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Ministry of Health

National eHealth Strategy and Change Management Office
(SCMO)

Enabling Standards-Based eHealth Interoperability

UC0001

Saudi eHealth Laboratory Interoperability Use Case

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Table of Contents

LIST OF TABLES

LIST OF FIGURES

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Document Revision History

Version	Date	Type of update	Prepared/Revised by
1.0	February 22, 2015	First Release	eHealth Strategy Management Office – eHealth Standards Department

PREFACE

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 which support interoperable exchanges of information between systems.

Services: Services describe 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 work flow 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 work stream 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 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

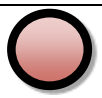
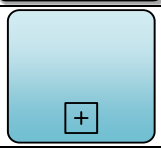
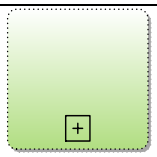
This document has adopted the following conventions for representing the Use Case concepts and information workflow.

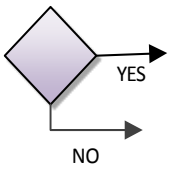
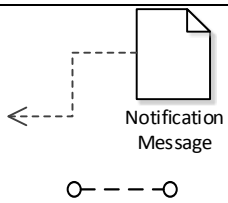
Process Flow Diagrams

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 shape such as an event (a circle shape denotes start/end of process), an activity (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. Complete explanations of the business process diagram elements used within this document are in the table below.

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

TABLE 1.1 SEHE 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.
	Activity 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 activity 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.

SHAPE	DESCRIPTION
	Activity that represented with a light colored rectangle and describes **physical** action performed by the actor
	Gateway that determines forking and merging of paths depending on the conditions expressed
	Sequence flow that shows in which order the activities are performed and the intermingling of actions between different actors or other systems.
	Message flow that shows the flow of messages between two actors or systems that are prepared to send and receive messages.
	Message event used to send a message and to invoke other activity within the business processes then the token will immediately moves to the invoked flow of the process

Requirements Language

Throughout this document the following conventions[1] are used to specify requirement levels:

SHALL: the definition is an absolute requirement of the specification.

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.

[1] Definitions based upon RFC 2119

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.

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 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 the a Saudi Health Information Exchange (HIE) platform and its internal Systems which includes patient identification management, provider directory, document and image repository, and 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.

depicts the general scope and focus of the project highlighted in red.

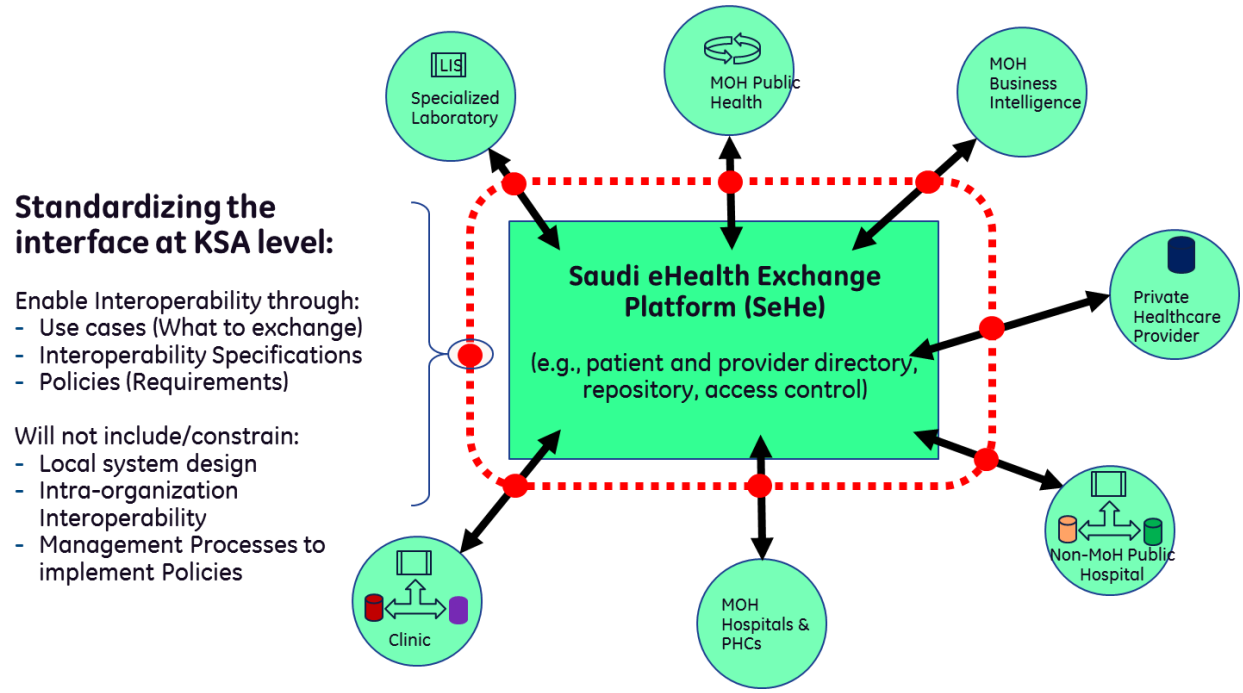


Figure 1 SCOPE OF EHEALTH STANDARD BASED INTEROPERABILITY SPECIFICATIONS AND POLICY PROJECT

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 national Saudi Health Information Exchange platform (HIE).

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 HIE Platform.

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.

Error! Reference source not found. 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).

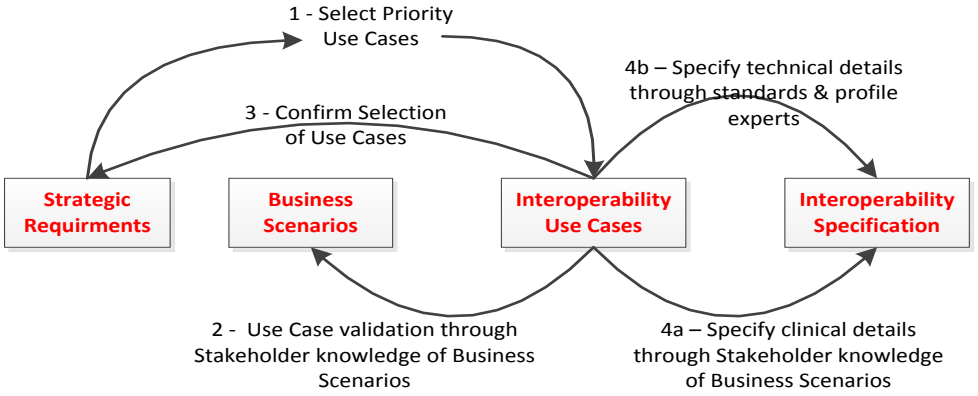


Figure 2 METHODOLOGY STEPS FOR THE EHEALTH STANDARDS-BASED INTEROPERABILITY SPECIFICATIONS AND POLICY PROJECT

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 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 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.

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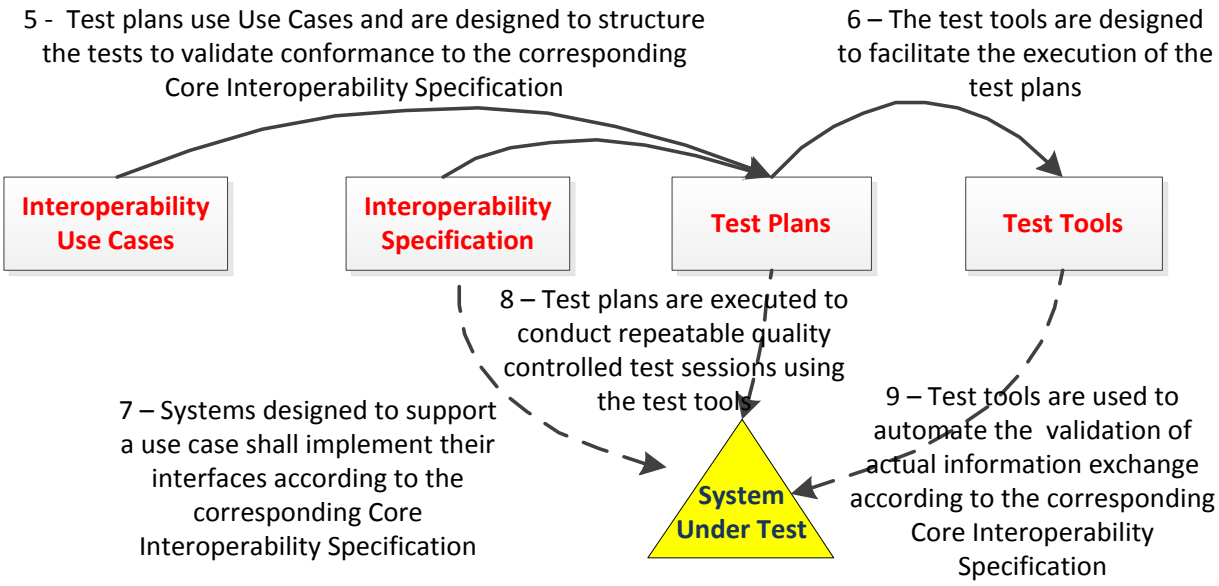

Figure 3 VERIFICATION OF CONFORMANCE TO A CORE SAUDI EHEALTH INTEROPERABILITY SPECIFICATION

LABORATORY BASED USE CASES

1. SHARING CODED LABORATORY RESULTS REPORTS - INTEROPERABILITY USE CASE

1.1 Description

This Use Case describes the sharing of laboratory test results and making them accessible via the SeHE System. These laboratory test results are generally used by primary and hospital care providers but may also be used by MOH business applications, including public health organizations. Note that policies may require that patient information be pseudonymized for use in MOH business applications.

