



White Paper

# Assure Health IT Standards for Public Health

## *Part I: Health IT Standards in Public Health Laboratory Domain*

2012

Baltimore, Maryland

The ***Public Health Data Standards Consortium*** (PHDSC, The Consortium) is a national non-profit membership-based organization of federal, state and local health agencies, professional associations, academia, public and private sector organizations, international members, and individuals.

The Consortium is committed to bringing a common voice from the public health community to the national efforts of standardization of health information technology and population health data in order to improve individual and community health.

To fulfill its mission the Consortium:

***Identifies priorities for new national standards*** for population health data;

***Promotes integrating health-related information systems*** to meet the needs of public and private organizations, agencies and individuals;

***Participates in national and international efforts*** to standardize health-related information;

***Represents public health interests*** in standards development organizations, data content committees and standards harmonization entities; and

***Educates*** the public health community about health information technology standards and the health information technology community about public health.

PUBLIC HEALTH DATA STANDARDS CONSORTIUM
PHDSC
Promoting Standards Through Partnerships

111 South Calvert Street
Baltimore, MD 21202
Phone: (410) 385-5201
Fax: (866) 637-6526
www.phdsc.org

The ***Association of Public Health Laboratories*** (APHL) is the national nonprofit representing governmental laboratories that protect the public's health by detecting and monitoring health threats. Members include state, territorial and local public health labs; state environmental testing labs; state agricultural and food safety labs; and individual scientists, public health officials and academicians.

APHLs mission is to promote the role of public health laboratories in shaping national and global health objectives, and to promote policies, programs, and technologies which assure continuous improvement in the quality of laboratory practice and health outcomes.

To fulfill its mission, APHL's focuses on the following areas:

***Workforce***: Advance the training, leadership development, recruitment & retention of a competent workforce to meet the needs of the public health laboratory system;

***Advocacy and Outreach***: Enhance the visibility, status & influence of the public health laboratory community through effective advocacy, strategic communications & public relations;

***Networking and Community Building***: Act as a focal point for the collection and dissemination of information throughout the public health community and to external partners;

***Informatics*****:** Improve the informatics capabilities of APHL & its members; and

***Laboratory Science, Standards and Practices***: Advance the development, use, and evaluation of technologies, quality systems and practices

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8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
Phone: (240) 485-2745
Fax: (240) 485-2700
www.aphl.org

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### Public Health Data Standards Consortium (PHDSC, The Consortium)

*Dr. Anna O. Orlova*, PHDSC's Executive Director and Visiting Associate Professor, Johns Hopkins School of Medicine is the Principal Investigator of this project. The project team includes *Ms. Alla Fridman,* PHDSC Project Manager; *Ms. Eileen Koski*, Medco Health Solutions; *Mr. Todd Watkins, Scientific Technologies Corporation (STC); Ms. Lori Reed-Fourquet,* eHealthSign, LLC; *Ms. Sondra Renly*, IBM Research; and *Ms. Maiko Minami*, HLN Consulting, LLC.

### Association of Public Health Laboratories (APHL)

APHL Informatics Committee members and staff.

# Table of Contents

# Executive Summary

Public Health Laboratories (PHLs) provide specialized testing for clinical care, surveillance and surge capacity during disasters. "Laboratories are key stakeholders in providing critical data to local, state, tribal and federal public health agencies to investigate individual cases of communicable and chronic diseases as well as to characterize and mitigate population-based public health threats."[1]

Health information technology (HIT) standards are the key to enabling electronic information exchanges (i.e., interoperability) between senders and receivers of laboratory information. A survey conducted by the Association of Public Health Laboratories (APHL) revealed tremendous variability, despite of the efforts for implementation of messaging standards at the partner labs,[2] which rendered data sharing almost impossible, without additional effort to agree on a standard representation of the data across the laboratories. On the national level several efforts are under way to improve data exchange capabilities with a focus on the clinical domain. Integration of that domain with the work of public health laboratories needs to be improved upon.

The Public Health Data Standards Consortium (PHDSC) and APHL partnered (1) to document and analyze the state of HIT standards available for laboratory practices and in use in information exchanges to date; and (2) to develop an implementation strategy (a Roadmap) for HIT standardization of laboratory data exchanges to support public health laboratory business practices, their integration with clinical partners and preparedness activities.

The outcomes of these efforts are presented in this White Paper "*Assure HIT Standards for Public Health*" that includes two documents as follows:

*Part 1: HIT Standards in Public Health Laboratory Domain* – an overview of HIT standards and their implementation efforts by public health laboratories and national organizations to date*, i.e., Where Are We Now, a*nd

*Part 2: A Roadmap on HIT Standardization for Public Health Laboratories – a* proposed implementation strategy and a roadmap to improve laboratory information management systems (LIMS) interoperability with all its partners and suggestions for future PHDSC-APHL projects, *i.e., Where Are We Going.*

Part 1 of the White Paper serves as an informational resource about HIT standards available for PHL data exchanges focused on testing of mostly human samples. Part 2 describes activities with various HIT standardization entities related to the laboratory HIT standards based on the respective phase of HIT standardization in question. The proposed PHDSC-APHL HIT standards implementation strategy and near future (2012-2013) roadmap for PHLs are focused on addressing incomplete and inconsistent adoption of the existing standards and absence of a sustainable approach for standardization of information systems in public health by ***operationalizing*** HIT standards that already exist for laboratory information exchanges and developing new standards that meet PHL business needs, where needed.

[1] Zarcone P, Nordenberg D, Meigs M, Merrick U, Jernigan D, Hinrichs SH. Community-Driven Standards-Based Electronic Laboratory Data-Sharing Networks. Public Health Reports. 2010. Suppl 2; Vol. 125: 47-56. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846802/

[2] Public Health Data Standards Consortium (PHDSC). Business Case: The Role of Public Health in National HIT Standardization. URL: http://www.phdsc.org/standards/business_case.asp

The White Paper is targeted to the following three audiences:

*1 – Leadership* - public health leadership and decision-makers at the local, state and federal levels; national HIT leaders; and leadership of State Health Information Exchanges (HIEs) including State Chief Information Officers (CIOs). The goal is to communicate to them the challenges and possible solutions for enabling adoption of interoperable HIT solutions for public health laboratory data exchanges

*2 – Health professionals involved in laboratory data exchanges* – directors and staff of public health laboratories, directors and staff at partner organizations of the public health laboratory such as providers, public health preparedness programs and other programs involved in laboratory data exchanges at the local, state and federal levels to engage them in HIT standardization activities (standards development, harmonization and testing; standard-based products certification; and selection of standard-based HIT products for their agencies/programs)

*3 – IT professionals involved in HIT standardization* – vendors of electronic health record systems (EHR-S), laboratory information systems (LIS) and LIMS products involved in HIT standardization activities (standards development, harmonization and testing; and standard-based products certification and deployment) to address business needs of public health laboratories and programs in HIT standards to support laboratory health information exchanges.

This document represents *Part 1: HIT Standards in Public Health Laboratory Domain* of the White Paper *Assure HIT Standards for Public Health*.

## Section 1 Introduction

Public Health Laboratories provide specialized testing for clinical care, surveillance and surge capacity during disasters. Laboratory information management and business practices form the backbone of public health surveillance and healthcare delivery ". As stated by Zarcone, et al: "Laboratories are key stakeholders in providing critical data to local, state, tribal and federal public health agencies to investigate individual cases of communicable and chronic diseases as well as to characterize and mitigate population-based public health threats."[3]

With hundreds of Public Health Laboratories (PHLs) operating on various state and local levels throughout the United States, approximately 100 of these laboratories provide comprehensive, high complexity services. This includes "centralized laboratories with multiple branch facilities (e.g., Texas, Florida); university-affiliated laboratories (e.g. Wisconsin, Nebraska); and consolidated laboratory services (e.g., Virginia). A PHL can have up to 10 different recipients of similar or identical information such as other public health laboratories; commercial laboratories; primary care providers; hospital infectious control practitioners; health program directors; state public health departments; the state chief medical/health officer; city or county chief medical/health officers; state epidemiologists; and federal agencies (e.g., Centers for Disease Control and Prevention (CDC), Environmental Protection Agency (EPA))."[4]

According to a national survey,[5,6] in 2007 almost 90% of PHLs had laboratory information management systems. However the capabilities of these LIMSs differ from the Electronic Health Records Systems (EHR-S), integrated laboratory Information systems (LISs) and among themselves. Just as varied as the services provided across the PHLs is the technical support for the LIMSs and thus their technical capabilities. A Lack of integration between PHL LIMSs and their recipients' systems leads to duplication of efforts and increased costs of providing laboratory information. [7,8] Various software products and varying data formats/standards used by individual systems make integration projects costly and often infeasible.[9]

Health information technology standards are the key to enabling interoperability between senders and receivers of laboratory information. However, the survey conducted by the Association of Public Health Laboratories (APHL) revealed tremendous variability in the correct implementation of HIT standards, which rendered data sharing impossible without additional effort to map the data across the laboratories to a standard representation. [10] This is a result from the frequent use of proprietary data, variability in the underlying data standards and set up within the

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[3] Zarcone P, Nordenberg D, Meigs M, Merrick U, Jernigan D, Hinrichs SH. Community-Driven Standards-Based Electronic Laboratory Data-Sharing Networks. Public Health Reports. 2010. Suppl 2; Vol. 125: 47-56. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846802/

[4] Same.

[5] 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011

[6] PHLIP Influenza ELSM - Messaging Capabilities Assessment Survey (and follow up conversations) – APHL March 2011

[7] Centers for Disease Control and Prevention (CDC). Lesson Five: Public Health Surveillance. Principles of Epidemiology in Public Health Practice. Third Edition (Print-based). 336-409. Available at: http://www.cdc.gov/training/products/ss1000/ss1000-ol.pdf

[8] Building a Roadmap for Health Information Systems Interoperability for Public Health. Public Health Uses of Electronic Health Record Data. Baltimore, MD; Public Health Data Standards Consortium; 2008. URL: http://static.ihe.net/Technical_Framework/upload/IHE-PHDSC_Public_Health_White_Paper_2008-07-29.pdf

[9] Public Health Data Standards Consortium (PHDSC). Business Case: The Role of Public Health in National HIT Standardization. URL: http://www.phdsc.org/standards/business_case.asp

[10] 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011

LIMS as well as multiple choices of information exchange standards, security protocols, and network infrastructure in the U.S.[11]

Today, neither public health laboratories, nor other laboratories, are fully interoperable in electronically reporting/exchanging data with their information exchange partners. Though due to its resource scarce nature the PHL community has always been collaboratively working on improving their workflows, service delivery and communications with their partners.

In 2006, members of the APHL Informatics Committee reviewed the need for and obstacles to building national interoperability of information systems in healthcare and public health.[12] They identified the need to:

- harmonize the adoption of technical interoperability standards to support PHL electronic data exchange
- reduce the overhead or expense of transmitting laboratory test orders and results
- provide continuity of operations and surge capacity among PHLs
- share best practices in the adoption of LIMSs
- work more effectively with vendors of public health LIMS products and
- increase the effectiveness of identifying and propagating the adoption of new methodologies and technologies.

General barriers to effective electronic laboratory information exchange are (not in the order of priority):

Barrier I - The incomplete and inconsistent adoption of existing standards by the wide array of laboratories responsible for reporting laboratory results as well as by the EHR-S and the public health information systems they report to.

Barrier II - The lack of adoption of EHR-S[13] in clinical settings (i.e., test order senders and result receivers) preventing electronic communication between providers and LIMS.

Barrier III - The use of proprietary, non-standardized information systems in public health preventing electronic communication between LIMS and public health programs (i.e., receivers of test results on public health threat conditions). .

Barrier IV - The absence of a sustainable approach and funding to support the development of laboratory standards and their testing; and of certification and adoption of standards-based IT products in clinical, laboratory and public health settings.

Barrier V – The need for informatics-savvy personnel in PHLs to operate in a new HIT and information communication environment

Sections that follow provide an overview of HIT standards applicable to PHL domain as well as the current use of these standards in various national initiatives and projects.

[11] Zarcone P, Nordenberg D, Meigs M, Merrick U, Jernigan D, Hinrichs SH. Community-Driven Standards-Based Electronic Laboratory Data-Sharing Networks. Public Health Reports. 2010. Suppl 2; Vol. 125: 47-56. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846802/

[12] Same.

[13] Office of National Coordinator for Health IT. DHHS, Health IT Adoption. URL: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1152&parentname=CommunityPage&parentid=28&mode=2&in_hi_userid=11113&cached=true

## Section 2 Background of HIT Standards and Their Implementation Efforts in Public Health Laboratories and National Organizations

Electronic communication across public health laboratory stakeholders is critical to assure that their data needs are addressed in real-time and in a high-quality manner. A PHL can have up to 10 different recipients of similar or identical information such as

1. Other public health laboratories
2. Commercial laboratories
3. Primary care providers
4. Hospital infectious control practitioners
5. Health program directors
6. State public health departments
7. State chief medical/health officer
8. City or county chief medical/health officers
9. State epidemiologists, and
10. Federal agencies.[14]

To support these communications, PHL LIMSs have to exchange data with clinical EHR-S, other LIMSs, Public Health Information Systems (PH-IS) from various agencies and regional Health Information Exchanges (HIEs) using a variety of standards. In order to better understand how to reach the goal of interoperability with all partners in the PHL domain, a review of the different types of standards and their current use is provided here.

Standards are the key to information systems interoperability.[15] **Standardization**, as defined by the International Organization for Standards (ISO) [16], is the process of agreeing on standards, which represent the common language that allows the exchange of data between disparate data systems. The goals of standardization are to achieve comparability, compatibility, and interoperability between independent systems; to ensure compatibility of data for comparative statistical purposes; and to reduce duplication of effort and redundancies.

A **Standard** is a definition, set of rules or guidelines, format, or document that establishes uniform engineering or technical specifications, criteria, methods, processes, or practices that have been approved by a recognized standard development organization (SDO), or have been accepted by the industry as de facto standards, or de jure standards, i.e. formal legal requirements. De facto standards have become standards because a large number of companies have agreed to use them. They have not been formally approved as standards, but they are standards nonetheless.

In order to provide semantic interoperability several HIT **Standards Categories** need to be considered.

[14] Zarcone P, Nordenberg D, Meigs M, Merrick U, Jernigan D, Hinrichs SH. Community-Driven Standards-Based Electronic Laboratory Data-Sharing Networks. Public Health Reports. 2010. Suppl 2; Vol. 125: 47-56. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846802/

[15] Public Health Data Standards Consortium (PHDSC). Health IT Standards. Web-Resource Center. Information Content Standards. URL: http://www.phdsc.org/standards/health-information-tech-standards.asp

[16] International Organizations for Standardization (ISO). URL: http://www.iso.org/iso/iso_technical_committee.html?commid=54960

In February 2006, the Health Information Technology Standards Panel (HITSP)[17] identified the following health information technology standards categories[18] with the respective examples:

| Standards Categories | Examples |
|---|---|
| Data Standards | Vocabularies and terminologies |
| Information Content Standards | Reference information models (RIM) |
| Information Exchange Standards | Message-based and structured document-based |
| Identifier Standards | National Provider Identifier (NPI)[19] |
| Privacy and Security Standards | Access control, audit, electronic consent |
| Functional Standards | Work processes, workflow and dataflow models |
| Other Standards | Internet standards, transport mechanisms |

## Data Standards

***Data Standards***[20] are documented agreements on representations, formats, and definitions of common data. Data standards provide a method to codify in valid, meaningful, comprehensive, and actionable ways, information captured in the course of doing business. Data Standards are represented in vocabulary and terminology standards.

