CDS in RSP Alignment

Executive Summary

This technical advisory bulletin (TAB) provides refined guidance for encoding Clinical Decision Support (CDS) information within HL7 v2 query response (RSP) messages. Building on the original Implementation Guide and LOINC guidance, this document reduces variability by establishing a more specific structure and encoding for immunization evaluations and forecasts.

The key changes IIS and receiving systems should be aware of include:

- **Standardized grouping of forecast information**: All forecast data must now be grouped under a single ORC/RXA order group, eliminating the practice of sending each forecast in separate order groups.
- **Constrained OBX codes for evaluations and forecasts**: The guidance standardizes the observation/results (OBX) codes used, reducing variability and aligning with the current practices of most IIS.
- **Use of LOINC 59783-1 answer codes**: This critical field or a local equivalent must be used to signal immunization status, clarifying whether the next dose is due or if all necessary doses have been completed.
- **Specific guidance for M&I readiness**: Systems should implement these specifications to ensure readiness for AIRA's Measurement and Improvement (M&I) program testing.
- **Future adjustments expected**: While this TAB establishes a consistent baseline, further refinements will be introduced as CDS standards continue to evolve.

These updates are essential for ensuring accurate encoding and reliable reading of immunization recommendations.

Background

The creation of immunization evaluation and forecasting information (aka Clinical Decision Support or CDS) is informed by the Clinical Decision Support for Immunization (CDSi) project. CDSi resources provide guidance on translating Advisory Committee on Immunization Practices (ACIP) immunization recommendations into logic for implementation in CDS engines. The immunization evaluation and forecasting information generated by a CDS engine can be shared in a Z32 or Z42 RSP message.

This document provides guidance on structuring CDS data within these RSP messages using OBX segments. It builds on the National HL7 Implementation Guide (IG) and the *Guidance on Detailed Message Structure and the Use of Specific LOINC Codes* (LOINC

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Guidance), which readers are expected to refer to. This TAB does not repeat the LOINC guidance but adds specificity to ensure consistent implementation

The goal of this document is to further standardize how CDS data are encoded in RSP messages, focusing on two key objectives. First, it ensures that receiving systems, such as electronic health records (EHRs), can reliably interpret and use CDS information to support clinicians. Second, it enables AIRA's M&I program to effectively assess IIS by ensuring CDS evaluations and forecasts are reported in a way that allows for consistent measurement. This addresses a gap in current reporting, where incomplete CDS information has limited the ability to measure and improve IIS performance.

By adhering to this guidance, IIS will not only improve their interoperability with external systems but also enhance their ability to be evaluated under the M&I program. This alignment with existing standards helps drive more accurate, useful CDS data for clinicians while also allowing IIS to improve their CDS logic over time based on measurable outcomes.

Scope

In scope

What is expected to be returned by an IIS for immunization evaluation and forecasting in an RSP message when a single patient match is found in response to a query, including:

- The formatting and structuring of immunization evaluation and forecast information in Z32[1] and Z42 RSP messages, specifically requirements related to the use of order groups, OBX segments, and LOINC values
- Which vaccinations are expected to be returned by an IIS and which of these are expected to have associated evaluation and forecast information

Out of scope

- The underlying logic and outputs of the CDS engine in terms of adherence to ACIP immunization recommendations (i.e., if the CDS engine's evaluation or forecast is in alignment with ACIP)
- The patient matching process used to identify a single patient for return in a response message
- How receiving systems use, display, or interpret the returned RSP data
- Modifications to the LOINC answer codes for 59783-1, Status in immunization series
- Representation of risk-based or shared clinical decision-making recommendations in an RSP

[1] A Z32 RSP MAY include evaluation and/or forecasting information. If this information is returned in a Z32 RSP, these specifications apply.

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Implications of Adopting This Guidance

Adhering to these requirements ensures that CDS engine results are communicated consistently and that systems are prepared for thorough testing and evaluation. The use of standardized data formats enables IIS to support clinical decision making while also participating fully in AIRA's M&I program.

