observation segments. Each distinct piece of information is found in its own OBX segment and follows its associated RXA.

The basic structure for including evaluation in a message is:

RXA-the immunization and vaccine
OBX-vaccine group⁴
OBX-the schedule
OBX-series used
OBX-dose number in series (ordinal position)
OBX-doses in series
OBX-dose validity
OBX-series status

The basic structure for evaluation of combination vaccine components is:

RXA-the immunization and vaccine
OBX-vaccine group¹⁷
OBX-the schedule
OBX-series used
OBX-dose number in series (ordinal position)
OBX-doses in series
OBX-dose validity
OBX-vaccine group¹⁸
OBX-the schedule
OBX-series used
OBX-dose number in series (ordinal position)
OBX-doses in series
OBX-dose validity
OBX-series status

The basic structure for the recommendation in the message is:

RXA-vaccine, CVX-NOS (no dose given)
OBX-the schedule
OBX-the series used
OBX-dose number in the series
OBX-number of doses in the series
OBX-earliest next dose due
OBX-recommended next dose due
OBX-overdue next dose due

¹⁷ All of the related observations are linked to the vaccine group using the OBX-4, observation sub-id.

¹⁸ All of the related observations are linked to the vaccine group using the OBX-4, observation sub-id.

OBX-series status

This document will first illustrate how to build each OBX to support reporting the key information. The next section will show how to put these pieces together to create evaluation and recommendations in VXU. Note that the same approach may be used in an RSP that returns an immunization history.

Indicating the Schedule that was used:

Evaluation is only meaningful in the context of a defined schedule. Schedule is a required element in a message that is carrying evaluation or recommendation information.

The only schedule supported by CDC is the ACIP schedule. Some systems may choose to develop other schedules that meet local needs. We assume that ACIP is the schedule used in our examples.

There are no differences between recommendation and evaluation in the OBX indicating the schedule used.

<< example segments >>

Indicating Vaccine Group associated:

Evaluation is considered by vaccine group. Some immunizations are composed of one vaccine group while others are combinations of several vaccine groups. The first is more straightforward when constructing a message. The vaccine group is indicated in an OBX. All following OBX relate to that vaccine group, using the OBX-4 Observation sub-id.

Single Vaccine group Vaccine:

<<example>>

In the case where a combination vaccine is given, each vaccine group is identified and has segments describing its evaluation. This case requires that the information about each vaccine group be handled separately. Each vaccine group is associated with a group of OBX, using the OBX-4 observation sub-id.

Combination vaccine:

<<example with pediarix >>

Reporting the Series Used for Evaluation and Recommendation:

Some vaccine groups may have the goals for completion met by different series. For example, adolescents who receive Recombivax, Hepatitis B vaccine may satisfy the goals for Hep B with only 2 doses, appropriately timed, instead of the usual 3 doses.

Whether the OBX is used for recommendation or evaluation, this is useful information and should be messaged. The list of series is specific to the local implementation.

<< example >>

Reporting The Ordinal Position In A Series:

Evaluation:

Reporting the ordinal position in a selected series may be reported in an OBX segment. The ordinal position is the dose number being satisfied by a given immunization. (dose #1 in a 3 dose series) The next section illustrates how to report the expected number of doses in the series. (3 in the example above) It would be empty for a booster dose and for doses which are not valid.

<<example >>

Recommendation:

There is a different code to be used for indicating the number of the next dose due.

Note that the preferred LOINC codes are not vaccine group specific. The use of old vaccine specific LOINC should not occur. For example, **30936-9 DTaP/DTP dose count in combination vaccine** should not be used.

<<example >>

Reporting the Number of Doses in a Series:

There are no differences between recommendations and evaluations. This numeric field indicates the number of doses required to meet the goals of the primary series for this vaccine group. It would be empty for a booster dose.

<< example >>

Reporting the Evaluation Status (Validity) of a Dose:

The evaluation status of a dose is an indicator of whether the dose received was given appropriately, based on the series rules. There are 2 types series. Primary series are

Comment [RS4]: The values have not been determined at this time. One alternative is to simplify the codes to Y and N.

meant to help a person achieve immunity. Some vaccines are repeated intermittently after the primary series is completed. This boosts the immune system's memory of the antigen. Hence it is called a booster dose. There are 4 states that a dose may be in:

The values have not been determined at this time. One alternative is to simplify the codes to Y and N.

Category	Definition
Valid dose in a primary series	Indicates that the dose being evaluated was given appropriately for the doses of a primary series, according to the rules of the schedule selected.
Valid booster dose	Indicates that the dose being evaluated was given appropriately for the booster doses of a series, according to the rules of the schedule selected.
Not valid dose	Indicates that the dose being evaluated was not given appropriately according to the rules of the schedule. It may have been a potential primary series dose or a booster dose.
Unvalidated	Indicates that the dose was not evaluated according to a series schedule. This may occur if a given vaccine group is not evaluated by a given schedule. It may also occur if the person has already completed the needed doses for the vaccine group. For example, if a person had already received 2 valid doses of MMR and now has received a third dose.

Evaluation relates to a specific vaccine group. There will be separate Evaluation status for each member of a combination vaccine (more than one vaccine group).