**Vocabulary and terminology standards that are used in LIMS and LIS and should also be supported in EHR-systems**:

- Logical Observation Identifiers Names and Codes (LOINC)[21] for test orders and resulted tests
- INTSDO/Systematic Nomenclature for Medicine (SNOMED)[22] should be used for lab tests results and specimen terms; it may also be used for procedures as well as diagnosis
- The Unified Code for Units of Measure (UCUM)[23] for units of analysis
- Accredited Standards Committee X12 (HIPAA Transaction Format)[24] for billing purposes
- International Classification of Diseases (ICD10/ICD)[25,26] for diagnosis
- Health Level Seven (HL7) Version 2.x and Version 3[27] for vocabulary
- Project-specific value sets, e.g., CDC Public Health Information Network -Vocabulary Access and Distribution System (PHIN VADS).[28]

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[17] Health Information Technology Standards Panel (HITSP). URL: http://www.hitsp.org

[18] Public Health Data Standards Consortium (PHDSC). Health IT Standards. Web-Resource Center. URL: http://www.phdsc.org/standards/health-information-tech-standards.asp

[19] Centers for Medicare and Medicaid Services, US Department of Health and Human Services; National Provider Identifier Standard. URL: http://www.cms.hhs.gov/NationalProvIdentstand/

[20] Public Health Data Standards Consortium (PHDSC). Health IT Standards. Web-Resource Center. Data Standards. http://www.phdsc.org/standards/health-information/D_Standards.asp

[21] Logical Observation Identifiers Names and Codes (LOINC). URL: http://loinc.org/

[22] International Health Terminology Standards Development Organization (IHTSDO), former SNOMED-Systematized Nomenclature of Medicine – Clinical Terminology. URL: http://www.ihtsdo.org/snomed-ct

[23] The Unified Code for Units of Measure. URL:http://aurora.regenstrief.org/~ucum/ucum.html

[24] Accredited Standards Committee X12. URL: http://www.x12.org

[25] International Classification of Diseases, 10th Edition, Clinical Modification. URL: https://www.cms.gov/ICD10/11b1_2011_ICD10CM_and_GEMs.asp

[26] International Classification of Diseases, 9th Edition, Clinical Modification. URL: https://www.cms.gov/icd9providerdiagnosticcodes/

[27] Health Level Seven (HL7). URL: hhtp://www.hl7.org

[28] Centers for Disease Control and Prevention (CDC). Vocabulary Access and Distribution System (PHIN VADS). URL:http://phinvads.cdc.gov

**Table 2** presents data from the 2010 survey of laboratory information systems (LIS) vendors on their capabilities to support the use of data standards if clients so wish, i.e., LIS vendors have capabilities to support these standards, but may not necessarily actually use them.

**Table 2**. Support for Data Standards by Laboratory Information Systems – 2010[29]

| Data Standards | LIS Vendors = 35 |
|---|---|
| X12 (HIPAA Transaction Format) | 33 |
| LOINC | 31 |
| SNOMED | 26 |

No data available about the use of data standards by PHLs.

**Reportable Conditions Mapping Tables (RCMT) Project**[30] through a process engaging a wide range of stakeholders, including subject matter experts in laboratory medicine, epidemiology, infection prevention and informatics (especially vocabulary standards), as well as members of the EHR/LIS vendor community provided mapping of the laboratory tests and result codes related to Nationally Notifiable Conditions and Jurisdictional Reportable Conditions to standard vocabulary codes to achieve semantic interoperability. Specifically, it provides mappings between conditions and their associated codes in LOINC for laboratory tests and in SNOMED for test results. The RCMTs were previously known as the "Dwyer tables", "Sable tables" or Notifiable Condition Mapping Tables (NCMTs). RCMT content for 109 reportable conditions has been published on June 30th, 2011, with on-going updates since laboratory tests and standard codes change over time via the CDC PHIN VADS.

The RCMT project was coordinated by the Standards Workgroup under the CDC and Council for State and Territorial Epidemiologists (CSTE) Joint Electronic Laboratory Reporting (ELR) Task Force, a collaborative effort between the CDC, APHL and CSTE to promote the implementation of ELR to public health.

The RCMTs can be used in EHR decision support systems to help identify patients who have reportable conditions, which would trigger public health case reporting and ELR.

**Reportable Condition Ontology/Knowledgebase Project.** Laboratory results are often a vital part in identifying communicable diseases that are of interest to public health. Automated laboratory data reporting will improve quality and timeliness of surveillance. The idea behind the Reportable Condition Ontology project is to provide a repository of all the laboratory tests and related results that should trigger a report to public health by jurisdiction based on the underlying CSTE position statements and the respective Technical Implementation Guides (TIGs). The vision is to have this repository be accessible in real time by any of the participating systems to review and identify the laboratory data that need to be reported to public health surveillance program in the affected jurisdiction. The RCMT are the underlying concept by which this Ontology would function – linking specific LOINC/SNOMED pairs to the reportable condition.

[29] College of American Pathologists (CAP). An Interactive Guide to Laboratory Software and Instrumentation. Annual Survey of Laboratory Information Systems (LIS). URL: http://www.captodayonline.com/productguides/software-systems/laboratory-information-systems-cap-today-november-2010.html

[30] Centers for Disease Control and Prevention (CDC). Reportable Conditions Mapping Tables Project. URL: http://www.cdc.gov/ehrmeaningfuluse/rcmt.html

## Information Content Standards

***Information Content Standards***[31] define the content of information exchanges. First level information content standards define the structure and content organization of the electronic message/document information content. An example of a first level information content standard is the HL7 Reference Information Model (RIM)[32] - a pictorial representation (an object model) of the clinical data (domains) which identifies the life cycle of events that a message or groups of related messages will carry. It is a shared model between all the domains and as such, is the model from which all domains create their messages. RIMs are information content standards, i.e., shared models of data organization between domains and, as such, are the models from which all domains create information exchange standards.

Second level information content standards define a 'package' of content standards (messages/documents). An example of a second level information content standard is HL7 – Continuity of Care Document (CCD).[33]

## Information Exchange Standards

***Information Exchange Standards***[34] define the structure and syntax of the electronic communication and are referred to as the standard ways of sending and receiving information. There are two information exchange standards: message-based, i.e., information is sent as a message; and document-based, i.e., information is sent as a structured document (form).

There are two types of information standards developed by HL7:

- message-based standard (messaging standard) - HL7 Version 2 and Version 3
- document-based standard – HL7 Version 3.

These two standards are not interchangeable, but work is ongoing to make them more compatible.

**Message-based Information Exchange Standard (Messaging Standard).** ***HL7 Version 2*** **(V2)** message-based standards are used in the United States. This standard enables point-to-point communication via direct interfaces between information senders and receivers, with each partner having a mean of 358 (24 -1000) point-to point interfaces according to the 2010 CAP Survey.[35]

There are multiple versions of the international HL7 V2 standard (also referred to as 2.x) in use, V2.8 being balloted in 2012. These versions are backwards compatible with each other, i.e., a system updated to a newer version is able to exchange data with any previous version. Each version also accommodates multiple message structures, based on the needs for each use case. These versions contain a high level of optionality to accommodate different needs in par-

[31] Public Health Data Standards Consortium (PHDSC). Health IT Standards. Web-Resource Center. Information Content Standards. URL: http://www.phdsc.org/standards/health-information/IC_Standards.asp
[32] Health Level Seven (HL7). HL7 Reference Information Model. URL: http://www.hl7.org/implement/standards/rim.cfm
[33] Hl7 Continuity of Care Document (CCD). URL: http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32
[34] Public Health Data Standards Consortium (PHDSC). Health IT Standards. Web-Resource Center. Information Exchanges Standards. URL:http://www.phdsc.org/standards/health-information/IE_Standards.asp
[35] Same

ticipating countries. In order to use these standards business partners (stakeholders) remove the optionality by creating an Implementation Guide (IG). However, due to the variance among these implementation guides, LIMS supporting one or another HL7 V2.x are not necessarily interoperable.

Data gathered from 56 state and local jurisdictions in 2010 by the National ELR Taskforce[36] and APHL[37] showed that there are multiple versions of HL7 messaging standards in use to send data from the laboratories to public health agencies (HL7 V2.3.x, V2.4 and V2.5.1). The most commonly used messaging standard in PHLs is V2.3.1 **(Table 3)**.

**Table 3.** Use of Information Exchange Standards by PHL LIMS, 2010

| Information Exchange Standards | Number of Respondents (Total of 56 Jurisdictions) | | |
|---|---|---|---|
| | ELR Survey[38] | | APHL- Survey[39] |
| | Send | Receive | |
| HL7 V2.2 | 1 (2%) | 4 (8%) | NA |
| HL7 V2.3.z | 4 (8%) | 25 (44%) | 6 (11%) |
| HL7 V2.3.1 | 25 (44%) | 46 (82%) | 47 (84%) |
| HL7 V2.4 | 2 (4%) | 6 (10%) | 4 (7%) |
| HL7 V2.5 | 7 (12%) | 7 (12%) | NA |
| HL7 V2.5.1 | 12 (22%) | 9 (16%) | 20 (36%) |

Examples of nationally defined HL7 implementation guides for laboratory related data exchange are the *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (ELR251PH-IG)*[40] and the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1- US Realm (LRI251-IG)*.[41]

***HL7 Version 3 (V3)*****,** similar to HL7 V2.x, is an international standard for exchanging data between information systems. The HL7 Reference Information Model is the cornerstone of the HL7 Version 3 development process that was created as part of the Version 3 methodology to explicitly retain the context in which the information exchanged is used. The RIM is essential to increasing precision and reducing implementation costs thus V3 strives to improve the V2 process and its outcomes.

The development principles behind HL7 V3 lead to a more robust, fully specified standard. New capabilities offered in Version 3 include:

- Top-down message development emphasizing reuse across multiple contexts and semantic interoperability
- Representation of complex relationships
- Formalisms for vocabulary support
- Support for large scale integration
- Solving re-use and interoperability across multiple domain contexts

[36] 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011
[37] PHLIP Influenza ELSM - Messaging Capabilities Assessment Survey (and follow up conversations) – APHL March 2011
[38] 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011
[39] PHLIP Influenza ELSM - Messaging Capabilities Assessment Survey (and follow up conversations) – APHL March 2011
[40] https://www.hl7.org/store/index.cfm
[41] http://www.hl7.org/ctl.cfm?action=ballots.home&ballot_cycle_id=524&ballot_voter_id=0

- A uniform set of models and
- Expanded scope to include community medicine, epidemiology, veterinary medicine, clinical genomics, security, etc.[42]
- Document based data exchange (Clinical Document Architecture – CDA)

***Document-based Information Exchange Standard.*** In September 2011 the Federal Advisory Committee Act (FACA) HIT Standards and Policy Committees approved the use one message-based standard - HL7 V2.5.1 - for laboratory, immunization and syndromic surveillance data exchanges for MU Stage 2 while also recommending the use of *HL7 Clinical Document Architecture (CDA) standard* as a future direction for HIT standards adoption in public health.[43] CDA standard was recommended in the proposed rules for MU Stage 2 for cancer reporting.[44]

The HL7 CDA standard is part of the HL7 Version 3 standards family that is derived from the HL7 Reference Information Model to enable semantic consistency across platforms for the purpose of exchange and re-use of clinical data.[45] CDA allows representation of clinical or public health information in a structured format (i.e., CDA templates) that is similar or identical to the paper forms formats. Thus CDA standard closely mirrors traditional paper-based reporting workflows as information is exchanged as documents not strings of words.

The HL7 CDA standard has persistence, stewardship, potential for authentication, wholeness, and is human readable while using RIM structured and controlled vocabulary to ensure semantic interoperability. It is implemented in Extensible Markup Language (XML). A CDA document has a header and a body. The header contains information about the patient, the encounter, and service providers. The body contains clinical content. [46] HL7 is actively working on CDA Release 3.

CDA Release 2 (R2) has become widely used in implementation guides for document sharing such as the Continuity of Care Document, Medical Summary (MS), Emergency Department Referral Document (EDR), and Laboratory Reports. Additionally, CDA R2 document implementation guides have been created for public health use cases such as the Healthcare Associated Infection Report (HAI), Public Health Case Reports (PHCR), and the Immunization Document.

Outside the US a few countries have successfully implemented the HL7 CDA document information exchanges for *Salmonella* and *Shigella* notifiable conditions between sentinel clinical laboratories performing initial microbiology isolations, public health laboratories performing epidemiological typing, federal public health agency, regional epidemiologists analyzing the data and investigating outbreaks, and data managers/analysts dedicated to collaborative sharing of data and regional analysis.[47]

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[42] Health Level Seven (HL7). Frequently Asked Questions (FAQ). URL: http://www.hl7.org/about/FAQs/index.cfm
http://www.hl7.org/ctl.cfm?action=ballots.home&ballot_cycle_id=524&ballot_voter_id=0

[43] Health IT Standards Federal Advisory Committee. Recommendations from the Public HeLth Surveillance Summer Camp. September 28, 2011. URL:
http://healthit.hhs.gov/portal/server.pt?open=512&objID=1817&parentname=CommunityPage&parentid=28&mode=2&in_hi_userid=11673&cached=true#092811

[44] Centers for Medicaid and Medicare Services. proposed rule for Stage 2 requirements for the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs. URL:
https://www.cms.gov/apps/media/press/factsheet.asp?Counter=4286&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date

[45] Health Level Seven (HL7) Clinical Document Architecture (CDA). URL: http://www.hl7.org/implement/standards/cda.cfm

[46] Health Level Seven (HL7). Frequently Asked Questions. URL: http://www.hl7.org/about/FAQs/index.cfm

[47] Renly SR, Knoop SE, Ram R. Show Me Your CDA: Public Health Laboratory Reports. IHIC 2008. URL;
https://wiki.phdsc.org/images/2/29/PHIAD_Case_Study_Submitted.pdf

The HL7 CDA Release 2[48,49] document-based information exchange standard provides benefits over HL7 electronic laboratory messaging. Today LIMSs have highly complex and expensive software for the determination of report copies, report routing, report preferences, report rendering, and report archiving. Once a laboratory has installed a LIMS, one is often confined to the abilities of that system or by the LIMS vendor fees for additional features, e.g., HL7 message interface. The generation of HL7 CDA R2 laboratory reports allows for more flexible management of these laboratory requirements. A report can be generated once, either within a LIMS or by a data import from a CDA generation system. Add-on technologies can then be responsible for the importing, transforming, routing, rendering and auditing functions.[50]

An example of a CDA document (i.e., template, form) building tool is the **Model Driven Health Tool (MDHT) Project**.[51] IBM Research has developed an open source Model-Driven Health Tool – MDHT - that allows the building of CDA templates for clinical documents. MDHT currently supports the Meaningful Use Standard, Healthcare Information Technology Standards Panel (HITSP) Patient Summary Document (C32)[52] and the Consolidated CDA Project.[53] MDHT was successfully used by the used by the Veterans Health Administration (VHA). On November 23, 2011, ONC has announced that this tool will be used by the ONC S&I Framework Initiatives, e.g., the Transitions of Care and the Consolidated CDA initiatives.

No national survey data is available from PHLs on the ability of their LIMS to use CDA for laboratory result reporting today. For LIS the CAP Survey shows that about 30% of LIS vendors can use CDA. [54]

***When should one use messaging and when would the use of documents be more appropriate?***[55] The development of HL7 V3 Messaging as well as CDA-document artifacts is based on the HL7 V3 HL7 Development Framework (HDF) and the Reference Information Model, RIM. HL7 itself hasn't created any recommendation in this area. HIT vendors that have implemented both messages as well as documents mostly respond to the question by focusing on the nature of the use case and looking for a match with the characteristics of either messages or documents:

- Messages are generally used to support an ongoing process in a real-time fashion. They convey status information and updates related to one and the same dynamic business object. Messages are about "control" - they can represent requests that can be accepted or refused by the system and there are clear sets of expectations about what the receiver must do.