Laboratory results reports are grouped as they are produced by laboratories, results reports contain information such as:

- General information about the laboratory order.
- The performing laboratory.
- Information about the sample.
- The set of releasable results produced by a clinical laboratory for fulfillment of one or more test orders for a patient.

The laboratory results report is created in a format that supports both human-readable rendering and machine-processing (i.e. coded results data).

1.2 Use Case Benefits

- Produces laboratory results reports in both human and machine readable format.
- Provides timely access to laboratory results reports across all stakeholders, such as hospitals, primary care centers, MOH business applications, etc.
- Reduces errors in patient care related to accessing prior (i.e. earlier) laboratory results reports.
- Organizations that didn't have access to the information before can now access structured, coded laboratory results reports.

1.3 Actors

The Actors defined in this Use Case are described in

Table 1.2-1 Actors

.

Table 1.2-1 Actors

ACTOR NAME	DESCRIPTION	EXAMPLE REAL-WORLD IT SYSTEMS
Laboratory Report Creator	This Actor is responsible for the creation of laboratory content of the electronic document and publishing the results report to the Document Repository. It is also responsible for managing the updates to lab results report documents, such as replace, amend and/or deprecate.	Clinical Laboratories Hospital Laboratory Private Laboratory National Laboratory Center(s)
Laboratory Report Consumer	This Actor is responsible for querying and retrieving laboratory results reports for viewing, importing, or other processing of content from the Document Repository.	Point of Care Systems such as: • Hospital Information Systems (HIS) • Primary Healthcare (PHC) Electronic Medical Record Systems • Laboratory Information Systems (LIS) • Patient Portal • Other Point of care systems • MOH Business Applications
Document Repository	This Repository stores the laboratory results reports that include the coded laboratory tests and maintains metadata about each registered laboratory results report.	SeHE System – Document Registry/Repository

1.4 Main Flow of Events

A clinical laboratory creates and publishes a coded laboratory results report to the SeHE System for access from various stakeholders such as primary care physicians, hospital care, and MOH business applications.

Error! Reference source not found. and the text below provides a typical high level example of the main workflow for sharing a patient's laboratory report.

The patient is admitted to the hospital and is provided with necessary healthcare. The hospital physician orders laboratory test(s) for the patient, which are performed. The physician uses the hospital Laboratory Information System (LIS) (acting as a Laboratory Report Creator) to publish the laboratory results report to the SeHE System (acting as a

Document Repository). The laboratory results report is available for use by all authorized stakeholders that have access to SeHE (acting as a Document Repository).

The patient visits a PHC and the physician uses the PHC EMR (acting as a Laboratory Report Consumer) to query the Document Repository. The physician learns about the documents available for review related to the patient's recent hospital stay (such as a hospital discharge, health summary record, prior coded laboratory results reports, etc.). The physician retrieves all relevant documents (including the laboratory results report), reviews them and patient care is given based upon these documents.

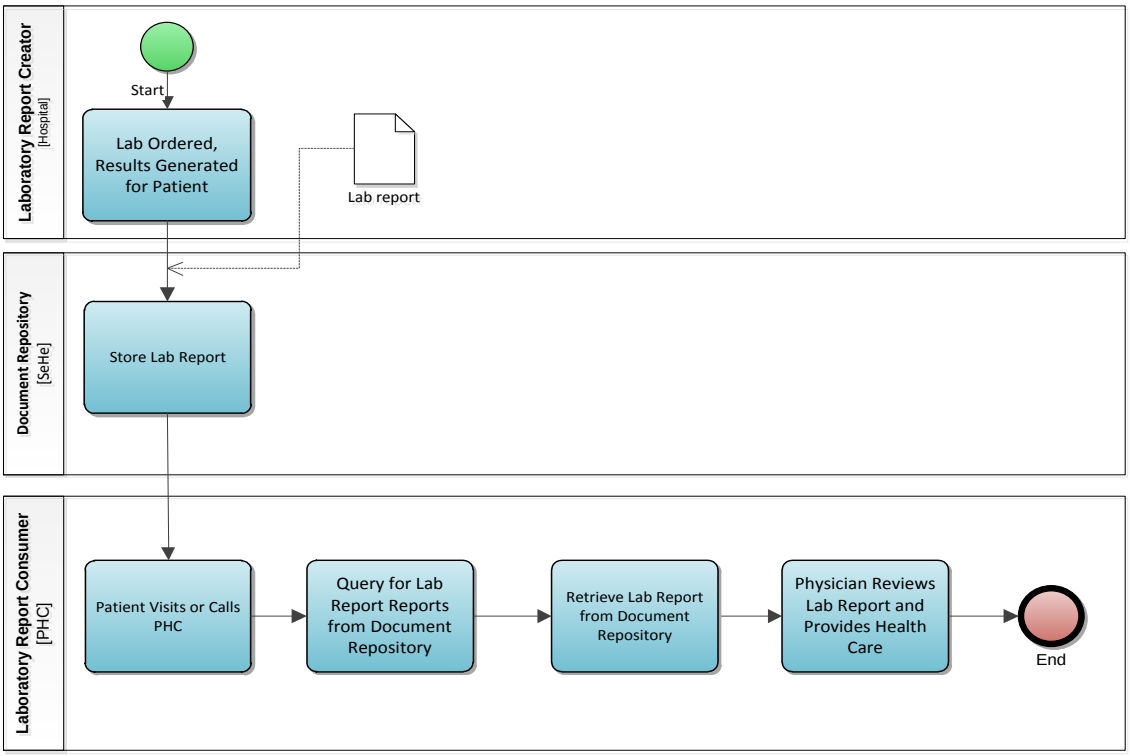

Figure 4 Sharing Laboratory Results Reports Main Flow

1.5 Alternative Flow of Events

1.5.1 Updated Lab Results and Notification Delivered

Error! Reference source not found. and the text below provides a typical high level example of the information workflow for the scenario when a laboratory report has been updated.

The patient admitted to the hospital and is provided with necessary healthcare. The hospital physician orders laboratory tests for the patient, which is performed. The physician uses the hospital LIS (acting as a Laboratory Report Creator) to publish a laboratory report to the SeHE System (acting as a Document Repository). The laboratory report is available for use by all authorized stakeholders that have access to SeHE (acting as a Document Repository).

The patient visits a PHC and the physician uses the PHC EMR (acting as a Laboratory Report Consumer) to query the Document Repository. The physician learns about the documents available for review related to the patient's recent hospital stay (such as a hospital discharge, health summary record, prior coded laboratory results reports, etc.).

The physician retrieves all relevant documents (including the laboratory results report), reviews them and patient care is given based upon these documents.

The above described workflow is a pre-condition to creating an amended report and has already been shown in, therefore is not shown in **Error! Reference source not found.** and the text below.

The laboratory that created the original results report creates an updated results report. The laboratory stores the updated results report using the LIS (acting as a Laboratory Report Creator) into the Document Repository. This new results report references the original results report and informs the Document Repository that it is an update to the original. This information is used by the Document Repository to manage the two versions (i.e. deprecate the original laboratory results report). The physician is notified that an updated results report was created (either automatically from the Document Repository or manually from the hospital). The physician uses the PHC EMR (acting as a Laboratory Report Consumer) to retrieve the updated results report for review. Patient follow-up care is given based upon the new results report.

