Implementing Electronic Laboratory Reporting to the North Carolina Division of Public Health

This presentation is an overview of the process involved with implement an electronic laboratory reporting interface to the North Carolina Division of Public Health. The presentation is approximately 1 hour long.

For More Information

- http://epi.publichealth.nc.gov/cd/meaningful_use/elr.html

If you have any additional questions after reviewing the presentation, please contact the ELR Project Manager whose information can be found on the Division of Public Health's ELR website, the URL for which is shown here.

Overview

- This presentation provides an overview of electronic reporting of laboratory results to the North Carolina Division of Public Health (N.C. DPH) via the North Carolina Electronic Disease Surveillance System (NC EDSS) and the North Carolina Lead Surveillance System (NC LEAD).

As I said, this presentation provides an overview of electronic reporting of laboratory results that are required by law to be reported to the North Carolina Division of Public Health. This reporting occurs through the North Carolina Electronic Disease Surveillance System (NCEDSS) and the North Carolina Lead Surveillance System (NC LEAD). These surveillance systems are used for recording and investigating reportable instances of communicable disease as well as elevated blood lead levels.

Hospitals Only

- N.C. DPH is not requesting and will not receive Electronic Laboratory Reports from providers.

Currently, the North Carolina Division of Public Health is only accepting ELR from hospitals, not provider offices.

The first document is the ELR checklist that outlines each of the steps involved in implementing an ELR interface to the Division of Public Health.

The second document is the Guidelines for Electronic Laboratory Reporting to the North Carolina Division of Public Health. This document is additional information regarding each of the steps in the process that we will be reviewing during this presentation.

The final document is the ELR Mapping template which is a tool developed by the North Carolina Division of Public Health to assist laboratory facilities with mapping their local codes to the standard vocabularies required for electronic reporting. We will discuss this process in more detail during this presentation.

Step 1: Registration of Intent

- Complete the Registration Survey to register your intent to submit ELR to N.C. DPH.

  https://ncdphmeaningfuluse.org/

Step 1 in implementing an electronic laboratory interface with Public Health is to register your intent to submit electronic laboratory data.

This step is especially significant for facilities that want to attest to the Electronic Health Record Incentive Program, also known as Meaningful Use. To attest to Stage 2 of Meaningful Use, each facility must register their intent to submit data to their public health agency within the first 60 days from the start of their chosen reporting period.

In order to complete your registration with the North Carolina Division of Public Health for any of the public health meaningful use measures including ELR, you must complete registration at the website noted.

What you will need:

- LIS Information
  - ☐ Vendor Name
  - ☐ Product Name
  - ☐ Product Version
  - ☐ Version of HL7 message
  - ☐ LOINC capabilities
  - ☐ Information regarding plans to transition to a new LIS and estimated timelines

In order to complete this survey, you will need information about your Laboratory Information System, including the name of the vendor who makes the software, the product name and version, and what version of HL7 messages it is capable of sending. In order to meet Meaningful Use, the system must be sending HL7 version 2.5.1.

You will also need to know if the software is capable of storing a LOINC code, which is one of the standard vocabularies that is required to meet Meaningful Use.

Also, if your facility has plans to transition to a new LIS product or version, please include that information as well as any estimates timelines of when the transition will be completed.

Why data from the LIS?

- More complete information

- Data is formatted in a way that can be directly utilized in decision making algorithms

- Easier to troubleshoot issues and problems

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The Division of Public Health is requesting information specifically about the Laboratory Information System because we ask that the data ben sent directly from the Lab System instead of sending the data from the electronic medical record. We ask for data from the LIS for multiple reasons.

First, data from the lab system is more completed and it includes all of the pieces of information that are need for a full laboratory report, including the codes required for meeting Meaningful Use, such as LOINC and SNOMED codes.

Also, data in the lab system is formatted into fields that can be used in decision making algorithms. For example, laboratory information that is displayed in the medical record is meant to be human readable, so it is often displayed as text value that a physician can understand as positive or negative. Unfortunately, the system is not able to interpret free text and thus our surveillance system can not determine if a result is actually reportable or not.

