

**Techniques for recording and messaging H1N1-09 possible vaccine adjuvant for IIS
8/7/09**

Purpose of Document:

The purpose of this document is to give guidance on electronic messaging of the adjuvant lot number and manufacturer for the H1N1 vaccine. In addition, it gives suggestions on updating applications to allow capture of adjuvant lot number in electronic systems. It is still unknown if an adjuvant will be used in the vaccine. Should the adjuvant be needed this technical guidance can be used to expedite system and electronic reporting changes.

Audience:

The intended audience for this guidance document includes Immunizations Information Systems (IIS) managers and technical staff, Electronic Health Record system technical staff and immunization program managers.

One of the uncertainties heading into the fall regarding vaccine recommendations for Novel Influenza H1N1-09 vaccine is whether adjuvant will be recommended in the vaccine. For planning purposes, Immunization Information Systems (IIS) and others with electronic health record systems should be prepared to capture lot number and manufacturer of the adjuvant component. Tracking lot numbers may be important. Tracking of this second lot number (for the adjuvant) may necessitate modifications to the database and user interface. In addition, systems that use electronic data exchange will need to be able to carry the information in the message that they exchange. The current CVX codes assume that either injectable formulation will have similar recommendations regarding adjuvant. That is, either the vaccine will both be given with adjuvant or neither will be given with adjuvant. If this is not the case, additional CVX codes are likely. This document will give specifications for the messaging and suggestions for the system modifications.

Messaging Guidance

HL7 anticipates medication administration that is composed of more than one product. The RXA segment, which carries the data on an immunization event includes fields for both lot number and manufacturer. Both of these fields allow repeats. Specifically, more than one lot number may be entered into the lot number field. These are separated by the tilde (~) character, which separates repeats in a field. The Manufacturer field is handled in a similar style. Systems need to have the ability to accept and process repetitions in these fields to support this functionality.

Lot Number (Reported in the RXA-15 Substance Lot Number field)

Data Type	String (ST)
Repeats allowed	Yes
Vaccine lot number	Shall be the first repetition
Adjuvant lot number	Shall be the second repetition

Manufacturer (Reported in the RXA-17 Substance Manufacturer field)

Data Type	Coded entry (CE)
Repeats allowed	Yes
Vaccine manufacturer	Shall be the first repetition
Adjuvant manufacturer	Shall be the second repetition

The following example RXA segment shows an immunization with novel H1N1-09, preservative free. The vaccine was manufactured by GSK with a lot number of 33k2a. The adjuvant was manufactured by Novartis with a lot number of 99e43¹. Note the tilde (~) separating each repetition.

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RXA|0|1|20091015132511|20091015132511|126^Novel H1N1-09 preservativefree^CVX|999|||||||33k2a~99e43|
|SKB^GlaxoSmithKline^MVX~NOV^Novartis^MVX <CR>
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Suggestions On Capturing Adjuvant Lot Number in Electronic Systems

Most IIS or Electronic Health Record systems (EHR) can capture a unique lot number with each vaccination. The Adjuvant component of the H1N1 vaccine may be manufactured by a different company than the vaccine manufacturer. It may also be added at the time of administration. Tracking the lot numbers is very important for clinical documentation and patient safety tracking.

Each immunization that included adjuvant should be able to be associated with the lot number for that adjuvant. At the simplest, a new field may be added to the table storing immunizations that allows a string to be entered that indicates the lot number. While this will be the simplest to accomplish, it has a number of weaknesses. Hand keying the lot number for each immunization will add time to the recording effort and slow things down in a mass clinic. In addition, hand keyed text is prone to typographic errors, putting the data quality at risk.

Using pre-populated pull downs speeds things up and prevents the risk of typographic errors. This requires more modifications to the application capturing the data. First the user interface for recording immunizations must allow for selection of the adjuvant lot number. Since it is not clear how much advance notice there will be regarding specific lots to be used in a clinic, systems should not rely on backend database management processes to set up the pull downs. A better approach would be to have a simple user interface that allows the end user to enter the list of adjuvant lot numbers at the clinic. It would be good practice to allow the user to filter or otherwise constrain the current lot numbers to those in use at the specific clinic. A simple flag in the table that can be set to active or inactive is one way to accomplish this.

For systems with robust inventory management capabilities, a more sophisticated approach is possible. Setting up a table that is similar to the table for vaccine lots will allow capture of more information and will allow for ordering and transfers. It could also allow for real time tracking of inventory on hand. In this case, there would need to be a user interface for setting up lots, perhaps at the clinic. In addition there would need to be modifications to the user interface for entering immunizations that presents the user with the opportunity to select the correct lot number for the adjuvant.

¹ Note that these are hypothetical examples only.