Vermont Department of Health

Electronic Laboratory Reporting HL7 2.5.1
Implementation Guide
Version 2.0

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September 12, 2012	1.1	Revised per review comments and added Appendix A	Kimberly Jones
January 28, 2013	1.2	Added option of NIST message testing tool to "Test Constructed Messages" Added section "VDH-Specific Messaging Criteria" Added "Gain VDH Epidemiological approval test results proposed for electronic transmission"	Kimberly Jones
March 27, 2013	1.3	Modified section on secure transport to reference connecting via VITL instead of VDH Delete Appendices A & B Remove steps in Partner Laboratory Preparation that reference spreadsheet defining ELR reportables. Add Appendix A "Reportable Laboratory Findings Required to be Submitted Electronically" Add link to VDH's Meaningful Use page Added MSH 6 requirement per VITLs specification Specify address information is required for jurisdiction.	Kimberly Jones
June 24, 2013		Remove reference and link to MQF validator as NIST tool has been enhanced and is preferable. Modify Section 5.1 to include the Registration of Intent process Add link to HL7 2.5.1 ELR Public Health Specification as it is now freely available Section 5.3 updated to add sterile site code	Kimberly Jones

		requirement when HL7 advised that this table was locally defined. See Appendix B to sites approved by VDH Epidemiology. Added requirement to Section 5.4 that hospitals periodically verify that all notifiable conditions, and only those conditions, are being sent to VDH Added additional data quality measure of semi-annual reporting to Section 5.7	
June 28, 2013	V1.4	Corrected typos and referenced Section in 6/24/2013 revision history per review. Changed * in title on Appendix A to †; explained * in footnote.	Kimberly Jones
September 17, 2013	V1.5	Section 5.3 modified to indicate VDH will work directly with hospitals on establishing a secure transport mechanism to avoid delays that could negatively affect their meeting meaningful use incentive measures.	Kimberly Jones
December 23, 2013	V1.6	Modified Section 5.3 to indicate that VITL will not be at all involved in the ELR MU measure.	Kimberly Jones
February 7, 2014	V1.7	Modified Appendix A to include Blood lead as required to report electronically Modified Appendix A to include CSF cultures as required to report electronically Modified Appendix A to require Nontreponemal tests for syphilis Revise Section 5 to reference the VDH Meaningful Use website, added hyperlink to NIST message testing site, and clarified the testing/validation steps and tracking of actions. Corrected several typos/grammar	Kimberly Jones
May 14, 2014	V1.8	Update criteria for MSH-4	Kimberly Jones
June 24, 2014	V1.9	Update link on for Section 5.1.7	Kimberly Jones
July 24, 2015	V1.10	Updated Reportable Laboratory Findings in Appendix A as of 03/26/2015	Suhasini Siva
October 6, 2015	V1.11	Update Section 2 with a link to current reportable findings document on VDH website. Remove Appendix A; Appendix B became Appendix A	Kimberly Jones

October 27, 2015	V2.0	Change to Version 2.0; update all references to version/date.	Kimberly Jones

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1 Acronyms and Definitions

Acronym	Expanded name	Definition or Description
CDC	Centers for Disease Control and Prevention	An agency within the U.S. Department of Health and Human Services and is the public health agency at the federal level.
EHR	Electronic Health Record	A term used to describe both an individual's record and the software system used to present the information of the record. An individual patient's health history consisting of information such as demographic, billing, current medications, medical history, immunization status, allergies, x-rays, laboratory results, etc., originates from a wide variety of sources stored in different data formats. The EHR is designed to gather all of this information from the various sources and formats within a single interface easily accessible to clinicians at the point of care. The standardization required for this level of data sharing also makes it possible to automate manual tasks which have traditionally been tedious and labor intensive.
ELR	Electronic Laboratory Reporting	A sending information system generates a standardized (in structure & content) message which is transmitted by electronic means to a receiving system capable of receiving and consuming the standardized message.
ETOR	Electronic Test Orders and Results	Refers to an electronic data exchange project between the CDC and state public health laboratories. State public health laboratories submit electronic test orders to the CDC. The CDC performs tests and returns electronic results to the public health laboratories.
HL7	Health Level Seven	An all-volunteer, non-profit organization involved in development of international healthcare informatics interoperability standards and the standard for exchanging health information between medical applications.
LIMS	Laboratory Information Management System	Software and processes that facilitate accessioning orders, analysis of results, quality control and reporting results
LOINC	Logical Observation Identifiers Names and Codes	A universal code system for identifying laboratory and clinical observations. LOINC codes are used in ELR messages to convey information related to the laboratory tests that have been requested and performed.
NIST Message	Similar to MQF, but performs more robust structure/content	A newer message validation tool provided by the

