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## Developing Nationwide Consensus on Bidirectional Query Immunization Information Exchange

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August 2013

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## Executive Summary

In February of 2013, the Public Health Informatics Institute (the Institute) convened a two day, face-to-face workgroup meeting to identify, define and document a standardized use case for bidirectional query and immunization information exchange. The expert workgroup included 24 experts with backgrounds in Immunization Information Systems (IIS), national policy, and Electronic Health Record (EHR) systems. Additionally, EHR experts who were unable to travel participated remotely in sections of the meeting, to provide input into the final result.

One of the primary motivations for the meeting was to establish consensus within the IIS community on a single approach to bidirectional query exchange, in time for Stage 3 Meaningful Use regulations. One purpose was to effectively communicate to the Office of the National Coordinator for Health Information Technology (ONC-HIT), Centers for Medicare and Medicaid Services (CMS), and the HIT Policy and Standards Committees, that public health was serious in its commitments to reduce variability across jurisdictions in requirements for data exchange. An additional intent was to have the consensus recommendations meet the needs of both the IIS and EHR communities, and avoid the unnecessary and costly duplication of human and financial resources that would occur if each IIS program created its own approach.

While the decisions of this workgroup are neither binding nor definitive, they provide the consensus position and collective wisdom of experts representing the IIS and EHR communities.

During the two-day meeting, each of the workgroup members was assigned to one of four small groups, each group focused on one of the following areas:

- 1. Adoption of Standards**

Consistent use of nationally accepted vocabulary and messaging standards, by both IIS and EHR systems.

- 2. Transport & Security**

Practices and standards around secure interoperability between IIS and EHR systems.

- 3. Patient Identification**

Processes used to allow EHR systems to identify the right patient in the IIS.

- 4. Query for IIS Record**

Standards and format of the patient vaccination record returned by the IIS to the EHR.

Each group discussed the standards, made recommendations, and on the second day, presented the results to the entire workgroup, including the external reviewers. After the presentations, all workgroup members and external reviewers were encouraged to give their personal response to the recommendations. From this, the group identified areas of consensus, as well as those that needed further discussion.

Recommendations for which there was unanimous or near-unanimous agreement included:

- A national verification process should be established that provides strong standards and specifically verifies that IIS can connect with certified EHR systems.
- IIS should make available the standard CDC WSDL, and EHR systems should be able to support the standard CDC WSDL.
- IIS should continue to support point-to-point connections with providers.
- Standards for transport/security should be the same for HIE and point-to-point interfaces to IIS.

- When an EHR system queries an IIS, it should use the demographic record that is recorded in the EHR.
- The EHR should send an EHR patient ID with every update to the IIS.
- The IIS should associate EHR patient IDs with patient records.
- The IIS should use the EHR patient ID as a strong query parameter for the site that originally submitted that EHR patient ID.
- A best practice is that clinicians should manually query the IIS in preparation for or during patient encounter.
- The HL7 QBP/RSP standard, as currently defined in the version 2.5.1 implementation guide, is the optimal message format to send back to an EHR system (a printable form or CDA are certainly permitted but less optimal).

The discussion and subsequent review indicated that much of the standardization work has been completed, and that the benefit and feasibility of bidirectional query exchange is very well established. The recommendations reflect the group's opinion on what is needed in order to ensure that bidirectional query exchange can be successfully supported by all IIS and EHR systems. 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.

## Meeting Process

### Focus Areas

Prior to the face-to-face meeting, the Institute conducted a series of interviews with the meeting participants, including those EHR experts who would be unable to attend the meeting in person. Information collected from these interviews was collated and categorized into four focus areas, each considered important to bidirectional queries. Based on this information, a set of four informal background documents was created to be used as the starting material for discussion at the meeting (see Appendix A).

### Primary Use Case

Participants were asked to focus their recommendations on what would be minimally needed to support the following use case:

1. Clinician using an EHR requests a vaccination record from the IIS.
2. The IIS finds the patient record, attaches a forecast and evaluation. If the record is not found, the IIS returns a 'not found' message.
3. The IIS creates a response that includes the vaccination history and the recommendations (i.e., immunization clinical decision support, aka vaccine forecast) and sends it back to the EHR.
4. The EHR displays the results to the clinician.

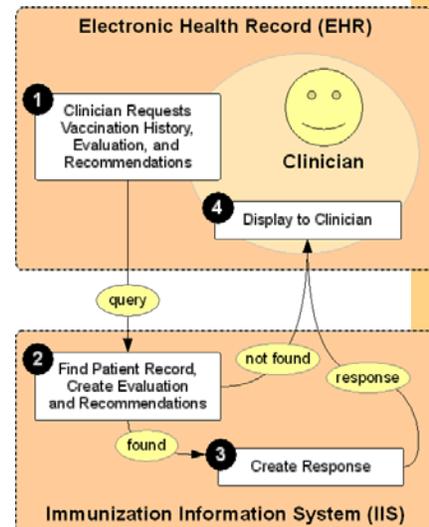
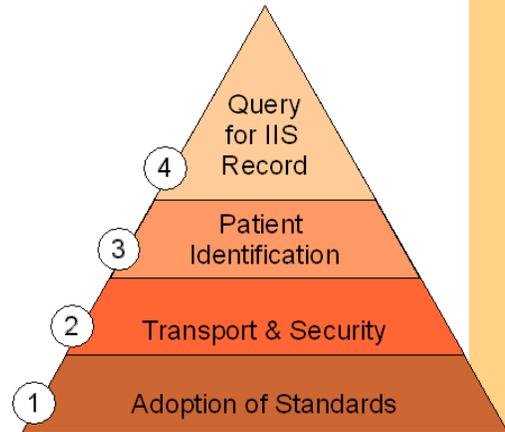
The recommendations reflect the group's opinion on what is needed in order to ensure that this use case can be successfully supported by all IIS and EHR systems.

Several other use cases were deemed to be out-of-scope for the conversation:

- Support for EHR reminder/recall activities.
- Quality Reporting or Population Health Management.
- Updates (VXU messages) sent from the IIS back to the EHR.
- EHR connecting directly to a forecast engine to get forecast/recommendations for a patient.

### Meeting Organization

The face-to-face meeting was held over two days at the Institute's offices in Decatur, GA. After introductions and a project overview, a presentation was given to outline the four focus areas. These areas were familiar to most of the group, having been introduced to them during the pre-meeting interview process. In addition, four group members were asked to familiarize themselves with the background material, each on a particular focus area, so that each could lead a small group discussion. Each focus group was asked to create a presentation in which would be listed decision points relevant to their respective focus areas. The goal was to complete the presentations by the end of the day.



The focus groups met and reviewed the background material, and started preparing their presentations. After a period of time, participants were asked to move to a new group, with the exception of one designated person from each focus group. This person then reviewed the previously identified decision points with the visitors from the other groups, and took notes. This process was repeated two more times, allowing the circulating group members to visit each of the groups. Afterwards, the groups came back together and finished documenting their decision points and determining a group-level recommendation.

On the second day, each of the four groups presented their decision points, followed by open discussion. These presentations were also shared online in a web meeting with the external EHR and immunization experts, who were also able to comment and ask questions during the presentations.

Following the presentations, an online survey was sent to everyone who had watched the presentations, both in Decatur and remotely, to collect individual votes/recommendations. The external EHR experts were given up to four days to complete the online survey; most completed it at the same time as the face-to-face group.

### Recommendations

Participants were asked to recommend one of three positions on each of the decision points identified by the small groups:

- **Positive Impact– Recommend:** Required for supporting the primary use case. (This was described to the group as a “thumbs up” or approval of the idea.)
- **No impact - Permit:** Could be done, will not distract from primary use case, but is not essential. (This was described to the group as taking a neutral position towards the idea.)
- **Negative impact – Discourage:** Would distract from or harm the primary use case. (This was described as a “thumbs down” or disapproval of the idea in the specific context defined by the small group.)

