CalREDIE Electronic Laboratory Reporting (ELR) Quality Control Guide

Purpose

The purpose of this document is to describe a recommended protocol for local health departments (LHDs) to use when performing Quality Control on CalREDIE electronic laboratory reporting (ELR) results. **LHDs can customize this protocol as needed.**

Background

As laboratories transition from sending paper lab reports to ELR, local health departments will want to ensure that incoming ELR results match the lab results received via paper. Below is a recommended protocol for performing ELR Quality Control which was developed based on CDPH and ELR Pilot County experiences. **Ultimately, it is up to each LHD to decide what level of Quality Control to perform.** LHD users should be aware that when ELR is ready for Quality Control by the LHD, several levels of Quality Control have already taken place (see below for a description).

Key Terms

ELR: ELR is the electronic submission of laboratory results to CalREDIE.

Submitter: Submitter is the entity that sends ELR to CalREDIE. This can be a laboratory, hospital or Health Information Exchange (HIE).

HL7: HL7 is the message format that ELR is sent in; it is highly standardized and used worldwide.

ELR Staging Environment: The ELR Staging Environment is a special version of CalREDIE which will only be used for ELR testing. The ELR Staging Environment contains real patient data. It is NOT expected that data in CalREDIE production will match all data in the ELR Staging Environment. Data in the ELR Staging Environment are not migrated to CalREDIE production. The data in the ELR Staging Environment are destroyed periodically.

Disease Incident Staging Area (DISA): This is the area in CalREDIE where ELR reports appear. LHD users must review the reports in the DISA and then import them into CalREDIE, unless systematic changes have been implemented for certain diseases to be auto-imported.

Protocol

LHD Set-up

1. Determine which staff member(s) will be involved in ELR Quality Control.
    - *Pilot County Tip: Individuals doing this work should be computer savvy, already familiar with CalREDIE and detail oriented. They should also have an understanding of how to read laboratory values so they will be able to check the accuracy of the lab information that has been imported.
2. Select the scope of Quality Control
    - Date Range: Determine the time period for your Quality Control. This can vary from 1 day to several weeks. *CDPH recommends:* two to four weeks.
        - *Pilot County Tip: The date a paper lab report is sent and date an ELR is sent may not be the same. This is something to be aware of when conducting Quality Control.
        - In addition, if a test is part of a panel or reflex testing, the ELR for each test may come as the test is completed but the paper report may not come until all the tests on the panel are completed, so there may be many "dates received".
    - Diseases: Determine which diseases you will use for the Quality Control process. *CDPH recommends:* For low-volume diseases, check each lab report. For high-volume diseases (e.g. STD and hepatitis B and hepatitis C) check approximately 10%-50% of reports expected during the established time period, pending LHD staff availability. If 10%-50% of reports are still too many check a certain number, such as 30-50 reports.

LHD QA/QC

1. Verify the paper report has a corresponding ELR result in the CalREDIE DISA.
    - With the paper lab report in hand, log into the CalREDIE ELR Environment (https://calrediestaging.cdph.ca.gov/WebCMRELR/Pages/Login/Login.aspx) and go to the DISA.
    - Visually inspect the paper report and locate the corresponding result in the DISA.
        - *Pilot County Tip: Within the DISA, select the incident and click on View Patient's Lab Report to check the data before importing the record. This brings up information that will be imported to the Electronic Filing Cabinet (EFC). It is easier to pre-check the data, as opposed to importing the record and then verifying the data. Pre-screening in the staging area allows for easier QA vs. catching errors following import.
2. Import ELR report from DISA.

3. Open imported report and verify that Lab System Section and PDF report in EFC are populated correctly, including dates, specimen types, values, units, interpretation, comments.
4. Keep a record of which reports have been reviewed.

Reporting Errors and Issues

1. Report Quality Control Issues and Questions using the Excel template.
    - The template contains the following:
        - LHD Name
        - LHD ELR Contact Person
        - Date QC Issue Occurred
        - Date of Incoming Lab or Result Date
        - CalREDIE ID Number (either Incident ID if imported or Case ID if in DISA)
        - Lab Report Accession Number
        - Lab Name
        - CLIA #
        - Description of Issue
        - Description of any steps taken by LHD to address issue

CDPH Support

1. CDPH will follow-up on all reported issues and questions. ELR quality issues usually fall into one of the following categories:
    - **Submitter Issues**
        - For example, the submitter is sending the wrong information or information which does not make sense. In this case, the CalREDIE ELR team will help the LHD work with the submitter to facilitate a way to mitigate the issue.
    - **CalREDIE Issues**
        - For example, the submitter sends the correct information, but CalREDIE processes the information incorrectly. In this case, the CalREDIE ELR team is responsible to investigate and propose a way to mitigate the issue.
    - **Issues requiring a change in business process locally**
        - For example, the submitter is sending the correct information, and CalREDIE is processing it correctly, but the local health department does not have a process to handle this information. In this case, the LHD is responsible for adapting its business processes.
    - **Policy Issues**
        - Lab reporting policy issues are those issues where the submitter is complying with the existing reporting regulations (or other law or policy) but the public health agency is still not satisfied with the

reporting result, i.e. the regulations do not specifically require the submitter to submit the information that public health professionals need to do their jobs. An example of this might be negative results, [treponemal EIA positives that are RPR and TPPA-negative] which are not specifically reportable, but which are frequently significant for public health case management or interpretation. In this case, the CalREDIE ELR team will note the policy need and the LHD will be responsible to take the policy need to the appropriate forum, such as CCLHO.

Submitter + CDPH/CalREDIE Quality Control

Keep in mind that by the time a submitter is ready to send ELR for LHD Quality Control, several layers of QC testing have already take place, both by the submitter and CDPH**.**

Submitter Quality Control

- CDPH/CalREDIE operates under the assumption that the submitter performs compliance testing and quality control within its own systems to ensure that it complies with 17CCR2505 and other applicable regulations and laws governing lab reporting to public health agencies. CDPH/CalREDIE does not analyze or approve the submitter lab information system trigger logic for reportable conditions.

CDPH/CalREDIE Quality Control

- At CDPH/CalREDIE, incoming ELR messages go through a program driven, automated structural validation scheme. ELR messages are parsed and analyzed in order to determine whether the reported item is allowed in CalREDIE and whether the result belongs to a jurisdiction using CalREDIE. Reports for non-CalREDIE jurisdictions are routed appropriately.
- CDPH/CalREDIE ELR team performs quality control measures for incoming lab messaging on the basis of the mechanics of messaging and data flow.
- CalREDIE ELR team reviews message exceptions/errors captured in the automated intake.
- CalREDIE ELR team has developed an automated algorithm to detect and alert system administrators when a submitter falls significantly outside of its established submission pattern. When this occurs, CalREDIE ELR team contacts the submitter for further information.

Things to Remember

- Although it is reasonable to expect that for every paper report (existing reporting standard) there will be an ELR result (new reporting standard), the ELR and paper reports will often NOT match up exactly, one-to-one. Other local health departments and other states that have already transitioned to ELR report up to a

30% increase in ELR results as opposed to paper. The goal is to have the new reporting standard at least as good if not better than the old reporting standard.

- The CDPH/CalREDIE team will host weekly calls to discuss Quality Control questions and issues.