IIS FUNCTIONAL GUIDE, VOL.1

QUERY AND RESPONSE

8.17.2017

AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

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1 INTRODUCTION

A functional guide focuses on the capabilities and requirements a system will need in order to enable business functions needed by their end users.

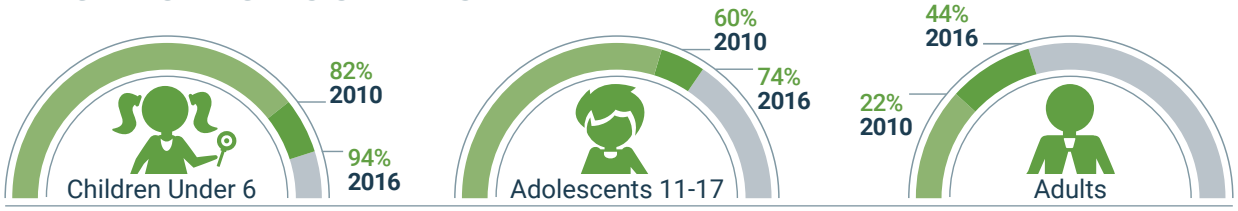
1 INTRODUCTION

The percentage of children younger than six years of age and participating in an immunization information system (IIS) has steadily grown nationally from 82%[1] in 2010 to 94%[2] in 2016.

Participation increases can also be seen in the adolescent (60% to 74%) and adult (22% to 44%) populations over the same time period.[3] Electronic data exchanges (EDE) between various health information systems (e.g., electronic health records (EHRs), pharmacy systems) and IIS continue to be an increasingly common way to populate an IIS, as they eliminate the need for providers to perform dual data entry (once in the health information system and once in the IIS). To this end, a well-populated IIS becomes a wealth of data for providers, public health officials, neighboring IIS, schools and others needing to see a consolidated picture of a patient's past immunizations and future recommended vaccinations. By leveraging the same standards used by health information systems to submit data to an IIS, these health systems can request data from the IIS for a specific patient through a query to the IIS.

Many end users rely on EDE to perform business functions that were once performed both in the EHR and an IIS (i.e., double data entry). A functional guide focuses on the capabilities and requirements a system will need in order to enable business functions needed by their end users; this volume in particular focuses on what two systems will need to conduct query and response. In essence, a functional guide is a requirements document that leverages previously published material (e.g., MIROW Chapters, Functional Standards, CDC Endorsed Data Elements, CDSi, etc.) as input to develop implementable requirements to carry out those business functions.

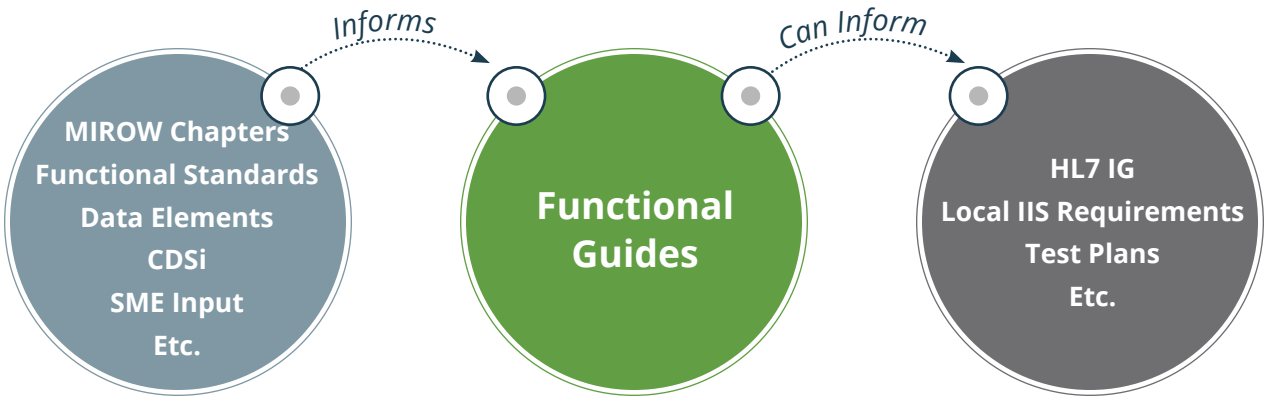
PARTICIPATION INCREASES IN AN IIS



[1]http://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/downloads/2010-data-child-map.pdf
[2]https://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/downloads/2016-data-child-map.pdf
[3]http://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/rates-maps-table.html

From a broader methodology perspective, a functional guide is designed to be developed before technical requirements (e.g., HL7 Implementation Guide (IG)) are developed. This places a premium importance on a functional guide and those who participate in developing it. The high-level diagram (Figure 1) below shows where this Functional Guide fits in with other community-developed artifacts, showing both inputs into the Functional Guide and where/how the Functional Guide can be used to develop other artifacts.

Figure 1 | *Diagram illustrating where the Functional Guide fits in with other community artifacts*



The Functional Guide strives to note differences between this Functional Guide chapter and the current HL7 Implementation Guide (HL7 version 2.5.1, release 1.5 plus addendum). The differences are intended for future versions of an HL7 Implementation Guide and are not intended to change or override currently published HL7 Implementation Guides.

1.1 AUDIENCE

This volume of the Functional Guide is intended for all audiences focused on immunization-related EDE between two health information systems (e.g., EHR, pharmacy system, school-based system, IIS, etc.). The audience should have a solid foundation of the problems for which the Functional Guide defines solutions, as the Functional Guide does not provide extensive background on the problems but, rather, uses previous community developed documents as input. These predecessor documents would provide a good foundation of the background and problem.

1.2 FUNCTIONAL GUIDE SCOPE

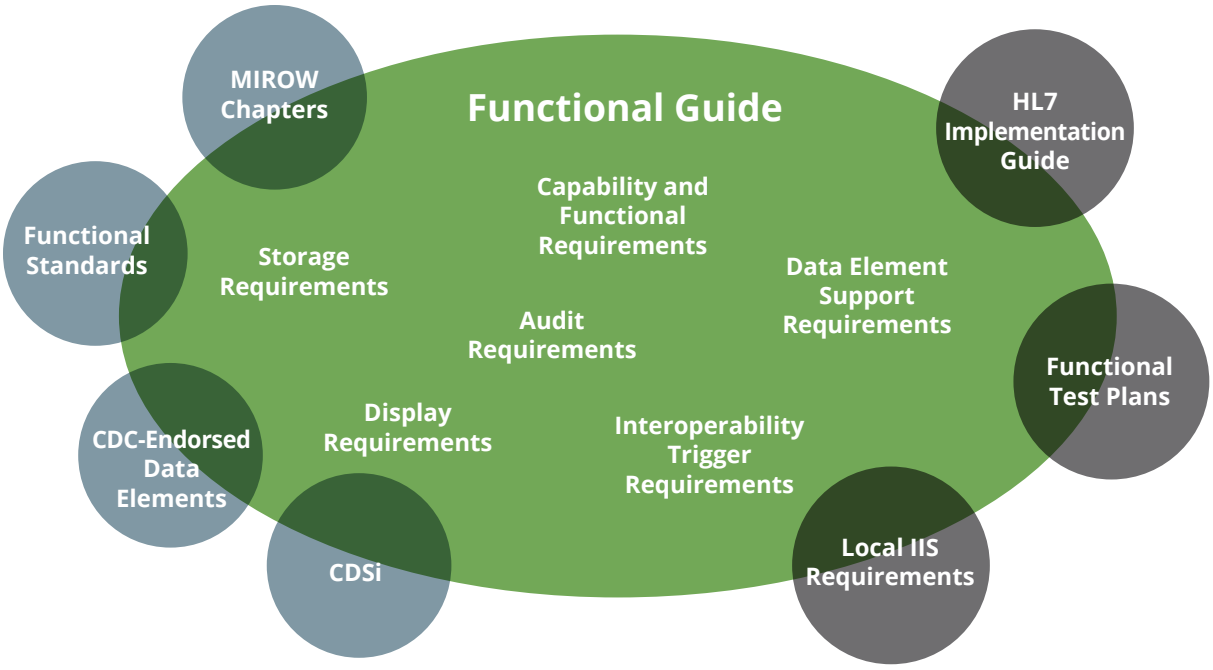
The Functional Guide is a new resource within the IIS community, and as such, it needs to serve a distinct purpose not served by other resources. To achieve this, the Functional Guide must leverage existing resources to ensure a consistent picture across resources and reduce gaps between resources. To help illustrate this idea, the following Venn diagram (Figure 2) was developed using the same colors and resources from Figure 1.

The most common overlap between the resources in Figure 2 and the Functional Guide are the vocabulary terms and definitions. Wherever possible, the Functional Guide reuses terms and definitions from existing resources rather than creating new terms for the same concepts. The glossary (Appendix B) cites the existing resources.

In other places, the Functional Guide uses existing resources to frame and develop functional requirements, which may have been documented in various fashions in other resources. Sometimes this is intentional and necessary (e.g., a MIROW best practice is further refined in a Functional Guide). Other times this was due to the lack of a functional guide (e.g., a functional requirement in the HL7 IG). As resources are updated, it will be important to ensure functional requirements exist in a functional guide and overlap is limited as much as possible.

The most common overlap between other community resources and the Functional Guide are the vocabulary terms and definitions.

Figure 2 | *Venn diagram illustrating overlap between Functional Guide and other resources*

