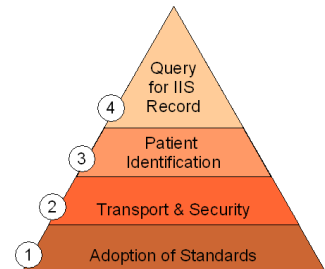


Focus Area #1: Adoption of Standards

Background Material

This focus area concerns the adoption of standard by both IIS and EHR systems. EHR systems are currently required to certify to rigorous set of test cases for Meaningful Use 2. What steps can be taken to bring both IIS and EHR into closer alignment with national standards.



Information for the Group

In order for the group to understand this section they will need to be familiar with:

- Meaningful Use & NIST Certification

This information for the group is not covered here in the background material.

EHR Immunization Interface Certification

Tests for Meaningful Use Stage 2 certification were put together last summer. Rob Savage and Nathan Bunker worked with NIST to use the latest CDC Implementation Guide 1.4 to inform the development of seven test scenarios that EHR's must demonstrate to be certified. In each of these scenarios the EHR was required to create an HL7 VXU message to report the following information:

- Immunization administered to a child.
- Immunization administered to an adult.
- Historical immunization on child's record.
- Historical immunization on child's record and that the child is consented to be in the immunization registry.
- Refusal of vaccination.
- History of Varicella of disease.
- Two immunizations administered to a child (one is a combination vaccination) and historical immunization from child's record.

The first version of NIST testing only required EHRs to generate an HL7 VXU message that past a basic HL7 v2.3.1 or v2.5.1 validation, with no specific test scenarios. Many of the important fields for IIS were optional and not tested.

In this new version the scenarios test specific functionality that is needed by IIS and the EHR has to demonstrate the ability to support the scenario. Here is a comparison of the differences in the NIST stage 1 and stage 2:

Scenario	NIST 2 Certification	NIST 2 Certification
IIS requires IIS to submit the patient address.	Address is an optional field. EHR can pass certification with a	The first scenario requires the EHR to enter a specific address,

	message that does not contain an address. The EHR may or may not be capable of sending an address.	supplied by NIST, and include it in the message it produces. EHRs who pass this test should be cable of submitting an address to the IIS when required to do so.
IIS requires the Lot Number for all administered vaccinations.	Lot Number was optional and so not required to be included in the test message. The EHR may or may not be capable of sending the Lot Number.	In all scenarios where the vaccination is administered the lot number is specified in the test case and must be included in the message. EHRs who pass this test should be able to submit lot numbers with all administered vaccinations.

For EHR's Meaningful Use stage 2 certification is a large jump in capability and support for immunizations. This is good news for IIS, as they should expect the ability of EHRs to message required information to increase.

As we move to Stage 3, all of the standards set in Stage 2 will be kept and enhanced. Stage 3 will add to it new standard which we hope will include items we are discussing in this meeting, this week.

Additional Standardization Needs for EHRs

EHR vendors need to be more involved in the IIS community so that they are able to give feedback and understand the position of IIS. There are several barriers to this:

- Immunization is not core functionality for most EHR software. They have many other concerns and problems and are not focused exclusively on immunizations. It's easy for immunizations to get lost in the noise.
- Immunizations are most important to pediatrics and pediatrics is not a high priority specialty for EHR software.
- The IIS community is very public health focused and is not geared or structured to specifically include EHR vendors.
- There are people who work for EHR vendors that are very concerned with immunizations as they are tasked with connecting their software to IIS. But these people are not able to travel to meetings, spend time on public health improvement projects, or volunteer extra time on national committees. Many of these people would be happy to contribute and be involved but have no way to do so.

Getting EHRs Involved in the IIS Community

If EHRs could be more involved in the IIS community this would help them as they create interfaces. We need to come up with some ideas of how we could do this in the coming years.

Here are some ideas to start off with:

- Create an AIRA mailing list of EHR immunization experts that can be used for communication purposes.

- Create a monthly EHR-IIS call that we invite EHR technical contacts to in order to update on IIS activities and create forum for questions and answers.
- Identify technical resources for EHR experts that they could tap when they are designing, developing or testing their HL7 interfaces.

Assignment

Brainstorm and collect ideas of how EHR vendors and technical experts could be supported as they implement stage 2 of Meaningful Use. Create a complete list and then narrow it down to a manageable list of recommendations. Create a list of Decision Points for the group based on these options.

Discovering and Documenting EHR Capabilities

IIS have very little insight and visibility into how EHR systems work. This hampers interoperability. One successful tool is to do a quick walk through of an EHR before connecting to the IIS to see how the user interacts with the EHR. This process sheds light on potential issues and helps the EHR and IIS integrate better.

One proposal is to conduct a nationwide survey of EHR systems and ask them to demonstrate their vaccination functionality. The entire process could be conducted on using a web meeting and recorded for others to view at a later time. This information could be used by IIS who are troubleshooting issues, EHR clients who are trying to understand how to use their system properly, and by clinicians looking to understand how an EHR they are looking to use would work for immunizations. This type of survey would take very little time for EHR vendors but could provide a great benefit to the community.