Lastly, the fewer systems that we have to track a result through, the easier it is to troubleshoot the problem when an issue with the data arises. For example, if Public Health receives a positive HIV result, but it looks like there might be a problem with the data and it takes us a week to determine which system caused the issue, we have lost the window to provide public health intervention and possibly prevent

another infection.

What you will need:

- **Laboratory Volume estimates**
  - ☐ Total specimens processed weekly
  - ☐ Results most frequently reported to Public Health
  - ☐ Number of tests offered
  - ☐ Percentage sent out to a reference laboratory
  - ☐ Percentage of in-house tests that are reportable

In addition to the LIS information, you will also be asked to provide estimates of the volume of specimens and reportable results coming from your facility. Please provide information about: the total number of specimens processed by your laboratory on a weekly basis, what the most frequently reported public health results that are reported by your facility (for example, Gonorrhea, Chlamydia, etc.). In addition, we would like an estimate of the total number of services offered, what percentage of that total are sent out to a reference lab, such as LabCorp, and what percentage of those services that are performed in-house are actually reportable to Public Health.

We utilize this information to help estimate the scope of the project and to prioritize facilities that are interested in building an ELR interface.

What you will need:

- Contact Information for:
  - ☐ Laboratory
  - ☐ IT
  - ☐ Vendor

You will also need to provide information for the contact points in the laboratory, the IT group, as well as your vendor contact. We have found that if we involve these groups early in the process, we are more successful in getting the interface into production in a timely fashion.

What you will need:

- Tax ID Name of the facility
  - ☐ Same name used for attestation

- Contact Information for Meaningful Use Contact
  - ☐ Person to receive Meaningful Use related notifications

Finally, to complete the actual registration of intent, we will need the Tax ID Name of the facility. This should be the same name the facility will use to attest to Meaningful Use so that the documentation we provide will match your attestation documentation.

We also need the contact information for the facility's Meaningful Use Coordinator. This will be the individual to whom we address all the Meaningful Use notifications.

Step 1: Registration of Intent

- Once your registration is complete, you will receive notification from N.C. DPH

Once the registration survey is completed, the DPH will send you a notification stating that your registration is complete along with the date that is was completed for your records. All notifications will be sent to the Meaningful Use Contact via email.

This completes the first milestone on the ELR Checklist.

Step 2: Initial Planning Discussion

- Participate in an initial planning meeting with key groups to review:
  - ☐ Project Scope
  - ☐ Goals
  - ☐ Timelines
- Key groups that should be involved:
  - ☐ IT staff
  - ☐ Laboratory staff
  - ☐ LIS Vendor Contact

The next milestone on the ELR Checklist is to participate in an initial planning discussion with the ELR Implementation Team at the Division of Public Health. During this meeting we will review the project scope, goals, and timelines, as well as answer any questions you might have regarding the process for implementing ELR.

Again, we have found it extremely helpful to include the key stakeholders early in the project so we recommend that at least one contact from the lab, the IT group, and your LIS vendor be involved in this initial discussion.

If you would like to schedule an initial planning discussion with the ELR Implementation Team, please contact the ELR Project Manager.

Step 2: Initial Planning Discussion

- After the initial planning discussion, you will receive an "Invitation to On-board" from N.C. DPH

Following the initial planning discussion, the ELR Implementation Team will evaluate the scope of building an ELR interface with your facility and your preferred timelines. Based on that evaluation, your facility will be placed into the queue of facilities waiting to start the on-boarding process with the NC Division of Public Health for ELR.

When the Division of Public Health is ready to proceed with on-boarding of your facility, you will receive an invitation to start the on-boarding process. This completes milestone 2 on the ELR Checklist

Step 3: Identify reportable results

- In the Lab Information System, select the lab results that are required by N.C. regulations to be reported to the N.C. Division of Public Health.

Step 3 is the process of identifying laboratory results that are required by law to be reported to the Division of Public Health.

Reporting to the N.C. Division of Public Health

- North Carolina General Statutes and Administrative Code require that positive laboratory tests shall be reported to the North Carolina Division of Public Health electronically, by mail, by secure telefax or by telephone.