The breakdown of participant votes on each decision point is depicted in tables for each question, as shown below:

Question Under Consideration	Participant Vote Breakdown			Legend
	Recommend	Permit	Discourage	
1. Description of first decision point.	2	4	<b>16</b>	Bold value, dark shading indicates consensus of approx. 2/3 or more of total votes
2. Description of second decision point.	8	7	7	Light shading indicates agreement of approx. 1/3 or more, but less than 2/3 of total votes
3. Description of third decision point.	<b>16</b>	2	4	No shading indicates a position of less than 1/3 of total votes

These recommendations should not be viewed as definitive, but rather as indications of where the community is likely to have consensus, or where more discussion is needed. The details of these recommendations will need further validation and refinement in other projects and efforts.

## Focus Area 1: Adoption of Standards

### Background

This area focused on the technical and policy aspects of consistent use of nationally accepted vocabulary and messaging standards by both IIS and EHR systems. These standards allow IIS and EHR systems to develop and maintain compatible interfaces, supporting both technical and semantic interoperability.

A great deal of progress has been made towards adopting common standards:

- The IIS community has long defined a common standard for immunization update and query messages, which has become part of the ONC’s national certification program for EHR systems.
- Many EHR systems are being certified to these national standards as part of the ONC’s certification process.
- Many EHR systems have had unidirectional interactions with many different IIS in the past ten years.
- Bidirectional query exchange is gathering momentum as more IIS develop this capability and find willing data sources and EHR vendors.

While there has been much success in achieving interoperability, there is still room for greater standardization and a need for new processes to verify and ensure that IIS and certified EHR systems can interoperate bidirectionally.

### Q1. Constraining Local Implementations

The group generally felt that local IIS Implementation Guides should be constrained by the CDC Implementation Guide. This means that either local variations would be brought in line with national standards, or the national standards would be broadened to allow for *common* local requirements. In this way, there would be a single national standard that the vast majority of IIS could adopt. (Idiosyncratic local laws or policies may result in a few IIS programs having unique requirements.)

FA1 - Q1. Constraining Local Implementations Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. Keep things as is. IIS implementations should be allowed to add requirements to the CDC Implementation Guide.	2	4	16
2. CDC Implementation Guide should summarize and communicate the requirements from all the US IIS guides. (Everywhere in the document where the phrase ‘local rules may apply’ would be replaced with specific information about <i>which</i> local rules apply.)	8	7	7
3. IIS implementations should be constrained by the CDC Implementation Guide.	16	2	4

## Q2. Certification

The group also discussed certification of IIS HL7 interfaces. There was a general consensus that there should be some type of national verification, validation or certification process for IIS that ensures local implementations adhere to the national standards. Furthermore, many in the group felt that there should be a process to certify the IIS are ready to integrate information with EHR systems, while a few did not agree. The idea of certification will need more discussion.

FA1 - Q2. Certification Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. IIS Interoperability Status Check project should be continued and further standardized to support verifying that IIS interfaces meet national standards.	23	0	0
2. A national verification process should be established that provides strong standards and specifically verifies that IIS can connect with certified EHR systems.	22	1	0
3. An IIS certification process should be established to certify that IIS are ready to integrate with EHR systems.	19	2	2

## Focus Area 2: Transport & Security

### Background

Of all the focus groups, this one was the most challenging. Transport is a critical consideration for effective real-time interfaces. For immunization queries, transport is complicated by several factors:

- The HL7 version 2.x standard specifically avoids defining a particular transport standard.
- There are various standards proposed for transmission of public health data.
- Any national standard chosen may or may not align with jurisdictional standards for transport.
- The IIS community has chosen SOAP web services<sup>1</sup> as a national standard, but adoption by all IIS is not yet complete.
- Increasingly, IIS are receiving data indirectly through third parties, such as Health Information Exchanges (HIE), so do not directly control or define the transport standard the EHR is required to use.

### Q1. CDC Transport Standard

Most of the group recommended that IIS and EHR systems continue to work towards supporting the CDC-defined web service transport standard (which includes community-defined common Web Service Definition Language (WSDL)), and discouraged the IIS community from considering adoption of a different common standard.

FA2 - Q1. CDC Transport Standard Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. IIS should make available the standard CDC WSDL.	22	2	0
2. EHR systems should be able to support the standard CDC WSDL.	23	1	0
3. The IIS community should consider adopting a different transport standard.	0	5	19

### Q2. Point-to-Point or HIE Connections

The group believed that IIS should continue to support point-to-point connections (where possible) and, to a lesser degree, support connections through HIE or other centralized messaging systems. In particular, the group recommended that the standards for transport and security should be the same for the HIE as for the point-to-point interfaces. In other words, if an HIE operates between an EHR and an IIS, the HIE should be able to support the same transport standard that the IIS and EHR use to interoperate directly. In this way, all IIS and EHR systems can be written to support a single common standard, and the EHR can be integrated with the IIS whether or not an HIE is used. Furthermore, many in the group felt that the HIE should be held to the same certification standards as the EHR.

<sup>1</sup> <http://www.cdc.gov/vaccines/programs/iis/interop-proj/downloads/ehr-interop-trans-layer-tech-recs.pdf>

FA2 - Q2. Point-to-Point or HIE Connections Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. IIS should support bidirectional connections through HIE or other centralized messaging systems.	14	10	0
2. IIS should continue to support point-to-point connections with providers.	23	2	0
3. Standards for transport/security should be the same for HIE and point-to-point interfaces to IIS.	22	3	0
4. HIE should be held to the same certification standards as EHR systems.	15	6	2

### Q3. Sender Authentication

The process of authenticating the EHR connecting to an IIS continues to be a critical issue for connecting with the CDC-defined transport specification. The group was mixed, but tended to believe that the CDC transport standard could be “tightened down” more. The group discussed the use of digital certificates for two-factor authentication, which is permitted but not defined by the current standard. Some felt that client-side certificates add a level of complexity that is too great for query interfaces, while others recommended this. As for single-factor authentication, which is currently defined by the standard, the group recommended that this standard remain in place for use by IIS, and that further standardization of single-authentication may be needed.

FA2 - Q3. Sender Authentication Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. The CDC WSDL standard is well enough defined; no more development is needed.	4	7	11
2. The IIS community should utilize digital certificates for the second factor in two-factor authentication.	7	11	4
3. The IIS community should continue to support and standardize single-factor authentication.	18	5	0

### Q4. Sender Identification

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. The group recommended that the IIS community work to establish a common standard for identifying the sending system, the provider organization, and possibly the EHR username, in the query message.

FA2 - Q4. Sender Identification Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. IIS community should decide on one standard for identifying the sending system, the provider organization, and the EHR username, in query messages.	18	5	0
2. Leave current IIS variability as is.	1	3	20

### Q5. Query Tracking at User Level

The group also discussed the responsibility of logging queries. Currently, the transport standard authenticates or identifies at the submitting-system level, but the group identified the need to be able to identify and log the actual person who initiated the query. The group was divided about whether this was the responsibility of the IIS or the EHR, but agreed that some standard should be set.

FA2 - Q5. Query Tracking at User Level Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. IIS community should decide on one standard for query tracking.	16	6	0
2. IIS should log, for auditing purposes, the EHR username, text reason for query, time of query, and patient returned.	12	10	1
3. EHR should log, for auditing purposes, the EHR username, text reason for query, time of query, and patient returned.	16	7	0

## Focus Area 3: Patient Identification

### Background

Once an EHR has connected to an IIS, it must communicate some sort of patient information in order to identify to the IIS which patient is being queried. This matching can be accomplished in three primary ways:

1. The EHR sends the IIS patient ID, which the EHR has received from the IIS during previous queries or other exchanges with the IIS.
2. The EHR sends the EHR patient ID, which the IIS has saved on the patient record, if the patient record was previously submitted by the EHR to the IIS.
3. The EHR sends the patient's demographic information and the IIS searches for and returns exact or possible matches, based on its own criteria and local policy and/or regulation.