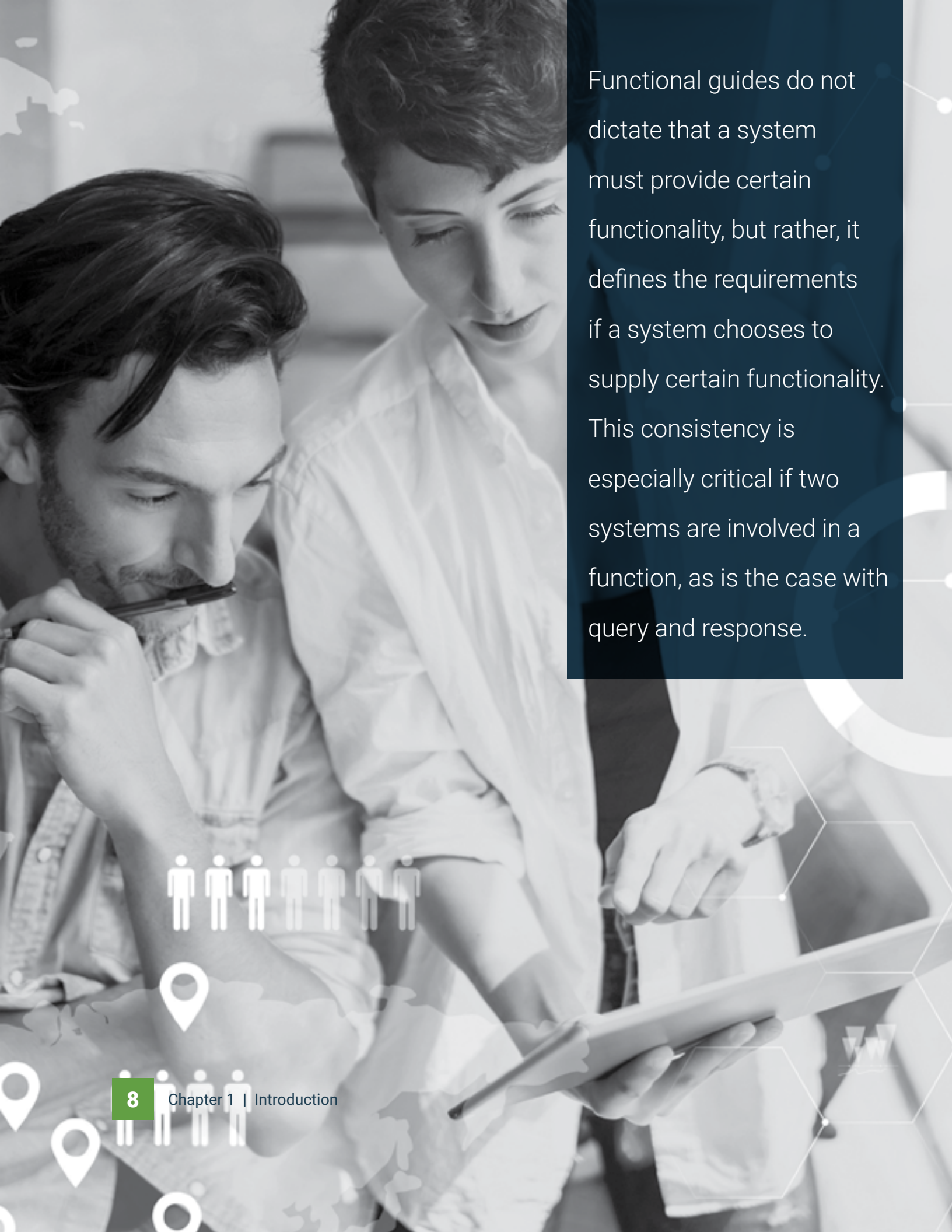


The Functional Guide uses existing resources to frame and develop functional requirements, which may have been documented in various fashions in other resources.

1.3 FUNCTIONAL GUIDES

Functional guides do not dictate that a system must provide certain functionality, but rather, it defines the requirements if a system chooses to supply certain functionality. This consistency is especially critical if two systems are involved in a function, as is the case with query and response. This document is the first volume of the IIS Functional Guide and focuses on select aspects of query and response. The longer-term vision will be additional functional guides focusing on other topics to be determined by workgroup members, with a second functional guide projected to be published in Fall 2018.

The remainder of this document is devoted to query and response requirements. As new functional guides are developed, this material will be revamped (or moved) to reflect the collection of functional guides. This Functional Guide – Query and Response was selected based on a definitive need by EHR and IIS alike in preparation for Meaningful Use Stage 3, which introduces query and response requirements.



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2 DOCUMENT ORGANIZATION

2 DOCUMENT ORGANIZATION

This guide is comprised of several major chapters each with a specific purpose. Each chapter is related to other chapters, so understanding the whole document at a high-level is important. The following table provides a high-level synopsis of each chapter.

CHAPTER 3

ACTORS

The actors chapter defines the types of roles that could be played to achieve the interoperability defined in chapters 6, 7, and 8.

CHAPTER 4

CORE CONCEPTS

The core concepts chapter defines conformance criteria and descriptions on the different types of requirements used in chapters 6, 7, and 8.

CHAPTER 5

SCOPE AND CAPABILITIES

This covers the scope of this query and response functional guide.

CHAPTER 6

QUERYING SYSTEM REQUIREMENTS

In this chapter, system and functional requirements further define the capabilities associated with querying system.

CHAPTER 7

RESPONDING SYSTEM REQUIREMENTS

In this chapter, system and functional requirements further define the capabilities associated with a responding system.

CHAPTER 8

VALUES

In this chapter, some terms used in the functional guide have a finite list of possible values. The finite list of values is enumerated in this chapter to aid in consistent understanding and usage across disparate systems.

APPENDIX A

INFORMATIVE DISCUSSIONS

Appendix A is reserved for informative and/or background discussions which may help better explain concepts and decision points. Placing them in an appendix will help keep the core requirements clear of fuzzy language. Efforts have been made to reference specific sections of the appendix within chapters 6, 7, and 8 where necessary to improve readability and understanding.

APPENDIX B

GLOSSARY

Appendix B is the Glossary and defines the terms used throughout this document. It is a critical piece in consistent implementation. The Glossary should be referenced regularly when reading the Functional Guide.

APPENDIX C

ACRONYMS

This is a list of acronyms used in the document.

APPENDIX D

HL7 MAPPING TABLE

As noted in the introduction, the Functional Guide and the HL7 Implementation Guide have overlap. This appendix provides a mapping table between the Functional Guide terms and the location of the field in the HL7 message.

APPENDIX E

SELECTED REFERENCES

This is a list of references used during the creation of this Functional Guide.

APPENDIX F

ACKNOWLEDGMENTS

This is a list of individuals and organizations that contributed to the creation of this Functional Guide.

Each chapter is related to other chapters, so understanding the whole document at a high-level is important.

3 ACTORS

Two actors are defined for this document, and requirements are placed on each actor as necessary. The two actors are:

- Querying System
- Responding System

3 ACTORS

This Functional Guide volume on query and response focuses on interaction and requirements between two actors. These actors could be the only two actors in the network chain (e.g., EHR directly to IIS), or they could be the two actors at the farthest end of a network chain (e.g., EHR through an HIE to an IIS).

Either way, this Functional Guide focuses on the requirements of the two actors at the ends of these exchanges. The number of hops (e.g., systems, HIEs, interface engines, etc.) between these two actors is a technical nuance that is not germane to functional requirements. As such, they are not discussed in this Functional Guide.

Two actors are defined for this document, and requirements are placed on each actor as necessary. The two actors are:

- Querying System
- Responding System

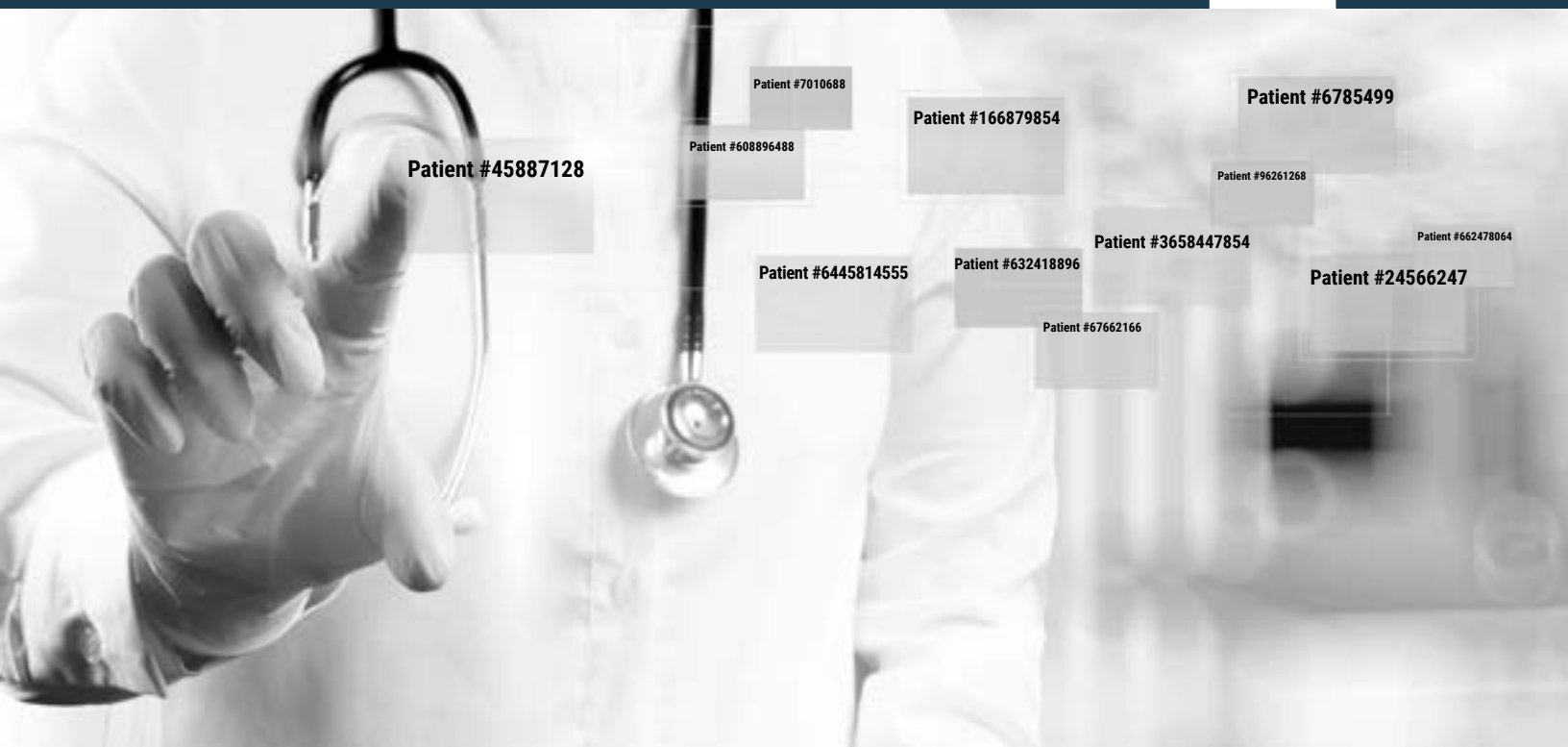
A simple interaction diagram between these two systems would look like the following:

Figure 3 | *Diagram of interacting actors*

The actors can then be played by any system. For example, if an EHR intends to query an IIS, then the EHR would need to meet the requirements placed on the "Querying System" actor and the IIS would need to meet the requirements placed on the "Responding System" actor. In an IIS-to-IIS interaction, the IIS querying would need to meet the requirements placed on the "Querying System" actor, and the IIS responding to the query would need to meet the requirements placed on the "Responding System" actor. While not technically required, in reality one of these systems will always be an IIS. The most common example in place at the time of this writing is the EHR or pharmacy system being the Querying System and the IIS being the Responding System.

4

CORE CONCEPTS



This Functional Guide attempts to cover all known data elements that are exchanged today.