In North Carolina we have both General Statutes as well as Administrative Code that requires that positive laboratory results identifying certain organisms or conditions be reported to NC DPH via multiple mechanisms including electronic reporting, by mail, fax or phone.

N.C. Regulations

- General Statutes: Chapter 130A
  - Communicable Disease
  - Environmental and Blood Lead for Children

- Administrative Code: 10A NCAC 41A
  - Reportable Conditions
  - Laboratory Testing
  - Occupational Health Safety - Adult Blood Lead

Here are links to the appropriate regulations for further detail.

What should be reported?

- Communicable Diseases:
  - ☐ Isolation or other specific identification of 38 different organisms from any clinical specimen
  - ☐ Isolation or other specific identification of 3 different organisms from a sterile site
  - ☐ Positive serologic test result for 17 different infections
  - ☐ CD4 counts and Viral Loads

- Lead
  - ☐ All environmental lead test results and blood test results for children less than six years of age
  - ☐ Elevated blood lead levels for adults aged 18 years of age and above

Overall, the regulations require reporting the identification of approximately 60 different organisms and conditions, including communicable diseases and elevated blood lead levels.

As of July 1, 2013, we have actually had a new rule change go into effect requiring the reporting of ALL CD4 results and ALL viral load results (regardless of detected or not detected results). Previously, these results were only reportable if they were under a certain threshold; however, now all CD4 results are reportable. This includes CD4 results on cancer patients, etc.

In addition to those results that are required by law to be reported in North Carolina, the Division of Public Health can also accept certain positive laboratory results that the facility is willing to voluntarily report. You can find a list of these conditions in Appendix B of the Guidelines for electronic laboratory reporting to NC DPH.

These conditions are not required to be reported by law; however, they do have public health significance and if a facility is willing to report them, DPH would utilize that information to assist with it's investigations.

This list is not an "all or nothing" list; a facility can choose to report some or all the conditions.

Results to Include in ELR:

- Reportable results performed in-house at your laboratory facility
  - Including both results that are required by law and those that the facility is voluntarily reporting

- Please DO NOT Include
  - Laboratory results of tests that were performed at reference laboratory facilities.
  - Laboratory results for CAP or other proficiency testing
  - Laboratory results for internal quality testing (e.g. tests used to test the system, not real patients)

Only results that are performed in-house at the laboratory facility should be included in the ELR interface to NC DPH. This includes all results that are required by law to be reported as well as those that are being voluntarily reported by the facility.

Please do not include any reportable results sent out to a reference laboratories or internal quality/proficiency testing results.

Step 3: Identifying reportable results

- Download the NC ELR Mapping Template from the NC DPH website
- Fill in the NC ELR Mapping Template with the entire menu of services for your facility and indicate which tests are performed in-house versus sent out to a reference lab.
- Indicate for each of the tests that are performed in-house if they are required to be reported under N.C. law. Also indicate which tests the facility is willing to voluntarily report to NC DPH.

Once you have an understanding of the reportable conditions, the next step is identify those reportable tests that are performed in-house at your facility. This is where the ELR Mapping template tool comes into play.

In the Mapping template, please fill completely fill out either columns C for the Order Name (i.e. a battery of tests) or column I for the test name, with your entire menu of services. We ask each facility to enter their entire menu of services so we can be assured your facility is reporting all required results.

For each test listed in the mapping template, please indicate (in column Q) which tests are performed in-house verses sent out to a reference lab, and which ones are reportable. Those that are reportable would either be those that are required by law to be reported or ones that your facility is willing to voluntarily report.

Once you have completed the three columns of the template, please return it to DPH. From this document we can evaluate which results should be included in the ELR interface and which data elements need to be coded into the standard vocabularies.

This completes the third milestone on the ELR checklist.

Step 4: Translation to Standard Vocabularies

- Lab tests or observations are identified by LOINC codes.

- Lab test results (other than quantitative) and Specimen sources are identified by SNOMED-CT codes.

Once you have identified the reportable tests performed in-house, this subset of tests must be coded using the standard vocabularies required for meeting Meaningful Use.