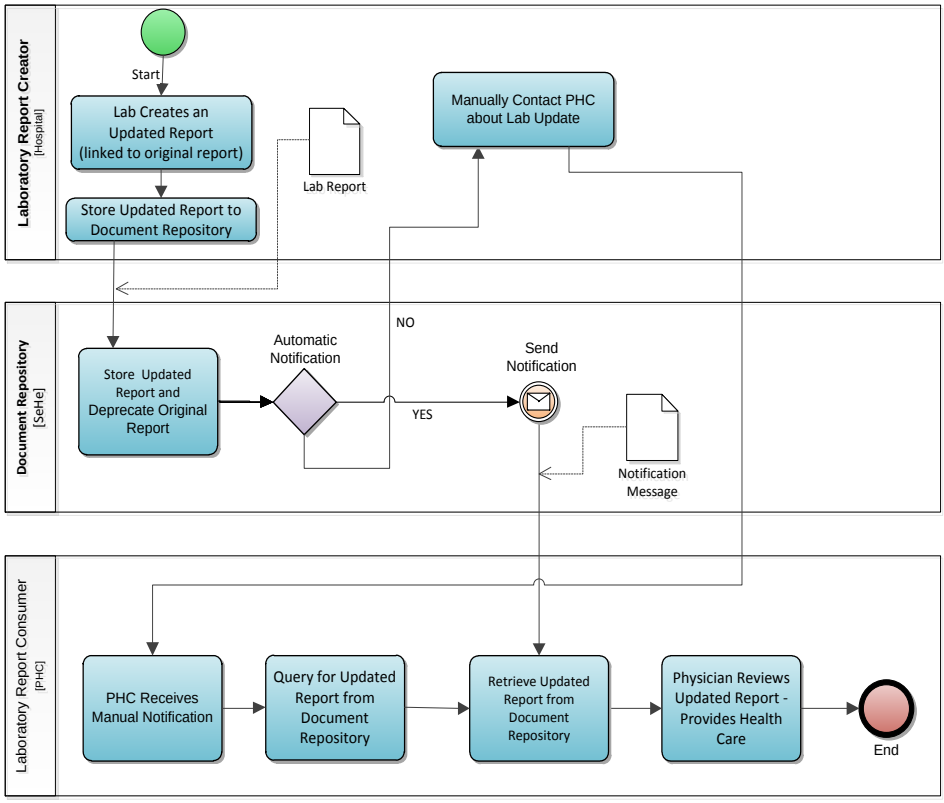

Figure 5 Updated Laboratory Results Reports Typical Process Flow

1.6 Exceptions Work Flow

N/A

1.7 Specific Workflow Scenarios

The following sections provide short descriptions of scenarios that complement the use case flow of events by using the defined transactions in specific ways. Some of these scenarios highlight variants to the use case main flow of events while others describe interactions with local workflow situations that are beyond the scope of the use case but consistent with it. These workflow scenarios are not intended to be an exhaustive list.

1.7.1 Scenario 1: Laboratory Creates a Laboratory Results Report for a Shared Coded Laboratory Order

A laboratory performs the requested tests for a shared coded laboratory order. As part of this process, the Laboratory Report Creator creates a laboratory results report and publishes it to the Document Repository.

1.7.2 Scenario 2: Laboratory Creates a Partial Laboratory Results Report for a Shared Coded Laboratory Order

A laboratory begins performing the requested tests for a shared coded laboratory order. Laboratory protocol indicates that the partial test results should be shared (e.g. a wound culture indicates that a given bacteria is present, but further testing is required to determine the susceptibility). The Laboratory Report Creator creates a laboratory results report with the available laboratory results and a comment indicating the reason for publishing the partial results. The partial laboratory results report is stored on the Document Repository.

1.7.3 Scenario 3: Laboratory Amends a Partial Laboratory Results Report With the Final Reportable Results

A laboratory completes the requested tests for a shared coded laboratory order, which has previously released a shareable laboratory results report (e.g. a wound culture indicates that a given bacteria is present without the susceptibility information). Now that all of the test results are available, the existing laboratory results report needs to be amended with the additional results. The amended results report references the original results report and replaces the original (both versions of the laboratory results report remain accessible through the Document Repository).

1.7.4 Scenario 4: Laboratory Amends/Corrects a Final Laboratory Results report

An authorized laboratory determines that a final laboratory results report that has already been shared to the Document Repository needs to be corrected/amended (e.g. wrong patient linked to results report, erroneous information needs to be corrected, defective interpretation). The Laboratory Report Creator retrieves the existing laboratory results report and amends the laboratory results report with the corrections/additions. The amended results report references the

original results report and replaces the original (both versions of the laboratory results report remain accessible through the Document Repository).

1.7.5 Scenario 5: Laboratory Order to Be Shared Requires Laboratory Results Reports from Multiple Specialties

A Healthcare Provider creates a laboratory order which requires laboratory tests from multiple laboratory specialty areas to be performed (e.g. Cerebrospinal fluid requested tests for culture and chemistry results). Shared laboratory orders are created for each of the laboratory specialty areas (e.g. Chemistry and Microbiology) and published to the Document Repository. Each of the laboratories performs the requested test(s) and creates a laboratory results report, which the Laboratory Report Creator sends to the Document Repository.

1.7.6 Scenario 6: Laboratory Shares a Laboratory Results Report for a Non-Shared Coded Laboratory Order

A request has been made to share a patient's laboratory results report for a previously created local laboratory order. The Laboratory Report Creator creates a shareable laboratory results report and sends it to the Document Repository.

1.7.7 Scenario 7: Access to Prior Laboratory Results Report(S) From SeHE

A patient-based query is made to the Document Repository, using the KSA-Wide Health ID, to get a list of all laboratory information that may be relevant to this patient. In addition to the standard Saudi eHealth query parameters, there are additional query parameters that are unique to laboratory. These include the Laboratory Specialty/Department (e.g. Microbiology, Chemistry, and Hematology), the Requested Tests (e.g. A1C, Metabolic Panel, Blood Culture) and the facility setting (e.g. Hospital, Primary Healthcare).

1.7.8 Scenario 8: Access All Versions of a Laboratory Results Report

There are cases where deprecated versions of a laboratory results report may need to be retrieved from the Document Repository (e.g. QA). Therefore, the ability to query and retrieve deprecated results is supported by SeHE.

1.7.9 Scenario 9: Report Is Amended After Pre-Fetch Has Occurred To Local System

A request may be made to the Document Repository to receive notification of an update to the laboratory results report. Alternatively, if laboratory results reports are pre-fetched and stored locally, it is recommended that the Laboratory Report Consumer re-query the Document Registry to verify that it has not been deprecated and replaced by an amended results report.

1.8 Service Model

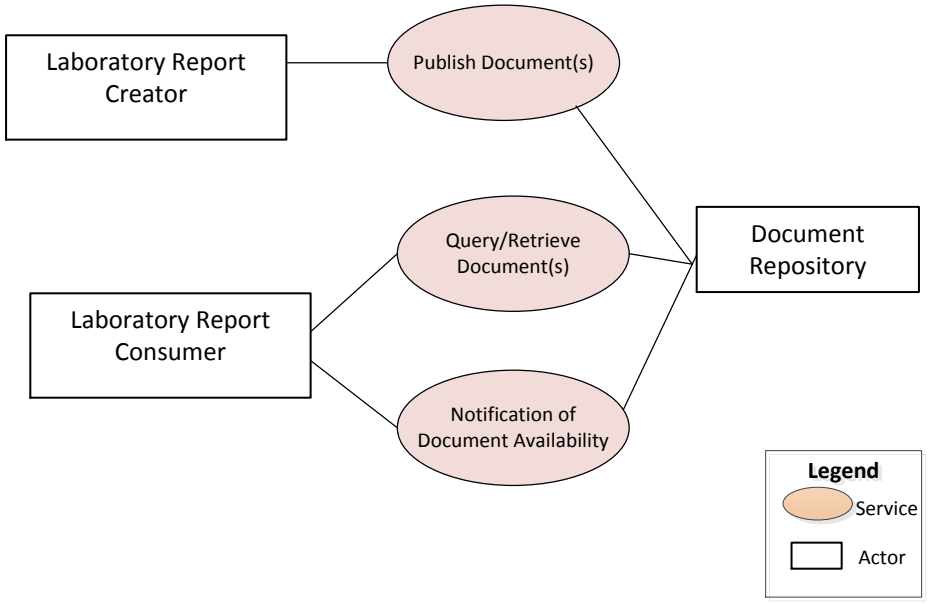

Figure 6 SHARING CODED LABORATORY RESULTS REPORTS SERVICE MODEL

1.9 Service Description

The Services defined in this Use Case are described in Table 1.2-2 Services

Table 1.2-2 Services

SERVICE NAME	DESCRIPTION
Publish Document(s)	Publish Document(s) is used to provide a set of laboratory results reports to a Document Repository. It also requests that the Document Repository store these results reports and then register them with a Document Registry. Documents may be managed such as replaced, amended and/or deprecated.
Query/Retrieve Document(s)	Query the Document Repository for information about laboratory results reports stored and indexed in a registry. This also includes the retrieval of one or more results reports.
Notification of Document Availability	This service is issued by the Document Repository to notify a Laboratory Report Consumer Actor of a laboratory results report of interest that is available to be retrieved.

