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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 Immunization Interoperability Use Case

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PREFACE

HOW TO READ THIS DOCUMENT

Sections 1 and 2 provide a high-level overview of the Use Cases being addressed by this document and the actors and services that support these Use Cases.

Sections 3 and 4 provide an overview of each of the Use Cases and the associated business scenarios and process flows.

Section 5 defines the reusable business processes that result from the Use Cases described in sections 3 and 4.

Section 6 elaborates the business processes from section 5 into a service architecture.

KEY CONCEPTS

Key concepts used in this document are introduced below. Consult *IS0302 SeHE Project Glossary* for other terms used within this document.

Interoperability Use Case: In software engineering, a Use Case is a technique for capturing the requirements of a new or updated system. Each Use Case provides one or more business scenarios that convey how the system should interact with end-users or other systems to achieve a specific business goal. Interoperability Use Cases use language that end-users and domain experts can understand, rather than technical jargon. Use Cases are often co-authored or co-developed by business analysts and end-users.

Business Scenario: The business scenario is defined as a sequence of activities by one or more users (e.g. patients, clinicians, etc.) that describe a real-world story. A business scenario executes one or more business processes in a sequence of end-user interactions called a process flow. Business scenarios are the starting point of the analysis leading to the discovery of actors and services necessary to meet the requirements of the assigned Use Case.

Actors: In this specification, actors describe the interoperable software components that support interoperable exchanges of information between systems.

Services: Services describe the collections of capabilities of a system that enable communication and exchange through standards-based messages and information content. A capability within a service describes the smallest unit of useful work that facilitates information exchange between systems.

Process Flow: A process flow represents a possible sequence of business processes being executed to perform the work of the Use Case. Process flows are identified by analysis of business scenarios through the identification of common reusable sequences of business processes.

Main Flow: The main flow of a Use Case usually describes the simplest path through the smallest set of business processes necessary to complete the work of the Use Case. It describes the minimal skeleton of the Use Case which appears in common across the various business scenarios which explore the scope of the Use Case. The main flow is the sequence of business processes that is both common to and required to be executed in all normal business scenarios.

Alternative Flow: Alternative flows describe additional paths that can be taken to provide additional capabilities to the main flow of work. Alternative flows are described as auxiliary paths that can be added-on to the main flow in one or more locations.

Exception Flow: Exception flows describe alterations to the main flow under exceptional or out of the ordinary circumstances. The existence of exception flows allows for alternative exit paths from the main flow that allow a workflow to complete under extreme situations, even though it deviates from the main flow.

Business Process: A business process is a reusable unit of interaction between an end-user and one or more information systems. Business processes perform work through the execution of services provided in the information system environment.

APPROACH

The approach used to develop this Use Case specification starts with the identification of a stakeholder group of end-users, beneficiaries and implementers of systems which may be affected by implementation of interoperability specifications supporting the Use Cases in the workstream described by this document. These stakeholders identify real-world scenarios in which users and other individuals (e.g., patients) interact with systems to perform or receive a service. The process used is as follows:

- Scenarios are identified by first identifying the simplest (but not necessarily the most common) case in which the Use Case can be completed. More complex scenarios are added which illustrate the range of complexity of the Use Case until essential requirements have been identified.
- Through analysis of these scenarios, a main flow, and often one or more alternative and exception flows are identified. These process flows identified need not match one-to-one with the real-world scenarios originally used to explore the Use Case; however, they are derived from them.
- The process flows are decomposed into business processes, where a business process is described as an end-user initiated interaction with one or more systems in order to complete some essential task in the Use Case.
- The systems and business processes are analyzed to identify the common system components (Actors) responsible for supporting the end-user in the work being done.
- The actors and business processes are further analyzed to identify the necessary services which support the requirements identified in the Use Case.
- The collection of actors and services that forms the solution space for the Use Case, representing the system components and the interoperability that is necessary to meet the requirements of the Use Case.
- From business scenarios implemented by systems and operated by users to actors and services, the derivation of the service model can be shown through a clear progress of analysis.

Lastly, stakeholders contribute candidate data elements to the use case that support the information exchanges identified in the business scenarios.

CONVENTIONS






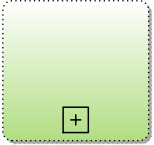
This document has adopted the following conventions for representing the Use Case concepts and information workflow.

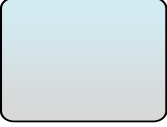
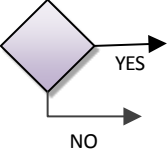


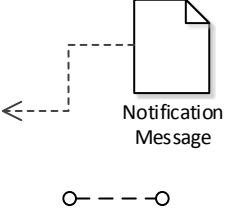

Process Flow Diagrams

The descriptions of interoperability Use Cases that follow include process flow diagrams that illustrate a series of visual representation of related tasks that a person, business, and/or system executes to achieve a desired outcome of the Use Case. The process flow diagrams are created using the Business Process Modeling Notation (BPMN) format. The notations of the diagram represent different shapes such as an event (a circle shape denotes start/end of process), an process (a rectangle describes actions performed by the actor), a gateway (diamond shape determines forking and merging of paths depending on the conditions expressed), and a connector to show in which order the activities are performed and the intermingling of actions between actors and other systems.

There are main process flows, followed by optional alternative or exception flows.

TABLE 0-1SEHE BUSINESS PROCESS MODELING NOTATION CONVENTIONS

SHAPE	DESCRIPTION
 Start	Start event acts as a trigger to launch the business process.
 End	End event acts as a trigger to terminate the business process.
	Process that represented with a rounded-corner rectangle and describes systematic action performed by the actor
	Sub-process used to denote additional levels of business process by referring to an action that can be broken down to a finer level of details or to another business process name.
	External process that represented with a rounded-corner rectangle and describes systematic action performed by the actor
	External sub-process used to denote additional levels of business process by referring to an action that can be broken down to a finer level of details or to another business process name.

	<p>Process that represented with a light colored rectangle and describes physical action performed by the actor</p>
	<p>Gateway that determines forking and merging of paths depending on the conditions expressed</p>
	<p>Gateway that indicates alternative paths depending on the choice made at the time of execution.</p>
	<p>Sequence flow that shows in which order the activities are performed and the intermingling of actions between different actors or other systems.</p>
	<p>Message flow that shows the flow of messages between two actors or systems that are prepared to send and receive messages.</p>
<p>Send Notification</p> 	<p>Message event used to send a message and to invoke other process within the business processes then the token will immediately moves to the invoked flow of the process</p>

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.

¹ Definitions based upon RFC 2119

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.

PROJECT PURPOSE

The National eHealth strategy has established a number of key business objectives for the Saudi eHealth program including the definition and implementation of healthcare applications to support critical business scenarios. This is further described in National eHealth Strategy referenced in the section of that title below.

Within this overarching strategy, an eHealth Standards-based Interoperability Specification and Policy project has been identified, with scope defined to:

- Deliver the interoperability specifications (i.e. standards, profiles, terminologies, etc.)
- Deliver test plans, test tools , and testing and certification policies to support the associated conformance testing and certification for new and existing information systems (Hospital Information Systems [HIS], Primary Healthcare [PHC] Systems, Electronic Medical Record [EMR] Systems, Laboratory Information Systems [LIS], Radiology Information Systems [RIS]/ Picture and Archiving Communication Systems [PACS] etc.). These test plans, test tools and testing and certification policies will ensure that these systems connect to Health Information Exchange (HIE) Platform and its internal Systems, which includes patient identification management, provider directory, document and image repository, access control, etc.
- Establish the policies for health information exchange in Saudi Arabia. These policies ensure trust relationships between the various healthcare organizations sharing information as well as the health professionals and patients in the Kingdom.

The project's goal is to enable interoperability and to mainly specify the external interfaces of the local edge systems (i.e. point of care HIS or PHC applications), without constraining:

- The local systems' internal design.
- The intra-organization interoperability policies or management processes used to implement such polices.

Figure i-1 Scope of eHealth Standard based Interoperability Specification and Policy Project depicts the general scope and focus of the project highlighted in red

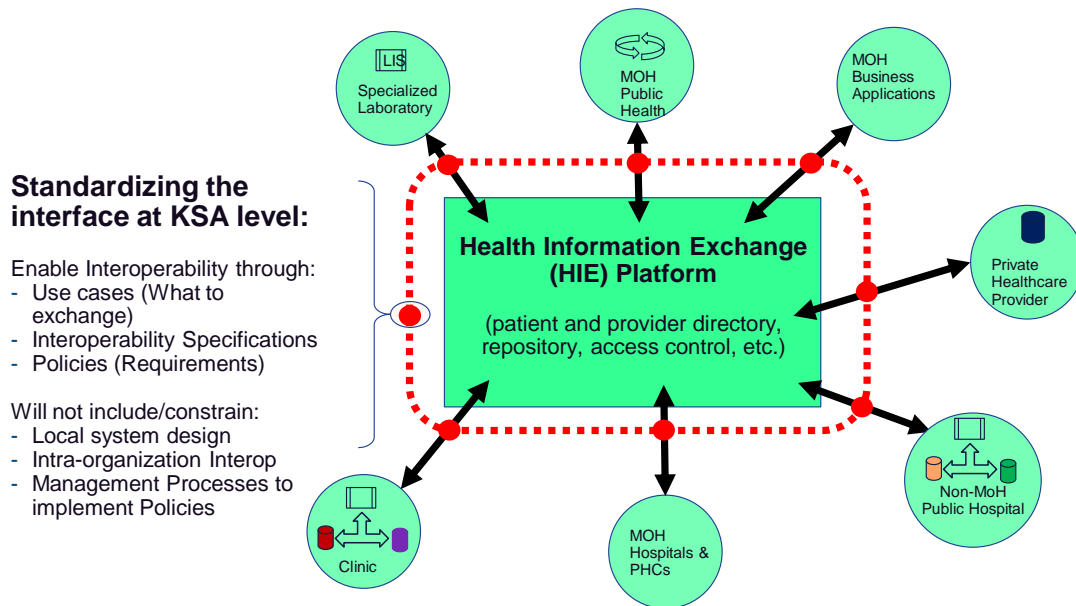


FIGURE 0-2 SCOPE OF eHEALTH STANDARD BASED INTEROPERABILITY SPECIFICATION AND POLICY PROJECT

REFERENCES

National eHealth Strategy

See the Saudi Ministry of Health Portal (Arabic: <http://www.moh.gov.sa/Ministry/nehs/Pages/default.aspx> English: <http://www.moh.gov.sa/en/Ministry/nehs/Pages/default.aspx>) for more information.

Saudi eHealth Interoperability Specification Document

A Saudi eHealth Interoperability Specification documents the selection of profiles and standards that support specific Saudi eHealth Interoperability Use Cases. Such Interoperability Specifications apply to new and existing information systems (HIS, PHC, Laboratory, etc.) and ensure their connection to the HIE Platform.

Saudi Health Information Exchange Policy Document

IS0303 *Saudi Health Information Exchange Policies* is used to set the policies applicable to users and systems connected to the national Health Information Exchange .

Examples of such policies are:

- Authentication Policy
- Consent and Access Control Policy
- Identity Management Policy

- Breach Notification Policy
- Others

The Use Cases specified in this document operate within the context of these Health Information Exchange policies.

MIDDLE- OUT METHODOLOGY

Like most eHealth programs around the world the challenge to identify and document a large number of business Use Cases and variants is avoided by using a “middle-out” methodology. The core requirements start with the Interoperability Use Cases, especially when those are “classical Use Cases” that have been analyzed by the profiles and standards development organizations in their prior work.

Figure i-2 Methodology steps for the eHealth Standard based Interoperability Specification and Policy Project illustrates the main steps of this methodology, where the knowledge of the array of Business Scenarios come from the stakeholders and a validation performed through their experiences (i.e. issues and gaps corrected based on their feedback).

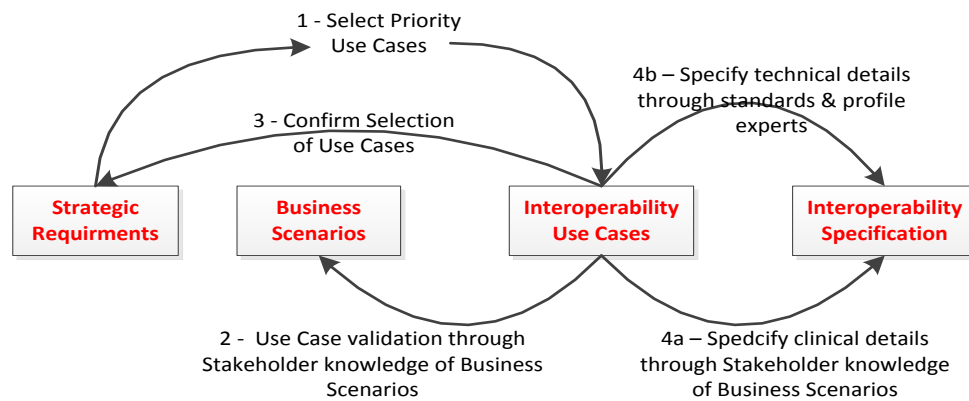


FIGURE 0-1 METHODOLOGY STEPS FOR THE eHEALTH STANDARD BASED INTEROPERABILITY SPECIFICATIONS AND POLICY PROJECT

The Interoperability Use Cases provide a description of the workflows that need to be addressed and the main exception situations. They are not expected to cover all design details in term of error codes, data element specification and terminology code sets to be used.

