



**Testimony of the American Immunization Registry Association  
National Committee on Vital and Health Statistics (NCVHS)  
Hearing on Public Health Data Standards  
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**Testimony of Rebecca Coyle on behalf of the American Immunization Registry Association.**

AIRA is a membership organization that promotes the development and implementation of immunization information systems (IIS) as an important tool in preventing and controlling vaccine preventable diseases. As a leader in immunization informatics, AIRA is committed to sharing collective knowledge and successes, representing IIS programs on emerging public health issues that may impact IIS operations, and identifying and representing IIS in evolving health information trends.

**1. Current state of public health related standards; coordination of standards development activities; representation and participation by public health in standards activities; where is public health strongest and where is weakest?**

AIRA is the organization that represents the Immunization Information Systems (IIS) community, a community that is strong and visionary. AIRA grew out of the desire of the IIS community to collaborate as one entity to respond to the various challenges of managing and implementing a public health information system. Since AIRA was founded in 1999 we have formed committees within the organization to assist with standards development, education, interoperability, and resource development.

Our strength is in our community, in our recognition of the importance of standards and in our long-term collaborative efforts to keep pace with both external and internal development. We have focused on message standardization, standardization of terminology and semantics used within the community, and have a strong foundation in these areas. We also understand that standards are a living, changing entity. The IIS community has experienced the pressure to change and to

develop new requirements necessitated by new use cases, such as Vaccines For Children (VFC) eligibility at visit and the move towards bidirectional (query/response) interoperability between IIS and Electronic Health Record Systems (EHRs).

As an organization we are actively involved with other organizations that participate in standards development activities. These organizations include the Health Level 7, IHE, S & I Framework, Public Health Data Standards Consortium, and the Joint Public Health Informatics Taskforce

AIRA in coordination with CDC created the HL7 implementation guide for IIS and continues to jointly maintain this guide. Code sets embedded in the HL7 implementation guide have strong acceptance and use, as well as inclusion in the ONC Meaningful Use Final Rule(s) which institutionalize certain code sets for IIS data submission. Functional standards were developed by the Immunization Information Systems Support Branch, CDC/NCIRD, through a consensus process involving input from a variety of IIS managers and technical experts from across the U.S. During the process of updating the standards, it was recognized that there is a growing importance of IIS to the broader Health Information Technology landscape, and the revised standards are intended to lay a framework for the development of IIS through 2017. These standards supersede the "Minimum Functional Standards for Registries" which were adopted by the National Vaccine Advisory Committee (NVAC) in 2001. Bi-directional data exchange standards have been developed in response to an increasing movement towards exchanging data between an EHR and IIS.

AIRA has committees comprised of community members that are devoted to developing and maintaining standards. AIRA also has a modeling of immunization registry operations workgroup that reviews current trends and hot topics and then develops best practices for these issues. These best practices have become the standard for IIS. Seven best practice guides for functional and technical IIS related topics have been developed. Each best practice guide includes:

- An overview of the topic being reviewed
- Principles, business rules, and general recommendations associated with the topic
- Various models, such as business process models, state transition models, and others
- Agreed upon terms and definitions
- Challenges to and solutions for implementing the best practice recommendations
- Select references for peer-reviewed literature
- Examples of implementation

Each guide may be downloaded in complete, or in summarized "mini guide" form from our website free of charge.

These best practice guides are developed by selecting a panel of subject matter experts from the community, dissecting each topic, creating consensus-based recommendations by the subject matter experts, and finally the guides are sent for broad community review prior to being finalized. CDC has cited these best practices as standards Immunization Programs should achieve during the current Cooperative Agreement cycle. There are many topics that need and are in queue for additional review and best practices development. The process is resource intensive, but AIRA is dedicated to its continuation.

In 2011 CDC began the task of developing the clinical decision support and logic specification for the immunization schedule. This was finalized in 2012. This is a huge effort towards standardizing the forecast that providers use to evaluate the needs of their patients. However, we still have work to do related to implementation, but the foundation now exists.

