**VAERS 2.0 HL7 2.3.1 Messaging**

Technical Documentation

**Revision History**

| **Version Number** | **Modification Date** | **By** | **Description of Changes** |
| --- | --- | --- | --- |
| 1.0 | 25 Mar 2019 | C. Wright | Initial version |

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# Overview

VAERS 1.0 HL7 messaging was based on the “Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol”, version 2.2, dated June 2006. This document describes the methods of extending the 2.3.1 version HL7 standard to meet the needs of VAERS Phase 2 reporting. It provides descriptions of the message’s purpose and structure, the changes made from the VAERS 1.0 form to the new VAERS 2.0 form, and the extensions that were made.

An example VAERS 2.0 HL7 message is provided in section 5 to demonstrate the structure and format of the transmitted data, as it relates to the VAERS 2.0 form.

# Background

VAERS reporting uses the “Unsolicited Transmission of an Observation (ORU)” message format as described on page 13 of the Implementation Guide. This message format uses a three-level hierarchy to describe a clinical report. The Patient Identification (PID) segment at the top level, followed by Order Record (OBR) segments at the next level, each of which may contain one or more Observation Reports (OBX) segments at the third level.

None of the ORU message format’s optional segments (PD1, PV1, PV2, CTI, and DSC) are included in a VAERS message.

# Changes from VAERS 1.0 to 2.0

There are several differences between the version 1.0 and 2.0 VAERS forms. The changes include removals of some data fields, renaming of others, and the addition of quite a few more fields. Where possible, additional information about the field or the sections they belong to have been added in brackets to increase clarity.

These field changes affect the “essential” set of fields to be completed. VAERS 2.0 Questions 2, 3, 4, 5, 6, 17, 18 and 21 are currently essential fields to complete.

## Removed fields

* Q2. County where administered
* Q16. Vaccine purchased with [type of funds]
* Q20. Have you reported this adverse event previously?

*[Only for children 5 and under]*

* *Q*22. Birth weight
* Q23. No. of brothers and sisters

*[Only for reports submitted by manufacturer/immunization project]*

* Q25. Date received by mfr./imm.proj
* Q26. 15 day report? [Yes,No]
* Q27. Report type

## Renamed/altered fields

There are a few minor alterations to the constitution or name of previous fields. The single text box for age at time of vaccination, which could have been years or months (if less than a year old), are now two separate fields, one each for years and months.

One other field was effectively renamed from VAERS 1.0. “Vaccine administered by” is now “Best doctor/healthcare professional to contact about the adverse event” (Q14).

## Newly added fields

* Use the space below to provide any additional information (indicate item number) [Unnumbered text box at the end of the form]
* Q8. Pregnant at time of vaccination? [Yes, No, Unknown]
* Q24. Race
* Q25. Ethnicity

*[Complete only for U.S. Military/Department of Defense (DoD) related reports]*

* Q27. Status at vaccination [Active Duty, Reserve, National Guard, Beneficiary, Other: <Textbox>]
* Q28. Vaccinated at Military/DoD site? [Yes, No]

# Extensions to the Version 2.3.1 HL7 Standard

Our extensions to the standard revolve around the use of additional OBX data segments and the use of local codes to identify data points that do not have corresponding LOINC codes. The use of local codes instead of LOINC is allowed in OBX segments, using the OBX-3 format, ^^^LocalCode^LocalCodeDecription^L.

Except for a few new or renamed fields that corresponded to an existing segment, like Race and Ethnicity falling under the PID segment, an OBX segment is used to transmit data. The following fields use Observation record (OBX) segments to convey their values:

|  |  |  |
| --- | --- | --- |
| OBX-3 Local Code | OBX-3 LC Description | VAERS field |
| YEAR AGE | Age at vaccination year | Q6 Age at vaccination > Years |
| MONTH AGE | Age at vaccination month | Q6 Age at vaccination > Months |
| PREGNANT | Pregnant at time of vaccination | Q8 Pregnant at time of vaccination |
| POC | Best Healthcare Professional to Contact | Q14 Best doctor/healthcare professional to contact about the adverse event |
| VAX AT OTHER | Vaccinated At Other | Q16 Vaccinated at > Other |
| ALLERGIES | Allergies | Q10 Allergies to medications, food, or other products: |
| HOSPNAME | Hospital Name | Q21 Hospital Name |
| HOSPCITY | Hospital City | Q21 City |
| HOSPSTATE | Hospital State | Q21 State |
| PREVAE | Adverse event following any previous vaccine | Q23 Adverse event following any previous vaccine |
| PREVAETEXT | Adverse event following any previous vaccine Text | Q23 Adverse event following any previous vaccine Text |
| MILSTATA | Active Duty | Q27 Status at vaccination > Active Duty |
| MILSTATR | Reserve | Q27 Status at vaccination > Reserve |
| MILSTATN | National Guard | Q27 Status at vaccination > National Guard |
| MILSTATB | Beneficiary | Q27 Status at vaccination > Beneficiary |
| MILSTATO | Other Military Status | Q27 Status at vaccination > Other Military Status |
| MILSTATOTEXT | Other Military Status Text | Q27 Status at vaccination > Other Military Status Text |
| DODSITE | Vaccinated at Military/DoD site | Q28 Vaccinated at DoD site |

The new VAERS 2.0 message continues to the use existing three-tier ORU message format. Additionally, no changes or updates have been made to the use of the code tables in Appendix 1 of the Implementation Guide. These tables should continue to be utilized, as is, for all messaging.