4 CORE CONCEPTS

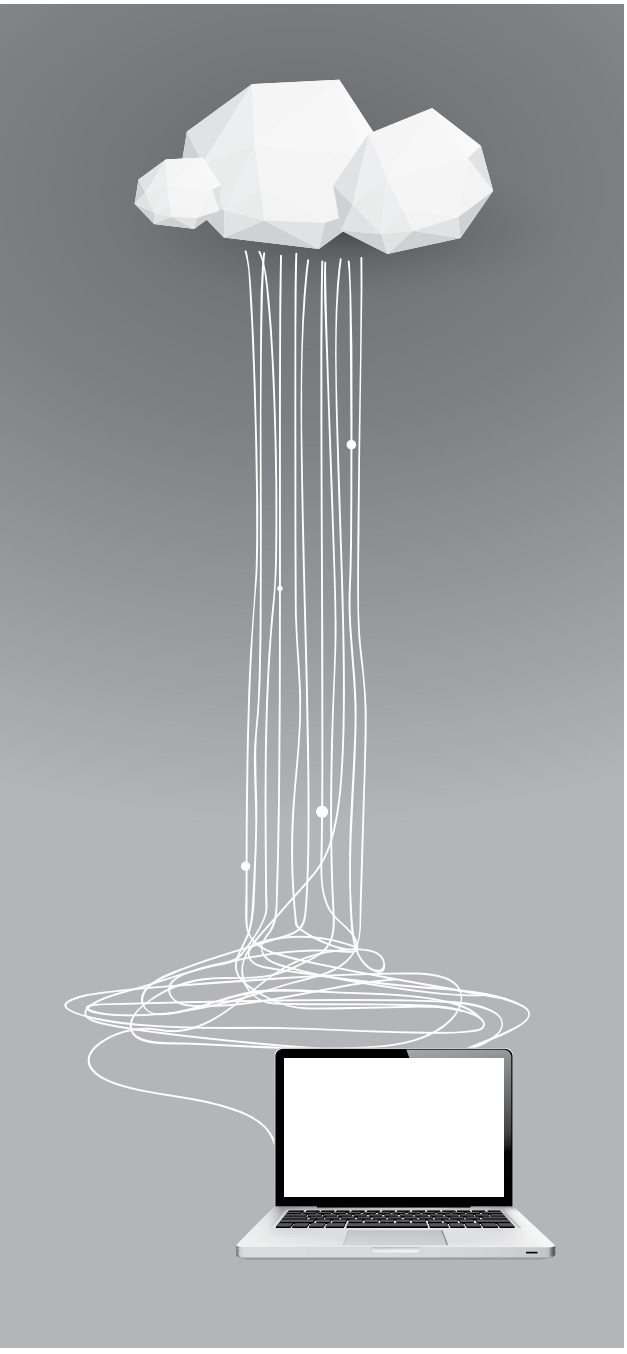
The following conformance statements are used in this Functional Guide.[4] This Functional Guide attempts to cover all known data elements that are exchanged today.

In the event the functional guide does not discuss a data element, the element should be considered a MAY requirement, and agreement would be needed by both trading partners.

Table 1 | *Conformance Verbs*

CONFORMANCE KEYWORDS	MEANING
SHALL	Indicates a mandatory requirement to be followed or implemented 100% of the time in order to conform. Synonymous with "is required to" and "must."
SHALL HAVE THE ABILITY TO OR SHALL INCLUDE IF KNOWN	Indicates a mandatory requirement to be followed or implemented in order to conform, but the requirement may not be possible or necessary 100% of the time across all clinical settings, workflows, and/or use cases.
SHOULD OR SHOULD HAVE THE ABILITY TO	This word and the adjective "RECOMMENDED" mean that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
MAY OR MAY HAVE THE ABILITY TO	Indicates an optional or permissible requirement to be followed or implemented. Synonymous with "is permitted." These requirements serve to enhance data quality and interoperability above and beyond the required functionality.
SHOULD NOT	This phrase and the phrase "NOT RECOMMENDED" mean that there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.
SHALL NOT	Indicates a prohibited action. Synonymous with "prohibited" and "must not."

[4]The basis of these terms is from RFC 2119 with further refinement to the purpose of the functional guide. https://tools.ietf.org/pdf/rfc2119.pdf



Three levels of requirements help define the scope and requirements of the Functional Guide.

CAPABILITIES

Capabilities define the basic ability of an actor. They are the highest-level requirements, and each capability is further defined through system and functional requirements. Capabilities are also helpful in clearly defining the scope of this guide.

SYSTEM REQUIREMENTS

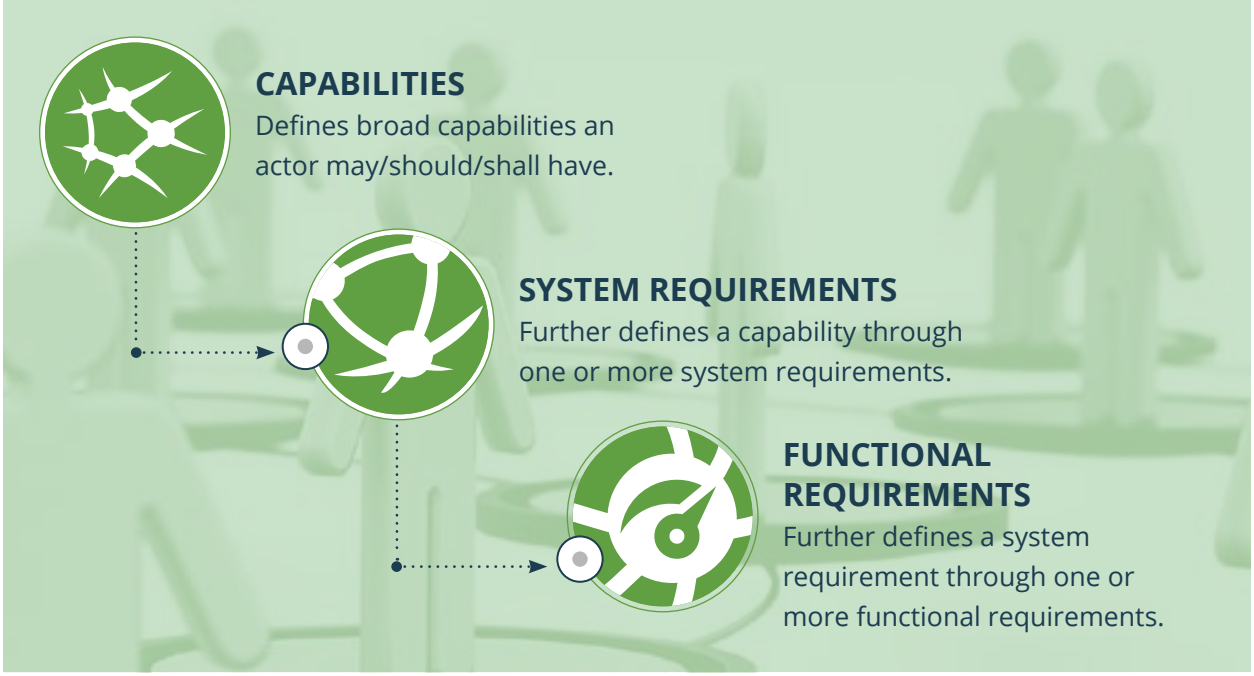
System requirements describe the functionality a system must—or may—have in order to effectively interoperate with another system. System requirements are loose concepts which are further defined through functional requirements. System requirements with a "SHALL HAVE THE ABILITY TO" criterion simply mean the system must have the functionality to perform the system requirement under the proper situation. It does not mean that the system must perform the system requirement in all situations all the time.

FUNCTIONAL REQUIREMENTS

Each system requirement is further refined through functional requirements. These are used to ensure consistent implementation of the system requirements. At the functional level, requirements are defined to support different scenarios. That is, the functional requirements for when a patient is found and returned are different from the functional requirements when a patient is not found.

When put together, they develop a “drill-down” approach to requirement documentation as depicted in Figure 4 below:

Figure 4 | *Requirement relationships in this document*



5

SCOPE AND CAPABILITIES

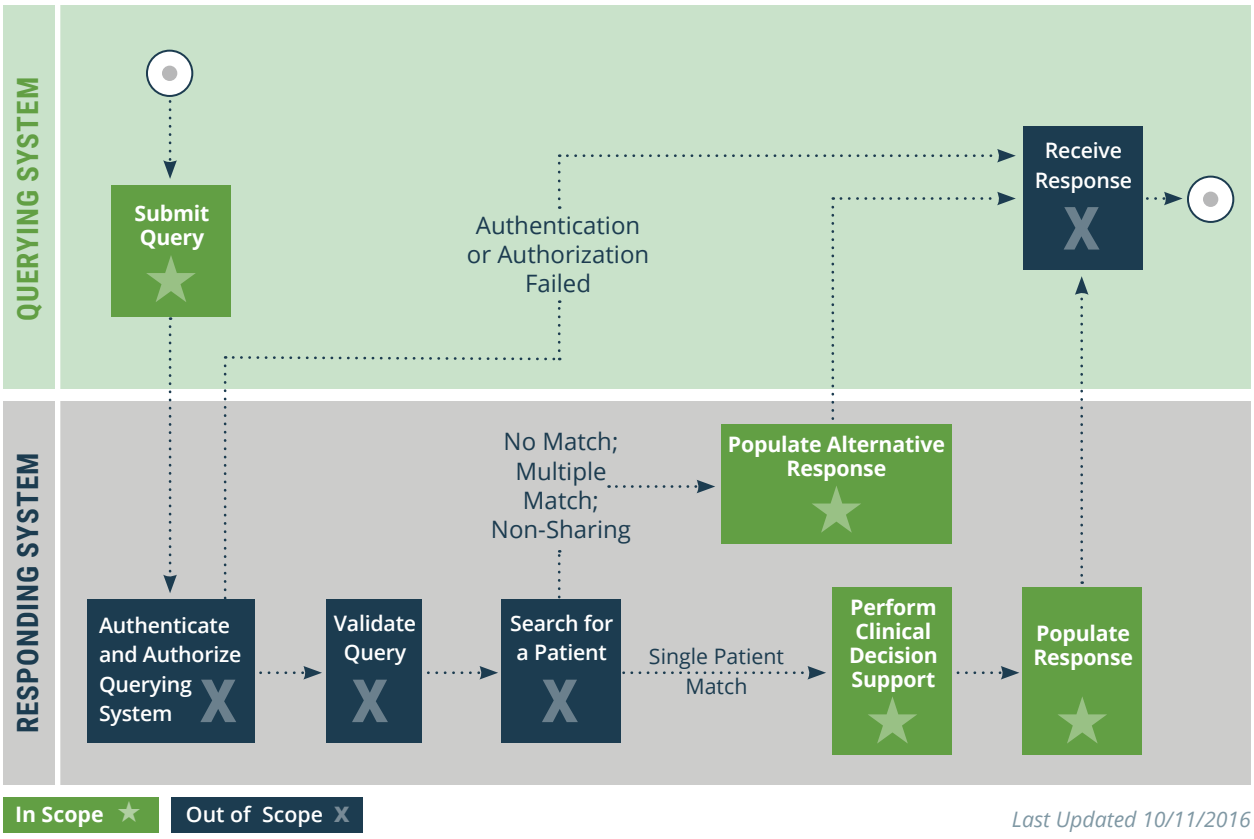
The scope of this guide is devoted to query and response functionality.

5 SCOPE AND CAPABILITIES

The scope of this guide is devoted to query and response functionality. In an effort to control the scope, the initial scope within query and response was further limited.

Figure 5 below depicts a high-level swim lane diagram of the query and response exchange between two systems and whether or not the capability is addressed in this guide. For a fully functioning query and response between two systems, all of the capabilities would need to be implemented.

Figure 5 | *Scope diagram of query and response functionality*



Last Updated 10/11/2016

5.1 IN SCOPE

5.1.1 CAPABILITIES

The following capabilities from Figure 5 are in scope and further defined in the remainder of this document.

1. **Submit a Query:**
   - The Querying System SHALL HAVE THE ABILITY TO submit a query.
     - **Note:** This excludes the receipt (e.g., consumption, reconciliation, display, etc.) of the response to the submitted query.
2. **Respond to a Query:**
   - The Responding System SHALL HAVE THE ABILITY TO respond to a query.
     - **Note:** This includes the following:
       - Perform Clinical Decision Support
       - Populate Response
       - Populate Alternative Response

5.2 OUT OF SCOPE

5.2.1 CAPABILITIES

The following capabilities from Figure 5 are currently out of scope. They are not discussed any further in this document. In time—and as the community finds value—these capabilities could be moved into scope.

