U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

General Laboratory Orders

Draft AHIC Extension/Gap

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1.0 Preface and Introduction

1.1 Background

In April and June of 2008, the American Health Information Community (AHIC) approved a recommendation to develop documents that address extensions/gaps from the use cases published between 2006 and 2008. One of the extensions/gaps prioritized for subsequent processing in the national health agenda activities in 2009 was General Laboratory Orders. AHIC specifically requested that the General Laboratory Orders Extension/Gap address the electronic exchange of general laboratory orders between Electronic Health Records (EHRs), Laboratory Information Systems (LISs), and other related systems, as well as the ability to link laboratory orders with laboratory results.

This extension/gap document is being developed by the Office of the National Coordinator for Health Information Technology (ONC) to represent the AHIC priorities and provide context for the national agenda activities, beginning with the selection of harmonized standards by the Health Information Technology Standards Panel (HITSP). Components that need to be considered during the standards identification and harmonization activities include standardized datasets, data elements, vocabularies, naming conventions, capabilities, and technical standards that support the information needs and processes of the ordering clinician and receiving laboratory. During the development of the document, there will be an opportunity for review and feedback by interested stakeholders within both the private and public sectors.

1.2 Progress to Date

To date, the national health agenda, including the activities of AHIC and HITSP, have not formally addressed the communication of general laboratory orders between clinicians and laboratories.

Previously published AHIC use cases incorporate several concepts that have been evaluated by HITSP and could be leveraged during standards harmonization for this extension/gap.

- The 2006 EHR – Laboratory Results Use Case describes the need for communicating laboratory results from an LIS to an EHR or other clinical system;

- The 2008 Personalized Healthcare Use Case describes the need for communicating clinician-initiated genetic/genomic laboratory orders from an EHR to an LIS;
- The 2007 Medication Management Use Case describes the need for communicating clinician-initiated medication orders from an EHR to a pharmacy;
- The 2006 Biosurveillance Use Case describes the need for communicating information about laboratory orders and results from laboratories to public health; and
- The 2008 Public Health Case Reporting Use Case describes the need for communicating and reporting laboratory test results to public health when specific reporting criteria are met. This use case also describes the need for communicating public health case reporting criteria for incorporation into EHR systems and utilization by clinicians.

2.0 Overview and Scope

2.1 Document/Request Overview

This extension/gap document is focused on information needs to facilitate the electronic exchange of general laboratory orders. The General Laboratory Orders Extension/Gap Document is divided into the following sections:

- Section 1.0, Preface and Introduction, describes the progress to date, the additional priorities identified by the AHIC, the resulting extensions/gaps, and their purpose;
- Section 2.0, Overview and Scope, describes the sections of an extension/gap document, the request being made to HITSP, and the scope of that request;
- Section 3.0, Functional Needs, describes the combination of end-user needs and system behaviors that support interoperability and information exchange;
- Section 4.0, Stakeholder Communities, describes individuals and organizations that participate in activities described in this extension/gap;
- Section 5.0, Issues and Obstacles, describes issues and obstacles which may need to be planned for, addressed, or resolved to achieve the capabilities described in the extension/gap;
- Section 6.0, References to Use Case Scenarios, describes various scenarios and information exchanges that assist in the communication of information. Scenarios may re-used from previously published 2006 – 2008 Use Cases and/or new scenarios may be described;
- Section 7.0, Information Exchange, describes information exchange capabilities that are needed to support the scenarios and the high-level role of information exchange;
- Section 8.0, Dataset Considerations, identifies specific information opportunities relevant to this extension/gap document that may support future identification, development, and harmonization of standards;
- Appendix A, Glossary, provides contextual descriptions of key concepts and terms introduced in this extension/gap document; and
- Appendix B, Analysis and Examples, identifies specific data types, datasets, data elements, vocabularies, naming conventions, capabilities, and technical standards that may support future industry efforts in the identification, development, and harmonization of standards.

2.2 Scope

General Laboratory Orders includes the process whereby clinicians request and order laboratory tests, and laboratories receive the order and process the requests. Consumer-initiated ordering, also described as direct access to testing (DAT), is out of scope for this

extension/gap. Therefore, requirements for General Laboratory Orders can be summarized as:

- The ordering clinician's ability to view, select, place, and communicate general laboratory orders; and
- The receiving laboratory's ability to receive, acknowledge, process, and communicate the status of a general laboratory order.

The identification, development, and harmonization of standards to support the processes associated with general laboratory ordering still requires additional work. As mentioned in Section 1.0, these needs have not yet been fully addressed by the national health agenda's standardization efforts. Examples of gaps in industry standards are outlined in the upcoming sections of this extension/gap document.

3.0 Functional Needs

This section describes a combination of end-user needs and system behaviors needed to support users during the exchange of laboratory orders between EHRs, LISs, and other systems. Rather than an all-inclusive list of functional requirements, key capabilities are outlined below. The descriptions in this section are not intended to prescribe policy nor propose architectures required to implement capabilities.

