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Ministry of Health



National eHealth Strategy and Change Management Office
(SCMO)

Enabling Standards-Based eHealth Interoperability

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Saudi eHealth Core Interoperability Specification for Immunization

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Document Revision History

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1.0	February 22, 2015	First Release	eHealth Strategy Management Office – eHealth Standards Department

PREFACE

DOCUMENT PURPOSE

The purpose of this document is to address the Saudi eHealth Core Interoperability Specification for the UC0009 *Saudi eHealth Immunization Interoperability Use Case*. It forms a set of requirements that complements the set of IHE Profiles, HL7 and vocabulary Standards required by this specification with eHealth Information Exchange specific constraints. It also aligns with the Saudi e-Government Interoperability Standards (YEFI) to expedite national adoption.

This Core Interoperability Specification is applicable to existing and new information systems that will exchange Health Information. In particular this Interoperability Specification applies to the deployment of eHealth Information Exchange Platforms such as the Saudi Health Exchange (SeHE).

HOW TO READ THIS DOCUMENT

This document contains five normative sections, as well as informative appendices for your convenience. The document is structured as follows:

Section 1: Describes the Use Case, including design constraints and assumptions. Please refer to UC0009 *Saudi eHealth Immunization Interoperability Use Case* for workflows.

Section 2: Establishes the Core Interoperability Requirements for the Interoperability Specification

Section 3: Establishes the Conformance Requirements for the Interoperability Specification

Section 4: Establishes the conformance requirements for the Interoperability Specification to UC0009 *Saudi eHealth Immunization Interoperability Use Case*.

Section 5: Lists the Saudi eHealth reference documents, as well as the international standards which underpin the Interoperability Specification.

Appendix A: illustrates sample documents and messages associated with Immunizations

REFERENCES

The Saudi eHealth Interoperability Core Specification (IS) is the sole entry point for the technology developers, the **assessor/testers and certifiers**, and the purchaser of IT systems in terms of technical requirements.

It references a number of Supporting Interoperability Specifications:

- IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*
- IS0002 *Saudi eHealth Core Interoperability Specification for KSA-Wide Healthcare Provider Directory Query*
- IS0003 *Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*
- IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries*

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification*
- IS0102 *Saudi eHealth Document Sharing Interoperability Specification*
- IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications*
- IS0200 *Saudi eHealth Terminology Repository*

The Saudi eHealth Interoperability Specifications include precise references to internationally adopted profiles and standards as well as Saudi specific constraints. Further descriptions and references for the documents identified below are provided in Section 5 Referenced Documents and Standards

This document fits into an overall specification framework described in **Error! Reference source not found.**

Implementations are required to conform to the requirements within this Interoperability Specification, all Saudi eHealth referenced Interoperability Specifications, and the standards and profiles they specify.

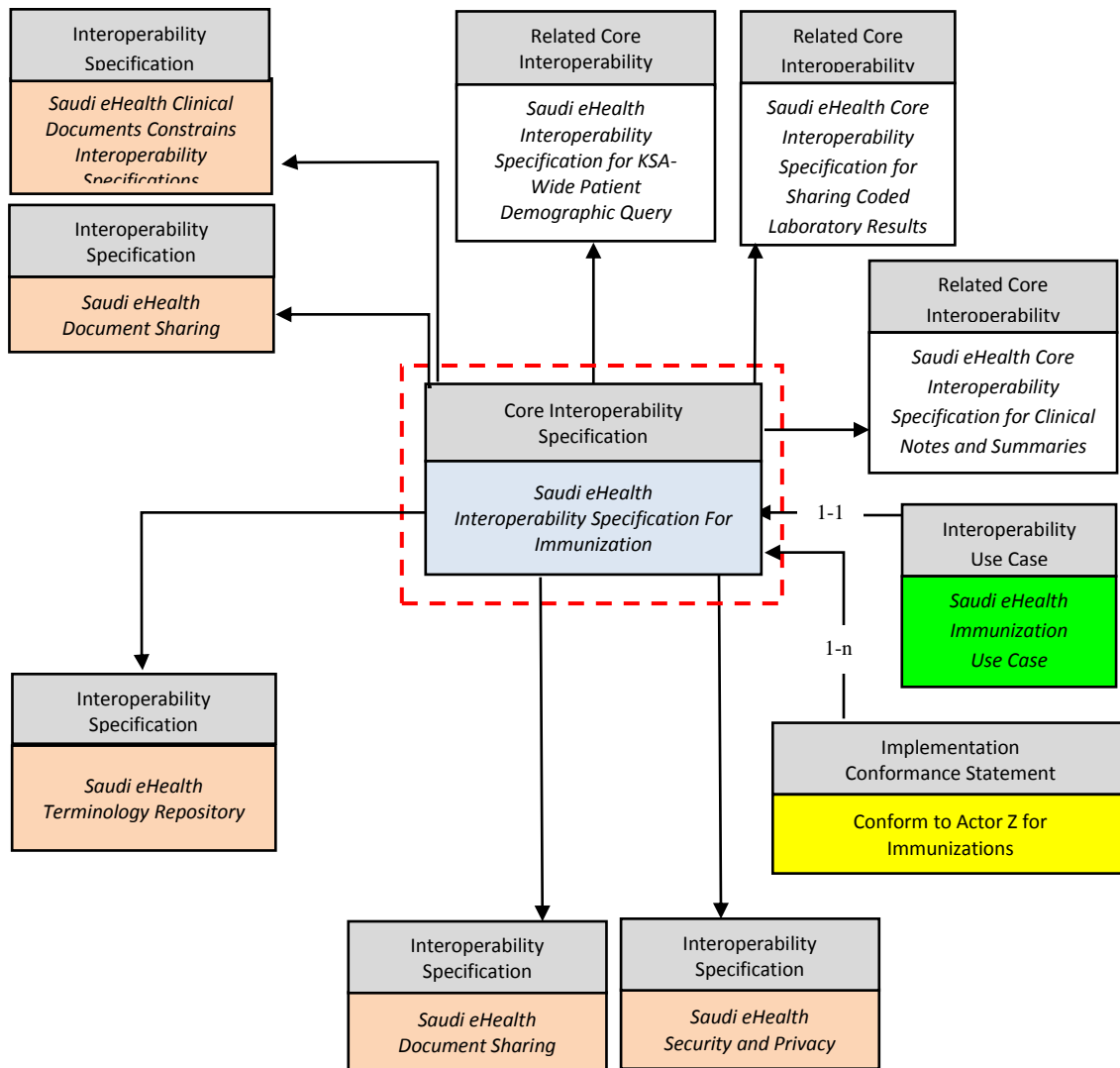


FIGURE I-1 IMMUNIZATION DOCUMENT ORGANIZATION

DESCRIPTION

This Core Interoperability Specification describes the technical interface requirements to support the information exchanges needed to fulfill the requirements of the Saudi eHealth Immunization Use Case, which requires support for vaccination decisions, collection and reporting of vaccination information to the public health system, along with vaccination monitoring. The immunization decision is informed by the patient clinical status including:

- The vaccination history.
- The patient clinical condition.
- The immunization schedule defined by MOH.
- The assessment of vaccinations due as determined by MOH.
- The vaccination record, including the immunizations administered and due dates for pending immunizations, is provided to the patient to inform the patient/parents and to set expectations for the child's immunization needs.

Vaccination monitoring includes support for:

- Patient Education regarding the vaccines administered.
- A summary of vaccinations administered including the vaccine forecast to inform the patient of future immunization requirements as part of the care plan supporting immunizations.

DOCUMENT CONVENTIONS

Requirements Numbering Conventions:

All Saudi eHealth Interoperability Specifications contain numbered requirements that follow this format:

- [ABCD-###], where ABCD is a three or four letter acronym unique to that Interoperability Specification for convenient purposes, and ### is the unique number for that requirement within the Interoperability Specification.
- “Where a specific value set or code is required to be used, it can be found in the “IS0200 Saudi eHealth Terminology Repository”. The location and process to access the terminology repository will be specified in mechanisms external to this document.

Saudi eHealth numbered requirements are the elements of the Interoperability Specification that the system can claim conformance to. In other words, in order to implement a system that fully supports the Use Case and Interoperability Specification, the system shall be able to demonstrate that it conforms to every numbered requirement for the system Actors to which it is claiming conformance.

Please note that all Saudi eHealth numbered requirements are numbered uniquely, however numbered requirements are not always sequential.

Requirements Language

Throughout this document the following conventions¹ are used to specify requirement levels:

SHALL: the definition is an absolute requirement of the specification. (Note: “SHALL IF KNOWN” means that the tag must be sent. However, if there were no information, then this tag should be sent with a <nullflavor>)

SHALL NOT: the definition is an absolute prohibition of the specification.

SHOULD: 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.

SHOULD NOT: 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.

MAY or **OPTIONAL:** means that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item.

METHODOLOGY

This Interoperability Specification has been developed with input from various Saudi stakeholders collected during several months through workshops and teleconferences. Stakeholders included Physicians from many different disciplines (e.g. Pediatricians, Surgeons, Specialists) and Public Health subject matter experts from all over the Kingdom.

The development of a Core Interoperability Specification relies on the high-level requirements set by the associated Use Case. These high-level requirements are not restated in this specification and readers should review UC0009 *Saudi eHealth Immunization Interoperability Use Case*.

¹ Definitions based upon RFC 2119

1. USE CASE OVERVIEW

This section provides an overview of the Immunizations Use Case. For full details see UC0009 *Saudi eHealth Immunization Interoperability Use Case*.

This section describes the driving Use Case, including all design constraints and assumptions as well as the flows of information that describe how the specified workflows may be used in the eHealth Information Exchange Platform context.

1.1 SCOPE

In Scope:

The scope of this document is the specification of bi-directional communication of immunization information both from the perspective of clinical care needs and public health monitoring and management.

The following topics are in scope for this Use Case Specification:

- Providing to the clinician the information needed to determine that a vaccination should be administered at the time of a clinical encounter.
- Reporting to public health that a vaccination has been administered.
- Communicating to the patient the relevant information about current and pending immunizations.

The scope of this document is further constrained as follows:

- Immunization Summaries may only be shared for patients with KSA-Wide Health IDs. Any person who is legally in Saudi Arabia may obtain a KSA-Wide Health ID. This includes newborns and foreign visitors who are assigned KSA-Wide Health IDs during the initial hospital encounter, and unidentified patients who are assigned temporary Health IDs which will later need to be reconciled with the patient's permanent KSA-Wide Health ID.

Out of Scope:

The following is a list of content and specifications that are specifically out of scope for this Interoperability Specification:

- The clinical encounter and specific patient flow within the encounter.
- Details associated with overlapping aspects of Use Cases that are covered in other Interoperability Specifications.
- Batch immunizations.
- The method by which the Immunization Data in the Immunization Data Repository is populated.
- The method by which the Clinical Data from Clinical Documents or otherwise sourced Clinical Data is populated into the Clinical Data Repository.
- The specification of a Clinical Knowledge Directory is out of scope as the clinical knowledge request and response capabilities are specific to Immunization education support.

1.2 USE CASE ACTORS AND SERVICES

The Use Case Actors and the Services that are used by IS0010 *Saudi eHealth Core Interoperability Specification for Immunization*. Readers that wish to understand the mapping of Use Case Actors to real world products are recommended to read this Saudi eHealth Interoperability Use Case document. A summary is provided in the following tables.

TABLE 1.2-1 USE CASE ACTORS

USE CASE ACTOR NAME	DESCRIPTION
HIE Document Repository	Stores documents such as Immunization Documents, including documents supporting the patient immunization card. It also provides access to related information about the patient and/or about the patient's medical documentation. Submits Immunization Reports for vaccines administered to the patient to the Immunization Data Repository.
Clinical Data Repository	Maintains detailed demographic and clinical data for each patient. The Clinical Data Repository responds with clinical data in response to queries from the Immunization Document Source to construct the On-Demand Immunization Summary. Receives updates on immunizations from the Immunization Data Repository.
Immunization Data Repository	Responds with immunization data as the authoritative source of immunization information using the Immunization Registry (e.g., MOH Health Electronic Surveillance Network (HESN)) in response to queries from the Immunization Document Source to construct the On-Demand Immunization Summary. Receives immunization reports and incorporating the information regarding the vaccines administered into the Immunization Registry. Sends updates on Immunizations received to the Clinical Data Repository.
Immunization On-Demand Document Source	Creates the on-demand immunization summary and Immunization card content, and provides this content through an on-demand based interaction with the Immunization Data Repository (Immunization Registry) and the clinical data currently stored in the Clinical Data Repository.
Immunization Summary Content Consumer	Queries and retrieves the Immunization Summary information for viewing, importing, or other processing of content from the Document Repository. This requires support for on-demand document query to enable query for dynamically generated documents constructed through the Document Repository's interaction with the Immunization Registry.
Immunization Card Content Creator	Creates the Immunization Card content that is provided to the patient as an electronic document that represents the same information as is communicated on the paper immunization card. This includes support for 'proof of immunization' in support of Hajj as per Saudi Ministry of Health policy.
Immunization Card Content Consumer	Queries and retrieves the Immunization Card information from the Document Repository or from portable media, including email, provided by the patient. NOTE: the Immunization Card Content Consumer is primarily intended to be supported by patient-directed applications (e.g. Personal Health Record). It is expected that connected provider systems would support the Immunization Summary Content Consumer.
Immunization Education Requestor	Responsible for requesting education information related to the Immunizations provided to the patient
Immunization Education Responder	Responsible for providing the education material and responses to requests for education information.

How implementations support Use Case Actors may vary. For example, some implementations may support a Use Case Actor entirely by a single system, while other implementations may support a Use Case Actor using a gateway system integrated with the point of service system.

The typical implementation architecture aligns the Use Case Actors capabilities as defined in this Core Interoperability Specification with a single system or integrated set of systems under the design and responsibility of one vendor. In specific implementation situations, the vendor boundary may not align with the Use Case Actor. For example, a point of service system from one vendor and a gateway system which converts the point of service system to the Use Case Actor from a different vendor. The interface between the two systems is not specified by this Core Interoperability Specification and is the responsibility of the implementation project.