This level of detail is appropriately addressed in the Interoperability Specification (See step 4a in the diagram methodology steps). It contains the detailed design specification against which implementations will be tested and certified. An Interoperability Use Case is a scoping document and is a stepping stone to the development of a Core Saudi eHealth Core Interoperability Specification and supporting Saudi eHealth Core Interoperability Specifications. Together these Interoperability Specifications cover five complementary aspects:

- The specification of the information transport running above the Internet TCP/IP layer.

- The specification of one or more data exchange services suitable for the workflow needed by the Use Case that runs over the above transport.
- The specification of one or more information content data structure enabling the structured representation of the health information data elements and their specific attributes to be conveyed.
- The specification of one set of coded values, each to be placed into a specific attribute of a selected data elements to be conveyed by the above data structure.
- The specification of the technical measures to ensure security and privacy of the information conveyed and accessed.

These Interoperability Specifications and the standards and profiles they reference are designed to form a complete specification covering all aspects necessary to achieve the standards-based exchange of information across the HIE Platform (except for interoperability policy matters that are addressed separately). The Saudi eHealth Interoperability Specifications are the authoritative documents for software implementers and system deployment teams.

As a consequence, rigorous but concise test plans (i.e., a set of test scripts) may be developed and when executed result in a reasonable assurance of interoperability between successfully tested systems. Such testing for interoperability may be performed against test tools as well as between systems under test, a combination that is widely accepted as the most efficient testing process. These test plans and test tools provide closure against the Core Interoperability Specifications and supporting Interoperability Specifications, thus bringing the necessary level of quality in interoperable IT systems development and deployment.

This is depicted in Figure i-3 Verification of Conformance to a Core Saudi eHealth Interoperability Specification.

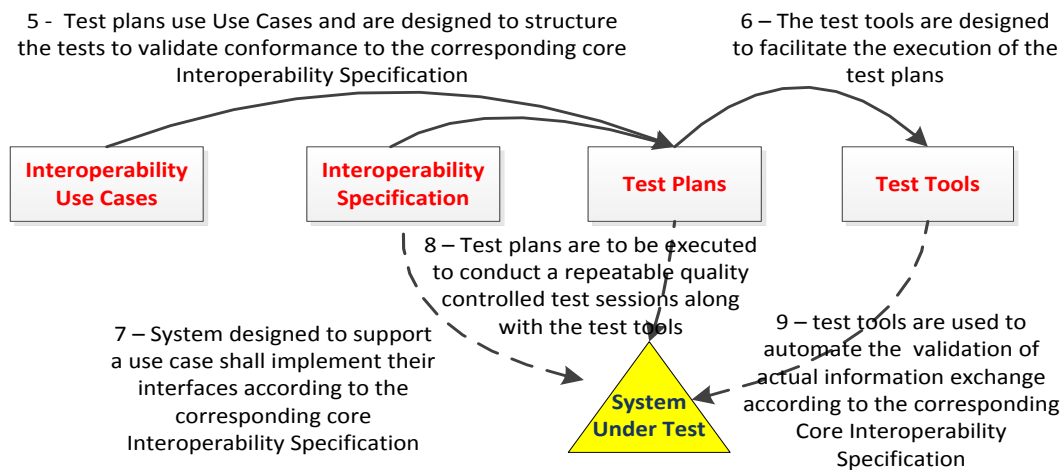


FIGURE 0-2 VERIFICATION OF CONFORMANCE TO A CORE INTEROPERABILITY SPECIFICATION

1. IMMUNIZATION USE CASE

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:

- Providing the clinician with the information needed to determine if 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.
- Capturing information from the vaccine given that would be needed to support adverse event reporting

Out of Scope:

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

- Details associated with aspects of the Use Case that are covered in other Workstreams or in existing Interoperability Specifications
- Batch immunizations
- Adverse Event Reporting

2. WORKSTREAM OVERVIEW

The purpose of this document is to address the Kingdom of Saudi Arabia's (KSA) eHealth Interoperability Use Cases for Immunization. These Use Cases are applicable to existing and new information systems. The systems will be connected to the national Health Information Exchange (HIE) Platform.

The Immunization Use Case defines requirements that will support improved communication of electronic immunization information between providers and public health. This includes the record of immunizations provided to public health, vaccine forecasts provided to the provider and to the patient, and the vaccination history provided to the clinician treating the patient and to the patient himself.

2.1 CURRENT STATE

Currently, immunizations for children are collected and monitored in detail from birth through to school age. Immunizations are also administered and collected during specific campaigns and administered for Hajj. The information collected is submitted on paper to the recently implemented Health Electronic Surveillance Network (HESN) Immunization Registry where automation of reminders, vaccine validity and vaccine forecast has been implemented. In addition, specific immunization campaigns are managed through the Immunization Registry.

Ministry of Health (MOH) facilities and staff are solely responsible for collecting and managing immunization information. Currently, information from the private sector is collected only through a patient immunization card. Immunization information from the private sector is captured either during a visit to an MOH facility or as part of school immunization screening.

2.2 EXPECTED BENEFITS

- Provides point-of-care access to information needed to determine vaccinations that should be administered to the patient at the time of the visit. This information includes:
 - Vaccinations due according to the Saudi MOH Vaccination Schedule,
 - vaccine history,
 - indications,
 - contraindications,
 - alignment with vaccination campaigns and
 - patient demographics.
- Supports electronic reporting of immunization events to public health and therefore improves the efficiency, accuracy, and timeliness of immunization information.
- Provides for the communication of immunization history and pending immunization needs to a patient/guardian in an electronic form.
- Supports communication of immunization education information to a patient/guardian regarding a child's immunizations.
- Ensures that a child is immunized with all recommended vaccinations.
- Provides electronic vaccination records through the HIE Platform.

- Provides vaccination recommendations through the HIE Platform.

2.3 USE CASE OVERVIEW

The workflow identified through input from the Saudi MOH Immunization Interoperability Use Case Workgroup is incorporated as the basis of the Immunization Interoperability Use Case. The purpose of the Immunization Interoperability Use Case is to enable the patient-centric sharing of immunization information between clinicians and public health using the HIE System. This immunization information includes both vaccinations administered and immunization recommendations. The focus of the Use Case is the creation, dissemination, and usage of the immunization information for sharing purposes, as opposed to the current primarily paper-based workflow.

2.4 ACTORS

The Actors defined for these Use Cases are described in Table 2.4-1 Actors.

TABLE 2.4-1 ACTORS

ACTOR NAME	DESCRIPTION	EXAMPLE REAL-WORLD IT SYSTEMS
HIE Document Repository	Stores and registers dynamic and persistent documents such as Clinical Summaries, on-demand Immunization Summaries, and on-demand Immunization Card documents. 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	HIE Platform - HIE Document Registry/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 On-Demand Document Source to construct the On-Demand Immunization Summary.	HIE Platform – Clinical Data Repository
Immunization Data Repository	Responds with immunization data as the authoritative source of immunization information (using the Immunization Registry e.g. MOH HESN) in response to queries from the Immunization On-Demand Document Source to construct the On-Demand Immunization Summary. Receives immunization reports and incorporating the information regarding the vaccines administered into the Immunization Data Repository.	Immunization Registry

ACTOR NAME	DESCRIPTION	EXAMPLE REAL-WORLD IT SYSTEMS
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.	HIE Document Repository
Immunization Summary Content Consumer	Queries and retrieves the Immunization Summary information for viewing, importing, or other processing of content from the HIE Document Repository. This requires support for on-demand document query to enable query for dynamically generated documents constructed through the HIE Document Repository's interaction with the Immunization Registry	Point of Care Systems such as: <ul style="list-style-type: none"> • Hospital Information Systems (HIS) • Primary Healthcare (PHC) Electronic Medical Record Systems • Other Point of care systems • MOH Business Applications
Immunization Card Content Creator	Responsible for the creation of the Immunization Card content that is provided to the patient as an electronic document, which represents the same information as is communicated on the paper immunization card. This includes support for 'proof of immunization' in order to support the Hajj requirements per Saudi Ministry of Health policy.	<ul style="list-style-type: none"> • Primary Healthcare (PHC) Electronic Medical Record Systems • Hospital Information System (HIS) • Other Point of care systems
Immunization Card Content Consumer	Responsible for querying and retrieving the Immunization Card information from the HIE 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. patient portal, Personal Health Record). It is expected that connected provider systems would support the Immunization Summary Content Consumer.	Point of Care Systems such as: <ul style="list-style-type: none"> • Hospital Information Systems (HIS) • Primary Healthcare (PHC) Electronic Medical Record Systems • Patient Portal • Other Point of care systems
Immunization Education Requestor	Responsible for requesting education information related to the Immunizations provided to the patient	Point of Care Systems such as: <ul style="list-style-type: none"> • Primary Healthcare (PHC) Electronic Medical Record Systems • Hospital Information System (HIS)
Immunization Education Responder	Responsible for providing the education material and responses to requests for education information.	Public Health Information System Immunization Registry System

2.5 HIGH-LEVEL SERVICES OVERVIEW

For the purpose of Interoperability, Services provide an abstract for the communication between Actors through standards-based messages, services, and information content.

2.5.1 Service Descriptions

The Services defined in this Use Case are described in Table 2.5-1 Overview of Immunization Services.

TABLE 2.5-1 OVERVIEW OF IMMUNIZATION SERVICES

SERVICE NAME	DESCRIPTION
Report Immunization	Communicates the immunization event to public health
Publish On-Demand Immunization Documents	Publishes records that show that Immunization Summary and Immunization Card documents are available from the Immunization Registry which 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. Patient Portal, 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.

2.5.2 Service Model

The service model for the Immunization Interoperability Use Case appears in the diagram below.

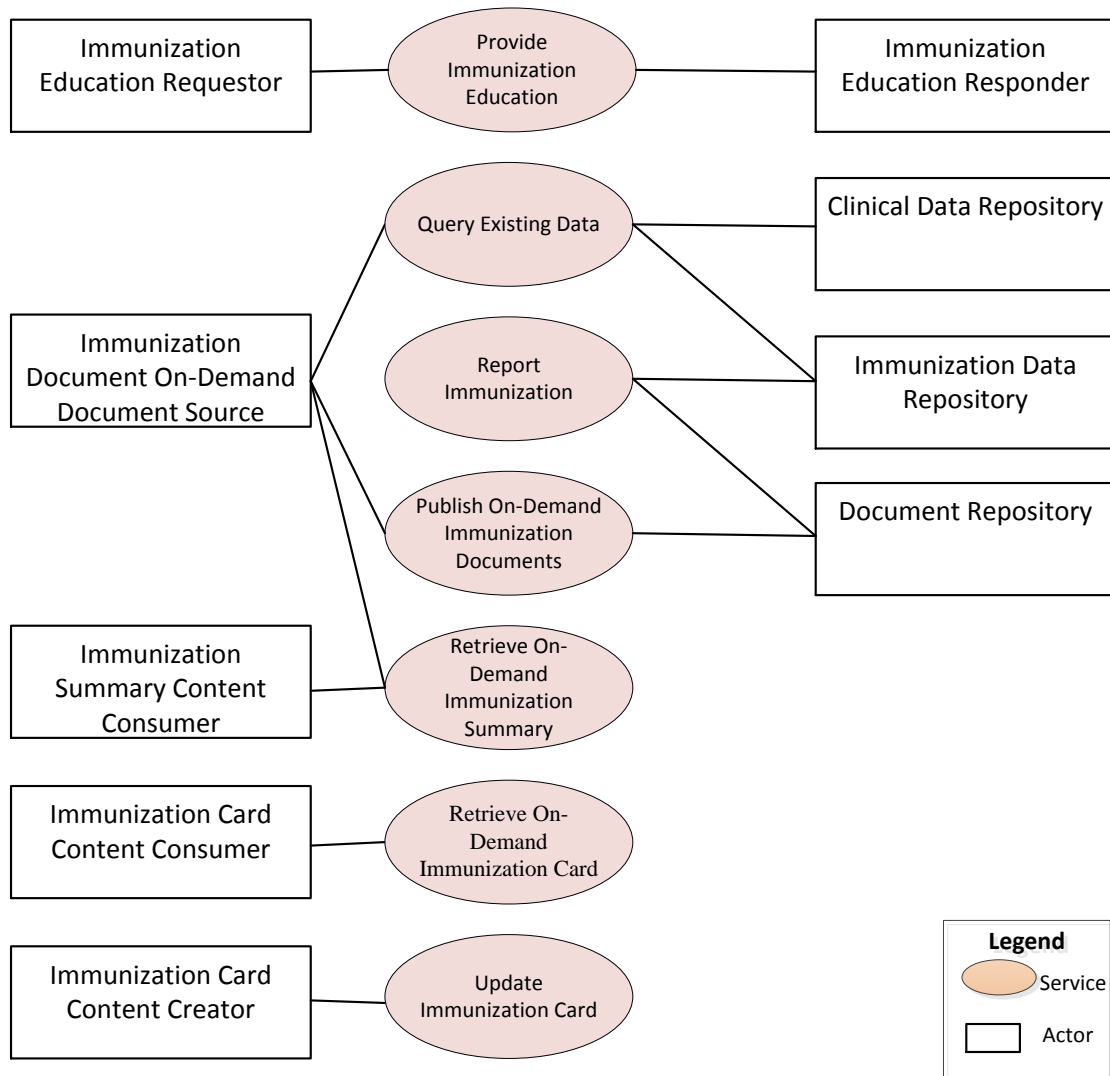


FIGURE 2.5-1 IMMUNIZATION SERVICE MODEL

3. IMMUNIZATION USE CASE

This Use Case describes the information workflow of Immunization, which requires collection and reporting of immunizations to the public health system, along with vaccination monitoring. The immunization decision is informed by the patient clinical status including:

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

3.1 IMMUNIZATION SCOPE

The Immunization Use Case covers support for providing needed information to the clinician for determination if a vaccination should be administered at the time of a clinical encounter, reporting to public health that a vaccination has been administered, and communicating to the patient information about current and pending immunizations.

