

The Wisconsin Immunization Registry Experience: Comparing Real-time and Batched File Submissions From Health Care Providers

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ABSTRACT

Context: The Wisconsin Immunization Registry is a confidential, web-based system used since 1999 as a centralized repository of immunization information for Wisconsin residents.

Objective: Provide evidence based on Registry experiences with electronic data exchange, comparing the benefits and drawbacks of using the Health Level 7 standard, including the option for real time data exchange vs the flat file method.

Design: For data regarding vaccinations received by children aged 4 months through 6 years with Wisconsin addresses that were submitted to the Registry during 2010 and 2011, data timeliness (days from vaccine administration to date information was received) and completeness (percentage of records received that include core data elements for electronic storage) were compared by file submission method.

Results: Data submitted using Health Level 7 were substantially more timely than data submitted using the flat file method. Additionally, data submitted using Health Level 7 were substantially more complete for each of the core elements compared to flat file submission.

Conclusions: Health care organizations that submit electronic data to immunization information systems should be aware that the technical decision to use the Health Level 7 format, particularly if real-time data exchange is employed, can result in more timely and accurate data. This will assist clinicians in adhering to the Advisory Committee on Immunization Practices schedule and reducing over-immunization.

BACKGROUND

Immunization information systems (IIS) have been used since the 1990s to serve as central repositories of immunization information. The primary foci of IIS use include sharing immunization data among health care entities and serving as a mechanism for immunizers to determine current and future vaccination needs.

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As of 2009, 56 federal grantees in the United States (includes states, territories, and select cities) have an IIS.¹ The Centers for Disease Control and Prevention (CDC) Healthy People 2010 Initiative encouraged direct data entry of immunization information by state and local public health departments and was the impetus to create links between the IIS and state vital records systems, thereby systematically populating the IIS with vital records data for each new birth cohort. Subsequently, private health care providers became the focus of outreach activities to provide immunization data for individuals, particularly as electronic medical/health records (EMR/EHR) become more commonly used. This new focus has resulted in the need for health care providers to be included in technical decisions regarding EMR/EHR and IIS because information exchange between these 2 systems can have clinical implications.

One important consideration is the format (standard) for securely and accurately sending health data between an electronic health data system and an IIS. There are currently 2 main standards used to send the message or, more specifically, arrange the message so all the different pieces are received and accurately read by the receiver. These standards are ASCII flat file (flat file) and the worldwide standard Health Level 7 (HL7). These 2 standards differ in their flexibility and the timeliness and completeness of data transmitted.

The initial format available for data exchange when the *Wisconsin Immunization Registry* (WIR) was launched was ASCII flat file, an older format with a relatively rigid structure. These files typically are submitted by health care providers on a weekly, monthly or quarterly basis. During 2001, the WIR also began accepting HL7 messages. The HL7 standard was created in 2001

by a technical working group of the National Immunization Program, with the goal of providing a standard for the exchange of data that eliminates or substantially reduces the custom interface programming and program maintenance that may otherwise be required.² Since May 2002, the WIR has had HL7 real-time data exchange capability, which allows an EMR/EHR to communicate in real time with the WIR and update both systems immediately with the newly added information. Currently, the WIR supports data exchange using HL7 versions 2.3.1, 2.4 and 2.5.1.^{3,4}

While the decision regarding which mechanism to use appears to be primarily one of a technical nature, it has clinical and technical implications that health care entities need to consider. Accordingly, in this report we provide evidence based on WIR experiences regarding the benefits and drawbacks of using the standard of HL7 for data submission compared to flat file data submission.

MATERIALS AND METHODS

Data from the WIR were extracted using Business Objects version 11.5 (SAP Business Objects, San Jose, California) in March 2011 and in December 2011. We defined an immunization record to be the record representing 1 administration of a vaccine to an individual. Thus, an individual who received 3 separate vaccinations during a single clinic visit would have 3 separate immunization records for that immunization encounter. To maximize completeness of data, all immunization records received by the WIR during calendar year 2010, regardless of when the vaccines were administered, were included in the analysis. Data elements examined included date of administration, vaccine group, Current Procedural Terminology (CPT) code, vaccine manufacturer, trade name, vaccine lot number, route of injection, body site, Vaccines for Children eligibility of the client (federal entitlement program), dose size, and administering physician. Immunization records were separated based on the method of submission (HL7 or flat file) and the percentage of immunizations that had a particular data element (eg, vaccine lot number) recorded in the WIR was calculated for each submission method.