- Authenticate and Authorize Querying System
- Validate Query
- Search for a Patient
- Receive a Response

5.2.2 OTHER

The following list includes, but is not limited to, additional topics that are also currently out of scope:

- Interoperability Triggers:
  - Interoperability triggers define events, conditions, or workflows where a query would be initiated.
- Display Requirements:
  - Display requirements define which data needs to be displayed on a User Interface.

6

QUERYING SYSTEM REQUIREMENTS

It should be noted that only one type of query is defined in this guide, which differs from the two in Release 1.5 of the HL7 Implementation Guide.

6 QUERYING SYSTEM REQUIREMENTS

The capability to submit a query is further defined in this chapter in Table 2. It should be noted that only one type of query is defined in this guide, which differs from the two in Release 1.5 of the HL7 Implementation Guide.

For more background information on query types, refer to Appendix A.1. Additionally, Patient and Vaccination Event System IDs exist in both the Querying System and the Responding System. Background on how these interact is important and well documented in the MIROW chapter on *Consolidating Demographic Records and Vaccination Event Records*[5] in the "Implementation Considerations" section. Functional requirements for these—based on the MIROW chapter—are documented below.

[5]http://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/

APPENDIX A.1 KEY TAKEAWAY

The overlap in what can/must be returned in the two profiles is large. The first requires more data elements about the vaccination event be returned, but does not require an evaluation and forecast. The second requires less data elements but requires an evaluation and forecast. During requirement gathering, the workgroup felt it was easier—and more valuable—to return as much data as the Responding System is allowed to return per local policy and to always include the clinical decision support (i.e., evaluation and forecast). This will allow Querying Systems to use what data they need to use across different use cases and ignore the data that isn't needed. Future HL7 implementation guide versions will need to consider reducing the number of query/response profiles to one.

6.1 SUBMIT INITIAL QUERY

Table 2 defines the system and functional requirements placed on the first capability to submit a query. Please refer to Appendix D for mapping between these data elements and the HL7 fields.

Table 2 | *Submit a query for a patient: system and functional requirements*

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
General Requirements	
1.1 The Querying System SHALL HAVE THE ABILITY TO query for a patient.	The Querying System SHALL construct an appropriately formatted and populated query with information from the Querying System.
	The Querying System SHALL include the maximum number of patients it is willing to accept in response.
	The Querying System SHALL include all known data from the Querying System at the time of the query.
Patient Identifying Information	
1.2 The Querying System SHALL HAVE THE ABILITY TO supply patient identifying information as part of the query.	The Querying System SHALL HAVE THE ABILITY TO exchange the following data elements from the Querying System: • Patient Name • Patient Date of Birth • Patient Gender • Querying System Patient ID • Mother's Maiden Name • Patient Address • Patient Phone Number The Querying System MAY HAVE THE ABILITY TO exchange the following data elements: • Responding System Patient ID • Other identifiers (e.g., Medicaid ID, etc.) • Patient Email Address • Multiple Birth Indicator • Multiple Birth Order

6.2 SUBMIT SECOND QUERY WITH RESPONDING SYSTEM INFORMATION

In the event an IIS returns a List of Possible Patients (Section 7.4), the querying system should submit a second query to distinctly identify the patient from the list of possible patients using patient demographic data from the responding system.

Table 3 | *Submit a second query: system and functional requirements*

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
General Requirements	
1.3 The Querying System SHOULD HAVE THE ABILITY TO query for a selected patient using data from a list of possible patients returned by the responding system.	The Querying System SHALL construct an appropriately formatted and populated query with information from the List of Possible Patients returned by the Responding System.
	The Querying System SHALL limit the maximum number of patients it is willing to accept in response to one patient.
	The Querying System SHALL include all data from the selected patient returned by the Responding System.
Patient Identifying Information	
1.4 The Querying System SHOULD HAVE THE ABILITY TO supply patient identifying information returned by the Responding System.	The Querying System SHALL HAVE THE ABILITY TO exchange the following data elements returned by the Responding System: • Patient Name • Patient Date of Birth • Patient Gender • Responding System Patient ID • Mother's Maiden Name • Patient Address • Patient Phone Number The Querying System MAY HAVE THE ABILITY TO exchange the following data elements: • Querying System Patient ID • Other identifiers (e.g., Medicaid ID, etc.) • Patient Email Address • Multiple Birth Indicator • Multiple Birth Order

7

RESPONDING SYSTEM REQUIREMENTS

Responding to a query can manifest itself in a few different ways depending upon the number of patients found, jurisdictional policy, and patient consent wishes (i.e., opt in, opt out).

7 RESPONDING SYSTEM REQUIREMENTS

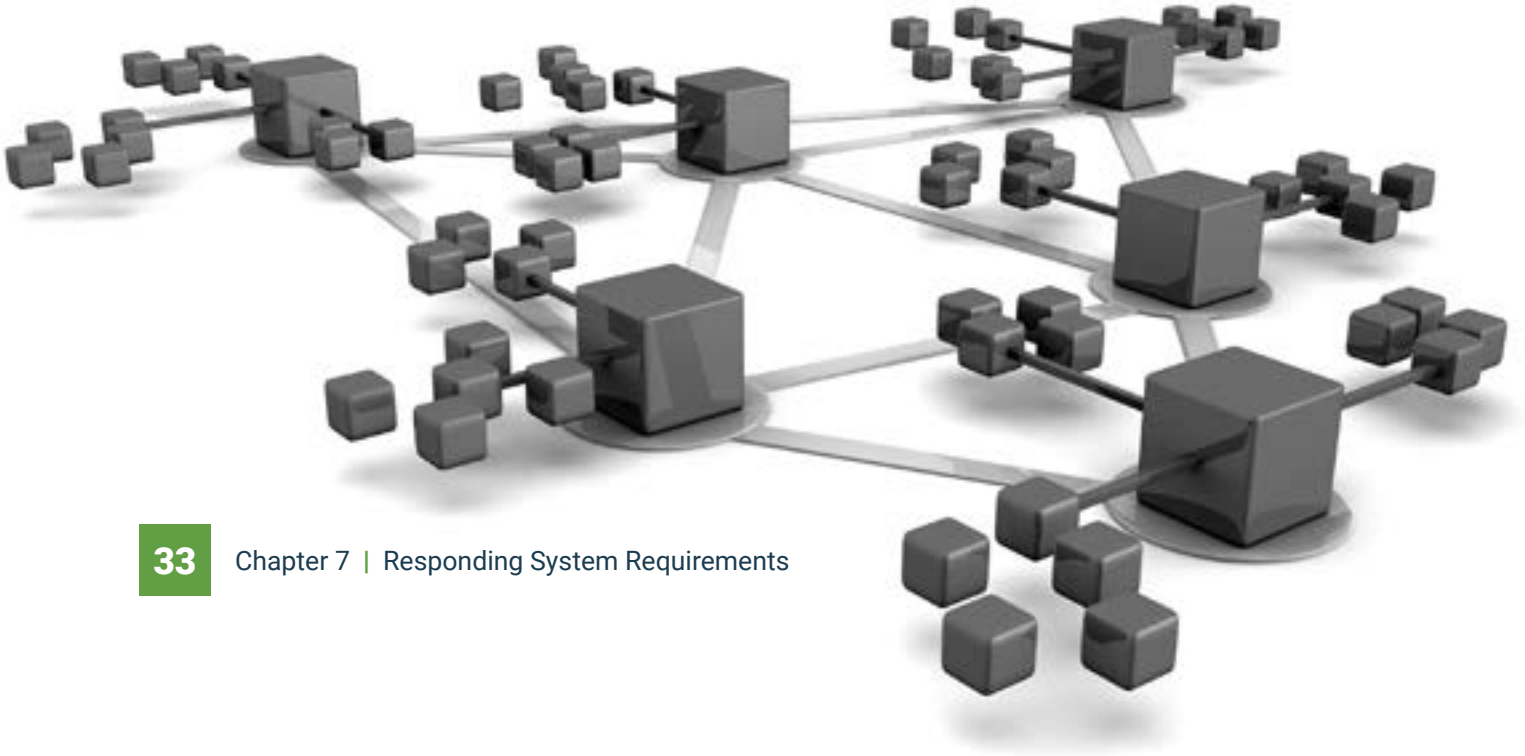
Responding to a query (Capability 2) can manifest itself in a few different ways depending upon the number of patients found, jurisdictional policy, and patient consent wishes (i.e., opt in, opt out).

This chapter provides foundational requirements followed by the various possible types of responses in the following sections:

- Section 7.1 – Foundational Requirements
- Section 7.2 – Single Patient Found
- Section 7.3 – No Patient Found
- Section 7.4 – List of Possible Patients Found
- Section 7.5 – Too Many Patients Found
- Section 7.6 – Patient Does Not Consent to Share

Additionally, Patient and Vaccination Event System IDs exist in both the Querying System and the Responding System. Background on how these interact is important and well documented in the MIROW chapter on *Consolidating Demographic Records and Vaccination Event Records*[6] in the "Implementation Considerations" section. Functional requirements for these—based on the MIROW chapter—are documented below.

[6]http://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/



7.1 FOUNDATIONAL REQUIREMENTS

Foundational requirements describe system and functional requirements to support responding to a query. Please refer to Appendix D for mapping between these data elements and the HL7 fields.

Table 4 | *Foundational requirements*

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
2.1 The Responding System SHOULD HAVE THE ABILITY TO store the request and results of a query.	The Responding System SHOULD store for audit purposes all of the following for each query submitted to the Responding System: 1. Authenticated entity who submitted the query 2. Demographic information supplied in the query 3. Patient or patients returned in the response
2.2 The Responding System SHALL HAVE THE ABILITY TO return information submitted in the query.	The Responding System SHALL include the patient-related data submitted by the Querying System as part of the response regardless of query outcome (e.g., found, not found, multiple patients, etc.)

7.2 SINGLE PATIENT FOUND

The Responding System must be prepared to properly and consistently respond when a single patient is found. Please refer to Appendix D for mapping between these data elements and the HL7 fields. This section is explicitly for situations where the patient consents to share his/her data. See Section 7.6 for when the patient does not consent to share.

Table 5 | *Respond to a query: system and functional requirements – single patient found*

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
General Requirements	
2.3 The Responding System SHALL HAVE THE ABILITY TO respond based on patient matching results and patient consent wishes.	The Responding System SHALL respond with a single patient found response when one high-confidence match is found in the Responding System and the patient consents to share.
	The Responding System MAY include a patient it believes to be deceased.
	The Responding System SHALL include exactly one patient in the response.
	The Responding System SHALL include as much data as is known by the Responding System regarding the patient and is allowable by local policy or law.

Continued on following page.

7.2 SINGLE PATIENT FOUND

Continued from previous page.