3.2 IMMUNIZATION EXPECTED BENEFITS

For benefits of the Immunizations Use Case please refer to the list described in section 2.2 above.

3.3 IMMUNIZATION BUSINESS SCENARIOS

This section provides an analysis leading to refining the scope of a specific Use Case within the domain of interest.

The scope of each Use Case is defined to support a wide number of Business Scenarios relevant to the health information domain being considered. This is generally done in a flow-down discovery analysis, especially for Use Cases that are not well established.

The following section illustrates typical Business Scenarios that involve the identification of patients and obtaining the provider and/or organization information.

The following Users are associated with these Business Scenarios.

TABLE 3.3-1 SCENARIO USERS

USER	USER ROLE
Care Providers	The Healthcare Provider (physician, clinician, nurse, etc.) responsible for examination and treatment of the patient
Patient/Guardian	The person visiting a PHC or Private Physician or the person acting on their behalf
Administrative Staff	The person registering the patient in the Information System for the encounter
Public Health Immunization Registry Users	The person(s) responsible for the management of the public health immunization programs.

The following Information Systems are associated with these Business Scenarios.

TABLE 3.3-2 SCENARIO INFORMATION SYSTEMS

INFORMATION SYSTEM	SYSTEM ROLE
EMR	The Electronic Medical Records System used by a Physician or other Healthcare Providers.
HIE Platform	KSA-wide Interoperability Environment responsible for storing Clinical Documentation and also an Interoperability Environment enabling healthcare providers to share the clinical information of the patient.
HIS	The Electronic Healthcare Information System used by Administrative Staff and other Healthcare Providers within hospitals.
IIS	The Immunization Information System used by the public health Immunization Registry program (HESN)

3.3.1 Immunization Business Scenario 1: Childhood Immunization

3.3.1.1 Variant 1: Immunization Business Scenario 1: Childhood Immunization - Newborn

A child is born in the hospital. At the time of the birth the sex of the baby and the Name and ID of the mother are used to identify baby (along with their footprints). A new Health ID is created for the newborn [1]. As this is the first clinical encounter for the baby, there is no retrieval of the On-Demand Immunization Summary [3]. The baby is vaccinated within 24 hours of delivery for Bacillus Calmette–Guérin (BCG) and Hepatitis B (HepB) according to the Saudi Childhood Immunization Schedule. The parents are provided with the patient’s copy of the newly created Immunization Card [4] for the baby, generated by the POS, which is a new record, and educational material regarding the immunizations given [6]. A Newborn Discharge Summary is then published [7] to the HIE Document Repository. The HIE Publishes the On-Demand Immunization Summary and On-Demand Immunization Card documents [8]. In this case, the additional immunization document is provided containing immunization-related clinical history, and patient-directed immunization history and forecast information. Vaccinations administered to the patient are reported [5] to the Immunization Registry through the HIE.

3.3.1.2 Variant 2: Immunization Business Scenario 1: Childhood Immunization - Routine

Until the child reaches school age, each subsequent well-child visit requires that the patient be identified and their Health ID be obtained [2] from the Patient Demographic Supplier so that the Immunization Summary can be retrieved from the HIE Document Repository to inform the immunization decisions. The Immunization Summary includes the vaccination history along with the vaccine forecast and immunization-relevant clinical information compiled on-demand [3] by the HIE Document Repository from the Immunization Data Repository and the Clinical Data Repository. The provider determines whether there are any contraindications prior to administering the vaccine(s). The parents are provided with the patient’s copy of the updated

electronic Immunization Card containing the vaccine history and vaccinations due [4] which is generated by the POS and which will be an update replacing the previous card information, along with education material for the vaccines administered [5]. The Outpatient Encounter Summary (i.e. the summary of the visit) is published [7] to the HIE Document Repository. HIE Publishes the On-Demand Immunization Summary and On-Demand Immunization Card documents [8]. Vaccinations administered to the patient are reported [6] to the Immunization Registry through the HIE Document Repository.

3.3.1.3 Variant 3: Immunization Business Scenario 1: Childhood Immunization – Non-Hospital Birth, Defaulters, and Catch-Up

This flow applies in situations of non-hospital birth, defaulters, (Children who began the vaccination series (i.e. had access to services), but did not return for subsequent immunization doses.), and catch-up immunizations. In these cases, the child is identified and their Health ID is obtained [2] from the Patient Demographic Supplier. The clinical information and prior immunization history will be patient-reported or sourced from other historical records. The HIE Document Repository may still be queried to retrieve of the On-Demand Immunization Summary [3] through the HIE Platform using the Immunization Registry would also most likely result in no records found. The provider checks for contraindications prior to administering the vaccine(s) that are due. The parents are provided the patient’s copy of the updated electronic immunization card [4] generated by the POS, which will be a new record. (Subsequent visits would include an update to the Immunization Card [4], replacing the prior record.) Education materials are provided to the patient/guardian for the vaccines administered [5]. The Outpatient Encounter Summary (i.e. the summary of the visit) is published [7] to the HIE Document Repository. The HIE Publishes the On-Demand Immunization Summary and On-Demand Immunization Card documents [8]. Vaccinations administered to the patient are reported [6] to the Immunization Registry through the HIE.

3.3.1.4 Variant 4: Immunization Business Scenario 1: Childhood Immunization – Out-Of-Country Birth

If the child is born outside of Saudi Arabia, the clinical information and prior immunization history will be primarily patient-reported or sourced from other historical records. However, the child will be identified, and their Health ID will be obtained [2] through the HIE Platform. The HIE Document Repository may still be queried for the the On-Demand Immunization Summary [3], but records are unlikely to be found at the time of the first immunization visit. Serology may be performed for verification of vaccination [9], [10]. The provider checks for contraindications prior to administering the vaccine(s) that are due. The parents are provided with patient’s copy of the updated electronic immunization card [4] generated by the POS, which is a new record. (During subsequent visits, the parents are provided with patient’s copy of the updated Immunization Card [4], replacing the prior record). Education material are provided to the patient/guardian for the vaccines administered [5]. The Outpatient Encounter Summary (i.e. the summary of the visit) is published [7] to the HIE Document Repository. The On-Demand Immunization Summary and Immunization Card documents are published [8] to the HIE Document Repository. In this case, the additional immunization document is provided containing immunization-related clinical history, and patient-directed immunization history and forecast information. Vaccinations administered to the patient are reported, along with vaccination history

as determined through parent-provided vaccination history, serology proofing, and prior physician reports [6] to the Immunization Registry through the HIE.

3.3.1.5 Variant 5: Immunization Business Scenario 1: Childhood Immunization – School Screening for Admission

In the case of school screening, the child will be identified, and their Health ID will be obtained [2] through the HIE Platform, and the vaccination history is retrieved along with the vaccine forecast [3], compiled on-demand through a query to the Immunization Registry. In this case, vaccine reporting is not necessary, as there are no vaccines administered in this variant.

TABLE 3.3-3 HIGH LEVEL BUSINESS PROCESSES FOR CHILDHOOD IMMUNIZATION (ALL VARIANTS)

STEP	FLOW	BUSINESS PROCESS	REFERENCE
1	Main Flow	Identify Baby	Section 4.2.2
2	Main Flow	Obtain Patient Health Identifier	Section 4.2.1
3	Main Flow	Retrieve On-Demand Immunization Summary	Section 4.1.1
4	Main Flow	Update Immunization Card	Section 4.1.2
5	Main Flow	Provide Education Material	Section 4.1.3
6	Main Flow	Report Immunization to Registry	Section 4.1.4
7	Main Flow	Publish Clinical Summary Document	Section 4.2.7
8	Main Flow	Publish On-Demand Immunization Documents	Section 4.1.5
9	External Flow	Order Laboratory Tests	Section 4.2.4
10	External Flow	Review Laboratory Results	Section 4.2.6

3.3.2 Immunization Business Scenario 3: Indication-Based Immunization -

There are many other indication-based reasons for immunization, including risk of specific exposure due to travel plans, social exposure, demographics, and health conditions. Immunizations may be administered to mitigate a specific risk at the time of a clinical visit, or may be administered as part of an outreach campaign. A patient may present to the clinician for purposes of vaccination, or as part of a routine clinical encounter.

In these cases, the patient is identified and their Health ID is obtained [1] through the HIE Platform. The Clinical history and Immunization history is reviewed [2], along with information gathered for the current visit. This information is used to inform indications or contraindications

for immunizing the patient, and alignment with any immunization campaigns. For instance, a memorandum may:

- Advise who should receive an influenza vaccine.
- Indicate exposure to pertussis, which may be determined through case investigation.
- The patient may be elderly and at risk for pneumonia.
- The patient may be planning travel to a country where vaccination is recommended.

Immunization status is determined from the patient clinical record and the patient interview. Laboratory serology tests may be ordered [3] and laboratory results reviewed [4] to confirm the immunity status of the patient prior to administering the vaccine. The patient is provided with educational material [5] regarding the immunizations given. The Outpatient Encounter Summary (i.e. the summary of the visit) is published [7] to the HIE Document Repository. A report of the vaccination is sent to the Immunization Registry through the HIE where the records of the campaign vaccinations are managed [6]. No Immunization Summary document is updated for indication-based vaccinations.

TABLE 3.3-4 HIGH LEVEL BUSINESS PROCESSES FOR INDICATION-BASED IMMUNIZATION

STEP	FLOW	BUSINESS PROCESS	REFERENCE
1	Main Flow	Obtain Patient Health Identifier	Section 4.2.1
2	Main Flow	Review Historical Medical Documentation	Section 4.2.8
3	External Flow	Orders Laboratory Test	Section 4.2.4
4	External Flow	Laboratory Results	Section 4.2.6
5	Main Flow	Provide Education Material	Section 4.1.3
6	Main Flow	Report Immunization to Registry	Section 4.1.4
7	Main Flow	Publish Clinical Summary Document	Section 4.2.7

3.3.3 Immunization Business Scenario 2: Hajj

During the application process for Hajj, the patient needs to show proof of having received a Meningitis vaccination. This Business Scenario is a category of the Indication-Based Immunization Scenario in section 3.3.2, and uses the same flows. Typically, no records will be found if the Immunization History is queried, until the Immunization Registry is expanded to include Hajj vaccinations, and these would only be available for those that receive healthcare in Saudi Arabia. For this reason, there is no Immunization History queried in the Hajj Business Scenario. Laboratory serology tests may be ordered to confirm the immunity status of the patient prior to administering the vaccine. The patient is provided with proof of the immunization (immunization card), along with educational material regarding the immunizations given. Hajj vaccinations are not currently collected and managed by the Immunization Registry, but this may be a future capability which would use the same reporting flows as the Indication-Based Immunization Scenario.

3.4 IMMUNIZATION PROCESS FLOWS

3.4.1 Immunization Process Overview

The Immunization Business Process Model shown in the figure below is a composite of all of the process flows developed for this Use Case. It has been developed based on analysis of all of the process flows and identified from the Use Case scenarios described above. The diagram below depicts the user roles and the associated activities. The following are the Business Processes associated with the immunization encounters.