[48] Dolin RH, Alschuler L, Boyer S et.al. HL& Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standards; May 2005. Ann Arbor, Mich: Health Level Seven, Inc.
[49] Dolin RH, Alschuler L, Beebe C et.al. Review: The HL7 Clinical Document Architecture. JAMIA. 2001; **8**: 552-569 doi:10.1136/jamia.2001.0080552
[50] Renly SR, Knoop SE, Kaufman JH, Ram R. Creating CDA R2 Laboratory Reports to Meet Public Health Surveillance Requirements: IBM Research Report
[51] Open Health Tools. Model-Driven Health Tool (MDHT). Release 1.0. URL: https://mdht.projects.openhealthtools.org.
[52] Health Information Technology Stabdards Panel (HITSP).Component C32: HITSP Summary Documents Using HL7 Continuity of Care Document (CCD).URL: http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32
[53] Office of National Coordinator of Health IT (ONC. Standards and Interoperability (S&I) Framework. CDA Consolidation Project. URL: http://wiki.siframework.org/CDA+Harmonization+WG
[54] College of American Pathologists (CAP). An Interactive Guide to Laboratory Software and Instrumentation. Annual Survey of Laboratory Information Systems (LIS). URL: http://www.captodayonline.com/productguides/software-systems/laboratory-information-systems-cap-today-november-2010.html
[55] Ringholm White Paper. HL7 version 3: Message or CDA Document? URL:http://www.ringholm.com/docs/04200_en.htm

    - In such situations the latest version of the data is of importance to support an ongoing process, historic versions of one and the same object are generally not of importance apart from regulatory (e.g. auditing) purposes.
    - Messages by and large contain “current” data.
    - The more interactive and tightly coupled your communication process is, the more the use of messages is applicable.
- Documents are persistent in nature, have “static” content and tend to be used “post occurrence”, i.e. once the actual process is done. Documents are about persisting "snapshots" as understood at a particular time.
    - Documents contain data “as it was” when the document was originally created. For documents such as referrals and discharge summaries, it may be more appropriate to see the data as it was understood at the time the referral or summary was constructed rather than viewing the data as it exists now.
    - Documents are "passive". They capture information and allow that information to be shared. Documents can be superseded and corrected, but they are still "static documents" rather than dynamic objects.
    - The more passive and loosely coupled your communication process is, the more the use of documents is applicable.
- Allow for both paradigms to coexist – use a use case driven approach to determine what paradigm forms the better solution for the use case.

## Identifier Standards

***Identifier Standards***[56] provide a universal method to identify entities such as an individual (consumer), a healthcare provider, a healthcare organization, a payer, or others (clearinghouses, vendors, products, etc). Identifiers (IDs) are used extensively in virtually all information processing systems.  Identifiers are the lexical tokens that name entities. The concept is analogous to that of a "name", which is essential for any kind of symbolic processing.

A number of national and international standard identifiers have been adopted in healthcare. In the United States, a National Standard Identifier for Individual and Organization Health Care Providers -- ***National Provider Identifier (NPI)***[57] *,* a unique 10-digit identification number issued to healthcare providers in the United States by the Centers for Medicare and Medicaid Services (CMS) *and a National* ***Employer Identification Number*** *(****EIN****)*[58] have been adopted for use in all electronic administrative and financial transactions, i.e., claims, claim payments, eligibility.for providers engaged in transaction involving

Laboratories that perform diagnostic testing are required to be certified by Clinical Laboratory Improvement Amendments (CLIA) regulation.[59] After successful inspection by CLIA, each laboratory under CLIA regulations is assigned an identifier (***CLIA identifiers***). These Identifiers apply to the entire laboratory organization.

[56] Public Health Data Standards Consortium (PHDSC). Health IT Standards. Web-Resource Center. Identifiers Standards. URL: http://www.phdsc.org/standards/health-information/I_Standards.asp
[57] Center for Medicare and Medicaid Services (CMS) National Provider Identifier, NPI. URL: https://www.cms.gov/NationalProvIdentStand/01_Overview.asp#TopOfPage
[58] Internal Revenue Service (IRS). Employee Identifier Number (EIN). URL; http://www.irs.gov/businesses/small/article/0,,id=98350,00.html
[59] Centers for Medicaid and Medicare Services (CMS). Clinical Laboratory Improvement Amendments (CLIA) regulation. URL: https://www.cms.gov/clia/

***Object Identifiers*** (OIDs) can be used to identify facilities, for example within a laboratory organization. The CDC maintains a database that matches a CDC assigned OID to each CLIA number. The LIMS track providers by identifiers as well as the related organizations those providers work for.

The creation of a national patient identifier standard is still outstanding though many organizations have implemented internal ***Master Patient Index (MPI)*** applications, i.e., the systematic matching and merging of records in information systems to create an accurate, unique health record for each individual.[60]

There are other identifiers for ingredients for drugs and biologics, identifiers for medical devices and durable medical equipment.

***Laboratory Identifiers (order, specimen, patient).*** Within the laboratory every specimen is assigned a specimen ID or accession number. CLIA requires at least two IDs that allow for positive identification of the patient (name, date of birth, patient identifier). Other identifiers are used to track the test order both on the requestor side (placer order number) and on the laboratory side (filler number). The laboratory also tracks any identifier submitted to them by the test requestor (order placer), so that when the results are sent back they can be associated with the correct sample and patient. In order to maintain unique identifiers across all the organizations working with the laboratory, it is a best practice to keep track of who assigned the identifier in question (assigning authority), which in turn can also be done by identifier, like an OID, CLIA number or the NPI.

## Privacy and Security Standards

***Privacy and Security Standards***[61] are intended to ensure information security and confidentiality. ***Information security*** means protecting information and information systems from unauthorized access, use, disclosure, disruption, modification or destruction. Security refers to physical, technological, or administrative safeguards or tools used to protect identifiable health information from unwarranted access or disclosure. Security is the set of actions an organization takes to protect that information. ***Confidentiality*** has been defined by the International Organization for Standardization (ISO) as "ensuring that information is accessible only to those authorized to have access" and is one of the cornerstones of information security. Confidentiality is one of the design goals for many cryptosystems, made possible in practice by the techniques of modern cryptography.

In 1996, the Department of Health and Human Services enacted the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Provisions[62] to reduce the cost and administrative burdens of health care by allowing standardized, electronic transmission of administrative and financial transactions. HIPAA also introduced the first comprehensive federal privacy and security rules and guidelines to support and enable data and transaction standardization and exchange.

[60] Public Health Informatics Institute. The Unique Records Portfolio. URL: http://phii.org/resources/UniqueRecordsPortfolio.asp
[61] Public Health Data Standards Consortium (PHDSC). Health IT Standards. Web-Resource Center. Privacy and Security Standards. URL: http://www.phdsc.org/standards/health-information/PS_Standards.asp
[62] Department of Health and Human Services (DHHS). Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Provisions. URL: http://www.hhs.gov/ocr/privacy/

There are a number of security and privacy standards that can support public health laboratory data exchanges. These standards enable transport security, identification of persons and systems, privilege management and access controls, audit, policy agreements, and pseudonymization. These standards are generic and must be support by any systems participating in electronic health information exchanges, so they are viewed as the information technology infrastructure (ITI) standards.

**Integrating the Healthcare Enterprise (IHE)**[63] is a multi-year initiative under the leadership of Health Information Management & Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE began in November 1998 as a collaborative effort to improve the way computer systems in healthcare share clinical information. IHE Technical Committees develop ***Integration Profiles*** and ***Content Profiles*** to assure that health information passes seamlessly from application to application, system to system, and setting to setting — across the entire healthcare enterprise.

***IHE Technical Frameworks***, the volumes in which IHE profiles are published, are annually expanded and continuously maintained by the IHE Technical Committees in 13 domains. Each domain is sponsored and overseen by organizations representing healthcare providers and HIT stakeholders in the domain. IHE domains include Anatomic Pathology; Cardiology; IT Infrastructure; Laboratory; Patient Care Coordination; Patient Care Device; Quality, Research and Public Health; Radiology; Eye Care; Radiation Oncology; and newly established Dental; Endoscopy; and Pharmacy domains.

IHE profiles provide precise implementation specifications (implementation guides) based on established standards to address specific HIT interoperability issues. They detail required actions for HIT systems to acquire, manage and communicate medical information effectively, while supporting efficient provider workflows and protecting private health information.

IHE profiles have provided the foundation for health information exchange networks in the US and worldwide. **IHE IT Infrastructure (ITI) Technical Framework**[64] contains a number of IT infrastructure Integration Profiles that specify interoperability standards for information security infrastructure such as patient identity resolution, pseudonymization and others. **Appendix 2** provides detail description of these standards.

## Functional Standards

***Functional Standards***[65] describe, in an organized format, the participants (people and information systems), required functions & features and operational capabilities needed in a Software Application as defined by a qualified group of users (domain experts/stakeholders). ***Functional requirements*** are derived from the description of user's business activities ***(business requirements)***. ***Business requirements*** are aimed to explain why a Software Application is needed. ***Functional standard*** describes what a Software Application must do, i.e. ***functional requirements***, by translating ***Business Requirements*** into the following five functional categories:

1. ***Collect/Input Data***, i.e. get data into the Software Application

[63] Integrating the Healthcare Enterprise (IHE). URL: http://www.ihe.net
[64] Integrating the Healthcare Enterprise Information Technology Infrastructure Technical Framework. URL: http://www.ihe.net/Technical_Framework/index.cfm#IT
[65] Public Health Data Standards Consortium (PHDSC). Health IT Standards. Web-Resource Center. Functional Standards. URL: http://www.phdsc.org/standards/health-information/F_Standards.asp

2. ***Manage Data***, i.e. receive data, verify data, store data, send data
3. ***Analyze Data***, i.e. group data by similar attributes (location, condition, etc.)
4. ***Integrate Data***, i.e. receive data from more that one data system/source
5. ***Generate Output***, i.e. reports, summaries, alerts, notifications, etc.

For example, patient's visit to a doctor ***(business activity)*** creates encounter data that the doctor will record/enter ***(collect data)*** in the Electronic Health Record System (EHR-S). This data entry has to be checked for quality assurance and added into the patient's medical record in the EHR-S ***(manage data)***. This encounter data can be compared with the previous encounters' data on this patient or with other patients' data ***(analyze data)***. This encounter data may include medication prescription to be sent to a Pharmacy information system ***(integrate data)***. This encounter data may be given to a patient as a visit's summary or has to be reported to a Public Health Agency ***(generate output)***.

***Functional requirements*** are written by users (stakeholders) in a non-technical language in an organized format of the ***Functional Requirements Analysis Document (FRAD)***.[66,67] FRAD is used in software engineering to summarize the user's functional requirements for a Software Application.

The Functional Requirements Analysis Document includes the following components:

1. ***Problem-Solution*** - description of the Problem; the business activity and health information exchange needs related to this activity, that the software application will help to address
2. ***Goal*** - goal of the software application
3. ***Actors*** - business actors (stakeholders) and technical actors (information systems, i.e. data sources) that will interact with the software application
4. ***Functional Requirements*** - actions that the software application will support
5. ***Non-Functional Requirements*** – descriptors of the software application operation, e.g., privacy and security requirements, periodicity of data exchanges and others
6. ***Use Case Description*** - a real clinical or public health scenario that describes the use of the software application in the context of business actors' work processes
7. ***Unified Modeling Language (UML)[68] Diagrams*** that depict actors and actions interactions in the context of the software application, i.e., Use Case Diagram and Workflow and Dataflow Diagram
8. ***High-Level Architecture*** of the software application
9. ***Hardware and Software Requirements*** of the software application
9. ***Evaluation*** of the software application development
10. ***Timeline*** for the software application development

A ***Functional Standard*** is a vehicle to assure that the work processes of users related to a particular business activity, i.e., patient care management, public health surveillance, etc., that involve electronic data exchanges are well understood and agreed upon first by users themselves and then communicated clearly to the developers as functional requirements for a Software Ap-

[66] Public Health Data Standards Consortium (PHDSC). Towards Functional Standards on Electronic Data Exchanges between Clinical Care and Public Health. Report to the Health Resources and Services Administration (HRSA). 2007. URL: http://www.phdsc.org/about/pdfs/PHDSC-HRSA%20Panel%20-%20December%205-6%202006%20-%20Final%20Report.pdf
[67] Bruegge B. and Dutoit A.H. Object-Oriented Software Engineering. Pearson Prentice Hall. Upper Saddle River, NJ. 2nd Edition. 1-172.
[68] Grady Booch, Ivar Jacobson & Jim Rumbaugh (2000) OMG Unified Modeling Language Specification[dead link], Version 1.3 First Edition: March 2000. Retrieved 12 August 2008.

plication. To ensure semantic interoperability those functional requirements need to be well described and implemented in all systems participating in data exchange. Sections that follow provide examples of projects aimed to define functional standards for PHLs.

**Public Health Collaborative Business Requirements Project**[69] was one of the first comprehensive assessments of the information needs of the PHL community. APHL and the Public Health Informatics Institute (PHII) worked with a number of PHLs to define core business processes relevant to the function and management of PHLs. Specifically, a detailed inventory of the 16 business processes of a typical PHL was developed such as:

1. Laboratory Test Processing (Clinical and Environmental), i.e. Receive/Process Test Orders
2. Test Scheduling
3. Proactive Specimen/Sample Collection (Pre-Scheduled Tests)
4. Specimen and Sample Tracking/Chain of Custody
5. Media, Reagent, Stains, Control, etc. Manufacturing
6. Inventory Control Including Kits & Forms Management
7. General Laboratory Reporting, *i.e., Report Test Results*
8. Statistical Analysis and Surveillance
9. Billing for Laboratory Services
10. Contract and Grant Management
11. Training, Education and Resources Management
12. Laboratory Certification/Licensing
13. Customer Concerns/Suggestions
14. Quality Control and Quality Assurance Management
15. Laboratory Safety and Accident Investigation
16. Laboratory Mutual Assistance/Disaster Recovery

This assessment documented laboratory workflow for each business process, information system involved, data requirements, and interdependencies across business processes. From the list above only Business Processes 1 and 7 (Orders/Results) require interoperability, therefore, the focus of this White Paper is on the following business processes:

- Business Process 1 (Tests Orders) requires interoperability between senders (e.g., EHR-S, HIE, and other LIMS) and receivers (e.g., PHL LIMS, PH-IS)

- Business Process 7 (Test Results) requires interoperability between senders, e.g., PHL LIMS and receivers (e.g., EHR-S, HIE, other LIMS).

**HL7 Public Health Reporting Requirements Standard**[70] is a new standard to extend the HL7 Healthcare Quality Measure Framework (HQMF) standard, originally defined to support the specification of quality measures (eMeasures), to also support the expression of public health reporting requirements. As a structured document specification, this will allow for both a human readable expression as well as a machine-readable expression of the jurisdiction-specific reporting requirements. This standard will support the capability of a system to consume the requirements, and process those requirements against CDA-expressed content to determine

[69] Association of Public Health Laboratories and Public Health Informatics Institute. Requirements for public health laboratory information management systems: a collaboration of state public health laboratories, Washington: APHL; 2003.
[70] Public Health Data Standards Consortium (PHDSC). HL7 Public Health Reporting Requirements Standard. URL: https://wiki.phdsc.org/index.php/PH-Lab

whether a report should be made to public health, what to report, to whom to send the report, how to report, and when to report.

In order to facilitate better interoperability between EHR-S and PHL LIMS the **HL7 Public Health Functional Profile (PHFP),** [71] a joint project of the PHDSC, CDC National Center for Health Statistics (NCHS) and the public health community at large is being updated requirements for data exchange with PHLs. The PHFP conforms to the HL7 Electronic Health Record System Functional Model (EHR-S FM) Release 1.1 and identifies functional requirements and conformance criteria for public health-clinical information collection, management and exchanges. The PHFP contains a core or common set of functional requirements identified across public health domains as well as specific functional requirements for these domains. The PHFP-Phase 1, successfully balloted in May 2011, is limited to specifying functional requirements in three public health domains:

- Early Hearing Detection and Intervention,
- Vital Records and
- Cancer.