Table 1. Interpretation of SHALL and SHOULD immunization CDS requirements

SHALL Requirements	SHOULD Requirements
IIS that meet all "SHALL" requirements ensure essential clinical support and are fully prepared for comprehensive CDS testing as part of the M&I program.	IIS that meet all "SHOULD" requirements offer optimal clinical support and position themselves for future expansions in CDS testing and functionality.

Future considerations

This document remains silent on additional guidance for certain LOINC codes classified as "MAY" requirements, particularly where code tables are not specified. In cases where LOINC codes already have associated tables in the LOINC guidance, this document does not conflict, as it allows for future specification. Looking ahead, we anticipate that some of these "MAY" requirements will be elevated to "SHOULD" status in future updates, with added details, such as specified code tables to promote greater consistency in implementation.

Specific areas where further guidance may be developed include:

- Requiring invalid dose reason
- Standardizing the coding and counting of dose numbers and dose series counts
- Increasing dose validity codes
- Requiring reasons for recommendations in certain cases
- Clarifying or adding additional status categories within immunization series
    - Current guidance recommends using LOINC Answer codes
    - Future guidance may expand or replace these codes

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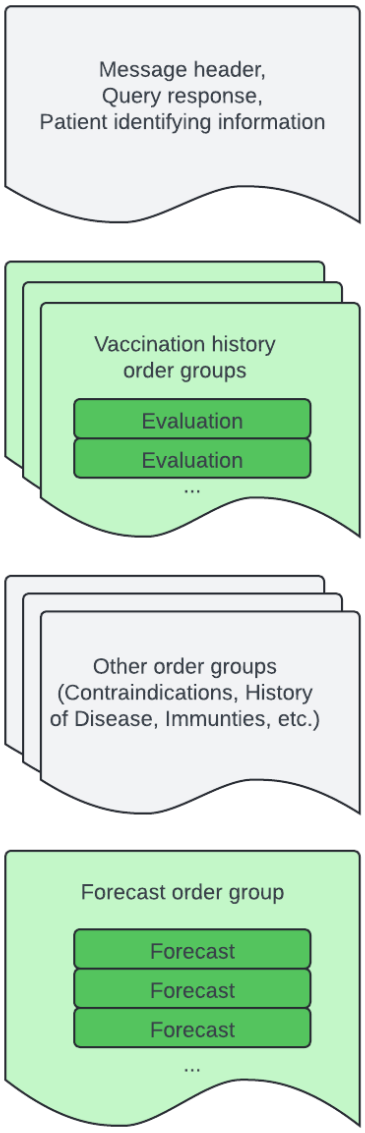
Clarifications and Conformance Expectations

CDS in RSP messages

Evaluation and forecast information are sent separately in the RSP. Evaluation information is embedded in vaccination history order groups, and forecast information is conveyed in one forecast order group.



CDS requirements

- The RSP SHALL include evaluation and forecast results for "standard" recommendations, i.e., routine, age-based recommendations.
- The RSP MAY include evaluation and forecast results for "risk" recommendations, i.e., recommendations for patients with specific characteristics or underlying conditions which put them at increased risk.

Organization requirements

Vaccination history/evaluation

- The vaccination history section SHALL include all complete vaccinations on the IIS consolidated immunization record (i.e., all vaccinations accepted and stored in the IIS), without filtering or exclusion.[2]
- Each of the order groups SHALL have zero or more evaluations, one evaluation for every vaccine group that is evaluated.
- All vaccinations that may complete a standard series SHALL have corresponding observations indicating the evaluation information.
- Combination vaccinations that are evaluated in more than one vaccine group SHALL have a separate set of observations for each associated vaccine group evaluated.

[2] If the vaccination is noted on the patient's IIS consolidated record as a completed administration (for example, viewable in the patient's IIS immunization history when accessing the IIS record via a web interface), it is expected to be returned in the RSP message. Some vaccinations on the patient's history may not have associated evaluation/forecasting information. For example, an IIS may accept and store a Japanese encephalitis vaccination but not support evaluation/forecasting for this antigen. In that case, the IIS would still return the Japanese encephalitis vaccination in the response message.

