PROTOCOL FOR THE PILOT STUDY OF HEALTH LEVEL 7 MESSAGE-EXCHANGE BETWEEN IMMUNIZATION INFORMATION SYSTEMS AND MINI-SENTINEL/PRISM DATA PARTNERS

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Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA) to inform and facilitate development of a fully operational active surveillance system, the Sentinel System, for monitoring the safety of FDA-regulated medical products. Mini-Sentinel is one piece of the Sentinel Initiative, a multi-faceted effort by the FDA to develop a national electronic system that will complement existing methods of safety surveillance. Mini-Sentinel Collaborators include Data and Academic Partners that provide access to health care data and ongoing scientific, technical, methodological, and organizational expertise. The Mini-Sentinel Coordinating Center is funded by the FDA through the Department of Health and Human Services (HHS) Contract number HHSF223200910006I.

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Table of Contents

I. BACKGROUND

In 2009, the Department of Health and Human Services created the new Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program, which used data from national health insurance plans (Data Partners) and Immunization Information Systems (IIS registries) to monitor the safety of the H1N1 influenza vaccine (1). Immunization Information Systems (IIS) are centralized population based repositories of vaccination information operated by state and local public health authorities. During the 2009 H1N1 pandemic, PRISM's data linkages with IIS registries were a crucial source of vaccination data and greatly improved the safety evaluation of the H1N1 vaccine. Of the first 3 million doses of H1N1 vaccine monitored by PRISM, more than 60% were identified via immunization registry data alone and would not have been captured through health plan data (2).

Building upon the success of the H1N1 experience, eight immunization information systems renewed their commitment to the second and third year of the PRISM program (Florida, Michigan, Minnesota, New York State, New York City, Pennsylvania, Virginia and Wisconsin), and additional participants are being explored. Due to their increasing role in health information exchange, IIS systems have undergone enhancements and modifications to standardize how they receive and exchange health information. Health Level Seven (HL7) is a nationally recognized standard for electronic data exchange between systems housing health care data and many IIS have adopted this standard or are striving to implement it. As a result, FDA has supported the development of HL7 based interoperability specifications to sustain the vital IIS data linkages in Mini-Sentinel's PRISM program.

II. SCOPE OF WORK

The current process for sharing immunization data with the Data Partners is through ASCII text file format (flat file). The Data Partners must create a unique file format for each IIS to pull the immunization data required for the PRISM project. This requires a great deal of programming on the part of both the sending and receiving applications. These interfaces are expensive because there is no standard collection of patient attributes or standard set of events.

In a recent initiative, IIS registries across the country are redesigning their applications to receive and send Health Level Seven (HL7) 2.5.1 messages with electronic health record systems. The HL7 standard is a key factor that supports this two-way exchange of information because it defines a syntax, or grammar, for formulating the messages that carry this information. It further describes a standard vocabulary that is used in these messages. It does not depend on specific software and is platform independent. HL7's prime objective is to simplify the implementation of interfaces between healthcare software applications and various organizations in order to reduce the cost involved in custom interface programming. The increasing adoption of HL7 by the IIS for data exchange has created an opportunity for Mini-Sentinel's PRISM program to align with this national standard of data exchange.

The purpose of this study is to pilot the use of HL7 data exchange with one Data Partner and one IIS registry with a view to future implementation of HL7 as a standard method of data exchange between all participating Data Partners and IIS registries.

III. METHODS

A. HL7 IMPLEMENTATION

In a prior related activity, PRISM created an HL7 2.5.1 implementation guide for IIS registries and the Data Partners based on the Center for Disease Control's HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.3 (3). This section provides an overview of the technical details of that implementation guide.

The use of HL7 provides a standard message structure and constrained, structured vocabulary that Data Partners will use to:

- request immunization histories for their members
- receive these histories from an IIS for their members with records in that IIS
- receive acknowledgement of these requests and feedback on problems with the request

Using the same standard message structure, IIS registries will:

- receive requests for immunization histories from Data Partners
- return to a Data Partner complete immunization histories for their members with records in the IIS
- return acknowledgement of the request and feedback on problems with the request
- return a standard HL7 Version 2.5.1 response (RSP) that will contain an immunization history for an individual

In some IIS implementations, the constraints may be stricter on the needed support and usage for segments, components and sub-components. In no IIS implementation will use less strict constraints. The Guide will indicate which data elements will be ignored if received. An IIS can populate a standard RSP message with any data element. The Data Partner will ignore data elements that are not of interest.

