Oregon Public Health Division Manual for Electronic Laboratory Reporting

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ACDP.Informatics@dshoha.state.or.us Tel. 971-673-1111

FAX 971-673-1100



Oregon Electronic Laboratory Reporting

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Introduction to Electronic Laboratory Reporting (ELR)

The Oregon ELR Project supports the conversion of laboratory reporting from traditional paper-based reporting to electronic data interchange 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. Sites using electronic systems that are not HL7 capable, may be approved to use the Oregon specific comma delimited file to submit ELR information. Laboratories and clinicians report notifiable condition data to public health, and public health acts upon the data. The ELR data becomes available to the local public and tribal health departments soon after the record is received and processed. With this information, the departments perform appropriate investigative responses.

Reports received by ELR are propagated within integrated electronic disease surveillance systems, Orpheus and Opera. The systems are intended for tribal, 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 and Opera are compatible with national standards, and comply 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 laboratories, healthcare providers, 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

Healthcare Provider benefits include:

- Improved reporting patient demographics which reduce the need for additional outreach
- Increased accuracy of data being reported
- Offers consistency checks for various data sources

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 to improve 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. All healthcare providers ordering laboratory testing must also report the results (dual-reporting) for any laboratory testing completed in clinic or sent out to an off site laboratory.

Failure to maintain ELR submissions may result in civil penalties <u>Oregon Administrative Rules</u>. For lower volume sites, 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 <u>How and Where to Report</u>. Please also review the general disease reporting requirements on the following pages <u>Oregon Disease Reporting Requirements</u> and <u>What and When To Report</u>.

OPHD declared readiness to receive ELR in 2015 and will work with eligible providers trying to meet the <u>Promoting Interoperability Program</u> (aka Meaningful Use) ELR objectives for Public Health Reporting. ELR interfaces fulfill one of the Public Health and Clinical Data Exchange objective measures for the 2022 IPPS final rule requirement.

Reporting laboratory data for special studies (i.e., non-reportable conditions, sequencing of historic specimens, or collection of data elements beyond what is required in rule), may be reported through alternative mechanisms as specified and approved by the special study coordinator.

References and Tools

If you have this document, you've probably already found the Oregon ELR website. Here you can access the Oregon's local HL7 2.5.1 ELR Implementation Guide, Oregon's .csv ELR Implementation Guide, Oregon's Laboratory Reportable Poster, and links for nationally recognized standards like LOINC and SNOMED. Sites using electronic systems that are not HL7 capable There are also links for Promoting Interoperability Information 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.

ELR Readiness Checklist

The following checklist can be used to help determine a site's readiness to participate in ELR submission to Oregon. We are happy to provide assistance to sites as they work toward meeting these criteria. Laboratory and ordering provider's 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.

Laboratories and ordering provider's 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 or Electronic Health Record System which can, in turn, be sent to Oregon Public Health in a readable format. See the Oregon Administrative Rules (OARS) for Disease Reporting at (Disease Reporting) and the Laboratory Reporting Poster			
Site	es 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 site 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, Variant Reporting Requirements, and Special Studies reporting requirements.		
	Provide complete patient first and last name, date of birth, race, ethnicity, language, and sex.		
	Provide complete patient contact information in the report (phone, 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 the APHL AIMS Platform. Sftp credential provision will be provided by OPHD. Site 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.

☐ Site 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. Please do this by completing the <u>Electronic Laboratory Reporting Partner Onboarding Questionairre</u>. 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 confirm registration as a business with the Oregon Secretary of State <u>Find a Business</u> OR <u>Register your Business</u> and sign a User Access Agreement provided to you by Onboarding Staff to establish transport credentials.

We recommend pre-testing structure and content of HL7 2.5.1 ORU messages using the National Institute of Standards and Technology (NIST) <u>ELR validation tool</u>. This tool 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). Sites 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.) require immediate remediation. Failure to address issues will result in a return to acceptance testing (e.g., fax) until resolved. Issues not resolved in a timely manner, or failure to dual-report as requested may result in civil penalties.

Format

Health Level 7 (HL7) version 2.5.1 unsolicited observation messages (ORU) that conform to Centers for Disease Control and Prevention standards and meet Oregon's programmatic requirements are the preferred submission format. HL7 2.5.1 format must be utilized to meet Promoting Interoperability requirements. Oregon maintains a <u>local implementation guide</u> that mirrors the national standard but is abbreviated to include only those required and recommended elements relevant to Oregon ELR. Some items listed in the local implementation guide are considered programattically required as they are data elements necessary to complete Public Health Investigations in Oregon. This guide also includes an example of an HL7 message with susceptibility results that sites may find helpful.

The option of an Oregon specific comma separated value file is available on a case by case basis for sites that are unable to generate HL7 messages. <u>Oregon's CSV (Alternative Format) ELR Implementation Guide (pdf)</u>

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) and other code sets can be located in PHIN VADS Tables. In some instances, it may be acceptable to provide a table of local laboratory codes, with the provision that the site is actively working towards a goal of utilizing standardized codes. In this case, you will be asked to provide your local code set to the ELR team in advance.

Transport Method

Sites must utilize an OPHD-approved secure transmission methodology. Currently accepted methods include secure file transfer protocol (SFTP) or via the <u>APHL AIMS Platform</u>. Credentials will be provided by OPHD for SFTP to partners after a user access agreement is signed by the partner organization.

Ongoing Quality Assurance

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

Stage I: Onboarding and Development			
☐ Submit information to the ELR Project team to be added to the onboard queue			
 ELR Partner Onboarding Questionairre 			
☐ Establish transmission method			
 Confirm registration as a business with the state of Oregon 			
	 Sign user access agreement for Oregon sftp 		
☐ Set up procedures and begin formatting			
☐ Internal testing, confirm using NIST ELR validation tool			
Stage II: Testing			
☐ Site 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			

	Site 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		
Sta	age IV: Production and Maintenance		
	Monitor ongoing lab data quality and quantity. Serious problems may result in regression to Stage III: Acceptance Testing		
	Site will participate in a yearly review of ELR submitted to ensure the integrity of Oregon Public Health's reporting system; this will include use of proper LOINC and SNOMED codes as well as an audit list of selected reports determined by OPHD.		

Contact Us

Please contact the Oregon ELR Project via email at <u>ACDP.Informatics@dshoha.state.or.us</u>, the ACDP main line at 971-673-1111, or visit our website at <u>www.healthoregon.org/elr</u> for more information.

Version History

Revision History	Issue Date	Summary of Changes
3	March 7, 2012	Version created by JA Magnuson
4	May 26, 2016	Major revisions completed
5	August 27, 2021	Appendix A for COVID-19 Variants of Concern and Variants of Interest, COVID-19 Sequencing reporting requirements.
6	October 6, 2021	Updates to Appendix A for COVID-19 Variants of Concern and Variants of Interest, COVID-19 Sequencing reporting requirements. Added new language for OHA sanctioned special studies and new terms Variants being Monitored and Vaiants of High Consequence as listed in OAR 333-018-0016.
7	January 4 th , 2023	Removed PHINMS as a sending option, added link to COVID-19 reporting amendment, updated hyperlinks, changed acceptable version of messaging from HL7 2.3.1 to CSV. Requiring HL7 2.5.1 as standard. Updated ELR Readiness Checklist and Quality assurance checklist. Updated contact email. Added new language addressing programmatic requirements.

Appendix A – Reporting of COVID-19 Related Test Results, Cases, and Deaths in Oregon

Update to <u>OAR 333-018-0016</u> requires that any site 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).