In PHFP-Phase 2 will be balloted in spring 2012. It includes the following new public health domains:

- Public Health Laboratory,
- Birth Defects
- National Surveys
- Occupational Health and Safety
- Deep Venous Thrombosis and Pulmonary Embolism (DVT/PE)

The PHFP will be used as a reference for certification of EHR systems that include functionality to support public health domains (programs). Specifically, this profile will be used for developing certification criteria for EHR-S to support information exchanges for the EHDI and PH-Lab domains.

The **Integrating the Healthcare Enterprise Laboratory Technical Framework**[72] includes interoperability standards specifications (profiles) addressing workflow and information sharing involving laboratories and their supporting systems (**Table 4**):

**Table 4**. IHE Lab Technical Framework Profiles

| # | Profile Name |
|---|---|
| 1 | Laboratory Testing Workflow (LTW) |
| 2 | Laboratory Device Automation (LDA) |
| 3 | Laboratory Point Of Care Testing (LPOCT) |
| 4 | Laboratory Code Set Distribution (LCSD) |
| 5 | Laboratory Specimen Barcode Labeling (LBL) |
| 6 | Sharing Laboratory Reports (XD-LAB) |

[71] Public Health Data Standards Consortium (PHDSC).Public Health Functional Profile Project. HL7 Public Health Functional Profile. Overview Chapter. 2011. URL: https://wiki.phdsc.org/index.php/EHR-PH_APY3
[72] Integrating the Healthcare Enterprise Laboratory Technical Framework. URL: http://www.ihe.net/Technical_Framework/index.cfm#laboratory

The ***laboratory workflow*** transactions related to the exchange and sharing of ***laboratory test orders and results*** support not only the clinical workflow, but can be leveraged to support public health laboratory data exchanges and reporting.

A work in progress, the **IHE Public Health Reporting Integration Profile**[73] describes the use of IHE profiles to support patient- and population-level public health case reporting based on the HL7 Public Health Reporting Requirements Standard to automate the decision processing for triggering a report to public health. Laboratory reporting is one of multiple public health reporting use cases addressed by this profile. The profile uses examples of five notifiable conditions (*Anthrax*, *Tularemia*, *Hepatitis B (hep-B)*, *Tuberculosis (TB)* and *Influenza*).

This profile also defines a high-level framework for harmonization of business areas, business processes and functional requirements for information systems across various public health domains/programs, e.g. communicable diseases, chronic diseases, maternal and child health, health statistics, environmental health and others.

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This profile also defines a high-level framework for harmonization of business areas, business processes and functional requirements for information systems across various public health domains/programs, e.g. communicable diseases, chronic diseases, maternal and child health, health statistics, environmental health and others.

## Other Standards: Transport Mechanisms as Standards

**IHE IT Infrastructure (ITI) Technical Framework**,[75] in addition to the privacy and security standards described above, also defines other IT infrastructure interoperability standards for health information exchanges including those for public health. For laboratory data exchanges, the IHE ITI Integration Profiles specify interoperability standards for (a) a document sharing infrastructure (cross-document sharing (XDS), (b) form management (i.e., pre-populate electronic forms (retrieve form for data capture (RFD) for reporting); (c) a cross-enterprise document workflow (XDW) which defines the status of the workflow events (steps) by tracking the documents generated by those events; and others. **Table 5** lists examples of IHE IT Infrastructure profiles that support laboratory data exchanges.

[73] Public Health Data Standards Consortium (PHDSC). IHE Public Health Reporting Integration Profile. URL: https://wiki.phdsc.org/index.php/PH-Lab
[74] Public Health Data Standards Consortium (PHDSC). IHE Public Health Reporting Integration Profile. URL: https://wiki.phdsc.org/index.php/PH-Lab
[75] Integrating the Healthcare Enterprise Information Technology Infrastructure Technical Framework. URL: http://www.ihe.net/Technical_Framework/index.cfm#IT

**Table 5.** Examples of IHE IT Infrastructure Profiles for Laboratory Data Exchanges

| # | Profile Name |
|---|---|
| 1 | Basic Patient Privacy Consents (BPPC) |
| 2 | Cross-Enterprise Document Sharing (XDS) |
| 3 | Cross-Enterprise Document Reliable Interchange (XDR) |
| 4 | Cross-Enterprise Document Media Interchange (XDM) |
| 5 | Cross-enterprise Sharing of Scanned Documents (XDS-SD) |
| 6 | Document Metadata Subscription (DSUB) |
| 7 | Document-based Referral Request (DRR) |
| 8 | Document Digital Signature (DSG) |
| 9 | Sharing Value Sets (SVS) |
| 10 | Notification of Document Availability (NAV) |
| 11 | Patient Demographics Query (PDQ) |
| 12 | Patient Identifier Cross Reference Manager (PIX) |
| 13 | Patient Administration Message (PAM) |
| 14 | Retrieve Form for Data Capture (RFD) |
| 15 | Retrieve Process for Execution (RPE) |

**Table 6** lists IHE profiles that define interoperability standards for test order/results workflow for the two public health conditions: *Anthrax* (public health preparedness) and *Influenza* (public health surveillance).

**Table 6**. Examples of the IHE Interoperability Standards for Patient-level Information Exchanges in PH-Lab Domains by Business Processes and Activities (Tasks)

| Business Processes / Activities (Tasks) | PH-Lab Domain | | Examples of IHE Interoperability Standards[76] |
|---|---|---|---|
| | Preparedness Reporting (*Anthrax*) | Public Health Surveillance (*Influenza*) | |
| Order test | **Input**:<br>Consent (or by statute)<br>**Output**:<br>Test order | **Input**:<br>Consent (or by statute)<br>**Output**:<br>Test order | BPPC<br>IHE-LAB TF |
| Conduct test | **Input**:<br>Test order<br>**Output**:<br>Test results | **Input**:<br>Test order<br>**Output**:<br>Test results | IHE-LAB TF (XD-Lab)<br>IHE ITI TF<br>(RFD/XDR/DSUB, NAV) |
| Interpret and report test results meeting reporting criteria | **Input**:<br>Test results; Public Health Reporting Requirements<br>**Output**:<br>Flags on abnormal results; Public Health Report | **Input**:<br>Test results; Public Health Reporting Requirements<br>**Output**:<br>Flags on abnormal results; Public Health Report | IHE ITI TF (RFD/RPE/ XDS/MPQ, DSUB, NAV)<br>IHE-LAB TF<br>IHE PH Reporting Profile<br>&<br>HL7 Public Health Reporting Requirements |

[76] Integrating the Healthcare Enterprise (IHE). URL: http://www.ihe.net

The **CDC's Public Health Information Network Messaging System (PHIN MS)**[77] is a software installed locally at each data exchange partner. The system securely sends and receives encrypted data over the Internet using Electronic Business Extensible Markup Language (ebXML) technology. PHIN MS enables the exchange of format agnostic data (text or binary file formats like .doc, .xls, .zip, .txt. .jpeg, .gif, etc as well as HL7 messages) a common approach to security and encryption, methods for dealing with a variety of firewalls, and Internet protection schemes. PHIN MS provides a standard way for addressing and routing content and exchanging transport level confirmations. PHIN MS supports the use of Route-not-Read (RnR) hubs.

The **Nationwide Health Information Network (NwHIN)**[78] is the national initiative that defines standards, services and policies that enable secure health information exchange across diverse entities, within communities and across the country. A group of federal agencies, local, regional and state-level Health Information Exchange Organizations (HIEs) and integrated delivery networks, formerly known as the NHIN Cooperative, has been helping to develop the network services and policies for information sharing. The participating entities include

- Centers for Disease Control and Prevention contracts to receive biosurveillance data
- Social Security Administration
- ONC - Beacon Communities and
- ONC - State HIE Cooperative Agreements.

The **Direct Project**,[79] launched in March 2010, is defining standards and services required to enable secure, directed health information exchange among trusted providers via internet in support of Stage 1 Meaningful Use of Health IT incentive requirements (e.g., a primary care provider sending a referral or care summary to a local specialist electronically, or a physician requesting lab tests electronically).[80]

The Direct Project has identified the use of Simple Mail Transfer Protocol (SMTP) as its primary mechanism for delivering healthcare content from a sender to a receiver.[81] The SMPT is an internet standard for e-mail transmission across Internet Protocol (IP) networks. Participants in exchange are identified using standard e-mail addresses associated with X.509 certificates. The data is packaged using standard Multipurpose Internet Mail Extensions (MIME) content types. S/MIME (Secure/Multipurpose Internet Mail Extensions) is a standard for public key encryption and signing of MIME data. S/MIME functionality is built into the majority of modern email software and interoperates between them.

Authentication and privacy are obtained by using Cryptographic Message Syntax (S/MIME), and confirmation delivery is accomplished using encrypted and signed Message Disposition Notification. Optionally, certificate discovery of endpoints is accomplished through the use of the DNS (Domain Name System) -- a hierarchical distributed naming system for computers, services, or any resource connected to the Internet or a private network.

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[77] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN).PHIN Messaging System. (PHIN MS). URL: http://www.cdc.gov/phin/tools/PHINms/index.html
[78] Nationwide Health Information Network. URL: http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__nationwide_health_information_network/1142
[79] Office of National Coordinator for Health IT (ONC). Project Direct. URL: http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__direct_project/3338
[80] Meaningful Use Stage 1 Final Rule; Federal Registrar. URL: http://edocket.access.gpo.gov/2010/pdf/E9-31217.pdf
[81] Office of National Coordinator for Health IT (ONC). Project Direct. Specifications for Secure Health Transport. URL: http://wiki.directproject.org/Specifications+and+Service+Descriptions

The Direct Project' SMTP choice supports the environments which have minimal capabilities in terms of using Web Services and generating detailed metadata. In the healthcare ecosystem there are several existing environments which have adopted the use of Simple Object Access Protocol (SOAP)-based Web Services and detailed metadata. These environments have adopted a family of IHE profiles, each applied to a different type of use case, which have a common metadata model and make use of Web Services in a common way.

The most applicable IHE Information Technology Infrastructure Profiles to the Direct Project environment are:

- IHE Cross-Document Repository (XDR) Integration Profile which supports a direct push model from sender to receiver using Web Services transport
- IHE Cross-Enterprise Document Media Interchange (XDM) Integration Profile which supports a direct push model of a package of content where one of several optional transports is via SMTP.

On February 2, 2011 ONC announced that providers and public health agencies in Minnesota and Rhode Island began exchanging health information using specifications developed by the Direct Project. Other Direct Project pilot programs will be launched soon in New York, Connecticut, Tennessee, Texas, Oklahoma and California to demonstrate the effectiveness of the streamlined Direct Project approach, which supports information exchange for core elements of patient care and public health reporting.

**CONNECT**[82] is a free, open source software solution that supports health information exchange – both locally and at the national level. CONNECT uses Nationwide Health Information Network standards, services, and policies to make sure that health information exchanges are compatible with other exchanges being set up throughout the country. CONNECT is the result of collaboration among federal agencies that is coordinated through the Federal Health Architecture program under ONC. This software solution, initially developed by federal agencies to support their health-related missions, is available for free to all organizations to help set up health information exchanges and share data using nationally recognized interoperability standards.

[82] Office of National Coordinator for Health IT (ONC). CONNECT. URL: http://www.connectopensource.org/

# Section 3 Public Health Laboratories and Health IT

## Public Health Laboratory Community-Based Initiatives

To work towards establishing electronic communications between PHL partners and their information systems, the PHL community has been working on several electronic data exchange initiatives. We have divided these initiatives into two categories:

- Public Health Laboratory Community Initiatives and
- National Initiatives.

The following sections provide examples of these initiatives related to standardization of laboratory data exchanges in addition to those mentioned under the related standards categories above.

**Public Health Laboratories Interoperability Project (PHLIP)**.[83] In 2006, APHL and CDC collaborated on a, PHLIP initiative to support automated electronic data exchange between PHLs, CDC, and regional partners. PHLIP technical work on standards is conducted by the PHLIP Vocabulary & Messaging Workgroup. The goals of PHLIP include, but are not limited to: improving the quality of interoperable data; piloting sustainable architecture for laboratory data exchange; sending test results from states to CDC programs using HL7 V2.3.1 message standards; increasing the use of Route-not-Read hubs for regional data exchange; and expanding these efforts beyond National Notifiable Diseases (NNDs). The initial prototype of the PHLIP electronic laboratory surveillance message (ELSM) for Influenza has been successfully implemented in over half of the World Health Organization (WHO) collaborating laboratories participating nationwide. What made the deployment of PHLIP so effective was the approach of using Technical Assistance Teams (TATs).

Another PHLIP initiative, the electronic order and test result (ETOR) message, is piloting HL7 V2.6 message with 3 PHLs sending harmonized Salmonella reference test orders to CDC and receiving related results back. Additionally, efforts have been made to prepare for Influenza surge capacity situations between several PHLs. Future directions include continued efforts by the TATs, capturing sentinel provider data, results of resistance testing and implementation of the HL7 V2.5.1 ELR constrainable profile for ELSM. PHLIP is also a founding member of the Laboratory Messaging Community of Practice (LabMCoP).[84] **Table 7** summarizes PHLIP key products and services.

[83] Zarcone P, Nordenberg D, Meigs M, Merrick U, Jernigan D, Hinrichs SH. Community-Driven Standards-Based Electronic Laboratory Data-Sharing Networks. Public Health Reports. 2010. Suppl 2; Vol. 125: 47-56. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846802/

[84] http://www.phconnect.org/group/laboratorymessagingcommunityofpractice

**Table 7**. PHLIP: Key Products and Services

| # | Product/Service | Purpose |
|---|---|---|
| 1 | Management of an innovative community that leverages laboratorians, technical experts, informaticians, and public health experts | Advance standards-based electronic data sharing for public health |
| 2 | Support for a PHL's selection, implementation, and management of an internal electronic data management capability (e.g., LIMS) | Advance standards-based electronic data sharing for public health |
| 3 | Development of use cases and workflows for each of the nationally notifiable diseases | Advance standards-based electronic data sharing for public health |
| 4 | Development of vocabulary coding schema and messaging | Support use cases and workflows (PHLIP creates mapping workbooks and encoding guidelines to document the data-exchange schema) |
| 5 | Provision of a forum and working groups | Support PHLs in their implementation of data exchange standards |
| 6 | Validation of data-exchange capabilities | Identify any issues with the data and initiate performance improvement activities, if necessary |
| 7 | Provision of a forum between states and CDC to determine opportunities and methodologies | Enable the emerging data-sharing network to improve the performance of public health programs and their outcomes (e.g., food safety, water safety, and influenza) |
| 8 | Leverage of an open-innovation network to accelerate progress in scientific discovery, technology adoption, and healthcare transformation | Advance standards-based electronic data sharing for public health |

In terms of interoperability, PHLIP is focused on the lab data information exchanges as follows (**Figure 1**):

- PHL LIMS (sender) communicates with other laboratories LIMSs (receiver) for surge capacity, continuity of operations and access to analytic capability lacking at one's own laboratory

- Clinical EHR-S and HIEs (sender/receiver) communicate with PHL LIMS (receiver/sender) for test order and result communication and

- PHL LIMS (sender) with CDC PH-IS (receiver) for epidemiological services.

