MINI-SENTINEL PRISM

HEALTH LEVEL 7 MESSAGE-EXCHANGE BETWEEN IMMUNIZATION INFORMATION SYSTEMS AND DATA PARTNERS: PILOT

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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.

Mini-Sentinel PRISM

Health Level 7 Message-Exchange between Immunization Information Systems and Data Partners: Pilot

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A. INTRODUCTION

The Post-Licensure Rapid Immunization Safety Monitoring (PRISM) initiative is a collaborative effort that uses data from national health insurance plans and immunization registries to monitor vaccine safety by linking vaccines to health outcomes of interest through a distributed database.[1] Three national health insurance plans (Data Partners) maintain databases within their separate organizations and contribute aggregated information about vaccines and health outcomes of interest found in medical claims to PRISM. However, vaccine capture in medical claims is not complete. Thus, PRISM developed relationships between Data Partners and eight Immunization Information Systems (IIS) to share immunization data and increase overall vaccine capture within each Data Partner's distributed database.[2]

Data Partners currently obtain immunization data from IISs by exchanging data in an ASCII text file format (flat file). Each IIS has different data requirements for the flat file so the IIS can receive and match the Data Partner's member demographic data with their immunization information. The flat file created by the Data Partner contains at minimum member name and date of birth. The data is sent to the IIS in batch transmissions through secure web portals. The process to upload and download files differs among IISs. Some batch transmissions are completely automated while other batch transmissions require email notification between the Data Partner and IIS that a file is ready to be processed or has been processed.

In the future, IISs prefer to conduct all data exchanges with HL7 messaging (HL7 format) instead of flat file format.[3] The HL7 format has two benefits; standardized formats for all data requests and results as well as the capability to provide additional immunization information, such as vaccine type and lot number. The benefits to PRISM of HL7 format is that 1) standardization of immunization data exchange would allow additional IIs to share data with Data Partners without additional development time for Data Partners to create specific IIS flat files and 2) the additional immunization information may increase understanding the safety of vaccines.

The purpose of this pilot was to 1) determine if Data Partners and IISs could share data in the HL7 format and 2) compare the performance of flat file and HL7 file formats as methods of data exchange. The results of this pilot will inform efforts to use HL7 data exchange as a standard method of data transmission between all participating PRISM Data Partners and IIS registries.

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[1] Nguyen M, Ball R, Midthun K, & Lieu TA. (2012). The Food and Drug Administration's Post-Licensure Rapid Immunization Safety Monitoring program: Strengthening the Federal vaccine safety enterprise. Pharmacoepidemiology & Drug Safety, 21(S1), 291-297. DOI: 10.1002/pds.2323

[2] Yih, W.K., Lee, G.M., Lieu, T.A., Ball, R., Kulldorff, M., Rett, M., Wahl, P.M., McMahill-Walraven, C.N., Platt, R., Salmon, D.A. 2012. Surveillance for adverse events following receipt of pandemic 2009 H1N1 vaccine in the Post-licensure Rapid Immunization Safety Monitoring (PRISM) system, 2009-2010. *American Journal of Epidemiology*, 2012. doi: 10.1093/aje/kws197.

[3] HL7 is a nationally recognized standard for electronic data exchange between systems housing health care data. Protocol for pilot study of Health Level 7 Message-exchange [unpublished].

B. METHODS

This pilot of the HL7 format data exchange was between Aetna and the Minnesota IIS.

Aetna Informatics-Evaluation and Analysis team was new to the HL7 format data exchange and only has the capability to send HL7 VXQ (query) messages in a batch file process through an existing secure method, the Minnesota Immunization Information Connection's (MIIC).

Minnesota IIS has over eight years of experience with HL7 VXU (immunization submission) format data exchange, both real-time submissions as well as batch submissions, with dozens of healthcare service providers but no live, production experience in using HL7 VXQ (query) format data sharing with health insurance plans; no providers in Minnesota are using VXQ batch submissions to receive data on their patients or members. The Minnesota VXQ code has never been used by an outside entity, other than a pilot system over five years ago.

