TN Department of
Health

Communicable and Environmental Disease and Emergency Preparedness
Surveillance Systems and Informatics Program

Electronic Laboratory Reporting Frequently Asked Questions

The following are answer to questions commonly asked by trading partners before and during the on-boarding process. If you have additional questions, please contact the ELR team at CEDS.Informatics@tn.gov.

1. **What constitutes ELR in TN?**
   In TN, ELR is the electronic submission of laboratory results thought to be indicative of a reportable condition, disease, or event, as described by the TDH, using interoperability standards (HL7 messaging). Flat file submissions, emails, and other formats are not considered to be ELR in TN, even if transmitted electronically.

2. **How will TDH use the data I send in ELR messages?**
   The ultimate goal of ELR is for the TDH surveillance systems to be able to consume that data so it can be used for public health action. TDH must ensure adequate and reliable information in those systems. Because of this, TDH will not use the data during testing in production surveillance systems. Once the ELR message content and structure is at an agreeable state, TDH will discuss moving the trading partner into production.

3. **What HL7 versions can TDH currently receive for ELR?**
   TDH is currently able to receive both HL7 2.3.1 and HL7 2.5.1 for ELR following the respective standards and implementation guides. TDH expects messages to be formatted based on the following hierarchy, where each document is a constraint upon the one below
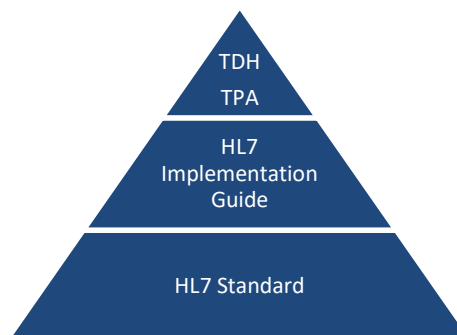
it.

The HL7 Standard contains the order and structure of data fields in detail and the HL7 Implementation Guide contains constraints specific to public health reporting and focuses on one type of HL7 message, the ORU^R01 message. This handbook and the TDH TPA contain TDH-specific constraints and exceptions to the HL7 Implementation Guide as well

as additional requirements specific to TDH to support electronic exchange of laboratory results of reportable diseases in the State of Tennessee.

For more information on the HL7 standards and the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with errata, please visit http://www.hl7.org/implement/standards/product_section.cfm?section=5. To obtain a copy of the Implementation Guide for Transmission of Laboratory–Based Reporting of Public Health Information using Version 2.3.1 of the HL7 Standard Protocol (dated March 2005), please visit https://www.cdc.gov/elr/technicalstandards.html. Please contact TDH for a draft copy of the TDH Trading Partner Agreement.

4. **Do you require the use of standard vocabulary?**
Yes, we require the use of standard vocabulary and value sets, including but not limited to LOINC, SNOMED, and UCUM. LOINC codes and associated descriptions are required for all observation identifiers (OBX-3). TDH expects all coded observations values (OBX-5) to use SNOMED codes and associated descriptions. This applies to all ordinal results such as positive and reactive as well as nominal results for organism names. This does not apply to numeric or structured numeric observation values.

5. **Why am I required to submit a vocabulary list to TDH?**
TDH has found that vocabulary is one of the most time-intensive aspects of ELR validation. To expedite that process, TDH has worked vocabulary validation into the ELR on-boarding process. During this validation, TDH will work with your facility to ensure only reportable lab results are being sent, verify the tests that are performed in-house and those performed by reference laboratories, confirm that the LOINC and SNOMED codes being sent are valid and descriptions are accurate, check for internal consistency between LOINC code, result type, and specimen source, and work out potential content issues on the front-end.