A. The ability to review a listing of available general laboratory orders.

   i. When selecting orders, the clinician may need the ability to review a listing of the available general laboratory orders. These listings may be acquired through libraries of commonly used general laboratory orders. These listings of laboratory orders may be grouped by order type and examples may include: anatomic pathology, microbiology, bio-chemistry, and hematology.

B. The ability to select a general laboratory order.

   i. Using the list of available general laboratory orders, the clinician may select and order general laboratory tests through an EHR or other clinical order entry system.

C. The ability to incorporate listings of available laboratory orders provided by external sources into an EHR or clinical order entry system.

   i. The listings of available orders, as described above, may be available through libraries of commonly used, general laboratory orders. These libraries may also include ordering instructions and order requirements that may be specific to certain orders or order types. These libraries of general laboratory orders may be available from the ordering entity, the receiving laboratory, external knowledge suppliers, laboratory associations, public health, and regulatory associations.

D. The ability to receive information/instructions which may assist in clinician ordering and laboratory processing.

   i. As part of the ordering process, the clinician may receive instructions that may include information concerning testing indication, patient preparation, timing/sequence, and specimen collection.

E. The ability to provide required and optional order details by using pre-populated and/or manually populated fields within a general laboratory order.

   i. During the ordering process, information may be requested from the ordering clinician to meet the needs of the receiving entity or comply with local, state, or

federal regulations. Depending on the system being used to place the general laboratory order, the information may be pre-populated, entered manually, and/or a combination of both. Examples of this information may include: patient demographics, indication for test, relevant clinical information, ordering clinician information, general specimen information, and billing or insurance information.

F. The ability to provide additional information regarding the general laboratory order.

   i. The clinician may want to provide additional information to the laboratory. Depending on the system being used to place the general laboratory order, the additional information may be pre-populated, entered manually, and/or a combination of both. Examples of additional information may include instructions to the laboratory regarding a specified order or specimen.

G. The ability to modify and/or complete the general laboratory order.

   i. Intra-organizational policies and functionality will determine the exact steps an ordering clinician must follow to complete the placement of or modify a general laboratory order.

   ii. The ordering clinician may need to identify a specific laboratory which will process the laboratory test. Intra-organizational, local, state, and federal policies and regulations may also govern which laboratory is to be the recipient of the general laboratory order.

H. The ability to electronically communicate the general laboratory order or modified general laboratory order from the EHR or clinical order entry system to the appropriate laboratory.

   i. The laboratory order is communicated from the ordering clinician's system to the receiving laboratory. Depending on patient care needs, business needs, and public health needs, information about the general laboratory order may also be communicated to other recipients including public health, government agencies, personally controlled health records, and payors.

I. The ability to electronically send an acknowledgement to the ordering clinician, communicating the laboratory's or LIS's receipt of the original or modified general laboratory order.

   i. Intra-organizational policies and functionality will determine the exact steps a receiving laboratory will follow to acknowledge the receipt of a general laboratory order. This includes the laboratory and/or LIS, having the ability to receive and acknowledge the general laboratory order, order modifications, and order

cancellations. This acknowledgement should be communicated to the ordering clinician.

J. The ability to view patient, specimen, or result information that is associated with the general laboratory order.

   i. The laboratory receives the order along with any additional information provided by the clinician.

K. The ability to electronically communicate a modification to the general laboratory order.

   i. As described previously, an ordering clinician may communicate a modification to a previously sent general laboratory order to the receiving laboratory. There may be circumstances where the receiving laboratory may need to modify the general laboratory order. The modified general laboratory order along with any relevant information should be communicated to the ordering clinician.

L. The ability to view the status of a general laboratory order.

   i. A clinician and/or a laboratorian may need to view the status of a general laboratory order. This information could include status of specimen collection, status of processing, and a history of order modifications.

M. The ability to unambiguously associate an order to its specimen and test result.

   i. A clinician and/or a laboratorian may need the ability to identify the specific specimen or test result associated with the general laboratory order

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4.0 Stakeholder Communities

Examples of stakeholders who may be directly or indirectly involved in the exchange of general laboratory orders have been listed below. Specific descriptions of each type of stakeholder can be found in the previous 2006 – 2008 AHIC Use Cases.

Stakeholders that may be directly involved in the exchange of general laboratory orders may include: Ordering Clinicians, Clinical Support Staff, and Laboratories.

Stakeholders that may assist in laboratory order communication may include: EHR System Suppliers and LIS System Suppliers.

Stakeholders that may be sources or recipients of order information and/or order requirements may include: Patients, Consumers, Knowledge Suppliers, Public Health, Government Agencies (such as Clinical Laboratory Improvement Amendments (CLIA) regulatory bodies within the FDA), Laboratory Organizations, and Healthcare Payors.