<<example>>

Reporting Next Dose Recommendation Dates:

Forecasting next dose due is an important function that can be reported in a message. There are a number of key dates that can be communicated:

Date type	Definition
The earliest acceptable date based on the schedule used	This is the earliest date that a person should receive the next dose for the vaccine group. It does not include any grace period. For example the earliest data a person should receive a DTAP is

	age 42 days.
The recommended date	This is the date that a person should ideally receive the next dose for the vaccine group.
The overdue date (the date the person is considered late for getting the vaccine)	This is the date that the person is considered late for getting the next dose for the vaccine group. It is a locally defined value.
The latest date that a dose should be given (e.g. for HIB it is currently 5 years old)	This is the last possible date that a person should receive the next dose for the vaccine group. Generally, this is related to age of recipient. For example the oldest a person should receive a dose of HIB is 5 years old.

Not all dates may be relevant and so may be omitted.

<<examples>>

Reporting a non-potent dose:

A system may record doses that are given that are considered not potent for some reason. These reasons may include out of date vaccine, vaccine that has not been stored properly or an incomplete vaccination. (This may occur is a person jumps away while being injected. An undetermined amount of vaccine may be received.)

<<examples>>

This may be a good situation to motivate an NTE segment where details may be conveyed.

Reporting Series Status:

Completion of a recommended series infers that a person is protected against the diseases the series targets. There are several states that a person can be in relative to series completion.

Comment [RS5]: Codes need to be confirmed.

Codes need to be confirmed.

Status	Definition
Complete	The client has received all of the recommended doses in the primary series at acceptable intervals and ages. Not valid dose do not count towards this goal.
In progress	The client is not currently recommended for a dose in this series and is not overdue nor too old to complete. The client has started the series.

Due	The client is currently recommended to receive a dose for this series. The client is not overdue.
Overdue	The client is overdue for a dose of this series. The client is not too old to complete.
Too old to complete	The client has not completed the series and is now too old to complete the series.
Too young to start	The client is too young to start the series.
Undetermined	The client's status for this series is not determined.

<< example >>

Reporting Recommendation Reasons:

Sometimes a dose may break a specific rule in the schedule. Alternatively conditions may trigger special rules, such as the need for accelerating the recommendations to catch up with the preferred schedule. This may be reported from the system in a message. The list of values is locally determined. These should be documented locally.

<< example >>

Using The NTE Segment Associated With An OBX To Provide More Information:

Each OBX may have an associated NTE segment. This may be used for sending notes or comments that the receiving system may choose to display to a user. Any use of this is local and requires local documentation.

Issues That Are Outside Of Messaging But Impact The Value Sent In A Message

1. There are some series where doses may be skipped. For instance a person who gets significantly behind on some HIB series may skip a dose and complete "early". Local profiles should specify how these doses will be handled and messaged.
2. Some vaccines have a numbered primary series and are followed by intermittent booster doses. These do not increase the number of doses in the primary series.
3. Persons who have been previously infected may not need further doses of vaccine. This can be messaged in an OBX reporting client immunity.

Example VXU #4 - Send client specific conditions

Evaluation of immunization history and forecasting next dose due are important services provided by many IIS. There are a number of factors that can impact these evaluations and forecasts. In general terms, some factors contraindicate next doses, while others recommend next doses. These factors may be messaged in OBX segments associated with an RXA.

Evidence of immunity:

Infection with the diseases that are the target of immunizations leads to long-term immunity. Further immunizations against the disease is not likely to provide benefit.

Definition:

Evidence of immunity indicates that a person has plausible evidence that they have already developed immunity to a particular disease. The definition of plausible evidence is a local decision, but best practice would suggest that serological evidence of immunity is the strongest indicator of immunity.

<<example>>

Contraindications to immunization:

There are a number of contraindications to immunization. These may be temporary or permanent. One is a history of reactions to previous immunization. That is dealt with above. Others include allergies to components of vaccines, physical conditions, current medication and current illnesses.

Definition:

A contraindication is any physical condition, current medication or other factor that indicates that a person should not receive an immunization that may be associated with the contraindication. This contraindication may be temporary or permanent.

LOINC: 30945-0

<<example>>

Factors which indicate the need for an immunization or a changed recommendation:

Several factors can drive the need for a specific immunization or a change in the normal schedule for immunization. These may be an exposure to an infection, such as rabies. Other risk factors may include membership in a risk group.

Definition:

A risk factor is some characteristic of an individual, which may lead to a recommendation for a specific vaccine.

The general message structure for these messages is:

- RXA indicating the vaccine group using the CVX code for the vaccine, NOS and also indicating that no vaccine was given.
- OBX indicating the condition or immunity

Reporting Evidence of Immunity:

Note that the definition of evidence of immunity requires either laboratory evidence of disease (e.g. serology) or physician diagnosed history of disease. The physician diagnosing the disease should be listed in OBX-16, Responsible Observer.

The following table lists the value list for use in this function.

<< examples >>

Example VXU #5 – Send immunizations associated with reactions (adverse events)

Some people experience adverse events after receipt of an immunization. In many cases, Immunization Information Systems (IIS) record these in conjunction with a specific immunization event. Occasionally, the exact immunization event information is unknown. (e.g. anaphylaxis occurred after a previous dose, years in the past.)

Definition:

An adverse reaction is a negative physical condition that occurs shortly after one or more immunizations have been received.