1.10 Pre-Conditions

Table 1.2-3 Pre-Conditions

identifies pre-conditions for this Use Case.

Table 1.2-3 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 to the Saudi eHealth Interoperability Polices and Interoperability Specifications.
Laboratory Report Creator	Publish Document(s)	Test results have been produced and approved for sending to the ordering provider, other potential health professionals and possibly the patient.
		Laboratory results reports for unidentified patients are excluded and expected to be stored locally (unless a temporary Health ID has been obtained), such as in the local Laboratory Information System.
Laboratory Report Consumer	Query/Retrieve Document(s)	How the laboratory results reports are rendered to the physician is outside the scope of the Use Case. Local applications are responsible to process coded laboratory data, filter the subset of interest to the health professional and provide a user friendly layout in context with other information needed to deliver care.

1.11 Post-Conditions

Table 1.2-4 Post Conditions

identifies post-conditions for this Use Case.

Table 1.2-4 Post Conditions

ACTOR NAME	SERVICES	DESCRIPTION
Document Repository	Query/Retrieve Document(s)	Laboratory results reports are available for access throughout the national SeHE System.

1.12 Data 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.

1.12.1 Coded Laboratory Results Report Data

The information content of a Laboratory Results Report includes the laboratory test results.
Table 1.2-5 Coded Laboratory Results Report Data Content

provides a minimum set of information content for a laboratory results report.

Table 1.2-5 Coded Laboratory Results Report Data Content

LABORATORY REPORT MODULES	DESCRIPTION	TEXT/ CODED
Source and context information of the Laboratory Results Report		
Patient Demographics	A group of data elements which identify the patient, and provide additional information about them (e.g., Gender) that may be used to help determine normal ranges for results.	Text and Coded
Encounter Information	Encounter information describes the encounter in which the order was placed, including the ordering provider, facility, and location.	Text and Coded
Laboratory Order Information	Describes the test or tests that are being ordered.	Text and Coded
Laboratory Order Data Processing Entry	Used to encapsulate information on the laboratory test being performed.	Text and Coded
Specimen Information	Describes the specimen, how it was collected and the methods/timing of its handling.	Text and Coded
Laboratory Results (one or more observations)		
Laboratory Results	This includes data about current test results from laboratory testing performed on the patient. Such as: laboratory value, units, normal ranges, normal/abnormal flag, etc. The supported laboratory specialties are: • Anatomic Pathology • Blood Banking • Biochemistry • Cytology • Serology • Microbiology • Molecular Biology • Toxicology	Text and Coded

1.13 Assumptions and Dependencies

Table 1.2-6 Use Case Dependencies

identifies and describes Use Cases which this Use Case depends upon for information workflow.

Table 1.2-6 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).
Healthcare Provider Directory Query	The Healthcare Provider Directory Query Use Case is used to obtain provider and organizational information. It may be used to identify ordering physicians and organizations and also laboratory personal and laboratory organization information.
Coded Laboratory Orders	The Coded Laboratory Orders Use Case manages the laboratory ordering process that resulted in sharing of a laboratory results report. Note: A laboratory results report may be generated without an electronic order (i.e. manual paper order).

1.14 Special Requirements

N/A

1.15 Notes and Issues

1.15.1 Displaying Laboratory Results Report Documents

How patient clinical documents, including laboratory results reports, are rendered to the physician is the responsibility of the local application such as a HIS or PHC. This is outside the scope of this Use Case. This application provides the flexibility to provide a user friendly layout in context with the information needed to deliver care. For example:

- The local application may process coded laboratory data and filter the subset of interested data to the health professional to import into the HIS/PHC application. This may occur automatically or manually, depending on the local application. Such import is critical for clinical decision support at the point of care.
- A shared provider portal application may be provided for sites that do not have a connected HIS/PHC. These applications will perform the rendering.
- These applications may aggregate the laboratory results report across multiple laboratory results reports, such as producing specific time curves on specific types of lab results.

1.15.2 Querying for Laboratory Results Report Documents

This Use Case includes a query that spans a wide range of health information among which laboratory coded results form a subset. One can also consider cases, where a PHC may be looking for a specific test results or category of set of past test results (e.g. to determine a trend). Although not thoroughly discussed in this Use Case, there are several levels of requirements in accessing health information:

1. **Broad queries**: to access a broad range of records, across a certain period of the past to obtain a composite view/dashboard.
2. **Query by class of information:** to access a specific class of records (e.g. past EKGs, surgeries, laboratory tests across a certain period of the past in order to obtain a "list of past procedures" without all clinical details, etc.).
3. **Health system based queries:** to access a list of encounters, hospital or ambulatory care to provide a patient's encounter history.
4. **Narrow information queries:** these are quite specialized, but target very common health information such as dispensed or prescribed medication lists, lists of diagnoses, specific lab test result trending, etc. Each of them assumes specific pre-processing or reconciliation, which is sometimes automated or sometimes performed manually by the physician for a correct interpretation.

In the case of laboratory results reports, at least three of these levels need to be supported (1, 2 and 4). Many factors are accounted for in deciding the best balance between the flexibility of the queries using the local IT systems and queries using the SeHE System. This Use Case does not rule on the respective role of the SeHE System and that of the local IT system.

2. SHARING CODED LABORATORY ORDERS - INTEROPERABILITY USE CASE

2.1 Description

This Use Case establishes the initiation of a coded laboratory order and making the order accessible via the SeHE System. It addresses two types of orders:

- Laboratory orders that are created by primary and hospital care providers to perform laboratory tests on their patients. Laboratory test facilities (i.e. hospital, private and national laboratory centers) access the coded orders and fulfill them.
- Laboratory orders created by laboratories that rely on other laboratories to perform tests that cannot be performed locally. For example, small hospital laboratories typically only perform common tests and use a regional or national lab for advanced tests.

In either case, the Coded Laboratory Order Use Case is used to manage both types of orders.

A laboratory order is made of a requested test or a battery of requested tests ordered by a physician or other authorized personnel. These tests are to be performed on specimens collected from the patient, in general by a laboratory or a specimen collection service. The actual ordered test or batteries of tests are specified by using structured codes, therefore they are termed as "coded laboratory orders".

The output from the laboratory that performed the order is a set of results. These results contain general information about the laboratory order, the performing laboratory and the set of releasable test results produced by a clinical laboratory. The laboratory results report is created in a format that supports both human-readable rendering and machine-processing (i.e. coded results data). For details of the laboratory report see the Sharing Coded Laboratory Results Reports Use Case in Section 1.

2.2 Use Case Benefits

- Consistent generation of laboratory orders using the same order codes from all KSA stakeholders (i.e. care providers from hospitals, primary care centers, etc.).
- Timely access to laboratory orders by the various laboratory centers in the KSA.
- Enable lab tests to be performed by laboratory centers best suited for the patient's choices or the type of test to be performed.
- Reduces errors in patient care related to laboratory orders and results reports.
- Facilitate timely generation of laboratory results reports for patients.

2.3 Actors

The Actors defined in this Use Case are described in Table 1.3-1 Actors

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Table 1.3-1 Actors

ACTOR NAME	DESCRIPTION	EXAMPLE REAL-WORLD IT SYSTEMS
Laboratory Order Creator	This Actor is responsible for the creation of coded laboratory orders as an electronic order and publishing the order to the Document Repository. It also manages the order status such as new order or canceled.	Point of Care Systems such as: • Hospital Information Systems (HIS) • Primary Healthcare (PHC) Electronic Medical Record Systems • Laboratory Information Systems (LIS) • Other Point of care systems
Laboratory Order Fulfiller	This Actor is responsible for querying and retrieving coded laboratory orders from the Document Repository for their fulfillment. It is also responsible to provide updates to the order, such as completed or Aborted.	Clinical Laboratories Hospital Laboratory Private Laboratory National Laboratory Center(s)
Document Repository	This Repository stores the coded laboratory orders for access by both the Laboratory Order Creator and Laboratory Order Fulfiller Actors.	SeHE System Document Registry/Repository

2.4 Main Flow of Events

A healthcare provider creates and publishes a coded laboratory order to the SeHE System for access from various laboratory test performing entities such as hospitals, private or national laboratory centers.