The flat file and the HL7 file format were compared against the Minnesota Immunization Information Connection's (MIIC) Graphical User Interface (GUI). All three methods (flat file, HL7 format, and GUI) were views of the same data source. The methods were compared on the availability of fields in each format, data completeness, time latency, and the ability to implement the HL7 messaging.

Aetna created a sample of 100 members who resided in Minnesota, were between the ages of two months and 21 years, for whom Aetna had received vaccine information from a previous Minnesota IIS data exchange. Member name and date of birth from the sample were transformed from SAS database format into flat file and H7 file formats for data exchange.

1. Outcome

The outcomes measured were availability of fields, data completeness, time latency, and implementation of HL7 messaging protocol. Costs for implementation were not evaluated at this time.

Availability of fields was measured as the field presence in the file format and the population of data in the flat and HL7 file fields. Fields that are necessary for Data Partner matching or were important for public health surveillance were noted.

Data completeness included member information and vaccine information.

Member information data completeness was that the member was returned with any vaccine information in the flat file, HL7 file and GUI screen shots. The types of HL7 returned messages were counted.

Vaccine information data completeness was measured as the presence of vaccine administration, lot number, manufacturer and administering provider on the flat and HL7 files. The GUI was the gold standard, that is, vaccine information on the GUI should also be on the flat and HL7 files.

The following specific vaccine information measures were calculated:

1. The proportion of members with vaccines.
2. The proportion of members without a vaccine.
3. The number of vaccines.
4. The proportion of missing vaccines.
5. The proportion of members with missing vaccines broken down by 1, 2 and 3 or more vaccines.
6. The proportion of vaccines with lot number.
7. The proportion of vaccines with manufacturer.
8. The proportion of vaccines with administering provider.

Vaccines were displayed by antigen in the flat file and on the GUI so that a multiple antigen immunization (e.g. Diphtheria, tetanus, and pertussis (DTap)) had multiple rows of data. The HL7 file reported the multiple antigen vaccine as a single administration. For HL7 and GUI comparison purposes, the HL7 single administration was matched to the GUI antigen.

Time latency was the time interval between Aetna uploading the flat and HL7 batch files to Aetna downloading the vaccine information from the MIIC secure web portal.

Implementation of HL7 messaging protocol was the size description of the Data Partner vaccine request files.

C. RESULTS

Aetna uploaded the flat file and HL7 file on August 29th, 2012 and manually retrieved the files from the Minnesota's Immunization Information Connection (MIIC) secure web portal on August 30th 2012. Aetna printed the sample members' immunization history from the MIIC Graphical User Interface (GUI) on August 31st, 2012.

Flat file: The 100 member sample vaccine request in the flat file format was uploaded, processed, and downloaded from the MIIC secure web portal without technical problems. All members sent in the flat file format were returned and their demographic information matched the demographic information displayed for that member in the GUI.

HL7 file: The 100 member sample vaccine request in the HL7 file format was uploaded to the MIIC secure web portal without technical problems. The MIIC technical staff split the HL7 file into ten files with each file containing ten members, processed the ten files, and combined the results into two HL7 file with the return messages; this was because the VXQ code was intended to be used one person at a time. When member immunization history was returned, demographic data on the member was consistent with demographic data on the GUI.

GUI: Information on all 100 member sample was printed from the GUI (screen shots).

2. Availability of Fields

The availability of fields on the flat file, HL7 file and GUI are shown in Table 1. Of the 27 fields available, none of the formats contained all the fields and some of the available fields were not populated with any data.

Flat file: The flat file format contained 19 fields. All 19 fields had some populated data. The flat file used one field for the cpt/cvx code and a *vaccine type* field to distinguish whether the data was a cpt or cvx code.