LOINC code: 31044-1

<<value set>>

<<example>>>

Example VXU #6 –Delete an Immunization Record

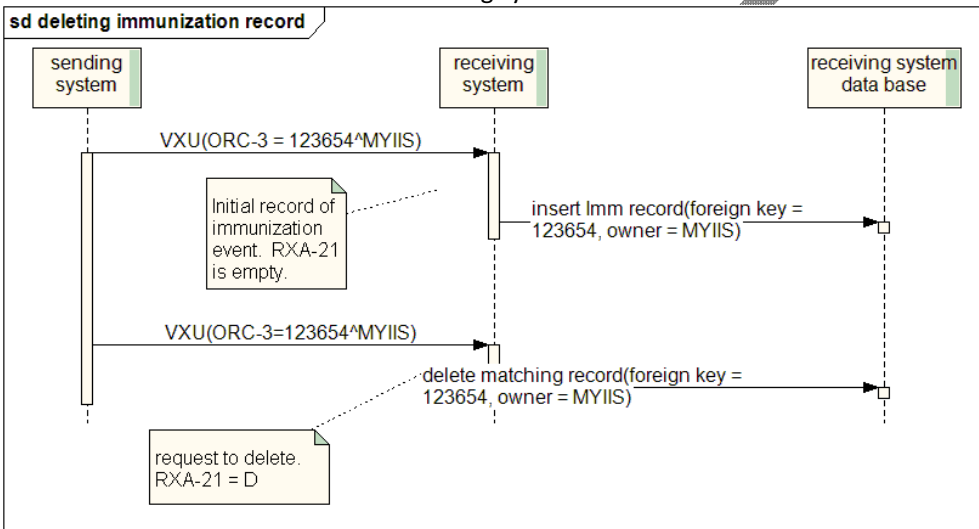
There are occasions when a system that has sent an immunization record to another system wishes to delete the record on the other system. There are several approaches that may be taken. The approach selected depends on the rules and capabilities of both systems.

One approach uses a snap shot approach. Each time an immunization history is sent, it replaces the entire immunization history on the receiving side.

Another approach is to use the RXA-21, Action Code to request deletion of a specific record. Some systems will match the request with an existing immunization record based on vaccine, vaccination date and other factors implicit in the record and the request. They may also use the ORC-3, Filler Order Number, to uniquely delete the record of interest.

The following diagram illustrates how the ORC-3 may be used to identify an immunization record for deletion¹⁹. Note that the sending system includes the sending system unique id in the ORC-3 first component. The second component is the assigning authority, in this case a system that is labeled MYIIS. In order for a later delete request to be successful, the receiving system must store those values. A subsequent request to delete an immunization record includes the sending system id and assigning authority. The receiving system searches for an immunization record with the same sending system id and assigning authority. In this case we show that the record match is made and the record is deleted from the receiving system.

Comment [RS6]: This may change if we are required to use OIDs by HITSP



VXU Example #7--Send Information About Vaccine Information Statement (VIS)

The Vaccine Information Statement (VIS) is a document that explains the reasons for a vaccine and the potential risks from receiving the vaccine. IIS track the fact that a VIS was shared with the client or parent. There are two pieces of information about each event.

- the date that the VIS was presented to the client/parent.
- the publication date of the VIS that was presented.

These are carried in separate OBX segments associated with a vaccination event (RXA). For a vaccine that is a combination of vaccines, there are often separate VIS for each vaccine. This may be handled by sending 2 sets of OBX, one for each vaccine.

Example 1-Single vaccine

Example 2-Combination vaccine

¹⁹ The other approaches will not be further illustrated here.

VXU Example #8—Send Information About Immunization Refusal

Clients or their parents may choose not to be immunized against a particular disease or diseases. It is important to share this information when sending immunization histories using HL7. There are several components to messaging a refusal. The refusal reason is indicated in RXA-18. The Completion Status in RXA-20 indicates that the vaccine was not given. The following example illustrates how to accomplish this.

<<example>>

VXU Example #9—Send Two Lot Numbers in RXA

There are occasions when two vaccines are combined at the time of administration. The RXA segment should be used to capture this information, specifically the RXA-15 field. This field allows repetition. Each separate Lot number can be placed here with a ~ separating the two lot numbers. Each component belongs to one or more vaccine groups or families.

This document does not specify the order of the lot numbers.

For example, if we needed to include an immunization record where the vaccine was Pentacel, we would put the lot number from the first component in sequence 15, followed by a ~ and then the second lot number. The specific RXA field is highlighted below in yellow.

Example²⁰:

RXA|0|1|20080907|20080907|120^DTAP-IPV-HIB^CVX^^|.5|ML^ISO+||00^NEW IMMUNIZATION RECORD^NIP001|1234567890^SMITH^SALLY^S^^^^^^VEI~1234567891^O'BRIAN^ROBERT^A^MDR^MD^^^^^^OEI|^|^CHILD HEALTHCARE CLINIC^^^^101 MAIN STREET^BOSTON^MA|^1234ad~455sd||PMC^Sanofi^MVX|||CP|A|20080907120030|<CR>

VXU Example #10—Recording Birth Information

Birth information can be a powerful tool in identity resolution. Components of birth information are listed in the NVAC core data elements. The information that can be carried in an HL7 message includes:

Field	HL7 message Component	Example
-------	-----------------------	---------

²⁰ Snipped from current Implementation Guide and modified in the date fields and the RXA 5,15 and 17 fields. The other parts have not been evaluated for accuracy.

Birth date	PID-7	19500512
Birth Registration Number	PID-3 (as one identifier in list)	12345^^^need OID
Birth order	PID-24	2
Multiple Birth Indicator	PID-25	Y
Birth State	PID-11 (as one address in list, use address type BDL)	^^^WJ^^^BDL
Birth facility	PID-23	Children's Hospital

VXU Example #11—Recording an incompletely administered dose

There are occasions when a dose is not completely administered. For example a child may jump away during injection and an unknown quantity was administered. In this case, the dose needs to be recorded to support accurate inventory management and to allow for recall of the client if there is a recall of the vaccine. This is accomplished using the Completion status in RXA-20. The RXA is completed as usual, but the completion status is set to PA.

