

Electronic Laboratory Report (ELR) Implementation Guide

West Virginia requires both the ordering hospital and the reporting facility to send the results of reportable disease to the West Virginia Bureau for Public Health (WVBPH). Disease reporting requirements can be found at: <http://www.dhhr.wv.gov/oeps/disease/Manual/Pages/default.aspx>

The WVBPH utilizes the NEDSS Base System (NBS) in order to conduct surveillance, case management, and analysis of reportable diseases. The West Virginia Electronic Disease Surveillance System (WVEDSS) is capable of receiving HL7 2.5.1 ELR messages. Messages can be submitted through the West Virginia Health Information Network (WVHIN) or directly to WVBPH through a PHIN-MS - transport mechanism. This document serves to outline the steps that will be undertaken with each laboratory working towards ELR implementation of reportable diseases to WVBPH. Meaningful Use specific items will be identified with a “**(MU note:)**”.

Hospitals seeking to meet Meaningful Use are required to register their intent to attest at the WVBPH online registration system. A link to the system can be found at:
https://oeps.wv.gov/pi_qpp/pages/default.aspx

Transitioning to ELR provides a benefit to WVBPH in that laboratory results are received much quicker and there will be a decline in data entry errors. From the laboratory side, benefits include reduction in cost/waste via faxing, mailing, and printing of paper records, decrease in laboratory data entry, increased automation of notification, and increased data security. In addition, hospitals can also meet the ELR Meaningful Use objective.

ELR implementation in West Virginia will vary by laboratory, but it is comprised of five major phases which will require time, patience, and resources. No single phase should be seen as more important than another.

The process for WVHIN Participants may be slightly different as the WVHIN may manage some of these phases on behalf of their Participants. WVHIN Participants will submit a test file as part of the pre-implementation activity.

Phase 1: Enrolment

The engagement phase begins when an interested laboratory contacts WVBPH or the WVHIN, or is contacted to begin ELR implementation as a result of their on-line registration. There are a series of questions that will need to be discussed before a hospital can move further with implementation. These questions may include:

1. Name and location of facility / system.
2. Contact information for the project.
3. Is your facility composed of multiple facilities?
 - a. If YES, list all other facilities.

- b. If YES, will laboratory results be reported from one location or multiple locations? Identify the source of ELR messages.
4. Does your facility/system serve inpatient, outpatient, or both types of patients?
5. Are you interested in HL7 2.5.1 ELR messaging? (**MU note:** Hospital ELR implementation requires the transmission of HL7 2.5.1 compliant messages)
6. Name of EHR/LIS product, vendor, and version.
 - a. Does your EHR/LIS support LOINC and/or SNOMED?
 - b. **MU Note:** Is your EHR/LIS a certified MU product and/or certified for ELR?
 - i. If NO, when do you anticipate having a certified EHR/LIS?
7. What secure data transport mechanism do you currently have in place?
 - a. Note: the WVEDSS only supports going through WVHIN or PHIN-MS secure transport mechanisms
8. **MU Note:** Has your facility started their reporting period for a stage of Meaningful Use?
 - a. If YES, what stage and when did you start?
 - b. If NO, when do you anticipate starting?

In addition to the questions, the initial dialogue will also discuss:

1. Sharing of contact information for key personnel responsible for ELR implementation on both the WVBPH and laboratory side.
2. Implementation Guides: WV utilizes the HL7 2.5.1 specification spreadsheet for Electronic Laboratory Reporting.
3. WVBPH will also ask for:
 - a. A list of what diseases will be reported via ELR.
 - b. An estimate on total volume by month or year.
 - c. List of LOINC and SNOMED codes.
 - i. LOINC and SNOMED codes will be reviewed by WVBPH staff to ensure that codes are appropriate for transmission to WVEDSS.
 - ii. **MU Note:** LOINC and SNOMED are required, local codes will not be accepted
 - d. Quality assurance method in which the laboratory will ensure that all laboratory results expected to be submitted are submitted via ELR. For every ELR received, we must receive a full validation copy of the lab report and for every lab report we must receive an ELR.
 - i. WVBPH will need the name and contact information for the person responsible for sending validation copies.

Phase 2: Connectivity

Phase 2 begins once all elements from Phase 1 are collected. In Phase 2, WVEDSS asks laboratories to test the connection between the EHR/LIS and the WVEDSS. West Virginia only supports connection through WVHIN or PHIN-MS.

PHIN-MS is free and can be obtained from the CDC at <http://www.cdc.gov/phn/tools/PHINms/installation.html> and support is also offered via the PHIN help desk at 800-532-9929 or phintech@cdc.gov. Please note that a certificate required for PHIN-MS expires annually and will need to be replaced, WVBPH ELR coordinator will assist in this action. WVHIN Participants will use MLLP + VPN. Certificates are not required.

WV requires that laboratories test their HL7 2.5.1 message via the CDC Message Quality Framework (MQF) or the National Institute of Standards and Technology (NIST) tools. The MQF tool can be accessed at: <https://www.cdc.gov/phn/index.html> and NIST via <http://hl7v2-elr-testing.nist.gov/mu-elr/>. West Virginia prefers that any identified errors are resolved or discussed prior to submitting a test message, along with sending the actual error report.