The HL7 QBP/RSP process directly supports all three options using a single common standard. An EHR will typically send the EHR patient ID, the IIS patient ID (if known) and patient demographic information. Many IIS also support all three options, in a tiered way. For example, when an IIS receives a query request it may perform the following checks to find a match:

1. If the EHR sends the IIS patient ID, that record is found and returned; if not, continue.
2. If the EHR sends the EHR patient ID, look to find this patient ID reported by this EHR; if found, return; otherwise, continue.
3. The patient demographic information is used to perform a query and/or fuzzy-match selection of exact or possible matches.

**Technical Note:** The IIS patient ID is assigned by the IIS, and is unique across the entire IIS. The EHR patient ID is assigned by the local EHR installation, and is only guaranteed to be unique for a single EHR system. IIS are typically built to store multiple EHR patient IDs, one for each submitting EHR, and can distinguish between EHR patient IDs defined by different EHR systems.

The task for the group was to recommend what parts of this process (if not all) should be recommended as a national standard for IIS and EHR systems.

### Q1. Matching Options

The group completely agreed that the EHR patient ID (scenario #2, above) should be used for matching. The group felt nearly as strongly that the IIS patient ID could be used as well. Most of the group felt that if a match was not found by ID, the patient demographic information should be used, and that the IIS should return *possible* matches (where allowed by local IIS policy and regulation) if an *exact* match was not found. Many also felt that the EHR should give the user the option to see possible matches, if they were returned, and allow the user to select the correct patient and re-query to retrieve the immunization records.

The largest question posed by this section arose in cases where either one good match is found or none at all are found. In these cases, the question was whether to limit the current standard to the simplest use case, or keep the standard as is, allowing the user to see and pick the best match when the IIS can't find an exact match. The group was largely in favor of supporting the current standard and giving the user an opportunity to pick an exact match when the IIS is not sure. This decision has a direct impact on the amount of functionality that an EHR must be able to support in order to query an IIS.

FA3 - Q1. Matching Options Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. IIS patient ID should be utilized for patient matching.	20	6	0
2. EHR patient ID should be utilized for patient matching.	26	0	0
3. IIS should return an exact match based on the patient demographics when the patient IDs are not recognized.	20	3	2
4. IIS should return possible match(es) based on patient demographics when an exact match is not found. (Where allowed by local IIS policy and regulation.)	20	5	1
5. EHRs should support the return of possible matches by allowing the EHR user to pick the correct match and re-query.	17	9	0

## Q2. EHR Functionality

Many of the group believed the EHR should be able to store the IIS patient ID on the patient record, either during queries, when the user confirms that an EHR patient is a match for a specific IIS patient, or when the EHR receives an exact match back from the IIS. There were some who believed the IIS patient ID could be displayed to the EHR user, but the group did not agree on whether the EHR user should be allowed to remove/delete the IIS patient ID from the record. Most of the group agreed that EHR users should not be allowed to directly edit or update the IIS patient ID on a patient’s record in the EHR system.

Most believed that the EHR patient ID should always be sent, and that when the EHR queries, it should use the patient demographic record that is recorded in the EHR, as opposed to using a patient demographic record copied from a list of possible matches returned for a previous query. Furthermore, many recommended that the patient demographics should be sent as well, when querying only by ID.

For the return data, many of the group believed that the EHR should provide the user with the ability to indicate that an exact match is correct, before any data is populated or merged into the patient record.

FA3 - Q2. EHR Functionality Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. The EHR should be able to store the IIS patient ID as part of the patient record.	19	7	0
2. The EHR should display the IIS patient ID to the user.	6	19	1
3. The EHR should automatically store the IIS patient ID on records when an exact match is returned.	15	11	0

FA3 - Q2. EHR Functionality Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
4. The EHR could provide the clinician with the ability to indicate that an incorrect match was found, and prevent the data from populating the patient’s record.	14	10	1
5. The EHR should store the IIS patient ID on the patient record when the user confirms the match.	17	8	1
6. The EHR should allow the user to remove or delete the IIS patient ID from the patient record.	7	13	5
7. The EHR should allow the user to edit, update or add the IIS patient ID to the patient record.	2	10	13
8. When the EHR queries, it should use the demographic record that is recorded in the EHR.	22	2	0
9. The EHR should send patient demographics when querying by ID.	17	6	0
10. The EHR should send an EHR patient ID with every update to the IIS.	22	1	0

### Q3. Re-querying for Exact Match

When the EHR user is presented with a list of possible matches and selects an exact match, the EHR must initiate a new query to the IIS for the exact match. There are two possible standards; one is to send the patient demographics as they are stored in the EHR, and the other is to mimic what the IIS returned in the possible match list, to ensure that the IIS returns an exact match the second time around. This question was partially answered in the previous section, but when posed with the same question in greater detail, the group gave a mixed set of recommendations. While some in the group were open to either option, and the group leaned towards the EHR always sending the EHR patient demographics, there were some in the group who preferred that the EHR resend the query with the IIS demographics.

The smaller focus group also recommended that when the EHR re-queries, it should send the IIS patient ID that was given by the IIS. This question was inadvertently not posed to the entire group, so there is no indication of group consensus.

FA3 - Q3. Re-querying for Exact Match Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. When the EHR queries again to get an exact match, it should use the demographic record that is recorded in the EHR.	13	9	2

FA3 - Q3. Re-querying for Exact Match Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
2. When the EHR queries again to get the exact match, it should use the demographic data for the patient that was sent back from the IIS, and which the user selected.	8	12	3
3. When the EHR re-queries (based on the clinician's selection), the IIS ID should be used in the re-query.	<i>inadvertently left off of survey</i>		

#### Q4. IIS Functionality

The group agreed that IIS should store EHR patient IDs with the IIS record, and many recommended that the IIS be able to store more than one EHR patient ID per EHR, per patient, thus keeping a historical record of all EHR patient IDs submitted to the IIS. The group agreed that the EHR patient ID should be used as a strong query parameter for the original EHR that submitted it. Many recommended that although the EHR patient ID is a strong query parameter, the IIS should not automatically return an exact match on this ID alone, but should consider other patient demographic fields as verification before returning an exact match.

FA3 - Q4. IIS Functionality Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. The IIS should associate EHR patient IDs with patient records.	24	0	0
2. The IIS should remember all EHR patient IDs, even if the IIS has two or more EHR patient IDs for the same patient, from the same practice. (This would happen if the EHR has a duplicate, and assigned the same person two different patient IDs, and the IIS was able to merge the records. The IIS will need to keep both IDs.)	19	5	1
3. The IIS should use the EHR patient ID as a strong query parameter for the site that originally submitted that EHR patient ID.	25	0	0
4. The IIS should not automatically return an exact match based on patient ID alone; other patient demographics should be considered.	19	5	1

## Focus Area 4: Query for IIS Record

### Background

An emerging and critical aspect of interoperability is what is known as *process interoperability*. This refers to effective use of information and information technology within the context of daily workflows. For bidirectional query and immunization information exchange, this means the EHR system can query an IIS and present the results with little, if any, human action needed. The goal is to have the right information on the right patient available to the clinician when and where needed, to support making the right decision.

### Q1. Best Practice

The group agreed that IIS and EHR systems should support the EHR user to query the IIS in preparation for or during a patient encounter. There was further discussion about using this same mechanism in different ways, such as allowing the EHR system to automatically query the IIS for patients who are scheduled for visits, or for all patients in the EHR system; but the group did not come to a consensus on best practice, beyond supporting the most basic use case.

FA4 - Q1. Best Practice Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. Clinician manually (attended) queries IIS in preparation for or during patient encounter.	24	0	0
2. EHR automatically queries IIS in preparation for a specific type of visit/patient criteria (criteria will vary by jurisdiction and may change over time).	13	9	2
3. EHR automatically queries IIS when patient is scheduled for any visit.	6	9	9
4. Practice/organization initiates process to query IIS for all patients or a large subset of patients.	3	10	10

### Q2. Message Format

Most of the group recommended continuing with the HL7 QBP/RSP standard that is currently defined and in use with the version 2.5.1 implementation guide. There was discussion about support for the printable document, such as returning a PDF or HTML page. On the whole, the group was not opposed to the idea, but did not recommend it as the primary method or a common standard. There was some interest among the group for adopting a Consolidated Clinical Document Architecture (CDA), but most of the group preferred to continue using QBP/RSP. While Consolidated CDA is emerging as an appropriate standard for other public health use cases, such as case reporting, it was considered less suitable for the more dynamic use case of immunization information and decision support exchange.