For Stage 2 of Meaningful Use, the two required standard vocabularies are LOINC and SNOMED Codes. In North Carolina, we actually require a specific subset of the SNOMED codes, called SNOMED – CT codes (which stands for SNOMED – Clinical Terminology).

These vocabularies are used to translate local laboratory codes into standard values that can be recognized universally across multiple systems. LOINC codes are used for the coding of test names. For example, a blood culture has a specific LOINC code.

SNOMED codes are used to translate test results, such as the organism identified in cultures, as well as the source of the specimen, such as arterial blood.

On the receiver side, we use LOINC and SNOMED codes to not only display the correct test information, but to also validate the result is reportable to the Division of Public Health.

Business rules driven by standard vocabularies

- LOINC code (lab test) + SNOMED-CT code (test result) + SNOMED-CT code (specimen source)
    - ➔ NC EDSS import rule
- Initially a microscopic examination of a sputum smear: 11545-1 (Acid fast Stain XXX) + 10828004 (Positive)
    - ➔ create disease event of Tuberculosis-active with status "SUSPECT"
- Several weeks later, for same lab specimen the culture result: 543-9 (Mycobacterium XXX Cult) + 113861009 (MTB)
    - ➔ update disease event of Tuberculosis-active with status "CONFIRMED"

Based on the combination of the LOINC code for the test name, the SNOMED – CT code for the test result, and the SNOMED – CT code for the specimen source, we have import rules that can determine if the result is actually reportable. The reason why all three pieces must be included in the message is because there are only certain organisms that are only reportable in NC if they are identified from a sterile site. For example, an identification of Group A Strep from a throat culture is not reportable; however, identification of Group A Strep from CSF is reportable.

Another example of the combination of the fields would be with a TB result. For example, if you initially reported a positive Acid Fast Stain, you would use the LOINC code for an Acid Fast Stain paired with the SNOMED-CT code for a positive result. This would create an event in our disease surveillance system with a status of Suspect, as a suspected case of TB.

Moreover, if you later result the positive culture, you would use the LOINC code for a mycobacterium culture paired with the SNOMED-CT code for the MTB organism. This result would update the event to be a confirmed case of TB.

Step 4: Translation to Standard Vocabularies

- Complete the NC ELR Mapping Template with the LOINC and SNOMED-CT codes corresponding to the reportable results
  - Separate sheets for:
    - LOINC codes
    - SNOMED codes for results
    - SNOMED codes for specimen source

Coding of the tests, results, and specimen sources can be done directly in the ELR Mapping template. There are separate sheets for each type of data value.

Enter your LOINC coding information on the first sheet. The second for the result and the corresponding SNOMED code, and the last for the specimen source or type with it's appropriate SNOMED code.

If you have any questions regarding which LOINC or SNOMED code to choose, just contact the ELR Coordinator and we will be happy to assist you. The review process for the mapping template is very back and forth between the facility and DPH so please don't hesitate to ask questions.

In addition to requiring LOINC coding for the ELR measure, Meaningful Use also has a separate measure requiring that hospitals provide 55% of their laboratory results back to their providers using LOINC codes. Some hospitals have found that by focusing initially on the reportable tests, they come close to meeting, if not fully meeting, the 55% threshold.

Once you have completed your mapping, return the mapping template to DPH and we will review it and provide feedback. Once the document has been finalized, you will have completed the 4th milestone on the ELR checklist.

Step 5: Develop HL7 Message

■ Develop an HL7 message conformant to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health.

The 5th step in the process is to develop and test an HL7 message generated from your LIS system that contains a reportable result. This message must conform to the HL7 2.5.1 Implementation Guide for Electronic Laboratory Reporting to Public Health. This guide is the required standard that must be used to comply with the Meaningful Use regulations.

North Carolina does not require any additional data elements other than those outlined in the Implementation Guide.

Acceptable Implementation Guides

- HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm), HL7 Version 2.5.1: ORU^R01, HL7 Informative Document, (February, 2010)

- Currently, there is no comprehensive HL7 implementation guide for the use case of environmental lead test results.

The specific Implementation guide for ELR that is referenced in the Meaningful Use regulations can be downloaded from the HL7 website for free. Unfortunately, we cannot provide the guide to you because you must agree to the licensing of the product from HL7 but it is provided at no cost.