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Non-CDS Order Groups

- Other non-CDS order groups, which include information such as refusals, contraindications, adverse reactions, history of disease, and immunities, SHALL follow the vaccination history if present.

Forecast

- A forecast SHALL be included for all vaccines that may complete a standard series.
- All forecasts SHOULD appear in the message after the immunization history, if present, and after other order groups, if present.

See the CDSi Logic Specification "Create Relevant Patient Series" for additional discussion of standard (age-based) series and recommendations.

Evaluation observations

Within a **vaccination history order group:**

- Evaluation information SHALL be communicated using a series of OBX segments using the LOINC as indicated in Table 2.
- Observations SHALL be linked by an identical value in OBX-4.

Table 2. LOINC requirements to convey immunization evaluation information

LOINC OBX-3 Value	Label	Requirements
30956-7	**Vaccine type**	**SHALL return first, before all other evaluation OBX segments** **OBX-5: SHALL use CVX**
38890-0	Component vaccine type	SHOULD NOT return *
59781-5	**Dose validity**	**SHALL return** SHOULD return after the OBX with LOINC 30956-7 but before all the other evaluation-related OBX OBX-5: SHALL return 'Y' if valid and 'N' if not valid **
30982-3	Reason for validity	SHOULD return when vaccination is indicated as 'N' (not valid) in the OBX segment with LOINC 59781-5 If multiple reasons to indicate, SHALL repeat with additional OBX segments
59780-7	Series name	MAY return
59782-3	Total number of doses in the series	MAY return

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LOINC OBX-3 Value	Label	Requirements
30973-2	Dose number of the evaluated event	MAY return
59779-9	Schedule used	MAY return

* Originally two LOINC were defined to identify the vaccine being evaluated. For consistency, LOINC 38890-0 is being deprecated in favor of LOINC 30956-7. IIS that are currently using LOINC 38890-0 should collaborate with messaging partners and plan a transition to using only LOINC 30956-7.

** CDSi defines a concept of "extraneous" for doses which may be administered but do not count toward the final series. Only doses that are valid and count toward the final series should be marked as 'Y'. All others should be marked as 'N'.

Forecast observations

Within the **forecast order group:**

- The forecast order group SHALL consist of a single ORC/RXA pair where RXA-3 indicates the date of the forecast, RXA-5.1 is '998' and RXA-20 is 'NA'.
- The following OBX segment types and LOINC SHALL be repeated for all age-based recommendations as defined by CDSi, as indicated in Table 3.
- Associated OBX segments SHALL be linked via identical subID in OBX-4.

Table 3. LOINC requirements to convey immunization forecast information

LOINC OBX-3 Value	Label	Requirements
30956-7	**Vaccine type**	**SHALL return first, before all other associated OBX** **OBX-5: SHALL use CVX; CVX returned SHALL be unique for all forecasts**
30979-9	Vaccines due next	SHOULD NOT return
38890-0	Component vaccine type	SHALL NOT return
59783-1	**Status in the immunization series**	**SHALL return** SHOULD be after the OBX with LOINC 30956-7 but before all the other forecast-related OBX

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LOINC OBX-3 Value	Label	Requirements
		OBX-5: SHOULD return LOINC Answer codes; MAY return equivalent local codes; MAY return both LOINC and equivalent local codes *See Status in Immunization Series, Table 4 below*
30982-3	Reason for recommendation	MAY return MAY return more than once if there are multiple reasons to indicate
30981-5	**Earliest date**	**If OBX 59783-1 indicates another dose should be given, SHALL return *****
30980-7	**Recommended date**	**If OBX 59783-1 indicates another dose should be given, SHALL return *****
59778-1	Overdue date	If OBX 59783-1 indicates another dose should be given MAY return ***
59777-3	Latest date	If OBX 59783-1 indicates another dose should be given, MAY return ***
59779-9	Schedule used	MAY return
59780-7	Series name	MAY return
59782-3	Total number of doses in series	MAY return
30973-2	Dose number of next event	MAY return
93123-8	Preferred vaccine type	MAY be valued MAY repeat SHOULD NOT be used to indicate specific vaccination if any vaccination would work equally well
93122-0	Contraindicated vaccine type	MAY be valued MAY repeat