While there are many standards that have been developed within the IIS community, we have been much slower at developing or even agreeing on the need to create a certification system for IIS. AIRA is in the process of reviewing what certifications would mean to our community.

One of the needs that have been identified is the need for increased communication with the EHR vendor contacts that work on IIS interfaces. Often these EHR vendor contacts are not necessarily in prominent positions within the EHR vendor organization and thus are not connected to any other national efforts.

## **2. What are the incentives and drivers for adopting and using public health data standards; what are the barriers and challenges?**

Ten years ago a few IIS were exchanging data with EHRs because it made sense. Data exchange can reduce errors, increase productivity, and create a consolidated immunization record to prevent both missed opportunities and over immunization. Meaningful Use has driven many providers to seek data exchanges with IIS; however Meaningful Use has also created some pain points for IIS as I will discuss later in my testimony.

Incentives for adopting and using public health data standards include establishing more accurate and complete immunization records for individuals and populations, which are then used to support interventions to improve immunization coverage. Incentives for adopting Public Health data standards as drivers for interoperability between EHRs and IIS also include improved workflow for clinical staff, making it easier for medical providers to assist Public in creating more complete data sets and improving public health. The drivers for adopting and using public health data standards include community developed standards, desire to be transparent in our work and create comparability across jurisdictions.

Barriers and challenges to adopting data standards include legislative or policy restrictions, funding, staffing, and the related impact on IIS ability to react or develop standards in a timely manner.

- Legislative or policy restrictions might deter the adoption of national guidance and create local variation. The IIS community is sensitive to this issue and recognizes that there are local guidance variations that the EHR community would like to see eliminated. Much of this is due to local legislative restrictions. For example, a social security number or a part of a

SSN is commonly used as a unique identifier. However in some states, the IIS is prohibited by law from collecting such information.

- Funding is disproportionate across the states and is based upon the priorities of the state. There currently is no line item for funding an IIS. Short term funding for specific projects has surfaced in recent years, but IIS are unable to channel such funds to maintenance or long-term stabilization efforts.
- Public health often cannot compete with the private workforce salaries creating high staff turnover and a less experienced workforce. There is a lack of informatics-trained (or even informatics-aware) workforce. Many states have experienced hiring freezes or the inability to hire new staff with necessary skills.
- We have seen an increasing trend to centralize IT services which moves technical staff further from the program staff, or even out of the public health agency altogether creating a general lack of understanding of the public health needs.

**3. What is the state of information exchanges of public health data from EHR systems; what are the standards being used; what are the drivers, and incentives; what are the challenges and issues?**

Information is currently being exchanged uni-directionally between EHR systems and IIS. Most IIS are capable of receiving patient demographic information, vaccinations administered, and vaccination histories through HL7 messaging. Many IIS are also exchanging data bi-directionally – that is EHR queries IIS, IIS returns immunization histories and the patient forecast to the EHR for display within the EHR. Additionally, one of the most significant exchanges that are now occurring in many jurisdictions is the exchange of ordering and inventory information, this includes vaccine lot numbers, quantity, expiration dates, etc.

The current standard for data exchange is the IIS HL7 implementation guide.

Challenges exist on both sides. On the IIS side, not all IIS are capable of exchanging data bi-directionally (query/response) with EHR systems for several reasons including

local law or policy that prevents the exchange of data or the resources don't exist to upgrade current systems to allow this type of exchange.

On the EHR side EHR systems may not capture all of the information needed by the IIS, specifically the Vaccines for Children program requirements are often not captured. A timely example of this is that there is a new Vaccines For Children (VFC) directive to record the VFC eligibility at the patient shot level. However many EHR systems are simply populating a visit eligibility status across all shots administered.