5.0 Issues and Obstacles

A number of issues in today's health information technology environment are obstacles to achieving the full potential of electronic health information exchange (HIE). Some general issues were described within the 2006 – 2008 AHIC Use Cases. Examples of specific issues and obstacles related to general laboratory orders are outlined below.

A. Order Names:

i. In order for clinicians, laboratories, and other entities to effectively exchange general laboratory orders, standard terminology and naming conventions may be needed.

a. Without the ability to map current standards and/or establish specific interoperable standards (e.g., LOINC, SNOMED, CPT, or other vocabularies identified by Standard Development Organizations (SDOs)) to ensure communication, it may be difficult to efficiently view, select, and place general laboratory orders.

b. There may be instances, such as in research settings or evolving medical sciences (e.g., pharmacogenetics), where the laboratory order which is needed may not be available for selection. Without the ability to query for and include standardized orders, it may be difficult for healthcare entities to maintain and utilize standardized lists of laboratory orders.

B. Order Types & Order Details:

i. In order for clinicians, laboratories, and other healthcare entities to effectively exchange general laboratory orders, standard order types and order detail requirements may be needed.

a. Healthcare entities may differ on their categorization of order types. For example, while the category "microbiology" may be commonly used, there may be discrepancies on the classification of "virology" as a sub-classification under microbiology or as its own category. The classification and sub-classification of "immunology" is another example of this issue.

b. Healthcare entities may use order types to assist in determining the required order details. Without the identification and adoption of standard order types, it may be difficult to standardize required order details.

c. There may be order types that require general or complex order details. The standardization of anatomic pathology (excluding cervical cytology/pap smears and less complex derma-pathology) may be challenging because of its specialized information needs.

C. Order Source & Identification:

i. For clinicians, laboratories, and entities to effectively exchange general laboratory orders, systems may need to be capable of generating unique order identifiers (e.g., order identifier, order update identifier, or date/time stamp).

a. If systems do not have capabilities to generate or utilize a combination of order identification information to uniquely identify an order, it may be difficult to effectively communicate general laboratory orders and link them to associated specimens and results.

b. If systems do not have the ability to denote the library/source from which the order name/code came, it may be difficult to effectively communicate laboratory orders across systems.

D. Order Routing:

i. The functional requirements expressed in this extension/gap document rely on the identification and utilization of appropriate information and triggers to complete health information exchange routing activities.

a. Without the ability to determine, communicate, and incorporate general laboratory order requirements into EHRs, LISs, and other systems, it may be difficult to appropriately route and deliver information to laboratories and public health.

6.0 References to Prior Use Case Scenarios

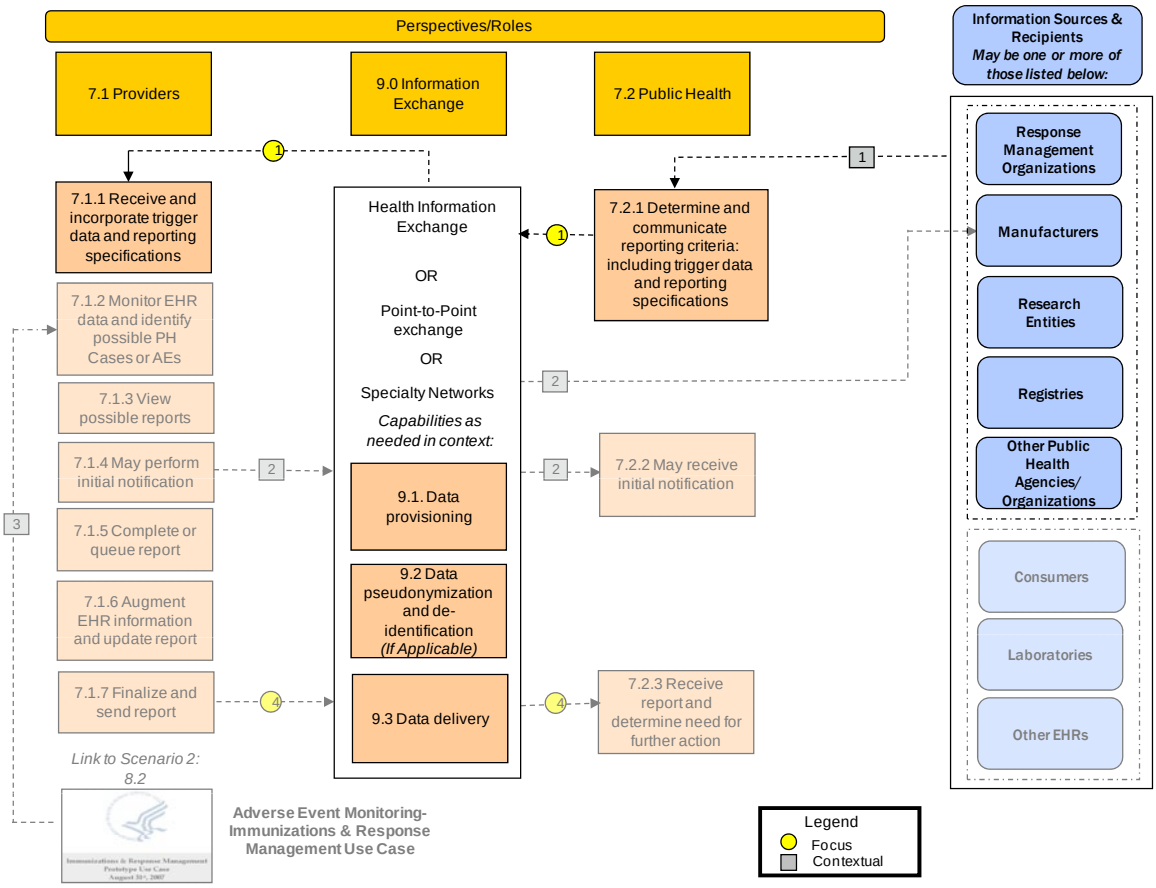
The General Laboratory Orders Extension/Gap Draft Document focuses on the exchange of a core set of information between clinicians, care settings, and laboratories. Specific events and information exchanges have been selected from previous use cases for contextual purposes.