TABLE 1.2-2 USE CASE SERVICES

SERVICE NAME	DESCRIPTION
Report Immunization	Communicates the immunization event to and from public health.
Publish On-Demand Immunization Documents	Publishes records that show the Immunization Summary and Immunization Card documents are available from the Immunization Registry. This will be constructed at the time of query for this document.
Retrieve On-Demand Immunization Summary	Generates dynamic immunization summaries by querying the Immunization Data Repository (Immunization Registry, e.g., MOH HESN) and the Clinical Data Repository.
Provide Immunization Education	Queries and responds with Immunization Education materials pertaining to the vaccination that is the subject of the education materials request.
Query Existing Data	Supports retrieval of detailed clinical data for a patient from the Clinical Data Repository, and the retrieval of immunization history and vaccine forecast from the Immunization Data Repository.
Retrieve On-Demand Immunization Card	Generates dynamic immunization cards by querying the Immunization Data Repository (Immunization Registry, e.g., MOH HESN). NOTE: This Service is intended for use by non-clinical systems (e.g. Personal Health Record). KSA clinical systems SHALL use the Retrieve On-Demand Immunization Summary.
Update Immunization Card	Supports the creation of the Immunization Card. The Immunization Card output to portable media to be provided to the patient.

1.3 DESIGN CONSTRAINTS AND ASSUMPTIONS

The following design principles underlie this interoperability specification:

- It is expected that all services initiated or provided by these Actors operate in accordance to the Saudi eHealth Information Exchange Polices.

- The KSA-Wide Patient Demographic Query is used to obtain a Health ID and demographic attributes for the patient that is the subject of the immunization. The actors and transactions associated with patient identification are fully specified in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.
- Temporary KSA-Wide Health IDs can be created to enable the sharing of critical Immunization Summaries.
- A permanent KSA-Wide Health ID can be created for a newborn.
- The vaccination decision may be informed by order and review of laboratory results. The actors and transactions associated with laboratory orders and results are fully specified by the IS0003 *Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*.
- The vaccinations are provided as part of a clinical encounter, and once the vaccinations that are part of the encounter are shared as part of the clinical summary with the HIE, the information is available for the Document Repository to generate the report using this information. The clinical summary actors and transactions associated with the encounter are fully specified in IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries*.

2. CORE INTEROPERABILITY SPECIFICATION REQUIREMENTS

2.1 ACTOR MAPPING TO SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS

A system conforming to this Core Interoperability Specification shall claim conformance at the level of a Use Case Actor. A system may claim conformance to one or more Use Case Actors. Multiple systems may fulfill a Use Case Actor.

The Use Case Actors and the Services they support are described at a functional level in the Saudi eHealth Interoperability Use Case document. Services may be required, conditional or optional. The Use Case Actors, Service(s) and Optionality are conveyed in the first three columns of Interoperability Conformance Requirement tables shown below.

The second part of the table (columns 4-7) provides the mapping for the Use Case Actor to the detailed specifications (such as IHE Profiles, Technical Actors, Optionality) that systems shall implement to exchange healthcare information in the context of this Use Case.

For a selected Use Case Actor (a single row in the table), all the requirements listed in the second part of the table (columns 4-7) shall be implemented. This includes the referenced profiles and the standards specified (terminology or other). For each Technical Actor (whether required or optional), the last column references the detailed specification that constrain and extend of the implementation of this profile for KSA specific requirements. These specifications may be found in Sections in this core specification or in other referenced Saudi eHealth Interoperability Specifications (e.g. Saudi eHealth Security and Privacy Interoperability Specification, etc.).

TABLE 2.1-1 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMMUNIZATION SUMMARY ON-DEMAND DOCUMENT SOURCE ACTOR

IMMUNIZATIONS			MAPPING TO TECHNICAL CONSTRUCTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
Immunization On-Demand Document Source	Publish On-Demand Immunization Documents	R	Content Creator	R	IHE – Immunization Content (IC)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Sections 5.9 and 5.10

IMMUNIZATIONS			MAPPING TO TECHNICAL CONSTRUCTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
			On-Demand Document Source	R	IHE – Cross-Enterprise Document Sharing (XDS.b) IHE – On-Demand Documents	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.3 and 3.6
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Query Existing Data	R	Immunization Record Seeker	R	HL7 V3 Immunization (POIZ_AR99020 4UV01)	See Section 4.1
			Immunization Record Seeker with the Additional Immunization Queries Option	O	HL7 V3 Immunization (POIZ_AR99020 4UV01)	See Section 3.1.1
			Clinical Data Consumer	R	IHE –Query for Existing Data	See Section 4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

TABLE 2.1-2 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMMUNIZATION SUMMARY
CONTENT CONSUMER

IMMUNIZATIONS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
Immunization Summary Content Consumer	Retrieve On-Demand Immunization Summary	R	Document Consumer	R	IHE – Cross-Enterprise Document Sharing (XDS.b) IHE – On-Demand Documents	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Sections 3.3 and 3.6
			Content Consumer	R	IHE – Immunization Content (IC)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.9
			X-Service User	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.1
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

*TABLE 2.1-3 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMMUNIZATION CARD CONTENT
CREATOR ACTOR*

IMMUNIZATIONS			MAPPING TO TECHNICAL CONSTRUCTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/STANDARD	REFERENCED SPECIFICATION
Immunization Card Content Creator	Update Immunization Card	R	Content Creator	R	IHE – Immunization Content (IC)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.10
			Portable Media Creator	R	IHE – Cross-Enterprise Document Media Interchange (XDM)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.2

R=Required, O = Optional, C= Conditional

*TABLE 2.1-4 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMMUNIZATION CARD CONTENT
CONSUMER*

IMMUNIZATIONS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/STANDARD	REFERENCED SPECIFICATION
Immunization Card Content Consumer	Retrieve On-Demand Immunization Card	R	Document Consumer	R	IHE – Cross-Enterprise Document Sharing (XDS.b) IHE – On-Demand Documents	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Sections 3.3 and 3.6
			Content Consumer	R	IHE – Immunization Content (IC)	IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.10
			X-Service User	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.1

IMMUNIZATIONS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/STANDARD	REFERENCED SPECIFICATION
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.2
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

TABLE 2.1-5 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR CLINICAL DATA REPOSITORY

IMMUNIZATIONS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/STANDARD	REFERENCED SPECIFICATION
Clinical Data Repository	Query Existing Data	R	Clinical Data Source	R	IHE –Query for Existing Data (See Note 1)	See Section Requirements for Clinical Data Repository
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Report Immunization	R	Immunization Recorder	R	HL7V3 Immunization (POIZ_AR9901 04UV01)	See section 4.7
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability

IMMUNIZATIONS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/STANDARD	REFERENCED SPECIFICATION
						Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

Note 1: The Clinical Data Repository **SHALL** support the following IHE-Query for Existing Data [QED]
Options: Vital Signs, Problems and Allergies, Diagnostic Results, Medications, Immunizations and Professional Services.

TABLE 2.1-6 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR HIE DOCUMENT REPOSITORY

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/STANDARD	REFERENCED SPECIFICATION
HIE Document Repository	Publish On-Demand Immunization Documents	R	Document Repository	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.4
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Retrieve On-Demand Immunization Summary and Retrieve On-Demand Immunization Card	R	Document Registry and Document Repository	R	IHE – Cross-Enterprise Document Sharing (XDS.b)	IS0102 Saudi eHealth Document Sharing Interoperability Specification – Section 3.4
			X-Service Provider	R	IHE – Cross-Enterprise User Assertion (XUA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.4.2
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1

CLINICAL NOTES AND SUMMARIES			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Report Immunization	R	Immunization Recorder	R	HL7V3 Immunization (POIZ_AR990 104UV01)	See section 4.6
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

TABLE 2.1-7 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMMUNIZATION DATA REPOSITORY

IMMUNIZATIONS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
Immunization Data Repository	Query Existing Data	R	Immunization Query Responder	R	HL7V3 Immunization (POIZ_AR9902 06UV01)	See Section 4.7
			Immunization Query Responder with the Additional Immunization Queries Option	R	HL7V3 Immunization (POIZ_AR9902 06UV01)	See Section 4.7

IMMUNIZATIONS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2
	Report Immunization	R	Immunization Repository (HL7V3)	R	HL7V3 Immunization (POIZ_AR9901 06UV01)	See Section 4.7
			Immunization Recorder	R	HL7V3 Immunization (POIZ_AR9901 04UV01)	See section 4.6
			Secure Node	R	IHE Audit Trail and Node Authentication (ATNA)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Sections 3.2 and 3.3.1
			Time Client	R	IHE Consistent Time (CT)	IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

R=Required, O = Optional, C= Conditional

Note 2: The Immunization Data Repository **SHALL** support the following IHE-Query for Existing Data Options: Immunizations.

TABLE 2.1-8 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMMUNIZATION EDUCATION REQUESTOR

IMMUNIZATIONS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION
Immunization Education Requestor	Provide Immunization Education	R	Clinical Knowledge Requestor	R	IHE Retrieve Clinical Knowledge (RCK)	See Section 4.5

R=Required, O = Optional, C= Conditional

TABLE 2.1-9 INTEROPERABILITY CONFORMANCE REQUIREMENTS FOR IMMUNIZATION EDUCATION RESPONDER

IMMUNIZATIONS			MAPPING TO TECHNICAL DOCUMENTS OF SAUDI EHEALTH INTEROPERABILITY SPECIFICATIONS			
USE CASE ACTOR	SERVICE SUPPORTED	OPT	TECHNICAL ACTOR	OPT	PROFILE/ STANDARD	REFERENCED SPECIFICATION AND COMMENTS
Immunization Education Responder	Provide Immunization Education	R	Clinical Knowledge Resource Repository	R	IHE Retrieve Clinical Knowledge (RCK)	See section 4.5

R=Required, O = Optional, C= Conditional

2.2 INTEROPERABILITY SEQUENCE DIAGRAMS

The following Sequence diagrams provide an overview of the combined flow of transactions resulting from the above selected profiles and standards. The Main Flow Sequence Diagram illustrates a very common (i.e., typical) workflow and other sequence diagrams are shown to provide an alternative or exception to the main flow. Other sequence diagrams are possible but they cover the same key transactions with only slight variants of information exchange between the Use Case Actors, therefore, have been omitted.

There are three Main and one Alternative Flow Sequence Diagrams. In addition, a number of pre-conditions and other requirements exist.

2.2.1 Sequence Diagram Pre-conditions

A number of pre-conditions must exist in order to enable the main and alternate sequence diagrams.

- First, prior to retrieving documents from the HIE Document Repository; the Healthcare Provider or Organization **SHALL** obtain the patient's KSA-Wide Health ID. The requirements on how to obtain a patient's KSA-Wide Health ID and key patient demographics are defined in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*. The Health ID and key patient demographics attributes are used to identify the patient for which the documents and reports are shared. This ensures KSA-Wide identification of the patient in health records. This is not shown in any of the sequence diagrams, and the details to accomplish this are defined in IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.
- Second, the IHE XDS.b: [Register Document Set – b ITI-42] transaction is listed without first performing the authentication between the two systems [IHE ATNA Profile: Authenticate Node ITI-19]. This is because it is very common that the IHE Document Repository and Registry actors are implemented within the same

system. If these Actors are implemented in separate systems the authentication transaction would be required.

The following transactions must occur prior to the start of the main or alternate Sequences:

1. Time synchronization **SHALL** occur at least once prior to communicating between the HIE System and the Document Consumer.
2. Before the information exchanges can take place, an authentication process takes place between the Document Consumer/Secure Node Actor and the Document Repository System/Secure Node Actor occurs [IHE ATNA Profile: Authenticate Node ITI-19].

Note: It is assumed that once a secure connection has been established, it will be maintained. If this is not the case, then an additional authentication transaction will need to occur before continuing any exchange transactions.

Figure 2.2.1-1 Pre-condition Sequence Diagram depicts the pre-condition in the case that the Document Consumer is acting as a Document Source or as a Document Consumer.

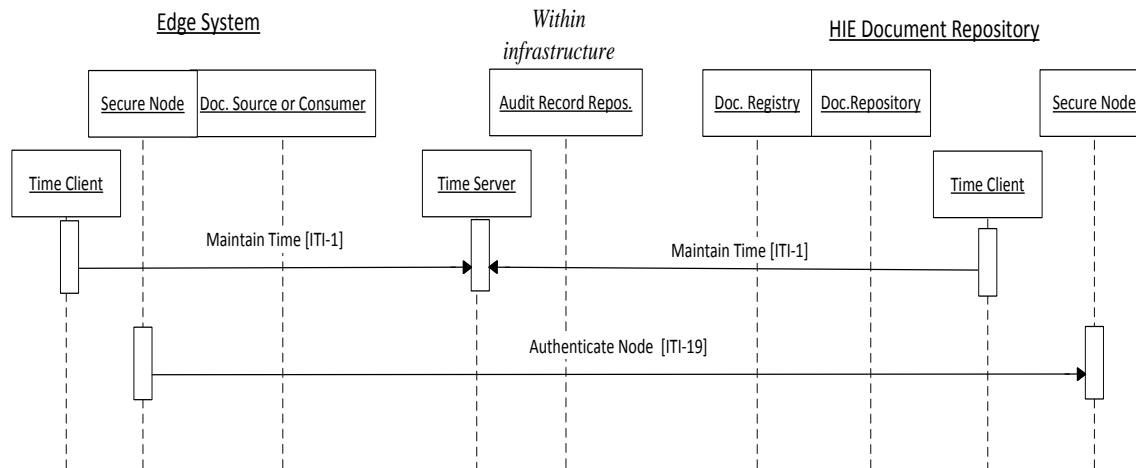


Figure 2.2.1-1 Pre-condition Sequence Diagram

2.2.2 Other Sequence Diagram Requirements

In order to simplify the sequence diagrams, the following transaction pairing should be taken into account.

2.2.2.1 Registry Stored Query to the HIE Document Repository

Query depicts the transactions associated with a Registry Stored Query. When a query is made from the Document Consumer to the HIE Document Repository, the following transactions **SHALL** all take place.

1. The Document Consumer sends a query request. As part of the query request, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an

- authorized user to obtain patient information [IHE XDS-b: Registry Stored Query ITI-18] and [IHE XUA: Provide X-User Assertion ITI-40].
- The Document Consumer /Secure Node generates a local audit record of the access to patient health information using the data content as defined by IHE ATNA Profile and the appropriate technical actor's ATNA conformance requirements in Section 3 Immunizations Actor Conformance [IHE ATNA Profile: Record Audit Event ITI-20].