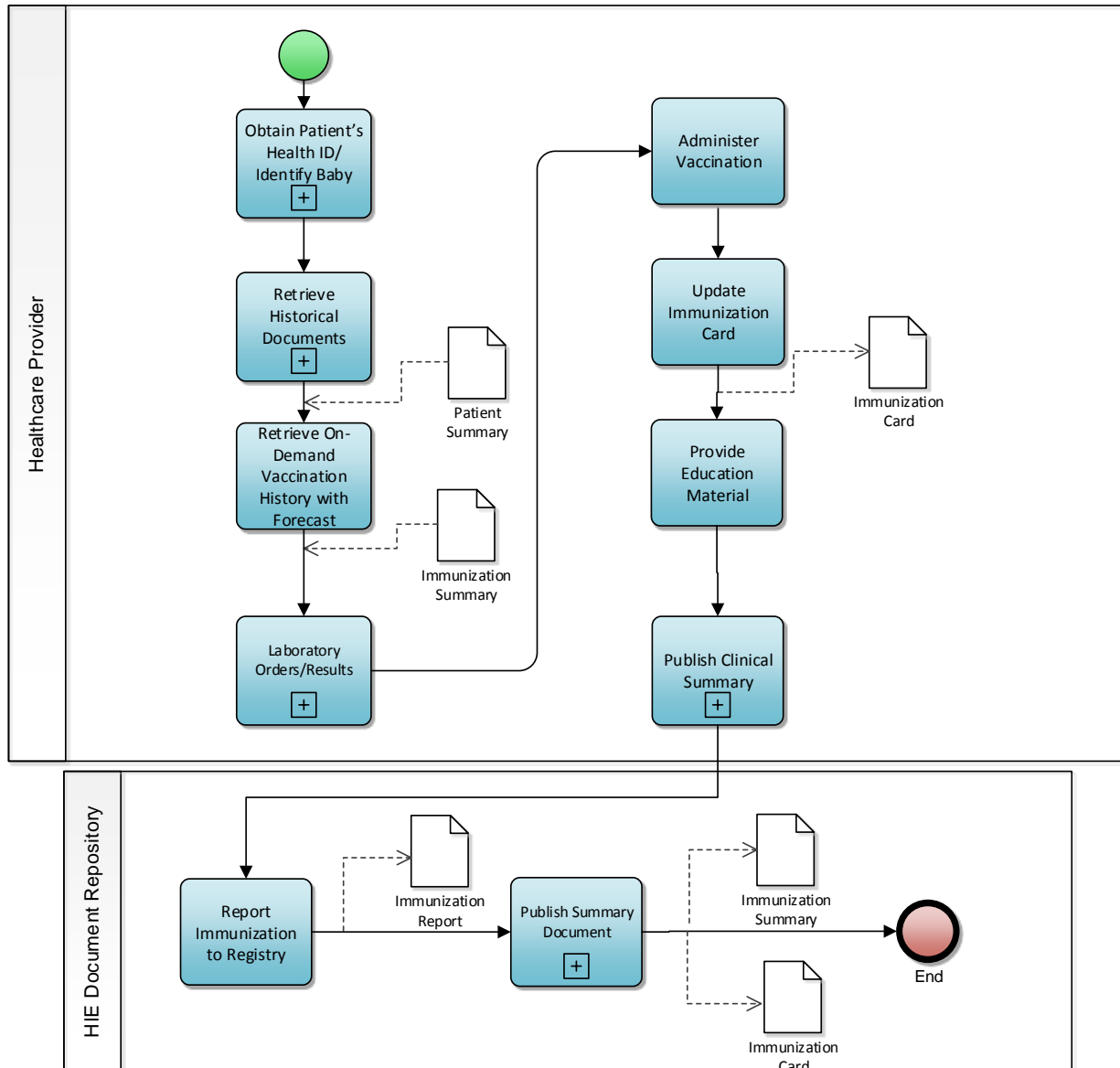


FIGURE 3.4-1 IMMUNIZATION PROCESS DIAGRAM

The details of the Business Processes may be found in Section 4 Detailed Business Processes

3.4.2 Immunization Main Flow of Events

A patient is vaccinated based upon indications determined at the time of the patient encounter, and the vaccination is reported to the immunization registry.

The main flow of events for the Immunization Use Case is the following:

1. At the beginning of the encounter the Healthcare Provider uses the Patient Demographic Consumer Actor (e.g. EMR or HIS) to **obtain the Patient Health Identifier**. For the newborn, this includes the processes to **Identify the Baby** as defined by the KSA Patient Demographic Query.
2. The patient's immunization history and vaccine recommendations are verified by **Retrieving the On-Demand Immunization Summary** that is dynamically constructed to reflect the most current history and recommendations.
3. Immunization relevant laboratory results are reviewed to inform the vaccination decision.
4. The patient is examined and history verified for indications and for contraindications prior to administering the vaccination. The patient is vaccinated.
5. The education information is requested by the Healthcare Provider using the Immunization Education Requestor and the information is provided by the Immunization Education Responder. The **Clinical Summary document is Published** to the HIE Document Repository.
6. The vaccination is **Reported to the Immunization Registry** by the HIE Document Repository and received by the Immunization Data Repository actor where the information is incorporated into the Immunization Registry (e.g. HESN).
7. The patient **On-Demand Immunization Summary Document and the On-Demand Immunization Card** will be generated internally inside the HIE where they will be made available for next the patient encounter.
8. Once the patient is vaccinated, an electronic copy of the **Immunization Card is** generated by the Immunization Card Content Creator Actor and provided to the patient

3.4.3 Immunization External Flow of Events

3.4.3.1 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 Use Case, would be added prior to the vaccination in step 5 of the main flow of events. When laboratory testing is not conducted inside of the organization, then the following steps apply:

1. A laboratory serology test **order is published** by the Laboratory Order Creator to assess the immunity status of the patient

2. The HIE Document Repository sends a **Notification of Document Availability** to the Laboratory Order Fulfiller that there is a serology order of interest.
3. Laboratory Order Fulfiller **queries and retrieves the serology order** from the HIE Document Repository
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 HIE Document Repository
6. The Laboratory Results are available to the Immunization Document On-Demand Document Source in steps 3 and 4 of the main Immunization Workflow.

3.4.4 Immunization Exceptions Workflow

There are no Exception Workflows defined for the Immunization Use Case. All workflows are identified under the main flow of events.

3.5 IMMUNIZATION INFORMATION REQUIREMENTS

This section defines the general scope of the type of data needed for this Use Case. However, it does not define the entire detailed data set, as this will be discussed in the Saudi eHealth Interoperability Specification design document.

TABLE 3.5-1 IMMUNIZATION SUMMARY DATA CONTENT

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
Source and context of demographic information needed to support immunization decisions patient identification		
PATIENT DEMOGRAPHICS - DATA ELEMENTS THAT IDENTIFY THE PATIENT, AND PROVIDE ADDITIONAL INFORMATION ABOUT THEM THAT MAY BE IMPORTANT IN THE TRANSITION OF CARE FOR A PATIENT. THE FOLLOWING ATTRIBUTES HAVE BEEN IDENTIFIED AS IMPORTANT:		
HealthID	Healthcare Identifier of the patient.	Text
Name	Patient names including (First, Middle, Last): Mothers; grandfather.	Text
Date of birth	Birth date of the patient in both Hijri and Gregorian.	Date/ Timestamp
Gender	Patient's gender	Coded
Citizenship	Country of citizenship of the patient (e.g. Saudi Arabia, UK).	Coded
Contact Phone Numbers	Phone numbers where the patient may be reached for follow-up (including mobile).	Text
Catchment Area	Service area for the immunizations given.	Text
Address	Address where the patient resides.	Text

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
VACCINATION HISTORY DATA - DATA ELEMENTS WHICH DESCRIBE INFORMATION ABOUT THE VACCINATION. THE FOLLOWING ELEMENTS WILL BE REPEATED FOR EVERY VACCINE ADMINISTERED TO THE PATIENT		
Vaccination Given Indicator	Indicates whether the vaccination reported was completed or was not given.	Coded
Vaccination Information Informant	Indicates the source of the vaccination information (i.e. patient, patient agent, provider), used to identify historical vaccination information.	Text and Coded
Vaccination Generic name	Vaccine agent (e.g. BCG, DTaP, DT, Diphtheria)	Coded
Manufacturer	Manufacturer of the vaccine administered (e.g. GSK, Sanofi Pasteur)	Coded
Product	Name of product used for the vaccination (e.g. Measles Vaccine 2000 UNT/ML Injectable Solution [Attenuvax],).	Coded
Batch Number/Lot Number	Batch/Lot number of the vaccine administered.	Text
Expiration Date	Expiration date of the substance administered.	Date/ Timestamp
Dose	Amount/Dose used in the vaccination.	Text
Dosage Unit	Units associated with the vaccine dose (e.g. ml).	Coded
Route Administered	Route used to administer the vaccination (e.g. Oral, Intramuscular).	Coded
Body Site of Administration	Location on the body where the vaccination was administered (e.g. left arm, right thigh).	Coded
Date of Administration	Date the vaccination was given.	Date/ Timestamp
Reason for Administration	Reason for the vaccination (e.g. Campaign, Hajj, Routine, etc.).	Coded
Exemptions/Reason Not Given	Reason the vaccination was not given to the patient [Only on reporting and new administration and not on vaccine history data]. (e.g. Cost-related, Vaccine Supply Issues)	Coded

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
Campaign Identifier or Name	Associated with the vaccination campaign (if applicable) associated with the vaccination administered.	Text
Contraindications and Indications	<p>Reasons that an immunization should not be administered, including:</p> <ul style="list-style-type: none"> • Allergies (to medications, food, a vaccine component, or latex). • Risk Factors primarily from problem lists, laboratory results, and social history: • Some vaccinations cannot be administered in some situations; diseases, immunocompromised, HICVAIDS, cancer. • Serious reaction to a vaccine in the past. • History of a health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, or a blood disorder. • Patient is on a long-term aspirin therapy. • Patient is between the ages of 2 and 4 years, with provider-documented wheezing or asthma in the past 12 months. • Baby with intussusception. • Child, a sibling, or a parent has had a seizure. • Child had brain or other nervous system problem. • Child has cancer, leukemia, HIV/AIDS, or any other immune system problem. • In the past year, the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug. • the patient is pregnant or is there a chance she could become pregnant during the next month • The child received vaccinations in the past 4 weeks. 	Text and Coded

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
Risk Factors of infection	Primarily from problem lists, procedure history, laboratory results, and social history <ul style="list-style-type: none"> • Surgery • Pregnancy • Prior Exposures/disease History • Employment • Lab results (serology) indicating not immunized (Immunoglobulin G) • Travel 	Text and Coded
Problems	Clinical conditions impacting immunization decisions, including support for responding to the Saudi Screening Questionnaire for Child and Teen Immunizations. : <ul style="list-style-type: none"> • Has the child had a health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy? • If the child to be vaccinated is between the ages of 2 and 4 years, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months? • If your child is a baby, have you ever been told he or she has had intussusception? • Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problems? • Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem? • Has the child had a serious reaction to a vaccine in the past? 	Text and Coded
Allergies	Allergies impacting immunization decisions, including support for responding to the Saudi Screening Questionnaire for Child and Teen Immunizations. <ul style="list-style-type: none"> • Does the child have allergies to medications, food, a vaccine component, or latex? • Has the child had a serious reaction to a vaccine in the past? 	Text and Coded

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
Medications	<p>Medications the patient is taking impacting immunization decisions, including support for responding to the Saudi Screening Questionnaire for Child and Teen Immunizations.</p> <ul style="list-style-type: none"> Has the child had a health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy? In the past 3 months, has the child taken medications that weaken their immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments? 	Text and Coded
Procedures	<p>Procedures impacting immunization decisions including support for responding to the Saudi Screening Questionnaire for Child and Teen Immunizations.</p> <ul style="list-style-type: none"> In the past year, has the child received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? In the past 3 months, has the child taken medications that weaken their immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or had radiation treatments? 	Text and Coded
Serology Results	Laboratory Results for Serology indicating the patient has been exposed to the vaccine antigen to serve as an indication or contraindication for a given immunization.	Text and Coded
VACCINE FORECAST: LIST OF VACCINATIONS AND DATES DUE AS DETERMINED BY MOH IMMUNIZATION SCHEDULE		
Vaccination Generic Name	Vaccine agent (e.g. BCG, DTaP, DT, Diphtheria)	Coded
Date Due	Date by which the vaccine is needed to effectively protect the patient.	Date/ Timestamp

TABLE 3.5-2 PATIENT IMMUNIZATION CARD DATA CONTENT

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
Source and context of demographic information needed to support immunization decisions patient identification		
PATIENT DEMOGRAPHICS - DATA ELEMENTS THAT 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	Healthcare Identifier of the patient.	Text
Name	Patient names including (First, Middle, Last): Mothers; grandfather.	Text

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
Date of Birth	Birth date of the patient in both Hijri and Gregorian.	Date/ Timestamp
Gender	Patient's gender	Coded
Citizenship	Country of citizenship of the patient (e.g. Saudi Arabia, UK).	Coded
Contact Phone Numbers	Phone numbers where the patient may be reached for follow-up (including mobile).	Text
Catchment Area	Service area for the immunizations given.	Text
Address	Address where the patient resides.	Text
VACCINATION HISTORY DATA - DATA ELEMENTS WHICH DESCRIBE INFORMATION ABOUT THE VACCINATION INCLUDING:		
Vaccination Given Indicator	Whether or not the vaccination reported was completed or was not given.	Coded
Vaccination Information Informant	Source of the vaccination information (e.g. patient, patient agent, provider, etc.), used to identify historical vaccination information.	Text and Coded
Vaccination Generic Name	Vaccine agent (e.g. BCG, DTaP, DT, Diphtheria).	Coded
Manufacturer	Manufacturer of the vaccine administered (e.g. GSK, Sanofi Pasteur).	Coded
Product	Name of product used for the vaccination (e.g. Measles Vaccine 2000 UNT/ML Injectable Solution [Attenuvax]).	Coded
Batch Number/Lot Number	Batch/Lot number of the vaccine administered.	Text
Expiration Date	Expiration date of the substance administered.	Date/ Timestamp
Dose	Amount/Dose used in the vaccination.	Text
Dosage Unit	Units associated with the vaccine dose (e.g. ml).	Coded
Dose Number	the dose number for a component of a combination vaccine	Numeric
Route Administered	Route used to administer the vaccination (e.g. Oral, Intramuscular).	Coded
Body Site of Administration	Location on the body where the vaccination was administered (e.g. left arm, right thigh).	Coded
Date of administration	Date that the vaccination was given.	Date/ Timestamp
Reason for administration	Reason for the vaccination (e.g., Campaign, Hajj, Routine, etc.).	Coded
Exemptions/Reason Not Given	Reason that the vaccination was not given to the patient [Only on reporting and new administration and not on vaccine history data] (e.g. Cost-related, Vaccine Supply Issues).	Coded
Campaign Identifier or Name	Identifier associated with the vaccination campaign (if applicable) associated with the vaccination administered.	Text