FA4 - Q2. Message Format Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. HL7 v2 RSP.	24	1	0
2. Printable document.	2	17	6
3. Consolidated CDA.	9	13	2

### Q3. EHR Support for Storing Results

At a minimum, the EHR would be expected to show the results of a query to the user; the next question is what the EHR should do with this returned information. Many of the group recommended that the EHR allow the EHR user to review differences between the IIS and EHR records, and select specific vaccinations to transfer into the EHR. Many in the group also recommended that the EHR system be able to store the results for later viewing by the EHR user. The group disagreed when discussing whether an EHR system should automatically merge the query results into the official patient record on the EHR without EHR-user input. While many of the group thought this should be permitted, a number of the group discouraged automatic merging.

FA4 - Q3. EHR Support for Storing Results Decision Points	Participant Vote Breakdown		
	Recommend	Permit	Discourage
1. Store and display the IIS vaccination record as is for later viewing by the clinician.	15	8	0
2. Display the data from both the EHR and the IIS, so that individual fields can be easily compared.	12	11	0
3. Clinician should be able to review differences between IIS and EHR record and select specific vaccinations to transfer to the EHR, as needed.	17	6	0
4. EHR should automatically update EHR record with updates from the IIS.	2	15	7

### Q4. IIS Patient Demographics

Most in the group agreed that the IIS should return a limited amount of patient information, and not the complete patient demographic record. The group was also in favor of, or did not oppose, the IIS practice of sending back the same patient demographic information that was originally submitted by the EHR system. In addition, many in the group were in favor of—and the rest were not opposed to—the EHR displaying the patient demographic data to the EHR user. However, the group generally discouraged merging this patient-level information into the EHR patient record.

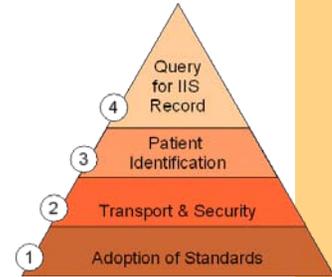
## Appendix A – Background Materials

The following four focus area documents were used as background information to prepare the working group members for the two-day meeting and as discussion tools during the meeting. They were used during the pre-meeting interview phase of the project as a way to both inform and solicit information from the interviewees. The documents appear here as they were originally presented to the workgroup members, and so do not necessarily reflect the final recommendations of the workgroup.

## Focus Area 1: Adoption of Standards

### Background Material

This focus area concerns the adoption of standards by both IIS and EHR systems. EHR systems are currently required to certify to rigorous set of test cases for Meaningful Use Stage 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 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 has consented to be in the immunization registry
- Refusal of vaccination
- History of Varicella 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 EHR to generate an HL7 VXU message that passed 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 message that does not contain an address. The EHR may or may not be capable of sending an address.	The first scenario requires the EHR to enter a specific address, supplied by NIST, and include it in the message it produces. EHR that pass this test should be cable of submitting an address to the IIS when required to do so.

Scenario	NIST 2 Certification	NIST 2 Certification
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. EHR that pass this test should be able to submit lot numbers with all administered vaccinations.

For EHR, 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 EHR 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 who 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 EHR Involved in the IIS Community**

If EHR 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 to which we invite EHR technical contacts 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 online 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 jurisdictions, 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 [to interoperability] in place.”
- “IIS do not appear to be focused on creating IIS that serve 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 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 personally 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 toward integration.

### 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 locations, and the behavior of each deployment 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 into how ready IIS are for Meaningful Use 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 Stage 2. Rather, it is designed to highlight basic hurdles that exist for an IIS to take a Meaningful Use 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 the 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 for 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 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 example of what we have now, and how it would work under a constrained guide:

	<b>Current Procedure</b>	<b>Constrained Standard Procedure</b>
Local IIS requires that all submitters indicate the nationality of all patients being submitted to the IIS.	<p>IIS would change their guide to indicate that PID-28 Nationality be changed from Optional to Required.</p> <p>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.</p>	<p>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 faced by the IIS, 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.</p> <p>In the next version of MU, this RE field will be included in testing and EHR that write to this version of the standard will now have the capability to send it for those states that require it.</p>

**Benefits vs. Drawbacks**

	<b>Benefits</b>	<b>Drawbacks</b>
<b>Current Practice</b>	IIS are free to set their own requirements.	EHR do not discover the IIS specific requirements until after they have finished developing, testing, certifying, selling, installing, and training their customers.
<b>Constrained Profiles</b>	<p>IIS will know if their systems are ready for EHR participation.</p> <p>Less discussion with EHR to determine and ensure interfaces are working to the same standard.</p> <p>EHR will design a single interface that must meet a rigorous standard, but do not have to support unbounded customization.</p>	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 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 EHR 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 EHR.			
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 unprepared 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 case 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.

## Focus Area #2: Transport & Security

### Background Material

This focus area concerns various areas, ranging from standards used to send messages, to methods used to ensure that the query is being conducted by an authorized clinician for an authorized use.

### Information for the Group

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

- HTTPS
- Transport Layer Expert Panel (TLEP) WSDL
- HL7 v2 queries (QBP)

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

### Included Information

Review the document *Architectures and Transport Mechanisms for Health Information Interchange of Clinical EHR Data for Syndromic Surveillance*.

### Transport Standard

A common transport standard is critical for Meaningful Use Stage 3, as HL7 messages will need to be submitted and processed in real-time. This requires that the IIS community promote and support a common transport standard.

Two years ago, the immunization community selected SOAP/Web Services as the preferred method for transmitting HL7 messages. A standard definition of this web service, called a WSDL, was developed and disseminated by CDC’s IISB. This method is now be adopted by various IIS. Despite this, the following issues remain:

- So far, only a handful of IIS have implemented this method.
- This method is specific to IIS and is not shared by any other standard.

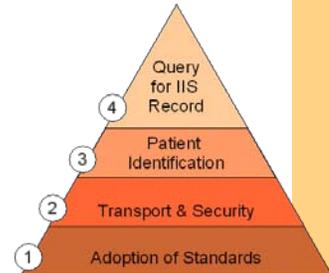
### Decision Point

	Recommend	Permit	Discourage
IIS should make available a TLEP compatible interface.			
EHRs should be able to support TLEP standard.			
IIS community should consider adopting a different transport standard.			

### Direct Connection to IIS

Creating a connection from every EHR in a state to the IIS can be a very daunting task for many reasons:

- IT department policies at the state level are often very restrictive, risk averse, and usually a barrier to public health policies.
- IT department policies are increasingly requiring complicated two-factor authentication schemes.
- Connecting individual organizations to the IIS can take a great deal of IIS staff time.



- Outside organizations, particularly smaller organizations, have neither the time nor technical capability to meet IT department policies.

One solution to this problem is to move the task of connecting with local providers to an intermediary party. This can include the following solutions:

- Health Information Exchange
- EHR vendor's centralized messaging system
- Other clearing house

A clearing house is an outside system that receives data and then moves it on to its final destination. This is a common model in other areas, such as submitting patient claims. The clearing house allows for easy connections to the local site, without the red-tape and requirements of a State IT department, while the clearing house does basic checks and relays this information to the IIS. In its most basic form, an HIE is a clearing house.

#### **Assignment**

Discuss the movement away from direct connections. Will this be the norm in the future? What should IIS be ready for? What are the decision points we need to address?

#### **Identify Risks**

IIS face risks when opening their interface to respond to queries. Some of these risks include:

- Unauthorized persons querying for records.
- Authorized persons querying for records for the wrong purpose.

#### **Assignment**

Identify all the security risks that IIS face specifically for queries.

#### **Authentication**

The TLEP standard has built-in support for single-factor authentication. Two-factor authentication is possible, and can be implemented on top of the TLEP standard, and doing so is left to the decision of the IIS. Because of this, there are different standards being used for authentication, some at the message level and some at the certificate level.