Once a PHIN-MS or WVHIN connection is set up at the laboratory and any errors with HL7 are corrected, the connection will be tested by a transmission of an HL7 message (with de-identified data) to the WVEDSS.

(MU Note: For the purposes of on-going submission, WV considers the MU ELR objective met when messages are successfully received through WVHIN or PHIN-MS, then validated and processed by the WVEDSS.)

Phase 3: Testing

Phase 3 starts once the connection between WVEDSS and the laboratory has been established. The primary purpose of the Testing Phase is to verify that the HL7 messages meet content and implementation guide criteria. CURRENT METHODS OF REPORTING WILL CONTINUE (i.e. fax or mail) until completion of Phase 4 – Production. The testing process may continue for 2-4 weeks and will not end until all issues identified are resolved.

Below we outline the main steps that will occur during this phase.

1. Test messages that are sent from the laboratory can be test cases found on the NIST site <http://hl7v2-elr-testing.nist.gov/mu-elr/> under the 'Context-based Validation' selection in the menu bar, "stock" test messages which have been used during testing with other states/partners with de-identified 'live' messages, or see Appendix A. The HL7 content should be identical to a "real" laboratory result with the exception that patient data are de-identified. A corresponding fax should also be sent to the WVEDSS staff person assigned.
 - a. Messages that are successfully consumed by WVEDSS will be checked against the paper result to ensure that all required information is available via ELR.

2. If the message fails to be consumed by the WVEDSS, the laboratory will be notified with the errors and assistance offered to resolve the issue if necessary/possible.
3. Lab results will also be reviewed to ensure that clinical information being presented is applicable to the disease.
 - a. While it is understood that all types of laboratory results that will be submitted to WVEDSS in Phase 4 cannot be accounted for in Phase 3, ensuring that clinical content is accurate should decrease the time spent in Phase 4.

Phase 4: Production

Phase 4 is divided into two stages: Parallel Production and Live Production.

Parallel Messaging starts when ELRs are sent to the WVEDSS Production Environment, while still sending paper laboratory results. The messages in this phase will contain actual patient demographic data and correspond to actual laboratory test results that are being reported to WVEDSS in real-time.

Parallel Production will be an ongoing process for 2-3 months. During this stage, paper laboratory results will continue to be submitted for each corresponding ELR. As in Phase 3, WVBPH staff will compare the paper laboratory results with those received electronically for content, accuracy, and completeness. West Virginia anticipates Parallel Production will be in place for 2-3 months before discussing shutting off paper reporting. The timeline is dependent on: the types of laboratory results verified, volume of anticipated laboratory results, and frequency of errors reported during Phase 4.

Live Production begins when WVEDSS determines that all issues with incoming ELRs during the Parallel stage have been resolved **and** there has been a minimum of 2 weeks of Parallel Production without any errors.

Phase 5: Maintenance

Once Phase 4 has been completed, the laboratory will have successfully transitioned to ELR reporting. Thereafter, the laboratory will be expected to notify WVEDSS of any changes to codes, HL7 message structure, addition/deletion of ELR for a disease, etc. Any changes that are determined to have a significant impact on ELR will require that some aspect of reporting will revert to Phase 4 of the guide and need to be tested and validated before changes can be implemented.

Contact Information

If you have questions please contact: Brittany Toler at brittany.a.toler@wv.gov and ELRonboarding@inductivehealth.com

Appendix A.

Tests and Findings for ELR Structural Validation

The following are different test scenario results that can be used to create HL7 messages for testing.

- 1) Order: Bacterial identification
Specimen: sputum
Finding: AFB 3+ positive smear.
Finding: Culture on same specimen identified *M. avium*
Finding: Sensitivity testing reveals sensitivity to Rifampin 1 ug/m
- 2) Order: Viral Hepatitis A,B,C or Acute Hepatitis Panel
Specimen: blood
Finding: Detected
Corrected finding: Not detected
- 3) Ordered: Bacterial culture
Specimen: stool
Finding: identified *Salmonella* (If lab does further speciation/typing please provide as much of the following information as the lab has the ability to determine, and present it as results from your lab would be presented: *S. enterica* subspecies *enterica* serovar Typhi.)
- 4) Order: *Borrelia burgdorferi* IgM Ab
Specimen: blood
Finding: EIA positive for *Borrelia burgdorferi*. Western blot band pattern P41, P 39, P23.
- 5) Ordered: Shiga-like toxin 1 (STX1) gene by probe
Specimen: stool
Finding: Detected
Corrected finding: Not detected
- 6) Ordered: Ova and parasite
Specimen: stool
Finding: *Giardia lamblia*
- 7) Ordered: Prenatal panel
Specimen: blood
Finding: HIV positive by DNA PCR
Finding: Reagin Ab titer in serum by RPR of 1:128

- 8) Ordered: HIV 1 RNA viral load by Probe and target amplification
Specimen: serum
Finding: <20

- 9) Ordered: Gonorrhea and Chlamydia by probe and target amplification method
Specimen: genital swab
Finding: *Neisseria gonorrhoea* Positive
Finding: *Chlamydia trachomatis* Negative

- 10) Ordered: SARS CoV-2 RNA (COVID-19)
Specimen: nasopharyngeal swab
Finding: Detected
Corrected Finding: Not detected