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
Vaccine Forecast: List of vaccinations and dates due as determined by MOH Immunization Schedule		
Vaccination Generic Name	Vaccine agent (e.g. BCG, DTaP, DT, Diphtheria)	Coded
Date Due	Date by which the vaccine is needed to effectively protect the patient.	Date/ Timestamp

TABLE 3.5-3 IMMUNIZATION REPORTING DATA CONTENT

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
Source and context of demographic information needed to support immunization decisions patient identification		
PATIENT DEMOGRAPHICS - DATA ELEMENTS THAT 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	Healthcare Identifier of the patient.	Text
Name	Patient names including (First, Middle, Last): Mothers; grandfather.	Text
Date of Birth	Birth date of the patient in both Hijri and Gregorian.	Date/ Timestamp
Gender	Patient's gender	Coded
Citizenship	Country of citizenship of the patient.	Coded
Contact Phone Numbers	Phone numbers where the patient may be reached for follow-up (including mobile).	Text
Catchment Area	Service area for the immunizations given.	Text
Address	Address where the patient resides.	Text
VACCINE FORECAST: LIST OF VACCINATIONS AND DATES DUE AS DETERMINED BY MOH IMMUNIZATION SCHEDULE		
Vaccination Given Indicator	Indicates whether or not the vaccination reported was completed or was not given	Coded
Vaccination Information Informant	Source of the vaccination information (e.g. patient, patient agent, provider, etc.), used to identify historical vaccination information.	Text and Coded
Vaccination Generic Name	Vaccine agent (e.g. BCG, DTaP, DT, Diphtheria)	Coded
Manufacturer	The manufacturer of the vaccine administered (e.g. GSK, Sanofi Pasteur).	Coded
Product	Name of product used for the vaccination (e.g. Measles Vaccine 2000 UNT/ML Injectable Solution [Attenuvax]).	Coded
Batch Number/Lot Number	Batch/Lot number of the vaccine administered.	Text

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
Expiration date	Expiration date of the substance administered.	Date/ Timestamp
Dose	Amount/dose used in the vaccination.	Text
Dosage Unit	Units associated with the vaccine dose (e.g. ml).	Coded
Route Administered	Route used to administer the vaccination (e.g. Oral, Intramuscular).	Coded
Body Site of Administration	Location on the body where the vaccination was administered (e.g. left arm, right thigh).	Coded
Date of Administration	Date that the vaccination was given.	Date/ Timestamp
Reason for Administration	Reason for the vaccination (e.g. Campaign, Hajj, Routine, etc.).	Coded
Exemptions/Reason Not Given	Reason that the vaccination was not given to the patient [Only on reporting and new administration and not on vaccine history data] (e.g. Cost-related, Vaccine Supply Issues).	Coded
Campaign Identifier Or Name	The vaccination campaign (if applicable) associated with the vaccination administered.	Text
FACILITY INFORMATION: DATA ELEMENTS WHICH DESCRIBE THE HEALTHCARE ORGANIZATION OF THE HEALTHCARE PROFESSIONAL IMMUNIZING THE PATIENT AND REPORTING THE IMMUNIZATION INCLUDING:		
Author Identifier	Provider who created the immunization record.	Text and Coded
Organization Identifier	Provider identifier of the Organization that administered the vaccine (as recorded in the KSA Provider Directory).	Text and Coded
Organization Name	Provider name of the Organization that administered the vaccine (as recorded in the KSA Provider Directory).	Text
Organization Address	Provider address Organization that administered the vaccine (as recorded in the KSA Provider Directory).	Text
Organization Contact Information	Provider contact information for the Organization that administered the vaccine (as recorded in the KSA Provider Directory).	Text
HEALTHCARE PROVIDER INFORMATION (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 from the Healthcare Provider Directory associated with the Healthcare Professional	Text and Coded
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
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

IMMUNIZATION INPUT CONCEPTS	DESCRIPTION	TEXT/ CODED
Healthcare Professional profession	Specialty from the Healthcare Provider Directory associated with the Healthcare Professional of the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory Individual Provider Type of the KSA Provider Directory).	Text and Coded
Healthcare Contacts	Provider contact information for the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory Individual Provider Specialty of the KSA Provider Directory).	Text
HEALTHCARE PROVIDER INFORMATION (PERSON ADMINISTERING VACCINE): DATA ELEMENTS WHICH DESCRIBE THE HEALTHCARE PROFESSIONAL PERFORMING THE VACCINE ADMINISTRATION INCLUDING:		
Healthcare Professional identifier	Provider identifier from the Healthcare Provider Directory associated with the Healthcare Professional who administered the vaccine.	Text and Coded
Healthcare Professional name	Provider name of the person who administered the vaccine for the vaccination (as recorded in the KSA Provider Directory) (e.g. Applied Medical Sciences, Nursing).	Text
Healthcare Professional specialty	Specialty from the Healthcare Provider Directory associated with the Healthcare Professional of the person who administered the vaccine (as recorded in the KSA Provider Directory Individual Provider Type of the KSA Provider Directory)..	Text and Coded
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
Healthcare Contacts	Provider contact information for the person that conducted the pre-exam for the vaccination (as recorded in the KSA Provider Directory).	Text
VACCINATION REPORT ADDITIONAL INFORMATION:		
Adverse Reaction	Documentation indicating that there was an adverse reaction associated with the vaccination given.	Text and Coded

4. DETAILED BUSINESS PROCESSES

These are comprised of a number of Business Processes, some are defined in this document and others are defined in documents external to this Use Case.

4.1 IMMUNIZATION BUSINESS PROCESSES

These business processes aggregate several business processes from the Use Cases described in this workstream of the health standard-based Interoperability Specification and Policy Project..

4.1.1 Retrieve On-Demand Immunization Summary

Retrieve On-Demand Immunization Summary includes the initiation of an on-demand request of the Immunization Summary by the Immunization Summary Content Consumer Actor. This request uses the Query Registry transaction to query the HIE Document Repository with the Health ID, but includes an indicator to include on-demand registered documents in the query results. The Immunization Summary Content Consumer issues a Retrieve Document request, the Immunization Document On-Demand Document Source queries the Immunization Data Repository for the current immunization history with the vaccine forecast information which is included in the summary document as determined by the Immunization Registry as the authoritative source of the Saudi Immunization Schedule. The Immunization Document On-Demand Document Source also Queries the Clinical Data Repository for the relevant immunization related clinical history to be included in the Immunization Summary Document. .

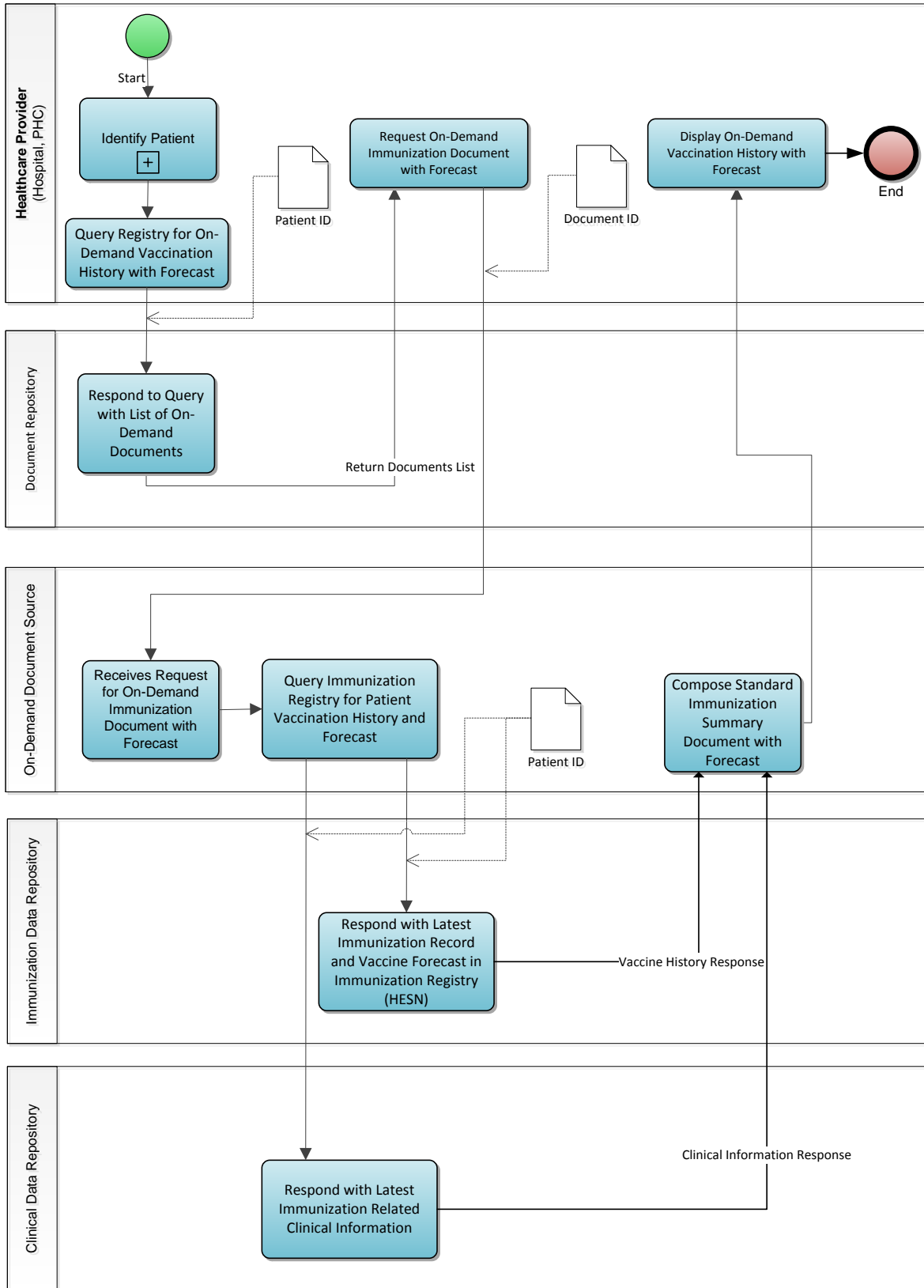


Figure 4.1.1-1: Retrieve On-Demand Immunization Summary workflow below depicts the workflow associated with the Retrieve On-Demand Immunization Summary.

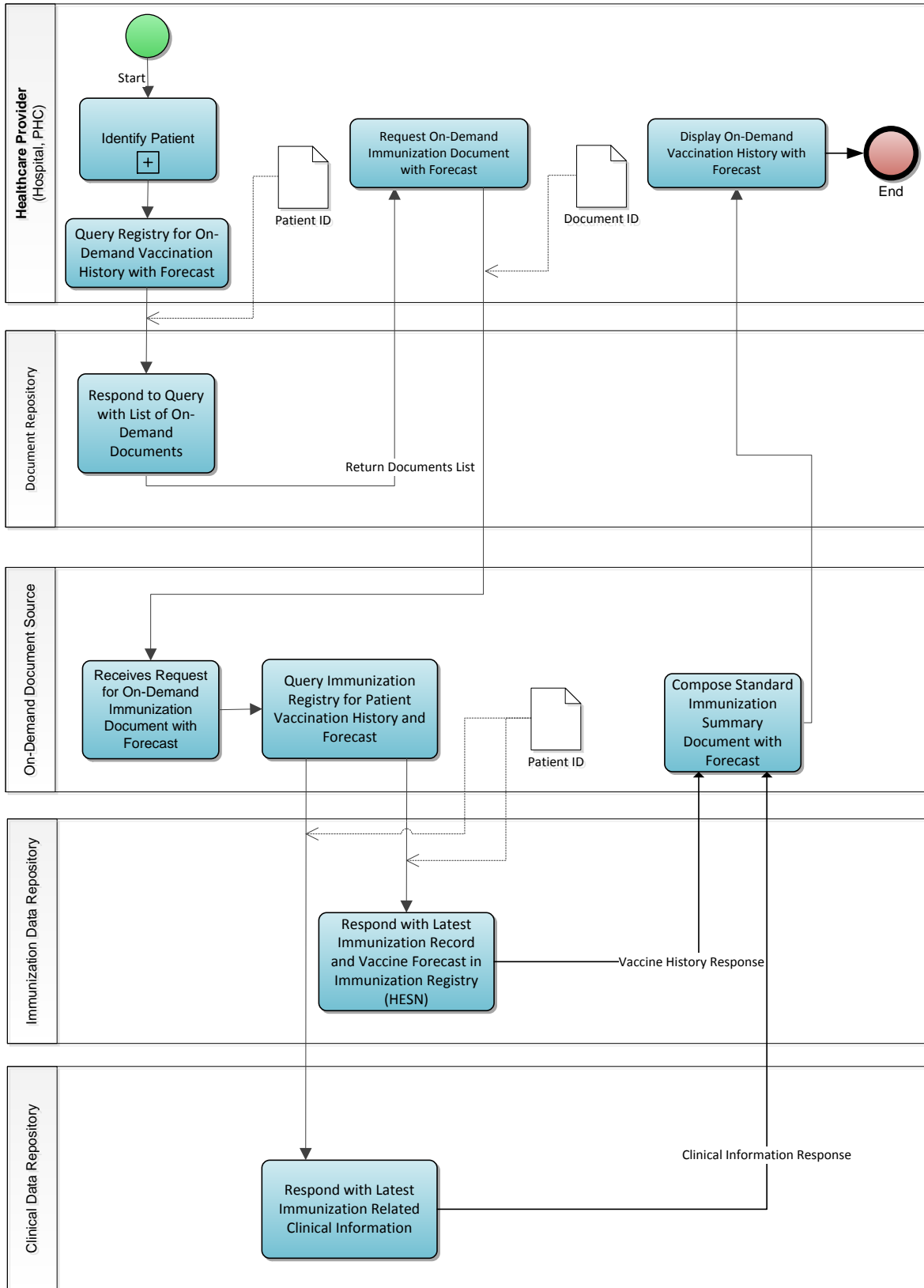


FIGURE 4.1.1-1: RETRIEVE ON-DEMAND IMMUNIZATION SUMMARY WORKFLOW

4.1.2 Update Immunization Card

The Update Immunization Card business process includes the ability to write the Immunization Card to portable media or send via email. The Immunization Card needs to be updated for each vaccination and as such requires a document replacement of any prior Immunization Card.