The 2008 Public Health Case Reporting Use Case contains a scenario that describes the communication of requirements by various sources and the incorporation of these requirements into EHRs. The 2008 Personalized Healthcare Use Case and the 2007 Medication Management Use Case contain scenarios that describe the communication of clinician-initiated orders. Included in this section are applicable copies of the scenarios and information flows from the Public Health Case Reporting, Medication Management, and Personalized Healthcare Use Cases.

The events and information flows which are pertinent to the General Laboratory Orders Extension/Gap are shown in bold. All other events and information flows have been faded out.

6.1 Reference to Prior Use Case: 2008 Public Health Case Reporting (Scenario 1)

Figure 6-1. Reporting from EHRS

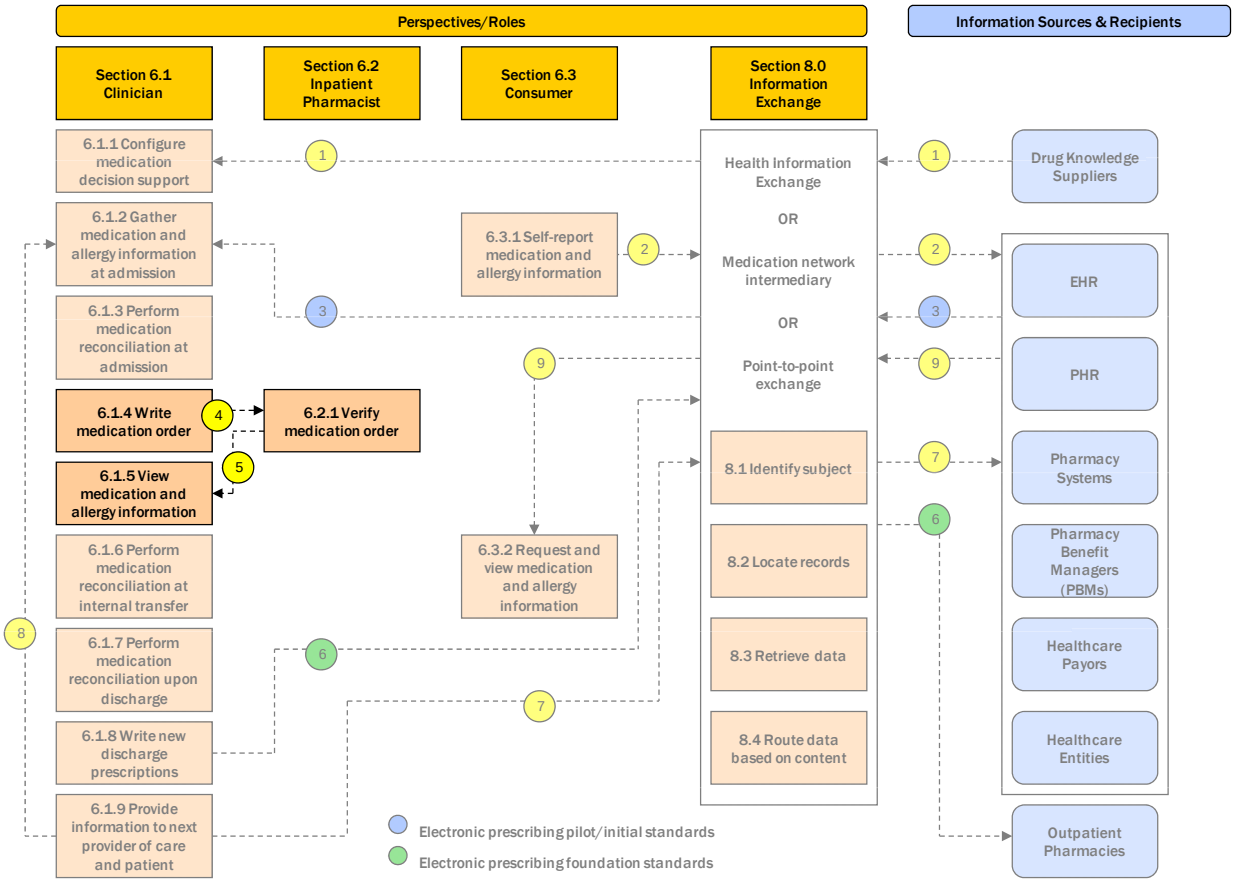


As expressed in the 2008 Public Health Case Reporting Use Case events 7.1.1, 7.2.1 and information flow 1, reporting criteria, including trigger data and reporting specifics, may be communicated via health information exchange activities and incorporated into provider systems (e.g., EHRs and/or public health systems).