There is a need for standardization of EHR functionality when connecting to IIS, which does not currently exist. IIS standards are established in the HL7 implementation guide for immunization, which drive what information is shared and how it is shared from IIS to EHR. However, there is currently no standard for what EHRs are expected to do with immunization histories and forecasts that are received from the IIS. In this vacuum, some EHR systems are creating functionality to allow medical providers to update the EHR with shots that were sent in a query response by the IIS and were not already in the EHR. Some EHR systems are also creating functionality that allows the medical provider to quickly see if the EHR has record of shots given that are not in the IIS and then report them to the IIS in seconds. Other EHR systems are simply displaying information received from IIS for the user to see, but not storing it. IIS can make suggestions for EHR implementation, but they cannot require or expect specific implementations due to the lack of standards or mandates in this area. It is crucial that standards and best practices be developed, as divergent approaches and logic intensive development needs mean that no two EHR systems are displaying immunization histories received from IIS in the same way, limiting the opportunity for providers to have access to a patient's complete history when needed and undermining the public health potential of EHR-IIS interoperability.

A meeting of EHR vendors, EHR users, IIS representatives and national policy makers is necessary in order to develop a common vision for how bi-directional interfaces should actually be used.

The incentive for providers and public health include a lower burden on end users, and integration of Immunization program functions like vaccine ordering, inventory management, accountability, population analysis, consolidated record management and forecasting.

Meaningful Use has driven providers to want to exchange data with IIS.

Unfortunately there has been NO funding carved out for public health to develop the additional interfaces. The unfortunate challenge that comes with the increased desire to exchange data is that public health must prioritize the development of interfaces in the midst competing priorities.

**4. What are implementation challenges from the public health agency perspective; what are the needs (technical, resources, education, etc.) to advance adoption and use of standards by public health agencies?**

The implementation challenges from the public health agency perspective are varied depending upon the maturity of the IIS. Challenges include state laws or policies that prevent the exchange of IIS data across state lines or re-disclosure of data that prevent an EHR from storing immunization information obtained by an IIS. For jurisdictions that are supported by an in-house IT department, the ability to implement or enhance systems is dependent upon the priorities of the department, and the IIS often is prevented from responding as quickly as the changing environment calls for. Health Information Exchanges or HIEs have increased their presence in the public health world. In some states this has created additional hurdles for the IIS and re-directs the resources to create new, but often duplicate connections with an EHR and IIS. In some states there is a mandate that all IIS data must be exchanged via the HIE. This creates a vulnerability for the IIS should the HIE fail or if it doesn't support the technologies that are being utilized (SOAP, WSDL, etc.). Often decision makers are not familiar with the capabilities of the IIS and assume that an HIE can replicate an IIS. Vaccine ordering, accountability, and vaccine forecasting are specialized and intricate systems that HIE are often ill-prepared to replicate.

Many IIS have been in existence for a number of years and the life cycle of the hardware or software need to be upgraded or replaced yet the funding resources are difficult to find.

Even when electronic health records can store and message appropriately all the data elements needed by the IIS, the end users (provider practices) often do not have adequate training or documentation on how to use the EHR. This is particularly true for the process of adding or updating coded fields like CVX, MX, etc.

**5. How is privacy and security covered in public health data standards? Are there privacy and security elements embedded in the standards? Is privacy and security under a different workflow process?**

Public Health considers privacy and security needs along with all other requirements for an application or a process. Public Health is very attuned to privacy and security needs, and relies on general healthcare standards in many cases. In regard to confidentiality of data in particular, HIPAA sets the floor for disclosure for covered entities, and also has public health exceptions. Much of the confidentiality protections are established at the state level through laws and policies. Variations in those laws and policies may in some cases be barriers to interstate data exchange, especially of identified data that can be re-disclosed, i.e. by an IIS.