*** For the earliest, recommended, overdue, or latest dates; these are only relevant when another dose is indicated to be given. This is when the LOINC 597831-1 Status in immunization series is valued as these LOINC answers or their local equivalent:

- LA13422-3 On schedule
- LA13423-1 Overdue

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Status in immunization series

For each vaccination forecasted, the Status in immunization series (LOINC 59783-1) indicates Clinical Decision Support regarding immunizations.

Concepts:

- IIS SHALL support the concepts 'Complete' and 'On Schedule'
- IIS SHOULD support the concepts 'Overdue' and 'Too Old'
- IIS MAY support additional concepts

For the corresponding value in OBX-5:

- IIS SHOULD return LOINC answer codes as indicated in Table 4
- IIS MAY return a local coded value that is equivalent to the concept conveyed by the LOINC answer code
- IIS MAY return both the LOINC answer code and an equivalent local code
- IIS returning local codes SHALL document use of these codes in a Local Implementation Guide.

Note: Modifications to the LOINC answer codes for 59783-1 Status in immunization series are out of scope for this TAB. However, future guidance may expand, replace, or modify these codes to support further alignment across the community.

Table 4. LOINC Answer codes for use in OBX-5 when OBX-3 is valued "59783-1," to indicate Status in the immunization series

OBX-5 Code	Description	Conformance Expectations	
		Usage	Notes
LA13421-5	Complete - all required doses have been received to meet the requirements for a target series.	R	SHALL use and/or equivalent local code
LA13422-3	On schedule - person is not overdue for a given dose in the series. Includes a person too young to start the series.	R	SHALL use and/or equivalent local code
LA13423-1	Overdue - person is late getting the next dose in the series.	P	SHOULD use and/or equivalent local code
LA13424-9	Too old - cannot complete the series because the latest age for receiving dose has passed.	P	SHOULD use and/or equivalent local code
LA27183-5	Immune	P	MAY use and/or equivalent local code
LA4216-3	Contraindicated	P	MAY use and/or equivalent local code

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OBX-5 Code	Description	Conformance Expectations	
		Usage	Notes
LA4695-8	Not recommended	P	MAY use and/or equivalent local code

RSP Example

The following example is intended to illustrate the structure of an RSP message containing immunization history, evaluated history, and forecasting information. Accuracy of the immunization evaluation and forecasting information is not verified; do not rely on this example for accurate CDS. Of note:

- Segments not containing pertinent history, evaluation, or forecasting information are not populated, for brevity.
- Italicized comments are provided throughout the example to highlight different sections of the RSP.
- A yellow fever vaccination does not have associated evaluation information in this example; however, it is still returned.
- Evaluation information for a Twinrix vaccination, a combination hepatitis A and hepatitis B vaccine, is returned in several OBX segments, for each component: hepatitis A and hepatitis B.
- The immunization history order groups start with an ORC/RXA pair where the RXA-3 indicates the vaccination date and RXA-5 indicates the vaccine code.
- The immunization forecast order group starts with an ORC/RXA pair where RXA-3 indicates the date of the forecast and RXA-5 indicates '998' for No Vaccine Administered.
- The order of how the forecasts appear in the forecast order group is not specified. E.g., it is not necessary to list "Complete" forecasts together or in a particular sequence within the forecast order group.
- The example may represent a Z32 or Z42 RSP, since Clinical Decision Support evaluation and forecasting information MAY be returned in a Z32 and SHALL be returned in a Z42.[3]