<<example>>

Send Acknowledgement In ACK In Response To VXU

Sending an acknowledgement can accomplish one of a number of tasks. It can indicate that the message that was sent was successfully received and processed. It can also indicate that the message had errors. When a message is sent, it can indicate when an acknowledgement is expected. The choices may include always, only on error or never.

The ability to accept ACK messages allows sending system managers to trouble-shoot communications. It allows them to identify systematic problems with message creation. Being able to send ACK allows receiving system managers to inform sending system managers about the nature of errors received.

Send acknowledgement of success in ACK

Some systems may wish to receive an acknowledgment message, regardless of whether the receiving system had problems with the message. In that case, there is a relatively straightforward response.

MSH|^~&|DCS|MYIIS|MYIIS||20090604||ACK^V04^ACK|9299381|P|2.5.1|||ER<CR>

MSA|AA|9299381<CR>

In the example above, the system with the code DCS is sending an acknowledgement to the system with the code MYIIS on June 4, 2009. The message indicates that there were no errors in processing. DCS only wants an acknowledgement if MYIIS encounters an error in processing the acknowledgement.

Send Error in ACK

When there are errors, these can either be fatal or non-fatal. Fatal errors indicate that the message that was sent was not able to be processed. Non-fatal means that the message that was sent had some type of error, which did not prevent the message from being processed. Some data may have been lost as a result of the error. In addition, the error may have been in the processing of the HL7 or violation of a local business rule.

Acknowledging A Fatal HL7 Processing Error:

There are a number of problems that may cause a fatal error when processing an HL7 message that are based on HL7 rules. These include missing required segments. If a required field is missing, then the segment is treated as missing. If this is a required segment, then the error becomes fatal.

```
MSH|^~|&|DCS|MYIIS|MYIIS||20090604||ACK^V04^ACK|9299381|P|2.5.1|||ER<CR>
```

```
MSA|AR|9299381<CR>
```

```
ERR||PID^5|101^required field missing^HL70357|E<CR>
```

```
ERR||PID|100^required segment missing^HL70357|E<CR>
```

In the example message above, we see that the PID-5 (patient name) field was missing. Since this is a required field in a PID, the PID is ignored and therefore is missing.

Note that local violation of local business rules may be returned in an acknowledgement message. Those rules are best represented in codes that are referenced in a local table. These may be recorded in the ERR segment. A local business rule may lead to rejection of parts or all of a message. For instance, a local business rule may state that the system requires a first name for every person. If no first name is included in the message, then the system rejects the field for name (PID-5). Since this is a required field in a required message, the entire message is rejected. There would be a third ERR segment indicating that a locally required component was missing. (No example is given, as there is no local table of errors in this appendix.)

Acknowledging A Non-Fatal HL7 Processing Error:

A non-fatal error may occur for a number of reasons. One example would occur when a non-required component or field is malformed. For instance, Last Update Date is not a required field. If the message indicated that the last update occurred on February

31,2009, then that field would be ignored. Since the field is not required, the segment would not be rejected.

Local business rules should specify what will occur for each type of error. In the case above, the field could be ignore, it could be accepted and flagged for further follow-up , the entire message could be rejected or the bad data could be stored in the data base as.

```
MSH|^~|&|DCS|MYIIS|MYIIS||20090604||ACK^V04^ACK|9299381|P|2.5.1|||ER  
MSA|AR|9299381  
ERR||PID^33|207^application internal error^HL70357||
```

The example above indicates that an error occurred in PID-33 (last updated date). It did not cause the message to be rejected.

Send Request for Vaccine History (QBP/RSP)

Process for requesting Immunization History

Requesting an immunization history is a key function supported by messaging. As described above, a complete immunization history includes all the information needed for evaluating what immunizations have been received and what ones are needed next. This query is defined in a Query Profile in Chapter 7 of the Implementation Guide. The requesting system sends a request some combination of demographic and identifier information²¹. This Implementation Guide replicates the functionality of the VXQ/VXX/VXR query and responses.

Description of the VXQ/VXX/VXR Process From Version 2.3.1

The following describes the process that was used when responding to a VXQ and is included to give background. As described in the use cases in Chapter 2 of this Guide, requesting an immunization history requires the responding system to find a matching client. The old VXQ query required implicit identity resolution. That is, the responding system used locally defined methods to find a person and if exactly one high-confidence match was found, returned an immunization history. If lower confidence matches were found, it returned a list of clients with their identifiers (PID,NK1) for review by a person on the requesting system. If one of the candidates was selected and returned in a second VXQ, then the one high-confidence match is returned. The following diagram illustrates the flow. (The messages between systems are bolded arrows.)