# Example HL7 message

| **VAERSItemNumber** | **EXAMPLE SEGMENTS THAT ANSWER THE VAERS QUESTIONS** | **Code Tables To Be Used** |
| --- | --- | --- |
|   | MSH|^~\&||WrightHealth VAERS vaersapp01|VAERS HL7 Processor|VAERS PROCESSOR|2019012920311548811889||ORU^R01|232|D|2.3.1|||NE|AL| |   |
| 1,2,3,24,25 | PID|||8675309^^^^MR||Testlastname^Robert^^^^^L||20180811|MALE||W~B|1234 Deadend Dr^Apt A^Anytown^MD^12345^^C||(301) 123-4567^PRN~rtest@example.com^NET|||||||||N|||||||2019012815131548706385|Y | User-defined 001User-defined 005User-defined 189 |
| 13 | NK1|1|PIERCE^BENJAMIN^^^MD^^L|FOT^Form completed by (Name)-Other^HL70063|WrightHealth Medical Center^2500 WrightHealth Drive^ANYTOWN^MARYLAND^21713^^B|778-2222^WPN~doc@example.com^NET||||||||||||||||| | HL7 063  |
| 14 | NK1|2|PIERCE^BENJAMIN^^^MD^^L|POC^Best Healthcare Professional to Contact^HL70063|||778-2222^311^WPN|||||||||||||||||||||||||||||| | HL7 063  |
| 15 | ORC|RE|||||||||||151522^Vaxerlast^Dexter^^^RN^^L|||||||||PED COMP CARE|WrightHealth Medical Center^2500 WrightHealth Drive^ANYTOWN^MARYLAND^21713^^B|778-8643^WPN^PH~778-8644^WPN^FX|WrightHealth Medical Center^2500 WrightHealth Drive^ANYTOWN^MARYLAND^21713^^B |   |
|   | OBR|1|||CDC VAERS-2 (FDA) Report|||20190130||||||||||||||||||||||||||||||||||| |   |
| 6 | OBX|1|NM|^^^YEAR AGE^Age at vaccination year^L||0|yr^year^ANSI|||||F|||||| | ANSI unit codes |
| OBX|2|NM|^^^MONTH AGE^Age at vaccination month^L||6|mo^month^ANSI|||||F|||||| | ANSI unit codes |
| 18 | OBX|3|FT|30948-4^Vaccination adverse events and treatment, if any^LN|1|Adverse effect of vaccines and biological substances, init on 2019-01-21, clinician comment: . ||||||F|||||| | NIP003 |
| 4 | OBX|4|TS|30952-6^Date of vaccination^LN||20190121||||||F|||||| | NIP003 |
| 5 | OBX|5|TS|30953-4^Adverse event onset date and time^LN||20190129||||||F|||||| | NIP003 |
| 8 | OBX|6|ST|^^^PREGNANT^Pregnant at time of vaccination^L||No||||||F|||||| | HL7 136 |
| 16 | OBX|7|CE|30962-5^Vaccinated at^LN||PVT^Private doctors office/hospital^NIP007||||||F|||||| | NIP007 |
| 16 | OBX|8|ST|^^^VAX AT OTHER^Vacinated At Other^L||Other location text||||||F|||||| |   |
| 9 | OBX|9|FT|30964-1^Other medications^LN||None||||||F|||||| | NIP003 |
| 19 | OBX|11|FT|30954-2^Relevant diagnostic tests/lab data^LN||None||||||F|||||| | NIP003 |
| 20 | OBX|12|FT|30951-8^Patient Recovered^LN||N^No^HL70136||||||F|||||| | NIP003HL7 0136 |
| 10 | OBX|13|FT|^^^ALLERGIES^Allergies^L||Amoxicillian||||||F|||||| |   |
| 11 | OBX|14|FT|30965-8^Illness present at time of vaccination^LN||None||||||F|||||| | NIP003 |
| 12 | OBX|15|FT|30966-6^Pre-existing physician-diagnosedallergies, birth defects, medical conditions^LN||None||||||F|||||| | NIP003 |
| 21 | OBX|16|FT|30949-2^Vaccination adverse event outcome^LN||E^Doctor or other healthcare professional office/clinic visit^NIP005||||||F|||||| | NIP003NIP005 |
| OBX|17|FT|30949-2^Vaccination adverse event outcome^LN||E^Emergency room or emergency department visit^NIP005||||||F|||||| | NIP003NIP005 |
| OBX|18|FT|30949-2^Vaccination adverse event outcome^LN|3|H^Required hospitalization^NIP005||||||F|||||| | NIP003NIP005 |
| OBX|19|NM|30950-0^Number of days hospitalized due to vaccination adverse event^LN|3|05|d^day^ANSI|||||F|||||| | ANSI unit codes |
| OBX|20|FT|^^^HOSPNAME^Hospital Name^L|3|Meritus Medical Center||||||F|||||| |   |
| OBX|21|FT|^^^HOSPCITY^Hospital City^L|3|Hagerstown||||||F|||||| |   |
| OBX|22|FT|^^^HOSPSTATE^Hospital State^L|3|MD||||||F|||||| |   |