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
Patient Identifying Information	
2.4 The Responding System SHALL HAVE THE ABILITY TO respond with patient identifying information.	The Responding System SHALL HAVE THE ABILITY TO exchange the following Patient Identifying data elements from the Responding System: • Patient Name • Patient Date of Birth • Patient Gender • Responding System Patient ID • Patient Address • Patient Phone Number • Patient Email Address • Querying System Patient ID • Mother's Maiden Name • Patient Death Indicator • Patient Death Date • Reminder/Recall Preference • Reminder/Recall Preference Effective Date • Protection Indicator • Protection Indicator Effective Date • IIS Status • IIS Status Effective Date • Multiple Birth Indicator • Multiple Birth Order The Responding System MAY HAVE THE ABILITY TO exchange: • Patient Race • Patient Ethnic Group • Patient Primary Language • Patient Alias • Other identifiers per jurisdictional policy (e.g., SSN, Medicaid ID, etc.)
Responsible Person Information	
2.5 The Responding System SHALL HAVE THE ABILITY TO respond with responsible person information.	The Responding System SHALL HAVE THE ABILITY TO exchange the following Responsible Person data elements from the Responding System: • Responsible Person • Relationship to Patient • Responsible Person Address • Responsible Person Phone Number • Responsible Person Email Address The Responding System MAY HAVE THE ABILITY TO exchange: • Responsible Person Primary Language • Responsible Person Date of Birth
Patient Observation	
2.6 The Responding System SHOULD HAVE THE ABILITY TO respond with patient observations.	The Responding System SHOULD HAVE THE ABILITY TO exchange the following Patient Observation data elements from the Responding System: • Patient Observation • Patient Observation Start Date • Patient Observation End Date

Continued on following page.

7.2 SINGLE PATIENT FOUND

Continued from previous page.

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
Vaccination Event	
2.7 The Responding System SHALL HAVE THE ABILITY TO respond with vaccination events.	The Responding System SHALL HAVE THE ABILITY TO exchange the following Vaccination Event data elements from the Responding System: • Administration Date • Vaccine Type • Entering Person • Ordering Provider • Entering Organization • Administering Provider • Administered-at Location • Lot Number • Lot Number Expiration Date • Manufacturer • Administered Amount • Vaccine Route of Administration • Vaccine Site of Administration The Responding System MAY HAVE THE ABILITY TO exchange: • Vaccine Information Statement (VIS) • VIS Given Date • Vaccine Funding Program Eligibility • Vaccine Funding Source
	The Responding System SHALL return the Querying System Immunization ID associated with the event when it is known; otherwise, it SHALL return the Responding System Immunization ID.
	The Immunization Information Source SHALL represent the Responding System's first-hand or second-hand knowledge of the vaccination event. • See Appendix A.2 for more information
Evaluation of a Vaccination Event	
2.8 The Responding System SHALL HAVE THE ABILITY TO respond with an evaluation of a vaccination event.	The Responding System SHALL HAVE THE ABILITY TO exchange the following Evaluation data elements from the Responding System: • Vaccine Type • Evaluation Reason • Evaluation Status The Responding System MAY HAVE THE ABILITY TO exchange: • Immunization Schedule Used • Dose Number in Series
	The Responding System SHALL include an Evaluation Reason when the Evaluation Status is one of the following values: • Not Valid • Substandard • Extraneous
Adverse Event	
2.9 The Responding System MAY HAVE THE ABILITY TO respond with Adverse Events.	The Responding System MAY HAVE THE ABILITY TO exchange the following Adverse Event data elements from the Responding System: • Adverse Event • Adverse Event Date • Vaccine Type • Administration Date

Continued on following page.

APPENDIX A.2 KEY TAKEAWAY

The workgroup concluded that the Responding System really needs to make the determination on whether or not it has first-hand knowledge of the vaccination event or not. The primary discussion—and current variation in practice—was the situation where the IIS has an "Administered" vaccination event (HL7 code "00") and must then represent that vaccination event in a response to a query. The biggest limitation in recommending that a responding system return what it has stored is in the definition of HL7 code "00" in the HL7 Implementation Guide. The definition reads: "The record of a newly administered dose of vaccine. The dose was administered by the organization that is reporting this dose."

7.2 SINGLE PATIENT FOUND

Continued from previous page.

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
Forecast when a dose is recommended to be given	
2.10 The Responding System SHALL HAVE THE ABILITY TO respond with a forecast when a dose is recommended to be given.	The Responding System SHALL HAVE THE ABILITY TO exchange the following Forecast data elements when a dose is recommended to be given: • Vaccine Type • Series Status • Earliest Date • Recommended Date The Responding System MAY HAVE THE ABILITY TO exchange: • Past Due Date • Latest Date • Forecast Reason • Immunization Schedule Used • Forecast Dose Number
	The Responding System SHALL include a forecast for each vaccine-preventable disease within the scope of the Responding System when a dose is recommended to be given based on currently available information. • See Appendix A.3 for more information
Forecast when a dose is not recommended to be given	
2.11 The Responding System SHALL HAVE THE ABILITY TO respond with a forecast when a dose is not recommended to be given.	The Responding System SHALL HAVE THE ABILITY TO exchange the following Forecast data elements when a dose is not recommended to be given: • Vaccine Type • Series Status • Forecast Reason The Responding System MAY HAVE THE ABILITY TO exchange: • Immunization Schedule Used The Responding System SHALL include a forecast for each vaccine-preventable disease within the scope of the Responding System when a dose is not recommended to be given based on currently available information. • See Appendix A.4 for more information
Vaccination Refusal	
2.12 The Responding System MAY HAVE THE ABILITY TO respond with refusals of previous vaccinations.	The Responding System SHALL HAVE THE ABILITY TO exchange the following Vaccination Refusal data elements from the Responding System: • Vaccine Type • Refusal Reason • Refusal Date

APPENDIX A.3 KEY TAKEAWAY

The best—and most consistently usable approach for Querying Systems—is to forecast the immediate dose and include all vaccine-preventable diseases within the scope of the Responding System.

This will provide a forecast which:

- **Is based on the facts (e.g., currently known information)**
- **Eliminates assumptions about vaccination recommendations**
- **Allows Querying Systems to use (e.g., display, consume, filter) based on individual and use case need**
- **Eliminates arbitrary decisions about what "near term" means**
- **Eliminates the unknown of silent recommendations (e.g., what does a lack of a Td forecast mean)**

7.3 NO PATIENT FOUND

The Responding System must be prepared to properly and consistently respond when it is unable to confidently match to any patient based on the information provided in the query. Please refer to Appendix D for mapping between these data elements and the HL7 fields.

Table 6 | *Respond to a query: system and functional requirements – no patient found*

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
General Requirements	
2.3 The Responding System SHALL HAVE THE ABILITY TO properly respond based on patient matching results and patient consent wishes.	The Responding System SHALL return a response indicating no patients were found.

7.4 LIST OF POSSIBLE PATIENTS FOUND

The Responding System must be prepared to handle a situation where more than one patient is found and return a list of patients. This happens when the Responding System finds more than one patient but less than either the maximum requested in the query or the maximum allowed by the Responding System's policies. This list returns patients who consent to have their record shared. Section 8.6 discusses when one patient is found but does not consent to share. However, there is not discussion in this guide regarding situations where more than one patient is found and at least one consents and at least one does not consent to share due to jurisdictional-specific consent policies and laws. Please refer to Appendix D for mapping between these data elements and the HL7 fields.

7.4 LIST OF POSSIBLE PATIENTS FOUND

Table 7 | *Respond to a query: system and functional requirements – list of possible patients found*

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
General Requirements	
2.3 The Responding System SHALL HAVE THE ABILITY TO properly respond based on patient matching results and patient consent wishes.	The Responding System SHALL return one of the following per jurisdictional policy: • A response containing a list of possible patients (this section) • A response indicating no patients were found (Section 7.3) • A response indicating too many patients were found (Section 7.5)
General Requirements	
2.3 The Responding System SHALL HAVE THE ABILITY TO properly respond based on patient matching results and patient consent wishes.	The Responding System SHALL include as much data as is known by the Responding System regarding each patient and is allowable by local policy or law. The Responding System SHALL include a list of possible patients in the response. The Responding System MAY include a patient it believes to be deceased.
Patient Identifying Information	
2.4 The Responding System SHALL HAVE THE ABILITY TO respond with patient identifying information.	The Responding System SHALL HAVE THE ABILITY TO exchange the following Patient Identifying data elements from the Responding System: • Patient Name • Patient Date of Birth • Patient Gender • Responding System Patient ID • Querying System Patient ID • Patient Address The Responding System MAY HAVE THE ABILITY TO exchange: • Patient Phone Number • Patient Email Address • Mother's Maiden Name • Multiple Birth Indicator • Multiple Birth Order • Patient Race • Patient Ethnic Group • Patient Primary Language • Patient Death Indicator • Patient Death Date
Responsible Person Information	
2.5 The Responding System SHALL HAVE THE ABILITY TO respond with responsible person information.	The Responding System SHALL HAVE THE ABILITY TO exchange the following Responsible Person data elements from the Responding System: • Responsible Person Name • Relationship to Patient • Responsible Person Address • Responsible Person Phone Number • Responsible Person Email Address The Responding System MAY HAVE THE ABILITY TO exchange: • Responsible Person Primary Language • Responsible Person Date of Birth

7.5 TOO MANY PATIENTS FOUND

The Responding System must be prepared to handle a situation where too many patients are found and returning even limited patient data is not a valuable exercise. This happens when the Responding System finds either more patients than the maximum requested in the query or the maximum allowed by the Responding System's policies. Please refer to Appendix D for mapping between these data elements and the HL7 fields.

Table 8 | *Respond to a query system and functional requirements – too many patients found*

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
General Requirements	
2.3 The Responding System SHALL HAVE THE ABILITY TO properly respond based on patient matching results and patient consent wishes.	The Responding System SHALL return one of the following per jurisdictional policy: • A response indicating too many patients were found • A response indicating no patients were found (Section 7.3)

7.6 PATIENT DOES NOT CONSENT TO SHARE

The Responding System must be prepared to handle a situation where exactly one patient is found but the patient does not want his/her information shared and the Responding System must protect the wishes of the patient.

Table 9 | *Respond to a query system and functional requirements – patient does not consent to share*

SYSTEM REQUIREMENTS	FUNCTIONAL REQUIREMENTS
General Requirements	
2.3 The Responding System SHALL HAVE THE ABILITY TO properly respond based on patient matching results and patient consent wishes.	The Responding System SHALL return one of the following per jurisdictional policy: • A response indicating a patient was found but the patient does not consent to share with the Querying System • A response indicating no patients were found (Section 7.3)
	The Responding System MAY include a patient it believes to be deceased.

8 VALUES

Responding Systems should not be creating one-off local values but, rather, working to expand national lists as needed for all Responding Systems to use.

8 VALUES

This chapter contains a list of functional guide terms that have a finite list of possible values.

The Functional Guide does not associate these with technical codes or coding systems (e.g., LOINC, SNOMED, etc.), but they are provided as a starting point for when values need to be associated with a code and coding system.

8.1 SYSTEM EXPECTATIONS

Not all Responding Systems will use all values. All responding systems should select and use values only from the list of values provided below. That is to say, Responding Systems should not be creating one-off local values but, rather, working to expand the list as needed for all Responding Systems to use.

On the other hand, Querying Systems should be prepared to receive any of the values listed below, as they may interoperate with multiple Responding Systems.