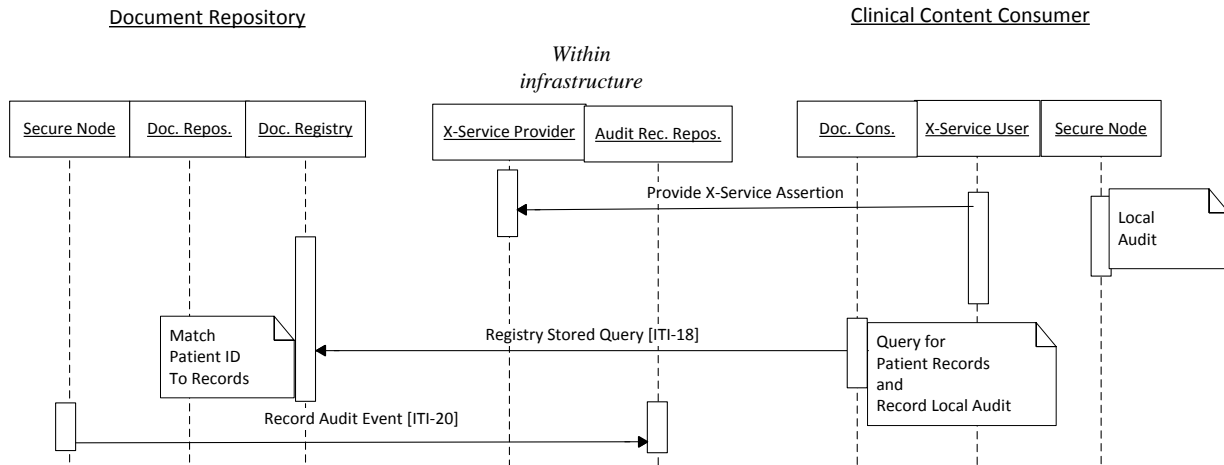


FIGURE 2.2.2-1 TRANSACTIONS ASSOCIATED WITH A REGISTRY STORED QUERY

2.2.2.2 Document Retrieval from the HIE Document Repository

Error! Reference source not found. depicts the transactions associated with document retrieval from the HIE Document Repository. When document(s) are retrieved from the HIE Document Repository, the following transactions **SHALL** all take place.

- The Document Consumer/X-Service User retrieves the document(s). As part of the retrieve, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40]. An internal audit record by document consumer actor.
- The Document Repository/Secure Node generates an audit record of the access to patient health information [IHE ATNA Profile: Record Audit Event ITI-20].

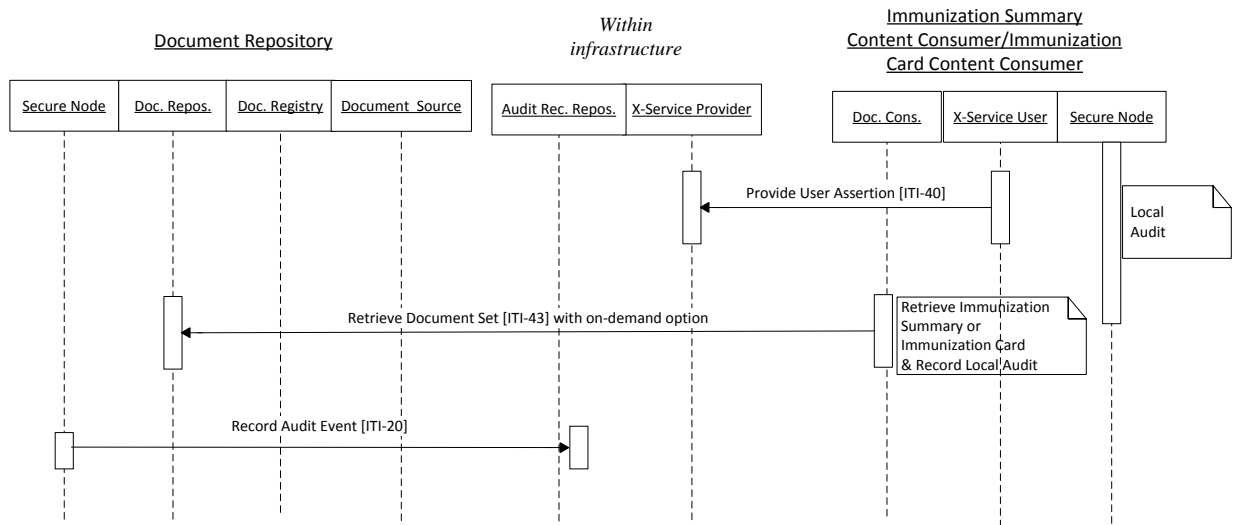
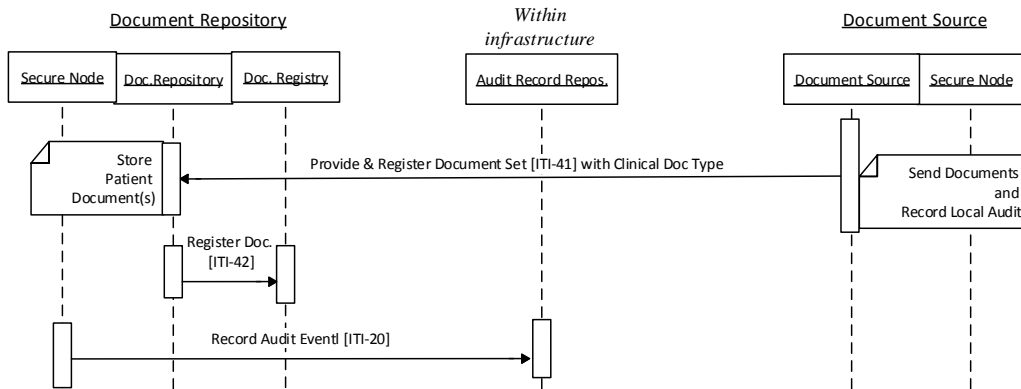


FIGURE 2.2.2-2 TRANSACTIONS ASSOCIATED WITH DOCUMENT RETRIEVAL

2.2.2.3 Publish Document(s) to the HIE Document Repository



depicts the transactions associated with storage of document(s) to the HIE Document Repository. When document(s) are stored to the HIE Document Repository, the following transactions **SHALL** all take place:

1. The Document Source/Secure Node sends the document set to the Document Repository. [Provide & Register Document Set [ITI-41] with Clinical Doc Type].
2. The HIE Document Repository registers the document with the HIE Document Registry [IHE XDS.b: Register Document Set – b ITI-42].
3. The Document Source/Secure Node generates a local audit record of the release of patient health information [using the data content as defined by IHE ATNA Profile] and

the Document Repository/Secure Node generates an audit record of the receipt of patient health information [IHE ATNA Profile: Record Audit Event ITI-20].

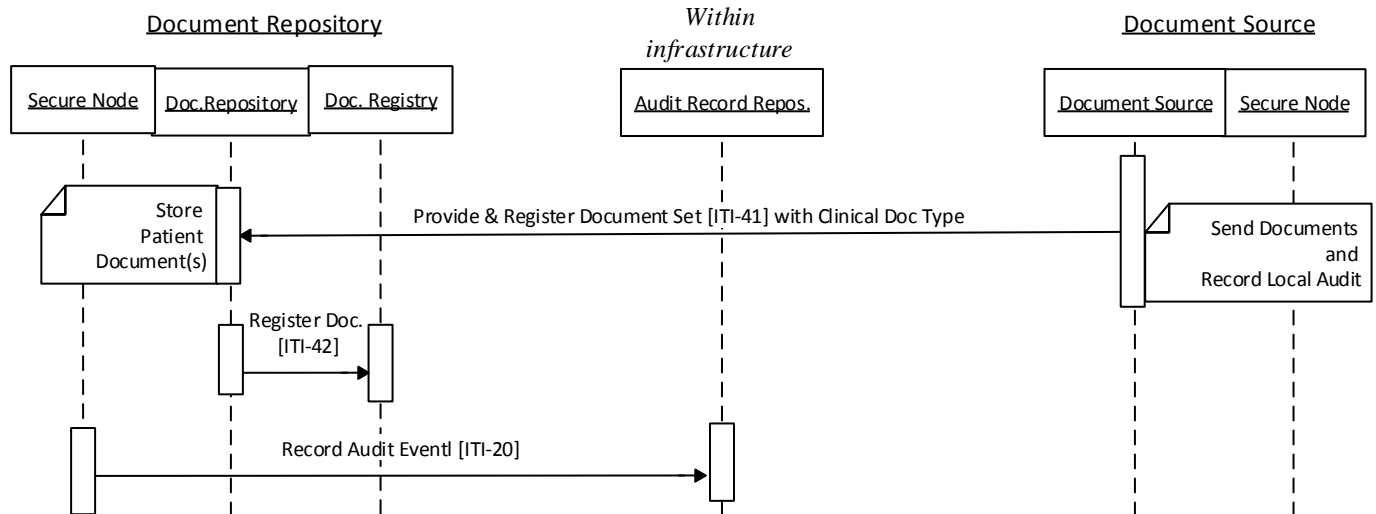


FIGURE 2.2.2-3 TRANSACTIONS ASSOCIATED WITH PUBLISH DOCUMENT

2.2.3 Immunizations Main Flow Sequence Diagrams

The Immunizations Main flow sequence diagrams provide a high level sequence of events for the exchange of information for retrieving On-Demand Immunization Summaries, Reporting Immunizations, Updating the Immunization Card, and Providing Patient Education. It also illustrates typical security exchanges for authorized network communications and audit trail of patient information access.

The main flow described below is broken out into the sequence diagram in the sub-sections below. These sequence diagrams depict Use Case Actors and a number of transactions between IHE Profile Actors specified in the tables in Section 2.1 Actor Mapping to Saudi eHealth Interoperability Specifications.

The main flow sequence starts with a scenario where a patient comes to a physician for receiving clinical care. The physician requests the medical history with information relative to the immunization decision to inform the decision of whether or not to vaccinate the patient. The patient is vaccinated based upon review of the immunization summary at the time of the patient encounter, and the vaccination is reported to the immunization registry by the HIE document repository.

The following steps describe main flow of events for the Immunizations

Note: all systems are secured with ATNA Authenticate Node [ITI-19] and CT Maintain Time [ITI-1]:

1. **Audit:** All actors are responsible for maintaining an audit logs for these transactions. PHCs may do so locally, whereas all other infrastructure nodes record the logs in the Infrastructure Audit Record Repository supporting the HIE Document Repository.

2. Retrieve Patient Histories: The patient visits a Healthcare Provider or Organization for care. The patient history relative to the immunization is retrieved through a query to the HIE Repository. The Healthcare Provider or Organization retrieves an On-Demand Immunization Summary using the On-Demand Immunization Summary Document Consumer/X-Service User which queries the Document Registry/X-Service Provider using the patient's KSA-Wide Health ID to locate On-Demand Immunization Summaries available at the time of the visit. [IHE XDS-b: Registry Stored Query ITI-18]. As part of the query, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XUA: Provide X-User Assertion ITI-40].
3. Query Registry for On-Demand Immunization Summary: The HIE Repository processes the query and responds with the information needed to retrieve the On-Demand Immunization Summary [IHE XDS-b: Registry Stored Query ITI-18].
4. Start Retrieval On-Demand Document: The Healthcare Provider or Organization uses the On-Demand Immunization Summary Document Consumer to retrieve the On-Demand Immunization Summary Document (e.g. Pre-fetch). As part of the retrieve, a user assertion is conveyed to verify that the Healthcare Provider or Organization is an authorized user to obtain patient information [IHE XDS-b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40].
 - 4.1 Request Clinical and Immunization Data: The On-Demand Document Source retrieves discrete clinical data through a query to the Clinical Data Repository using the patient's KSA-Wide Health ID to retrieve the clinical data [IHE PCC QED Profile: Query for Existing Data PCC-1], and to the Immunization Data Repository's (the Immunization Registry, (e.g. MOH HESN)) HL7v3 Immunization Query Responder actor [HL7v3 Patient Immunization Status Query Request (POIZ_IN070010UV01)].
 - 4.2 Respond with Clinical Data: The Clinical Data Repository process the query that was issued by the On-Demand Document Source and respond with the clinical data needed to create the clinical aspects of a new On-Demand Immunization Summary Document [IHE PCC QED Profile: Query for Existing Data PCC-1].
 - 4.3 Respond with Immunization Data: The Immunization Data Repository's HL7v3 Information Query Responder Actor (POIZ_AR990206UV01) process the query [Patient Immunization Status Query Request (POIZ_IN070010UV01)] for all immunizations for the patient (Note: the query could be constrained by timeframe) and responds with the immunization and vaccine forecast data needed to complete the creation of the On-Demand Immunization Summary Document [Patient Immunization Status Query Response (POIZ_IN070020UV01)].
 - 4.4 Construct and Return Immunization Summary Document: The On-Demand Document Source uses the data from these two queries to construct the Immunization Summary Document. The On-Demand Document Source returns this summary in response to the On-Demand Immunization Summary Document Consumer request to retrieve the On-Demand Immunization Summary.
5. Review Immunization Summary Document: The patient immunization history from this query response is reviewed along with the relevant clinical information needed for

- indications and for contraindications prior to administering the vaccination to determine vaccinations that will be administered (or not administered) during the visit.
6. Record Vaccination Information in EMR: The patient is vaccinated and the information is recorded in the provider EMR. Following the vaccination, the patient is provided with an updated Immunization Card using the Immunization Card Content Creator Actor [IHE ITI-32]. The patient may access this Immunization Card through patient targeted tools (e.g. Personal Health Record) using the Immunization Card Content Consumer Actor.
 7. Provide Education Materials: The patient and/or guardian is/are provided with education materials regarding the vaccine administered. The education information is requested by the Immunization Education Requestor and the information is provided by the Immunization Education Responder [IHE PCC-14].
 8. Publish Encounter Summary: The Clinical Summary is published for the visit including information regarding vaccinations administered (or not administered) to the HIE Document Repository using the Clinical Summary Content Creator. The requirements on how to publish the Clinical Summary are defined in IS0007 *Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries*.
 9. Report Vaccination to the Immunization Registry: The HL7v3 Immunization Recorder (POIZ_AR990104UV01) actor reports the vaccination to the Immunization Registry as the HL7v3 Immunization Repository (POIZ_AR990106UV01) actor by the HIE Document Repository using the HL7 V3 Record Immunization Request (POIZ_IN010020UV01) transaction through an HIE service that extracts the immunization reporting content to be used. This is received by the Immunization Report Recipient where the information is incorporated into the Immunization Registry (e.g. MOH HESN).
 10. Register On-Demand Immunization Card: The patient On-Demand Immunization Summary is registered to the Registry by the On-Demand Document Source Actor [IHE ITI-61]. This allows for the patient to access their Immunization Card through a Personal Health Record.
 11. Provide Immunization Card to Patient: Export electronic immunization card content and provide it to the patient.
 12. The patient requests the Immunization Card through a Personal Health Record: The HIE Repository processes the query and responds with the information needed to retrieve the On-Demand Immunization Card [IHE XDS-b: Registry Stored Query ITI-18].
 13. Start Retrieval On-Demand Immunization Card Document: The Patient's Personal Health uses the On-Demand Immunization Card Document Consumer to retrieve the On-Demand Immunization Card Document. As part of the retrieve, a user assertion is conveyed to verify that the Personal Health Record is an authorized user to obtain patient information [IHE XDS-b: Retrieve Document Set ITI-43] and [IHE XUA: Provide X-User Assertion ITI-40].
 - 13.1 Request Card Immunization Data: The On-Demand Document Source retrieves discrete immunization history and forecast data through a query to the Immunization Data Repository's (the Immunization Registry, (e.g. MOH HESN)) HL7v3 Immunization Query Responder actor [HL7v3 Patient Immunization Status Query Request (POIZ_IN070010UV01)].
-

- 13.2 Respond with Card Immunization Data: The Immunization Data Repository's HL7v3 Information Query Responder Actor (POIZ_AR990206UV01) process the query [Patient Immunization Status Query Request (POIZ_IN070010UV01)] for all immunizations for the patient (Note: the query could be constrained by timeframe) and responds with the immunization and vaccine forecast data needed to complete the creation of the On-Demand Immunization Card Document [Patient Immunization Status Query Response (POIZ_IN070020UV01)].
- 13.3 Construct and Return Immunization Card Document: The On-Demand Document Source uses the data from this query to construct the Immunization Card Document. The On-Demand Document Source returns this summary in response to the On-Demand Immunization Card Document Consumer request to retrieve the On-Demand Immunization Card.