6. **Will TDH map my local codes? If not, what tools are available for vocabulary mapping assistance?**
TDH will not map local codes to standard codes. TDH will only accept local codes if sent with the corresponding standard vocabulary. The two best places to find vocabulary mapping assistance include RELMA from the Regenstrief Institute (http://loinc.org/relma) and CDC's PHIN VADS (Vocabulary Access and Distribution System) where you can find a wide variety of vocabulary and tools, including the Reportable Condition Mapping Tables (RCMT) (http://phinvads.cdc.gov/vads/SearchHome.action).

7. **What web based tools are available to assist me in validating my message structure?**
TDH uses free, online ELR message tools to assist in validation. Examples include the NIST HL7 2.5.1 Validation Suite for certifying 2014 and 2015 Edition Meaningful Use EHR technology (http://hl7v2-elr-testing.nist.gov/mu-elr/) and the CDC's Message Quality Framework (MQF) tool (https://phinmqf.cdc.gov/). TN recommends potential trading partners, including those just interested in testing for Meaningful Use, to first validate their messages using the NIST tool and make any necessary corrections, prior to submitting to TDH for testing. TDH recognizes that not all errors received from the NIST or MQF validation are of equal importance; some may be accepted by TN.

8. **What is reportable in TN?**
   The list of reportable diseases and events is updated annually and can be found on the TDH website: https://apps.health.tn.gov/ReportableDiseases. For information specific to lab events, please see the Reportable Diseases and Events Laboratory Reporting Guidance document: https://apps.health.tn.gov/ReportableDiseases/Common/2017_Detailed_Laboratory_Guidance.pdf .

9. **What methods of transport are available to send ELR to TDH?**
   Secure file transport protocol, or SFTP, is the preferred method of transport for ELR with TDH. This can be set up either by creating a username and password for the account or by exchanging public keys. A username and password is created by default, but utilizing the exchange of public keys is ideal as passwords expire every 90 days. Additional mechanisms may be available and can be discussed upon establishment. TDH does not establish secure transport with trading partners until vocabulary validation is completed and most structural message errors have been resolved. Please see the ELR on-boarding process on page 5 for more information.

10. **If my lab starts to send ELR to TDH, will we have to continue sending paper lab reports?**
    Paper lab reports will only be discontinued once the ELR have been validated against them for a pre-determined amount of time, depending on lab report volume. Paper reporting can only be discontinued for the lab results included in ELR. If your facility is not utilizing ELR to meet all reporting obligations (e.g., not capturing results performed by reference laboratories), those lab reports will still need to be reported on paper. In the event that an ELR is not received, but TDH is notified of lab results from a provider, then TDH will require that paper/manual lab report submission from the lab resume until ELR is validated once again.

11. **Does ELR fulfill my reporting requirements to TDH?**
    Yes, however, ELR reporting by laboratories does not nullify the health care provider's or institution's obligation to report diseases and events, nor does reporting by health care providers nullify the laboratory's obligation to report reportable lab events. Laboratory reporting, including ELR, is not the same as case reporting by health care providers.

12. **Will my lab need to send the tests performed by reference lab facilities?**
    Yes. According to Tennessee Rules and Regulations, ELR must include lab reports for tests performed in-house and by reference laboratories, with the performing organization appropriately documented in the ELR message. If you are unable to appropriately document the performing organization or utilize standard vocabulary for those results sent to reference labs, paper lab reporting of those lab results will be expected.

13. **How long does the on-boarding process take?**
    For an estimated timeline, please see the ELR on-boarding process on page 5. The actual time to production really depends on the readiness of the trading partner and on how many other trading partners TDH is currently on-boarding. For this reason, we recommend that potential trading partners complete all of the pre-registration activities on page 8 prior to sending their first test message.