HL7 file: The HL7 file format contained 20 fields. Of the 20 fields, there were 14 fields with some populated data. *Vaccine Group, Trade Name, Administration Route, Body Site, Historical Indicator,* and *Historical Lot Number* fields were not populated with any data. The *Patient ID (PATID)* was not contained in the file and is critical to match the vaccine information to the Data Partner member. The HL7 file had separate fields for *cpt* and *cvx* codes.

GUI: The GUI screen shots contained 15 fields. All 15 fields had some populated data. The GUI had the *Vaccine Name* and *Vaccine Type* fields but did not contain *CVX Code, Vaccine Group* and *CPT Codes* fields.

Table 1: Data Field Availability for the Flat File, HL7, and GUI Data Formats

Data Field	Flat File	HL7	GUI
Patient ID (aka Chart 3 in GUI)	X		X
Patient IIS ID			
First Name	X	X	X
Middle Name	X	X	X
Last Name	X	X	X
Birth Date	X	X	X
Gender		X	X
Mothers First Name	X	X	
Mothers Maiden Name	X	X	
Vaccine Date	X	X	X
MIIC Client ID	X		
Vaccine Type	X		X
CVX Code	X	X	
CVX Description		X	
Vaccine Group	X		
Vaccine Quantity		X	
CPT Code		X	
CPT Description		X	
Trade Name	X		X
Administration Route	X		X

Data Field	Flat File	HL7	GUI
Body Site	X		X
Manufacturer Code	X		X
Vaccine Manufacturer			
Historical Indicator	X		X
Historical Lot Number	X		X
Provider Last Name	X		X
Provider First Name			
RED - essential to move forward with HL7 **Black - no field on file** **X - Field on file; Data in field** **Empty cell - Field on file; no data in field**			

3. Data Completeness

a. Member Information

Flat file: Of the 100 member sample, all members were returned on the flat file.

HL7 file: There were 94 members returned on one of two HL7 files: an HL7 formatted message results file and an HL7 formatted "results not found" file (**Table 2**).

The HL7 message results file had four members with messages that indicated the record was not found. Three members had HL7 message type QCK: member not located messages. One member had HL7 message type VXQ: returned in results file with not found message.

Eight members were returned in a separate "results not found" file. MIIC investigated the eight members and found that all eight members should have been returned with vaccine information.

There were six members who were not returned with any message to Aetna.

Table 2. Members requested and returned status

	Flat	HL7		GUI
	N	Message type	N	N
Aetna Members submitted to MIIC	100	VXQ	100	100
Returned Messages without Vaccines			18	
Members not located	-	QCK	0	-
Members not located	-	QAK	3	-
Returned in results file with not found message	-	VXQ	1	-
Queries with errors	-	ACK	0	-
Returned in separate "results not found" file	-	-	8	-
No messages received back on member	-	-	6	-
Returned Messages with Vaccines	100	VXR	82	-

b. Vaccine Information

Flat file: There were 1990 vaccines (antigens) returned on the flat file (Table 3). There were six (0.3% of the antigens) missing vaccines on the flat file compared to the GUI. Ninety-nine (99%) members had a complete match to the GUI vaccines. One (1%) member had six missing vaccines.

HL7 file: There were 1396 vaccines (administrations) returned on the HL7 file (Table 3). There were 386 (22% of the administrations) missing vaccines on the HL7 file compared to the GUI vaccines (antigens). Of the 100 member sample, 78 members (78%) had a complete match to the GUI vaccines. Two (2%) members had one missing vaccine. One (1%) member had two missing vaccines. There were 19 (19%) members, including the 18 members that were not returned on the HL7 return files, had three or more missing vaccines.

GUI: Of the 100 members, there were 1996 antigens and 1782 vaccine administrations found on the GUI screen shots (Table 3).