The analysis of the timeliness of data submission was based on immunizations administered during January 1, 2010, through December 31, 2011 to children aged 4 months through 6 years with Wisconsin addresses. For each vaccination, the difference in the number of days from the date the vaccine was administered to the date the immunization was successfully submitted by the provider to the WIR was calculated for each method of submission.

RESULTS

Data Submission Methods

Among data exchange methods supported by the WIR, flat file was the most commonly used. Of the approximately 20.81 mil-

Table 1. Completeness of Data Submitted to the Wisconsin Immunization Registry by Submission Method, January 1, 2010 through December 31, 2010

Data Field ^a	Percentage of Immunization Records with Data Submitted by Method Used	
	Flat File	HL7
Date of administration	100%	100%
Vaccine group	100%	100%
CPT code	85%	96%
Vaccine manufacturer	47%	62%
Trade name	37%	42%
Vaccine lot number	26%	63%
Route of injection (eg, intramuscular or subcutaneous)	9%	96%
Body site (eg, left deltoid)	7%	91%
Vaccines for Children eligibility	0%	95%
Dose size	0%	100%
Administering physician	3%	57%

^aRequired fields include the date of administration, vaccine group or CPT code. Abbreviations = HL7, Health Level 7; CPT, Current Procedural Terminology.

lion immunization records for children aged 4 months through 6 years with Wisconsin addresses that were processed by the WIR during 2010, approximately 11.87 million (57%) were provided using a flat file format and 8.94 million (43%) were provided using the HL7 format. Of those submitted using HL7, approximately 1.53 million (17%) were sent using a real-time interface. Of the approximately 18.92 million immunization records processed by the WIR during 2011, 7.61 million (40%) were provided using a flat file format and 11.31 million (60%) were provided using the HL7 format. Of those submitted using HL7, approximately 3.06 million (37%) were sent using a real-time interface. The decrease in total number of records submitted during 2011 (18.92 million), compared to 2010 (20.81 million) was likely a result of the influenza H1N1 vaccination campaign that evolved during the 2009 pandemic, which added a significant number of immunizations (monovalent H1N1 vaccine) during 2010 that typically are not given.

Completeness of Data

While both flat file and HL7 have the capability to transmit all the same immunization record data fields, such as the vaccine lot number and the site of injection, data received during 2010 using HL7 were substantially more complete. Both types of submissions supplied a date of administration and the vaccine group for 100% of doses, while data in fields such as the route of injection (eg, intramuscularly or subcutaneously) or the body site (eg, left deltoid) were supplied for 96% and 91% of doses, respectively, using HL7 and only 9% and 7% of doses, respectively, using the flat file (Table 1). Additionally, vaccine lot number was supplied for only 26% of the doses using flat file, compared to 63% of doses for HL7.

Table 2. Comparison of HL7 and Flat File Data Submission to the Wisconsin Immunization Registry (WIR), January 1, 2010 through December 31, 2011

	Flat File		HL7	
	2010	2011	2010	2011
Individual Immunization Records Received by the WIR ^a	11.87M (57)	7.61M (43)	8.94M (43)	11.31M (57)
Time from Date of Vaccination to Date WIR Received the Information:	Percentage of Immunization Records Received^b			
Same Calendar Day	0	0	10	23
Within 1 Calendar Day	8	5	8	17
2-7 Days	53	25	70	36
8-30 Days	27	21	6	11
>30 Days	12	49	6	13

Table shows the percentage of individual immunization records for children aged 4 months through 6 years received by the WIR by method of submission and the number of days after vaccination administration.

^aNumber of immunization records received by the WIR to the nearest 100,000 (M= million, percentages of yearly total in parentheses).

^bPercentage of immunization records received by method of submission (flat file and HL7) and year. Column percentages add up to 100%.

Abbreviations = HL7, Health Level 7.

Timeliness

Reducing the interval from the time of administration of a vaccine to the time when the record is successfully entered into an IIS is a continued focus of the WIR. During 2010 and 2011, the timeliness of data submitted to the WIR using HL7 was substantially greater than the timeliness using flat file submission. Among the immunization records submitted to the WIR during 2010 using HL7, 18% were received within 1 calendar day of vaccine administration (primarily because of real-time data exchange), and 12% were received > 8 days following vaccination. In contrast, among the immunization records submitted during 2010 using flat file, only 8% were received within 1 calendar day of administration (0% on the same calendar day) and 39% were received >8 days following administration (Table 2). During 2011, 40% of records submitted using HL7 were received within 1 calendar day of vaccine administration (including 23% on the same calendar day) and 24% were received > 8 days after vaccination. In contrast, among the immunization records submitted during 2011 using flat file, only 5% were received within 1 day of vaccine administration and 70% were received > 8 days after vaccination (Table 2).