#### **Two-Factor Authentication**

Two-factor authentication is a process of using two different kinds of information to authenticate a person. For example, to withdraw money from an ATM a person must both have the correct ATM card and know the secret PIN. A person may pick-pocket the ATM card, or someone else might guess the 4 digit PIN, but to do both is quite difficult.

Access to the IIS is often controlled by IT department policy, which has the following issues:

- IT departments are often not concerned with the goals and needs of the IIS program. They are not responsible with the success of the IIS.
- IT departments are focused on the risks. If there is a security problem, they are responsible.
- It is in the best interests of the IT department to support transport methods that they are familiar with, and which represent to them the least security risk.
- IT department policies continue to change and are moving towards reducing risks and limiting connections.

All of this points towards the adoption of two-factor authentication schemes. This process has a negative impact on providers wishing to connect to the state. Many of these immunization providers have the following characteristics:

- Very little technical support and expertise. While the IIS may have an IT department, the pediatric physician may be the only one available to help connect to the IIS.
- Low usage of connection. Many smaller providers may not be able to justify the cost of time to integrate with an IIS when so little information will actually be transferred. The layers of security and red-tape cancel the benefit.
- Very limited software and hardware availability and no budget for additional hardware or software to support interchange.
- A very low tolerance for dealing with technical issues. Most small practices need easy solutions or they will not want to bother. They are in the practice of giving patient care, not jumping through technical hoops that make no sense to them, just to meet the requirements of a government IT department.

It is important to discuss that there needs to be a solution that provides the correct level of security while not stifling the ability of the IIS to become the center of a patient’s immunization record.

Another important point about setting standards—and this applies to all the points in this meeting, but most particularly to this one—an adoption of a national standard that meets 80% of the use cases out there does NOT preclude an IIS from allowing other entities to connect in other ways with other levels of security. A national standard is not a requirement that all interfaces be done a certain way, but rather that a standard way is available at all IIS. Just like requiring all businesses to have a valid postal address so they can receive US mail does not prevent any business from receiving packages from FedEx. The discussion should not focus on the current operating interfaces; these do not have to change, even if a newer standard is adopted.

**Decision Point**

	Recommend	Permit	Discourage
TLEP standard is well enough defined, no more development needed.			
IIS community should standardize on a method or two methods (or perhaps even three) for two-factor authentication.			
IIS community should further standardize the use of MSH and other HL7 message fields for the purpose of authenticating and identifying the sender.			

**Sender Identification**

Currently, every IIS has a different method for identifying the sender of a message. Various IIS have identified senders by:

- Using security tokens in the message transport (username/password).
- Using the MSH-4 headers to request the EHR to set a specific value.

- Using BHS-4 field to request the EHR to set a specific value.
- Using other headers in the MSH segment.
- Requesting EHR to use OIDs in MSH segments.
- Using other fields in the HL7 message.

**Decision Point**

	Recommend	Permit	Discourage
IIS community should decide on one or two standards for identifying the sending system.			
Leave current IIS variability as is.			

**Sender Identification for Aggregated Data Feeds**

One of the areas for special discussion is how should the sender be identified for data feeds from EHR vendors who centrally host many different providers. Should the EHR vendor send each provider as a different feed, or can all of them be sent in the same feed?

**Assignment**

Discuss sender identification within the context of EHR vendors who aggregate data from many different, otherwise unconnected, providers. Create the appropriate decision points.

**Organization Mismatch**

The IIS organizes submitting systems into various collections of organizations and facilities. These organizations often reflect the IIS project needs and may not line up with how EHR systems are deployed or how submitting organizations are structured. The following problems can happen:

- The EHR is used by a single, completely integrated organization that is seen as two separate distinct organizations by the IIS.
- The EHR is used by an integrated organization with different sub-organizations that are seen by the IIS as a single organization.
- The EHR may be used by an integrated organization where the organizational structure and divisions differ from the IIS' view of the organization.
- The EHR is deployed separately at different locations, all of which are considered a single integrated organization by the IIS.

These organization mismatches means that EHR are often requested to:

- Put all data from disparate data sources into one coherent feed.
- Report data from a single system using two different accounts. The EHR must take extra steps to determine which data should be submitted under which account.
- Report data that is identified under an organizational identification system that does not match the IIS.

While this mostly involves the reporting of data, this impacts queries because the IIS needs to know the context for how the patient ID is stored and how to find patients when the EHR queries again. It may be very difficult for EHR vendors to determine how to query the IIS when the patient may have been reported under two different submission accounts.

**Assignment**

Discuss problem and determine if there is any way that this could be standardized nationally.

**Query Tracking**

Authentication normally authenticates the sending system but not the user who actually initiates the query. This is because managing external users is very complex. For the purposes of auditing queries, it is critical for both IIS and EHR to track:

- EHR username of the person initiating the query.
- The reason or the purpose for which the user is initiating the query.

The EHR username would not be entered by the user, but would rather be known by the EHR when the query was made as the user should be authenticated to the EHR before being able to query. This would be an easy field for the EHR to generate.

The text for the reason or purpose would also be generated by the EHR, and would indicate in a humanly readable way what activity the user was conducting that gives context for the query request. This requirement was suggested as something that may be asked for by future HIPAA regulations. Since the information would be easy for an EHR to generate, it would be good to add to the standard now.

For both of these fields, the IIS could use them or ignore them.

**Decision Point**

	Recommend	Permit	Discourage
Create requirement for query messages to include the EHR username and text giving the reason the user is initiating the query.			
IIS should log, for auditing purposes, the EHR username, text reason for query, time of query, and patient returned.			
EHR should log, for auditing purposes, the EHR username, text reason for query, time of query, and patient returned.			

**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.

## Focus Area #3: Patient Identification

### Background Material

This focus area concerns the process for connecting a patient in an EHR with a patient in the IIS, so the vaccination record can be returned.

### Information for the Group

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

- HL7 v2 query (QBP & RSP)

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

### Query Process

The standard for queries in HL7 follows a general process.

For the EHR:

- The EHR creates a query that includes the EHR patient ID, the IIS patient ID (if known), and patient demographic data that is known and that the EHR believes the IIS could use for matching. The contents of the query are normally the same for all queries; the EHR pulls all the data it has and sends it to the IIS, hoping the IIS will find the best match.
- If possible matches are returned, the EHR must present the matches to the user to determine choose one, if any is good match. If the EHR is doing the query automatically, then there is no user input and the EHR gives up and reports that there is no match.
- Once the choice is made by the user, the query is sent again, but this time the IIS patient ID is added. This ID was listed by the IIS on the list of choices. Normally, the EHR would also include the additional demographic information, just as it sent originally.
- The IIS returns one or no matches. The results are shown to the user.

For the IIS replying to the query:

- The IIS first checks to see if there is an IIS patient ID. If so, it searches and finds the matching IIS record. The IIS will normally do a basic check to ensure that the demographic data is a close match for the record that is found. If the record looks like a plausible match, then the record is returned.
- If that fails, then the IIS looks to see if the EHR patient ID is recognized. If there is a matching record for this, then the IIS performs the basic check to ensure that the demographic data is a close match. If the record looks like a plausible match then the record is returned.
- If that fails, then the IIS looks for a strong match based on the patient demographics. If the IIS finds one good match, then the record is returned. Otherwise, more than one possible match is returned.

### Patient Identifiers

There are three main ways a patient is identified between two systems:

- The EHR receives the IIS ID for the patient, and stores it in the EHR.
- The IIS receives the EHR's ID for the patient, and stores it in the IIS.
- The EHR submits all the patient's demographic information, and the IIS searches for and returns exact or possible matches, based on its own criteria.