14.

2.2.3.1 Main Flow Sequence Diagram-Reporting Immunizations and On-Demand Immunization Summaries

Figure 2.2.3-1 Immunizations Main Flow Sequence Diagram for Reporting Immunizations and On-Demand Immunization Summaries shows the flows for publishing the creation of the new Immunization Report from the Clinical Summary that is published at the end of a visit, and the publication of the On-Demand Immunization Summary. This diagram also shows the flows for subsequent query and retrieval of the On-Demand Immunization Summary and its composition from the HL7v3 Immunization Status Query Request (POIZ_IN070010UV01) to the Immunization Data Repository and the Query Existing Data (QED) query to the Clinical Data Repository (Note: the query could be constrained by timeframe). This reflects steps 1-6 and 8-9 of the main immunization flow detailed in section 2.2.3 Immunizations Main Flow Sequence Diagrams:

- Step 1: Audit
- Step 2: Retrieve Patient Histories
- Step 3: Query Registry for On-Demand Immunization Summary
- Step 4: Start Retrieval On-Demand Document
 - Step 4.1: Request Clinical and Immunization Data
 - Step 4.2: Respond with Clinical Data
 - Step 4.3: Respond with Immunization Data
 - Step 4.4: Construct and Return Immunization Summary Document
- Step 5: Review Immunization Summary Document
- Step 6: Record Vaccination Information in EMR
- Step 8: Publish Encounter Summary:
- Step 9: Report Vaccination to the Immunization Registry

NOTE: the reporting is triggered at the end of the visit and begins with the publication of the routine Clinical Summary for the visit that included a vaccination.

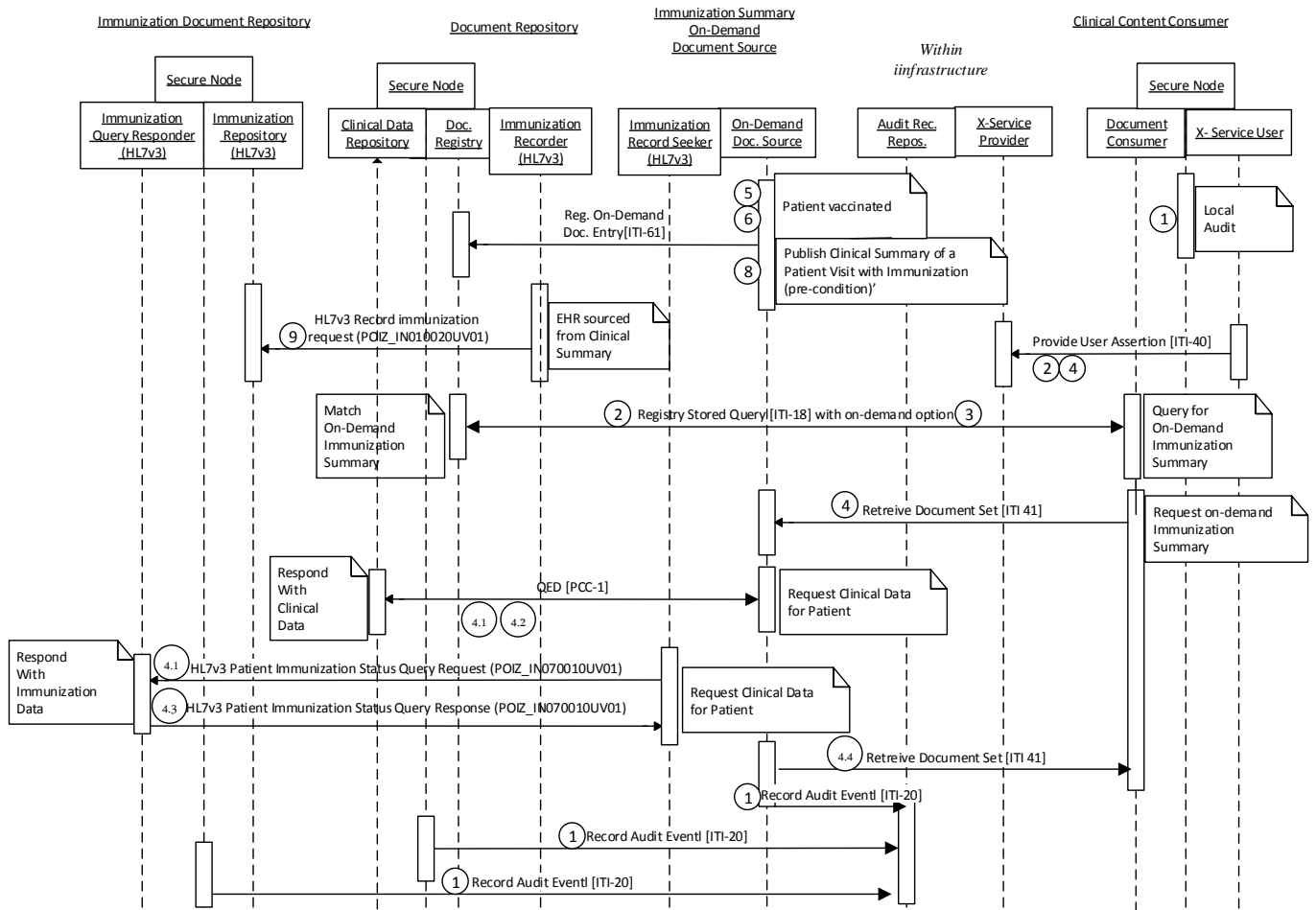


FIGURE 2.2.3-1 IMMUNIZATIONS MAIN FLOW SEQUENCE DIAGRAM FOR REPORTING IMMUNIZATIONS AND ON-DEMAND IMMUNIZATION SUMMARIES

2.2.3.2 Main Flow Sequence Diagram-Immunization Card

Figure 2.2.3-2 Immunizations Main Flow Sequence Diagram for Immunization Card shows the flows for registering and publishing the updated On-Demand Immunization Card to the HIE Document Repository and to provide the patient the Immunization Card on portable media. This reflects steps 1, 8, and 10-13 of the main immunization flow detailed in section 2.2.3 Immunizations Main Flow Sequence Diagrams:

- Step 1: Audit
- Step 8: Publish Encounter Summary
- Step 10: Register On-Demand Immunization Card
- Step 11: Provide Immunization Card to Patient
- Step 12: The patient requests the Immunization Card through a Personal Health Record
- Step 13: Start Retrieval On-Demand Immunization Card Document:

- Step 13.1: Request Card Immunization Data
- Step 13.2: Respond with Card Immunization Data
- Step 13.3: Construct and Return Immunization Card Document

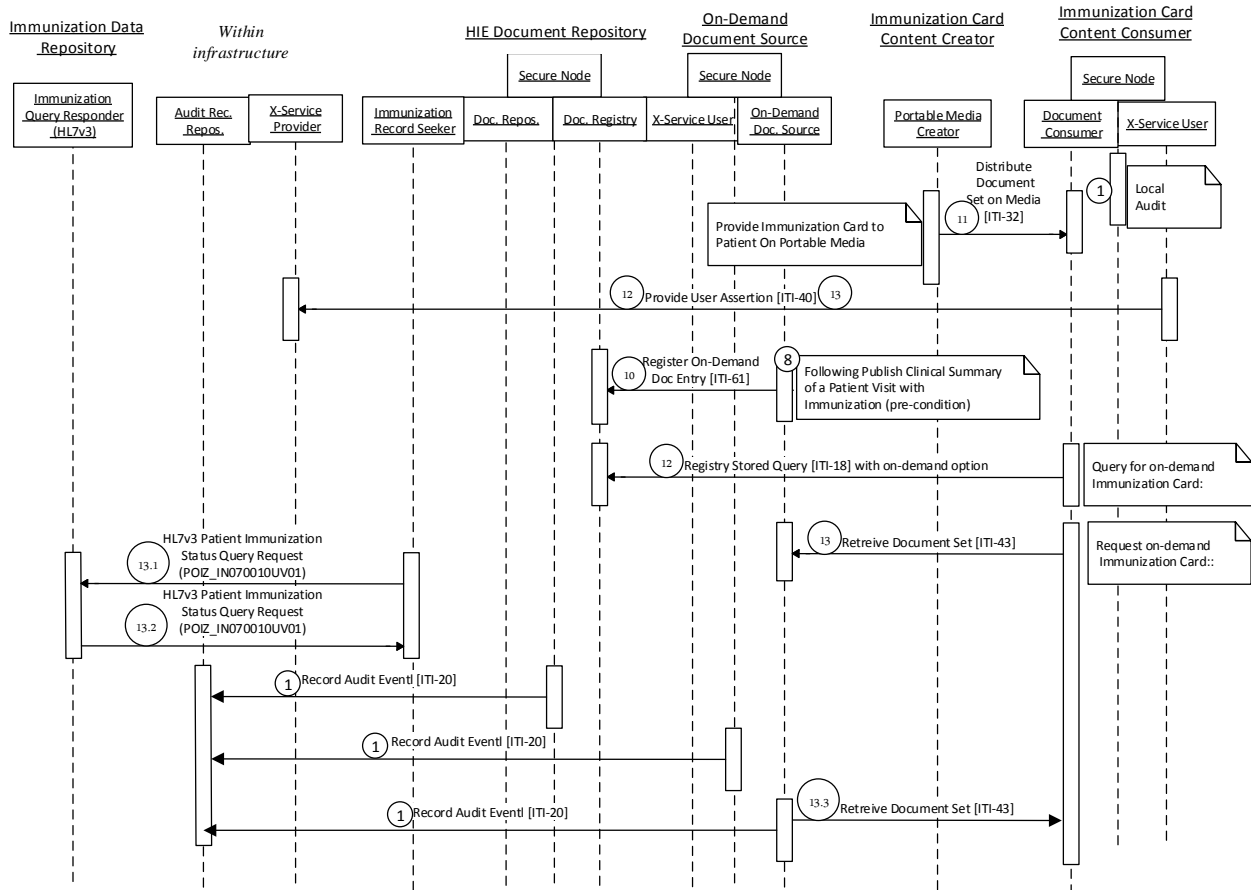


FIGURE 2.2.3-2 IMMUNIZATIONS MAIN FLOW SEQUENCE DIAGRAM FOR IMMUNIZATION CARD

2.2.3.3 Main Flow Sequence Diagram-Immunization Education

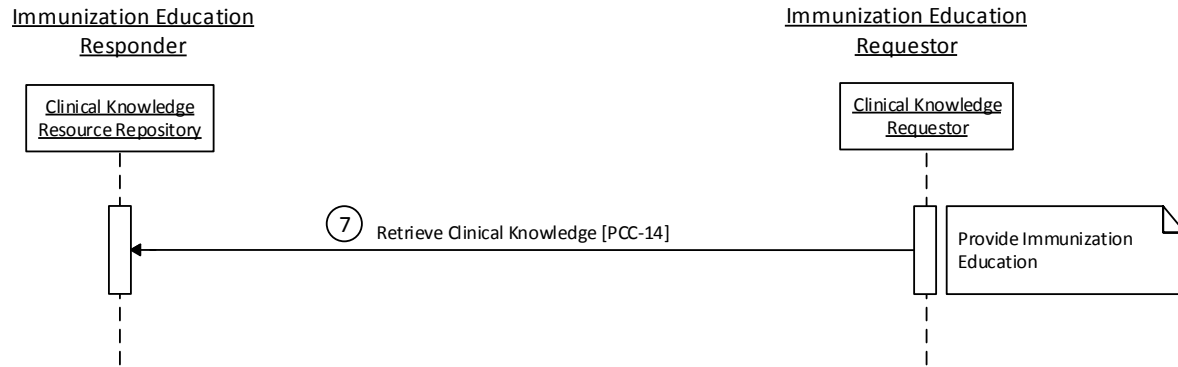


Figure 2.2.3-3 Immunizations Main Flow Sequence Diagram for Immunization Education shows the flows for Requesting Clinical Knowledge to retrieve Education materials to provide to the patient. This reflects step 7 of the main immunization flow detailed in section 2.2.3 Immunizations Main Flow Sequence Diagrams:

- Step 7: Provide Education Materials

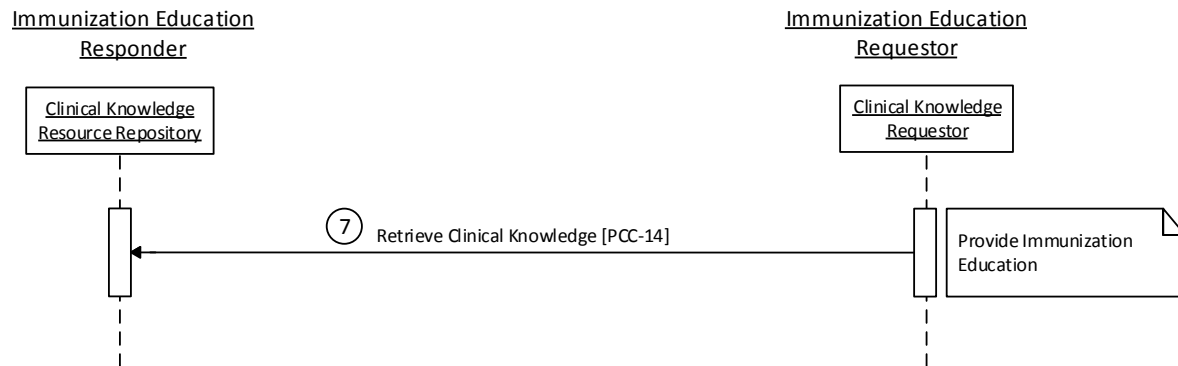


FIGURE 2.2.3-3 IMMUNIZATIONS MAIN FLOW SEQUENCE DIAGRAM FOR IMMUNIZATION EDUCATION

2.2.4 Immunization External Flow of Events – Serology Testing

This alternative flow of events extends the Immunization Main Flow. In the situation where the immunization status is unclear and verification is desired prior to administering a vaccine, serology testing may be conducted. This may be performed to minimize risks that would be associated with the vaccination (e.g. risks to a pregnant patient or family member). In this situation, the following alternative flow of events, which is fully supported by the IS0003 *Saudi*

eHealth Core Interoperability Specification for Sharing Coded Laboratory Results and not further specified by this specification, would be added prior to the vaccination:

1. A laboratory serology test order is published by the Laboratory Order Creator to assess the immunity status of the patient. The requirements on how to order the laboratory test are defined in *IS0003 Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*, and are therefore not shown in any of the sequence diagrams. Serology Order values supporting this specification are defined in the *IS0200 Saudi eHealth Terminology Repository*
2. The Document Repository sends a Notification of Document Availability to the Laboratory Order Fulfiller that there is a serology order of interest. The requirements on how to notify the Order Fulfiller are defined in *IS0003 Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*, and are therefore not shown in any of the sequence diagrams.
3. Laboratory Order Fulfiller queries and retrieves the serology order from the Document Repository. The requirements for this transaction are defined in *IS0003 Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*, and are therefore not shown in any of the sequence diagrams.
4. The serology testing is conducted by the laboratory
5. The Laboratory Report Creator publishes the laboratory result documents of the serology testing to the Document Repository. The requirements for this transaction are defined in *IS0003 Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results*, and are therefore not shown in any of the sequence diagrams. Serology Result values supporting this specification are defined in the *IS0200 Saudi eHealth Terminology Repository*.
6. The Laboratory Results are available to the On-Demand Immunization Summary Content Creator in steps 3 and 4 of the main Immunization Workflow.