Validator	checking	National Institute of Standards and Technology: Available at http://hl7v2-elr-testing.nist.gov/mu-elr/
OID	Object Identifier	A structured code used to identify an 'object' such as a hospital or a software application used at one of the facilities exchanging information with an HL7 message.
PHIN VADS	Public Health Information Network Vocabulary Access and Distribution System	PHIN VADS provides standard vocabularies to CDC and its Public Health Partners in one place. PHIN VADS 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. The PHIN VADS is available at the following web location: https://phinvads.cdc.gov/vads/SearchHome.action
RCMT	Reportable Condition Mapping Table	Provides mapping between a reportable condition and its associated LOINC laboratory tests and SNOMED laboratory results. The RCMT is available at the following web location: https://phinvads.cdc.gov/vads/SearchHome.action
SNOMED or SNOMEDCT	Systematized Nomenclature of Medicine--Clinical Terms	A comprehensive clinical terminology, originally created by the College of American Pathologists (CAP) and, as of April 2007, owned, maintained, and distributed by the International Health Terminology Standards Development Organization (IHTSDO), a not-for-profit association in Denmark. SNOMED codes relevant for ELR are found in the RCMT available at the following web location: https://phinvads.cdc.gov/vads/SearchHome.action
VDH	Vermont Department of Health	The Vermont Department of Public Health is the state level public health agency in the state of Vermont. VDH also serves as a clearinghouse for reportable conditions within the state meaning that if a condition is reported to the state department, VDH will refer the report on to the appropriate local public health agency through the Vermont Disease Surveillance System.

2 Introduction

The Vermont Department of Health is preparing for statewide implementation of Electronic Laboratory Reporting (ELR) of notifiable conditions, which assists hospital facilities achieve one of the Stage 1 Meaningful Use (MU) objectives for public health. The other two objectives of electronic exchange, immunization and syndromic surveillance information, are not covered by this guide.

In addition to potential MU incentive monies, ELR offers long-term benefits to both laboratories and public health.

Laboratory benefits include:

- Automation of reporting reduces laboratory person hours and duplicate data entry
- Single data depository removes need for multiple faxes and, in some case, phone calls
- Faster, more timely reporting
- Reduced human errors

Public health benefits include:

- Faster, more accurate data lead to improved public health efficacy
- Reduced duplicate data entry
- Reduced burden for laboratory partners

In order for disparate information systems to exchange data, the structure and content of the data to be exchanged must be standardized. There are three controlling documents that define how the Vermont ELR HL7 data exchange interface works. They are arranged in a hierarchy of documents, each refining and constraining the one below it.

The **first** document is the HL7 2.5.1 standard developed by Health Level Seven, a not-for-profit ANSI-accredited standards developing organization. This standard defines the structure and content of laboratory messages, but leaves many specific implementation details undecided. General information on HL7 and a copy of the proprietary HL7 message standard can be obtained from the Health Level Seven website at http://www.hl7.org.

The **second** document is the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) This guide gives specific instructions regarding how to report to laboratory information systems, but still leaves some implementation decisions to each state laboratory information management system (LIMS). This document is now available for free download at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98

The **third** document is this guide. The Vermont Department of Health (VDH) presents this implementation guide (IG) as a supplement to the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm). The Vermont Implementation Guide for HL7 2.5.1 Electronic Laboratory Reporting contains information regarding ELRs specific to the State of Vermont. All information presented here represents either a reiteration or constraint of the specifications outlined in the CDC HL7 Version 2.5.1 Implementation Guide Electronic Laboratory. All ELR messages sent must be structured and validated for content as described in this guide.

The regulations regarding reporting regulations may be found at http://healthvermont.gov/regs/documents/reportable_communicable_diseases_rule.pdf

Addition information on Meaningful Use at VDH can be found at:

http://healthvermont.gov/hc/meaningful_use.aspx

The current list of notifiable conditions can be found at
http://health.vermont.gov/prevent/reporting/documents/reportable_lab.pdf

3 Intended Audience

This guide is intended for technical groups charged with implementing and supporting the electronic laboratory reporting between VDH and its external laboratory partners. The reader of this Guide should have a solid HL7 foundation and be very familiar with the contents of the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm). The goal of this implementation guide is to provide an unambiguous specification for creating and interpreting messages.

4 Specialized Vocabularies and Mappings

Use of the standardized reporting codes LOINC® and SNOMED is required. As the partner laboratory is the subject matter expert regarding test samples and results, it is responsible for performing the mapping process to these vocabularies.

Below are links that may be of use in the mapping process.

Logical Observation Identifiers Names and Codes (LOINC®) Available at http://loinc.org/downloads

SNOMED CT (Systematized Nomenclature of Medicine-Clinical Terms). Reference available at http://www.ihtsdo.org/snomed-ct/

Reportable Condition Mapping Tables (RCMT): Tables containing mapping between reportable conditions, LOINC test codes, and SNOMED result codes, developed by the Standards Workgroup under the CDC/CSTE Electronic Laboratory Reporting (ELR) Task Force. Download the tables as well as associated information from http://phinvads.cdc.gov/

Mapper's Guide for the Top 2000 plus LOINC Laboratory Observations: Navigate to the LOINC site at http://loinc.org/usage to look at this data set, the "Mapper's Guide for the Top 2000 plus LOINC Laboratory Observations". Register on the LOINC site first, and then download the Mapper's Guide either as a pdf or an Excel files.