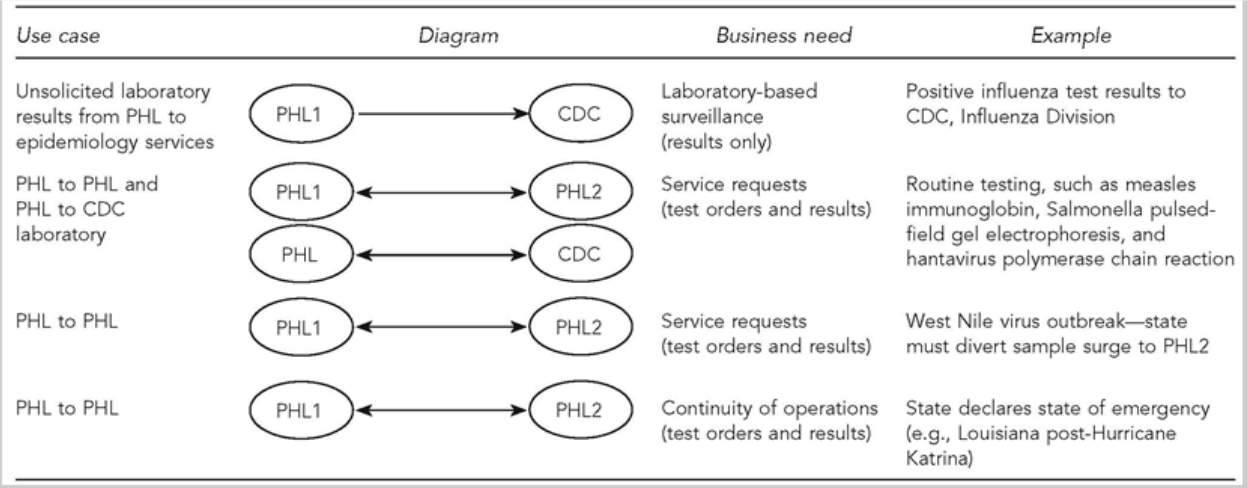


**Figure 1.** Public Health Laboratories: Data Exchange Scenarios (Use Cases) [85]

The **Public Health Laboratory Interoperability Solutions and Solution Architecture (PHLISSA)**[86] project is aimed at building PHL capacities for electronic exchange of laboratory orders and results – ETOR - with the similar stakeholders as in the PHLIP project (PHL - clinicians, PHL – PHL, and PHL- public health agencies) as mandated by American Recovery and Reinvestment Act (ARRA).[87] PHLISSA is focused on architecture, interoperability hub, and Enterprise Service Bus (ESB).

For data content, PHLISSA is focused on Salmonella (limited to human isolates only) scenario. The information exchange involves state PHLs who participated in PHLIP and the National Salmonella Reference Laboratory at the CDC Office of Infectious Diseases (OID). PHLISSA Hub is envisioned to serve as an HIE information management system with the data routing services (PHIN-Messaging System (MS) Gateway and Nationwide Health Information Network (NwHIN) Connect Gateway); metadata repository and document repository services; and data analytics services.

**Table 8** describes use cases included in PHLISSA. Please note that PHLISSA project uses the Test Order Placer/Order Filler terms to define senders and receivers of laboratory data. These terms were originally introduced in the IHE Laboratory Technical Framework documentation for interoperability standards.[88]

[85] Zarcone P, Nordenberg D, Meigs M, Merrick U, Jernigan D, Hinrichs SH. Community-Driven Standards-Based Electronic Laboratory Data-Sharing Networks. Public Health Reports. 2010. Suppl 2; Vol. 125: 47-56. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846802/

[86] Centers for Disease Control and Prevention (CDC).Public Health Laboratory Interoperability Solutions and Solution Architecture (PHLISSA). Scope Document. Version 4.2. OCTOBER 14, 2010

[87] American Recovery and Reinvestment Act (ARRA). URL: The American Recovery and Reinvestment Act. 2009. URL: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1enr.pdf.

[88] Integrating the Healthcare Enterprise (IHE). Laboratory Technical Framework. URL: http://www.ihe.net/Technical_Framework/index.cfm#laboratory

**Table 8**. PHLISSA Use Cases

| # | Use Case Name | Use Case Description |
|---|---|---|
| 1 | Electronic Test Order and Result (ETOR) | • PHL sends Laboratory Test Order to CDC Office of Infectious Diseases (OID) Laboratory<br>• CDC sends Laboratory Order Responses (acknowledgement, reject, etc.)<br>• CDC sends Laboratory Test Result to PHL |
| 2 | Report Notifiable Conditions | • Reportable laboratory findings (ELR) from<br>o Hospital EHR-S to a State/Local/Territorial Public Health Department (supports meaningful use). PHLISSA Hub will send a notification to sender (Clinical Care stakeholder or PHL)<br>o Clinical laboratory to a State/Local/Territorial Public Health Department<br>o PHL to a State/Local/Territorial Public Health Department<br>• Public Health Case Report from Clinical Care Stakeholder to a State/Local/Territorial Public Health Agency. PHLISSA Hub will send a notification to sender (Clinical Care stakeholder) |
| 3 | Register Healthcare Document with the Hub Document Registry for future retrieval | • Laboratory Results<br>• Public Health Case Report |
| 4 | Request and retrieve healthcare document from a Hub healthcare document registry | • Query the document registry for a list of available healthcare documents<br>o PHL to Hub registry<br>o CDC to Hub registry<br>o State Public Health Department to Hub registry<br>o Clinical Care stakeholder to Hub registry<br>• Retrieve specific healthcare documents document repository and return to requestor<br>o PHL document repository<br>o State/Local/Territorial Public Health Agency document repository<br>o Clinical care stakeholder document repository |
| 5 | PHL to PHL Test Order and Result | • PHL Order Placer sends Laboratory Test Order to PHL Order Filler<br>• PHL Order Filler sends order responses (acknowledgement, reject, etc.)<br>• PHL Order Filler sends Test Result to PHL Order Placer |
| 6 | EHR/EMR to PHL Lab Test Order and Result | • Clinical stakeholder Order Placer (EHR-S) sends Laboratory Test Order to PHL Order Filler<br>• PHL Order Filler sends order responses (acknowledgement, reject, etc.) to the Order Placer.<br>• PHL Order Filler sends Test Result to Clinical stakeholder Order Placer (EHR-S) |
| 7 | Optional: Send unsolicited Lab Test Results | • PHL to a CDC OID laboratory<br>• PHL to a Clinical stakeholder<br>(*Note: This is an optional Use Case)* |

**Laboratory Technical Implementation Assistance for Public Health (LTIAPH)**. In 2010, APHL received a Health Information Technology for Economic and Clinical Health (HITECH) grant to advance public health laboratory capacity to share laboratory orders and results electronically with clinical care and public health agencies in order to achieve Meaningful Use objectives. This project, The Laboratory Technical Implementation Assistance for Public Health (LTIAPH), provides guidance and technical assistance to state/territorial/large local public health laboratories and health departments to enhance critical IT infrastructure to support interoperabil-

ity of electronic laboratory data between clinical care (through EHRs) and public health agencies. LTIAPH works to identify data exchange strategies and feasible models of technical assistance that will build the framework for the interoperability of EHRs and public health to support meaningful use of lab data.

LTIAPH is working to define a common set of requirements for LIMS Minimum Data Elements, a Laboratory Reference Model and a Surveillance Data Reference Model, utilizing the HL7 Version 2.5.1 Implementation Guide for Electronic Laboratory Reporting to Public Health. LTIAPH also seeks to collect and harmonize terminology requirements across ELR, Lab-to-Lab and EHR data exchanges, in conjunction with all stakeholders (PHL, Public Health Agency and clinical care affiliates), and to document the minimum terminology requirements for a LIMS and/or broker infrastructure in a client PHL. LTIAPH is also collaborating with its sister grant the Laboratory Interoperability Cooperative (LIC), described below

Guiding Principles:

- Prioritize data flows that are relevant to Meaningful Use: Reportable Laboratory Results objective
- Assure that investments in one use case should carry over to many public health use cases
- Pilot successful working models of a use case prior to recommending for broader adoption
- Assure that implementation assistance is sensitive to current/existing systems
- Evaluate and enhance existing capacity to enable scalable architecture that can adapt to future opportunities
- Select technologies that leverage interoperability within public health organizations
- Focus on high-impact and/or high volume transactions

Approach:

- Offer menu-of-services that are grouped into general and targeted categories.
- Balance level-of-effort between providing and developing a common framework and reuseable components and one-on-one assistance
- Promote adherence to interoperability standards in areas like laboratory processes, vocabulary and information technology
- Engage with the Epidemiology & Laboratory Capacities for Infectious Diseases (ELC) grantees and develop scope-of-work based on their respective CDC approved Operational plans
- Collaborate with other ELR efforts
- Compile and share knowledge across grantees via different mechanisms
- Leverage APHL's efforts across the public health space to bring in expertise that can accelerate and enhance the solution, while contributing back from the project from a long-term interoperability strategy
- Collaborate within a pre-defined operational framework with other companion ARRA-HITECH grants.

The **Laboratory Response Network (LRN)**[89] is a coordinated network of public health and other laboratories for which CDC provides standard assays and protocols for testing biological and chemical terrorism agents. LRN Results Messenger (LRN RM) was created to provide LRN laboratories with the ability to manage and share standard laboratory results data securely with public health partners. LRN RM represents the first step in an incremental approach to providing full standards-based electronic data exchange for this vital laboratory network. \

The **LIMS Integration (LIMSi)**[90] project is a parallel effort to LRN RM. It represents the next generation of the incremental approach to data exchange for the LRN. Its purpose is to enable laboratories to fulfill data exchange needs for the LRN using their own systems. LIMSi is currently facilitating collaborative efforts between CDC and public health laboratory subject matter experts to refine system requirements needed to configure LIMS to manage LRN testing. The LIMSi project is also creating a constrained version of the PHIN Laboratory Generic message guide that specifically targets the messaging and data mapping needs for the LRN.

**LUNA and CDC STARLiMS**[91] work together to improve communication between CDC and its Public Health Partners. Laboratory User Network Application (LUNA) is a free, secure, user-friendly, web-based interface that requires only an internet connection and an Secure Data Network (SDN) Digital Certificate to allow state and local agencies to communicate electronic test requests to the CDC. With the integration with CDC STARLiMS, these requests are automatically loaded into CDC STARLiMS and then released to the submitter, eliminating the need for mailing a paper version of the request and subsequently manually entering the data into CDC STARLiMS – a process more apt to produce errors and delays than this automated system. The electronic test requests then follow today's standard testing and reporting procedures.

LUNA provides the means of uniquely identifying a specimen to make tracking the order and subsequent results an efficient process. At any time, the CDC and its partners can determine where the shipment is in transit, when it has been received, and once testing is complete, the results are immediately available to the partners as a Portable Document Format (PDF) file attached to the specimen record in LUNA. Having these electronic records has the additional benefit of providing the state laboratories and the CDC with an easily maintained and accessible record of each test.

LUNA, CDC STARLiMS, and Central Receiving (STAT) at the CDC Office of Infectious Diseases have been piloting the integration in the National Salmonella Reference Laboratory. The participating states sent requests for testing via LUNA. STAT will verify each test request, when the specimen is received. Upon verification, the request will go to the National Salmonella Reference Laboratory for testing.

To further enhance the efficiency of this process, LUNA provides a notification feature that sends email notifications and updates throughout the submission and testing process, ensuring that the organizations are informed of the status and progress of each specimen shipment. This

[89] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN). Laboratory Referene Network (LRN)Results Messenger and LIMS Integration. URL:http://www.cdc.gov/phin/tools/lrn/index.htm
[90] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN). Laboratory Referene Network (LRN)Results Messenger and LIMS Integration. URL:http://www.cdc.gov/phin/tools/lrn/index.htm
[91] LUNA and STARLiMS Integration. URL: http://www.cdc.gov/phin/tools/luna/index.html

feature is individually configurable, allowing each organization to choose the level of detail its personnel should receive during the course of the testing process.

The **CDC Electronic Laboratory Reporting (ELR) Task Force**[92] is a collaborative effort between the CDC, APHL and CSTE to promote the implementation of ELR.

The ELR Vision is that all labs (public and private) conducting clinical testing identify laboratory results that indicate a potential reportable condition for one of the jurisdictions they serve, format the information in a standard manner, and transmit appropriate messages to the responsible jurisdiction; all jurisdictions can and do receive and utilize the data.

The Task Force was formed in the spring of 2010 and its steering committee identified five high-level priorities and created five working groups (**Table 8**):

- Develop a strategic plan for coordination between states, CDC and ONC
- Develop, evaluate and endorse standards to reduce variation in what is required for ELR across the nation
- Collaborate with APHL to compare and assure that PHLIP messages (formats, vocabulary, and transmission) and National Electronic Disease Surveillance System (NEDSS) messages are consistent and compatible to leverage the laboratory message infrastructure to communicate with clinicians, CDC, or state/local surveillance systems
- Document legal considerations for electronic laboratory reporting and make available for other states to consider and
- Articulate the resources needed to implement state/local ELR through a needs/capacity assessment.

**Table 8**. CDC Electronic Laboratory Reporting (ELR) Task Force: Workgroups

| # | Workgroup Name | Charge |
|---|---|---|
| 1 | Standards Workgroup | • Facilitate the reporting of laboratory data to public health agencies throughout the US by<br>o Harmonizing existing ELR Messaging and Vocabulary Standards to reduce variations<br>o Providing guidance with regards to the implementation of ELR Messaging and Vocabulary Standards |
| 2 | LIS Vendors & Large Lab Workgroup | • Develop standards-compliant and efficient approach for vendors interfacing with public health<br>• Build on work with large national labs to ensure full implementation of ELR<br>• Get GIS software solutions to include appropriate ELR standards in their products prior certification |
| 3 | ELR Meaningful Use Workgroup | • Develop a strategic plan for coordination and communication among states, CDC and ONC |
| 4 | Legal Considerations Workgroup | • Identifying key issues surrounding the implementation of ELR in the states<br>• Research how selected states with illustrative or generalizable experience have coped with such legal issues<br>• Based on information acquired, and if appropriate, consider |

[92] Centers for Disease Control and Prevention (CDC). *Electronic Laboratory Reporting (ELR) Task Force. URL:* http://www.cdc.gov/ehrmeaningfuluse/ELRTF.html

| | | |
|---|---|---|
| | | whether law-related products or tools useful to states regarding legal issues should be developed in the future |
| 5 | Resources Needs & Assessment Workgroup | • Articulate what resources are needed to implement local/state ELR through a capacity assessment |

## Examples of National Public Health Initiatives

The **CDC Public Health Information Network (PHIN)** is a national initiative to improve the capacity of public health to use and exchange information electronically by promoting the use of standards and defining functional and technical requirements[93]. Through a set of standards-based services, applications and systems, PHIN has provided a framework to facilitate various types of information exchange. PHIN has the following goals and strategies[94]:

1. Provide leadership in the selection and implementation of shared policies, standards, practices, and services for nationwide public health information exchange
   - *1.1. Develop a PHIN decision-making and policy framework that supports public health information exchange and information security*
   - *1.2. Align PHIN standards and initiatives with national health IT initiatives*
   - *1.3. Support a public health Standardization and Interoperability Framework leveraging models established by the Office of the National Coordinator for Health Information Technology (ONC)*
   - *1.4. Promote and enable PHIN participation*

2. Define, advocate for, and support public health needs and roles in national health information technology and exchange initiatives
   - *2.1. Facilitate public health participation in national health IT and exchange policy, standards, and implementation processes*
   - *2.2. Develop and monitor metrics of participation in national public health information exchange*

3. Perform key public health information exchange and standards management roles
   - *3.1. Operate and improve vocabulary, messaging, and brokering infrastructure*
   - *3.2. Provision key public health data sets, including data sets of national importance*
   - *3.3. Provide technology to support collaboration of public health information exchange*