3. IMMUNIZATIONS ACTOR CONFORMANCE

This section is designed to establish the Conformance Requirements for the Interoperability Specification. It maps one-to-one, with the table in section [2.1](#).

3.1 IMMUNIZATION ON-DEMAND DOCUMENT SOURCE ACTOR CONFORMANCE

Systems may claim conformance to the IS0010 *Saudi eHealth Core Interoperability Specification for Immunization* as an Immunization On-Demand Document Source Actor as follows:

“Immunization On-Demand Document Source Actor”

This requires:

- to support the Publish On-Demand Immunization Documents Service by conforming to:
 - [IMM-001] IHE Immunization Content (IC) Integration Profile as a Content Creator Actor with the additional constraints specified in:
 - IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.9.
 - IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.10.
 - [IMM-002] IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile with the On-Demand Documents Option as an On-Demand Document Source Actor with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.3 and 3.6
 - [IMM-137] IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.2 and 3.3.1
 - [IMM-138] IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- Supporting the Query Existing Data Service by conforming to:
 - [IMM-003] IHE-Query for Existing Data Profile as a Clinical Data Consumer with the additional constraints specified in Section 4.1 Requirements for Immunization On-Demand Document Source

[IMM-004] IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification – Section 3.2 and 3.3.1*

[IMM-005] IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2*

[IMM-150] HL7v3 Patient Immunization Status Query Request (POIZ_IN070010UV01) transaction as an Immunization Record Seeker (POIZ_AR990204UV01) with the additional constraints specified in Section 4.1 Requirements for Immunization On-Demand Document Source.

[IMM-151] HL7v3 Patient Immunization Status Query Response (POIZ_IN070020UV01) transaction as an Immunization Record Seeker (POIZ_AR990204UV01) with the additional constraints specified in Section 4.1 Requirements for Immunization On-Demand Document Source.

3.1.1 Supporting the Additional Immunization Queries Option

- When the Additional Immunization Queries Option of the Query Existing Data Service is declared, by conforming to:

[IMM-152] HL7v3 Immunization Detail Query (POIZ_IN020010UV01) transaction as an Immunization Record Seeker (POIZ_AR990204UV01) with the additional constraints specified in Section 4.1 Requirements for Immunization On-Demand Document Source.

[IMM-153] HL7v3 Immunization Detail Response (POIZ_IN020020UV01) transaction as an Immunization Record Seeker (POIZ_AR990204UV01) with the additional constraints specified in Section 4.1 Requirements for Immunization On-Demand Document Source.

[IMM-154] HL7v3 Immunization List Query (POIZ_IN021010UV01) transaction as an Immunization Record Seeker (POIZ_AR990204UV01) with the additional constraints specified in Section 4.1 Requirements for Immunization On-Demand Document Source.

[IMM-154] HL7v3 Immunization List Response (POIZ_IN021010UV01) transaction as an Immunization Record Seeker (POIZ_IN021020UV01) with the additional constraints specified in Section 4.1 Requirements for Immunization On-Demand Document Source.

3.2 IMMUNIZATION SUMMARY CONTENT CONSUMER ACTOR CONFORMANCE

Systems may claim conformance to the IS0010 *Saudi eHealth Core Interoperability Specification for Immunization* as an Immunization Summary Content Consumer Actor as follows:

“Immunization Summary Content Consumer Actor”

This requires:

- to support the Retrieve On-Demand Immunization Summary Service by conforming to:
 - [IMM-006] IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Consumer Actor including support for the On-Demand Documents Option with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Sections 3.3 and 3.6
 - [IMM-007] IHE Immunization Content (IC) Integration Profile as a Content Consumer Actor with the additional constraints specified in:
 - IS0106 *Saudi eHealth Clinical Documents Constrains Interoperability Specifications* - Section 5.9.
 - [IMM-008] IHE Cross-Enterprise User Assertion (XUA) Integration Profile as an X-Service User Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.1
 - [IMM -009] IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2
 - [IMM -010] IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

3.3 IMMUNIZATION CARD CONTENT CREATOR ACTOR CONFORMANCE

Systems may claim conformance to the IS0010 *Saudi eHealth Core Interoperability Specification for Immunization* as an Immunization Summary Content Creator Actor as follows:

“Immunization Card Content Creator Actor”

This requires:

- to support the Update Immunization Card Service by conforming to:

[IMM-015] IHE Immunization Content (IC) Integration Profile as a Content Creator Actor with the additional constraints specified in:

- IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.10.

[IMM-016] IHE – Cross-Enterprise Document Media Interchange (XDM) Integration Profile as a Portable Media Creator Actor with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.2

3.4 IMMUNIZATION CARD CONTENT CONSUMER ACTOR CONFORMANCE

Systems may claim conformance to the IS0010 *Saudi eHealth Core Interoperability Specification for Immunization* as an Immunization Card Content Consumer Actor as follows:

“Immunization Card Content Consumer Actor”

This requires:

- supporting the Retrieve On-Demand Immunization Card Service by conforming to:

[IMM-017] IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Consumer Actor including support for the On-Demand Documents Option with the additional constraints specified in:

- IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Sections 3.3 and 3.6

[IMM-018] IHE Immunization Content (IC) Integration Profile as a Content Consumer Actor with the additional constraints specified in:

- IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications - Section 5.10.

[IMM -019] IHE Cross-Enterprise User Assertion (XUA) Integration Profile as an X-Service User Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.1

[IMM -020] IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.2

[IMM -021] IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 Saudi eHealth Security and Privacy Interoperability Specification – Section 3.1.2

3.5 CLINICAL DATA REPOSITORY ACTOR CONFORMANCE

Systems may claim conformance to the IS0010 *Saudi eHealth Core Interoperability Specification for Immunization* as a Clinical Data Repository Actor as follows:

“Clinical Data Repository Actor”

This requires:

- supporting the Query Existing Data Service by conforming to:

[IMM-022] IHE Query for Existing Data Profile with the options listed below as a Clinical Data Source Actor with the additional constraints specified in Requirements for Clinical Data Repository:

- The following Options **SHALL** be supported by Vital Signs, Problems and Allergies, Diagnostic Results, Medications, Immunizations and Professional Services.

[IMM-023] IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1

[IMM-024] IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

- supporting the Immunization Reporting Service by conforming to:

[IMM-203] HL7v3 Record immunization request (POIZ_IN010020UV01) transaction as an Immunization Repository (POIZ_AR990106UV01) with the additional constraints specified in Requirements for Clinical Data Repository.

[IMM-204] HL7v3 Record immunization request refused (POIZ_IN010040UV01) transaction as an Immunization Repository (POIZ_AR990106UV01) with the additional constraints specified in Requirements for Clinical Data Repository.

[IMM-205] Record Immunization Request Accepted (POIZ_IN010030UV01) transaction as an Immunization Repository (POIZ_AR990106UV01) with the additional constraints specified in Requirements for Clinical Data Repository.

3.6 HIE DOCUMENT REPOSITORY CONFORMANCE

Systems may claim conformance to IS0010 *Saudi eHealth Core Interoperability Specification for Immunization* as a Document Repository as follows:

“Document Repository Actor”

This requires:

- To support the Publish On-Demand Immunization Documents Service by conforming to:
[IMM-025] IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Repository with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.4
- [IMM-026] IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1
- [IMM-027] IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- To support the Retrieve On-Demand Immunization Summary and the Retrieve On-Demand Immunization Card Services by conforming to:
[IMM-028] IHE Cross-Enterprise Document Sharing (XDS.b) Integration Profile as a Document Registry with the additional constraints specified in:
 - IS0102 *Saudi eHealth Document Sharing Interoperability Specification* – Section 3.4
- [IMM-029] IHE Cross-Enterprise User Assertion (XUA) Integration Profile as an X-Service Provider Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.4.2
- [IMM-030] IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1
- [IMM-031] IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
 - IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2
- supporting the Report Immunization Service by constructing the immunization report from data provided in the Clinical Summary (see IS0007 *Saudi eHealth Interoperability Specification for Clinical Notes and Summaries*) conforming to:

- [IMM-032] HL7v3 Record immunization request (POIZ_IN010020UV01) transaction as an Immunization Recorder (POIZ_AR990104UV01) with the additional constraints specified in Section 4.6 Requirements for HIE Document Repository.
- [IMM-155] HL7v3 Record immunization request refused (POIZ_IN010040UV01) transaction as an Immunization Recorder (POIZ_AR990104UV01) with the additional constraints specified in Section 4.6 Requirements for HIE Document Repository.
- [IMM-156] Record Immunization Request Accepted (POIZ_IN010030UV01) transaction as an Immunization Recorder (POIZ_AR990104UV01) with the additional constraints specified in Section 4.6 Requirements for HIE Document Repository.
- [IMM-033] IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:
- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1
- [IMM-034] IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:
- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

3.7 IMMUNIZATION DATA REPOSITORY ACTOR CONFORMANCE

Systems may claim conformance to the IS0010 *Saudi eHealth Core Interoperability Specification for Immunization* as an Immunization Data Repository Actor as follows:

“Immunization Data Repository Actor”

This requires:

- supporting the Query Existing Data Service which will respond with information that originates both from the HIE and with information that is collected through the Immunization Registry (e.g. MOH HESN) data capture interface by conforming to:

- [IMM-035] HL7v3 Patient Immunization Status Query Request (POIZ_IN070010UV01) transaction as an Immunization Query Responder (POIZ_AR990206UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.
- [IMM-159] HL7v3 Patient Immunization Status Query Response (POIZ_IN070020UV01) transaction as an Immunization Query Responder (POIZ_AR990206UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository
- [IMM-160] HL7v3 Immunization Detail Query (POIZ_IN020010UV01) transaction as an Immunization Query Responder (POIZ_AR990206UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.
- [IMM-161] HL7v3 Immunization Detail Response (POIZ_IN020020UV01) transaction as an Immunization Query Responder (POIZ_AR990206UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.

[IMM-162] HL7v3 Immunization List Query (POIZ_IN021010UV01) transaction as an Immunization Query Responder (POIZ_AR990206UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.

[IMM-163] HL7v3 Immunization List Response (POIZ_IN021010UV01) transaction as an Immunization Query Responder (POIZ_AR990206UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.

[IMM-036] IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1

[IMM-037] IHE Consistent Time (CT) integration profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

➤ supporting the Report Immunization Service by conforming to:

[IMM-038] HL7v3 Record immunization request (POIZ_IN010020UV01) transaction as an Immunization Repository (POIZ_AR990106UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.

[IMM-157] HL7v3 Record immunization request refused (POIZ_IN010040UV01) transaction as an Immunization Repository (POIZ_AR990106UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.

[IMM-158] Record Immunization Request Accepted (POIZ_IN010030UV01) transaction as an Immunization Repository (POIZ_AR990106UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.

[IMM-200] HL7v3 Record immunization request (POIZ_IN010020UV01) transaction as an Immunization Recorder (POIZ_AR990104UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.

[IMM-201] HL7v3 Record immunization request refused (POIZ_IN010040UV01) transaction as an Immunization Recorder (POIZ_AR990104UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.

[IMM-202] Record Immunization Request Accepted (POIZ_IN010030UV01) transaction as an Immunization Recorder (POIZ_AR990104UV01) with the additional constraints specified in Section 4.7 Requirements for Immunization Data Repository.

[IMM-039] IHE Audit Trail and Node Authentication (ATNA) Integration Profile as a Secure Node Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Sections 3.2 and 3.3.1

[IMM-040] IHE Consistent Time (CT) Integration Profile as a Time Client Actor with the additional constraints specified in:

- IS0101 *Saudi eHealth Security and Privacy Interoperability Specification* – Section 3.1.2

3.8 IMMUNIZATION EDUCATION REQUESTOR ACTOR CONFORMANCE

Systems may claim conformance to the IS0010 *Saudi eHealth Core Interoperability Specification for Immunization* as an Immunization Education Requestor Actor as follows:

“Immunization Requestor Actor”

This requires:

- supporting the Provide Immunization Education Service by conforming to:

[IMM-041] IHE Retrieve Clinical Knowledge (RCK) as a Clinical Knowledge Requestor Actor with the additional constraints specified in Section 4.5.

3.9 IMMUNIZATION EDUCATION RESPONDER ACTOR CONFORMANCE

Systems may claim conformance to the IS0010 *Saudi eHealth Core Interoperability Specification for Immunization* as an Immunization Education Responder Actor as follows:

“Immunization Responder Actor”

This requires:

- supporting the Provide Immunization Education Service by conforming to:

[IMM-042] IHE Retrieve Clinical Knowledge (RCK) as a Clinical Knowledge Resource Repository Actor with the additional constraints specified in Section 4.5.

3.10 IMMUNIZATION DATA ELEMENTS

3.10.1 Immunization Reporting Data Elements

The following table provides a high-level overview of the data elements which are called out for reporting immunizations to the Immunization Data Repository, and from the Immunization Data Repository to the Clinical Data Repository in IS0010 *Saudi eHealth Core Interoperability Specification for Immunization*.