8.2 VALUES

SHALL be one of the following values:

● Valid	● Not Valid
● Extraneous	● Substandard

SHALL be one of the following values:

Vaccine Dose Administered was administered after the Lot Number Expiration Date.
Vaccine Dose Administered was deemed to be ineffective or sub-potent. (e.g., recalled, cold-chain break, partially administered).
Vaccine Dose Administered was administered at too young of an age.
Vaccine Dose Administered was administered at too old of an age.
Vaccine Dose Administered was administered too soon following a previous dose.
Vaccine Dose Administered was administered too close to another vaccine (e.g., live virus conflict).
Vaccine Dose Administered amount was less than the recommended amount.

SHALL be one of the following values when a dose is being recommended:

● On Schedule	● Overdue

SHALL be one of the following values when a dose is not being recommended:

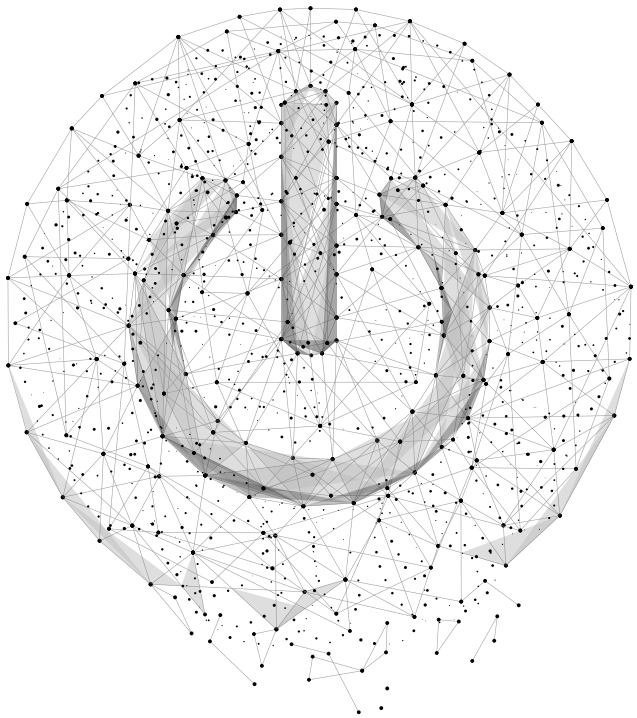
● Immune	● Complete
● Contraindicated	● Too Old
● Not Recommended	

SHALL be one of the following values:

A complete list of possible forecast reasons is documented by the CDSi project and is quite extensive. The reasons are not duplicated here and may be a bit more fluid than the other concepts noted above, as ACIP recommendations change and evolve. The list can be found here: **http://www.cdc.gov/vaccines/programs/iis/cdsi.html.**

[7]Evaluation Status values are from CDSi (http://www.cdc.gov/vaccines/programs/iis/cdsi.html).
[8]Evaluation Reason values are from CDSi (http://www.cdc.gov/vaccines/programs/iis/cdsi.html).
[9]Series Status values are from CDSi (http://www.cdc.gov/vaccines/programs/iis/cdsi.html) and known usages by production IIS.

APPENDICES



APPENDIX A INFORMATIVE DISCUSSIONS

As necessary, this Functional Guide will contain informative and/or background discussions which may help better explain concepts and decision points. Keeping the discussions here will help keep the core requirements succinct and clear of fuzzy language. The conformance verbs (e.g., shall, should, may) do not carry any formal weight in this appendix.




A.1 QUERY AND RESPONSE PROFILES

The HL7 Version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5[10] defines two different types of queries—called profiles.

- Request/Return Complete Immunization History
- Request/Return Evaluated History and Forecast

The overlap in what can/must be returned in the two profiles is large. The first requires more data elements about the vaccination event be returned, but does not require an evaluation and forecast. The second requires less data elements but requires an evaluation and forecast. During requirement gathering, the workgroup felt it was easier—and more valuable—to return as much data as the Responding System is allowed to return per local policy and to always include the clinical decision support (i.e., evaluation and forecast). This will allow Querying Systems to use what data they need to use across different use cases and ignore the data that isn't needed. Future HL7 implementation guide versions will need to consider reducing the number of query/response profiles to one.

[10]https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf

A.2 IMMUNIZATION INFORMATION SOURCE

A critical field for IIS when receiving vaccination updates from vaccinators is the Immunization Information Source field.

This field is described as follows in *Data Quality Assurance in Immunization Information Systems: Selected Aspects:*[11]

> Administered/Historical Indicator describes an association between a Vaccination Event and the IIS-AO that originates a Vaccination Event Submission for this Vaccination Event:
>
> > Values: Administered or Historical.
>
> "Administered" value for the Administered/Historical Indicator points out that the IIS-AO records and/or submits its own Vaccination Event, i.e., attests that it conducted the Vaccination Event ("I am Vaccinator IIS-AO").
>
> "Historical" value for the Administered/Historical Indicator points out that the IIS-AO originates a Vaccination Event Submission for a Vaccination Event that is owned by some other IIS-AO, i.e., attests that it did not conduct the Vaccination Event ("I am NOT Vaccinator IIS-AO; I am just Recorder IIS-AO").

[11] https://repository.immregistries.org/files/resources/5835adc2dd10f/data_quality_assurance_in_immunization_information_systems___selected_aspects_.pdf

This field is described as follows in the *HL7 Version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5:*[12]

> Definition: This field is used to indicate whether this immunization record is based on a historical record or was given by the reporting provider. It should contain the information source (see NIP-defined Table 0001 - Immunization Information Source). The first component shall contain the code, the second the free text and the third shall contain the name of the code system. (NIP001) Sending systems should be able to send this information. Receiving systems should be able to accept this information.
>
> This field may be used for other notes if specified locally. The first repetition shall be the information source. If other notes are sent when information source is not populated, then the first repetition shall be empty.

Other notes may include text only in component 2 of the repeat. Acceptance of text only is by local agreement only.

Information source is a CDC-endorsed data element. It speaks to the reliability of the immunization record. IIS rely on this information.

[12]https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf

The Implementation Guide (IG) further provides the following values:

VALUE	DESCRIPTION	OPERATIONAL DEFINITION
00	New immunization record	The record of a newly administered dose of vaccine. The dose was administered by the organization that is reporting the dose.
01	Historical information - source unspecified	The record of a vaccine dose from a reliable historical source, such as an immunization card.
02	Historical information - from other provider	The record of a vaccine dose from another health care provider's historical records.
03	Historical information - from patient's written record	The record of a vaccine dose from parentally maintained written records.
04	Historical information - from parent's recall	The record of a vaccine dose from a parents recall. The reliability of this record is considered low.
05	Historical information - from other registry	The record of a vaccine dose from another Immunization Information System (IIS).
06	Historical information - from birth certificate	The record of a vaccine dose from a birth record.
07	Historical information - from school record	The record of a vaccine dose from a written school record.
08	Historical information - from public agency	The record of a vaccine dose from a written public health agency record.

As can be seen, the IG has a more values than the MIROW chapter. However, in general, Administered in MIROW can be aligned with a value of "00" in the IG, and Historical in MIROW can be aligned with values "01" through "08" in the IG.

The scope of the MIROW chapter, which limits its use for this work, is devoted to submission of vaccination events to the IIS. It does not cover responding to a query and how that information should be represented when the data leaves the IIS.

The IG addresses both submission and query/response, the operational definition of each value is not ideal when attempting to respond to a query. Specifically, if an IIS has an "Administered" dose (MIROW definition) on file, how should an IIS classify this vaccination event in response to a query? Is the value different depending upon who is querying? Does a querying system even need this value? Is this an important value in a query/response transaction, or is it only important during submission?

In April 2016, the AIRA Interoperability and Testing project queried 19 different IIS and recorded what value was returned by the IIS when an "Administered" (00) vaccination event was on file. The results were as follows:

RETURNED VALUE	# OF IIS
00: Administered	15
01: Historical, Source Unspecified	10
02: Historical, from another provider	0
05: Historical, from another registry	0
Empty: IIS did not populate field	4

It is important to note that, in this testing, AIRA reported the administered vaccine and queried for the patient all within the same organization. This may lead to some skewing of results where 00 was returned. It is possible some IIS may respond differently under different scenarios.

The workgroup concluded that the Responding System really needs to make the determination on whether or not it has first-hand knowledge of the vaccination event or not. The primary discussion—and current variation in practice—was the situation where the IIS has an "Administered" vaccination event (HL7 code "00") and must then represent that vaccination event in a response to a query. The biggest limitation in recommending that a responding system return what it has stored is in the definition of HL7 code "00" in the HL7 Implementation Guide. The definition reads: "The record of a newly administered dose of vaccine. The dose was administered by the organization that is reporting this dose." The second sentence led the workgroup to recommend against returning HL7 value "00" in all cases because the Responding System—in nearly all cases—is not the organization that administered the dose.

For example, if an IIS receives a vaccination event from a provider through a submission and the provider claims to have administered it, then the IIS will likely store the immunization as an administered dose (HL7 code "00"). However, when a provider queries an IIS for this patient, the IIS really doesn't have first-hand knowledge of the vaccination event. The IIS simply has a report of a vaccination event where a provider claims to have administered the event. In these situations, the workgroup concluded it would be best for the IIS to represent this fact through the use of one of the historical codes indicating the IIS does not have first-hand knowledge of the vaccination event. The following decision table shows possible values an IIS would return depending upon the value they have stored for the vaccination event.

IIS STORED VALUE FOR A VACCINATION EVENT	IIS RETURNED VALUE IN RESPONSE TO A QUERY
00 – Administered	01 – 08 (any appropriate historical value)
01 through 08	01 – 08 (any appropriate historical value)

A.3 FORECASTING WHEN A DOSE IS RECOMMENDED TO BE GIVEN

Two significant decision points were needed to ensure consistent implementation of forecasts. The first is definition of what "next dose" means, and the second is how far into the future should a forecast be provided.

FORECASTING THE NEXT DOSE

Three different approaches have been seen by Responding Systems when it comes to forecasting the "next dose."

IMMEDIATE DOSE

In this approach, the Responding System returns the next dose due for each vaccine-preventable disease based on the information currently available. It does not assume doses which are due today or overdue today would be given. It is a snapshot-in-time forecast that is true for that moment in time. If—or when—the patient receives vaccinations, a subsequent request would be made to get a newly updated forecast based on new information (e.g., the new vaccination events).

IMMEDIATE DOSE + 1

In this approach, the Responding System returns the same forecast as the first approach, along with a secondary forecast assuming the patient will receive all doses which are due today or overdue today. It is forward looking and eliminates a second forecast request when a patient receives the forecasted doses as assumed. As noted, it is based on the assumption the patient will receive the due or overdue doses. This could be misleading if the patient doesn't receive those doses or the Querying System is not a vaccinator (e.g., HIE or another IIS).

FULL REMAINING SCHEDULE

In this approach, the Responding System returns the same forecast as the first approach for the next dose due but then also provides a forecast for all remaining doses for each vaccine-preventable disease based on recommended ages and intervals. This practice is quite limited but is included for completeness.

FORECASTING INTO THE FUTURE

Two different approaches have been seen by Responding Systems when it comes to including/excluding future doses based on how far into the future the next dose is recommended. For example, should a forecast for HPV at age 11 years be included for a 3-year-old patient (e.g., 8 years into the future)? What about Td for a patient who recently received Td (e.g., 10 years into the future)?

INCLUDE ALL

Some Responding Systems include all doses regardless of distance from today and let the Querying System determine which vaccines to use (e.g., display, consume, filter) based on need. This results in truthful but extremely future forecasted dates (e.g., Zoster 60 years into the future).