**Benefits & Drawbacks**

	Benefits	Drawbacks
Use IIS Patient ID	<ul style="list-style-type: none"> <li>■ ID is recognized by IIS and is universal for jurisdiction</li> <li>■ Should be returned in all queries to IIS</li> <li>■ EHR can store and use to query the IIS to pull back specific record</li> </ul>	<ul style="list-style-type: none"> <li>■ Depends on de-duplication and matching process in IIS or an EHR selecting the match when querying</li> <li>■ Can change as patient records are merged</li> <li>■ HL7 standard does not support for returning ID in response to VXU</li> </ul>
Use EHR Patient ID	<ul style="list-style-type: none"> <li>■ Most IIS currently require and accept the EHR patient ID</li> <li>■ ID can be registered with IIS when submitting vaccinations</li> <li>■ Most IIS use the EHR patient ID as a strong match for queries</li> <li>■ All EHR systems have an EHR patient ID</li> </ul>	<ul style="list-style-type: none"> <li>■ EHR Patient ID is not unique to jurisdiction, only guaranteed unique to installed instance of EHR. IIS must use the EHR Patient ID and the EHR facility ID as a unique pair.</li> <li>■ Can change when patient records are merged</li> <li>■ Depends on the de-duplication and matching process of IIS</li> </ul>
IIS support search by patient demographics	<ul style="list-style-type: none"> <li>■ Matches can be found even if submitted ID is not recognized</li> <li>■ Supports querying IIS for patients that are not yet registered with IIS, or the IIS has not yet received</li> </ul>	<ul style="list-style-type: none"> <li>■ IIS must establish process for search based on given parameters</li> </ul>
EHR supports picking possible match	<ul style="list-style-type: none"> <li>■ Users can search IIS and see other close matches that the IIS is not confident are actually matches.</li> <li>■ Support scenarios where patient has not been sent to the registry or the registry is unable to make an exact match.</li> </ul>	<ul style="list-style-type: none"> <li>■ EHR must add support to allow users to see query results and make a decision.</li> <li>■ The EHR must decide whether to remember this decision for future queries on a patient.</li> </ul>

**Decision Point**

	Recommend	Permit	Discourage
Patient linkage should depend on IIS patient ID.			
Patient linkage should depend on EHR patient ID.			

IIS should return an exact match based on the patient demographics when the patient IDs are not recognized.			
IIS should return possible match(es) based on patient demographics when an exact match is not found. (Where allowed by local IIS policy and regulation.)			
EHR should support the return of possible matches by allowing the EHR user to pick correct match and re-query.			

**IIS Patient IDs**

IIS patient IDs can be used by the EHR to link the patient to a specific IIS record. This ID has been obtained in one of the following ways:

- When the EHR queries the IIS, the IIS can send back the IIS Patient ID with an exact match or on a set of possible matches.
- The user can find the IIS patient ID (normally by logging into the IIS directly) and enter the ID directly into the EHR.
- The IIS returns the IIS patient ID when the EHR updates the IIS. (This method is not supported by HL7.)

In order for the IIS Patient ID to work effectively, the following must be ensured:

- The EHR must allow the user to remove any IIS patient ID, once it has been set.
- The EHR should make the linking of the record to the IIS patient ID visible to the user.
- The IIS must not forget the IIS patient ID. The IIS may re-assign a patient a new ID, or discontinue an ID when merging records together, but must retain a link between the old ID and the new one. This will allow the EHR to continue querying with the old ID until it receives the latest ID.

The following decision point will need to be considered if the group decides to recommend the use of patient ids.

**Decision Point**

	Recommend	Permit	Discourage
The EHR should be able to store the IIS patient ID as part of the patient record.			
The EHR should automatically store the IIS patient ID on records when it receives back an exact match.			
The EHR should store the IIS patient ID on the patient record when the user confirms the match.			
The EHR should automatically store the IIS patient ID when the user selects a possible match.			
The EHR should store the IIS patient ID on a record when the user selects a possible match and confirms that IIS patient ID should be stored.			

The EHR should allow user to remove or delete the IIS patient ID from the patient record.			
The EHR should allow the user to edit, update or add the IIS patient ID to the patient record.			

**EHR Patient Ids**

All EHR systems have some method of determining a unique ID for the patient. This unique ID is messaged to the IIS when the EHR sends a vaccination update. In order for the EHR patient ID to be used for queries, the following standards need to be set:

- All EHR must message the EHR patient ID in all vaccination updates.
- As the EHR can send any number of IDs in HL7 messages, there needs to be a standard for how the IIS knows which ID is the EHR patient ID.
- The IIS is required to store the EHR patient ID for the patient, and must keep all copies of the EHR patient ID for each EHR, even if the patient record is later merged in the IIS.
- The IIS must store the patient ID in connection with a unique IIS identifier for the submitting system. This is because EHR patient IDs are only unique to a single sending system, and can conflict with other EHR systems’ patient IDs.
- The IIS must use the EHR patient ID as one of the strong identifiers when responding to queries. Note: the IIS only has to support EHR patient ID querying for the system that submitted the ID. The IIS does not have to allow EHR A to query for a patient using EHR B’s patient ID.

**Decision Point**

	Recommend	Permit	Discourage
The EHR should always send an EHR patient ID with every update to the IIS.			
The IIS must associate EHR patient IDs with patient records.			
The IIS must remember all EHR patient IDs, even if the IIS has two or more EHR patient IDs for the same patient and for the same EHR. (This would happen if the EHR has a duplicate and assigned the same person two different patient IDs, and the IIS was able to merge the records. The IIS will need to keep both IDs.)			
The IIS should use the EHR patient ID as a strong query parameter for the site that submitted that EHR patient ID originally.			

**Linking Patients**

A patient is “linked” when the EHR either has the IIS patient ID stored on the EHR patient record, or when the IIS has the EHR patient ID stored on the IIS patient record. A “linked” record can now be retrieved easily from the IIS by simply querying with the shared ID. A record can likewise be “unlinked” by either side forgetting, or removing the linking ID.

For linking there are two basic options:

- Depend completely on the IIS de-duplication and matching process to find the match.
- Automatically link to start with, but get user input in cases where automatic linking cannot find a match.

**Decision Point**

	Recommend	Permit	Discourage
For simplicity, the national standard should assume that IIS de-duplication and match processes are sufficient by themselves to link patients.			
For completeness, the national standard should include some element where the clinician can help find the correct match. This will help in situations where the exact match has not yet been determined, or where other possible matches exist that have not been resolved.			

**Verifying Match by ID**

When the EHR queries the IIS, it can find an exact match by ID. The IIS often do a verification using the patient demographic data to assure that the patient is the correct one before returning. For example, if an EHR queried for patient 1234 “Sally Smith 4 years old” and the registry has patient 1234 “Tim Jones 2 years old” the registry would probably not return an exact match. Although the ID was correct, the patient demographics strongly indicate they are not matches.

This leads to another issue that has not been standardized. As the EHR is not aware of the criteria for returning an exact match, even with a known ID, some EHR send the patient demographics from the original possible match list in order to pull down the correct record. Need to standardize this behavior.

**Decision Point**

	Recommend	Permit	Discourage
When the EHR queries again to get an exact match, it should use the demographic record that is has recorded in the EHR.			
When the EHR queries again to get the exact match, it should use the demographic data from the patient that was sent back from the IIS, and which the user selected.			
The EHR should not send patient demographics when querying by ID.			
The IIS should apply some type of logic to not return exact matches if the patient demographics are sufficiently different.			
The IIS should return an exact match regardless of whether the patient demographics are similar.			

**Basic Use Case**

1. EHR sends vaccination update to IIS.
2. IIS adds the patient to the registry.
3. The EHR queries the IIS using the IIS or EHR patient ID.
4. The IIS returns that patient, if found; otherwise, returns a “not found” message.

**New Patient Use Case**

1. Patient is registered as a new patient in EHR.
2. Clinician wants to query for IIS record but does not know the IIS patient ID and IIS does not know the EHR patient ID, as it has not yet registered the patient with the IIS.
3. The EHR sends a patient query with all the demographic patient information known to the patient.
4. The IIS responds with no matches, a set of possible matches, or one exact match.
5. The clinician reviews the response and may attempt to query again, but this time using the IDs returned by the IIS to retrieve the exact record.
6. The EHR may store the IIS patient IDs associated with the patient for future queries to the IIS.

