Introduction to Electronic Laboratory Reporting (ELR)

The Oregon ELR Project is an effort to convert laboratories from traditional paper-based reporting to electronic data interchange (EDI) with the Oregon Public Health Division (OPHD). In this system, the state health department functions as an electronic hub to accept, translate, and route lab and clinical data contained in HL7-formatted files. Laboratories report notifiable condition data to public health, and public health acts upon the data. The data transfer to the county level will be virtually immediate, and the county health department will continue to perform its current investigative responses.

Reports received by ELR are propagated within our integrated electronic disease surveillance systems, Orpheus and Opera. Orpheus is intended for local and state public health epidemiologists and disease investigators to efficiently manage communicable disease reports. Most case investigations are initiated by ELR, which are automatically imported and accessible to both local and state users, who can work together on cases. Orpheus is compatible with national standards, and complies with the highest level of security and confidentiality. Opera is utilized specifically for Coronavirus monitoring and disease investigation.

Benefits
ELR offers long-term benefits to both laboratories and public health. ELRs are critical for an effective public health response both for routinely reportable diseases as well as conditions of potential public health concern.

Laboratory benefits include:
- Automation of reporting reduces lab person hours and duplicate data entry
- Single data depository removes need for multiple county faxes and 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

Oregon Administrative Rules and ELR Resources
In June 2010, in an effort toward improving disease surveillance and timely notification of disease reports for public health intervention, ELR was legally mandated for all laboratories licensed in Oregon sending an average of more than 30 records per month to public health. For these laboratories, failure maintain ELR submissions may result in civil penalties Oregon Administrative Rules. For lower volume labs, ELR may still be beneficial in that these facilities will incur the same benefits of lower human error, reduced duplicative entry, etc. If sites are not able to establish data exchange results should be entered into the portals available on the OHA’s reporting website How and Where to Report. Please also review the general disease
reporting requirements on the following pages Oregon Disease Reporting Requirements and What and When To Report.

Further, OPHD is interested in working with any laboratory that is interested in participating in ELR in an effort to meet the Meaningful Use objective for Public Health Reporting.

References and Tools
If you have this document, you’ve probably already found the Oregon ELR website: http://www.healthoregon.org/elr. Here you can access the Oregon’s local HL7 2.5.1 Implementation Guide, Oregon’s Laboratory Reportable Poster, and links for nationally recognized standards like LOINC and SNOMED. There are also links for Oregon Public Health Meaningful Use and Oregon Administrative Rules. This document, along with the Oregon HL7 ELR Implementation Guide will assist you in developing, testing, validating, and delivering production level reports to OPHD.

If you choose to participate in ELR, reports must be submitted directly to the state ELR program; laboratories not participating in ELR are required to report directly to the Local Health Department (LHD) of the patient’s County of Residence.

ELR Readiness Checklist

The following checklist can be used to help determine your readiness to participate in ELR in Oregon. We are happy to provide assistance to labs as they work toward meeting these criteria. Please contact the Oregon ELR Project at 971-673-1111, via email at elr.project@dhsoha.state.or.us, or visit our website at www.healthoregon.org/elr for more information.

☐ Laboratory must either perform tests for which results are reportable by law to Oregon Public Health or incorporate results received from reference laboratories into their Laboratory Information System which can, in turn, be sent to Oregon Public Health. See the Oregon Administrative Rules (OARS) for Disease Reporting at [Disease Reporting] and the Laboratory Reporting Poster (http://www.healthoregon.org/elrresources) for details.

☐ Laboratory must be prepared to meet OPHD-specified reporting guidelines:
  ☐ Report all reportable disease data, including HIV, blood lead (and other reportable environmental exposures) through ELR.
  ☐ Report required data fields in acceptable HL7 format (as specified in the Oregon HL7 Implementation Guide, unless otherwise approved). The ELR program will work with labs to validate sample messages containing test data in order to test message translation.
Use standardized reporting codes (e.g., LOINC, SNOMED, and ICD). In some instances, it will be acceptable to provide us with a table of local laboratory codes, with the provision that the laboratory is actively working towards a goal of utilizing standardized codes. In this case, you will be asked to provide your local code set to Oregon’s ELR Coordinator in advance. [Note: Local code sets are not acceptable if attempting to meet Meaningful Use.]

Review OAR 333-018-0016 for COVID-19 Reporting and Variant Reporting Requirements

Provide complete patient address information in the report (street, city, state, zip and county).

Provide complete specimen information (type, collection method, and source site as appropriate).

If performing genetic sequencing there are two options:
1.) Send the sequencing results/SARS-CoV-2 lineage with the original (RT-PCR) or NAAT result that led to the decision to perform sequencing, if performed at the same laboratory or facility (parent-child test result-linkage, if possible).
2.) Send the sequencing results/SARS-CoV-2 lineage with the original RT-PCR or NAAT result that resulted in the decision to perform sequencing, if performed at the same laboratory or facility (no parent-child test result linkage).

see CDC link in Appendix A for more information

Submit reports in a timely manner (meet or surpass the required time specifications listed in the Oregon Administrative Rules).