| OBX|23|FT|30949-2^Vaccination adverse event outcome^LN||P^Prolongation of existing hospitalization^NIP005||||||F|||||| | NIP003NIP005 |
| OBX|24|FT|30949-2^Vaccination adverse event outcome^LN||L^Life threatening illness^NIP005||||||F|||||| | NIP003NIP005 |
| OBX|25|FT|30949-2^Vaccination adverse event outcome^LN||J^Resulted in permanent disability^NIP005||||||F|||||| | NIP003NIP005 |
| OBX|26|FT|30949-2^Vaccination adverse event outcome^LN||D^Patient died^NIP005||||||F|||||| | NIP003NIP005 |
| OBX|27|FT|30949-2^Vaccination adverse event outcome^LN||C^Congenital anomaly or birth defect^NIP005||||||F|||||| | NIP003NIP005 |
| OBX|28|FT|30949-2^Vaccination adverse event outcome^LN||O^None of the above^NIP005||||||F|||||| | NIP003NIP005 |
| 23 | OBX|29|NM|^^^PREVAE^Adverse event following any previous vaccine^L||Yes||||||F|||||| |   |
| OBX|30|FT|^^^PREVAETEXT^Adverse event following any previous vaccine Text^L||Patient age: 10, vaccination dates: 19990217, vaccine type and brand name: Wonderdrug Injection||||||F|||||| |   |
| 27 | OBX|31|NM|^^^MILSTATA^Active Duty^L||Yes||||||F|||||| |   |
| OBX|32|NM|^^^MILSTATR^Reserve^L||Yes||||||F|||||| |   |
| OBX|33|NM|^^^MILSTATN^National Guard^L||Yes||||||F|||||| |   |
| OBX|34|NM|^^^MILSTATB^Beneficiary^L||Yes||||||F|||||| |   |
| OBX|35|FT|^^^MILSTATO^Other Military Status^L||Yes||||||F|||||| |   |
| OBX|36|NM|^^^MILSTATOTEXT^Other Military Status Text^L||Yes||||||F|||||| |   |
| OBX|37|NM|^^^DODSITE^Vaccinated at Military/DoD site^L||No||||||F|||||| |   |
| 17 | OBR|2|||30955-9^All vaccines given on date listed in #10^LN|||||||||||||||||||||||||||||||||||||| | NIP003 |
| OBX|1|CE|30955-9&30956-7^Vaccine type^LN|1|08^HepB-Adolescent/pediatric^CVX||||||F| | HL7 227 |
| OBX|2|CE|30955-9&30957-5^Manufacturer^LN|1|MSD^Merck^MVX||||||F| | HL7 292 |
| OBX|3|ST|30955-9&30959-1^Lot number^LN|1|MRK12345||||||F| |   |
| OBX|4|CE|30955-9&30958-3^Route^LN|1|IM^Intramuscular^HL70162||||||F| | HL7 162 |
| OBX|5|CE|30955-9&31034-2^Site^LN|1|LA^Left arm^HL70163||||||F| | HL7 163 |
| OBX|6|NM|30955-9&30973-2^Dose number in series^LN|1|01||||||F| |   |
| OBX|7|CE|30955-9&30956-7^Vaccine type^LN|2|50^DTaP-Hib^CVX||||||F| | HL7 227 |
| OBX|8|CE|30955-9&30957-5^Manufacturer^LN|2|WAL^Wyeth-Ayerst^MVX||||||F| | HL7 292 |
| OBX|9|ST|30955-9&30959-1^Lot number^LN|2|W46932777||||||F|<CR> |   |
| OBX|10|CE|30955-9&30958-3^Route^LN|2|IM^Intramuscular^HL70162||||||F| | HL7 162 |
| OBX|11|CE|30955-9&31034-2^Site^LN|2|LA^Left arm^HL70163||||||F| | HL7 163 |
| OBX|12|NM|30955-9&30973-2^Dose number in series^LN|2|01||||||F| |   |
| 22 | OBR|3|||30961-7^Any other vaccinations within 4 weeks prior to the date listed in #10^LN|||||||||||||||||||||||||||||||||||||| | NIP003 |
| OBX|1|CE|30961-7&30956-7^Vaccine type^LN|1|10^IPV^CVX||||||F| | HL7 227 |
| OBX|2|CE|30961-7&30957-5^Manufacturer^LN|1|PMC^Aventis Pasteur^MVX||||||F| | HL7 292 |
| OBX|3|ST|30961-7&30959-1^Lot number^LN|1|PMC123456||||||F| |   |
| OBX|4|CE|30961-7&30958-3^Route^LN|1|SC^Subcutaneaous^HL70162||||||F| | HL7 162 |
| OBX|5|CE|30961-7&31034-2^Site^LN|1|LA^Left arm^HL70163||||||F| | HL7 163 |
| OBX|6|NM|30961-7&30973-2^Dose number in series^LN|1|01||||||F| |   |
| OBX|7|TS|30961-7&31035-9^date given^LN|1|20001216||||||F| |   |
| 26 | OBR|4|||^Only for reports submitted by manufacturer/immunization project|||||||||||||||||||||||||||||||||||||| |   |
| OBX|1|ST|30975-7^Mfr./Imm. Proj. report no.^LN||WRIGHTHEALTHESP2012232||||||F|||||| | NIP003 |

# Appendix A – VAERS 2.0 Form