In addition to providing information on the data elements, this table also provides information on whether the data element includes terminology constraints and whether the information is required, required if know, or optional. Other Immunization attributes not referenced below are constrained as per the underlying HL7 V3 Immunization specification (See Section 5 Referenced Documents and Standards)

TABLE 3.10-1 DATA ELEMENTS FOR IMMUNIZATION REPORTS

ATTRIBUTE NAME/HL7 CONSTRAINTS	ATTRIBUTE DEFINITION	FORMAT	REQUIREMENT	CONSTRAINT	IMMUNIZATION TERMINOLOGY
Patient Demographics: Data elements which identify the patient, and provide additional information about them that may be important in the transition of care for a Patient. The following are attributes which have been identified as important:					
HealthID		Alphanumeric	R	[IMM-086]	NA
Name	Patient names including (First, Middle, Last): Mothers; grandfather (F, M, G, and L).	Text	C (R if present in the source patient summary or KPDQ Arabic = R; and English RE)	[IMM-087], [IMM-088]	NA
Date of birth	Hijri Birth date of the patient.	Date/ Timestamp	C (R if present in the source patient summary or KPDQ)	[IMM-089]	
Gender	Patient's gender (e.g. Male, Female).	Coded Value	C (R if present in the source patient summary or KPDQ)	[IMM-090]	KSA-Gender
Citizenship	Country of citizenship of the patient (e.g. Saudi Arabia, UK).	Coded Value	C (R if present in the source patient summary or KPDQ)	[IMM-091]	Country
Contact Phone Numbers	Phone numbers where the patient may be reached for follow-up (including mobile).	XTN	C (R if present in the source patient summary or KPDQ)	[IMM-092]	NA
Catchment Area	May be determined from provider's address.	Alphanumeric	RE	[IMM-093]	NA
Address	Address where the patient resides.	Alphanumeric	C (R if present in the source patient summary or KPDQ)	[IMM-093]	NA
Vaccination Data: Data elements which describe information about the vaccination including:					
Vaccination Given Indicator	Indicates whether or not the vaccination reported was completed or was not given.	Boolean	C (R for current vaccination, O for Historical)	[IMM-094]	NA

ATTRIBUTE NAME/HL7 CONSTRAINTS	ATTRIBUTE DEFINITION	FORMAT	REQUIREMENT	CONSTRAINT	IMMUNIZATION TERMINOLOGY
Vaccination Information Informant	Indicates the source of the vaccination information (e.g. patient, patient agent, provider, etc.), used to identify historical vaccination information.	Structured	C (R for Historical, O for current vaccination)	[IMM-095]	NA
Vaccination Generic name	Vaccine agent (e.g. BCG, DTaP, DT, Diphtheria)	Coded Value (e.g. BCG, DTaP, DT, Diphtheria)	R	[IMM-096]	KSA Vaccine Name Value Set
Manufacturer	The manufacturer of the vaccine administered (e.g. GSK, Sanofi Pasteur).	Coded Value	C (RE for current vaccination, O for Historical)	[IMM-097]	KSA Vaccine Manufacturer
Product	Name of product used for the vaccination (e.g. Measles Vaccine 2000 UNT/ML Injectable Solution [Attenuvax],).	Coded Value	C (R for current vaccination, RE for Historical) (Note 2)	[IMM-098]	KSA Vaccine Product
batch #/lot #	The batch/lot number of the vaccine administered.	Alphanumeric	C (R for current vaccination, RE for Historical) (Note32)	[IMM-099]	NA
Expiration date	Expiration date of the substance administered.	Date/ Timestamp	C (R for current vaccination, O for Historical)	[IMM-100]	NA
Dose	The amount/dose used in the vaccination.	Numeric	C (R for current vaccination, O for Historical)	[IMM-101]	NA
Dosage Unit	The units associated with the vaccine dose (e.g. ml).	Coded	C (RE for current vaccination, O for Historical)	[IMM-101]	KSA Medication Quantity Units
Dose Number	The dose sequence number for this vaccination.	Numeric	RE	[IMM-139]	NA

ATTRIBUTE NAME/HL7 CONSTRAINTS	ATTRIBUTE DEFINITION	FORMAT	REQUIREMENT	CONSTRAINT	IMMUNIZATION TERMINOLOGY
Route administered	The route used to administer the vaccination (e.g. Oral, Intramuscular).	Coded Value	C (R for current vaccination, O for Historical)	[IMM-102]	KSA Vaccine Route Administered
Body Site of administration	Location on the body where the vaccination was administered (e.g. left arm, right thigh).	Coded Value	C (R for current vaccination, O for Historical)	[IMM-103]	KSA Vaccine Body Site of Administration Value Set
Date of administration	The date that the vaccination was given.	Date/ Timestamp	C (R for current vaccination, Minimum of granularity of year for Historical)	[IMM-104]	NA
Reason for administration	The reason for the vaccination (e.g. Campaign, Hajj, Routine, etc.).	Coded value	RE	[IMM-105]	KSA Vaccine Purpose Value Set
Exemptions/Reason Not Given	Indicates the reason that the vaccination was not given to the patient [Only on reporting and new administration and not on vaccine history data].	Coded Value (e.g. Cost-related, Vaccine Supply Issues)	RE	[IMM-106]	KSA Reason Vaccine Not Given Value Set
Campaign identifier or name	The identifier associated with the vaccination campaign (if applicable) associated with the vaccination administered.	Text	RE	[IMM-107]	NA
Facility Information: Data elements which describe the Healthcare Organization of the Healthcare Professional immunizing the patient and reporting the immunization including:					
Author Identifier	The provider who created the immunization record.	Text and Coded	R	[IMM-108]	NA

ATTRIBUTE NAME/HL7 CONSTRAINTS	ATTRIBUTE DEFINITION	FORMAT	REQUIREMENT	CONSTRAINT	IMMUNIZATION TERMINOLOGY
Organization identifier	Provider identifier of the Organization that administered the vaccine (as recorded in the KSA Provider Directory).	Text and Coded	R	[IMM-109]	NA
Organization name	Provider name of the Organization that administered the vaccine (as recorded in the KSA Provider Directory).	Text	RE	[IMM-110]	NA
Organization address	Provider address Organization that administered the vaccine (as recorded in the KSA Provider Directory).	Text	RE	[IMM-111]	NA
Organization contact information	Provider contact information for the Organization that administered the vaccine (as recorded in the KSA Provider Directory).	Text	RE	[IMM-112]	NA
Healthcare Provider Information – Responsible Party (Person conducting pre-examination and who is responsible for the administration of the vaccine): Data elements which describe the Healthcare Professional performing the pre-examination including:					
Healthcare Professional identifier	Provider identifier of the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory).	Text and Coded	RE	[IMM-113]	NA
Healthcare Professional name	Provider name of the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory) (e.g. Applied Medical Sciences, Nursing).	Text	RE	[IMM-114]	NA

ATTRIBUTE NAME/HL7 CONSTRAINTS	ATTRIBUTE DEFINITION	FORMAT	REQUIREMENT	CONSTRAINT	IMMUNIZATION TERMINOLOGY
Healthcare Professional specialty	Provider specialty of the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory) (e.g. Medical Microbiology & Immunology).	Text and Coded	RE	[IMM-115]	KSA Individual Provider Specialty
Healthcare Professional profession	Provider profession of the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory).	Text and Coded	RE	[IMM-116]	KSA Individual Provider Type
Healthcare Contacts	Provider contact information for the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory).	Text	RE	[IMM-117]	
Healthcare Provider Information – Performer (Person administering vaccine): Data elements which describe the Healthcare Professional performing the vaccine administration including:					
Healthcare Professional identifier	Provider identifier of the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory).	Text and Coded	C (R for current vaccination, RE for Historical)	[IMM-118]	NA
Healthcare Professional name	Provider name of the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory) (e.g. Applied Medical Sciences, Nursing).	Text	RE	[IMM-119]	NA

ATTRIBUTE NAME/HL7 CONSTRAINTS	ATTRIBUTE DEFINITION	FORMAT	REQUIREMENT	CONSTRAINT	IMMUNIZATION TERMINOLOGY
Healthcare Professional specialty	Provider specialty of the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory) (e.g. Medical Microbiology & Immunology).	Text and Coded	RE	[IMM-120]	KSA Individual Provider Specialty
Healthcare Professional profession	Provider profession of the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory).	Text and Coded	RE	[(IMM-121)]	KSA Individual Provider Type
Healthcare Contacts	Provider contact information for the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory).	Text	RE	[IMM-122]	
Additional Information					
Adverse Reaction	Documentation indicating that there was an adverse reaction associated with the vaccination given.	Text and Coded	RE	[IMM-123]	NA
Reference to Immunization Source Encounter Summary	Documentation of the Encounter Summary associated with this vaccination.	Text	RE	[IMM-124]	NA

Note 1: this is an EMR behavior requirement and not an interoperability requirement.

Note 2: This shall be sent whenever there is no lot number created by Public health team (e.g. if Private stock, the batch number association to manufacture/product is not available).

Note 3: Absent and unknown batch numbers MAY result in exception handling and rejection from the Immunization Registry.

4. SAUDI EHEALTH CONSTRAINTS ON IMMUNIZATION

This section defines required behavior rules for Use Case Actors defined in this Core Interoperability Specification.

4.1 REQUIREMENTS FOR IMMUNIZATION ON-DEMAND DOCUMENT SOURCE

The following rules shall be supported for the conformance to the Immunization On-Demand Document Source in support of the Publish On-Demand Immunization Documents Service.

[IMM-043] The Immunization On-Demand Document Source SHALL support the creation of Immunization Summary (IHE PCC Immunization Content (IC)) documents along with Document Sharing Metadata that shall include the following attributes:

[IMM-044] A **Title** Attribute SHALL be present and SHALL be “Immunization Summary”.

[IMM-045] A **documentClass** attribute SHALL contain the coded value “SUMMARIES” as defined in the “KSA Class Code” value set.

[IMM-046] A **practiceSetting** Attribute SHALL contain a coded value defined in the “KSA Organization Provider Type”.

[IMM-047] The **typeCode** Attribute SHALL contain the value “IND” as specified by the IHE-PCC Immunization Content Document profile.

[IMM-048] The **mimeType** attribute SHALL contain the value “text/xml” as described in the “MIME Type” value set.

[IMM-049] The **formatCode** attribute SHALL contain the value “urn:ihe:pcc:ic:2008”

[IMM-050] All other Document Sharing metadata with corresponding data elements in the Immunization Content document SHALL be as specified in the IHE PCC Immunization Content (IC) Profile.

[IMM-051] All other Document Sharing metadata SHALL contain values as specified in the IS0102 *Saudi eHealth Document Sharing Interoperability Specification*.

The following rules shall be supported for the conformance to the Immunization On-Demand Document Source in support of the Query Existing Data Service.

[IMM-052] For the Immunization Summary Document and the Immunization Card Document, The Immunization On-Demand Document Source’s Immunization Record Seeker (POIZ_AR990204UV01) actor SHALL query the Immunization Registry’s (e.g. MOH HESN) Immunization Query Responder POIZ_(AR990206UV01) actor for the latest immunization information using the HL7v3 Patient Immunization Status Query Request (POIZ_IN070010UV01) as the authoritative source of the information that will be populated in the Immunizations Section (OID:1.3.6.1.4.1.19376.1.5.3.1.3.23) and the Immunization Recommendations Section (OID:1.3.6.1.4.1.19376.1.5.3.1.1.18.3.1) of the Immunization Content document including the determination of dose validity, recommended immunization schedules, and timeframes.

[IMM-053] For the Immunization Summary Document, the Immunization On-Demand Document Source Actor SHALL query the Clinical Data Repository for the latest

clinical information using the [IHE PCC QED Profile: Query for Existing Data PCC-1] with the Vital Signs Option as the source of the information that will be populated in the Coded Vital Signs Section (OID:1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2) of the Immunization Content document.

[IMM-054] The Immunization On-Demand Document Source **SHALL** query the Clinical Data Repository for the latest clinical information using the [IHE PCC QED Profile: Query for Existing Data PCC-1] with the Problems and Allergies Option as the source of the information that will be populated in the following sections of the Immunization Content document:

Active Problems	OID:1.3.6.1.4.1.19376.1.5.3.1.3.6
History of Past Illness	OID:1.3.6.1.4.1.19376.1.5.3.1.3.8
Allergies and Other Adverse Reactions	OID:1.3.6.1.4.1.19376.1.5.3.1.3.13
Pregnancy History	OID:1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
Simple Observation	OID:1.3.6.1.4.1.19376.1.5.3.1.4.13

[IMM-055] The Immunization On-Demand Document Source **SHALL** query the Clinical Data Repository for the latest clinical information using the [IHE PCC QED Profile: Query for Existing Data PCC-1] with the Diagnostic Results Option as the source of the information that will be populated in the Coded Results (OID:1.3.6.1.4.1.19376.1.5.3.1.3.28) section of the Immunization Content document.

[IMM-056] The Immunization On-Demand Document Source **SHALL** query the Clinical Data Repository for the latest clinical information using the [IHE PCC QED Profile: Query for Existing Data PCC-1] with the Medications Option as the source of the information that will be populated in the Medications (OID:1.3.6.1.4.1.19376.1.5.3.1.3.19) section of the Immunization Content document.

4.2 REQUIREMENTS FOR IMMUNIZATION CARD CONTENT CREATOR

The following rules shall be supported for the conformance to the Immunization Card Content Creator in support of the Retrieve Update Immunization Card Service.

[IMM-057] The Immunization Card Content Creator **SHALL** support the creation of Immunization Summary (IHE PCC Immunization Content (IC)) documents along with Document Sharing Metadata that **SHALL** include the following attributes:

[IMM-058] A **Title** Attribute **SHALL** be present and **SHALL** be “Immunization Card”.

[IMM-059] A documentClass Attribute **SHALL** contain the coded value “HEALTH” as defined in the “KSA Class Code” value set.

[IMM-060] A practiceSetting Attribute **SHALL** contain the practiceSetting coded value as defined in the “KSA Organization Provider Type” value set.

[IMM-061] The **typeCode** Attribute **SHALL** contain the coded value “IND” as specified by the IHE-PCC Immunization Content Document profile.