**Variation on Basic and New Patient Use Case**

In practice, the need for the New Patient Use Case can occur during scenarios where the IIS patient ID or the EHR patient ID should be known to the other entity. This can occur under the following circumstances:

- The IIS has received the EHR patient ID, but has not yet associated it with the patient record in the IIS. This can happen because:
  - The IIS process for finding the match and adding to the registry has not completed.
  - The IIS process has found more than one possible match and is holding the record for manual review before associating the EHR patient ID with any record.
- The IIS has associated the EHR patient ID with only one of two possible matches.
- The IIS has received more than one EHR patient ID for the same patient, for the same EHR, and has only kept the most recent EHR patient ID.
- The IIS has associated the EHR patient ID with the wrong patient.

**Bad Links with IIS**

If the EHR stores the IIS patient ID, then it should be prepared to handle the situation where the IIS patient ID is not the correct one for the patient in the EHR. The EHR user may have to contact the IIS directly to resolve the issue on the IIS end, but most definitely needs the ability to “delink” the patient. In some EHR, the user is allowed to edit and erase the IIS patient ID. This is an effective way to allow the user full control over the IIS linking.

**Discussion**

Do we need a national standard for linking and unlinking?

**Search Parameters**

If the option for searching by parameters is recommended, then some decisions should be made to standardize which fields are used for searching. EHR should have a complete list of all fields that IIS may want searches to be performed by, and a national standard for a minimum number of fields. In addition,

there needs to be discussion about the treatment of the IIS Patient ID and the EHR Patient ID. Do these take precedent over other search fields? How much additional data needs to be sent with IDs?

### **Notes**

One member of the group recommends that Phone Number should be given more consideration than it has in the past. Phone numbers are now, more often than not, cell phone numbers, and are becoming stable for longer periods of time. This can be used to find matches at a better rate now than even 10 years ago.

An EHR vendor indicated that while they understand mother's maiden name is a great match for the registry, they don't collect it at the encounter with the patient. So it's not a good field to require or expect for searches.

### **Assignment**

Discuss and create decision points for the group. Do not need to have final answers now, but it would be good to decide on a starting list of fields that should be considered for queries. This list can be finalized later, not at this meeting.

### **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.

## Focus Area #4: Query for IIS Record

### Background Material

This focus area contains the primary use case and the focus for the meeting. All other focus areas support this one.

### Information for the Group

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

- HL7 v2 query and response messages (QBP & RSP)
- CDA

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

### Most Basic Use Case

The core use case, which we are proposing for support from Meaningful Use certification, involves getting the vaccination history for a single patient back to clinicians who are in the process of giving care to a patient. The goal of this use case is to ensure that the clinician has all the information necessary to determine if the patient needs to be vaccinated today. The most basic process is as follows:

1. Clinician using an EHR requests a vaccination record from the IIS.
2. The IIS finds the patient record, attaches a forecast and evaluation. If the record is not found, the IIS returns a not found message.
3. The IIS creates a response that includes the vaccination history and the recommendations and sends it back to the EHR.
4. The EHR displays the results to the clinician.

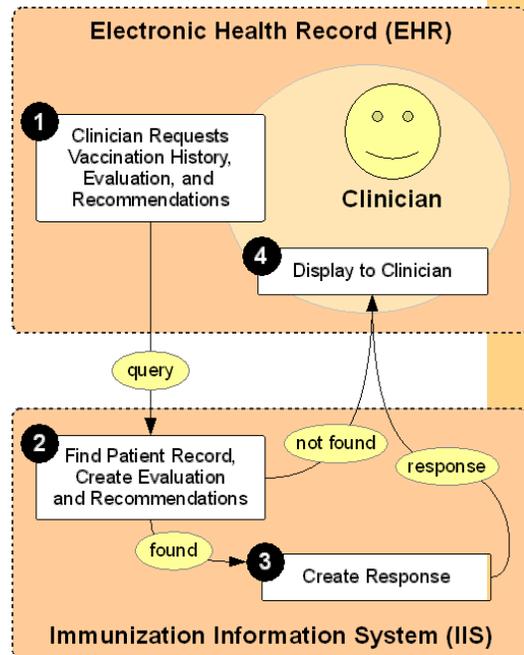
### Out of Scope Use Cases

These use cases are not being considered now but are being identified for future discussions:

- EHR is conducting reminder/recall activities
- Quality Reporting or Population Health Management
- IIS updates the EHR with changes to a patient record (i.e., IIS sends EHR VXU messages)
- Standards for connecting directly to a forecast engine to allow the EHR to get decision support

### Comment

These use cases could be supported by standards, even by the standard that is selected. These are not being considered here because they are not central to the primary use case. Once the base standard is solidified, adopted and used, these use cases can be re-addressed to see how the current functionality supports these activities. The goal of this project is to focus on a critical goal, with which, if we are

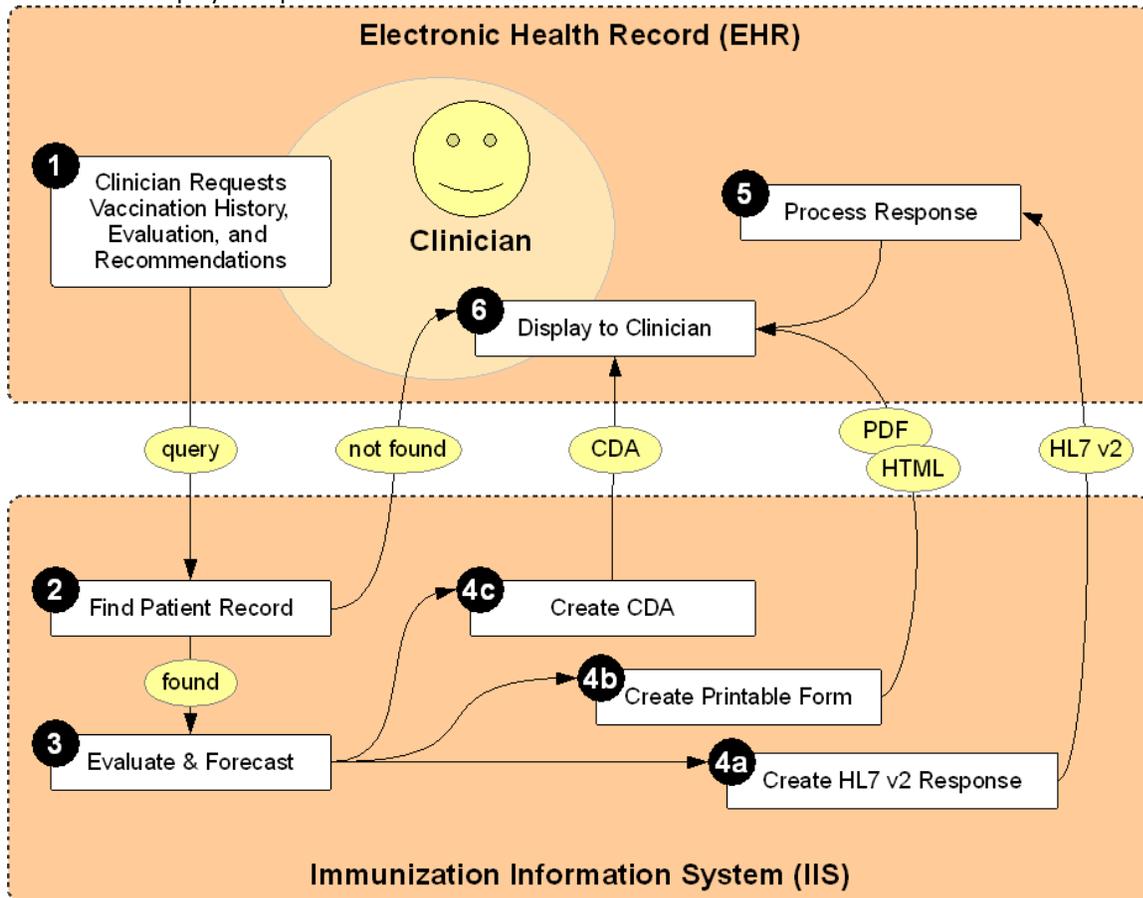


successful, we can build support for other beneficial uses. Of course, IIS and EHR can accomplish these use cases now, even without a unified national standard, and this can continue.