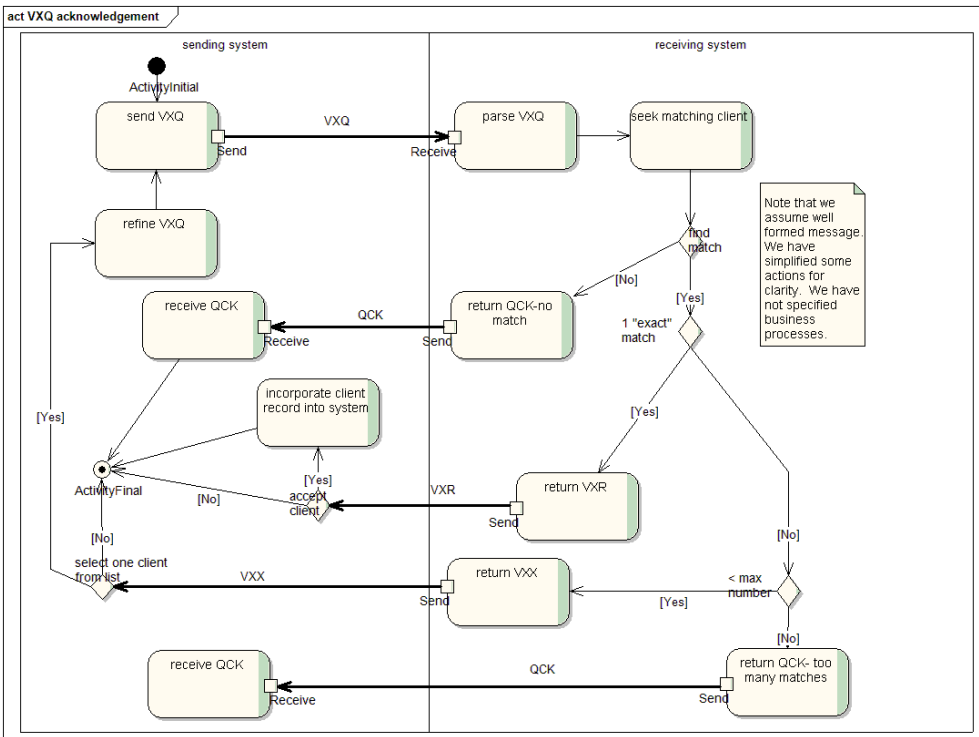


Figure 1--VXQ/VXX/VXR processes

The receiving system applies locally defined search logic. There are 4 possible outcomes if the message is successfully processed:

1. The search finds exactly one high confidence candidate client to return.
 - a. Immunization history is returned.
 - b. If sending system user may choose to accept the immunization history, the sending system follows local protocols for incorporating the new record.
2. The search finds one or more candidate clients.
 - a. Sending system user selects the one of interest and resends the VXQ with the more complete information.
3. The search finds no candidates to return.
 - a. An acknowledgement is returned to the sending system.
4. The message is malformed and no query is processed.
 - a. An acknowledgement is returned to the sending system.

Step 2 is the step where the implicit identity resolution occurs.

The newer QBP-style query allows identity resolution to be separated from request for content. This is accomplished using a two-step approach. It mirrors the flow of the VXQ

when lower confidence candidates are found and returned. One industry standard for accomplishing this two-step approach is the Patient Demographic Query (profile by IHE).

This Guide allows either exact replication of the VXQ/VXX/VXR approach or a two-step approach which. The two-step process accomplishes the same goal as the old process, but separates the request for immunization history and the request for identity resolution. The two-step approach takes the results of the selection from the identity resolution and requests the immunization history for the selected person. Note that this two-step approach also facilitates interaction with a Master Patient index (MPI).

This Guide and Appendix does NOT prescribe the search methods, so these should be described in a local profile or implementation guide.

In addition, this guide does not define the meaning of exact matches. This needs to be specified locally.

Using QBP query to replicate VXQ/VXX/VXR

The diagram for the new query is very similar to the previous diagram. The only real differences are the messages used. In place of the VXQ, a Request Immunization History query (QBP^Q11^QBP_Q11) is sent. In place of a VXX, a Return Candidate List response is returned (>> need new query profile identifier<<). In place of a VXR, a Return Immunization History response is returned.