Immunization history, evaluated history, and forecasting information in an RSP

`MSH` [purposefully left blank for brevity]
`MSA` [purposefully left blank for brevity]
`QAK` [purposefully left blank for brevity]
`QPD` [purposefully left blank for brevity]
`PID` [purposefully left blank for brevity]
`NK1` [purposefully left blank for brevity]

[3] *Technical Advisory Bulletin: Returning IIS Patient Immunization Record Information*

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/ Immunization History Order Group, Yellow Fever
[select content purposefully left blank for brevity] /

```
ORC|RE|8^IIS|
RXA|0|1|20200201||37^yellow fever^CVX||||||||||||||CP|A
```

/ Immunization History Order Group with Evaluation:
Hepatitis A and Hepatitis B evaluations for a Twinrix vaccination
[select content purposefully left blank for brevity] /

```
ORC|RE|13^IIS|
RXA|0|1|20240201||104^HepA-HepB^CVX||||||||||||||CP|A
OBX|1|CE|30956-7^Vaccine type^LN|1|45^HepB, unspecified
          formulation^CVX||||||F
OBX|2|CE|59781-5^Dose validity^LN|1|Y^Y^99107||||||F
OBX|3|CE|30956-7^Vaccine type^LN|2|85^HepA, unspecified
     formulation^CVX||||||F
OBX|4|CE|59781-5^Dose validity^LN|2|Y^Y^99107||||||F
```

/ Immunization History Order Group with Evaluation: Hepatitis A
[select content purposefully left blank for brevity] /

```
ORC|RE|15^IIS|
RXA|0|1|20240210||85^HepA, unspecified
     formulation^CVX|||||||||||||||CP|A
OBX|5|CE|30956-7^Vaccine type^LN|3|85^HepA, unspecified
formulation^CVX||||||F
OBX|6|CE|59781-5^Dose validity^LN|3|N^N^99107||||||F
OBX|7|CE|30982-3^Reason for validity^LN|5|NV003^Administered too soon
after previous^99107||||||F
```

/ Immunization Forecast Order Group
[select content purposefully left blank for brevity] /

```
ORC|RE||9999^IIS
RXA|0|1|20250304||998^No Vaccination
          Administered^CVX|999|||||||||||||NA
OBX|8|CE|30956-7^Vaccine type^LN|4|45^HepB^CVX||||||F
OBX|9|CE|59783-1^Status in series^LN|4|LA13422-3^On schedule
^LA||||||F
OBX|10|DT|30981-5^Earliest date^LN|4|20240328||||||F
OBX|11|DT|30980-7^Recommended date^LN|4|20240328||||||F
OBX|12|DT|59778-1^Overdue date^LN|4|20240328||||||F
OBX|13|DT|59778-3^Latest date^LN|4|21750214||||||F
OBX|14|CE|30956-7^Vaccine type^LN|5|115^Tdap Only^CVX||||||F
OBX|15|CE|59783-1^Status in series^LN|5|LA13422-3^On schedule
^LA||||||F
OBX|16|DT|30981-5^Earliest date^LN|5|19820214||||||F
OBX|17|DT|30980-7^Recommended date^LN|5|19820214||||||F
OBX|18|DT|59778-1^Overdue date^LN|5|19820214||||||F
OBX|19|DT|59778-3^Latest date^LN|5|21250214||||||F
```