Error! Reference source not found. and the text below provides a typical high level example of the information workflow for creating a patient's laboratory order.

The patient visits a PHC physician and it is determined a laboratory test is required. The physician using the PHC EMR (acting as a Laboratory Order Creator) orders one or more lab tests for the patient using standardized order code(s). The order is stored on the SeHE System (acting as a Document Repository). The laboratory order is available for use by all approved stakeholders (i.e. laboratory centers) that have access to the SeHE System.

The patient selects a laboratory center near his work and the laboratory technician using the Laboratory Information Systems (LIS) (acting as a Laboratory Order Fulfiller), queries the Document Repository to learn about the patient's order(s) that are available. The laboratory technician retrieves the order, performs the requested test(s) and generates a laboratory results report (via the features defined by the Sharing Coded Laboratory Results Reports Use Case). The technician updates the order status to "completed" using the LIS (acting as a Laboratory Order Fulfiller) and stores the update to the Document Repository.

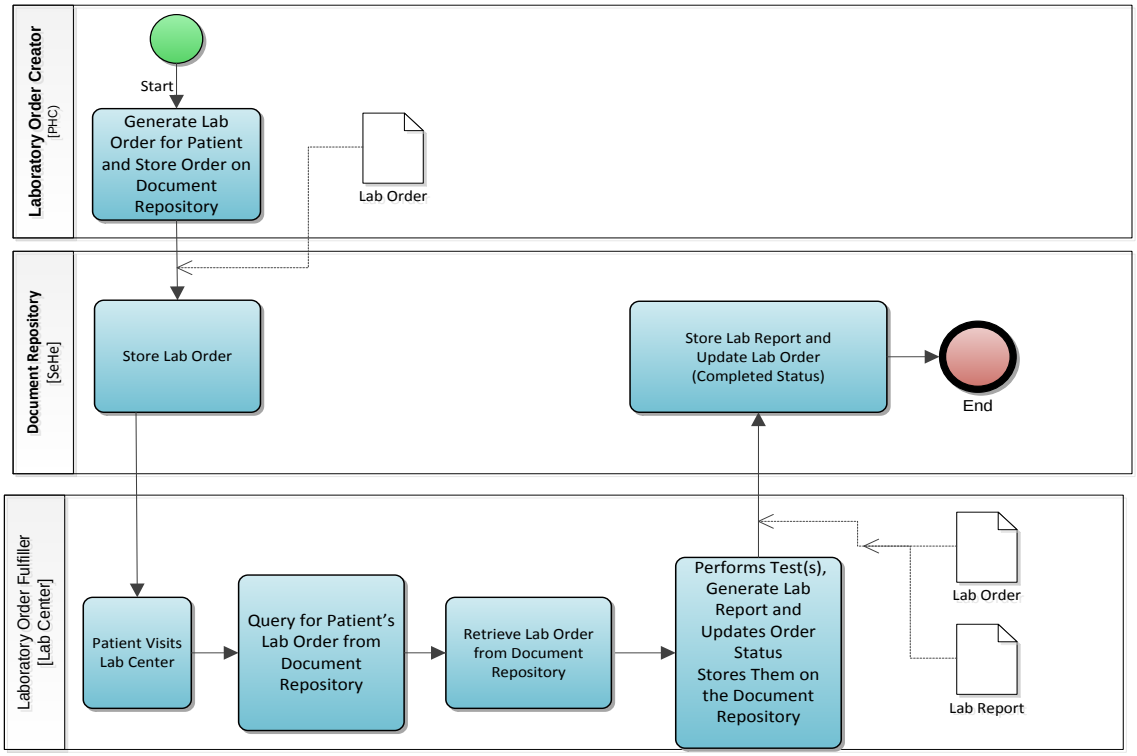

Figure 7 SHARING LABORATORY ORDERS MAIN FLOW

2.5 Alternative Flow of Events

2.5.1 Sample Sent to Lab - Notification Delivered

Error! Reference source not found. and the text below provides a typical high level example of the information workflow for creating a patient's laboratory order, capturing a blood sample and providing a notification for the order.

The patient visits a hospital and a physician determines a laboratory test is required. The physician orders the tests internally within the hospital using the LIS (this local order is out of scope of this Use Case). The hospital laboratory technician determines among the tests ordered by the hospital physician that some of the tests cannot be performed by the hospital laboratory. Therefore, the services of a Regional Lab are needed.

The technician uses the LIS (acting as a Laboratory Order Creator) to order the lab tests which cannot be performed locally (using standardized order codes). A blood sample is taken from the patient and manually shipped to a Regional Lab (a phone confirmation may be requested). The order is stored on the SeHE System (acting as a Document Repository). A notification of the order is sent by the Document Repository to the Regional Lab's LIS (acting as a Laboratory Order Fulfiller).

The regional laboratory technician using the LIS (acting as a Laboratory Order Fulfiller) retrieves the order from the Document Repository and matches the sample to the patient's order. The laboratory technician performs the requested test(s) and generates a laboratory results report (via the features defined by the Sharing Coded Laboratory Results Reports Use Case). The technician updates the order status to "completed" using the LIS (acting as a Laboratory Order Fulfiller) and stores the update to the Document Repository.

The hospital LIS (acting as a Laboratory Order Creator) processes the "completed" order status and retrieves the results report via the features defined by the Sharing Coded Laboratory Results Reports Use Case. The local order within the hospital is now complete and the laboratory results reports are available.

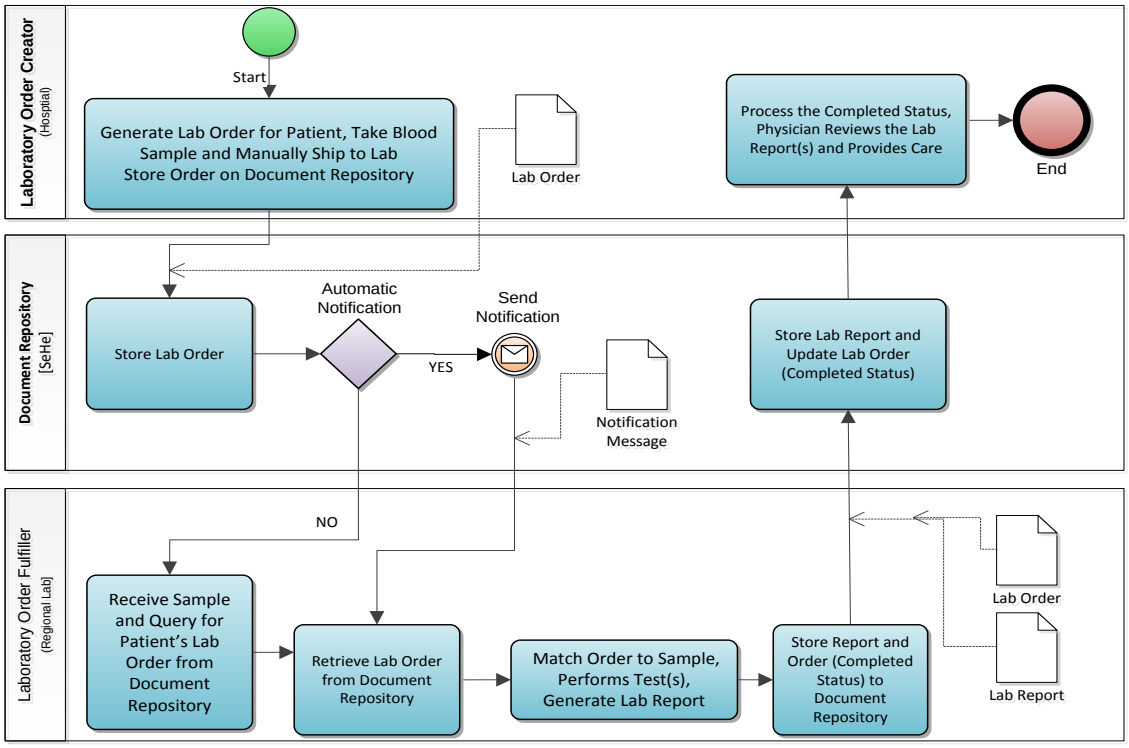

Figure 8 Updated Laboratory Order Typical Process Flow

2.6 Exceptions Work Flow

2.6.2 Order Canceled

Error! Reference source not found. and the text below provides a high level example of the information workflow for cancelling a patient's laboratory order.