The Steps for providing education materials are:

1. The Patient is Vaccinated and the immunization is recorded in the local EMR Record.
2. The provider uses the local EMR to create the Immunization Card.
3. The Immunization Card is written to portable media or email.
4. The patient card is provided to the patient by email or on portable media.

NOTE: The immunization card is provided to the Document Repository where it is registered for on-demand retrieval as part of the Publish On-Demand Immunization Documents service (see Section [4.1.5 Publish On-Demand Immunization Documents](#)) and is not depicted in this workflow.

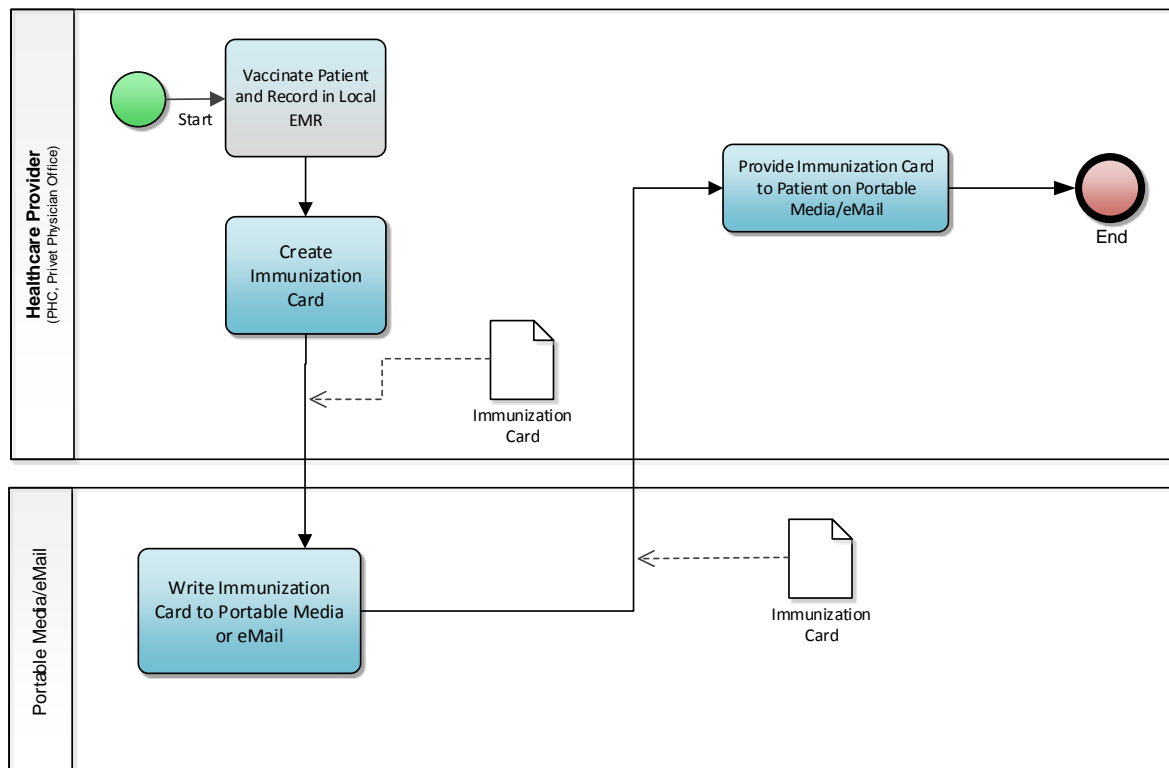


FIGURE 4.1.2-1 UPDATE IMMUNIZATION CARD WORKFLOW

4.1.3 Provide Education Material

The Provide Education Material business process includes the ability to query an information resource for education material relating to a given immunization. This allows the latest

information to be maintained and provided by the Immunization Registry (HESN) services. The Steps for providing education materials are:

1. The Patient is Vaccinated.
2. The Provide Education Materials Service uses the details of the vaccine administered to the patient to request education materials pertaining to the vaccine given.
3. The Immunization Registry (HESN) responds to the request for education materials with the latest education guidance for the patient.
4. The Healthcare Provider give the education materials to the patient.

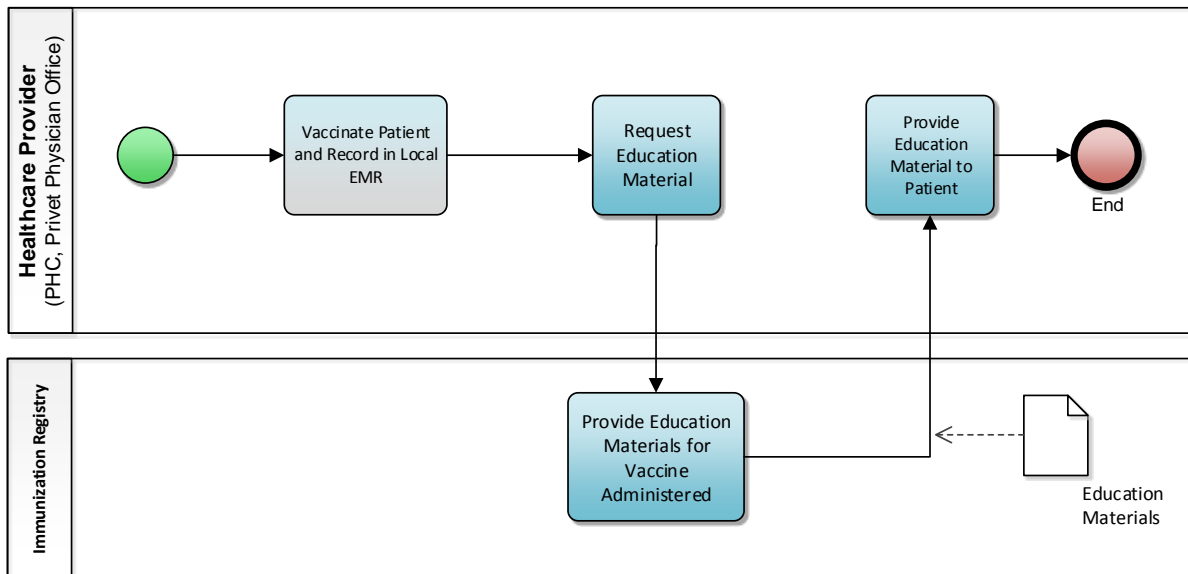


Figure 4.1.3-1: *Provide Education Material* Workflow below depicts the workflow associated with the Provide Education Material.

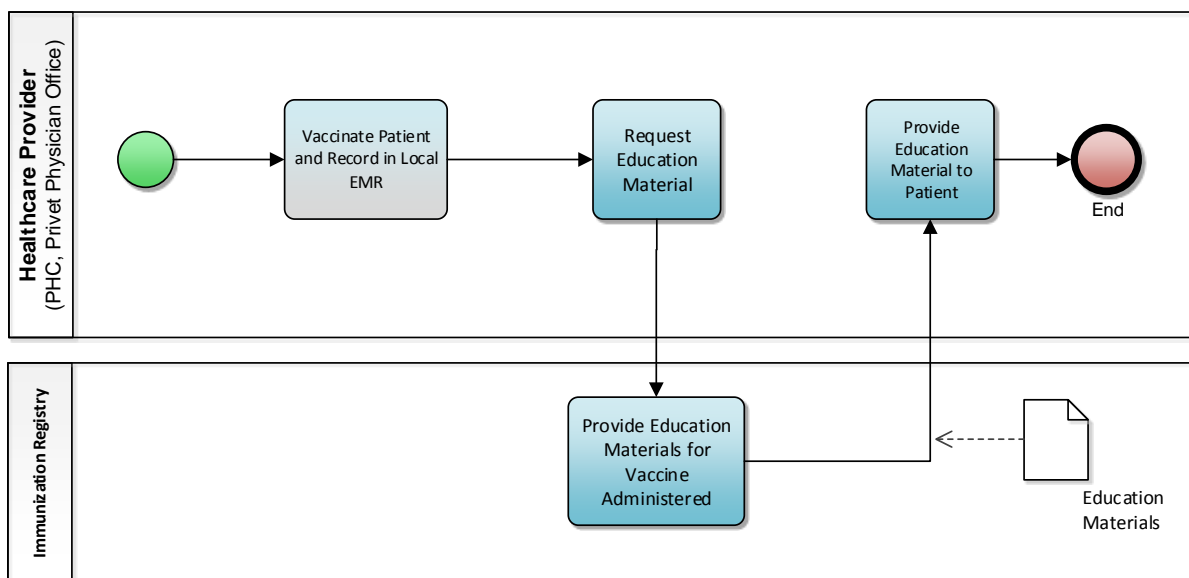


FIGURE 4.1.3-1: PROVIDE EDUCATION MATERIAL WORKFLOW

4.1.4 Report Immunization to Registry

The Report Immunization to Registry business process includes the ability to submit the vaccination of the patient to the Immunization Registry. The Steps for Reporting the Immunization to the Registry are:

Following a clinical encounter, the Healthcare Provider system sends the Clinical Summary that includes the report information that is needed for the Immunizations administered to the patient.

1. The HIE Repository receives the Registered Clinical Summary
2. The Report Immunization Service extracts the immunization report content from the Clinical Summary and transforms the immunization information to the Report Format.
3. The Report Immunization Service sends the formatted report to the Immunization Data Repository.
4. The Immunization Data Repository receives the report, and incorporates the report into the Immunization Registry (HESN).

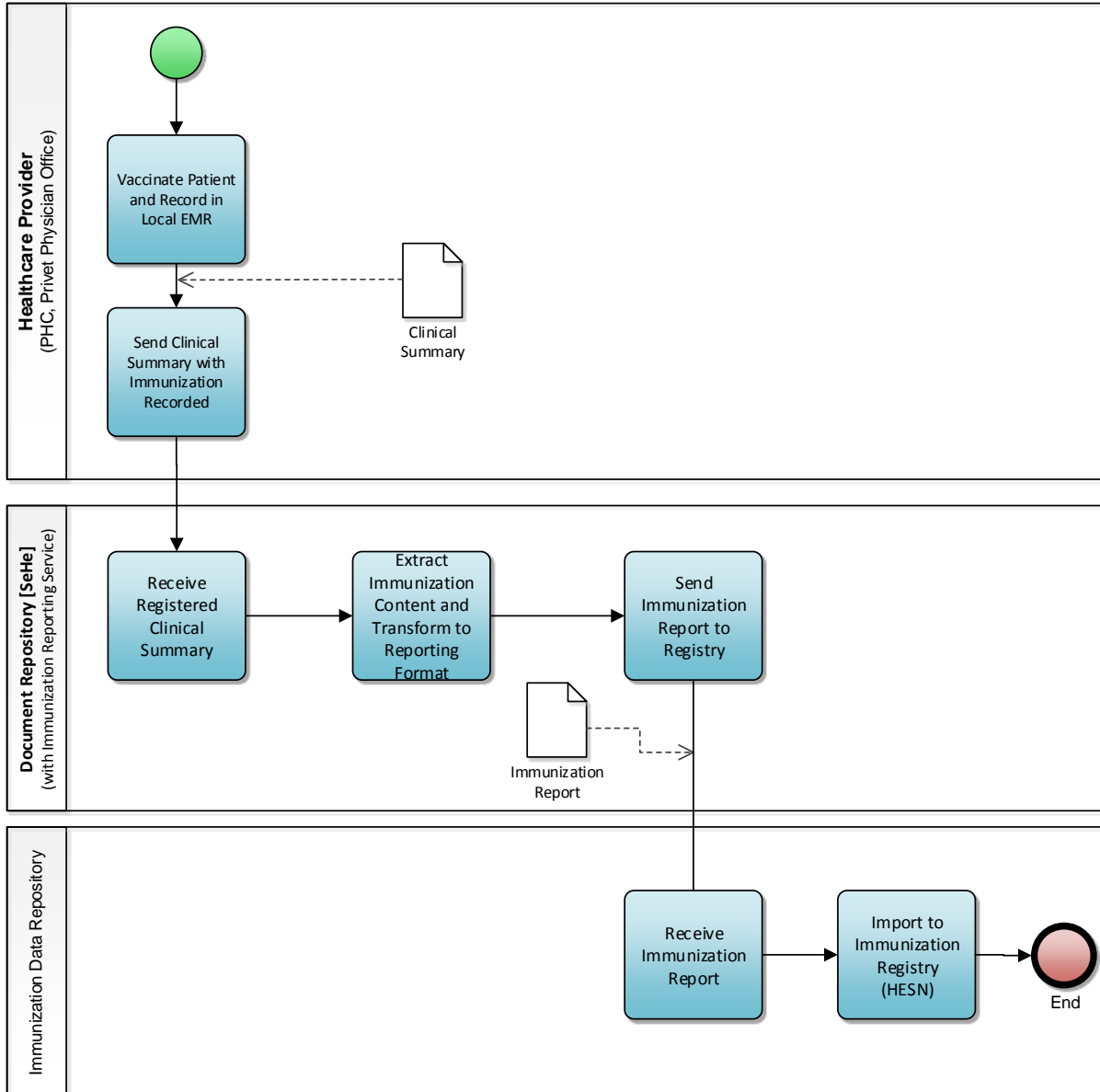


Figure 4.1.4-1: *Report Immunization to Registry* Workflow depicts the workflow associated with the Report Immunization to Registry.