Table 3. Immunization History Match Results

	Flat	HL7	GUI
Antigens / Administrations received	1990	1396	1996/ 1782
Antigens / Administrations missing compared to GUI	6 (0.3%)	386 (22%)	-
Members with complete match to GUI	99 (99%)	78 (78%)	-
Members missing vaccines	1 (1%)	22 (22%)	-
1 vaccine missing	0	2 (2%)	-
2 vaccines missing	0	1 (1%)	-
3+ vaccines missing	1 (1%)	19 (19%)	-

Lot Number was available on the flat file and GUI. There were 565 (28%) lot numbers on the returned flat file (Table 4). There were 29 (1%) lot numbers on the GUI.

Manufacturer was available on the flat file, HL7 file, and GUI (Table 4). There were 338 (17%) manufacturers on the returned flat file. There were zero manufacturers on returned HL7 file. There were 29 (1%) manufacturers on the GUI.

Administering Provider was available on flat file, HL7 file, and GUI (Table 4). Provider name was returned as one field on the flat file and two fields (last name and first name) on the HL7 file. There were 951 (48%) provider names on the returned flat file. There were zero provider names on the returned HL7 file. There were 1996 (100%) provider names on the GUI.

Table 4. Availability of Vaccine Information

	Flat (N=1990)		HL7 (N=1396)		GUI (N=1996)	
	Field Available	Field Populated N	Field Available	Field Populated N	Field Available	Field Populated N
Lot number	Yes	565	No	--	Yes	29
Manufacturer	Yes	338	Yes	0	Yes	29
Administrating Provider	Yes	951	Yes	0	Yes	1996

4. Time Latency

Flat file: The flat file was manually uploaded to the MIIC secure portal by Aetna. MIIC automatically processed the flat file and the immunization history results file was created. Aetna manually downloaded the result file from MIIC secure portal. The immunization history turnaround time for the flat file was less than 15 minutes.

HL7 file: The HL7 file format was manually uploaded to the MIIC secure portal. Aetna emailed MIIC that the HL7 file was uploaded so that it could be processed by the MIIC technology team. The immunization history results information was available in two days. If the 100 members had been sent in 100 individual VXQ messages, the response time would have been under 30 seconds per member. MIIC emailed Aetna that the results files were ready and uploaded the files to a secure FTP for Aetna to download.

GUI: The GUI screens were printed once the HL7 files were downloaded. The GUI screen prints took a total of 45 minutes.

5. Implementation

In future full implementation of the HL7 file messaging, the size of HL7 files will need to be considered for transmission between a large Data Partner and an IIS. For the 100 member sample, the flat file size was 19 kilobytes (kb) and the HL7 file size was 21 kb (Table 5). A large Data Partner may have an IIS catchment area of between 90,000 to 2,000,000 residents. The flat file sizes would be between 1.6 gigabytes (gb) and 36.2 gb. The HL7 file sizes would be between 1.8 gb and 40.0 gb.

Table 5. Request File Size by Number of Members

File type	Number of members in file		
	100	90,000	2,000,000
Flat file	19 kb	1.6 gb	36.2 gb
HL7 file	21 kb	1.8 gb	40.0 gb

The flat file format is slightly smaller than the HL7 file format. The size difference between the file types is not substantial.

D. DISCUSSION

PRISM monitors vaccine safety by linking vaccines and health outcomes of interest. Medical claims provide both vaccines and health outcomes of interest but the medical claim vaccine capture is not complete. Thus, combining vaccine medical claims and IIS vaccine records has been shown to increase overall vaccine capture by over 60%.[4] The current data exchange method between the PRISM Data Partners and IISs is a flat file format manually uploaded and downloaded by the Data Partners through secure web portals. IISs are moving towards HL7 file format data exchange. This pilot investigated the HL7 data exchange process and differences in field availability, data completeness, time latency and implementation between flat and HL7 file formats.