The patient visits a hospital and a physician determines a laboratory test is required. The physician orders the tests internally within the hospital using the LIS (this local order is out of scope of this Use Case). The hospital laboratory technician determines among the

tests ordered by the hospital physician that some of the tests cannot be performed by the hospital laboratory. Therefore, the services of a Regional Lab are needed.

The technician uses the LIS (acting as a Laboratory Order Creator) to order the lab tests which cannot be performed locally (using standardized order codes). A blood sample is taken from the patient and manually shipped to a Regional Lab (a phone confirmation may be requested). The order is stored on the SeHE System (acting as a Document Repository). A notification of the order is sent by the Document Repository to the Regional Lab's LIS (acting as a Laboratory Order Fulfiller).

The hospital physician decides to cancel the order (e.g. change of condition for the patient) and uses the LIS to cancel the local order. The LIS (acting as a Laboratory Order Creator) cancels the laboratory order that was intended for the Regional Laboratory. The cancelled order is stored on the SeHE System (acting as a Document Repository).

The Regional Laboratory receives the sample and uses the LIS (acting as a Laboratory Order Fulfiller) to query the Document Repository for the order related to the sample. The Regional Laboratory notices the order has been canceled, therefore, does not perform any tests.

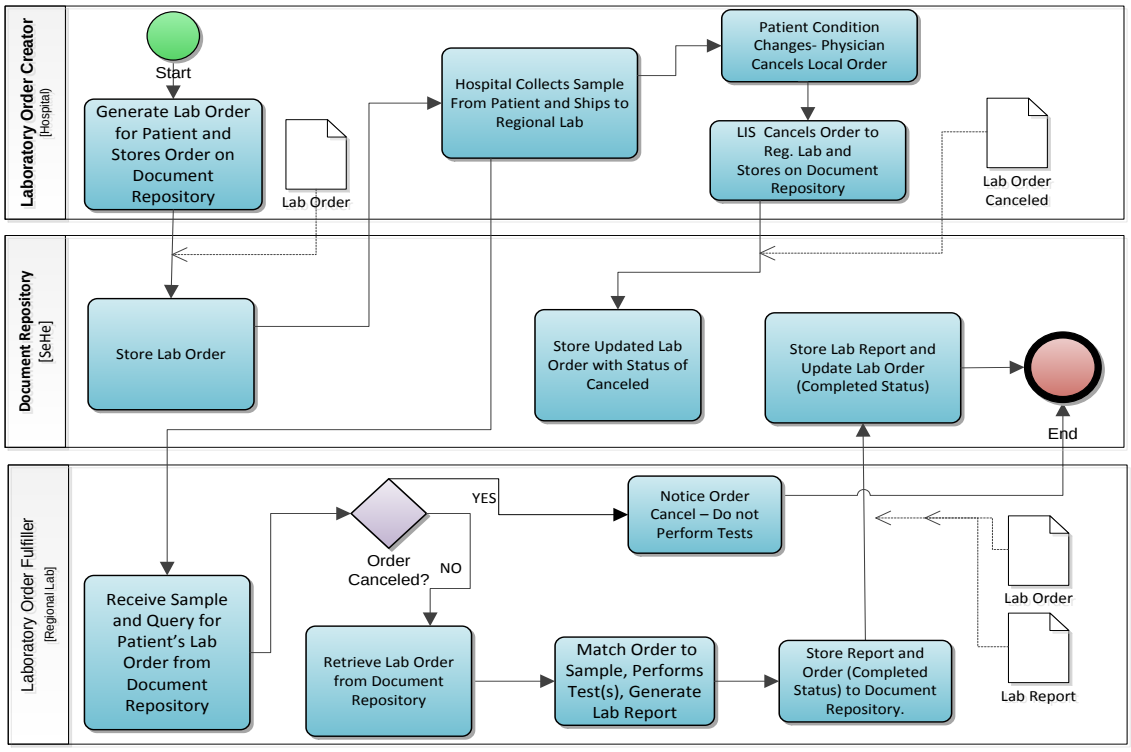

Figure 9 Cancel Laboratory Order Process Flow

2.6.3 Order Aborted

Error! Reference source not found. and the text below provides a high level example of the information workflow for laboratory center discontinuing a patient's laboratory order.

The patient visits a hospital and a physician determines a laboratory test is required. The physician orders the tests internally within the hospital using the LIS (this local order is out of scope of this Use Case). The hospital laboratory technician determines among the tests ordered by the hospital physician that some of the tests cannot be performed by the hospital laboratory. Therefore, the services of a Regional Lab are needed.

The technician uses the LIS (acting as a Laboratory Order Creator) to order the lab tests which cannot be performed locally (using standardized order codes). A blood sample is taken from the patient and manually shipped to a Regional Lab (a phone confirmation may be requested). The order is stored on the SeHE System (acting as a Document Repository). A notification of the order is sent by the Document Repository to the Regional Lab's LIS (acting as a Laboratory Order Fulfiller).

The regional laboratory technician using the LIS (acting as a Laboratory Order Fulfiller) retrieves the order from the Document Repository and matches the sample to the patient's order. The laboratory technician determines the blood sample is inappropriate to perform the requested test(s). The technician updates the order status to "aborted" using the LIS

(acting as a Laboratory Order Fulfiller) and the updated order is sent to the SeHE System (acting as a Document Repository). The SeHE System sends a notification to the ordering hospital laboratory.

The hospital LIS (acting as a Laboratory Order Creator) receives the notification and retrieves the updated order with the status of "aborted". The hospital laboratory technician may take another blood sample and issue a new order to the Regional Lab. In this case, the process is started over with a proper blood sample.

Alternately, the hospital laboratory technician could choose to update the local hospital order with the status of "aborted". Thus making the hospital physician aware that the test could not performed.

The hospital physician decides the next appropriate step, such as order a new test, re-order the same test, or not submit another order.

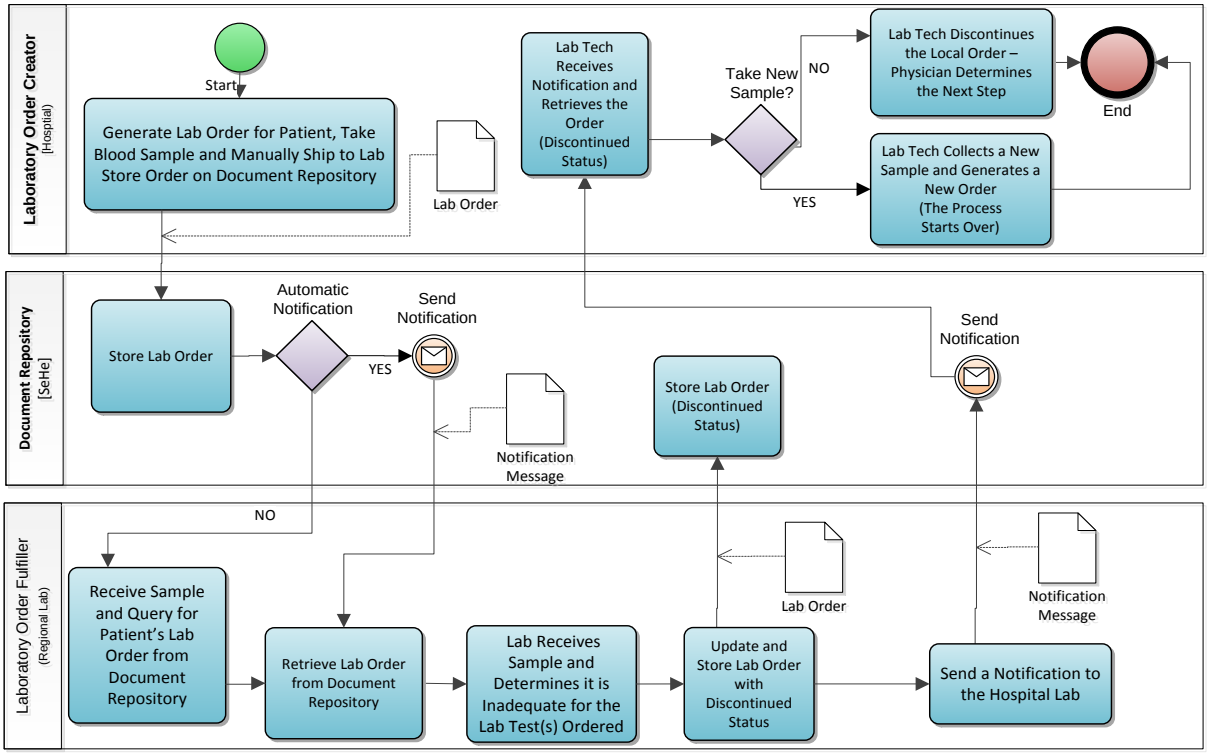

Figure 10 Aborted Laboratory Order Process Flow

2.7 Specific Workflow Scenarios

The following sections provide a state diagram of laboratory order transition states and short descriptions of scenarios that complement the use case flow of events by using the defined transactions in specific ways. Some of these scenarios highlight variants to the use case main

flow of events while others describe interactions with local workflow situations that are beyond the scope of the use case but consistent with it. These workflow scenarios are not intended to be an exhaustive list.