Security is addressed in sender authentication standards. Single-factor authentication is currently defined by the CDC-defined transport standard. However, not all states agree to use this standard as their security rules may be more restrictive. An IIS Bidirectional Exchange workgroup of 24 SMEs was convened by Public Health Informatics Institute (PHII) in February of 2013. The non-binding consensus of this group recommended that this standard remain in place for use by IIS, but that while further standardization of single-factor authentication may be needed this may be difficult given that security rules vary at the state level.

Closely related to authenticating is the issue of identifying the sender, either as a part of authentication, or immediately after it. Currently, there are several different methods of identifying the sender; some are directly connected to authentication,

while other IIS use various fields in the message itself. Efforts are currently underway in the IIS community to establish a standard for identifying the sending system, the provider organization, and possibly the EHR username, in the query message.

**6. What security standards should apply to what types of data possessed by public health?**

Security standards prevent data from inappropriate disclosure, alteration, or loss, so general healthcare best practice is usually appropriate for Public Health (e.g. encryption, backups, and physical security of computers).

For IIS, as we expand access to consumers we will need to review current security standards. This will vary from state to state, depending on the state's data practices laws and how their central IT enforces security. In particular, we need to make sure only authorized individuals gain access and that they cannot use IIS data for proscribed purposes (ex: a non-custodial parent trying to find a child). As IIS expand to lifetime registries, the community will also increasingly need to consider the ramifications of and possibly develop standards and solutions to state laws that provide added protection for adolescent health data and prevent sharing with a parent without consent.

**7. What interoperability standards are needed for transfer of data from electronic health records to public health?**

The HL7 Version 2.5.1 Implementation Guide (IG) for Immunization Messaging, Release 1.4, establishes standards for transfer of immunization data from electronic health records to public health. While CDA is popular with EHR vendors and others, it is inadequate for IIS because it does not define all the data required for IIS data submission (even if the EHR systems had it stored). Much of the standardization work for IIS interoperability has been accomplished, and the benefit and feasibility of bidirectional query exchange is very well established. The IIS community has been active at the forefront of bidirectional exchange, and is well positioned to support the increased use of bidirectional query standards. CDC and AIRA continue to collaborate on updates to this IG, and work is currently underway to improve and standardize the work within query/response.

It is important to point out that while there is a general perception in some sectors that there is a lack of standardization in IIS interfaces with EHR systems, this impression is due largely to minor differences in message structure (segment, field, and component requirements) which can be resolved and is currently being addressed within AIRA and the IIS community.

Standards should also be considered for EHR implementation of public health data received from bidirectional exchange (as described above in response to question 4); to support interstate data exchange; and additional discussion is needed about transport standards due to some of the inherent complexity as well as some of the inherent problems of trying to work with HIEs (for more information on the is topic see [http://www.immregistries.org/resources/iis-meetings/1.Building\\_Effective\\_HIE-IIS\\_Relationships\\_Results\\_of\\_Nationwide\\_Study.pdf](http://www.immregistries.org/resources/iis-meetings/1.Building_Effective_HIE-IIS_Relationships_Results_of_Nationwide_Study.pdf)).

In conclusion, we see the following areas most in need of additional work or development to support the advancement of IIS standards:

- Clear standards around how EHRs will interoperate with IIS re: data elements (vaccine eligibility codes, active/inactive status codes, etc.),
- Standards for the receipt and consumption of IIS data into EHRs, and receipt and processing of error messages/response messages
- We would like to see a meeting of EHR vendors, EHR users, IIS representatives and national policy makers to develop a common vision for how bi-directional interfaces should be used
- Interstate data exchange, this could be one of the major topics for a second workshop hosted by the Privacy/Confidentiality Subcommittee. In our federated system, HIPAA sets a floor for disclosure for covered entities, and also has public health exceptions. Much of the confidentiality protections are established at the state level through laws and policies. Variations in those laws and policies may be real or perceived barriers to interstate data exchange, especially of identified data that can be re-disclosed, i.e. by an IIS

Thank you for the opportunity to present our experiences and recommendations.