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OBX|20|CE|30956-7^Vaccine type^LN|6|85^HepA^CVX||||||F
OBX|21|CE|59783-1^Status in series^LN|6|LA13422-3^On schedule
^LA||||||F
OBX|22|DT|30981-5^Earliest date^LN|6|20240829||||||F
OBX|23|DT|30980-7^Recommended date^LN|6|20240829||||||F
OBX|24|DT|59778-1^Overdue date^LN|6|20240829||||||F
OBX|25|DT|59778-3^Latest date^LN|6|21250214||||||F
OBX|26|CE|30956-7^Vaccine type^LN|7|88^Influenza^CVX||||||F
OBX|27|CE|59783-1^Status in series^LN|7|LA13422-3^On schedule
^LA||||||F
OBX|28|DT|30981-5^Earliest date^LN|7|20240701||||||F
OBX|29|DT|30980-7^Recommended date^LN|7|20240801||||||F
OBX|30|DT|59778-1^Overdue date^LN|7|20241201||||||F
OBX|31|DT|59778-3^Latest date^LN|7|21250214||||||F
OBX|32|CE|30956-7^Vaccine type^LN|8|121^HerpesZoster^CVX||||||F
OBX|33|CE|59783-1^Status in series^LN|8|LA13422-3^On schedule
^LA||||||F
OBX|34|DT|30981-5^Earliest date^LN|8|20250214||||||F
OBX|35|DT|30980-7^Recommended date^LN|8|20250214||||||F
OBX|36|DT|59778-1^Overdue date^LN|8|20260214||||||F
OBX|37|DT|59778-3^Latest date^LN|8|20950214||||||F
OBX|38|CE|30956-7^Vaccine type^LN|9|187^RZV (Shingrix)^CVX||||||F
OBX|39|CE|59783-1^Status in series^LN|9|LA13422-3^On schedule
^LA||||||F
OBX|40|DT|30981-5^Earliest date^LN|9|20250214||||||F
OBX|41|DT|30980-7^Recommended date^LN|9|20250214||||||F
OBX|42|DT|59778-1^Overdue date^LN|9|20260214||||||F
OBX|43|DT|59778-3^Latest date^LN|9|20950214||||||F
OBX|44|CE|30956-7^Vaccine type^LN|10|213^Covid^CVX||||||F
OBX|45|CE|59783-1^Status in series^LN|10|LA13422-3^On schedule
^LA||||||F
OBX|46|DT|30981-5^Earliest date^LN|10|19910214||||||F
OBX|47|DT|30980-7^Recommended date^LN|10|19910214||||||F
OBX|48|DT|59778-1^Overdue date^LN|10|20950214||||||F
OBX|49|DT|59778-3^Latest date^LN|10|20950214||||||F
OBX|50|CE|30956-7^Vaccine type^LN|11|152^Pneumococcal^CVX||||||F
OBX|51|CE|59783-1^Status in series^LN|11|LA13422-3^On schedule
^LA||||||F
OBX|52|DT|30981-5^Earliest date^LN|11|20400214||||||F
OBX|53|DT|30980-7^Recommended date^LN|11|20400214||||||F
OBX|54|DT|59778-1^Overdue date^LN|11|20410214||||||F
OBX|55|DT|59778-3^Latest date^LN|11|20950214||||||F
OBX|56|CE|30956-7^Vaccine type^LN|12|89^Polio^CVX||||||F
OBX|57|CE|59783-1^Status in series^LN|12|LA13421-5^Complete ^LA||||||F
OBX|58|CE|30956-7^Vaccine type^LN|13|122^Rotavirus^CVX||||||F
OBX|59|CE|59783-1^Status in series^LN|13|LA13421-5^Complete ^LA||||||F
OBX|60|CE|30956-7^Vaccine type^LN|14|03^MMR^CVX||||||F
OBX|61|CE|59783-1^Status in series^LN|14|LA13421-5^Complete ^LA||||||F
OBX|62|CE|30956-7^Vaccine type^LN|15|21^Varicella^CVX||||||F
OBX|63|CE|59783-1^Status in series^LN|15|LA13421-5^Complete ^LA||||||F
```

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```
OBX|64|CE|30956-7^Vaccine type^LN|16|108^Meningococcal^CVX||||||F
OBX|65|CE|59783-1^Status in series^LN|16|LA13421-5^Complete ^LA||||||F
OBX|66|CE|30956-7^Vaccine type^LN|17|137^HPV^CVX||||||F
OBX|67|CE|59783-1^Status in series^LN|17|LA13421-5^Complete ^LA||||||F
OBX|68|CE|30956-7^Vaccine type^LN|18|164^MENINGB^CVX||||||F
OBX|69|CE|59783-1^Status in series^LN|18|LA13421-5^Complete ^LA||||||F
```

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