2.7.1 Laboratory Order Transition State Diagram

Error! Reference source not found. depicts the transition states depicts the transition states and the possible transitions which exist for a shared laboratory order. They are based upon the scenarios described below.

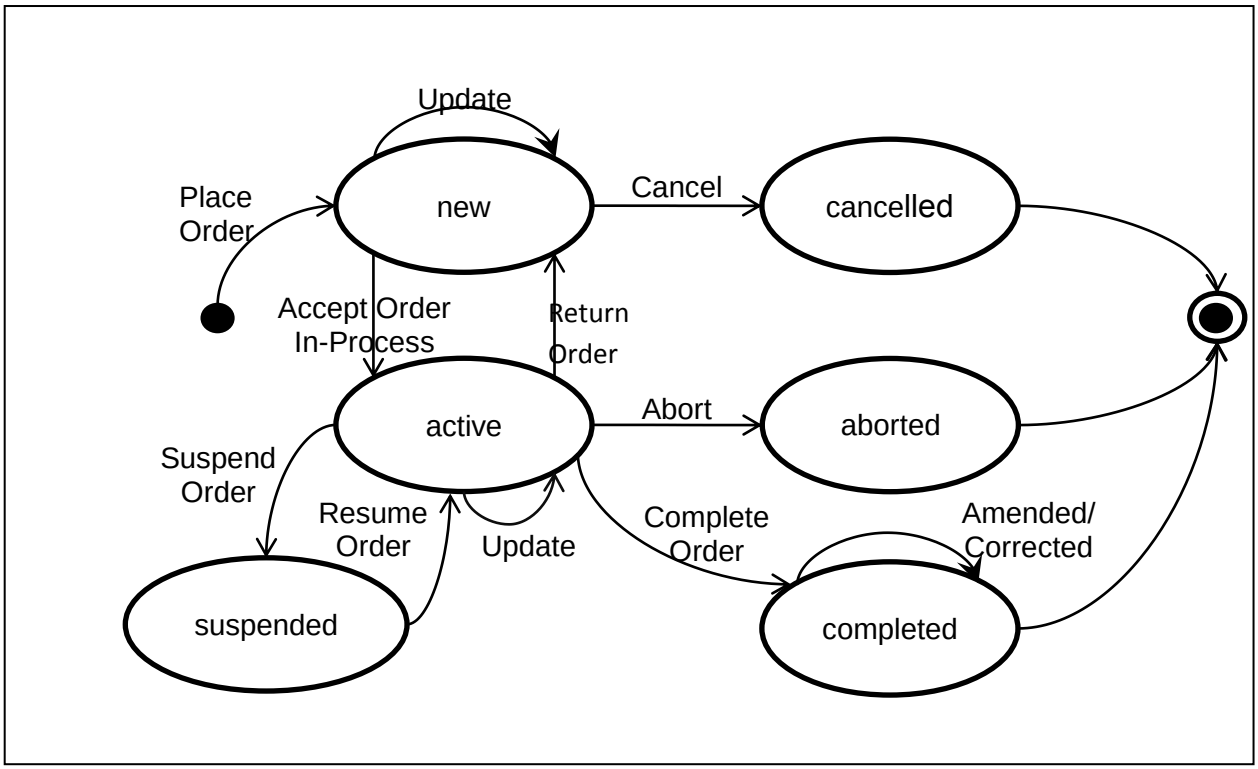

Figure 11 Laboratory Order Transition State Diagram

2.7.2 Scenario 1: Laboratory Order Fulfiller processes a successful order submitted remotely

A Laboratory Order Fulfiller receives a notification that a laboratory order has been created and retrieves the order document. When the sample is received and matched to the previously retrieved order, the Laboratory Order Fulfiller amends the laboratory order with the specimen receipt information and updates the laboratory order status to “active”. The laboratory performs the requested test(s) and stores the laboratory results report(s) to the Document Repository.

2.7.3 Scenario 2: Patient Visits the Laboratory Order Fulfiller to Provide a Specimen for Laboratory Tests Ordered by the Laboratory Order Creator

A patient visits a remote laboratory at the request of the Ordering Provider who has ordered laboratory tests on behalf of the patient. The Laboratory Order Fulfiller verifies that there is a "new" laboratory order and that the sample has not been collected by the Ordering Provider (i.e. the Laboratory Order Creator). Sample(s) are locally collected at the laboratory and the laboratory performs the requested test(s), and stores the laboratory results report(s) to the Document Repository.

2.7.4 Scenario 3: Laboratory Order Is Cancelled Before It Has Been Processed By a Remote Laboratory

An authorized Laboratory Order Creator determines that a previously shared laboratory order is no longer needed. The Laboratory Order Creator queries the Document Repository to check if the laboratory order has already been started. Finding that the laboratory order status is still "new", the Laboratory Order Creator updates the laboratory order in the Document Repository with a laboratory order status of "cancelled".

2.7.5 Scenario 4: A Laboratory Order Is Updated Before It Is Been Processed By A Remote Laboratory

An authorized Laboratory Order Creator determines that a previously shared laboratory order needs to be modified (e.g. additional tests). The laboratory order is amended with the modified laboratory order information, but the status of the laboratory order sent to the Document Repository remains "new". The Laboratory Order Fulfiller retrieves the laboratory order for processing. The laboratory reviews the amended laboratory order and performs it.

2.7.6 Scenario 5: Laboratory Order Is Processed By a Remote Laboratory and Is Aborted

Upon receiving a sample the laboratory technician determines the sample is inappropriate to perform the requested test(s). The Laboratory Order Fulfiller amends the laboratory order in the Document Repository with a laboratory order status of "aborted".

2.7.7 Scenario 6: Attempt to Cancel a Laboratory Order that has already been processed by a remote Laboratory

The remote laboratory has received a sample to be processed and simultaneously, the authorized Ordering Provider determines that the requested laboratory tests are no longer needed.

If the Laboratory Order Fulfiller's laboratory order update to the Document Repository occurs first, the Laboratory Order Creator's attempt to change the laboratory order in the Document Repository to be "cancelled" will fail.

If the Laboratory Order Creator's laboratory order update to the Document Repository occurs first, the Laboratory Order Fulfiller's attempt to amend the laboratory order in the Document Repository to "active" will fail.

2.7.8 Scenario 7: Patient without KSA-Wide Health ID Comes In and The Laboratory Test Needs To Be Performed Remotely

A patient requiring remote laboratory work has no KSA-Wide Health ID. Without a KSA-Wide Health ID laboratory orders cannot be shared through the Document Repository. Therefore a paper laboratory order is created for the patient to take with him/her to the remote laboratory.

The laboratory performs the requested tests using their local protocol, and stores the laboratory results report locally. Upon determining the patient's KSA-Wide Health ID, the laboratory results can be reconciled with the Health ID and shared on the Document Repository.

2.7.9 Scenario 8: Laboratory Order Requires Multiple Laboratory Specialties to Fill a Laboratory Order

A healthcare provider creates a Laboratory Order which requires tests from multiple laboratory specialties (e.g. hematology and microbiology). Using a process which is out of scope for this Use Case, the Laboratory Order Creator divides the laboratory order into multiple laboratory orders; each containing requested test(s) for an individual laboratory specialty.

2.7.10 Scenario 9: Remote Laboratory Processes a Laboratory Order and Provides Partial Results.

The laboratory performs some of the requested test(s) but is unable to perform some of the tests (e.g. equipment failure, resource failure or insufficient sample). The Laboratory Order Fulfiller amends the status of the individual requested test(s) to "Aborted". The laboratory order status is moved from the "Active" to the "Completed" state indicating that no further action will be taken on the laboratory order.