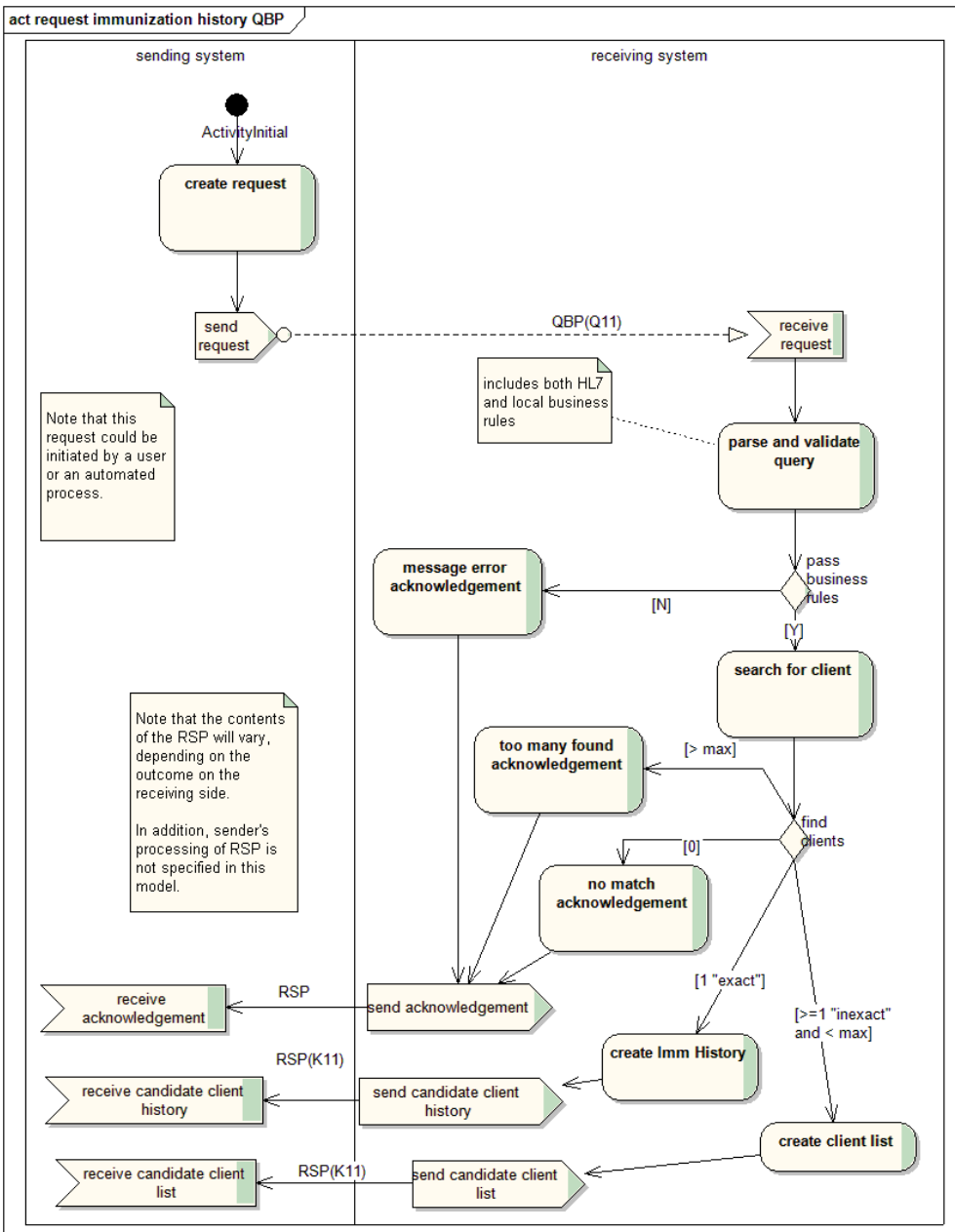


Figure 2--Request Immunization History

1. The process for sending a query requesting an Immunization history begins with the sending system building the message.
2. The sending system connects to the receiving system and sends the query message.

3. The receiving system accepts the message.
4. The receiving system parses the message and validates.
 - a. Determine if message meets HL7 rules
 - b. Validate based on local business rules²²
5. Seek matching client in receiver data base²³
 - a. No match is found
 - b. Exactly one match is found.
 - c. One or more inexact matches and less than maximum plus 1 allowed²⁴ matches found.
 - d. More than the maximum allowed matches found.
 - e. One or more clients are found, but they do not want their records shared.
6. The receiving system responds (see below).

When a client does not want his/her data shared and is found, local business rules need to be applied. For instance, some applications may behave as if the client record does not exist in the system. That is, it would respond with a “no records found” message. The exception to this would be if the requesting provider were the one who set the protection indicator. In this case, the person may be a candidate that is returned. Another response might be to send limited information notifying the requesting system that the person exists, but wants his/her records protected.

The sending system must deal with the returned messages. While it is outside the scope of this implementation guide, there are some logical actions. These actions should be documented locally. The following indicate some of the possibilities. The list is not prescriptive nor complete.

- One candidate immunization history is returned.
 - User reviews and accepts
 - User reviews and rejects
 - Requesting system accepts and marks for review.
- A list of candidates are returned
 - User reviews and selects one
 - New QBP is sent using the identifying information from the RSP list
 - User reviews and rejects all
 - User creates a new query with more or different information
 - Requesting system accepts and stores the list for later review.

²² The process for responding is documented below.

²³ Each case will be detailed below. Note that this is an area that should clearly be documented by each system in a local profile or implementation guide.

²⁴ This maximum may be set by the sending system and may be determined by the receiving system. The maximum will be the smaller of the two.

<<example one-step query and responses>>

Using a Two-step process to request an immunization history

The diagrams illustrating this approach share similar flow to the original VXQ/VXX and VXQ/ VXR messages. That is, the first query replicates a VXQ and VXX response. The second replicates the VXQ and VXR response.²⁵ These will be illustrated below.

Identity resolution step:

Identity resolution may rely on the services of a Master Patient Index or other identity supplier, including the immunization history source. The following diagram illustrates the use of PDQ to find a client, based on demographic information. The PDQ returns a list of candidates (PID and PD1).

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²⁵ It is possible that even with the two-step process, an exact match may not be found for the record of interest. This is especially true if the source of identity resolution is not exactly in synch with the source of the immunization history. Local rules should dictate the response to this situation.

