

Establishing Electronic Laboratory Reporting (ELR) Steps and Definitions

This document was created after the 2014 CSTE Annual Conference by the CSTE Electronic Laboratory and Disease Reporting Subcommittee – chaired by Kathryn Turner, PhD, MPH. The document was created by consensus within the subcommittee to define common steps throughout the ELR process, from registration to post-production. Variation may exist in the order of how steps are executed by jurisdiction.

STEP 1: PRE-INITIATION

Registration

Registration is a process in which a facility communicates with a Public Health Agency (PHA) their interest or intent to implement electronic laboratory reporting. During the registration process the PHA might collect information about the facility and their electronic health record (EHR) capabilities. For eligible hospitals participating in Meaningful Use (MU), this registration may serve as the ‘Registration of Intent’ as per Federal Register Rules for MU Stage 2. *Each PHA is responsible for providing the mechanism for registration and the registration process might differ between PHAs (e.g., questions asked on the registration form). PHA’s may permit the registration of more than one related (or affiliated) facilities at a time.*

Engagement Planning and Readiness Assessment

- *Engagement planning* is a process in which the PHA communicates with the registered facility to determine:
 - Review of facility registration
 - eligibility for onboarding;
 - PHA-specific process and steps;
 - expectations for communication and points of contact; and
 - additional information or documentation to be provided or received by the PHA (e.g., implementation guides, reportable disease and conditions list, required transport mechanisms, coding schema).
- *Readiness Assessment* activities will include an evaluation of the registered facility’s ability to engage in electronic laboratory reporting. The Readiness Assessment will vary by PHA, but may include:
 - A high level review and evaluation of vocabulary being used,
 - an assessment of message structure compliance ability, and
 - PHA requirements for the registered facility to use the National Institute of Standards and Technology (NIST) tool for testing messages.
 - Review of available transport methods.

Placement in Queue

Registered facilities are placed in queue to await an invitation from the PHA to onboard. *The date of placement in the queue is not an indicator of timeframe for invitation to onboard. The order in which the PHA will extend invitations to registered facilities will be based on jurisdiction-specific criteria (e.g., results of the Readiness Assessment, available PHA resources).*

Invitation to Onboard

When the invitation to onboard has been made by the PHA, specific response timeframes associated with Meaningful Use are effective, or, if not implementing ELR for Meaningful Use, the PHA will indicate expectations for communication and timelines specific to the PHA. These same timeframes may be used by the PHA with laboratories who are not enrolling in Meaningful Use. The PHA will request specific actions on the part of the registered facility to move toward Step 2: Initiation. Based on the Readiness Assessment and the specific needs of the PHA, some common parallel processes that *might* be started at this time include:

- A detailed review and evaluation of vocabulary,
- a detailed assessment of message structure and specific components, and
- a review of code mapping.

STEP 2: INITIATION

Review of Laboratory Results Generated and State Reportable Disease Mandates

If not previously completed, the facility and PHA will engage in an in-depth review of the test results generated by the facility, and what results are reportable to the PHA and in what timeframes, and whether there are conditional reporting requirements (e.g., only children, only invasive infections). *What is reportable to PHAs and required timeframes are NOT within the authority of federal-level agencies (e.g., CDC). The authority for requiring and enforcement of Public Health reporting and disease control activities resides with states, territories, and some local jurisdictions. Each PHA may choose which diseases or events are of public health importance within their jurisdiction and, therefore, there are differences between the diseases, conditions, and laboratory results each PHA requires to be reported.*

NIST Tool Validation

The PHA may require the facility to test their ELR messages using the National Institute of Science and Technology (NIST) Electronic Lab Reporting tool. NIST is the body that certifies Electronic Health Records and therefore tests the expectations for certified electronic health record technology. The ELR NIST tool is specifically intended to help facilities validate their messages meet the requirements of Meaningful Use. Results of the validation may be required to be submitted to the PHA before additional steps are taken. *Some PHAs may require other certification tools or alternative certification tools.*

Vocabulary Validation

During this process, if not completed earlier, the PHA will assess the data that are being sent in the messages to ensure the data are appropriate (content of the message meets expectations) and data provided are reliable, valid, and complete enough to take public health action on.

Mapping

Mapping of laboratory test order/result codes used by the facility to standard codes (LOINC and/or SNOMED) is a critical step. *The PHA may require facilities to use certain tools to accomplish mapping and some PHAs may have a person-resource available to aid facilities. The mapping process will vary between PHAs based on resources.* Tools that might be used include the Reportable Conditions Mapping Table (RCMT) available for nationally notifiable diseases, the Regenstrief LOINC Mapping Assistant (RELMA), or other PHA-specific tools.