In the case of general laboratory orders, Knowledge Suppliers/Sources may communicate order requirements via health information exchange activities. Order requirements may be incorporated from order systems (e.g., EHRs, laboratory systems, or LISs) Suppliers of order requirements may include healthcare entities, clinical laboratories, reference laboratories, laboratory associations, public health agencies, or public health associations. Therefore, Information Flow 1 should be referenced when addressing general laboratory orders.

6.2 Reference to Prior Use Case: 2007 Medication Management (Scenario 1)

Figure 6-2. Inpatient Medication Reconciliation

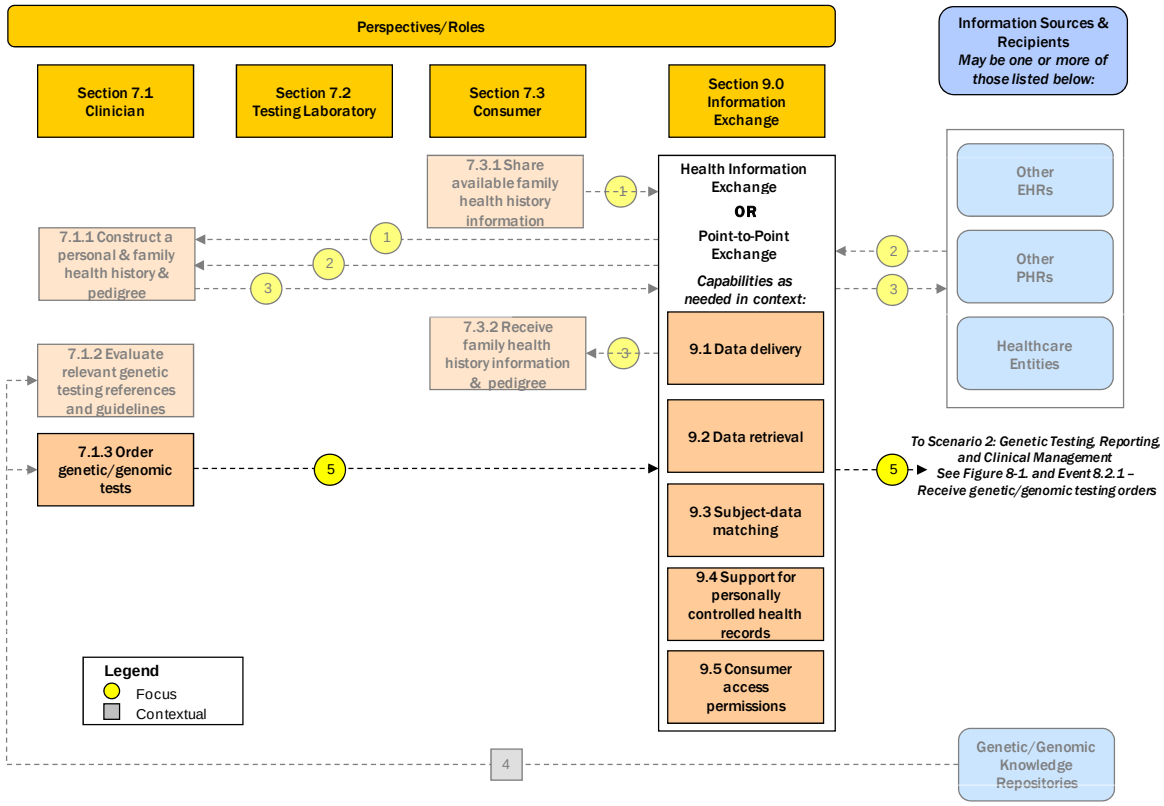


As expressed in the 2007 Medication Management Use Case Events 6.1.4, 6.1.5 and information flows 4 and 5, orders, including all order details, may be communicated directly between a clinician and an inpatient pharmacist.