INCLUDE ONLY NEAR TERM

Some Responding Systems have internal business rules to exclude forecasts that do not meet their definition of Near Term. This results in a smaller forecast but is not implemented consistently across different Responding Systems. However, it is impossible to know if the lack of a forecast for a specific vaccine-preventable disease is because the Responding System excluded it (e.g., too far into the future) or the Responding System does not forecast that particular vaccine-preventable disease (e.g., out of scope).

When considering these two somewhat dissimilar, yet somewhat overlapping, concepts together along with the rest of the functional guide approach, the best—and most consistently usable approach for Querying Systems—is to forecast the immediate dose and include all vaccine-preventable diseases within the scope of the Responding System.

This will provide a forecast which:

- Is based on the facts (e.g., currently known information)
- Eliminates assumptions about vaccination recommendations
- Allows Querying Systems to use (e.g., display, consume, filter) based on individual and use case need
- Eliminates arbitrary decisions about what "near term" means
- Eliminates the unknown of silent recommendations (e.g., what does a lack of a Td forecast mean)

This decision does imply that a forecast that is good for the moment is given and the Querying System should submit a second query to see a fresh forecast upon vaccination. Performing a query and receiving a response is a very quick operation, so this should not be a burden for users or systems.

A.4 FORECASTING WHEN A DOSE IS NOT RECOMMENDED TO BE GIVEN

The majority of the time, a patient is recommended to receive a vaccine. However, there are situations when a patient is not recommended to receive a vaccination either today or in the future. For example, once a patient completes his/her recommended doses for a vaccine-preventable disease, he/she is no longer recommended to receive a dose of the vaccine. In general, there are four situations when a patient is not recommended to receive a dose.

1. **Complete:** The patient has received all recommended doses and is complete.
2. **Immune:** The patient has some evidence of immunity (e.g., history of disease, birth date).
3. **Contraindication:** The patient has an active condition (e.g., pregnant, immunocompromised) that either temporarily or permanently contraindicates vaccination.
4. **Aged Out:** The patient has not received all recommended doses but is too old to receive any more doses.

If any of these situations exist, it is imperative for a Responding System to explicitly return this so the Querying System is not misinterpreting what a lack of a forecast for a specific vaccine-preventable disease means.

Similar to the section above on forecasting when a dose is recommended, the same principles can be applied for forecasting when a dose is not recommended.

This will provide a forecast which:

- Is based on the facts (e.g., currently known information)
- Eliminates assumptions about vaccination recommendations
- Allows Querying Systems to use (e.g., display, consume, filter) based on need
- Eliminates arbitrary decisions about what “near term” means
- Eliminates the unknown of silent recommendations (e.g., what does a lack of a Td forecast mean)

When both sections (A.3 and A.4) are considered broadly, a Responding System will be able to create an explicit forecast and eliminate any need for the Querying System to make assumptions about what a lack of a forecast might imply (e.g., not needed now, not needed ever, not in the scope of the Responding System, patient is complete, contraindication exists, etc.).

Similar to the section above on forecasting when a dose is recommended, the same principles can be applied for forecasting when a dose is not recommended.

This will provide a forecast which:

- Is based on the facts (e.g., currently known information)
- Eliminates assumptions about vaccination recommendations
- Allows Querying Systems to use (e.g., display, consume, filter) based on need
- Eliminates arbitrary decisions about what “near term” means
- Eliminates the unknown of silent recommendations (e.g., what does a lack of a Td forecast mean)

APPENDIX B GLOSSARY

To make sure everyone understands the terms used in the requirements the same way, the following glossary is provided. Wherever possible, definitions were pulled in from previously published material.

Table 10 | *Glossary of terms*

FUNCTIONAL GUIDE TERM	DEFINITION	NOTES
Administered Amount	A measurement of how much vaccine was administered, including units (e.g., 0.5 mL)	From *MIROW 2013 Data Quality Assurance: Selected Aspects* Alternate Names: Vaccine Dose Volume, Vaccine Dose Volume Units
Administered-at Location	Identifies the name and address of the facility that administered the vaccine. This may be a locally agreed-upon identifier.	Adapted from *HL7 Implementation Guide*
Administering Provider	Identifies the person who physically administered the vaccine. This may involve names and/or locally agreed-upon identifier(s).	Adapted from *HL7 Implementation Guide* Alternate Names: Vaccine administering provider – suffix, Vaccine administering – provider (person)
Administration Date	Date of the vaccination event	From *CDC Logic Specification for ACIP Recommendations* Alternate Names: Vaccine Administration Date
Adverse Event	A negative health consequence experienced by the patient related in time to administration of vaccine(s)	From *CDC Logic Specification for ACIP Recommendations* NOTE: "In time" means that it happens in some reasonable time after the immunization event. It might not be related to a specific vaccine dose administered, especially in cases when the patient receives several shots in one visit. NOTE: The Adverse Event description may include the severity of the event. Severity is not currently submitted or collected separately.
Adverse Event Date	The date the adverse event occurred	
Dose Number in Series	Indicates which dose in a series this given immunization fulfills.	From *HL7 Implementation Guide* NOTE: This is the dose number for vaccination events. See Forecast Dose number for future recommended vaccines.

FUNCTIONAL GUIDE TERM	DEFINITION	NOTES
Earliest Date	The date which the next dose could be given	From *CDC Logic Specification for ACIP Recommendations* NOTE: This date does not include the grace period nor any early allowed ages/intervals.
Entering Organization	Identifies the organization that the entering person belonged to at the time he/she enters/maintains the order, such as medical group or department	*From HL7 Implementation Guide*
Entering Person	Identifies the individual that entered a particular order. This may involve names and/or locally agreed-upon identifier(s).	Adapted from *HL7 Implementation Guide* Note from HL7: It may be used to indicate who recorded a particular immunization.
Evaluation Reason	The reason(s) why a vaccination event is or is not valid	From *CDC Logic Specification for ACIP Recommendations*
Evaluation Status	Indicates validity of a vaccination event	From *CDC Logic Specification for ACIP Recommendations*
Forecast Dose Number	Indicates which dose in a series is being forecasted	
Forecast Reason	The reason(s) why a target dose is or is not recommended to be administered	
IIS Status	Identifies the current status of the patient in relation to the Querying System	From *HL7 Implementation Guide* Alternate Names: Patient status indicator-provider level
IIS Status Effective Date	The date the IIS status was set by the Querying System during a previous vaccination update submission	Adapted from *HL7 Implementation Guide*
Immunization Information Source	Indicate whether the vaccination event is based on a historical record or was given by the reporting provider	From *HL7 Implementation Guide* Alternate Names: Vaccination event record type (administered/historical)
Immunization Schedule Used	Identifies the standards used. ACIP is the prototypical example.	From *HL7 Implementation Guide*
Latest Date	The latest point in time at which the next target dose could be given and still be valid	From *CDC Logic Specification for ACIP Recommendations*
Lot Number	The number assigned by the manufacturer to a specific batch of Vaccine Product Type	From *MIROW 2013 Data Quality Assurance: Selected Aspects* Alternate Names: Vaccine Lot Number
Lot Number Expiration Date	The date at which the lot is no longer considered potent	From *MIROW 2013 Data Quality Assurance: Selected Aspects* Alternate Names: Vaccine Expiration Date
Manufacturer	An organization that develops and distributes vaccines	From *MIROW 2013 Data Quality Assurance: Selected Aspects* Alternate Names: Vaccine Manufacturer Name

FUNCTIONAL GUIDE TERM	DEFINITION	NOTES
Mother's Maiden Name	The family name under which the mother was born (i.e., before marriage). This may involve the family name and first name.	Adapted from *HL7 Implementation Guide* Alternate Names: Mother's Name: First, Mother's Name: Maiden last
Multiple Birth Indicator	Indicates whether a patient was part of a multiple birth event (e.g., twins, triplets)	From *HL7 Implementation Guide* Alternate Names: Patient Multiple Birth Indicator
Multiple Birth Order	The order of birth within the multiple birth event	Alternate Names: Patient Birth Order
Ordering Provider	Identifies the person who is responsible for creating the request to vaccinate (i.e., ordering physician). This may involve names and/or locally agreed-upon identifier(s).	Adapted from *HL7 Implementation Guide* Alternate Names: Vaccine Ordering Provider (Person)
Past Due Date	The date at which the next target dose for the patient is considered overdue	From *CDC Logic Specification for ACIP Recommendations* Note: This is the standard recommended windows for vaccination. It is the end of the published recommended windows provided the patient is on schedule. See Recommended Date for the start of the recommended window.
Patient Address	A place where a patient may be communicated with, e.g., the residence of the patient. This may include the street, city, state, zip, county, country, and type of address.	Adapted from *MIROW 2013 Data Quality Assurance: Selected Aspects* Alternate Names: • Patient address: county of residence • Patient address: city • Patient address: country • Patient address: state • Patient address: street • Patient address: zip code
Patient Alias Name	A nickname or another assumed name	From *HL7 Implementation Guide* Alternate Names: • Patient alias name: first • Patient alias name: middle • Patient alias name: last
Patient Date of Birth	The birth date of the patient	From *MIROW 2013 Data Quality Assurance: Selected Aspects*
Patient Death Date	The date of the patient's death	From *MIROW 2013 Data Quality Assurance: Selected Aspects*
Patient Death Indicator	Indicates whether the patient is deceased	From *HL7 Implementation Guide*
Patient Email Address	Patient's personal email address	Adapted from *HL7 Implementation Guide*
Patient Ethnic Group	Defines the patient's ancestry	From *HL7 Implementation Guide* Alternate Names: Ethnicity

FUNCTIONAL GUIDE TERM	DEFINITION	NOTES
Patient Gender	Patient's sex	From *CDC Logic Specification for ACIP Recommendations* and *MIROW 2013 Data Quality Assurance: Selected Aspects*
Patient Name	The primary or legal name of the patient. This includes the patient's first, middle, and last name.	Adapted from HL7 Implementation Guide Alternate Names: • Patient Name: First • Patient Name: Middle • Patient Name: Last
Patient Observation	A factor related to a patient that may have an impact on the forecasting of future doses. It could result in an immunity, a contraindication, or an indication.	From *CDC Logic Specification for ACIP Recommendations* NOTE: This is a broad category that can include concepts that are sometimes defined as individual data elements, such as History of Disease/Titer, contraindication/precautions
Patient Observation End Date	The date a patient observation ended or subsided	
Patient Observation Start Date	The date a patient observation was first observed or is known to have begun	
Patient Phone Number	Patient's personal phone number. This includes the area code and number.	Adapted from *HL7 Implementation Guide*
Patient Primary Language	The primary (or preferred) language of the patient.	Adapted from *HL7 Implementation Guide*
Patient Race	The identified race of the patient	Adapted from *HL7 Implementation Guide*
Protection Indicator	Identifies whether a patient's information may be shared with others	From *HL7 Implementation Guide* Also known as: Consent, Privacy Indicator, Do Not Share NOTE: Local policy determines how data are protected. In general, it indicates who may view the patient's data.
Protection Indicator Effective Date	The date the patient declared his/her protection preference	Adapted from *HL7 Implementation Guide*
Querying System Immunization ID	The unique internal identifier for an immunization as assigned by a Querying System	If an EHR is acting as the querying system, this would be the EHR's unique identifier of the vaccination event. Alternate Names: Vaccination event ID, IIS vaccination event ID
Querying System Patient ID	The unique internal identifier for a patient as assigned by a querying system.	If an EHR is acting as the querying system this would synonymous with the medical record number. Alternate Names: Patient ID, IIS Patient ID
Recommended Date	The date at which the next dose should be given	From *CDC Logic Specification for ACIP Recommendations* NOTE: This is the standard recommended window for vaccination. It is the start of the published recommended windows (e.g., two months, four months, six months) provided the patient is on schedule. See Past Due Date for the end of the recommended window.