**Table 9** presents PHIN products related to standardization of laboratory data exchanges.

[93] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN). URL: http://www.cdc.gov/phin/index.html

[94] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN) Strategic Plan. Strategies to facilitate Standards-Based Public Health Information Exchanges. Version 2.2.1. March 17, 2011.URL: http://www.cdc.gov/phin/library/resources/Documents/PHIN_Strategic_Plan_v2_2_1.pdf

**Table 9**. CDC PHIN Products and Services

| # | Product/Service Name | Description |
|---|---|---|
| 1 | PHIN Vocabulary Access and Distribution System (PHIN VADS) | PHIN VADS[95] is a web-based enterprise vocabulary system for accessing, searching, and distributing vocabularies used within the PHIN. It promotes the use of standards-based vocabulary within PHIN systems to support the exchange of consistent information among Public Health Partners. Currently, there are 533 value sets and over 1,850,000 concepts in PHIN VADS based on the code system/domain recommendations from CHI (Consolidated Health Informatics) and value set recommendations from Health Information Technology Standards Panel (HITSP).[96] |
| 2 | PHIN Implementation Guides | PHIN implementation guides[97] support and manage the message specification. They contain information about a specific message that a public health partner can use to support their implementation of PHIN requirements and/or recommendations for messaging and interoperability of information systems. PHIN MS Implementation Guides include:<br>• PHIN Communication and Alerting (PCA) Guide v.1.3[98]<br>• PHIN Exchange Developer Guide v1.0[99]<br>• PHIN Directory Exchange Implementation Guide[100]<br>• PHIN Secure Message Transport Guide[101]<br>• PHIN Batch Specification[102] |
| 3 | HAN - Health Alert Network | CDC's Health Alert Network (HAN)[103] provides information to state and local public health practitioners, clinicians, and public health laboratories, about urgent health events. HAN also provides opportunities for public health professionals to network and share promising practices and lessons learned related to partner communications and alerting. |
| 4 | PHIN Messaging System | The PHIN MS (Public Health Information Network Messaging System)[104] is a software system to securely send and receive encrypted data over the Internet in a standard way for addressing and routing content and to exchange transport transaction confirmations. |
| 5 | PHIN Message Quality Framework (MQF) | PHIN Message Quality Framework (MQF)[105] is an automated testing tool that provides senders the capability to test HL7 messages on their own prior to submitting them to other health partners or the CDC, therefore, decreases the cost and time to implement integrated systems. The MQF tool ensures messages adhere to standards defined in the messaging |

[95] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN). PHIN Vocabulary Access and Distribution System (PHIN VADS). URL http://www.cdc.gov/phin/tools/PHINvads/index.html

[96] Health Information Technology Standards Panel (HITSP). URL: www.hitsp.org

[97] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN).PHIN Implementation Guides. URL: http://www.cdc.gov/phin/resources/PHINguides.html

[98] Centers for Disease Control and Prevention (CDC). PHIN Communication and Alerting (PCA) Guide v.1.3. URL: http://www.cdc.gov/phin/library/guides/PCA_Guide-v1.3.pdf

[99] Centers for Disease Control and Prevention (CDC). PHIN Exchange Developer Guide v1.0. URL: http://www.cdc.gov/phin/library/guides/PHIN_Exchange_Developer_Guide-v1.0.pdf

[100] Centers for Disease Control and Prevention (CDC). PHIN Directory Exchange Implementation Guide. URL: http://www.cdc.gov/phin/library/guides/PHIN_DirExchange_Implementation_Guide.pdf

[101] Centers for Disease Control and Prevention (CDC). PHIN Secure Message Transport Guide http://www.cdc.gov/phin/library/guides/PHIN%20Secure%20Message%20Transport%20Guide_v2.0_7-31-08.pdf

[102] Centers for Disease Control and Prevention (CDC). PHIN Batch Specification. URL: http://www.cdc.gov/phin/library/guides/PHIN_Batch_Specification_v1.1.pdf

[103] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN). Health Alert Network (HAN). URL:http://www.cdc.gov/phin/tools/han/index.html

[104] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN).PHIN Messaging System. (PHIN MS). URL: http://www.cdc.gov/phin/tools/PHINms/index.html

[105] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN).PHIN Message Quality Framework (MQF). URL:http://www.cdc.gov/phin/resources/certification/MQFtool-overview.html

| # | Product/Service Name | Description |
|---|---|---|
| | | guides by: validating the structure of the message, validating that messages are following the business rules defined for the message, and verifying that the vocabulary defined for the message is utilized.<br>MQF Release 2.2 provides the capability for implementers, who have interface engines such as Rhapsody, Mirth, Cloverleaf/Quovadx, etc, to download conformance profiles that were developed based on the message specifications. The formats available for download are XML and Rhapsody S3D. The conformance profile is what the MQF application uses to perform the validation of the messages.<br>MQF introduced vocabulary validation through a real-time integration with PHIN VADS by accessing the Web services to validate that the vocabulary is valid for the specified message. The release supports vocabulary validation against the following published message standards:<br>• Tuberculosis Case Notification Message Mapping Guide, Version 2.0, 01/09/2009<br>• APHL PHLIP Messaging Guide for Influenza Test Result Reporting by Public Health Laboratories, ORU R01 HL7 v2.3.1, Document version 1.0.2, Sept. 15, 2009<br>• All Meaningful Use Specifications |
| 6 | NEDSS (National Electronic Disease Surveillance System) | NEDSS[106] is an Internet-based infrastructure for public health surveillance data exchange that uses specific PHIN (Public Health Information Network) and NEDSS Data Standards. NEDSS also relies heavily on industry standards (including: standard vocabulary code sets such as LOINC, SNOMED, and HL7), policy-level agreements on data access, and the protection of confidentiality. NEDSS represents an ongoing close collaboration between the CDC and its public health partners.<br>NEDSS is not a single, monolithic application, but a system of interoperable subsystems, components and systems modules that include software applications developed and implemented by the CDC; those developed and implemented by State and Local health departments and those created by commercial services and vendors. |

**Meaningful Use (MU) of Health IT Stage 1.**[107,108] Three public health domains (programs) have been adopted for MU Stage 1 of the HITECH-funded CMS Incentive Program:

1. Capability to submit electronic **syndromic surveillance** data to public health agencies and actual transmission according to applicable law and practice.

2. Capability to submit electronic data to **immunization** registries of Immunization Information Systems and actual submission in accordance with applicable law and practice.

3. Capability to submit **electronic data on reportable** (as required by state or local law) **lab results** to public health agencies and actual submission in accordance with applicable law and practice.

[106] Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN). National Electronic Disease Surveillance System. URL:http://www.cdc.gov/phin/tools/NEDSS/index.html
[107] Meaningful Use Stage 1 Final Rule; Federal Registrar. URL: http://edocket.access.gpo.gov/2010/pdf/E9-31217.pdf
[108] Blumenthal D, Tavenner M. The "meaningful use" regulation for electronic health records. N Engl J Med. 2010 Aug 5;363(6):501-4. Department of Health and Human Services, Washington, DC, USA.

As more PHL partners adopt the new MU standards, the PHLs will also need to adopt those standards as well in order to remain relevant in today's changing health care landscape. **Public Health Laboratories and State Health Information Exchanges (HIEs)**. In July of 2010, the Office of National Coordinator for Health IT issued its "Requirements and Recommendations for the State Health Information Exchange Cooperative Agreement Program" [109] to provide directions to state level information exchange efforts. The key HIE objective and deliverable in 2011 is the "*receipt of structured laboratory results*" with the state responsibility to "build capacity of public health systems to accept electronic reporting of immunizations, notifiable diseases and syndromic surveillance reporting from providers." With funding from ONC, states are currently creating their HIE networks that will include electronic exchange of laboratory orders and results between EHR-systems and public health agencies.

The HIE architecture (**Figure 2**) is designed to enable collection and dissemination of data from disparate sources. HIE shared services may include but is not limited to:

- Electronic connectivity across stakeholders in the jurisdiction
- Electronic connectivity across jurisdictions
- IT infrastructure (e.g., servers, data and document storage, processing capability, bandwidth)
- Documents repositories and document location services
- Data repositories and data mapping/translational services
- Identify resolution services (e.g., master patient index (MPI)) and
- Decision support capability

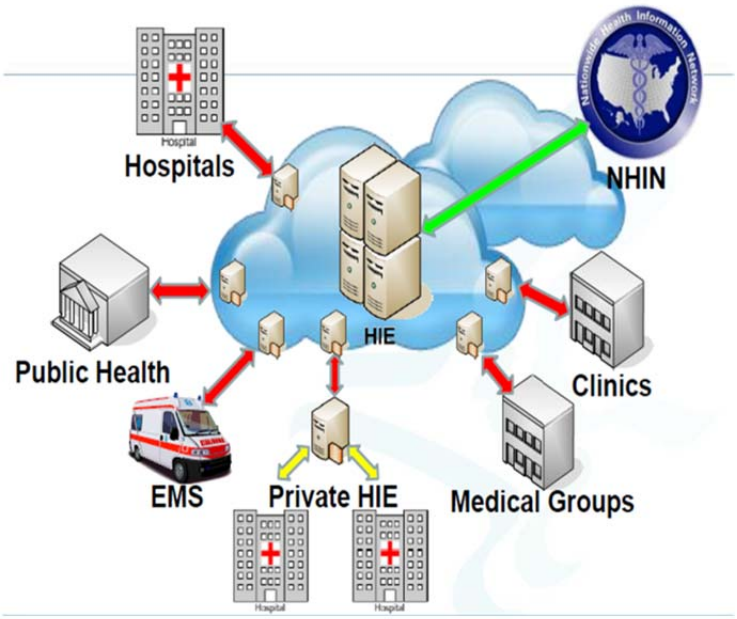


**Figure 2**. Example of State HIE Architecture[110]

[109] Office of National Coordinator for Health IT (ONC).. Requirements and Recommendations for the State Health Information Exchange Cooperative Agreement Program. URL: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1488&mode=2
[110] Johnson J. New Horizons with Health Information Exchange, Local Public Health Perspective. Presentation at the CCLHO Health Information & Data Committee on April 6, 2011

An HIE is viewed as a provider of IT infrastructure/data management services. In this role HIEs may compete with public health agencies that serve a similar role within a public health agency. The PHLISSA project described above clearly shows similarity of architecture and data management approaches/services between HIEs and public health.

Commonalities between HIE and public health approaches may serve as an enabler of interoperability for public health in general, and for laboratory data exchanges in particular. PHLs could utilize HIE infrastructure and services for communications with senders and receivers of laboratory data, including data mapping/translation services across proprietary LIMSs or data sharing across LIMSs with non-compatible information exchange standards.

**Laboratory Interoperability Cooperative (LIC)**[111] is a 2-year CDC-funded project started in 2011 to enable hospitals to meet the MU requirements for electronic submission of laboratory results for reportable conditions to public health agencies. While technical standards exist to enable the secure, electronic exchange of laboratory results, the implementation and use of these standards for public health reporting by the commercial labs, hospitals and providers has been limited. The goal of the LIC is to provide an array of services to hospital laboratories to enable submission of reportable laboratory results to public health agencies as defined in the Meaningful Use final rules. The LIC project involves Surescripts, the College of American Pathologists (CAP), and the American Hospital Association. The project will provide capability for real-time reporting of laboratory tests to public health. Additionally, LIC will assist clinical laboratories with appropriate encoding of the reportable tests results at the point of origin.

[111] Laboratory Interoperability Cooperative (LIC). Project. URL: www.LabInteroperabilityCoop.org

**Section 4**

# Appendicies

## Appendix 1: Terms and Definitions

The following terms are used in this White Paper (in alphabetical order):

| |
|---|
| **Content Profile** is a technical document that defines data content (data sets and value sets) standards for information exchanges within a context of user's business activity. This term is used by the Integrating the healthcare Enterprise (IHE). |
| **Electronic Health Record (EHR)**[112] is information, assembled and maintained in an electronic format which pertains to the health status of an individual and the health services delivered to an individual. |
| **Health Information Exchange (HIE)** is defined as the electronic movement of health-related information among organizations according to nationally recognized standards. To achieve its goals, the HIE itself must meet nationally recognized standards.[113] |
| **Implementation Guide** is a technical document that defines data content (data sets and value sets) and related standards for information exchanges within a context of user's business activity. Implementation guides define constraints on a particular standard. This term is used by standard development organizations, e.g. HL7. |
| **Integration Profile** is a technical document that defines standards for information exchanges within a context of user's business activity. This term is used by the Integrating the Healthcare Enterprise (IHE) and is synonymous to the Interoperability Specification. |
| **Interoperability**[114] is the ability of two or more systems or components to exchange information and to use the information that has been exchanged. |
| **Interoperability Specification** is the term used by the Health Information Technology Standards Panel (HITSP) for the technical documents that defines interoperability standards for a selected use case. |
| **Standardization** as defined by the International Organization for Standardization (ISO)[115], is the process of agreeing on standards, which represent the common language that allows the exchange of data between disparate data systems. The goals of standardization are to achieve comparability, compatibility, and interoperability between independent systems, to ensure compatibility of data for comparative statistical purposes, and to reduce duplication of effort and redundancies. |
| **Technical Framework** is a technical document that describes the relationship between Content Profiles (data sets and value sets) and Integration Profiles (information exchange standards) within a context of user's business activity. This term is used by the Integrating the Healthcare Enterprise (IHE). |

[112] Electronic Health Record. Definition is adapted from Institute of Medicine Report, 2002
[113] The National Alliance for Health Information Technology. Report to the Office of the National Coordinator for Health Information Technology. Defining Key Health Information Technology Terms. 2008.
[114] Interoperability. Definition is adapted from HL7 EHR Interoperability Working Group, 2007
[115] International Organization for Standardization (ISO) Technical Committee 215: Health Informatics. URL: http://www.iso.org/iso/iso_technical_committee.html?commid=54960

## Appendix 2. Privacy and Security Standards

There are a number of security and privacy standards that can support public health laboratory data exchanges. These standards enable transport security, identification of persons and systems, privilege management and access controls, audit, policy agreements, and pseudonymization. These standards are generic and must be support by any systems participating in electronic health information exchanges. The table below provides description of these standards.

| Standards Organization | Standard | Standard Identifier | Description |
|---|---|---|---|
| American National Standards Institute (ANSI) International Committee for Information Technology Standards Inter-National Committee for Information Technology Standards | Information Technology - Role Based Access Control | #359-2004 | This standard describes RBAC features that have achieved acceptance in the commercial marketplace. It includes a reference model and functional specifications for the RBAC features defined in the reference model. It is intended for (1) software engineers and product development managers who design products incorporating access control features; and (2) managers and procurement officials who seek to acquire computer security products with features that provide access control capabilities in accordance with commonly known and understood terminology and functional. Visit www.ansi.org for more information |
| American Society for Testing and Materials (ASTM) Standard | Specification for Audit and Disclosure Logs for Use in Health Information Systems | # E2147-01 | E2147-01 "is for the development and implementation of security audit/disclosure logs for health information. It specifies how to design an access audit log to record all access to patient identifiable information maintained in computer systems and includes principles for developing policies, procedures, and functions of health information logs to document all disclosure of health information to external users for use in manual and computer systems. The process of information disclosure and auditing should conform, where relevant, with the Privacy Act of 1974 (1)." Visit www.astm.org for more information |
| Centers for Medicare and Medicaid Services (CMS) | National Provider Identifier (NPI) | | NPI is a unique 10-digit identification number issued to healthcare providers in the United States by the Centers for Medicare and Medicaid Services (CMS). All individual HIPAA covered healthcare providers (physicians, nurses, dentists, chiropractors, physical therapists, etc.) or organizations (hospitals, home healthcare agencies, nursing homes, residential treatment centers, group practices, laboratories, pharmacies, medical equipment companies, etc.) must obtain an NPI for use in all HIPAA standard transactions, even if a billing agency prepares the transaction. Once assigned, a provider's NPI is permanent and remains with the provider regardless of job or location changes. Visit www.cms.gov for more information |