The survey could also document the basic capabilities of each system as well. Perhaps a table of all the EHRs and the capabilities they support.

Assignment

Discuss this idea. Make recommendation.

IIS HL7 Interface Conformance

IIS currently implement the CDC Implementation Guide for use within their jurisdiction and are free to change requirements in the guide to meet local conditions, requirements, and needs. The following local situations can cause barriers to interoperability:

- HL7 interface does not accept latest standard.
- IIS has additional requirements that were anticipated and permitted by the CDC implementation guide.
- IIS has additional requirements which were NOT anticipated by the CDC implementation guide but are allowed by the HL7 standard.
- IIS has additional requirements which are not defined by or violate HL7 standards.

This situation exists for many reasons including:

- IIS do not have funding to enable all functionality.

- Some technical staff are not well trained in HL7 standards.
- IIS have local needs that must be addressed immediately and do not have time to address them on a national level before they implement.
- IIS are not aware of all the ways they are different from the national standard.
- There is no standardized process to determine if an interface is on standard.
- IIS are allowed to make any local requirements that they wish to make.
- IIS are not always aware of how other IIS solve the same problems they are facing and may implement a solution to a common problem using a different method.

Comments from the EHR Vendor Community

Some of the comments I have heard from the community, in regards to IIS include:

- “IIS take conscious steps to put obstacles in place [for interoperability]”
- “IIS do not appear to be focused on creating IIS that serves physicians”
- “IIS [as they are current operated] are not useful for [increasing] immunization rates”
- “IIS are punitive to physicians”
- “Too many moving pieces” (commenting on the variability from state to state)
- “Why is the 300 page guide considered a national standard when it keeps repeating the phrase ‘Local rules may apply’”
- IIS stakeholder meetings have low representation from physicians and EHR vendors
- Asked me “How do we get this done?” Commentator does not see the a clear path forward to successful EHR-IIS integration on a national level.
- Comments that EHR was “selling products that don’t work” in the sense that while the software meets the national standard there is no guarantee it will interoperate easily with most of the state IIS because of state specific requirements.

In the analysis for the meeting, I was not able to find an EHR or outside entity that indicated that integration was working smoothly. Comments were quite consistent that significant barriers exist for good integration. Many of these comments came from individuals who are personal involved and very committed to connect to IIS, but are baffled by the variability.

In addition the feedback received from EHR vendors is being collaborated by the analysis being done in the IIS Interoperability Status Check. Most IIS have differences from the standard, and these differences are barriers to full integration.

We need to find a solution that puts the EHR Vendors and the IIS on the same page, working to integrate together.

Comments from the IIS Community

Some of the comments I heard from the IIS Community, in regards to EHR systems:

- There are many EHR vendors and even some of the vendors have many different products.

- The same EHR vendor can sell two products one that works well for IIS and another that does not.
- The same software can be deployed in two different location and the behavior of each can be quite different.
- It's hard to understand how to work with some EHR vendors, as there are changes in staff and difficulties in finding the right person to speak to.

Role of Local IIS

One important issue that needs to be addressed in the overall conversation is the juxtaposition of two major issues:

- We all need a national standard that is consistently implemented in order to ensure a national adoption of immunization interfaces.
- State and local jurisdictions have the right to change their immunization interfaces to meet local requirements.

While the discussion needs to find a balance between the need for local variation and national standardization is important to not over emphasize the differences between state needs. Most of the variability between state and local jurisdiction standards is related to technical implementation decisions and not to health department policy or statutory requirements. It appears that the general process in most cases has been to arrive at a technical solution and then make it health department policy to use this technical solution.

IIS Interoperability Status Check

Currently the CDC is conducting the IIS Interoperability Status Check. This project is very basic and will give a national view to a certain degree how ready IIS are for MU stage 2. But this project has the following limits:

- The Interoperability Status Check is not a testing process and does not have the rigor to make definitive statements as to the readiness of an IIS for Meaningful Use 2. Rather it is designed to highlight basic hurdles that exist for an IIS to take a MU stage 2 message.
- Participation in the status check project is voluntary, not all IIS have the time or capacity to participate.
- In most cases the status check is examining interfaces that are already in production and are what they are. This means that any issues found are unlikely to be resolved until another round of development changes.

The project is not yet complete and results are not available for this meeting. The following general observations about what has been seen so far in the process may be of help to the group:

- The variation of requirements that the EHR vendors have been reporting is being confirmed.
- Many IIS have additional requirements beyond what was tested by NIST and beyond what was required in the CDC Implementation Guide.

- The majority of the differences are not to satisfy an IIS specific requirement; rather they are a different way to solve a common problem.
- In some of cases, IIS are requiring changes to messages that violate both the CDC Implementation Guide and HL7 standards.