Currently, there is no comprehensive guide for reporting lead results, so if you have specific question about reporting those results, please contact the ELR Coordinator.

Step 5: Develop HL7 Message

- Test ELR messages via self-service online validation tools, resolve issues found, and provide your successful validation results to N.C. DPH.
  - CDC's Message Quality Framework (MQF) ELR receiver profile: https://phinmqf.cdc.gov/
  - National Institute of Science and Technology (NIST) website: https://hl7v2-elr-testing.nist.gov/mu-elr/

Once you have generated an HL7 message, please run that message through one of the online self-evaluation tools. These tools check the structure and format of the message against the HL7 Implementation guide. There are two tools that we recommend:

The CDC Message Quality Framework tool, or MQF, which you can just copy and past the HL7 message into and then you will receive an error report outlining any structural or formatting issues against the HL7 Implementation Guide.

The second tool is the National Institute of Science and Technology tool (or the NIST tool). This tool also allows you to copy and paste you message and then check it again the Implementation Guide. This particular tool is actually used for the Stage 2 certification process.

If you come across an error that you cannot resolve or that it would take a major engineering change to overcome, let the ELR Project Manager know and we might be able to develop a workaround on our side.

Once you have run your messages through one of the self-evaluation tools, please resolve any issues that have been identified and provide your successful validation results to DPH. This completes the 5th milestone on the ELR checklist.

Step 6: Set up connectivity

- There are two ways to transmit ELR to NC DPH:

  ☐ HealthConnex (NC HIEA)

  ☐ The Public Health Information Networking Messaging System (PHIN MS)

Step 6 is the process of setting up connectivity to DPH. Hospitals have the option to use a connection through HealthConnex aka NC Health Information Exchange Authority or PHINMS. Both options are free to use. Contact information is available in later slides.

Data Flow for ELR through HealthConnex/NC HIEA

Hospital Lab Information System → Batched reportable lab results → NC HealthConnex (Powering Health Care Outcomes) → ELR → NC EDSS electronic disease surveillance system
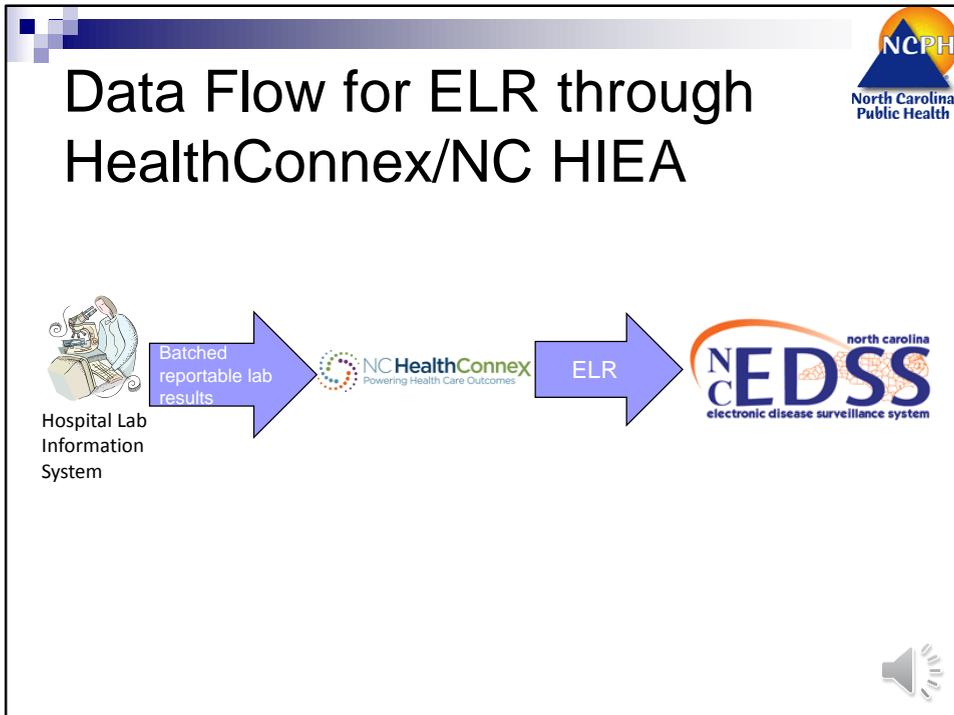
HealthConnex functions as a pass through for electronic laboratory results, with the reportable results originating in the hospital LIS. The batched results are ultimately transmitted through HealthConnex to NCEDSS.