Utilize an OPHD-approved secure transmission methodology. Currently accepted methods include secure file transfer protocol (SFTP) or via the Public Health Information Network Messaging System (PHINMS). Details on these methods and credential provision will be provided by OPHD.

Laboratory must have an emergency preparedness plan for reporting continuity in the event of emergency situations that would disrupt electronic communications. It is recommended that this backup plan utilize at least two alternative methodologies (e.g., fax, secure email). Initial and/or periodic tests of alternative methodologies may be requested.

Laboratory must agree to participate fully in Oregon’s Data Quality Control program. This includes specified duties such as periodic data checks, verification of reportable codes, etc.
Reporting Details

Initiating contact with the Oregon ELR Project is the first step in being able to craft a message for the purpose of communicating electronic laboratory reports. For sites that are attempting to meet the Meaningful Use objective, registration in the Public Health Meaningful Use Registration System (Oregon Meaningful Use) is also required. Once the request to establish an ELR feed with the ELR Coordinator is made, a kick-off call will be scheduled to discuss message format, standards, reportable conditions, and transport methodology. Once transport is decided, you will need to complete the requisite paperwork to establish transport credentials.

We recommend pre-testing structure and content of HL7 2.5.1 ORU messages using the Public Health Information Network Message Quality Framework (PHIN-MQF) as well as the National Institute of Standards and Technology (NIST) ELR Validation Tool (NIST Validation). These tools will aid in the construction of messages that conform to the Oregon Implementation Guide. Next, test messages will be sent to the Oregon ELR test environment where they will be reviewed by the ELR Coordinator. Once all parties are satisfied that the message content and structure are sufficient, you will move into an acceptance testing phase.

During acceptance testing you will send production data to our production environment, while continuing your existing reporting method (e.g., faxing the local public health authority). Laboratories will remain in acceptance testing for a minimum of 30 days. During this time, local public health nurses and state epidemiologists will compare the timeliness, completeness, and accuracy of the ELRs with your existing reporting method. As issues arise, they will be reported back to you for corrective action. If the volume of reporting is sufficient and when all identified issues have been resolved, the ELR Coordinator will solicit approval from the local health departments to move your facility to full production mode.

Once in full production, your facility will discontinue faxing reports and only send ELRs. Issues identified while in production (e.g., missing ELRs, lags, incorrect codes, etc.) are require immediate remediation. Failure to address issues will result in a return to acceptance testing (e.g., fax and ELR) until resolved. Issues not resolved in a timely manner, or failure to dual-report as requested may result in civil penalties.

Format

Currently, the recommended format for Oregon ELR is HL7 message type ORU R01, version 2.5.1. Oregon maintains a local implementation guide (available on our website) that mirrors the national standard but is abbreviated to include only those required and recommended elements relevant to Oregon ELR. This guide also includes an example of a susceptibility report that laboratories in Oregon may find helpful. We will consider accepting alternate formats (e.g., HL7 2.3.1) on a case by case basis, though it is important to note that any alternate format is not suitable for Meaningful Use.
**Standards and Coding**

Use of standardized reporting codes LOINC® and SNOMED is required. Links to these standards are available on our website and are referencing in the Oregon HL7 Implementation Guide. In addition, the Reportable Condition Mapping Tables (RCMT), which contain mapping between reportable conditions, LOINC test codes, and SNOMED result codes, can be accessed here as well. In some instances, it may be acceptable to provide a table of local laboratory codes, with the provision that the laboratory is actively working towards a goal of utilizing standardized codes. In this case, you will be asked to provide your local code set to in advance.

**Transport Method**

Laboratories must utilize an OPHD-approved secure transmission methodology. Currently accepted methods include secure file transfer protocol (SFTP) or via the Public Health Information Network Messaging System (PHINMS). The appropriate method will be determined on a case-by-case basis, and credential provision will be provided by OPHD once decided.

**Ongoing Quality Assurance**

The ELR data quality control plan consists of four-stages: development, testing, review, and maintenance. Labs entering ELR will progress through the stages as shown below. The following checklist summarizes the responsibilities of laboratories participating in Oregon ELR.

- **Stage I: Onboarding and Development**
  - Agree upon transmission method, set up procedures, begin formatting
  - Internal testing, confirm using NIST validation tool ([NIST Validation](#))

- **Stage II: Testing**
  - Laboratory transmits data to Oregon ELR for validation testing and transmission testing
  - Must conform to specification and include all required elements and code sets

- **Stage III: Acceptance Testing**
  - Laboratory begins regular transmission of production data in parallel with traditional reporting method (i.e., faxing to local health departments [LHD])
  - ELR timeliness and completeness are reviewed by state epidemiologists and LHDs
  - Remain in this stage for minimum of 30 days or until approval from state and LHDs