FUNCTIONAL GUIDE TERM	DEFINITION	NOTES
Refusal Date	Date the patient/responsible person refused a vaccination	Alternate Names: Exemptions/refusals date
Refusal Reason	The reason the patient/responsible person refused the immunization	From *HL7 Implementation Guide* Alternate Names: Exemption/refusals reason
Relationship to Patient	Actual personal relationship the responsible person has to the patient	From *HL7 Implementation Guide* Alternate Names: Responsible person relationship to patient
Reminder/Recall Preference	How the patient wishes to be contacted in a reminder and/or recall situation	From *HL7 Implementation Guide* Alternate Names: Reminder Recall Status
Reminder/Recall Preference Effective Date	The date the patient declared his/her Reminder/Recall Preference	Adapted from *HL7 Implementation Guide* Alternate Names: Reminder Recall Status Effective Date
Responding System Immunization ID	The unique internal identifier for an immunization as assigned by a responding system	If an IIS is acting as the responding system, this would typically be the internal immunization ID (e.g., primary key on its database table). Alternate Names: Vaccination event ID, IIS vaccination event ID
Responding System Patient ID	The unique internal identifier for a patient as assigned by a Responding System	If an IIS is acting as the responding system, this would typically be an internal patient ID (e.g., primary key on its database table). Alternate Names: Patient ID, IIS Patient ID
Responsible Person Address	A place where a responsible person may be communicated with. This may include the street, city, state, zip, county, country, and type of address.	Adapted from *MIROW 2013 Data Quality Assurance: Selected Aspects*
Responsible Person Date of Birth	The birth date of a responsible person	
Responsible Person Email Address	Personal email address of a responsible person	From *HL7 Implementation Guide*
Responsible Person Name	The primary or legal name of a person responsible for the patient. This includes first, middle, and last parts of the name.	Adapted from *HL7 Implementation Guide* Alternate Names: • Responsible person name: first • Responsible person name: middle • Responsible person name: last
Responsible Person Phone Number	Personal phone number of a responsible person. This includes the area code and number.	Adapted from *HL7 Implementation Guide*
Responsible Person Primary Language	The primary (or preferred) language of the responsible person.	Adapted from *HL7 Implementation Guide*

FUNCTIONAL GUIDE TERM	DEFINITION	NOTES
Series Status	Indicates the status of the patient's progress towards meeting the goals of the series (path to immunity)	From *CDC Logic Specification for ACIP Recommendations*
Social Security Number	A nine-digit number assigned to citizens, some temporary residents and permanent residents in order to track their income and determine benefit entitlements	http://www.investopedia.com/terms/s/ssn.asp
Vaccine Fund Type	A program (or a private payer) that paid for the vaccine	From *MIROW 2017 Decrementing Inventory via Electronic Data Exchange document* NOTE: This term is from the VTrckS ExIS Specification (possible values for direct ship orders: (VFC, 317, state, CHIP). There are also publicly purchased vaccines that are not purchased through VTrckS. Alternate Names: Vaccine fund source (dose level public/private)
Vaccine Funding Program Eligibility	The funding program that should pay for a given immunization	From *HL7 Implementation Guide* NOTE: It is determined based on characteristics of the patient and the type of vaccine administered. Alternate Names: Dose level eligibility
Vaccine Information Statement	A document, produced by CDC, that informs vaccine recipients—or their parents or legal representatives—about the benefits and risks of a vaccine they are receiving	From *NCIRD Vaccine Information Statement* NOTE: Technically this can be exchanged in a couple different manners to identify the document type and version of the document. The concept is the statement itself. How the type and version of the statement are exchanged are outside of the scope of the Functional Guide.
Vaccine Route of Administration	Indicates the route that was used to administer the vaccine	From *HL7 Implementation Guide*
Vaccine Site of Administration	Indicates the body site where the vaccine was administered	From *HL7 Implementation Guide*
Vaccine Type	Identifies the vaccine (group) either administered, evaluated, refused, or forecasted	NOTES from MIROW 2013 Data Quality Assurance: Selected Aspects • The Vaccine Type may indicate a generic or specific type of vaccine (e.g., pneumococcal or PCV13 or PPSV23). • The Vaccine Type can include single types of vaccines as well as combination vaccines, e.g., IPV or IPV-DTaP-HepB. Alternate Names: Vaccine Product
VIS Given Date	The date the Vaccine Information Statement was presented to the patient/responsible person	From *HL7 Implementation Guide* Alternate Names: Vaccine information statement given date

APPENDIX C ACRONYMS

To make sure everyone understands the terms used in the requirements the same way, the following glossary is provided. Wherever possible, definitions were pulled in from previously published material.

Table 11 | *List of acronyms*

ACRONYM	FULL DESCRIPTION
AIRA	American Immunization Registry Association
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
DI-v-EDE	Decrementing Inventory via Electronic Data Exchange
EDE	Electronic Data Exchange
EHR	Electronic Health Record
HL7	Health Level Seven International
IG	Implementation Guide
IIS	Immunization Information System
LOINC	Logical Observation Identifiers Names and Codes
MIROW	Modeling of Immunization Registries Operations Workgroup
SME	Subject Matter Expert
SNOMED	Systematized Nomenclature of Medicine
SSN	Social Security Number
VFC	Vaccines for Children
VIS	Vaccine Information Statement

APPENDIX D FUNCTIONAL GUIDE TO HL7 V2 MAPPING TABLE

This appendix will map the terms used in the Functional Guide to the fields and/or concepts in the National HL7 Implementation Guide release 1.5.

FUNCTIONAL GUIDE TERM	HL7 QBP FIELDS	HL7 RSP FIELDS	NOTES
Administered Amount		RXA-6 and RXA-7	
Administered-at Location		RXA-11	
Administering Provider		RXA-10	
Administration Date		RXA-3	
Adverse Event		OBX-3 and OBX-5	LOINC: 31044-1
Adverse Event Date		OBX-14	
Dose Number in Series		OBX-3 and OBX-5	LOINC: 30973-2
Earliest Date		OBX-3 and OBX-5	LOINC: 30981-5
Entering Organization		ORC-17	
Entering Person		ORC-10	
Evaluation Reason		OBX-3 and OBX-5	LOINC: 30982-3 NOTE: IG does not include a value set. List in Functional Guide needs to be considered in next release of IG.
Evaluation Status		OBX-3 and OBX-5	LOINC: 59781-5 NOTE: IG allows only for dose validity "Y" or "N." Functional Guide currently has more concepts 1 that correspond to "Y," 2 that correspond to "N," and 1 that is somewhere in between (Extraneous). Consideration needs to be given in next release of IG.
Forecast Dose Number		OBX-3 and OBX-5	LOINC: 30972-3 NOTE: IG contains only one concept for dose number in series. Functionally, this shows up as two different concepts, one for evaluation and one for forecasting. This may need to be investigated.

FUNCTIONAL GUIDE TERM	HL7 QBP FIELDS	HL7 RSP FIELDS	NOTES
Forecast Reason		OBX-3 and OBX-5	LOINC: 30982-3
IIS Status		PD1-16	
IIS Status Effective Date		PD1-17	
Immunization Information Source		RXA-9	
Immunization Schedule Used			
Latest Date		OBX-3 and OBX-5	LOINC: 59777-3
Lot Number		RXA-15	
Lot Number Expiration Date		RXA-16	
Manufacturer		RXA-17	
Mother's Maiden Name	QPD-5	PID-6	
Multiple Birth Indicator	QPD-10	PID-24	
Multiple Birth Order	QPD-11	PID-25	
Number of Doses in Primary Series		OBX-3 and OBX-5	LOINC: 59782-3 NOTE: This was intentionally excluded from the Functional Guide, as no existing interfaces used this value and the Functional Guide workgroup didn't find any value in keeping it around. Future IG's may consider deprecating and eventually removing it.
Observation End Date			
Observation Start Date		OBX-14	
Ordering Provider		ORC-12	
Past Due Date		OBX-3 and OBX-5	LOINC: 59778-1
Patient Address	QPD-8	PID-11	
Patient Date of Birth	QPD-6	PID-7	
Patient Death Date		PID-29	
Patient Death Indicator		PID-30	
Patient Email Address	QPD-9	PID-13	
Patient Ethnic Group		PID-22	
Patient Gender	QPD-7	PID-8	
Patient Name	QPD-4	PID-5	

FUNCTIONAL GUIDE TERM	HL7 QBP FIELDS	HL7 RSP FIELDS	NOTES
Patient Observation		OBX-3 and OBX-5	See RSP Message Structure Guidance Document http://repository.immregistries.org/files/resources/5938386822754/guidance_on_message_structure_and_use_of_loinc_codes.pdf
Patient Phone Number	QPD-9	PID-13	
Patient Primary Language		PID-15	
Patient Race		PID-10	
Protection Indicator		PD1-12	
Protection Indicator Effective Date		PD1-13	
Querying System Immunization ID		ORC-3	
Querying System Patient ID	QPD-3	PID-3	
Recommended Date		OBX-3 and OBX-5	LOINC: 30980-7
Refusal Date		RXA-3	
Refusal Reason		RXA-18	
Relationship to Patient		NK1-3	
Reminder/Recall Preference		PD1-11	
Reminder/Recall Preference Effective Date		PD1-18	
Responding System Immunization ID		ORC-3	
Responding System Patient ID	QPD-3	PID-3	
Responsible Person Address		NK1-4	
Responsible Person Date of Birth		NK1-16	
Responsible Person Email Address		NK1-5	
Responsible Person Name		NK1-2	
Responsible Person Phone Number		NK1-5	
Responsible Person Primary Language		NK1-20	

FUNCTIONAL GUIDE TERM	HL7 QBP FIELDS	HL7 RSP FIELDS	NOTES
Series Name		OBX-3 and OBX-5	LOINC: 59780-7 NOTE: This was intentionally excluded from the Functional Guide, as no existing interfaces used this value and the Functional Guide workgroup didn't find any value in keeping it around. Future IG's may consider deprecating and eventually removing it.
Series Status		OBX-3 and OBX-5	LOINC: 59783-1 IG does not include a value set. List in Functional Guide needs to be considered in next release of IG.
Social Security Number		PID-3	With identifier type of "SS"
Vaccine Fund Type		OBX-3 and OBX-5	LOINC: 30963-3
Vaccine Funding Program Eligibility		OBX-3 and OBX-5	LOINC: 64994-7
Vaccine Information Statement		OBX-3 and OBX-5	Preferred method: LOINC: 69764-9 with a barcoded value
Vaccine Type		RXA-5 for administrations and refusals OBX-3 and OBX-5 for evaluation and forecasting	For OBX-3 and OBX-5 LOINC: 30956-7
VIS Given Date		OBX-3 and OBX-5	LOINC: 29769-7

APPENDIX E SELECTED REFERENCES

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