For more information on HealthConnex

- Contact:

  Alice Miller

  Business Development and Outreach Specialist

  Health Information Exchange Authority (HIEA)

 North Carolina Department of Information Technology

  919-754-6955

  alice.miller@nc.gov

For more information about setting up an interface with HealthConnex, please contact Alice Miller. Setting up this connectivity completes the 6th milestone on the ELR checklist.

Data Flow for ELR through PHIN MS

Hospital Lab Information System → Batched reportable lab results → locally-installed PHIN MS → ELR → NC EDSS electronic disease surveillance system
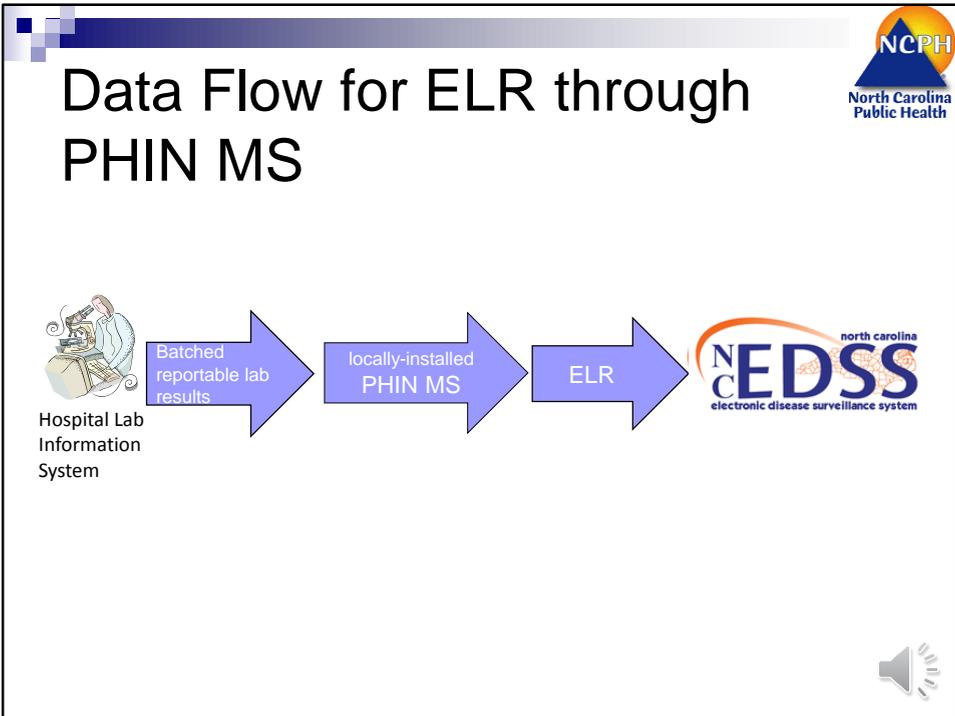
PHIN MS can securely send and receive any message type over the Internet, facilitating interoperability among myriad public health information systems.

For more information on PHINMS

- Visit http://www.cdc.gov/phin/tools/PHINms/index.html

PHIN MS is a CDC-provided software that can securely send and receive any message type over the Internet, facilitating interoperability among myriad public health information systems by employing Electronic Business using Extensible Markup Language (ebXML) technology.

Step 7: Transmit a test message

- Combine the HL7 transactions for the day into a single batch (within a single file) per HL7 standards for files and batches.

- Transmit a message containing a reportable result conformant to NC Regulations and to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm).

Once the interface is functioning, step 7 is to transmit a test message. The NC Division of Public Health can only receive a single batch file each day. We cannot accept real-time reporting because laboratory results must be uploaded into NC EDSS during off-peak hours when user traffic is low. If a record is being edited while the system attempts to upload a lab result, the upload fails and must be manually reloaded.