- [IMM-062] The **mimeType** attribute **SHALL** contain the coded value “text/xml” as described in the “MIME Type” value set.
- [IMM-063] The **formatCode** attribute **SHALL** contain the coded value “urn:ihe:pcc:ic:2008”.
- [IMM-064] All other Document Sharing metadata with corresponding data elements in the Immunization Content document **SHALL** be as specified in the IHE PCC Immunization Content (IC) Profile.
- [IMM-065] All other Document Sharing metadata **SHALL** contain values as specified in IS0102 *Saudi eHealth Document Sharing Interoperability Specification*.
- [IMM-066] The Immunization Card Content Creator **SHALL** support the update (replace) of a shared Immunization Card document, by replacing a shared Immunization Card document with an updated Immunization Card document.
- [IMM-067] The associated Document Sharing metadata **SHALL** include the attributes specified in [IMM-057] with identical values.
- [IMM-068] If an Immunization Card document has been published and assigned to an incorrect patient, the Immunization Card Content Creator (the XDS document source actor is grouped with an XDS Document Administrator Actor; See KXDS-072 in IS0102 *Saudi eHealth Document Sharing Interoperability Specification*) **SHALL** correct the error by using the [IHE XDS.b Supplement – Metadata Update: Delete Document Set Request ITI-62] to deprecate the original Immunization Card and a new Immunization Card shall be published and assigned to the correct patient. (See IS0102 *Saudi eHealth Document Sharing Interoperability Specification*).

4.3 REQUIREMENTS FOR IMMUNIZATION SUMMARY CONTENT CONSUMER

The following rules shall be supported for the conformance to the Immunization Summary Content Consumer in support of the Retrieve On-Demand Immunization Summary Service:

- [IMM-069] When retrieving a patient’s Immunization Summary document, it is the responsibility of the Immunization Summary Content Consumer to rely on the metadata associated with the Clinical Document to reconcile the KSA-Wide information with its local information and conventions. At a minimum, it **SHALL** reconcile:
- [IMM-070] The KSA-Wide Health ID with the local Patient ID
- [IMM-071] Any KSA-Wide provider identifiers with local provider identifiers
- [IMM-072] Any KSA-Wide provider organization identifiers with local provider organization identifiers
- [IMM-073] When retrieving a patient’s Immunization Summary document, the Immunization Summary Content Consumer **SHALL** be able to receive them in such a way that the user on the receiving system is able to display and process its content.

[IMM-074] At the beginning of the encounter the Immunization Content Consumer **SHALL** be able to reconcile the immunization data as follows:

[IMM-075] It **SHALL** query for the Immunization Summary Document.

[IMM-076] It **SHALL** retrieve the Immunization Summary Document returned from that query if it exists.

[IMM-077] It **SHALL** reconcile all problems, medications and allergies with data currently in the local system.

[IMM-078] It **SHALL** import all relevant labs and immunizations into the local system.

4.4 REQUIREMENTS FOR IMMUNIZATION CARD CONTENT CONSUMER

The following rules shall be supported for the conformance to the Immunization Card Content Consumer in support of the Retrieve On-Demand Immunization Card Service:

[IMM-079] The Immunization Card Content Consumer **SHALL** be able to display and process its content.

4.5 REQUIREMENTS FOR CLINICAL DATA REPOSITORY

The following rules shall be supported for the conformance to the Clinical Data Repository Actor in support of the Query Existing Data Service:

[IMM-081] The Clinical Data Repository **SHALL** be populated by content provided to the HIE Document Repository.

[IMM-082] When Clinical Data are returned by the Clinical Data Repository that originated in a clinical document, the Clinical Data Repository **SHALL** return a pointer to the document within the Document Repository from which that data originated.

[IMM-083] The Clinical Data Repository **SHALL** support queries using and respond using the same vocabularies used for Immunization Summary documents to access data about Vital Signs, Problems and Allergies, Diagnostic Data, Medications, Immunizations and Professional Services with the additional constraints specified in.

- IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications – Sections 6 and 7.

[IMM-084] The results found in **subject/registrationEvent/subject2/careProvisionEvent/recordTarget/patient/id** **SHALL** contain a Health ID that has been verified with the KSA-Wide Health ID.

The following rules shall be supported for the conformance to the Clinical Data Repository Actor in support of the Report Immunization Service:

[IMM-206] A Clinical Data Repository **SHALL** be able to receive and process the content of the Immunization Element as constrained and constructed by the Immunization Data Repository. The requirements of this message are the as those described for the Document Repository described in Section 4.6.1.

[IMM-207] When receiving an Immunization Report, the Clinical Data Repository **SHALL** be able to process its content and associate the content with the appropriate individual.

4.6 REQUIREMENTS FOR HIE DOCUMENT REPOSITORY

The following rules shall be supported for the conformance to the Document Repository actor in support of the Publish On-Demand Immunization Documents Service:

[IMM-085] The Document Repository **SHALL** support the [IHE XDS.b Supplement – Metadata Update: Delete Document Set Request ITI-62] to deprecate an active or deprecated document. This is used to correct an error when a document has been published and assigned to an incorrect patient (See IS0102 *Saudi eHealth Document Sharing Interoperability Specification* Section 3.2.8 for details).

4.6.1 Requirements of the Immunization Reporting Message

The following rules shall be supported for the conformance to the Document Repository actor in support of the Report Immunization Service:

The following rules shall be supported for the conformance to the Immunization Recorder (POIZ_AR990104UV01) actor for transactions identified in section 3.6:

[IMM-086] The `/Immunization/subject/patient/id` **SHALL** be populated to include the Health ID as managed in the Patient Demographic Supplier from IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.

[IMM-087] The `/Immunization/subject/patient/person/name` **SHALL** be populated to include the patient name as managed in the Patient Demographic Supplier from IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.

- Arabic name is Required.
- English name is Required **IF KNOWN**.
- **MAY** be omitted where Health ID is available as it may be obtained through KPDQ resources using the Health ID.

[IMM-088] The `/Immunization/subject/patient/personalRelationship[@code='MTH' and @codeSystem='2.16.840.1.113883.5.111']/relationshipHolder, the /Immunization/subject/` **SHALL** be populated to include the patient's mother's maiden name **IF KNOWN** as managed in the Patient Demographic Supplier from IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.

- Arabic name is Required.
- English name is Required **IF KNOWN**.
- **MAY** be omitted where Health ID is available as it may be obtained through KPDQ resources using the Health ID.

[IMM-089] The `/Immunization/subject/patient/person/birthTime` **SHALL** be populated to include the patient date and time of birth as managed in the Patient Demographic

Supplier from IS0001 Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query.

- [IMM-090] The `/Immunization/subject/patient/person/administrativeGenderCode` **SHALL** be populated to include the patient administrative gender as managed in the Patient Demographic Supplier from IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.
- [IMM-091] The `/Immunization/subject/patient/person/asCitizen/politicalNation/code` **SHALL** be populated to include the patient citizenship as managed in the Patient Demographic Supplier from IS0001 *Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query*.
- [IMM-092] The `/Immunization/subject/patient/telecom` **SHALL** be populated to include the patient contact phone number(s) as updated by the patient/patient agent at the time of the visit **IF KNOWN**.
- [IMM-093] The `/Immunization/subject/patient/addr` **SHALL** be populated **IF KNOWN** to include the patient Address as updated by the patient/patient agent at the time of the visit which may be used to determine the catchment area.
- [IMM-094] The value for `/Immunization/@actionNegationInd` **SHALL** be "FALSE" to indicate that the vaccination was administered or "TRUE" if the vaccination was not administered.
- [IMM-164] For current immunization, If `/Immunization/@actionNegationInd` is 'TRUE' indicating that the vaccination was not administered, then the value for `/Immunization/@actRelationshipType:RSON` **SHALL** be populated **IF KNOWN** with the reason that the vaccination was not administered using the "KSA Reason Vaccine Not Given value set .
- [IMM-095] The `/Immunization/informant/` **SHALL** be populated with the appropriate element: `patient`, `personalRelationship`, `licensedEntity`, or `immunizationRecord` to indicate the source of the immunization information (patient, patient representative, provider or immunization records).
- [IMM-096] Consumable `/Immunization/consumable/vaccineInstance/vaccine/code` **SHALL** include a code describing the vaccine which **SHALL** be populated using the "KSA Vaccine Name value set .
- [IMM-097] For current immunization, Consumable `/Immunization/consumable/vaccineInstance/manufacturer/id` **SHALL** include the identifier of the manufacturer of the vaccine product administered using `id/@root = MVX OID`, and `id/@extension = MVX code` as identified in the "KSA Vaccine Manufacturer". Note: **MAY** be determined through the assigned product number.

- [IMM-098] Consumable /Immunization/consumable/vaccineInstance/vaccine/formCode **SHALL** include the product used for the vaccination which **SHALL** be populated using the "KSA Vaccine Product" value set .
- [IMM-099] For current immunization, Consumable /Immunization/consumable/vaccineInstance/vaccine/id **SHALL** include the batch number/lot number which **SHALL** be populated **IF KNOWN** using the alphanumeric code assigned by the manufacturer for the product batch/lot used for the vaccine.
- [IMM-100] For current immunization, Consumable /Immunization/consumable/vaccineInstance/vaccine/expirationTime **SHALL** include the expiration date of the product used for the vaccine **SHALL** be populated **IF KNOWN** using the HL7 date/time stamp.
- [IMM-101] Immunization/doseQuantity **SHALL** be included for provider-reported vaccinations, and **SHALL** be submitted using the "KSA Medication Quantity Units" value set .
- [IMM-102] Immunization/routeCode **SHALL** be included for provider-sourced vaccination reports, and **SHALL** be populated using the "KSA Vaccine Route Administered" value set .
- [IMM-103] For Current Immunization, Immunization/approachSiteCode **SHALL** be populated if known using the "KSA Vaccine Body Site of Administration" value set .
- [IMM-104] Immunization/effectiveTime **SHALL** be populated with the date and time that the vaccine was administered using the HL7 date/time stamp.
- [IMM-105] For current vaccines that were administered, /Immunization/reason/immunizationReason/code **SHALL** be populated with the purpose that the vaccine was administered using the "KSA Vaccine Purpose" value set .
- [IMM-106] For vaccines that were not administered, /Immunization/reason/noImmunizationReason/code **SHALL** be populated using the "KSA Reason Vaccine Not Given" value set .
- [IMM-107] /Immunization/definition/immunizationAsPerProtocol **SHALL** be populated, **IF KNOWN**, with the campaign identifier in the id element and name in the name element.
- [IMM-108] author **SHALL** be populated as /Immunization/author/id/@root = '2.16.840.1.113883.3.3731.1.2.1' as the OID representing the Saudi Council of Health Specialties (SCHS), and author/id/@extension = the National/Regional Professional Identifier to reflect the provider that authored the immunization event record.
- [IMM-109] For a known KSA organization, /Immunization/location/serviceDeliveryLocation/serviceProviderOrganization/id/@root **SHALL** be populated as '2.16.840.1.113883.3.3731.1.2.4' as the OID representing the National Organizational Identifier issued by MOH. For non-KSA locations, or KSA locations that are unknown or unclear, location **SHALL** be populated with a text description.
- [IMM-110] For a known KSA organization, /Immunization/location/serviceDeliveryLocation/serviceProviderOrganization/name **SHALL** be

populated to include the organization name as recorded in the KSA Provider Directory, and with a text description for non-KSA locations or unknown KSA locations.

[IMM-111] For known KSA organization,

`/Immunization/location/serviceProviderOrganization/addr` **SHALL** be populated to include the organization address as recorded in the KSA Provider Directory, and with a text description for non-KSA locations or unknown KSA locations.

[IMM-170] the `/Immunization/location/serviceProviderOrganization/addr` **SHALL** implement Postal Code, PO Box, City, and Country using the "Country" value set, and the "KSA City", and "KSA Postal Code value sets .

[IMM-112] For known KSA organization,

`/Immunization/location/serviceProviderOrganization/telecom` **SHALL** be populated to include the organization contact information as recorded in the KSA Provider Directory, and with a text description for non-KSA locations or unknown KSA locations.

[IMM-113] For Responsible Party (the person accountable for the administration of the vaccine), `/Immunization/responsibleParty/assignedPerson/person/` **SHALL** be populated as `@root = '2.16.840.1.113883.3.3731.1.2.1'` as the OID representing the Saudi Council of Health Specialties (SCHS), and `@extension =` the National/Regional Professional Identifier if known.

[IMM-114] `/Immunization/responsibleParty/assignedPerson/person/` **SHALL** be populated, **IF KNOWN**, to include the provider name as recorded in the KSA Provider Directory.

[IMM-115] `/Immunization/responsibleParty/assignedPerson/code` **SHALL** be populated, **IF KNOWN**, to include the provider specialty as recorded in the KSA Provider Directory using the "KSA Individual Provider Specialty" value set.

[IMM-116] `/Immunization/responsibleParty/ksa:functionCode` **SHALL** be populated, **IF KNOWN**, to include the provider profession (Provider Type) as recorded in the KSA Provider Directory using the "KSA Individual Provider Type".

[IMM-117] `/Immunization/responsibleParty/assignedPerson/telecom` **SHALL** be populated, **IF KNOWN**, to include the provider contact information as recorded in the KSA Provider Directory.

[IMM-118] For Performer (the person administering the vaccine)

`/Immunization/performer/assignedPerson/id` **SHALL** be populated **IF KNOWN** as `@root = '2.16.840.1.113883.3.3731.1.002.1'` as the OID representing the Saudi Council of Health Specialties (SCHS), and `@extension =` the National/Regional Professional Identifier.

[IMM-119] `/Immunization/performer/assignedPerson/person/name` **SHALL** be populated, **IF KNOWN**, to include the provider name as recorded in the KSA Provider Directory.

[IMM-120] For current immunization,

`/Immunization/performer/assignedPerson/person/name` **SHALL** be populated, **IF KNOWN**, to include the provider specialty as recorded in the KSA Provider Directory using the "KSA Individual Provider Specialty".

[IMM-121] `/Immunization/performer/ksa:functionCode` **SHALL** be populated, if known, to include the provider profession (Provider Type) as recorded in the KSA Provider Directory using the "KSA Individual Provider Type".

[IMM-122] `/Immunization/performer/assignedPerson/telecom` **SHALL** be populated, **IF KNOWN**, to include the provider contact information as recorded in the KSA Provider Directory.

[IMM-123] `/Immunization/subjectOf1/investigationEvent/text` **SHALL** be included where there was an adverse event associated with the immunization, and contain a narrative description of the event.

[IMM-124] `/Immunization/referencedBy/healthDocument` **SHALL** contain the **documentID** of the patient's encounter summary used to generate the Immunization Message as published in the Document Registry.

4.7 REQUIREMENTS FOR IMMUNIZATION DATA REPOSITORY

The following rules shall be supported for the conformance to the Immunization Data Repository Actor in support of the Query Existing Data Service:

[IMM-127] The Immunization Data Repository **SHALL** support queries with responses using the same vocabularies used for Immunization Summary documents to access data about Immunizations and Immunization Recommendations.