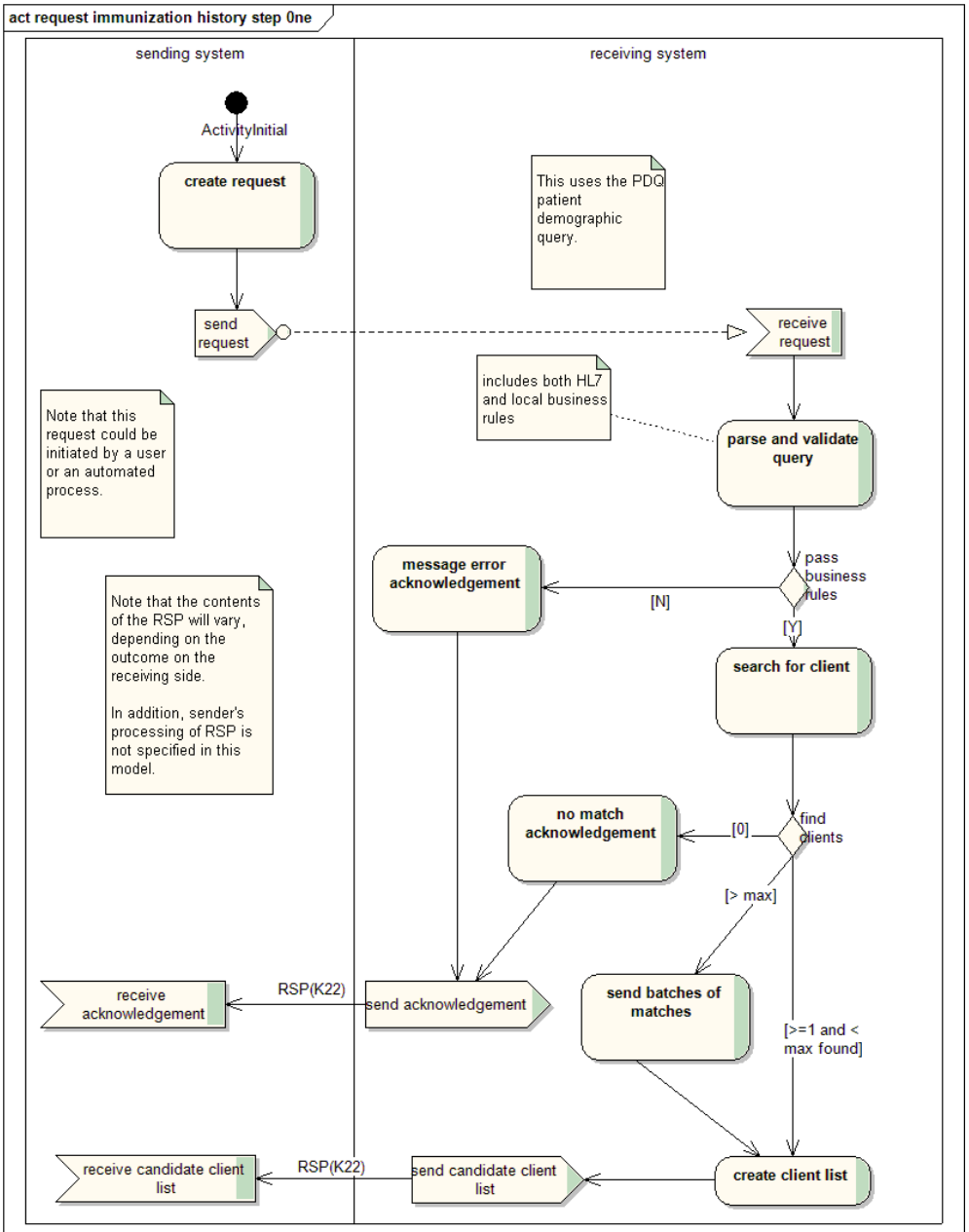


Figure 3--Requesting Identity Resolution Using PDQ

In the two-step process, the user selects the candidate of interest and the information from that selection is used to populate the Request for Immunization History query. If the responding system participates in the MPI or the initial identity resolution query

went to this responding system, then it is likely that the Request for Immunization History query will find an exact match.