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| Clinical Laboratory Improvement Amendments (CLIA) of 1988 | | | Establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. based on CLIA. Visit www.fda.gov and www.cms.hhs.gov for more information. |
| Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification | | | While not itself a standard, this federal regulation provides a listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial health care transactions, and protecting the security and privacy of health care information, as applied to the three types of defined covered entities: health plans, health care clearinghouses, and health care providers who conduct any of the specified health care transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. seq. for more information. |
| Health Level Seven (HL7) | Role Based Access Control (RBAC) Healthcare Permissions Catalog Version 2.0, July 2005 | | Presents the healthcare permissions that may be assigned to licensed or certified healthcare providers. Visit www.hl7.org for more information |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) | | | The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration and Content Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE transactions and document content defined and implemented as of August 22, 2007. Visit www.ihe.net for more information. |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) | Audit Trail and Node Authentication (ATNA) | | Provides a common standard audit trail for distributed applications. |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) | Consistent Time (CT) | | Coordinates time across networked systems to ensure time accuracy in patient records and to support security requirements. |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) | Document Digital Signature (DSG) | | Specifies the use of digital signatures for documents that are shared between organizations. |

| | | | |
|---|---|---|---|
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) | Supplement 2007 – 2008 Cross Enterprise User Assertion (XUA) | | The Cross-Enterprise User Assertion Profile (XUA) provides a means to communicate claims about the user identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross enterprise transactions there is a need to identify the requesting user in a way that the receiver can make access decisions and proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the entities, and others that may have chosen to use a third party to perform the authentication. The latest version of the IHE framework is available at www.ihe.net. |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) | Supplement 2007 – 2008 Standard digital patient authorizations (Basic Patient Privacy Consent IHE-BPPC) | | The XDS profile provides little guidance on supporting privacy policies within an affinity Domain. Documents can be marked with a confidentiality Code, but no information has been provided on how to use this information to support patient privacy concerns. This profile corrects that deficiency by describing a mechanism whereby an Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. EHR systems).<br>There are three key parts of the profile:<br>1. The profile provides a content module for capturing a patient consent to a privacy policy or policies.<br>2. The profile describes how the confidentiality Code attribute of the XDSDocumentEntry metadata is used to support the consent policies.<br>3. Finally it describes the method by which XDS Consumer Actors can enforce the privacy policies determined by the document confidentiality Code and the patient privacy consents |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) | Healthcare Provider Directory | HPD | The Healthcare Provider Directory (HPD) profile supports queries against, and management of, healthcare provider information that may be publicly shared in a directory structure. |
| International Organization for Standardization (ISO) | Health informatics – Information technology – Open Systems Interconnection – Systems Management: Security alarm reporting function | Technical Specification #10164–Part 7: Security Alarm Reporting Function, 1992 | Establishes user requirements for the service definition needed to support the security alarm reporting function, defines the service provided by the security alarm reporting function, specifies the protocol that is necessary in order to provide the service, defines the relationship between the service and management notifications, defines relationships with other systems management functions, specifies conformance requirements. The security alarm reporting function is a systems management function which may be used by an application process in a centralized or decentralized management environment to exchange information for the purpose of systems management. Visit www.iso.org for more information |

| | | | |
|---|---|---|---|
| International Organization for Standardization (ISO) | Health informatics – Information technology – Text and office systems – Office Document Architecture (ODA) and interchange format, Technical Report on ISO 8613 implementation testing | Technical Specification # ISO/IEC CD 10183 – Part 3: Testing procedure | Specifies a general framework for the provision of access control. The purpose of access control is to counter the threat of unauthorized operations involving a computer or communication system. Visit www.iso.org for more information |
| International Organization for Standardization (ISO) | Health Informatics – Pseudonymization | Technical Specification # 25237 | This technical specification provides a conceptual model of the problem areas, requirements for trustworthy practices, and specifications to support the planning and implementation of pseudonymisation services. |
| Internet Engineering Task Force (IETF) | Hypertext Transfer Protocol (HTTP) over Transport Layer Security (TLS) | RFC #2818, May 2000 | Describes how to use TLS to secure HTTP connections over the Internet. Current practice is to layer HTTP over SSL (the predecessor to TLS), distinguishing secured traffic from insecure traffic by the use of a different server port. |
| Internet Engineering Task Force (IETF) | Network Time Protocol Specification, Implementation and Analysis | RFC# 1305, March, 1992 | Describes the Network Time Protocol (NTP): the mechanisms to synchronize time and coordinate time distribution in a large, diverse internet operating at rates from mundane to lightwave. Visit www.ietf.org for more information. |
| Internet Engineering Task Force (IETF) | Simple Network Time Protocol (SNTP) | RFC # 2030, October, 1996 | Describes the Simple Network Time Protocol (SNTP) Version 4, which is an adaptation of the Network Time Protocol (NTP). SNTP can be used when the ultimate performance of the full NTP implementation is not needed or justified. When operating with current and previous NTP and SNTP versions, SNTP Version 4 involves no changes to the NTP specification or known implementations, but is rather a clarification of certain design features of NTP. Visit www.ietf.org for more information. |
| Organization for the Advancement of Structured Information Standards (OASIS) | Web Services Security SOAP Message Security Version 1.0 | | "Describes enhancements to SOAP messaging to provide message integrity and confidentiality. The specified mechanisms can be used to accommodate a wide variety of security models and encryption technologies. This specification also provides a general-purpose mechanism for associating security tokens with message content. No specific type of security token is required, the specification is designed to be extensible (i.e.. support multiple security token formats. Additionally, this specification describes how to encode binary security tokens, a framework for XML-based tokens, and how to include opaque encrypted keys. It also includes extensibility mechanisms that can be used to further describe the characteristics of the tokens that are included with a message." Visit www.oasis-open.org for more information |

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| Organization for the Advancement of Structured Information Standards (OASIS) | Security Assertion Markup Language (SAML) v2.0 OASIS Standard | ITU-T X.1141 | SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. Visit www.oasis-open.org for more information |
| International Standards Organization (ISO) | Healthcare Informatics – Functional and Structural Roles | TS21298 | This technical specification describes the concepts and vocabulary specifications to support static (structural) roles and relationship-based (functional) to express an entity's healthcare role. This is defined in support of identity management, (PKI, Directory services), and Privilege management. These are leveraged to reflect the regulated and supporting roles to bind to legal policy within the state. |
| International Standards Organization (ISO) | Health informatics — Classification of purposes for processing personal health information | TS14625 | This Technical Specification defines a set of high-level categories of purposes for which personal health information may be processed: collected, used, stored, accessed, analyzed, created, linked, communicated, disclosed or retained. |
| International Standards Organization (ISO) | Health informatics — Audit trails for electronic health records | DTS22789 | This Technical Specification specifies a common framework for audit trigger events and audit data. |
| International Standards Organization (ISO) | Health informatics — Electronic health record communication | TS 13606-4 (Sensitivity Class) | Part 4 of a multipart standard on Electronic Health Record Communication that describes requirements and a methodology for specifying the privileges necessary to access EHR data. Describes a set of 5 classes of sensitivity that may be used to classify health information to be shared.<br><br>Within the ISO 13606-4 is a vocabulary for a 5-level sensitivity class to reflect typical functional health care information access sensitivities:<br>• Personal care<br>• Privileged care<br>• Clinical care<br>• Clinical management<br>• Care management |
| International Standards Organization (ISO) | Healthcare Informatics – Directory services for security, communications and identification of professionals and patients | ISO TS21091 | This technical specification reviews the health care specific requirements of the directory services, and defines associated standard specifications for inclusion of healthcare related information in the health care directory. This is currently on the standardization track as DIS 21091. |

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| Organization for the Advancement of Structured Information Standards (OASIS) | Web Services Security SOAP Message Security Version 1.0 | | "Describes enhancements to SOAP messaging to provide message integrity and confidentiality. The specified mechanisms can be used to accommodate a wide variety of security models and encryption technologies. This specification also provides a general-purpose mechanism for associating security tokens with message content. No specific type of security token is required, the specification is designed to be extensible (i.e. support multiple security token formats. Additionally, this specification describes how to encode binary security tokens, a framework for XML-based tokens, and how to include opaque encrypted keys. It also includes extensibility mechanisms that can be used to further describe the characteristics of the tokens that are included with a message." Visit www.oasis-open.org for more information |
| Organization for the Advancement of Structured Information Standards (OASIS) | ebMS OASIS/ebXML Messaging Services Specifications v2.1 | | Defines a Message Service protocol for reliable Business-to-Business data interchange. ebMS v2.1 adds quality of service features on top of transfer protocols such as HTTP and SMTP. Key qualities of service features include guaranteed delivery and nonrepudiation of receipt. ebMS v2.1 can reliably transfer any data type including XML, X12, EDIFACT, or binary data between two parties over the Internet. Visit www.oasis-open.org for more information. |
| Organization for the Advancement of Structured Information Standards (OASIS) | Security Assertion Markup Language (SAML) v2.0 OASIS Standard | ITU-T X.1141 | SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. Visit www.oasis-open.org for more information |
| International Standards Organization (ISO) | Privilege Management and Access Control | TS26000/1/2/3 | This 3-part technical specification defines an overview, model, and framework for managing privileges an access to sensitive, distributed health information. Privilege management and access control addresses security services required for communication and distributed use of health information.<br>Part 1: Overview and policy management, describes the scenarios and the critical parameters in cross border information exchange. It also gives examples of necessary documentation methods as the basis for the Policy agreement.<br>Part 2: Formal models, describes and explains, in a more detailed manner, the architectures and underlying models for the privileges and privilege management which are necessary for secure information sharing plus examples of Policy agreement templates.<br>Part 3: Implementations, describes examples of implemental specifications of application security services and infrastructural services using different specification languages. |

| | | | |
|---|---|---|---|
| ASTM | Standard Guide for Information Access Privileges to health information | E1986 | This standards addresses access privilege and control requirements, healthcare professional roles within the US, and information/data requiring access control. |
| International Standards Organization (ISO) | Healthcare Informatics PKI/1/2/3 | IS17090 | This Standard describes the common technical, operational and policy requirements that need to be addressed to enable digital certificates to be used in protecting the exchange of healthcare information within a single domain, between domains and across jurisdictional boundaries |
| ASTM | Standard Guide for User Authentication and Authorization | E1985 | This standard specifies requirements, methods, and mechanisms to authentication users for access and management of health information in centralized or distributed environments. |
| FIPS | compliant tamper resistant media | 140-2 | Security requirements for cryptographic modules specifying tamper evident physical security or pick resistant locks. Level 2 provides for role-based authentication. |
| Federal Bridge | | | The FBCA consists of a collection of PKI components (Certificate Authorities, Directories, Certificate Policies, and Certificate Practice Statements) that are used to provide peer-to-peer interoperability among Federal Agency. |
| Auditing Standards Board of the American Institute of Certified Public Accountants (AICPA) | Statement on Auditing Standards (SAS) No. 70 | SAS-70 Level II | SAS 70 defines the professional standards used by a service auditor to assess the internal controls of a service organization. A SAS 70 certification demonstrates that industry approved quality controls have been intentionally integrated into the workplace. The Type II audit is the most comprehensive of the SAS 70 audits and confirms not only the existence of written procedures but also the effectiveness of these written procedures. |
| Auditing Standards Board of the American Institute of Certified Public Accountants (AICPA). | Statement on Standards for Attestation Engagements (SSAE) No. 16 | SSAE 16 | SSAE 16 supersedes Statement on Auditing Standards (SAS) No. 70 with the professional guidance on performing the service auditor's examination. |
| Electronic Healthcare Network Accreditation Commission | | EHNAC | The Electronic Healthcare Network Accreditation Commission (EHNAC) (www.ehnac.org) is a self-governing, peer-driven organization dedicated to advancing healthcare through:<br>• Establishment of standards for healthcare-related electronic transactions<br>• Accreditations that set benchmarks for assuring security, confidentiality, accountability, and efficiency |

| | | | |
|---|---|---|---|
| International Standards Organization (ISO) | Health informatics: Security management in health using IS17799 | IS27799 | This international standard provides guidance to health organizations and other custodians of personal health information on how best to protect the confidentiality, integrity and availability of such information by implementing ISO/IEC 17799116. Specifically, this standard addresses the special security management needs of the health sector and its unique operating environments. |
| International Standards Organization (ISO) | Security and privacy requirements for compliance testing of EHR systems | ISO DTS 14441 | This multi-part Technical Specification addresses security and privacy protection in electronic patient record systems at the point of care that are inter-operable with EHRs by providing:<br>• A set of core security and privacy requirements, along with the guidelines and best practices necessary for assessing and eventually ensuring compliance with those requirements;<br>• A profile of these requirements, including examples of proven testing procedures that have been developed to evaluate compliance with the necessary privacy and security requirements. |

[116] This guideline is consistent with the revised version of ISO/IEC 17799-1:2005.

## Appendix 3. IHE-Laboratory Technical Framework as an Example of Functional Standards

Section 2 above briefly described the **Integrating the Healthcare Enterprise Laboratory Technical Framework**[117] that includes interoperability standards specifications (profiles) addressing workflow and information sharing involving laboratories and their supporting systems (**Table 4**):

**Table 4**. IHE Lab Technical Framework Profiles

| # | Profile Name |
|---|---|
| 1 | Laboratory Testing Workflow (LTW) |
| 2 | Laboratory Device Automation (LDA) |
| 3 | Laboratory Point Of Care Testing (LPOCT) |
| 4 | Laboratory Code Set Distribution (LCSD) |
| 5 | Laboratory Specimen Barcode Labeling (LBL) |
| 6 | Sharing Laboratory Reports (XD-LAB) |

The ***laboratory workflow*** transactions related to the exchange and sharing of ***laboratory test orders and results*** support not only the clinical workflow, but can be leveraged to support public health laboratory information exchanges and reporting.

The IHE-Lab Technical Framework profiles introduce the following technical Actors (information systems) participating in the data exchanges (**Figure 3**):

- Order Placer (EHR-S)
- Order Filler (LIMS)
- Order Results Tracker (LIMS) and
- Automation Manager (LIMS).

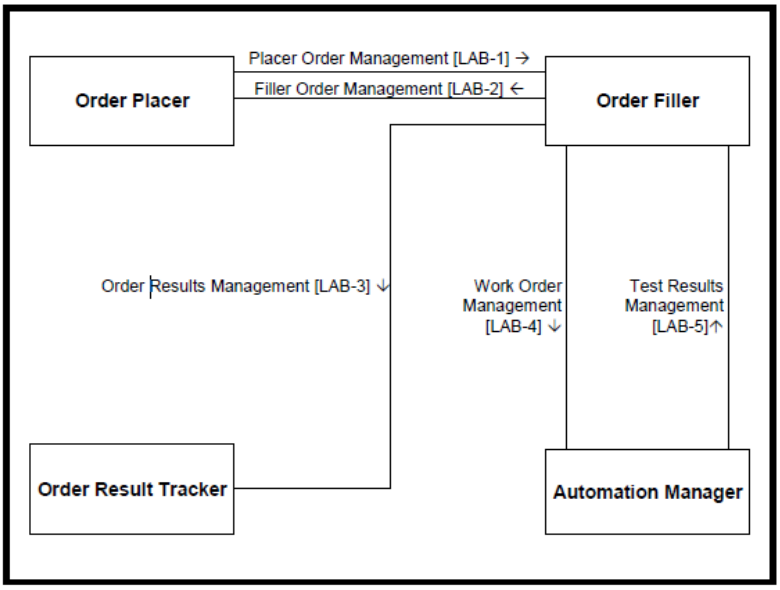



**Figure 3**. Laboratory Testing Workflow Actor Diagram

[117] Integrating the Healthcare Enterprise Laboratory Technical Framework. URL: http://www.ihe.net/Technical_Framework/index.cfm#laboratory

A laboratory uses an Order Filler (OF) application to fulfill its orders. It handles its technical automation with the help of Automation Managers (AM), each of which may manage one or more Laboratory Devices (LD). The systems: Laboratory Information System (LIS), Laboratory Automation System (LAS), Devices (Dev) that support the IHE actors, may be interconnected in various ways. Please note that the CDC PHLISSA project described below uses the same terminology for PHL workflow actors.