In the case of general laboratory orders, in an inpatient setting a clinician may communicate general laboratory orders, including all order details, directly with an in-house laboratory. Therefore, information flows 4 and 5 should be referenced when addressing general laboratory orders.

6.3 Reference to Prior Use Case: 2008 Personalized Health Care (Scenario 1)

Figure 6-3. Clinical Assessment

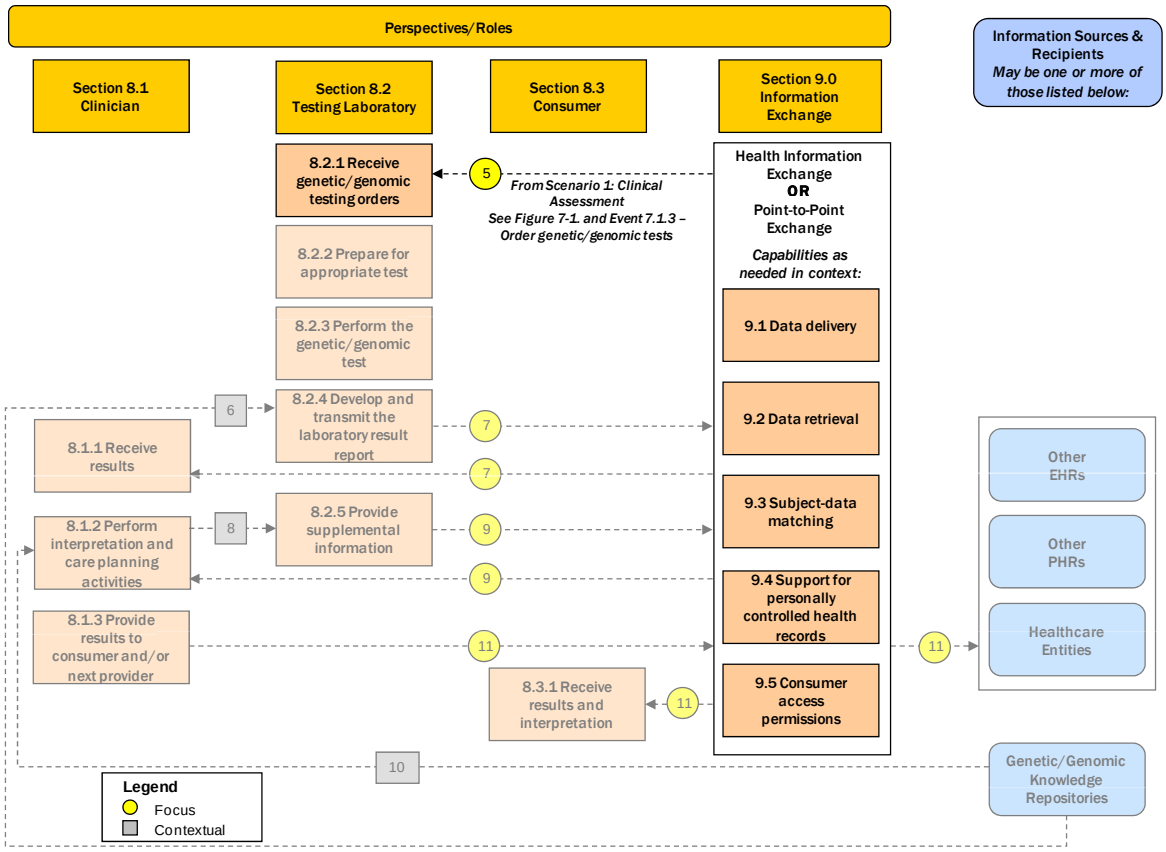


As expressed in the 2008 Personalized Healthcare Use Case Events 7.1.3, 8.2.1, and information flow 5, orders, including all order details, may be communicated directly between a clinician and a testing laboratory using health information exchange activities.

In the case of General Laboratory Orders in an outpatient or public health setting, a clinician may communicate orders, including all general laboratory order details, using HIE activities to laboratories or public health. Therefore, information flow 5 should be referenced when addressing general laboratory orders.

6.4 Reference to Prior Use Case: 2008 Personalized Health Care (Scenario 2)

Figure 6-4. Genetic Testing, Reporting, and Clinical Management



As expressed in the 2008 Personalized Healthcare Use Case Events 7.1.3, 8.2.1, and information flow 5, orders including all order details may be communicated directly between a clinician and a testing laboratory using health information exchange activities.

As described above in Figure 6-4, general laboratory orders, including all order details, using health information exchange activities may be communicated to laboratories or public health. Therefore, information flow 5 should be referenced when addressing General Laboratory Orders.