Request immunization history based on previous identity resolution

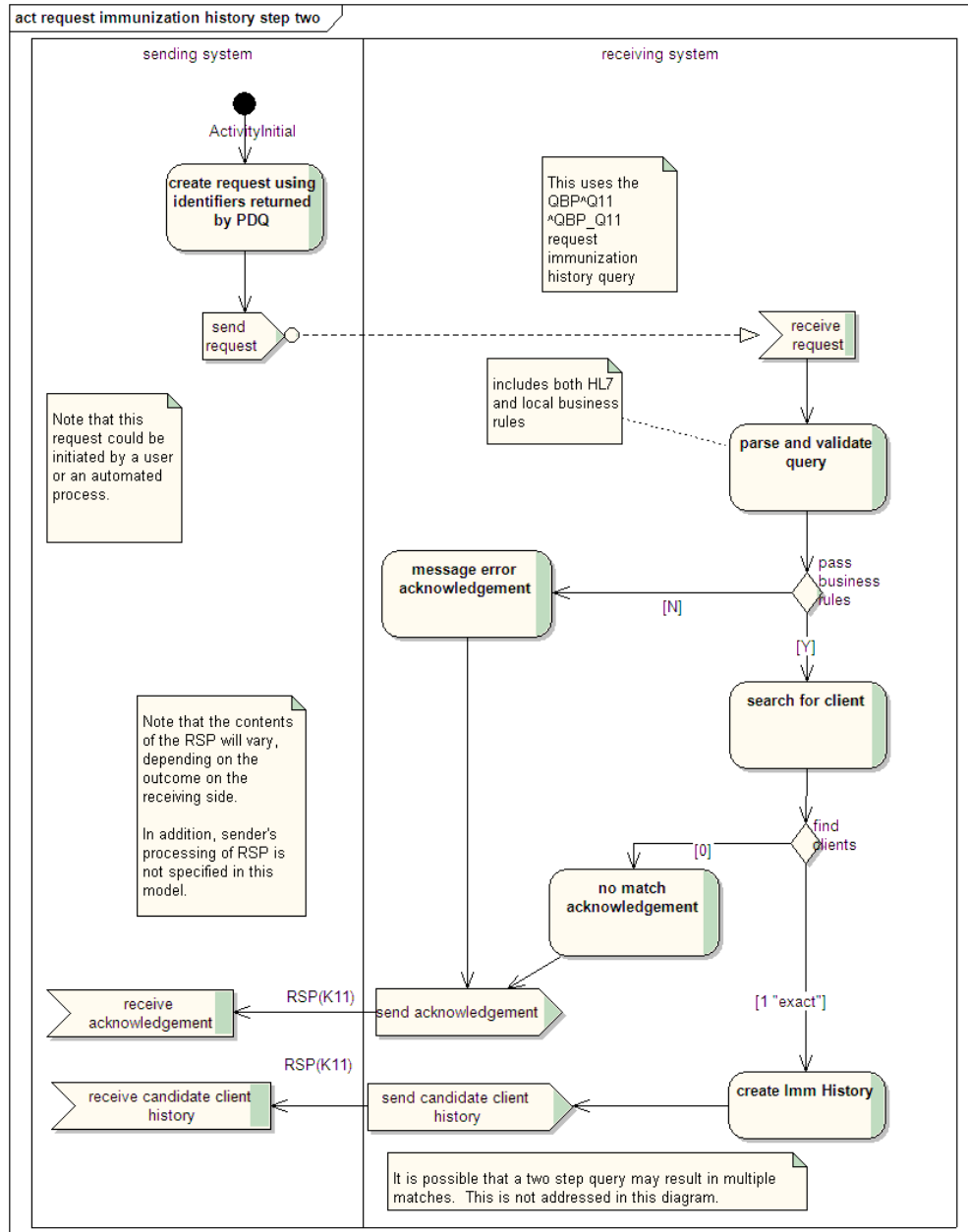


Figure 4-Requesting an Immunization History Based on Previous Identity Resolution

<example 2 step query and responses.>>

Request for Immunization Query Example

Receiving system determines that message has errors

HL7 Message Rule Errors

There are two classes of error related to HL7 message rules. The first is a fatal error. These are caused when a required segment is not present or flawed. The second occurs when some component of the message has an error, but is not required. In either case, errors are reported in the ERR segment of the RSP.

The following examples illustrate how each is reported.

Fatal HL7 error in Query:

Initiating Query:

Note that only the MSH and QPD segments will be displayed.

The QPD does not have data in a required field, the Last Name field.

Non-fatal HL7 error in Query:

An optional field in the QPD is not the correct data type.

Receiving System Business Rule Errors

Fatal Error:

Date sent in a required field is not legitimate (February 30, 2009)

Non-fatal error:

No Match Is Found

If no match is found, then the receiving system sends a response that indicates that the message was accepted and found no data. Note that this might occur if one client was found, but does not want his/her data shared with a different provider.

Seek Client Identifiers from Patient Demographic Supplier (QBP)

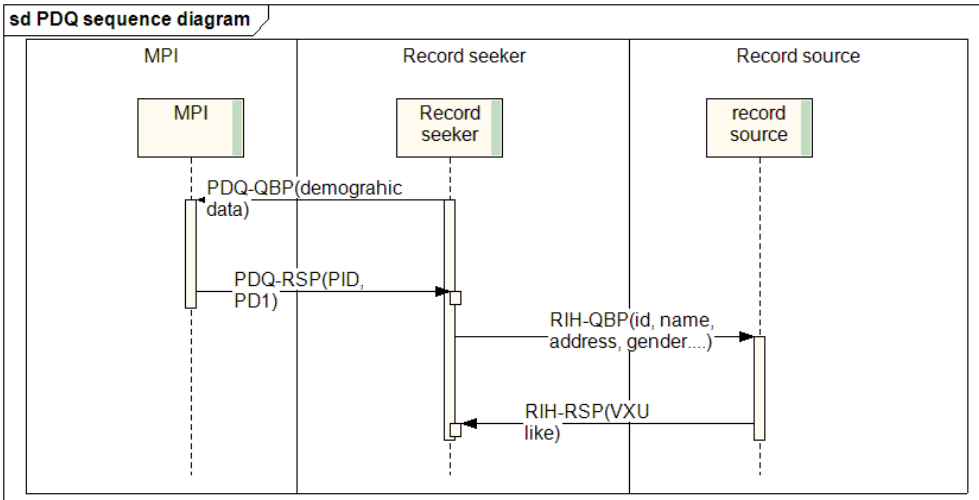
A Patient Demographic Supplier may be a Master Person Index or other source of patient demographic and identification information. While we will focus on an MPI below, any Patient Demographic Supplier may be substituted.

A Master Person Index is a database that contains demographic and locating information of registered persons and associates each person with the identifiers for the person from each of the participating systems. This allows one system to request the identifier for a person that was assigned by another system. This id may be used to request data from that second system and assures a positive match.

Systems that participate in an MPI must register each person they are interested in with the MPI. An excellent profile for maintaining and interacting with an MPI has been published by the group, Integrating the Healthcare Enterprise (IHE). That profile will not be replicated here. However, the process for requesting personal identifier outlined below is based on that profile. Registering a person and maintaining an MPI are not described below. Those interested in this process should consult the IHE profile documentation. (IHE IT Infrastructure Technical Framework)

The IHE profile defines 2 queries for obtaining an ID of interest. One query requests an id based on the demographic information included in the query (PDQ). When a match is found, it returns the relevant id and demographic information. The other query seeks an id for a person from one registered provider based on the id from another registered provider (PIX).

The following diagram illustrates the use of PDQ to obtain an id and how this would be used to request an immunization record. The record seeker uses a Patient Demographic Query (PDQ) to a Master Person Index (MPI), requesting the identifiers for the person of interest. The MPI finds the person of interest and returns the demographic information and identifiers. The record seeker system uses this information to create a request for immunization history (RIH), which it sends to the record source. The record source uses this information to find the immunization history for the person of interest.



Note that this interaction is simplified. The returned information may need to be evaluated to determine that it represents the person of interest. In addition, the PDQ may return a list of clients that must be reviewed. The client of interest would then be selected and that client's information would populate the query requesting an immunization history. To be assured of success, the record source system would need to have registered the person in the MPI. In that way the person id in the record source would be available in the MPI.

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