The Data Partner will create a VXQ message containing member identifiers. If the IIS finds a single matching patient, it will return a VXR message echoing back the query data submitted in the VXQ and containing the following patient information; Patient Identifier, First Name, Middle Name, Last Name, Date of Birth, Gender, and Immunization History. If a patient has immunization history, the VXR will include an RXA segment for each immunization. The RXA segment will include the administration date, vaccine code, vaccine description, and administering provider. If available, the RXA segment will include the lot number and manufacturer associated with the immunization.

If the IIS discovers errors in the message an ACK message will be returned. If the IIS does not locate the member sent in the VXQ message, a QCK message will be returned.

The pilot will evaluate the number of returned messages in these formats:

a) Number of queries received (VXQ)
b) Number of patients not located (QCK)
c) Number of queries with errors (ACK)
d) Number of immunization histories (VXR)

B. PILOT STUDY OF HL7

This pilot will compare three methods for collecting immunization surveillance data from a Data Partner and an IIS registry. The comparison will be made among immunization data received via HL7 format, data received in the standard ASCI format (flat file) and the web-based Graphical User Interface (GUI) at the IIS registry. This comparison is relevant to decision makers who are weighing the costs and benefits of these alternatives when sharing data for vaccine-safety surveillance studies.

The study will evaluate HL7 batch data feeds between a Data Partner and a statewide IIS registry. The Data Partner will manually upload member demographics in HL7 and flat file formats to the IIS, and the IIS will process the member demographics. The Data Partner will then manually download the immunization records from the IIS, develop acceptable HL7 formatted immunization requests for an IIS registry, and create a test file of 10 members to manually upload to the IIS registry. IIS will review the HL7 format messages and work with Data Partner to approve message format. Once the HL7 format is approved, the Data Partner will request immunization information on 100 members between the ages of 0 and 21 in both HL7 and flat file formats. The Data Partner will download immunization information from the IIS. Within 24 hours of the Data Partner download, the Data Partner will print screen shots of the GUI for the 100 member.

The comparison of the three formats (HL7, flat file, and GUI) will focus on the following outcomes: (1) availability of fields (2) data completeness; (3) time latency; (4) personnel and other technical effort required for implementation; and (5) cost. Each of these is described in detail below.

1. Availability of fields

The fields available in each format will be documented. An assessment of missing fields will be made based on Data Partners need for matching.

2. Data Completeness (also known as reliability)

The study will measure the data completeness of the electronic reporting process for collecting the surveillance data. To assess the completeness of the electronic reporting process the following measures will be collected and evaluated:

a) The total number of members in sample located in the IIS catchment area with returned immunization histories to the Data Partner during the project timeline

b) Proportion of immunizations that were present on HL7 message, flat file process, and present on the GUI
   i. percentage of members for whom the HL7, flat file, and GUI had a complete match
   ii. percentage of members in which HL7 and flat file data had 1, 2, or $\geq$3 missing vaccines compared to GUI
   iii. percentage of members in which HL7 and flat file data had 1, 2, or $\geq$3 additional vaccines compared to GUI

c) Proportion of other important public health information present on HL7, flat file and GUI formats
   i. percentage of records that include a lot number, manufacturer and administering provider information on HL7, flat file, and GUI

d) Identify the proportion of HL7 messages that were received without errors (ACK messages) by the IIS

3. Time Latency

The study will measure time latency as the interval between requesting an immunization record on a member from the IIS and receipt of the immunization record at the Data Partner.

4. Personnel and Other Technical Effort

The study will estimate technical implementation time for the initial set-up of HL7 exchange for a new data partner in terms of hours. This will be based on task breakdowns for setting up data transports (e.g., network connections) and setting up data interfaces (e.g., data formatting, HL7 listener setup). The study will also estimate personnel and other Data Partner costs for real time HL7 data exchange.

5. Cost

The costs of implementing a real time HL7 exchange system will be explored. It is likely that a third party will need to be contracted to transmit and receive the data at the scale that the Data Partners will need for real-time implementation. The study will obtain estimates for the cost of this service.

C. ANTICIPATED NEXT STEPS

The quality and quantity of returned messages for the same cohort, requested using HL7, flat files and GUI interface, will be compared. If the results from the HL7 file are at least as good as from the flat file, the next step will be to investigate the process for sending HL7 messages as an automated background process, both in terms of cost and process.

At the end of the study the results will be presented to the Data Partners, IIS partners, and the Stakeholder Committee. A final report describing the project and results will be posted on the Mini-Sentinel website.

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