5 ELR Implementation Phase

5.1 Partner Laboratory Preparation

The following steps need to be undertaken by a partner laboratory wishing to transmit ELRs:

5.1.1 Review instructions and information regarding engagement with VDH on Meaningful Use measures at this site. Note that Implementation Guides may be updated periodically.

5.1.2 Obtain copies of the HL7 Standard and ELR Implementation Guide as described above

5.1.3 Develop an overall project plan with vendor and organization staff

5.1.4 Map local laboratory test codes to LOINC and SNOMED vocabularies. Provide VDH with documentation of this mapping for epidemiological review

5.1.5 Construct HL7 ELR 2.5.1 ELR ORU^R01 test messages

5.1.6 Test constructed messages using the NIST ELR validation tool that is available here

5.1.6.1 Perform both context-free and context-based validation for each type of test that will be sent.

5.1.6.2 Work with vendor to resolve errors

5.1.7 When ready, engage with VDH per the instructions specified here.

5.1.8 Test messages with VDH until validation is successful.

5.1.9 Go-live in parallel processing with VDH.

5.1.10 Enter post-production and maintenance phase

Throughout this process, VDH will track dates of engagement, dates forms received, dates actions were requested and when those actions were completed.

5.2 VDH-Specific Messaging Criteria

- MSH-4.2 must contain the hospital partner's CLIA number
- MSH-4.3 must contain the literal value "CLIA"
- Ensure that the OID for the partner organization as assigned by VITL is being submitted. Contact VDH if you do not know this OID
- A single message (i.e. transmission block initiated by "MSH") may contain one and only one PID segment.
- The value for MSH5.1 Receiving Application shall be coded as the literal "NBS". Note that further delineation of MSH 5 may be required in the future.
- The value for MSH6.1 Receiving Facility shall be coded as the literal "VDH".
- Address information for the patient must be included in order to establish jurisdiction.
- For notifiable conditions that must be sampled from a normally sterile site, the sterile site codes listed in Appendix B must be used.

5.3 Establish secure transport mechanism

VDH will work with individual hospitals to establish secure transport. VITL will explicitly **not** be involved in the transport of electronic laboratory messages. Please contact Kimberly Jones at VDH to initiate connectivity.

5.4 Validation

Individual messages of each type that the partner laboratory plans to send electronically must be submitted to VDH and pass with 100% accuracy into the VDH test platform. Depending upon the tests performed by each partner laboratory, multiple examples of each test message may be required in the validation suite. Upon completion of individual message validation, several batches of messages must be submitted. Validation will include ensuring that non-reportable conditions are not being transmitted.

During this phase VDH and the partner laboratory will work closely together to test the message structure, content, vocabularies, and mappings.

Prior to go-live, the submitting laboratory is required to:

- Create an emergency preparedness plan for reporting continuity and provide a copy of this to VDH. This plan should include two alternative communication methods, such as fax, USPS or courier, in the event of disruption of electronic communications.
- Agree to participate fully in VDH's data quality control program. This will include periodic data checks, potential testing of emergency communication methods, and reversion to validation status if production ELR errors occur too frequently.
- Define and communicate a process that allows reconciliation of results sent to VDH and results received by VDH.
- Define and communicate a process to verify periodically that all current notifiable conditions, and only those conditions, are being routed to VDH

5.5 Go-Live

Upon completion of validation, laboratory reports may be electronically submitted to production in batches.

5.6 Parallel Processing

For a period of time to be specified by VDH, to be determined by both the volume and quantity of messages submitted, reports must be submitted to VDH using both the prior method and the format used by the partner for notifiable condition reporting. Upon completion of this time period, the sender may discontinue duplicate reporting.

5.7 Post-Production & Maintenance

Notifiable conditions can and do change, as well as guidances, LOINC and SNOMED vocabulary codes. Communication between VDH and the partner laboratory will remain open to ensure maintenance and quality assurance.

Note that if a partner onboards a new test for a reportable condition after go-live, those results will also need to be validated before moving into production. Please contact VDH in this event.

Semi-annually, VDH will report out to each partner how many results they have received. This report should be verified against the partner's own log of sent results. Please contact VDH in the event of discrepancies.

Appendix A

Sterile Site Codes

Value	Description
10	Blood
20	Cerebrospinal fluid (CSF)
30	Synovial fluid
40	Pleural fluid
50	Pericardial fluid
60	Peritoneal fluid
70	Tissue biopsy/aspirate
80	Surgical wound