2.7.11 Scenario 10: Laboratory Order is transferred from one laboratory to another and then processed successfully

A Laboratory Order Fulfiller finds and retrieves an order. Prior to performing the requested test(s) the laboratory determines that they are unable to perform the requested test(s) (e.g. equipment failure). Using laboratory protocol, the laboratory is able to make arrangements for another laboratory to perform the requested tests.

2.7.12 Scenario 11: A Laboratory Order Is Modified While It Is Being Processed By a Laboratory

A Laboratory Order Fulfiller finds and retrieves an order. The laboratory begins to perform the requested test(s) and determines that an amendment is needed to the laboratory order (e.g.

different test(s) need to be performed; additional tests need to be performed). The Laboratory Order Fulfiller amends the laboratory order with the updated information.

2.7.13 Scenario 12: Laboratory Order Is Put On Hold and Then Released

A Laboratory Order Fulfiller finds and retrieves an order. The laboratory starts to perform the requested test(s) and it is determined that the laboratory cannot complete the requested test(s) (e.g. additional sample is required, laboratory work is sub-contracted). The Laboratory Order Fulfiller updates the laboratory order status to "suspended", and the laboratory temporarily stops work on the requested test(s) until the reason for placing the laboratory order on hold is resolved.

2.7.14 Scenario 13: A Laboratory Order on Hold Is Resumed

The laboratory determines that the reason for suspending a laboratory order has been resolved. The Laboratory Order Fulfiller finds and retrieves the order and amends the laboratory order with whatever laboratory order information is necessary. The laboratory continues performing the requested test(s).

2.7.15 Scenario 14: Query Laboratory Orders

An Ordering Healthcare Provider needs to determine the status of a Patient's Laboratory Orders. The Laboratory Order Creator queries and retrieves shared orders using filtering mechanisms managed by the shared Document Repository or its local applications. When shared laboratory orders are created, the documents are stored in the Document Repository with key metadata attributes which can be used to filter the information about laboratory orders returned from a Document Repository query. Different levels of filtering are available to the application user.

2.8 Service Model

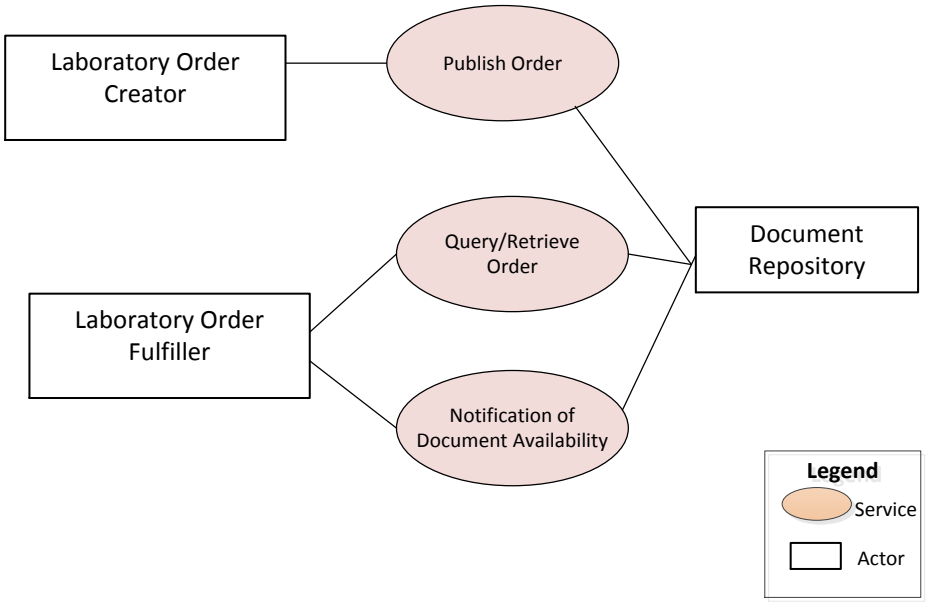

Figure 12 Coded Laboratory Order Service Model

2.9 Service Description

The Services defined in this Use Case are described in Table 1.3-2. Services

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Table 1.3-2. Services

SERVICE NAME	DESCRIPTION
Publish Order	Publish Order is used to create and manage the laboratory order with statuses such as completed, canceled and aborted to the Document Repository.
Query/Retrieve Order	Query the Document Repository for information about stored orders. It is also used to retrieve coded laboratory orders.
Notification of Document Availability	This service is issued by the Document Repository to notify a Laboratory Order Fulfiller Actor of a laboratory order of interest that is available to be retrieved. This service is also used to notify the Laboratory Order Creator Actor that a laboratory order of interest has been updated, such as completed or aborted.

2.10 Pre-Conditions

Table 1.3-3 Pre-Conditions

identifies pre-conditions for this Use Case.

Table 1.3-3 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 to the Saudi eHealth Interoperability Polices and Interoperability Specifications.
Laboratory Order Creator	Publish Order	An authorized provider and/or organization determine that one or more laboratory tests are needed for a patient.
Laboratory Order Fulfiller	Query/Retrieve Order	The laboratory center is authorized by the KSA to perform laboratory tests.
		The workflow for performing the laboratory order is outside the scope of this Use Case, such as which organization performs the test and how the patient is notified that the results are available (e-mail, phone call).

2.11 Post-Conditions

Error! Reference source not found. identifies post-conditions for this Use Case.

Table1.3-4 Post Conditions

ACTOR NAME	SERVICES	DESCRIPTION
Laboratory Order Fulfiller	All Services	A patient's laboratory order has been processed (i.e. completed, aborted, or canceled).

2.12 Data 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 documents.

2.12.1 coded Laboratory Order Data

Table 1.3-5 Coded Laboratory Order Data Content

provides a minimum set of information content for a laboratory order.

Table 1.3-5 Coded Laboratory Order Data Content

LABORATORY DATA CONTENT	DESCRIPTION	TEXT/ CODED
Source and Context information about the Laboratory Order		
Patient Demographics	A group of data elements which identify the patient, and provide additional information about them (e.g., Gender) that may be used to help determine normal ranges for results.	Text and Coded
Encounter Information	Encounter information describes the encounter in which the order was placed, including the ordering provider, facility, and location.	Text and Coded
Laboratory Order Data Processing Entry	Used to encapsulate information on the laboratory test being performed.	Text and Coded
Laboratory Order information	This includes coded terminology to identify the test or battery of tests requested from the laboratory. The list of supported laboratory specialties to be supported with coded orders are: • Anatomic Pathology • Blood Banking • Biochemistry • Cytology • Serology • Microbiology • Molecular Biology • Toxicology	Text and Coded
Specimen Information	Describes the specimen, how it was collected and the methods/timing of its handling.	Text and Coded

Laboratory Order Statuses	Given the cross-organizational nature of the laboratory order processes, only a limited number of statuses are needed and effectively managed (See Section 2.7.1 for a complete list): • Order cancelled by the requester. • Order completed by a performing lab (no further test results may be expected). • Order aborted by the performing lab (e.g. an issue with the sample that needs correcting, etc.). Note: Partial laboratory results reports may be released prior to the final completion of the laboratory order. The case of Orders that are performed in part by one laboratory center and for another part by another laboratory center are intended to be handled in a way where a single laboratory shall take ownership of the entire order. If it is not capable to respond to the entire set of requested tests (and takes responsibility for the order), this laboratory will be responsible to sub-contract with another laboratory for the missing tests.	Coded

2.13 Assumptions and Dependencies

Table 1.3-6 Use Case Dependencies

identifies and describes Use Cases which this Use Case depends upon for information workflow.

Table 1.3-6 Use Case Dependencies

USE CASE NAME	DEPENDENCY ASSUMPTIONS
KSA-Wide Patient Demographics Query	The KSA-Wide Patient Demographic Query Use Case is used to obtain a Health ID and demographic attributes for the patient the laboratory order is being performed. It is used to provide consistent data in the order and report header (i.e. consistent with all patient health record documents).
Healthcare Provider Directory Query	The Healthcare Provider Directory Query Use Case is used to obtain provider and organizational information. It may be used to identify ordering physicians and organizations and also laboratory personal and laboratory organization information.
Sharing Coded Laboratory Results	Upon the completion of the order, the performing laboratory generates a Lab Report which is shared and communicated to the order creator using the Sharing Coded Laboratory Results Reports Use Case. Note: A laboratory report may not be generated if the order was canceled or aborted. Note: A laboratory results report may exist without a shared order in SeHE. The Sharing Coded Laboratory Results Reports may also be used by the performing laboratory to access relevant prior laboratory results reports.

2.14 Special Requirements

N/A

2.15 Notes and Issues