Pre-Acceptance Structural Testing and Validation

The goal of pre-acceptance testing is to evaluate the structure and content of messages and the process will vary by PHA. For instance, the messages evaluated could include fake or “dummy” data or might be actual messages generated from the facility’s Test system. This process might require a stepwise approach based on results volume and the type of tests that are being sent and will vary based on the resources and the testing procedures of the PHA. During this time, if not completed earlier in the process, the facility will be responsible for ensuring they are able to conform to the **transport mechanism required by the PHA.**

STEP 3: ACCEPTANCE TESTING

Messages from Facility’s Production System

At this stage, the facility is sending actual production messages with actual patient data, but the *messages are not yet going through the PHA production system or being used for public health investigation or intervention.*

Additional Evaluation

Evaluation will continue regarding message structure, content, and transport. Refinements will be made as needed until messages are acceptable for PHA **production processing and usage** for PHA public health investigations and interventions.

Parallel Validation

A comparison of reporting via currently used reporting mechanism (e.g., paper) versus ELR might begin at this stage. Each PHA will address this process differently depending upon resources and processes specific to the PHA. *Criteria for the length of time or quantity of reports that must be received during parallel validation will vary by PHA.*

- PHAs will communicate expectations, timelines, and thresholds associated with parallel reporting evaluation if it begins during Acceptance Testing.
- In some PHAs, validation of laboratory data being received may be conducted by Subject Matter Experts (SMEs) (e.g., Epidemiologists) within the agency.
- PHAs will provide feedback to reporters regarding parallel validation activities.

STEP 4: PUBLIC HEALTH AGENCY PRODUCTION**Parallel Validation**

If parallel validation was implemented during Acceptance Testing, that process will continue during this stage. If parallel validation was not implemented, it will be initiated at this stage. *Criteria for the length of time or quantity of reports that must be received during parallel validation will vary by PHA.*

- PHAs will communicate expectations, timelines, and thresholds associated with parallel reporting evaluation.
- PHAs will provide feedback to reporters regarding parallel validation activities.
- In some PHAs, validation of laboratory data being received may be conducted by Subject Matter Experts (SMEs) (e.g., Epidemiologists) within the agency.

Error and Failure Queue Monitoring

The PHA will evaluate the facility's reporting by monitoring failed messages or errors, as determined by the PHA (e.g., missing minimum required fields, unexpected changes in message structure, or inappropriate content). The PHA will, in an ongoing manner, work with the facility on solutions for identified errors and failures. *Communication regarding errors and failures will differ by PHA, depending upon the systems, tools, and processes in place at the PHA for validation and monitoring.*

STEP 5: POST PRODUCTION

Quality Assurance – Internal Validation and Follow-up

The intent of internal Quality Assurance (QA) activities is to ensure in-production processes are working as expected. QA and internal validation activities are ongoing after ELR has been implemented and will vary substantially depending upon PHA processes, resources, and staffing. As part of the ongoing QA activities, PHAs will communicate with facilities as needed. Activities that might be ongoing include:

- Lab-specific volume reports may be run by the PHA to monitor quality. Feedback to facilities could be ad-hoc, during regular status check-ins, or on a pre-determined schedule, depending upon PHA processes and resources.
- Regular checks of the failed messages or error queues (e.g., missing minimum required fields). Feedback to facilities could be ad-hoc as problems are identified or more regular, regardless of whether problems have been identified or not, depending upon PHA processes and resources.

Quality Assurance – External Validation and Follow-up

The intent of external validation is to ensure a process is in place after paper reporting is discontinued to assess the comprehensiveness and quality of electronic reporting from facilities. In some jurisdictions, external validation activities might include all reporting facilities or a sample of facilities. It might be completed monthly, quarterly, annually, or on some other schedule. In some instances, it might be conducted ad-hoc if a problem is identified or suspected. Activities that might be ongoing include:

- The PHA provides reports to the facility for them to check against their system to identify missing or incomplete messages.
- The facility provides a report of messages or data that was sent to the PHA for the PHA to compare with what was actually received.
- The PHA might produce a “Report Card” or “Dashboard” of what is being received by the PHA by the facility.
- In some PHAs, the laboratory licensing authority might perform external validation activities.

Ongoing Communication

Each PHA will have processes for ensuring ongoing communication and will provide the facility with those processes and expectations. At the minimum, the facility is expected to ensure the PHA has current contact information. Minimum requirements of communication include:

- The PHA providing facilities with information regarding continuity of operations and processes that would be implemented in the event the electronic feed is not available for receiving ELR.
- Facilities must notify the PHA about changes to the structure and content of messages sent to the PHA or changes to the Laboratory Information System or technology at the facility.

- Facilities must notify the PHA about changes to testing methodologies and algorithms or if the facility adds or discontinues a test that would generate a reportable result.
- The PHA will provide facilities with information about changes in reportable disease rules and laws, requirements for what should be sent to the PHA, or changes in transport method.