14. **How do I get started?**

The first step in the ELR on-boarding process is registering intent with TDH. To assist trading partners with tracking their progress through the ELR on-boarding process, TDH developed the ELR on-boarding checklist (page 8). This list is recommended for trading partner use, but will not be required to be completed and submitted to TDH. Before starting the on-boarding process, TDH recommends:

   a. Mapping local lab test codes to LOINC standard vocabulary
   b. Mapping local, non-numeric test result values to SNOMED-CT standard vocabulary
   c. Mapping other local codes according to the HL7 2.5.1 Implementation guide: Electronic Laboratory Reporting to Public Health (US Realm)
   d. Obtaining a copy of the HL7 2.5.1 Implementation guide: Electronic Laboratory Reporting to Public Health (US Realm)
   e. Working to develop conformant messages for all result types
   f. Testing those messages using the NIST HL7 ELR 2.5.1 Validation Suite
   g. Resolving message issues found using the NIST HL7 ELR 2.5.1 Validation Suite

15. **I received a letter from Tennessee Department of Health stating my facility/health system is "not a target for continued testing and validation of ELR with TDH and has been placed in the TDH ELR on-boarding queue." What does this mean?**

This letter is to inform you that you are in our ELR on-boarding queue and will be contacted in the future to continue testing and validation of ELR with TDH. We ask that you continue to report all reportable diseases and events in accordance with your current reporting methods.

16. **What information should I include in the message subject header (MSH)?**

TDH accepts either CLIAs or OIDs in MSH-4 (Sending Facility). For MSH-5 and MSH-6, TDH expects the OIDs below. For other MSH components please see question 17.

   a. [MSH-5] Receiving Application – 'tdh-ELR^2.16.840.1.113883.3.773.1.1.3^ISO'
   b. [MSH-6] Receiving Facility – 'TDH^2.16.840.1.113883.3.773^ISO'

17. **Does TDH accept batch or real-time message transmission for ELR?**

Batch transactions will be utilized. Please see table 3-4 in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with errata for correct Accept Acknowledgement value, Application Acknowledgement value, and Profile ID to be used in MSH-15, MSH-16, and MSH-21, respectively. TDH does not currently accept real-time message transmission for ELR. TDH does not send message or batch acknowledgements for ELR.

18. **When do we sign the Trading Partner Agreement (TPA)?**

The TPA will remain in draft form and will not be signed by TDH or the trading partner until ELR is in production and paper reporting has been discontinued. TDH will share a draft version of the TPA with the trading partner early in the on-boarding process to help explain business rules.

19. **What is snapshot processing, and do I have to follow it?**

Any order that results in multiple observations must follow snapshot processing rules as detailed in section 2.1.4 of the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with errata. All information in subsequent message(s) associated with a specific patient and event will replace the corresponding information from the previous message(s) in the receiving application. Because of this, when an observation regarding a particular order is made and an ELR message is sent, any subsequent observations obtained and sent using the same order information must include all previously sent observations for that order.

20. **If something is listed as "RE," do I have to send it to TDH?**
    "RE" stands for "Required, but can be empty". This is <u>not</u> the same as "Optional". For values listed as RE, if the value is known, it is required to be sent. However, if the value is unknown, please leave the field empty. Conformant systems are required to be able to send this information, and the ability to send RE fields will be evaluated during on-boarding.

21. **Can I send more than one message type in the same file to TDH?**
    Although TDH encourages utilizing the same transport method for multiple business areas (e.g., ELR and Immunization Registry), mixed message types in one file will not be accepted. Separate files need to be sent to TDH for each type of message. For ELR, TDH expects only ORU_R01 message types to be sent in a batch that is then sent in a file to TDH.

22. **What kind of documentation will TDH provide to me that I can use for Meaningful Use attestation?**
    TDH will provide official letters documenting each completed step of the ELR on-boarding process. These letters can be used as documentation for your records. Neither TDH nor the Surveillance Systems and Informatics Program are the Meaningful Use regulators or the body which measures compliance. If you have specific questions about your attestation process, please contact representatives within those governing bodies.

For more information, please contact the Communicable and Environmental Diseases & Emergency Preparedness (CEDEP) Surveillance Systems and Informatics Program (SSIP) team at CEDS.Informatics@tn.gov and please include 'ELR' in the subject line.