[IMM-209] The responses **SHALL** be created with the additional constraints specified in Section 4.6.1 for the query parameters and the query response for:

- Patient Immunization Status Query Request (POIZ_IN070010UV01).
- Patient Immunization Status Query Response (POIZ_IN070020UV01).
- Immunization List Query (POIZ_IN021010UV01).
- Immunization List Query Response (POIZ_IN021020UV01).
- Immunization Detail Query (POIZ_IN020010UV01).
- Immunization Detail Query Response (POIZ_IN020020UV01).

The following rules shall be supported for the conformance to the Immunization Data Repository Actor in support of the Report Immunization Service:

[IMM-125] An Immunization Data Repository **SHALL** be able to receive and process the content of the Immunization Element as constrained and constructed by the Document Repository as described in Section 4.6.1.

[IMM-126] When receiving an Immunization Report, the Immunization Data Repository **SHALL** be able to process its content and associate the content with the appropriate individual.

[IMM-128] The values found in
/Immunization/subject/registrationEvent/subject2/careProvisionEvent
/recordTarget/patient/id **SHALL** contain a Health ID that has been verified with
the KSA-Wide Health ID.

The following rules shall be supported for the conformance to the Immunization Recorder
(POIZ_AR990104UV01) actor for transactions identified in section 3.7:

[IMM-208] The Immunization Data Repository shall be able to report Immunization Elements
to the Clinical Data Repository as constrained in Section 4.6.1

4.8 REQUIREMENTS FOR IMMUNIZATION EDUCATION REQUESTOR

The following rules shall be supported for the conformance to the Clinical Knowledge Requestor
Actor in support of the Provide Immunization Education Service:

[IMM-129] The Clinical Knowledge Requestor **SHALL** provide the following demographic
information to the Clinical Knowledge Resource Repository in the Retrieve Clinical
Knowledge transaction (IHE PCC-14):

- Age using years, months, weeks, or days.
- Gender using the "KSA Gender".

[IMM-130] The Clinical Knowledge Requestor **SHALL** provide the Audience (Patient, Clinician)
to the Clinical Knowledge Resource Repository in the Retrieve Clinical Knowledge
transaction (IHE PCC-14).

[IMM-131] The Clinical Knowledge Requestor **SHALL** provide the Preferred Language (e.g.
Arabic, English, etc.), using the "Language" Value Set to the Clinical Knowledge
Resource Repository in the Retrieve Clinical Knowledge Transaction (IHE PCC-14).

[IMM-132] The Clinical Knowledge Requestor **SHALL** provide the Vaccination Generic Name as
the Knowledge Request Topic using the KSA Vaccine Name Value Set to the Clinical
Knowledge Resource Repository in the Retrieve Clinical Knowledge transaction
(IHE PCC-14).

4.9 REQUIREMENTS FOR IMMUNIZATION EDUCATION RESPONDER

The following rules shall be supported for the conformance to the Clinical Data Repository Actor
in support of the Provide Immunization Education Service:

[IMM-133] The Clinical Knowledge Responder **SHALL** support age values specified in years,
months, weeks, or days in the Retrieve Clinical Knowledge transaction (IHE PCC-
14).

[IMM-134] The Clinical Knowledge Responder **SHALL** support content for both clinician and
patient audiences (e.g. providing appropriate reading comprehension content for each
audience) in the Retrieve Clinical Knowledge transaction (IHE PCC-14).

[IMM-135] The Clinical Knowledge Responder **SHALL** support Preferred Language content for
both Arabic and English providing knowledge response content in the requested
language, if available, or in English if the requested language is not available, in the
Retrieve Clinical Knowledge transaction (IHE PCC-14).

[IMM-136] The Clinical Knowledge Responder **SHALL** provide Education Materials for requested Vaccination Generic Names as requested using the KSA Vaccine Name Value Set in the Retrieve Clinical Knowledge transaction (IHE PCC-14).

5. REFERENCED DOCUMENTS AND STANDARDS

The following Saudi eHealth documents are referenced by this interoperability specification.

TABLE 5-1 INTERNAL REFERENCES

MOH DOCUMENT	DESCRIPTION
IS0001 Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query	Documents the specifications required to obtain patient IDs and demographic information for the patient. It is used to ensure that the nationwide Health ID is used to register laboratory orders for the correct patient.
IS0002 Saudi eHealth Core Interoperability Specification for KSA-Wide Healthcare Provider Directory Query	Documents the specification of the content and structure of the Saudi eHealth Healthcare Provider Directory services in support of the Healthcare Provider Directory Query Use Case. This service supports searches for providers and organizations and conveys authoritative attributes related to them. This information describes organizations that provide patient care, such as public and private hospitals, primary care centers, laboratories, pharmacies, etc. It is used by these organizations and by the MOH business applications.
IS0003 Saudi eHealth Core Interoperability Specification for Sharing Coded Laboratory Results	Describes the technical requirements for the interface to share coded Laboratory Results Reports via the Saudi eHealth Information Exchange (SeHE). These laboratory test results are generally used by primary and hospital care providers but may also be used by MOH Business Intelligence, including public health/MOH business intelligence organizations. Note that policies may require that patient information be pseudonymized for use in MOH business applications.
IS0007 Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries	Describes the technical interface requirements for sharing Clinical Notes and Summaries documents as well as access to clinical data through the eHealth Information Exchange (HIE). This capability is accessible to various “edge” applications including point of care systems and MOH business applications.
IS0101 Saudi eHealth Security and Privacy Interoperability Specification	Specifies the interoperability standards and profiles along with the Saudi specific constraints that are required to provide the technical security measures, data protection, and privacy management that will facilitate the implementation of the Saudi eHealth Policies for Health Information Exchange in the Kingdom of Saudi Arabia among communicating IT systems.
IS0102 Saudi eHealth Document Sharing Interoperability Specification	Forms a “container” for set of requirements that complements the IHE XDS Profile with Saudi eHealth specific constraints when it is called upon by any of the Core Interoperability Specifications.
IS0106 Saudi eHealth Clinical Documents Constrains Interoperability Specifications	Specifies common constraints for clinical documents such as data elements of document headers that are common across the eHealth Information Exchange Project.
UC0009 Saudi eHealth Immunization Interoperability Use Case	Describes the specification of bi-directional communication of immunization information both from the perspective of clinical care needs and public health monitoring and management.

MOH DOCUMENT	DESCRIPTION
IS0303 Saudi Health Information Exchange Policies	Contains the policies and supporting definitions that support the security and privacy aspects of the national eHealth Information Exchange [HIE] Platform. The Saudi Health Information Exchange Policies apply to all individuals and organizations that have access to the eHealth Information Exchange managed health records, including those connected to the eHealth Information Exchange Platform, their Business Associates, as well as any subcontractors of Business Associates. These policies apply to all information provided to or retrieved from the eHealth Information Exchange.

TABLE 5-2 EXTERNAL REFERENCES

STANDARD	DESCRIPTION
Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2)	An XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 further builds upon the Version 3.0 Reference Information Model (RIM) Standard. For more information See http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
Health Level Seven (HL7) HL7 Implementation Guide for CDA Release 2 IHE Health Story, Consolidation, Release 1.1 – US Realm	The Consolidated Template implementation guide contains a library of CDA templates, incorporating and harmonizing previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD). May be obtained at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
Health Level Seven (HL7) Version 3 Standard: Immunization, Release 1	This domain describes communication of information about immunization: the administration of vaccines (and/or antisera) to individuals to prevent infectious disease
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Final Text Section 7 – IHE Consistent Time (CT)	The Consistent Time Integration Profile (CT) provides a means to ensure that the system clocks and time stamps of the many computers in a network are well synchronized. This profile specifies synchronization with a median error less than 1 second. This is sufficient for most purposes May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Final Text Section 9: Audit Trail and Node Authentication (ATNA)	The Audit Trail and Node Authentication (ATNA) Integration Profile establishes security measures which, together with the Security Policy and Procedures, provide patient information confidentiality, data integrity and user accountability. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Section 10 Cross-Enterprise Document Sharing (XDS.b)	The Cross-Enterprise Document Sharing (XDS.b) IHE Integration Profile facilitates the registration, distribution and access across health enterprises of patient electronic health records. This profile is focused on providing a standards-based specification for managing the sharing of documents between healthcare enterprises, ranging from a private physician office to a clinic to an acute care in-patient facility. May be obtained at http://www.ihe.net/Technical_Frameworks/#iti

STANDARD	DESCRIPTION
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Section 13 Cross-Enterprise User Attestation (XUA) profile	<p>Cross-Enterprise User Assertion Profile (XUA) - provides a means to communicate claims about the identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross-enterprise transactions there is a need to identify the requesting principal in a way that enables the receiver to make access decisions and generate the proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the users, as well as others that may have chosen to use a third party to perform the authentication.</p> <p>May be obtained at http://www.ihe.net/Technical_Frameworks/#iti</p>
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Section 19 – Basic Patient Privacy Consent (BPPC)	<p>Basic Patient Privacy Consents (BPPC) provides a mechanism to record the patient privacy consent(s) and a method for Content Consumers to use to enforce the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. EMR systems).</p> <p>May be obtained at http://www.ihe.net/Technical_Frameworks/#iti</p>
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integrations Profiles, Supplement – Healthcare Provider Directory (HPD);	<p>The Healthcare Provider Directory (HPD) supports management of healthcare provider information, both individual and organizational, in a directory structure</p> <p>May be obtained at http://www.ihe.net/Technical_Frameworks/#iti</p>
IHE IT Infrastructure (ITI) Technical Framework – Volume 1 (ITI TF-1) Integration Profiles, Supplement -- XDS Metadata Update	<p>This supplement updates the XDS and XDR profiles to add support for the updating and deleting of metadata.</p> <p>May be obtained at http://www.ihe.net/Technical_Frameworks/#iti</p>
IHE IT Infrastructure (ITI) Technical Framework – Volume 3 (ITI TF-3) Integrations Profiles, Section 4 Metadata used in Document Sharing profiles	<p>Describes the metadata that is used in IHE profiles designed for sharing documents (Document Sharing profiles). The Document Sharing profiles are implementing the Document Sharing concept outlined in the ITI whitepaper entitled Health Information Exchange: Enabling Document Sharing Using IHE Profiles</p> <p>May be obtained at http://www.ihe.net/Technical_Frameworks/#iti</p>
IHE IT Infrastructure (ITI) Technical Framework Supplement – On Demand Documents	<p>The IHE On-Demand Document supplement updates the XDS and XCA profiles to support the sharing of dynamically created document content by adding an option for On-Demand Documents.</p> <p>May be obtained at http://www.ihe.net/Technical_Frameworks/#IT</p>

STANDARD	DESCRIPTION
IHE Laboratory (LAB) Technical Framework – Volume 1 (IHE LAB TF-1) Integrations Profiles, Section 9 – Sharing Laboratory Reports (XD-LAB)	<p>The Sharing Laboratory Reports (XD-LAB) content profile defines the laboratory report as an electronic content to be shared in a community of healthcare settings and care providers. Such an electronic document contains the set of releasable results produced by a clinical laboratory or by a public health laboratory in fulfillment of one or more test Orders for a patient. The report is shared in a human-readable format. In addition, this electronic laboratory report contains test results in a machine-readable format, to facilitate the integration of these observations in the database of a consumer system.</p> <p>May be obtained at http://www.ihe.net/Technical_Frameworks/#laboratory</p>
IHE Laboratory Technical Framework Volume 3 (LABTF-3) Content	<p>This Content Integration Profile describes a clinical laboratory report as an electronic document to be published towards a document sharing resource such as an Electronic Health Record (EHR) or a Personal Health Record (PHR) shared by a community of care providers, using one of the document sharing profiles defined in ITI-TF. Such an electronic document contains the set of releasable results produced by a clinical laboratory in fulfillment of one or more test Orders for a patient.</p> <p>The report is both human-readable and importable in the consumer systems so as to consolidate their patient medical records.</p> <p>The scope of this profile covers all laboratory specialties except anatomic pathology.</p> <p>May be obtained at http://www.ihe.net/Technical_Frameworks/#laboratory</p>
IHE Patient Care Coordination (PCC) Technical Framework – Volume 1 (IHE PCC TF-1) Integrations Profiles– Exchange of Personal Health Record Content Integration Profile (XPHR) – Section 4	<p>The IHE Exchange of Personal Health Record Content (XPHR) Profile describes the content and format of summary information extracted from a PHR system used by a patient for import into healthcare provider information systems, and vice versa. The purpose of this profile is to support interoperability between PHR systems used by patients and the information systems used by healthcare providers.</p> <p>May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc</p>
IHE Patient Care Coordination (PCC) Technical Framework – Volume 1 (IHE PCC TF-1) Integrations Profiles– Cross-Enterprise Sharing of Medical Summaries (XDS-MS) – Section 3	<p>The IHE Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Profile facilitates the identification of clinically relevant documents (and data elements those documents contain) that are used in typical "transfer of care" scenarios and then to provide interoperability standards to promote ease in transmission of those documents (and data elements). This is accomplished by defining the appropriate standards for document transmission and a minimum set of "record entries" that should be forwarded or made available to subsequent care provider(s) during specific transfer of care scenarios. In addition, this integration profile defines the utilization requirements/options for the receiving entity in order to ensure that the "care context" of the sending entity is appropriately maintained following the information transfer.</p> <p>May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc</p>

STANDARD	DESCRIPTION
IHE Patient Care Coordination (PCC) Technical Framework – Volume 1 (IHE PCC TF-1) Integrations Profiles– Immunization Content (IC)– Section 6	Immunization Content describes the content and format of documents for exchange of immunization data, including support for reporting vaccinations to the immunization registry, and to communicate the immunization 'card' to the patient. This profile also supports the communication of vaccine forecast. May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc
IHE Patient Care Coordination (PCC) Technical Framework Supplement – Reconciliation of Diagnoses, Allergies and Medications (RECON),	The IHE Reconciliation of Diagnoses, Allergies and Medications (RECON) Profile enables information contained in Health Information Systems and Exchanges to be used to support automation of these reconciliation tasks and clinical workflows. This profile explains what information can help reconciliation, and how it can be used to assist healthcare providers to automate this complex task. May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc
IHE Patient Care Coordination (PCC) Technical Framework Supplement – Retrieve Clinical Knowledge (RCK)	This profile describes how Health IT systems, Person Health Records, and HIEs can retrieve clinical knowledge on a topic suitable for presentation to a clinician or patient. May be obtained at http://www.ihe.net/Technical_Frameworks/#pcc
International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit www.ihtsdo.com

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6. APPENDIX B – SAMPLE MESSAGES

EXAMPLES WILL BE PROVIDED AS PART OF THE IS SPECIFICATION VALIDATION PROCESS. UNTIL THEN THIS SECTION WILL REMAIN BLANK.