DISCUSSION

Use of Flat File Versus HL7

Many of the providers who were early users of the WIR provided data using the flat file format and have continued to do so. While there are significant advantages to switching to HL7 data submission, only several of the largest institutions have changed to HL7 thus far because it requires significant upfront resources. Formatting data into the flat file message requires limited technical expertise and can be done in a matter of hours.

However, the change to HL7 requires a higher level of technical expertise to create and test the files and conduct maintenance. For example, updating HL7 messaging specifications likely will be an obstacle for those providers without an information technology department or a contract with an EMR/EHR vendor and for those who extract data from billing systems. Therefore, the flat file format continues to be the method used by many providers, particularly those with limited resources. Some of these financial obstacles are being addressed by federally funded “Meaningful Use” initiatives through the Medicaid and Medicare programs, which provide funding to health care providers who establish electronic interfaces with an IIS.⁵ This funding has increased greatly

the number of health care providers and EMR vendors interested and able to make changes regarding data submission to the WIR. Additionally, the Wisconsin Division of Public Health (WDPH) received an American Reinvestment and Recovery Act HITECH grant from the CDC, which provided Wisconsin with funds from 2010 to 2012 to assist providers and EMR/EHR vendors to make changes to facilitate bidirectional exchange of data using HL7.⁵

While the goal of ensuring all immunization providers are engaged in bidirectional, real-time data exchange with the WIR is desirable and health care providers and vendors are encouraged to consider these options, it is difficult to determine when this will be achieved, because progress depends on many different factors. Such factors include the organizations themselves (eg, whether they have interest and resources), the EMR/EHR vendor’s willingness or ability to make changes, and the capacity of the WDPH to provide technical assistance and feedback to organizations. Additionally, the gold standard continues to change with the availability of new EMR and EHR products, the continual merging and evolution of health care providers and organizations, which includes changes in their information technology systems and priorities, and with continual updating of the HL-7 standards.

Completeness of Data

The WIR is compliant with the National Vaccine Advisory Committee specifications for electronically storing the 12 core data elements and requires certain data elements for all immunizations, such as date of vaccine administration and vaccine type/group (eg, DTaP), regardless of how the data are submitted.⁶ However, other fields, such as manufacturer or body site of injection, are strongly recommended but not required.⁵⁻⁷ While flat

file format can provide the same pieces of information as HL7, in practice this usually does not occur. One reason for this disparity is often the organizations that submit flat files are extracting the information from billing systems, and these systems may not collect all data elements. Additionally, billing systems often submit immunization data using CPT codes, which can lack specificity.⁷ For example, the CPT code 90680 codes for 3 different categories: RotaShield, the no longer licensed tetravalent vaccine; RotaTeq, the currently licensed pentavalent vaccine, and the generic category “rotavirus” (Rotarix has its own CPT code). In these instances, the general vaccine group (ie, rotavirus) can be derived, but additional specific information regarding which vaccine was used is not available. This completeness of data is important to clinicians. For example, the Advisory Committee on Immunization Practices (ACIP) recommendations indicate that, when possible, doses of vaccine in a series come from the same manufacturer.⁸ Additionally, having information such as lot number can facilitate identification of patients in the event of a vaccine recall.

Timeliness

Our findings demonstrate that immunization data submitted using HL7 are entered into the WIR in a more timely fashion because immunization data submitted using the flat file format usually are batched together and sent to the WIR by the health care provider on a routine schedule—daily, weekly, or monthly. While at least 76% of immunization data (88% in 2010 and 76% in 2011) were received within 7 days using HL7, only 61% or less (61% in 2010 and 30% in 2011) were received within 7 days using flat file. During 2011, 23% of immunization data submitted using HL7 were submitted on the same day as vaccine administration, compared to none submitted using flat files. This difference likely reflects the strength of the HL7 real-time option because immunization data submitted to the EMR/EHR are nearly simultaneously entered into the WIR. The increase from 10% in 2010 to 23% of immunization records received on the same calendar day as administration using HL7 messaging during 2011 also may be indicative of recent efforts to encourage use of the real time option among health care providers and organizations.