This pilot used Aetna member demographic information to request immunization histories from Minnesota IIS in three formats: two files (flat file and HL7 file) and MIIC's graphical user interface (GUI). The data transmission – file upload, processing and download -- for the flat file had no technical problems. The HL7 message data transmission process was not ideal for a VXQ batch transmission. Minnesota's MIIC transmission process was not designed for this purpose. The 100 sample flat file data transmission was manually uploaded, processed automatically, and manually downloaded without problems. All members sent in the flat file format were returned. The 100 sample HL7 file data transmission was manually uploaded but could not be processed without MIIC technical staff splitting the data into ten files each containing ten members and combining the results into two HL7 return files. The HL7 format did not return 18 members immunization histories: four members had standard HL7 error messages, eight members had non-standard HL7 error messages, and six members had no message at all.

The same data source was used by MIIC to create the flat files and HL7 files as well as display vaccine information on the GUI. There were differences found between the flat and HL7 file formats in field availability, data completeness, time latency and implementation. The flat file format had more fields available, returned more members, and returned more vaccine information compared to the HL7 file.

[4] Yih, W.K., Lee, G.M., Lieu, T.A., Ball, R., Kulldorff, M., Rett, M., Wahl, P.M., McMahill-Walraven, C.N., Platt, R., Salmon, D.A. 2012. Surveillance for adverse events following receipt of pandemic 2009 H1N1 vaccine in the Post-licensure Rapid Immunization Safety Monitoring (PRISM) system, 2009-2010. *American Journal of Epidemiology*, 2012. doi: 10.1093/aje/kws197.

The flat file format contained very complete immunization history data with only one member missing six vaccines compared to 22 members with incomplete vaccine information from the HL7 file format.

Improvements. For PRISM Data Partners to use the HL7 format data exchange the following improvements are suggested.

- The data exchange process – upload, process, and download -- should have the capability to process large batch files in an automated way. This pilot transmitted 100 HL7 messages from Aetna to MIIC. MIIC could only process 10 messages at a time; thus, MIIC manually split the file. The processing of the HL7 file was not automated and MIIC had to be notified that the file was available.
- The HL7 format files returned to the Data Partners should include at minimum the Data Partner provided member id (i.e. *PatID* from the Common Data Model) and the additional vaccine information data fields *Trade Name, Administration Route, Body Site,* and *Lot Number*.
- The HL7 format file data completeness was not as robust as the flat file method. Since the same data source created the returned flat file and HL7 file and is used for the GUI display, it is suggested that data creation process and algorithms be reviewed.

Learning curve. Changing the current flat file process to HL7 file format messaging would also involve learning curves on behalf of both the Data Partners and the IIS's. Both Aetna and MIIC spent over 40 hours to create, process, evaluate, and work through technical issues of the HL7 file formats and transmissions.

Data transmission technical aspects. The technical aspects of data transmission would also need to be investigated. Minnesota IIS processes HL7 message requests from healthcare service providers for one patient at a time and instantaneously return HL7 messages. PRISM does not need instant communication on one patient; rather PRISM needs complete immunizations on a large population at the time of a public health emergency or initiative. Data Partners would send a large number of member immunization requests in one transmission or batch on a non-regular basis. While there is batch HL7 file format messaging technology available but it was not investigated in this pilot. [5]

In conclusion, the flat file format is the most accurate, complete, and expedient method for Data Partners to obtain IIS immunization histories at this time for health plans in the state of Minnesota. This conclusion is limited to the current state of flat file and HL7 file format transmissions and the organizations involved in the pilot. HL7 file format is a new data transmission method for health plans; the Minnesota IIS would need to make changes to its current data exchange process to be able to accept

[5] New York IIS has developed a process that will receive a batch file with HL7 message requests, recognize the batch has more than 10 messages, queue those message requests, and process them accordingly. – February 14, 2013 PRISM-IIS meeting.

VXQ messages in batch format. While the organizations involved in HL7 file transmissions become more experienced and the use of the flat file wanes, the HL7 file format transmissions may be the only method to share vaccine information between Data Partners and IISs.

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