7.0 Information Exchange

The information exchange capabilities for the effective selection and communication of general laboratory orders may comprise:

- The ability to communicate general laboratory order requirements;
- The ability to generate, communicate, and/or translate a unique order identification number;
- The ability to route general laboratory orders appropriately;
- The ability to communicate general laboratory order status;
- The ability to communicate modifications to general laboratory order status; and
- The ability to unambiguously maintain a relationship between patients, specimens, general laboratory orders, and results.

Examples of information exchange capabilities described above and in Section 3.0 may include: Data Delivery, Routing, Data Retrieval, and Subject Data Matching. Descriptions of each of these are contained in the previous 2006 – 2008 AHIC Use Cases.

The functional capabilities may be provided fully or partially by a variety of organizations including: free-standing or geographic health information exchanges (e.g., Regional Health Information Organizations), integrated care delivery networks, provider organizations, health record banks, public health networks, specialty networks, and others.

While not described in this section, HIE and point-to-point exchanges assist in the completion of the processes described in this extension/gap. Examples of HIEs and Point-to-Point exchanges can be found in the previous 2006 – 2008 AHIC Use Cases.

8.0 General Laboratory Orders Dataset Considerations

The following non-exhaustive information categories and limited examples illustrate some of the information needs outlined in this extension/gap document. Examples of commonly used general laboratory order names, order types, and order detail requirements, as well as a brief analysis of requirements for various order types are included in Appendix B.

Laboratory Order Types –General laboratory orders may be classified by order types. Order types may include but are not limited to: anatomic pathology, microbiology, bio-chemistry, and hematology. Order detail requirements may be determined at the order type classification, sub-classification, and/or specific order level. For example, determining standard order details for complex anatomic pathology orders may be challenging. However, pap smear or general derma-pathology orders may be placed and communicated using standardized order details.

Laboratory Orders - Determining and standardizing all laboratory order names may not be practical. However, focusing on commonly used general laboratory orders such as those addressed by LOINC, CPT, SNOMED, the National Library of Medicine (NLM), or other SDOs may be valuable. Specific information that further describes the order should also be considered. This information may include:

- Order Name
- Order Description
- Order Code
- Source of Order Code
- Panel Test Inclusion
- Order Type

Laboratory Order Instructions – Various order types and specific orders may also include standard order instructions. Order instructions may have standard formatting and sequence and may include:

- Ordering Indications
- Patient Preparation
- Specimen Collection
- Timing/Sequencing Information
- Routing Instructions

Laboratory Order Details – Order detail requirements may be determined at the order type and/or specific order level. Standard order details may be required or optional depending on the order, the needs of the receiving entity, or local, state, and federal regulations. Order details may include:

- **Patient – Identification Information**
  - **Demographics**
    - Gender
    - Age
    - Date of Birth
  - Clinical History
- **Patient – Clinically Relevant Information**
  - Chief Complaint/Reason for Visit
  - Diagnosis or Preliminary Diagnosis
  - Active Medications
- **Order – Required and Optional Information**
    - Source of Specimen
    - Specimen Collection Method
    - Date/Time Specimen was Collected
    - Specific Public Health Information
    - Ordering Clinician
    - Instructions per Ordering Clinician

General Laboratory Order Communication and Status – Specific information which assists in the communication and tracking of a general laboratory order may be considered. This information may include:

- System Generated Order Identification Information
- Order Status
- Order Update, Modification, Cancellation
- Associated Specimen & Result

Appendix A: Glossary

The 2006 – 2008 AHIC Use Cases contained general terms and their contextual descriptions. Listed below are the new terms that are specific to this extension/gap.

General Order Libraries: The listings of all possible general laboratory orders, including order types and order details that may be selected by a clinician and/or processed by a laboratory.

General Order Details: Information that may be provided to more fully describe an order. These details may be used within an ordering template and may include data fields such as preliminary diagnosis, site of specimen collection, method of specimen collection, and testing instructions.

Order Set Libraries: The listings of all available order sets that may be distributed by a knowledge supplier.

LIS System Suppliers: Organizations that provide specific EHR solutions to clinicians and laboratories such as software applications and software services. These suppliers may include developers, providers, operators, and others who may provide these similar services.

Appendix B: Analysis & Examples

General laboratory orders may be classified by order types. A brief analysis of requirements for various order types is listed in the table below. Order types such as hematology, bio-chemistry, microbiology, anatomic pathology (pap smear), and anatomic pathology (derma-pathology) are specified in the columns on the left. Public Health needs are expressed in the far right column. This example and analysis is included for discussion purposes and may or may not be included in the final document.