Notably, the percentage of immunization data submitted using flat file more than 30 days after administration increased from 12% in 2010 to 49% in 2011. This increase may be influenced by the type of organizations that continue to submit data using flat file. The organizations that are changing from flat file to HL7 submission tend to be those that administer the vaccines. Organizations that continue to submit data using flat file tend to be health maintenance organizations (HMOs) that do not administer vaccines, but compile immunization data from its associated health care providers. The HMOs often submit data to the WIR on a monthly basis. This is a concern because

timeliness is a priority for the WIR. There is a greater likelihood of over-immunization which results in additional costs to providers and patients. Also, when a client is identified through reminder/recall efforts as needing an immunization based on a record that has not been updated in the WIR, it can be confusing to patients or their parents. Additionally, in Wisconsin there are school entry requirements for immunizations that include provisions for exclusion when children do not comply by the 30th day of school. Therefore, timeliness of data reporting to the WIR helps schools to ensure that children meet the requirements, and reduces the burden of waiting for this information to be reported to the school by the parent or health care provider.

Other Advantages of HL7

HL7 messaging provides several other advantages not available with flat file data exchange. For example, HL7 can provide a client’s vaccine history and the forecast of future vaccinations needed back to an EHR/EMR. This allows the provider to use the updated information and determine, before the patient leaves the office, what vaccines are needed and when to schedule the patient’s next immunization appointment. Additionally, HL7 provides unique identifier numbers for the health care provider, including a WIR assigned identifier number for the client and a unique identifier for each immunization. This information can be used by the provider’s EMR/EHR to eliminate redundant duplicate data (“de-duplicate”) from their client and immunization data, which results in more accurate, cleaner data for both the EMR/EHR and WIR, ensuring that there is only 1 record for each client. Providers who submit data using HL7 also can delete an erroneous immunization and replace it with correct information. Notably, the ability to provide authentication is available with HL7. This allows the submitting organization to provide additional information to the WIR, which creates a link between the clients and the submitting organizations in the WIR and allows a subunit within an organization (eg, the pediatric clinic instead of the entire organization) to determine and monitor clinic-specific immunization coverage levels and progress towards goals. This also allows identification of clients seen at a particular location or clinic who need immunizations. Finally, HL7 provides an inventory function that automatically adjusts the electronic vaccine inventory as doses are administered and therefore assists clinicians in maintaining their vaccine stock.

Disadvantages of HL7

While HL7 confers advantages over flat file, there are some drawbacks. For example, the HL7 standard often is called the “non-standard standard” because most commercial software packages do not conform precisely to the standard and have unique idiosyncrasies that require additional technical effort to properly format the data.⁹ Health care providers can make choices regarding which optional data fields are submitted to the WIR, thus creat-

ing customized “packets” of information that may result in fewer of the recommended fields submitted to the WIR. This may, in part, have resulted in a recent trend noted in the WIR that as health care providers or clinics change from direct data entry to HL7 real-time interfaces, the data submitted is not as complete, with important information often missing including trade name and lot numbers. Accordingly, the WIR staff monitors this situation and works with providers and software vendors to encourage the collection and submission of data in all the recommended fields, instead of only the required fields.

CONCLUSIONS

The use of HL7 to submit data to IIS provides significant benefits when compared to flat file submission. This includes the ability to collect complete data and the option for real-time data submission, which has the advantage of substantially improved timeliness and an updated forecast of the vaccines recommended for a client. This assists clinicians in adhering to the ACIP schedule and reducing over-immunization. In addition, the use of HL7 provides nonmeasurable benefits, such as providing information back to an EMR for de-duplication and allowing providers to correct erroneous immunization data. Nonetheless, there are some important issues to consider such as cost and technical expertise needed for HL7-related implementation and ongoing support, and the effort needed to ensure data submitted using HL7 is complete in all necessary data fields and is kept up-to-date.

As more health care organizations begin to use (or change) vendors for EMR/EHR and submit data to a statewide or regional IIS, the technical decisions regarding which format to use should include clinicians within the health care organization who administer immunizations and rely on the data to ensure their patients are vaccinated appropriately. From the state immunization program perspective, it will be important to continue analyzing trends regarding data quality and timeliness as it relates to the method of submission, and discern EMR/EHR use throughout the state to ensure all immunization data is being submitted efficiently and accurately to the WIR. Our data sug-

gests that careful implementation of HL7 data submission, preferably with real-time, should result in more robust, accurate, and complete immunization records and assist health care providers to ensure their patients are appropriately protected against vaccine-preventable diseases.

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