***Updating Patient Information on the Test Order.*** Patient information updates are introduced into the system at various stages of the analytical process using IHE Patient Demographic Query (PDQ) and Patient Administration Message (PAM) Profiles from the IHE IT Infrastructure Technical Framework. Order Placer, Order Filler and Order Results Tracker are grouped with appropriate actors of the PAM profile and/or the PDQ profile. This grouping ensures that these three actors are provided at any time with up-to-date patient demographic and encounter data.

The IHE-Lab actors are committed to updating their patient data automatically and without delay as soon as their paired PAM or PDQ actor is notified of this update. Thus the new patient data will be visible by the laboratory staff and by the ward staff as they are working on an order related to that patient or viewing the results of that order. Conversely, the Automation Manager actor receives patient demographic and encounter data only within the context of a Work Order.

Whenever some of the patient data changes (e.g. update patient name, change patient identifier, etc.) it is the responsibility of the Order Filler to forward this update to the Automation Manager for all Work Orders which are in process related to that patient, using transaction LAB-4. If there is no Work Order currently in process for that patient, the Automation Manager is not informed of the patient update. Thus the new patient data will be visible by the laboratory technical staff in Work Orders of the Automation Manager application.

**Figure 4** shows the process flow of an Order, with patient data update occurring during this process. “Patient data update” is to be understood in a broad meaning: It can be an update of the patient demographics, a change of patient identifier, a merger of two patient records, a link between two patient records, a change of patient class, a transfer or its cancellation, a change of patient account, or a few other trigger events.

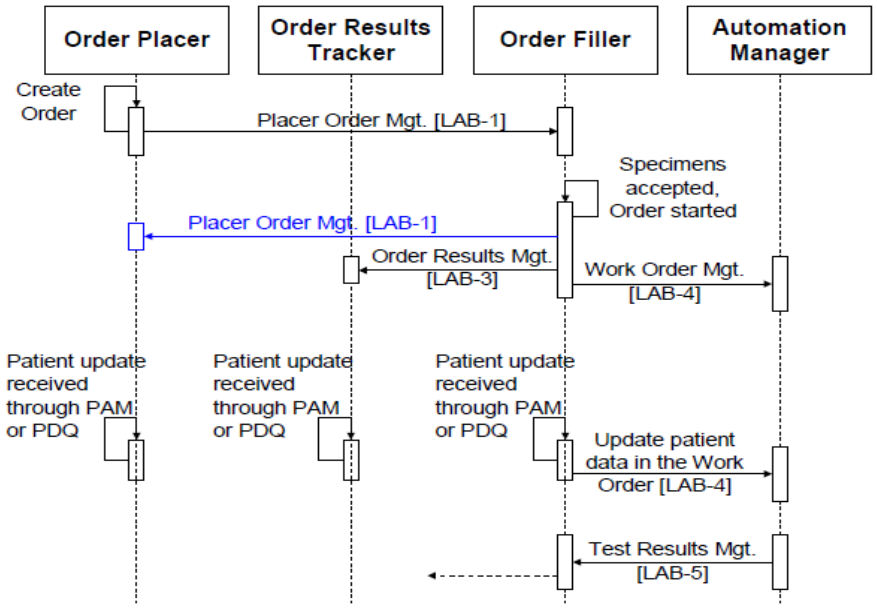



**Figure 4**. Laboratory Order Activity Diagram with Patient Data Update

***From Test Order to Test Result.*** The patient specimen testing starts with a Work Order sent by the Order Filler to the Automation Manager (**Figures 1 and 2**). The Automation Manager splits this Work Order into a sequence of Work Order Steps (WOS), and schedules each step on a laboratory device (LD), e.g., aliquoter, robotic conveyer, analyzer, according to the organization of the laboratory automation (**Figure 5**).

Each WOS contains all information required by the target device to perform it: container identification, specimen information, target ID, operation to perform, and scheduled time.
The Analytical Work Order Step (AWOS) also contains the list of clinical tests to perform, the patient identification, admission and clinical information, and the order information. The specimen information may include the ID, position, specimen type, volume, date and time of collection, ID of collector, and specimen pre-analytical status (e.g., “centrifuged”, “decapped”).

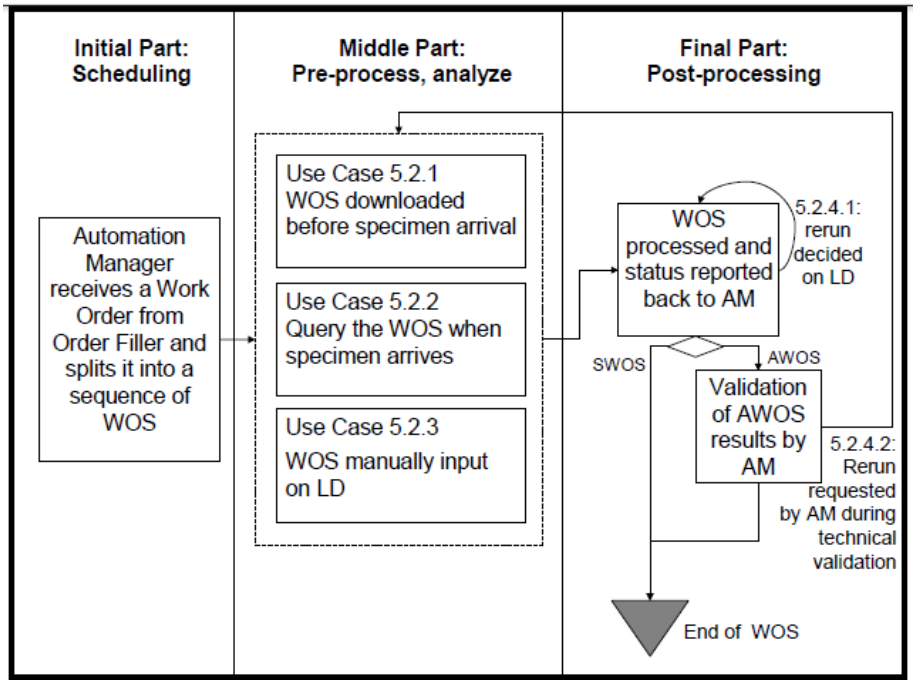



**Figure 5**. Specimen's Work Order Steps (WOS)

For some Analyzers that perform single tests (e.g., HbA1c), or a constant panel (Blood culture, Blood cell counts), the AWOS does not need to mention the tests to be performed.

By definition, a Work Order Step - WOS - is related to a single specimen. The specimen (primary or aliquot) is usually identified with a unique ID printed on a barcode label attached to the specimen container (see section above on ***Identifier Standards***).

The laboratory technical staff supervises the various WOS using the Automation Manager and operating all necessary devices. The technical staff performs the technical validation of the results on the Automation Manager, which then sends these results back to the Order Filler. Should a specimen be damaged or lost, the Automation Manager will suspend or cancel its Work Order until the replacement specimen arrives.

The Automation Manager supports transactions for the normal process of specimen analysis as well as transactions for quality control (QC) testing. In addition, it supports automatic reruns triggered by out of range results, reruns requested during technical validation, and urgent tests.

***Reporting Laboratory Results.*** **Figure 6** presents the animated diagram of the public health laboratory results reporting workflow in the case of salmonella as it is presented in the IHE Sharing Laboratory Reports – Cross-Documents Sharing-Laboratory Reports (XD-Lab) – Content Profile. This Profile describes a laboratory report as a CDA electronic document to be available to the ordering provider's EHR system, or patient's Personal Health Record (PHR), or to be reported to a public health agency using one of the document sharing profiles, as defined in the IHE IT Infrastructure Technical Framework such as Cross Document Sharing (XDS) and Retrieve Form for Data Capture (RFD), i.e., pre-populating the public health report form (described below),

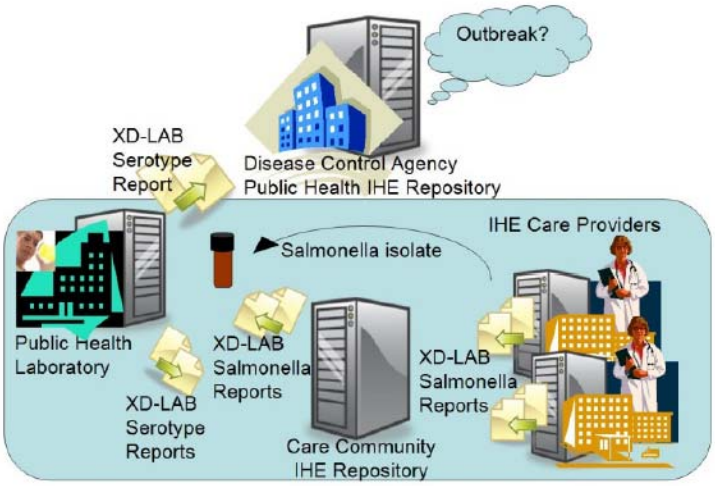



**Figure 6**. Specimen's Work Order Steps (WOS) for Test Result Report

As a CDA document, this electronic document contains the set of results produced by a clinical laboratory or by a public health laboratory in fulfillment of one or more test orders for a patient. The report is shared in a human-readable and a machine-readable format; the latter is to facilitate the integration of these observations in the database of a consumer system.

The IHE XD-Lab Profile covers all laboratory specialties except anatomic pathology. The human rendering of the laboratory report defined in this Profile is compatible with laboratory regulations in various countries, including CLIA in the USA. The laboratory report described in this Profile, with its set of test results in a machine-readable format, may also be used to share historical results with appropriate content anonymization and patient identification pseudonimization to create shared distributed repositories of laboratory information.

There are two actors in this profile, the Content Creator and the Content Consumer (**Figure 7**) as follows:

- ***Content Creator (Data Sender)*** Actor (e.g., LIMS) is responsible for the creation of content (e.g., test results) and its transmission to a Content Consumer, e.g., HIE, EHR-S, PH-IS, Personal Health Record (PHR) and
- ***Content Consumer (Data Receiver)*** Actor (e.g., EHR-S and PH-IS) is responsible for viewing, importing, or other processing of content created by a Content Creator Actor.

Thus, Content (i.e., a laboratory report) is created by a Content Creator and is to be consumed by a Content Consumer.

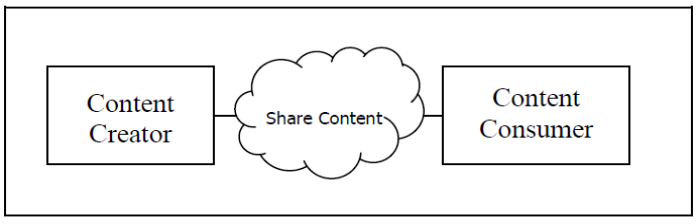
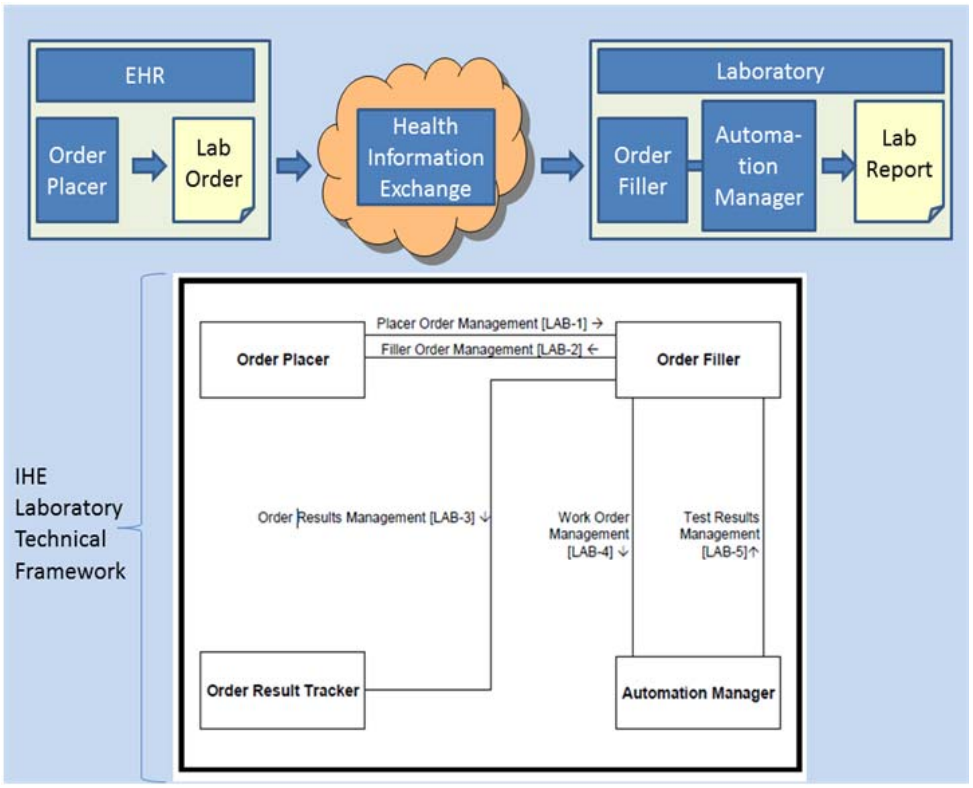
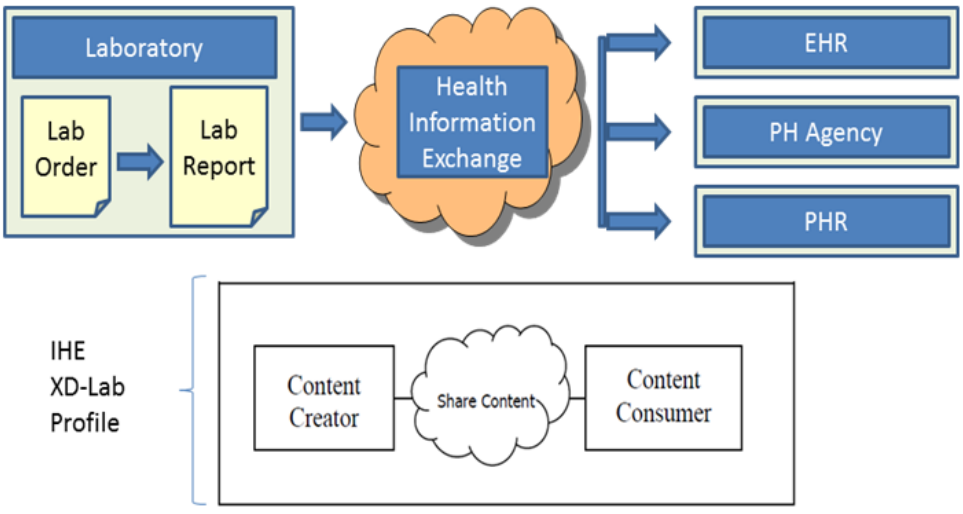



**Figure 7**. Exchanging the Laboratory Results: Actors in the XD-Lab Profile

**Figure 8** presents a generic laboratory workflow (processing laboratory test orders and laboratory test results reports) using IHE interoperability standards (Profiles).




a - Processing Laboratory Test Orders




b - Processing Laboratory Test Result Reports

**Figure 8**. Generic Laboratory Workflow and IHE Interoperability Standards