**Best Practice Use Case**

The use case above meets the very basic minimum requirements, but is not recommended as best practice as it does not account for the need to pull the data received back from the IIS and merge it with the patient’s record in the EHR system.

1. Clinician using an EHR requests vaccination record from IIS in preparation for patient care.
2. IIS finds the patient record. If not found, IIS returns not found message.
3. IIS creates evaluation and forecast and appends to record.
4. IIS puts the data in a format that the EHR can use and sends it to the EHR.
5. If applicable, the EHR processes the immunization and forecast data from the IIS.
6. The EHR displays the patient record in the EHR.



**Variation Using Same Best Practice Use Case**

The best practice use case imagines a clinician requesting the patient record with the patient present. The following variations differ only by the reason for the query, but must be considered as query interfaces have often been used this way:

- EHR automatically requests an updated vaccination record for all patients scheduled for certain selected appointments. For example, when a patient is scheduled for a well-child visit, the EHR automatically requests the latest vaccination record from the IIS.
- EHR requests updates for all patients or a large subset of patients.

**Decision Point**

	Recommend	Permit	Discourage
Clinicians query IIS during patient encounter			
Clinicians query IIS in preparation for patient encounter			
EHR automatically queries IIS when patient is scheduled for a specific type of visit			
EHR automatically queries IIS when patient is scheduled for any visit			
Clinician initiates process to query IIS for all patients or a large subset of patients			

**Other Potential Use Cases**

- Receiving and printing the official state school form or state immunization record.

**Comment on School Forms**

Support for school forms and immunization records is important in some IIS. This is not the primary use case, but this group could recommend the following:

- Creation of a new standard for getting printable forms. This standard may not be part of meaningful use certification, but may be of value, as states that do this would at least have a common standard.
- The standards being selected now could be designed in such a way as to support this use case.

At any rate, one of the comments made about this area was that printing out school forms is a bit backwards and should be done less in the future. The whole reason we have IIS is to contain the official immunization record. Schools should be getting access to the IIS to get those records directly, and not be looking for a printed record to hand-enter into their own system. So this standard may be important now, but maybe its use has a limited lifetime as we move towards a paperless world.

**Patient Matching**

This use case assumes that the EHR has some type of unique ID in common with the IIS, and is able to either get a single good match back, or no match. The use case for managing this unique ID is covered in Focus Area #3. For purposes of discussion here, assume that patient matching either (1) has completed, and a match is known, or (2) is not possible because the patient record is not in the IIS.

**Manual vs. Unattended**

EHR systems take one or two basic tactics towards querying the IIS:

- EHR involves the user directly in the process of querying the IIS.
- The EHR queries the IIS using a background process. The user may initiate the process and can check the status of the process, but is not directly involved.

**Format of Patient Record**

The data being sent back to the EHR can be in different formats:

- HL7 v2 RSP format. This is the format currently supported by many IIS.
- Image or printable format such as JPEG or PDF. This is used to support printing school forms or official state immunization forms.
- CDA. This is a new standard but could combine the benefits of both RSP format and the printable format.

**Benefits and Drawbacks**

	Benefits	Drawbacks
HL7 v2 RSP	<ul style="list-style-type: none"> <li>■ Well established standard</li> <li>■ Currently supported by many IIS and EHR</li> <li>■ Supports proposed use case very well</li> </ul>	<ul style="list-style-type: none"> <li>■ Requires EHR to properly parse and process data</li> </ul>
Image or printable document	<ul style="list-style-type: none"> <li>■ Simple to implement for EHR systems</li> <li>■ Supports school enrollment</li> <li>■ IIS has full control of display format</li> </ul>	<ul style="list-style-type: none"> <li>■ Does not allow EHR to read data or use it</li> <li>■ Only supports a set of narrow use cases and nothing else</li> </ul>
CDA	<ul style="list-style-type: none"> <li>■ Standard is being widely adopted by EHR</li> <li>■ Allows IIS to control display layout and format</li> <li>■ EHR can support simple use cases very simply</li> <li>■ EHR can pull data out easily and support more complicated use cases</li> </ul>	<ul style="list-style-type: none"> <li>■ Some work is needed to create a specific CDA document</li> <li>■ Has not yet been implemented by IIS</li> </ul>

**Future Standards**

The idea behind adopting CDA is to move forward now to adopt a standard that is being used more and more. Perhaps the IIS community should move towards this standard now, rather than delaying.

The other idea that was floated was that HL7 is working on a new standard call Fast Healthcare Interoperability Resources (FHIR) that is quite exciting and may have potential use in the IIS community. FHIR solves a lot of the problems we have been dealing with in HL7 v2 and is much easier to implement than HL7 v3. But the standard is still very new and won't be ready for use for another year or so. So we did not consider FHIR in preparation for this meeting. Perhaps the best choice is to stay with the standard we know works for now until we have a clearer view of the future. Of course, predictions are very hard to make, especially about the future. ☺

**Decision Point**

	Recommend	Permit	Discourage
HL7 v2 RSP			
Image or printable document			
CDA			

**EHR Support**

The data received back by the EHR can be treated in different ways. The following different ways have been observed:

- Display the IIS vaccination record as is to the clinician
- Store the IIS vaccination record as is for later viewing by the clinician
- Display the data from the IIS vaccination record next to the data in the EHR
- Merge the data from the IIS and EHR for display only
- Store the data from the IIS, but do not automatically merge with EHR record
- Allow clinician to merge specific data from IIS into the patient’s EHR record
- Merge the data from the IIS directly into the EHR patient record automatically

**Decision Point**

	Recommend	Permit	Discourage
Display the IIS vaccination record as is to the clinician			
Store the IIS vaccination record as is for later viewing by the clinician			
Display the data from both the EHR and IIS so that individual fields can be easily compared			
EHR can automatically read the data and store the individual information in a place reserved only for IIS data			
Clinician should be able to review differences between IIS and EHR record and select specific vaccinations to transfer to the EHR			
EHR should automatically update EHR record with updates from the IIS			

**Patient Demographic Data**

The IIS returns patient demographic data to the EHR. There can be different levels of completeness of this data:

- IIS may return the entire patient demographic record as it is officially recorded in the IIS
- The IIS may return a very limited amount of demographic data
- The IIS may return a hybrid of limited amount of demographic data or additional detailed information that was submitted by the EHR making the query

The EHR has two options when receiving patient demographic data:

- Only display the demographic data from the IIS, but do not merge with current record
- Allow some of the data fields to be merged into the EHR patient record

**Decision Point**

	Recommend	Permit	Discourage
IIS should return a complete demographic record			
IIS should return a limited demographic record			
IIS may return all data originally submitted by querying system			
EHR should allow the user to see the demographic information returned by the IIS			
EHR should merge the demographic information into the patient record			

**EHR Interpretation**

One of the issues that needs to be addressed is that if the EHR is required to parse and read an HL7 response, this opens up the potential for several issues:

- The EHR may misread the IIS record. Examples include:
  - EHR reads a ‘998’ placeholder record as an actual immunization.
  - EHR reads delete or not administered vaccinations as administered
- The EHR may not recognize duplicates because the vaccine code sent by the IIS does not exactly match the one stored in the EHR.
- The EHR may store the information in the wrong place in the EHR. (For example, one EHR implemented their interface to store immunizations from the IIS as administered vaccinations in their system. These were later reported to the IIS as being administered.)
- The EHR user may delete duplicate vaccinations and these deletes may be sent back to the IIS, which does not have duplicates. The IIS then deletes the vaccination from the official record.

**Assignment**

How can the IIS community help EHR vendors to correctly process incoming messages? We know that some EHR’s have successfully done so, but there are many others that are new to this area and could make mistakes. How do we setup up the process so these mistakes can be prevented?

**Artifacts Needed**

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

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- Use case diagram(s)
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- 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 case 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.