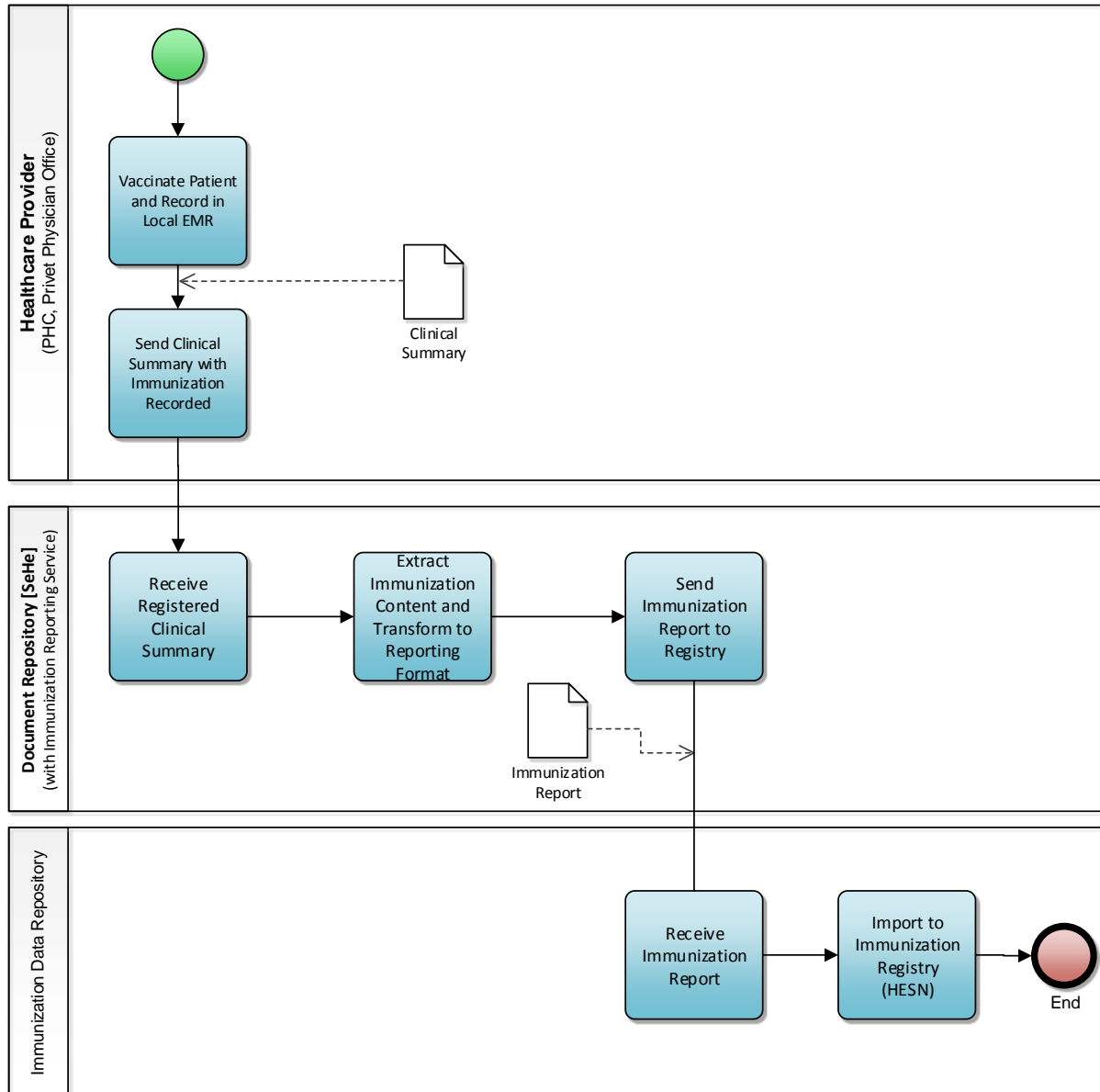


FIGURE 4.1.4-1: REPORT IMMUNIZATION TO REGISTRY WORKFLOW

4.1.5 Publish On-Demand Immunization Documents

The Publish On-Demand Immunization Documents business process includes the On-Demand Document Source registering of the Immunization Summary and Immunization Card documents to the HIE Document Repository based upon the dynamically generated Immunization information with the latest clinical and immunization registry content. The steps for publishing the On-Demand Immunization Documents are:

1. Following a clinical encounter, the Healthcare Provider system sends the Clinical Summary that includes the Immunizations administered to the patient
2. The HIE Repository receives the Registered Clinical Summary
3. Publish On-Demand Immunization Documents Service checks for immunizations, and if vaccinations have been administered during the visit,

- a. the Immunization Summary is published:
 - i. Immunization Summary Metadata is extracted, and
 - ii. an On-Demand Immunization Summary is provided to the Document Repository such that it can be dynamically constructed,
 - iii. The Immunization Summary Metadata is registered in the HIE Document Repository.
- b. The Immunization Card is registered
 - i. Immunization Card Metadata is extracted, and
 - ii. and On-Demand Immunization Card is provided to the Document Repository such that it can be dynamically constructed, and
 - iii. The Immunization Card Metadata is registered in the HIE Document Repository

Note: information may be entered into the Immunization Registry outside of the Saudi Health Information Exchange through the registry's application web interface. This information will be available through the On-Demand retrieval of Immunization Summary documents. This happens outside the Report Immunization to Registry Workflow and as such is not depicted in the diagram below.

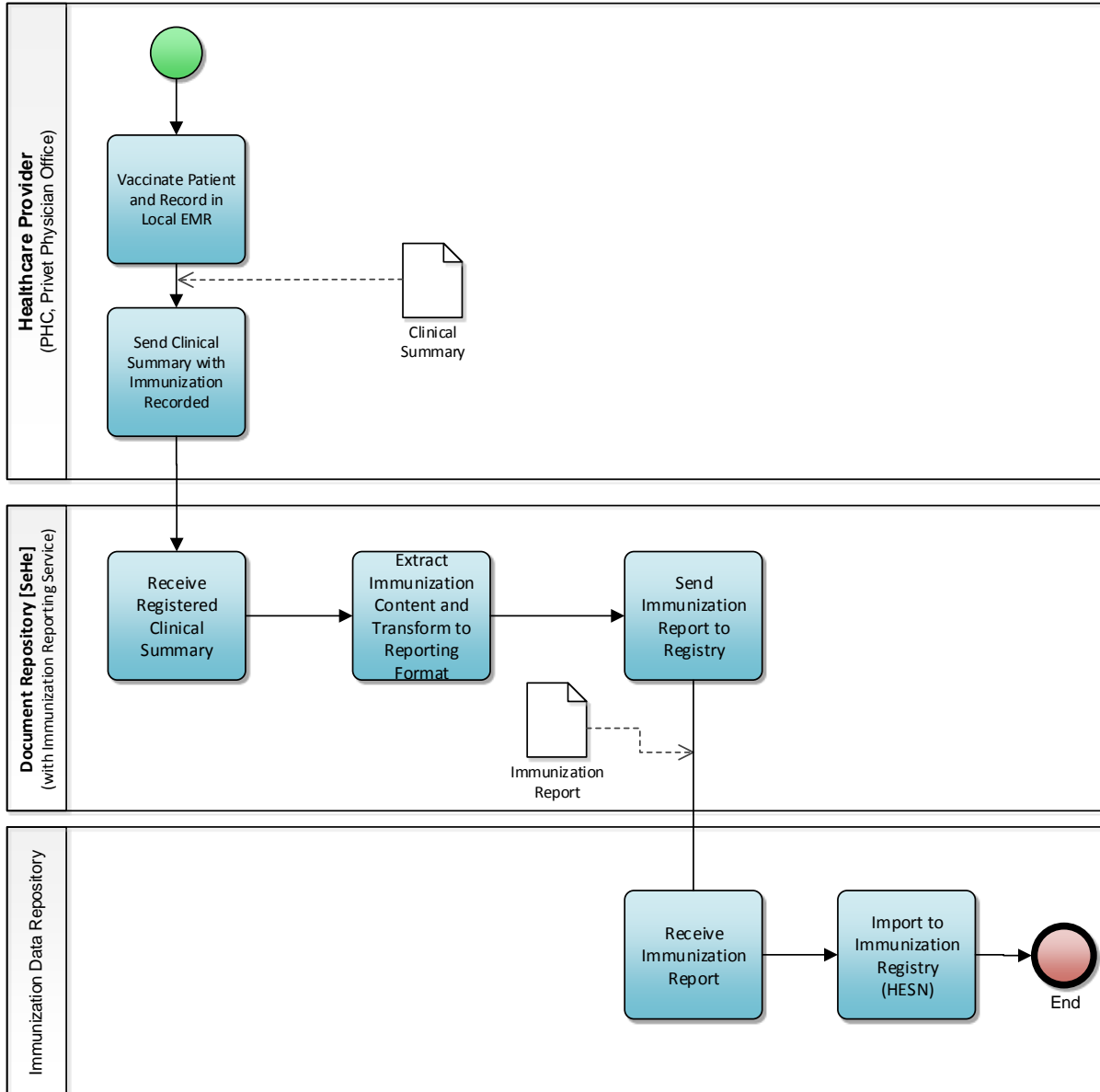


Figure 4.1.4-1: *Report Immunization to Registry* Workflow depicts the workflow associated with the Publish On-Demand Immunization Documents.

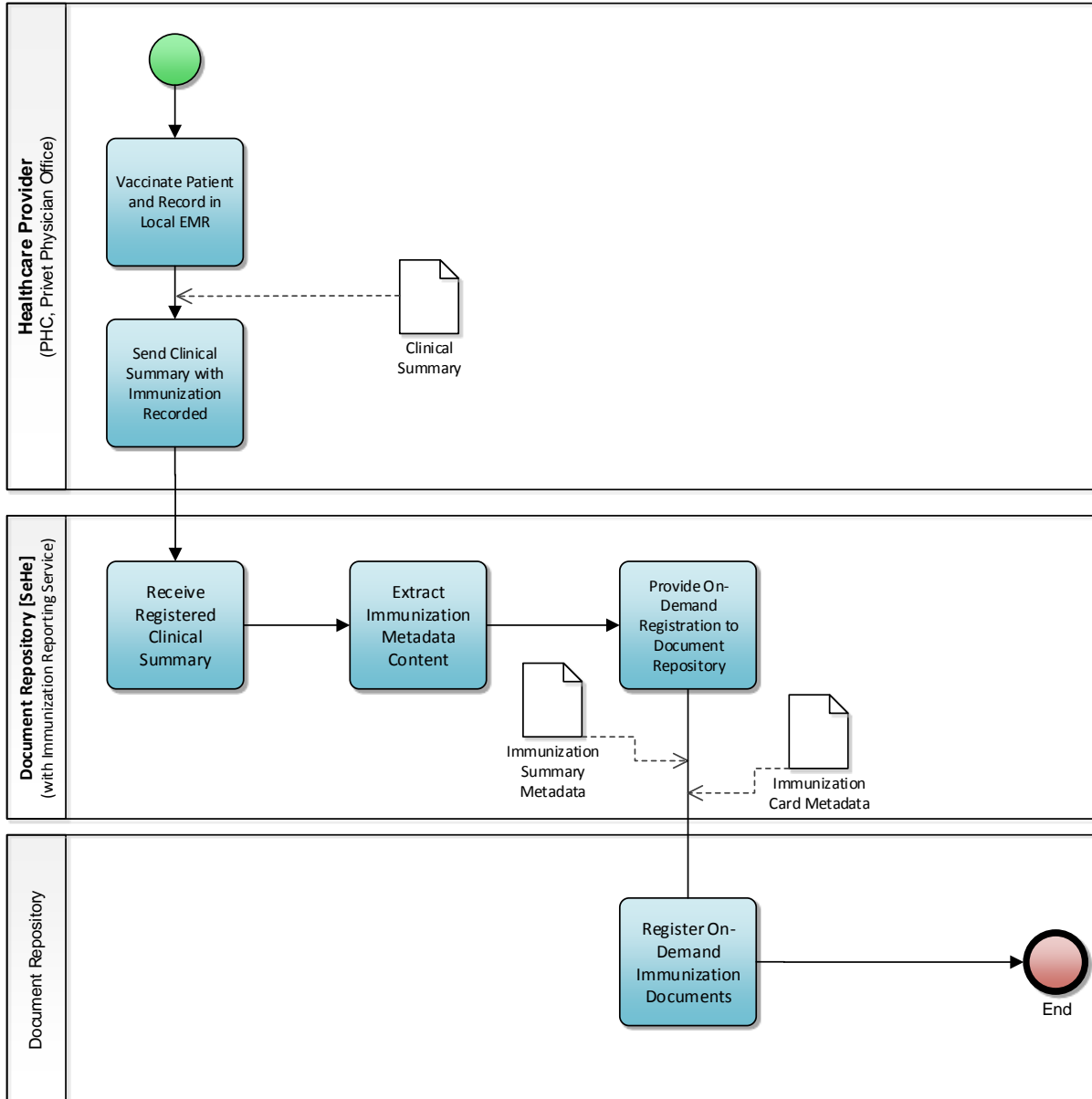


FIGURE 4.1.5-1: PUBLISH ON-DEMAND IMMUNIZATION DOCUMENTS WORKFLOW

4.2 EXTERNAL BUSINESS PROCESSES

The following Business Processes are referenced in the Immunization Use Case, but are defined in other Use Cases.