Data ID #	Types of Data Transferred During Laboratory Orders	Hematology	Biochemistry	Microbiology	Anatomic Pathology-Pap Smear	Anatomic Pathology Derma-pathology	Public Health
Order Information							
1	**Patient Information**	X	X	X	X	X	X
1.1	Patient Demographic Information	X	X	X	X	X	X
1.2	Patient Preferences	X	X	X	X	X	X
1.3	Formulary and Benefits	X	X	X	X	X	X
1.3.1	Indication of Medicare Patient	X	X	X	X	X	X
2	**Sending Provider Information**	X	X	X	X	X	X
2.1	Provider Identification	X	X	X	X	X	X
2.2	Provider Privileges	X	X	X	X	X	X
3	**Receiving Provider Information**	X	X	X	X	X	X
3.1	Provider Identification	X	X	X	X	X	X
3.2	Provider Privileges	X	X	X	X	X	X
4	**Sending Facility of Laboratory Information**	X	X	X	X	X	X
4.1	Sending Laboratory or Facility Identifier	X	X	X	X	X	X
5	**Receiving Facility Information**	X	X	X	X	X	X
5.1	Receiving Laboratory or Facility Primary Identifier	X	X	X	X	X	X
6	**Date/Time**	X	X	X	X	X	X
Order Details							
7	**Specimen Data**	X	X	X	X	X	X
7.1	Specimen Identification	X	X	X	X	X	X
7.2	Draw Date	X	X	X	X	X	X
7.3	Draw Time	X	X	X	X	X	X
7.4	Draw Method/Conditions/ Preparation	X	X	X	X	X	X

Data ID #	Types of Data Transferred During Laboratory Orders	Hematology	Biochemistry	Microbiology	Anatomic Pathology-Pap Smear	Anatomic Pathology Derma-pathology	Public Health
7.5	Send Date/Receipt Date	X	X	X	X	X	X
7.6	Specimen Preliminary Diagnosis	X	X	X	X	X	X
7.7	Special Specimen Instructions	X	X	X	X	X	X
7.8	Handling (routine/rushed)	X	X	X	X	X	X
7.9	Sender/Receiver	X	X	X	X	X	X
7.10	Sender/Receiver Processor	X	X	X	X	X	X
7.11	Specimen Units	X	X	X	X	X	X
7.12	Biopsy Method	X	X	X	X	X	X
7.13	Site of Specimen(s)	X	X	X	X	X	X
7.14	Clinical Description	X	X	X	X	X	X
7.15	Preoperative Diagnosis	X	X	X	X	X	X
7.16	Previous Biopsy Numbers on Patient	X	X	X	X	X	X
8	**Order Identification**	X	X	X	X	X	X
8.1	Services Desired	X	X	X	X	X	X
8.1.1	HPV only (no pap test)				X		
8.1.2	Test being ordered (e.g. screening pap-no risk, screening pap-high risk, screening pap-no cervix, diagnostic pap)				X		
8.2	Prior Authorization Information	X	X	X	X	X	X
8.3	Physician Signature	X	X	X	X	X	X
8.4	Reason for Consultation	X	X	X	X	X	X
8.5	Diagnosis	X	X	X	X	X	X
8.6	Order Process (Hold, Process, Sequence)	X	X	X	X	X	X
8.7	Frequency/Duration	X	X	X	X	X	X
8.8	Indication of Pre-clinic lab	X	X	X	X	X	X
9	**Test Information**	X	X	X	X	X	X
9.1	Laboratory Service Category	X	X	X	X	X	X
9.2	Laboratory Service Result Type	X	X	X	X	X	X
9.3	Test/Fluid Identifier(s)	X	X	X	X	X	X
9.4	Test/Observations Included	X	X	X	X	X	X
9.5	Specific Questions/Instructions for Path lab					X	
9.6	Request for written report	X	X	X	X	X	X
9.7	Data quality assurance and completeness						X
9.8	Data security						X
9.9	Reportable STD				X		X

Data ID #	Types of Data Transferred During Laboratory Orders	Hematology	Biochemistry	Microbiology	Anatomic Pathology- Pap Smear	Anatomic Pathology Derma-pathology	Public Health
10	**Patient History**	X	X	X	X	X	X
10.1	Biohazard labels						X
10.2	Bite						X
10.3	Case and disease data collection functions.						X
10.4	Case detection through the collection of reported health data, including laboratory reports						X
10.5	Case investigation data as needed to determine case morbidity status						X
10.6	Contact with saliva/nervous tissue						X
10.7	Drug user						X
10.8	Foreign born						X
10.9	Risk factors						X
10.10	Sexual history				X		X
10.11	Surveillance						X
10.12	Time of Death						X
10.13	Type of Animal Bite						X
10.14	Reflex HPV (high/intermediate risk types)				X		
10.15	Menstrual status				X		
10.16	Previous cytology				X		
10.17	Previous colposcopy (results, proceedure today?)				X		
10.18	Clinical Information (appearance of cervix, absence of cervix, free text)				X		
10.19	Previous treatments (appearance of cervix, absence of cervix, free text)				X		
10.20	Handling (routine/rushed)				X		