- **Stage IV: Production and Maintenance**
  - Monitor ongoing lab data quality and quantity. Serious problems may result in regression to Stage III: Acceptance Testing
Laboratory will participate in a yearly review of our ELR system to ensure the integrity of Oregon Public Health’s reporting system; this will include provision of LOINC and SNOMED codes as well as an audit list of selected reports determined by OPHD.
## Version History

<table>
<thead>
<tr>
<th>Revision History</th>
<th>Issue Date</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>March 7, 2012</td>
<td>Version created by JA Magnuson</td>
</tr>
<tr>
<td>4</td>
<td>May 26, 2016</td>
<td>Major revisions completed</td>
</tr>
<tr>
<td>5</td>
<td>August 27, 2021</td>
<td>Appendix A for COVID-19 Variants of Concern and Interest, COVID-19 Sequencing reporting requirements</td>
</tr>
</tbody>
</table>
Appendix A – Reporting of COVID-19 Related Test Results, Cases, and Deaths in Oregon

Update to **OAR 333-018-0016** requires that any laboratory that performs genetic sequencing of SARS-CoV-2 from a human specimen is required to report upon the completion of the genetic sequence analysis electronically to the Oregon Health Authority within 24 hours.

National standards for ELR message formatting should be used to report sequencing information ([CDC Coronavirus Sequencing Guidance and Technical Specifications](https://www.cdc.gov/coronavirus/2019-ncov/lab/seq-guidance.html)).

**OAR 333-018-0016**

**Reporting of COVID-19 Related Test Results, Cases and Deaths**

(1) Health care providers or other individuals described in OAR 333-018-0000(1) shall report, in accordance with section (3) of this rule and other applicable rules in OAR chapter 333, division 18, the following within 24 hours (including weekends and holidays):

(a) All human cases of COVID-19.

(b) All human cases of MIS-C.

(c) The hospitalization of any individual with COVID-19, whether or not the case was previously reported.

(d) The death of any individual due to COVID-19, whether or not the case was previously reported.

(2) Health care providers or any individual who is authorized to conduct a waived laboratory test in accordance with the federal Clinical Laboratory Improvement Amendments of 1988 shall report all negative test results for COVID-19 in accordance with section (3) of this rule and other applicable rules in OAR chapter 333, division 18, within one local public health authority working day.

(3) Health care providers shall report the information required in sections (1) and (2) of this rule, in one of two ways, in order of preference, in addition to complying with other applicable rules in OAR chapter 333, division 18:

(a) Submission of an Electronic Initial Case Report (eICR) in accordance with the Authority’s Electronic Case Reporting (ECR) Manual; or

(b) Through the Online Morbidity Report System, which can be found at: [www.healthoregon.org/howtoreport](http://www.healthoregon.org/howtoreport).

(4) When more than one health care provider may know the information that is required to be reported under sections (1) and (2) of this rule, they may establish policies and procedures to ensure that the information is reported to the local public health administrator or Authority as required, but duplicate reporting is minimized.
(5) Licensed laboratories shall report, in accordance with OAR 333-018-0013 and other applicable rules in OAR chapter 333, division 18:

(a) All test results indicative of and specific for COVID-19 within 24 hours (including weekends and holidays).

(b) All negative test results for COVID-19 within one local public health authority working day.

(6) Any laboratory that performs genetic sequencing of SARS-CoV-2 from a human specimen shall, within 24 hours of completion of the genetic sequence analysis, report to OHA electronically in accordance with the Authority’s Electronic Laboratory Reporting (ELR) Manual, the following:

(a) Required elements in the electronic reports;

(b) The identity of any SARS-CoV-2 sequence designated by the federal Centers for Disease Control and Prevention as a Variant of Concern or a Variant of High Consequence; and

(c) The GISAID Accession ID, if known.

(7) Any laboratory that has performed genetic sequencing of SARS-CoV-2 from a human specimen prior to April 19th, 2021, shall report to OHA electronically no later than April 30, 2021, the information required in subsection (6) of this rule, in a manner approved by OHA.

Laboratories that are performing COVID-19 Genetic Sequencing from a human specimen must report the results to the Oregon Health Authority in accordance with the Electronic Laboratory Reporting Manual’s direction: (6) Any laboratory that performs genetic sequencing of SARS-CoV-2 from a human specimen shall, within 24 hours of completion of the genetic sequence analysis, report to OHA electronically in accordance with the Authority’s Electronic Laboratory Reporting (ELR) Manual, the following:

(a) Required elements in the electronic reports;

(b) The identity of any SARS-CoV-2 sequence designated by the federal Centers for Disease Control and Prevention as a Variant of Concern or a Variant of High Consequence; and

(c) The GISAID Accession ID, if known.

(7) Any laboratory that has performed genetic sequencing of SARS-CoV-2 from a human specimen prior to 04/19/2021 THROUGH 10/15/2021, shall report to OHA electronically no later than April 30, 2021, the information required in subsection (6) of this rule, in a manner approved by OHA. Temporary Rule PH 15-2021 Chapter 333-COVID Sequencing.