If you are currently reporting to the NC HIEA using a real-time interface, please contact the NC HIEA regarding reporting of laboratory results in a batch format.

The submission and receipt of a reportable result conformant to NC Regulations and to the HL7 2.5.1 Implementation Guide constitutes a successful test message. Once a successful test message is received, you will receive a notification from NC DPH for your documentation.

This completes the 7th milestone of the ELR checklist.

Step 8: Structure and Content Validation

- N.C. DPH will review and validate the message to ensure that data received from your facility is conformant to N.C. DPH requirements with regard to format and content, that the data can be processed successfully into NCEDSS and that the data meets other data quality requirements.

Following the submission of a successful test message, please configure your LIS to begin sending daily production ELR messages to NC DPH for structure and content validation. During this phase, NC DPH will review and validate the message to ensure that it is conformant with our requirements and can be processed successfully into our disease surveillance system.

NC DPH will notify your facility during structure and content validation of any issues that have been identified and need to be resolved. If your facility is non-responsive, you will receive an official notification from DPH requesting resolution of the issues, and if you fail to response to these notifications, you may not meet the Meaningful Use Stage 2 measure for ELR.

Once structure and content validation is completed, your facility will have passed the 8th milestone on the ELR checklist.

Step 9: Parallel Data Validation

- N.C. DPH will perform data validation, comparing the electronic submissions from the production system against the existing reporting mechanism (e.g. mail or fax).

The final stage of testing is parallel data validation. During this testing stage, DPH will compare the electronic submission received from your production LIS to the existing reporting mechanism, i.e. paper- based reporting.

Step 9: Parallel Data Validation

- The laboratory will send N.C. DPH copies of the reports it issued to the ordering clinicians for all test results reportable to public health regardless of whether corresponding ELR was sent.
- This reporting is in addition to the regular mechanism through which the facility reports to their Local Health Department.

During parallel validation, the hospital laboratory will send NC DPH copies of the reports it issued to the ordering clinicians for all test results reportable to public health regardless of whether or not a corresponding ELR was sent. This reporting is in addition to the regular mechanism through which the facility reports to their Local Health Department.

The Subject Matter Experts (SMEs) at NC DPH will review the data imported into NCEDSS/NCLEAD to assure that all reportable results that should have been imported into NCEDSS/NCLEAD were imported correctly; the imported data is consistent with the original reports; and the data content does not require excessive exception handling.

Any issues that are identified are reported to the ELR Project Manager for discussion with Management regarding an appropriate solution. If changes/fixes to the laboratory's ELR are warranted, the identified issues are communicated to your facility and/or vendor and are tracked to resolution.

Once the SME from each disease group feels that enough paper laboratory reports have been reviewed and all major issues have been identified and corrected, the SME will "sign off" on the ELR feed for their disease group. This phase continues until the SMEs for each applicable disease group have signed off on their

acceptance.

After sign off is received from all SMEs, parallel data validation is concluded and the 9th milestone on the ELR checklist is complete.

Step 10: Discontinue submitting paper reports

- At the completion of parallel testing, N.C. DPH will transition your ELR reporting to the production surveillance system.
- Your facility will receive a notification from the North Carolina State Epidemiologist stating your laboratory can discontinue paper or faxed reporting of reportable laboratory results and solely submit ELR.

Following the completion of the parallel data validation, DPH will transition your ELR reporting from our test environment to the production surveillance system.

Typically after 30 days, the hospital will receive notification from the North Carolina State Epidemiologist your laboratory can discontinue paper or faxed reporting of reportable laboratory results and solely submit ELR.

After the interface is fully operational, N.C. DPH will perform continual quality control checks. When your facility adds new in-house tests or new reportable results, your facility must contact the ELR Project Manager to test and validate the new results via ELR.

Further Information

- Meaningful Use

  - http://epi.publichealth.nc.gov/cd/meaningful_use/

  - https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html

For further information, please review the following websites.

Contact Information

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If you have any questions or would like to request additional information regarding ELR to the NC Division of Public Health, please contact the ELR Project Manager.