4.2.1 Obtain Patient Health Identifier

This Business Process is initiated to retrieve a patient’s Health ID from the Patient Demographic Supplier. In order to query/retrieve any information (e.g. documents, images) for a patient from the HIE Document Repository; it is first necessary to **Obtain Patient Health Identifier** using Patient Demographic Consumer Actor.

TABLE 4.2-1: OBTAIN PATIENT HEALTH IDENTIFIER

BUSINESS PROCESS	REFERENCE
Obtain Patient Health Identifier	UC0001 Saudi eHealth Patient Identification Interoperability Use Case

4.2.2 Identify Baby

This Business Process is initiated to retrieve the newborn's identification to use with the HIE Platform. Since no Health ID exists for a newborn, new Health ID needs to be created as part of the process of identifying a newborn within the HIE Platform. The information that is required to create the new Health ID includes the following: Mother's Health ID, Date of Birth, Gender, Birth Order, and local Hospital Identifier. In order to query/retrieve any information (e.g. documents, images) for the newborn from the HIE Document Repository; it is first necessary to **Identify Baby** using Patient Demographic Consumer Actor.

TABLE 4.2-2 : IDENTIFY BABY

BUSINESS PROCESS	REFERENCE
Identify Baby	UC0001 Saudi eHealth Patient Identification Interoperability Use Case

4.2.3 Order Diagnostic Testing

This Business Process is initiated to **Order Diagnostic Testing** both locally and for the purpose of sharing diagnostic testing orders using the Composite Order Diagnostic Testing Actor. Currently, Laboratory Orders can be shared through the HIE Document Repository. Laboratory serology tests may be ordered to verify immunization status.

TABLE 4.2-3 : SHARED ORDER DIAGNOSTIC TESTING

BUSINESS PROCESS	REFERENCE
Order Laboratory Test	UC0003 Saudi eHealth Laboratory Interoperability Use Case

4.2.4 Order Laboratory Test

See Section Order Diagnostic Testing

4.2.5 Review Diagnostic Results

This Business Process is initiated to **Review Diagnostic Results** for a given patient. The Diagnostic Results may be stored locally or in the HIE Document Repository. Shared diagnostic results can be queried and retrieved from the HIE Document Repository using the Composite Clinical Content Consumer Actor. Laboratory serology results may be reviewed to verify

immunization status. The following types of diagnostic tests supported through the HIE Document Repository are pertinent to the Immunization Use Case:

TABLE 4.2-4 : SHARED DIAGNOSTIC TEST RESULTS

BUSINESS PROCESS	REFERENCE
Review Laboratory Results	<i>UC0003 Saudi eHealth Laboratory Interoperability Use Case</i>

4.2.6 Review Laboratory Results

See Section Review Diagnostic Results

4.2.7 Publish Clinical Summary Document

This Business Process is initiated to **Publish Clinical Summary Document** for the purpose of sharing a clinical summary using the Clinical Summary Content Creator Actor. A Clinical Summary document may be stored locally and/or in the HIE Document Repository. Shared clinical summaries can be queried and retrieved from the HIE Document Repository using the Clinical Content Consumer Actor. At this time Outpatient Encounter Summaries, Discharge Summaries, Maternal Discharge Summaries, Newborn Summaries and iEHR Summaries can be shared through the HIE Document Repository.

TABLE 4.2-5 : PUBLISH CLINICAL SUMMARY DOCUMENT

BUSINESS PROCESS	REFERENCE
Publish Clinical Summary document	<i>UC0007 Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries: Review Clinical Notes and Summaries</i>

4.2.8 Review Historical Medical Documents

This Business Process is initiated to **Review Historical Medical Documents** for a given patient. The history of a patient’s immunization is stored within the HIE Document Repository and may be queried and retrieved from the HIE Document Repository using the Composite Clinical Content Consumer Actor. Pertinent historical documents supporting the Immunization Use Case include:

TABLE 4.2-6 : REVIEW PRIOR HISTORICAL DOCUMENTS BUSINESS PROCESSES

BUSINESS PROCESS	ACTOR	REFERENCE
Review Historical Medical Documents	Composite Clinical Content Consumer	<i>UC0007 Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries: Review Clinical Notes and Summaries</i>
Review Clinical Summary Document	Clinical Content Consumer	<i>UC0007 Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries: Review Clinical Notes and Summaries</i>

BUSINESS PROCESS	ACTOR	REFERENCE
Review Laboratory Results	Laboratory Results Consumer	<i>UC0003 Saudi eHealth Laboratory Interoperability Use Case</i>
Review Clinical Notes and Summaries	Clinical Content Consumer	<i>UC0007 Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries: Review Clinical Notes and Summaries</i>

5. SERVICES

5.1 SERVICE DESCRIPTION

The Services defined in this Use Case are described in Table 5.1-1 Services

TABLE 5.1-1 SERVICES

SERVICE NAME	SERVICE USE
Report Immunization	Communicates the immunization event to public health
Publish On-Demand Immunization Documents	Publishes records that show that Immunization Summary and Immunization Card documents are available from the Immunization Registry which 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
Publish Document(s)	Publishes, amends, corrects, and updates Immunization Cards in the HIE Document Repository and request that documents are stored and registers their metadata.
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. Patient Portal, 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.

5.1.1 Pre-Conditions

Table 5.1-1 Pre-Conditions identifies pre-conditions for this Use Case.

TABLE 5.1-1 PRE-CONDITIONS

ACTOR NAME	SERVICES	DESCRIPTION
All Actors	All Services	It is expected that all services initiated or provided by this actor operate in accordance with IS0303 <i>Saudi eHealth Interoperability Policies</i> and Interoperability Specifications.
Patient Demographics Supplier	Patient Demographics Query	The local Electronic Medical Record systems support the Patient Demographics Query service as a Patient Demographics Supplier.
Patient Demographics Consumer	Patient Demographics Query	The local Electronic Medical Record systems support the Patient Demographics Query service as a Patient Demographics Consumer. .
Clinical Summary Content Creator	Publish Document(s)	The local Electronic Medical Record system supports Publishing Clinical Summaries as a Clinical Summary Content Creator.

Clinical Summary Content Consumer	Query/Retrieve Documents	The local Electronic Medical Record system supports the Query/retrieve of Clinical Summary Content as a Clinical Summary Content Consumer.
Immunization Document On-Demand Document Source	Publish On-Demand Immunization Documents	Patient is vaccinated. Immunization Record is created in the provider local Electronic Medical Record system.
Immunization Summary Content Consumer	Retrieve On-Demand Immunization Summary	Patient presents for clinical care. Patient has prior vaccinations known to the Immunization Registry (e.g.HESN).
Immunization Card Content Creator Actor	Update Immunization Card	Patient is vaccinated. Immunization Record is created in the provider local Electronic Medical Record system. The patient card is updated and provided to the patient on portable media or via email.
Immunization Card Content Consumer	Retrieve On-Demand Immunization Card	Patient has access to a standard formatted electronic Immunization Card.
Document Repository	Query/Retrieve Documents	The HIE Document Repository is accessible to the care provider.
Clinical Data Repository	Query Existing Data	The Clinical Data Repository is accessible to the Query Existing Data Service used by the Retrieve On-Demand Immunization Summary Service.
Immunization Data Repository	Query Existing Data	The Immunization Data Repository is accessible to the Query Existing Data Service used by the Retrieve On-Demand Immunization Summary Service and the Retrieve On-Demand Immunization Card Service.
HIE Document Repository	Publish Document(s)	The HIE Document Repository is accessible to the care provider.
HIE Document Repository	Publish On-Demand Immunization Documents	Patient is vaccinated. Immunization Record is created in the provider local Electronic Medical Record system.
Patient Demographics Supplier	Patient Demographic Query	Patient is born, presents for care for the first time to an HIE participating healthcare provider, or the patient exists in the HIE Platform.
Patient Demographics Consumer	Patient Demographic Query	Patient is born, presents for care for the first time to a SeHE participating healthcare provider, or the patient exists in the HIE Platform.
Immunization Education Requestor	Provide Immunization Education	Patient is vaccinated
Immunization Education Responder	Provide Immunization Education	Patient is vaccinated
Immunization Report Sender	Report Immunization	Patient is vaccinated. Immunization Record is created in the provider local Electronic Medical Record system.
Immunization Report Recipient	Report Immunization	Patient is vaccinated. Immunization Record is created in the provider local Electronic Medical Record system and the information is sent by the Immunization Report Sender.

5.1.2 Post-Conditions

Table 5.1-2 Post Conditions identifies post-conditions for this Use Case.

TABLE 5.1-2 POST CONDITIONS

ACTOR NAME	SERVICES	DESCRIPTION
HIE Document Repository,	Publish On-Demand Immunization Documents	On-demand Immunization Summary and Immunization Card documents are available for access throughout the HIE Platform.
Immunization Document On-Demand Document Source	Publish On-Demand Immunization Documents	Child immunized with all recommended vaccinations Vaccination records are available through the HIE Platform Vaccination recommendations are available through the HIE Platform
Immunization Card Content Creator Actor	Update Immunization Card	Patient has the Immunization Card available to them in electronic or paper form.
Immunization Education Responder	Provide Immunization Education	Patient is provided with immunization education information for vaccine(s) administered
Immunization Report Recipient	Report Immunization	Child immunized with all recommended vaccinations Vaccination records are available through the HIE Platform Vaccination recommendations are available through the HIE Platform Vaccination records are available to the Immunization Registry (e.g. HESN)

5.1.3 Assumptions and Dependencies

Table 5.1-3 Use Case Dependencies identifies and describes Use Cases that this Use Case depends upon for information workflow.

TABLE 5.1-3 USE CASE DEPENDENCIES

USE CASE NAME	DEPENDENCY ASSUMPTIONS
KSA-Wide Patient Demographic Query	The KSA-Wide Patient Demographic Query Use Case is used to obtain a Health ID and demographic attributes for the patient the laboratory test is being performed. It is used to provide consistent data in the report header (i.e. consistent with all patient health record documents).
Clinical Notes and Summaries	Clinical notes and summaries are used to retrieve the clinical encounters that will inform the provider of the clinical condition of the patient for indications and contraindications to be considered in determining immunization administration decisions. This Use Case also defines the summaries that are shared at the end of the encounter where the immunization is administered.
Laboratory Orders	Laboratory Orders are used to request serology tests that may be used to verify immunization status.

USE CASE NAME	DEPENDENCY ASSUMPTIONS
Laboratory Results	Laboratory Results are used to review serology tests that may be used to verify immunization status.

6. REFERENCED DOCUMENTS AND STANDARDS

The following Saudi eHealth documents are referenced by this Use Case.

TABLE 6-1 REFERENCED DOCUMENTS

MOH DOCUMENT	DESCRIPTION
UC0001 Saudi eHealth Patient Identification Interoperability Use Case	This Use Case describes the capability to match a patient with his/her identity. This capability is accessible to various “edge” applications including point of care systems and MOH business applications. It uses a set of patient demographic attributes (name, birth date, gender, etc.) and a unique nation-wide identifier called a Health ID. A Health ID is registered for Saudi citizens, residents, displaced people, GCC nationals and visitors/pilgrims. This Health ID is used for the unique identification of a patient and his/her health records. This Health ID and associated demographic attributes are managed centrally by a “patient client registry” system so that the information may be widely accessed via queries against such a registry.
UC0003 Saudi eHealth Laboratory Interoperability Use Case	The Laboratory Use Case describes the capability to share laboratory test results and to initiate a coded laboratory order, and making them accessible via the national Saudi Health Information Exchange (HIE) platform.
IS0303 Saudi Health Information Exchange Policies	Contains the policies and supporting definitions that support the security and privacy aspects of the Saudi Health Exchange. The Saudi Health Information Exchange Policies apply to all individuals and organizations that have access to the Saudi Health Exchange managed health records, including those connected to the Saudi Health Exchange, their Business Associates, as well as any subcontractors of Business Associates. These policies apply to all information provided to or retrieved from the Saudi Health Exchange.
UC0007 Saudi eHealth Interoperability Use Case for Clinical Notes and Summaries	Specifies the Saudi eHealth Interoperability Use Cases applicable to existing and new information systems to be connected to the national Health Information Exchange (HIE) platform. The Clinical Notes and Summaries Use Cases address improvement of patient care through increased healthcare provider access to information during a transition of patient care. Each Use Case provides one or more technical scenarios that convey how the system should interact with the end user, or another system, to achieve a specific business goal. These Use Cases provide a set of high-level functional requirements. Standards and Profiles supporting these Use Cases are documented in the Saudi Interoperability Specification and Interoperability Policies.