While Stage 2 meaningful use is good news because EHR vendors should be able to create better and more consistent messages than Stage 1, many IIS interfaces across the nation will probably not be ready for full scale deployment of these interfaces unless the IIS specific requirements are changed.

It is likely that all IIS interface have at least one or more changes that need to be made in order to be ready for Meaningful Use Stage 2. In order to standardize nearly all IIS will need to consider some changes to their interface.

Constrained IIS Implementation Guides

One of the ideas to solve this problem is to move from guides that are based off the national guide to IIS guides that are constrained by the national guide. This would mean that local IIS could not introduce local variability unless it was consistent with the national guide. Here is an examples of what we have now and how it work under a constrained guide:

	Current Procedure	Constrained Standard Procedure
Local IIS requires that all submitters indicate the Nationality of all patients being submitted to the IIS	IIS would change their guide to indicate that PID-28 Nationality be changed from Optional to Required. EHR systems certified to NIST stage 2 would not necessarily be able to conform to this standard. While some EHRs may support this requirement, most others would probably have to make changes to their messaging and patient data screens in order to accommodate this requirement. This will represent a major barrier to implementation.	IIS would discuss requirement at the national level. The use case and need for this would be examined and if the PID-28 Nationality was determined to be the correct place to message this data for the circumstance the IIS was facing then the CDC Implementation Guide could be changed to indicate that this field is Required if Known (RE). Which means that the EHR must be able to send it, if it is known. In the next version of MU this RE field will be included in testing and EHR's that write to this version of the standard will now have the capability to send it for those states that require it.

Benefits vs Drawbacks

	Benefits	Drawbacks
Current Practice	<ul style="list-style-type: none"> • IIS are free to set their own requirements. 	<ul style="list-style-type: none"> • EHRs do not discover the IIS specific requirements until after they have finished developing,

		testing, certifying, selling, installing, and training their customers.
Constrained Profiles	<ul style="list-style-type: none"> IIS will know if their systems are ready for EHR participation. Less discussion with EHRs to determine and ensure interfaces are working to the same standard. EHRs will design a single interface that must meet a rigorous standard but do not have to support unbounded customization. 	<ul style="list-style-type: none"> IIS will need to coordinate and communicate their IIS specific needs on a national level.

Decision Point

	Recommend	Permit	Discourage
Keep things as-is. IIS implementations should be able to add additional requirements to the CDC Implementation Guide.			
CDC Implementation Guide should communicate and summarize the requirements from all the US IIS guides. (Everywhere in the document where the phrase 'local rules may apply' will be replaced with specific information about which local rules do apply.)			
IIS implementations should be constrained by the CDC Implementation Guide.			

Certification

While EHR's are being asked to move to a higher standard and support IIS functions there is no matching activity for IIS. There is no guarantee that a certified EHR will be able to connect to IIS because there is no national process in place to verify that IIS is ready to connect to EHRs certified for MU stage 2.

It is important when discussing this point to keep in mind that the decision is not whether the IIS community has the capacity to do this or the funding, but rather deciding on what is the best option for IIS and EHR interoperability.

Decision Point

	Recommend	Permit	Discourage
IIS Interoperability Status Check project should be continued and further standardized to support verifying that IIS interfaces meet national standards.			
A national verification process should be established			

that provides strong standards and specifically verifies that IIS can connect with certified EHRs.			
An IIS certification process to certify that IIS are ready to integrate with EHR systems.			

Release of New Standards

The CDC Implementation Guide is released several times a year. IIS must synchronize their improvements to coincide with guide releases and with meaningful use regulations. Need to coordinate this so that IIS are not left un-prepared for changes that are coming. Some of the recommendations could include:

- Allowing for interim releases of the guide but only asking IIS to comply with releases tied to Meaningful Use stages.
- Reducing the number of releases of the guide so that IIS can keep up.

Assignment

Discuss, make recommendations and decision points if necessary.

Artifacts Needed

For the purposes of discussion the group needs to create the following items:

- Use case story(ies)
- Use case diagram(s)
- Lessons learned
- Decision points
- Recommendations
- Known needs
- Next steps

Use Case Story

A use case story is a list of steps taken by a user and the interaction of systems to achieve a specific goal. The goal of this focus area is to select a single use case but other use cases stories should be written as well if they are to be discussed in detail.

Use Case Diagram

Diagrams give a visual map to the story. Every use case story must have a corresponding diagram.

Lessons Learned

Past experience helps when making future plans. Gather information about lessons learned when implementing query support. Be sure to include lessons learned from both the IIS and the EHR perspective.

Decision Points

What are areas that need to be decided by the group? What are the options? What are the benefits and risks with each option?

Recommendation

What is the recommendation of the group for each decision point? If the group is divided then list the two or three top recommendations.

Known Needs

For each recommendation, list what support or help the EHR and IIS will need in order to meet the recommendation.

Next Steps

For each recommendation, list the next steps that will need to be taken.