POST-PRODUCTION ELR QUALITY ASSURANCE (QA) TOOLKIT

OVERVIEW

This toolkit encapsulates the factors that should be considered and finalized when developing and implementing an ELR quality assurance protocol. The toolkit does not have to executed in the order presented and can be adjusted for individual use.

1. Determine the reason for the implementation of a quality assurance program

Here are some typical reasons for developing a QA protocol. Discuss this with primary stakeholders to ensure goals are shared.

a. Prevent deterioration of ELR baseline feed
b. Improve or maintain data quality
c. Increase or maintain data completeness
d. Share feedback with laboratories
e. Establish incentives for compliance and/or disincentives for noncompliance
f. Assure compliance to changes in regulations for reporting

2. Seek feedback from management on need for quality assurance program

It is important to gain management buy in, especially if additional resources and/or management support are needed for imposing consequences on noncompliant laboratories or providing incentives to compliant laboratories.

a. Discuss possible need for (temporary) additional assistance (e.g. report writers, purchase of software, etc.)
b. Discuss management's need for update and involvement in QA process
c. Discuss incentive/disincentive structure, if applicable

3. Establish critical and supplementary review data set

Review and complete the Critical vs. Supplementary Data Set Template.

a. Use template to establish review data set
b. Add or delete data elements as needed for local use
c. Review list with pertinent stakeholders for feedback

4. Establish (scalable) review process

Determine how much time and resources will to be dedicated to QA planning and implementation process. Consider:

a. Who will be involved in QA process, permanently and temporarily
b. Determine if laboratories will participate in assessment and on what schedule
    i. Review of test compendium
    ii. Update of LOINC/SNOMED-CT code mapping
c. Frequency of assessments – daily, weekly, monthly, annually
d. Breadth of review – all labs, large labs only, staggered review (e.g. large-volume labs assessed quarterly and other labs assessed biannually)
e. Format – Crystal reports, database report (e.g. Maven report), SAS report, etc.
f. Other sources of data with which to compare ELR data
    i. Audit findings from external programs/offices
    ii. Laboratory reports consumed from other sources

5. Establish (scalable) compliance parameters

Discuss with pertinent stakeholders what compliance and noncompliance "looks like." Consider what incentives and disincentives management will be able and/or willing to support.

a. Determine what level of completeness is acceptable. Can be established by data element. Supplementary data should be assessed separately if included in review.
    i. Consider cyclical or intermittent missing data
b. Determine actionable events (optional)
    i. Incentives for exemplary performance
        1. List top performing labs on office webpage
        2. Recognition in program newsletter
    ii. Consequences for noncompliance. Determine levels of engagement. Example:
        1. First offense – Phone call to first-line contact and technical assistance
        2. Second offense – meet with interface engineer and/or vendor to formally discuss resolution
        3. Third offense – Letter of noncompliance
        4. Continued noncompliance – fine assessed per administrative code

6. Develop a communication plan

Results of your assessments may or may not be sensitive depending on content and/or format. Consider how your program will share results internally and/or externally.

a. Determine who will see and care about the results of the assessment
b. Determine the best communication channel for identified stakeholders
    i. Abbreviated report for management vs. in-depth reports for core stakeholders
    ii. Share report(s) on internal website or SharePoint
c. Information available on internet (optional)
    i. Recognition of top performing labs
    ii. Report cards with specific data for comparison
        Example: List completeness values for critical data elements by laboratory

Critical vs. Supplementary ELR Data Set Template

Data Element	Status (Critical vs. Supplementary)	Comments
Patient First Name		
Patient Last Name		
Patient Middle Name		
Patient Date of Birth		
Patient Gender		
Patient Race		
Ethnicity		
Patient ID(s)		
Patient Phone		
Patient Address (street address)		
Patient city, state and zip code		
Patient county		
Accession Number		
Result		
Result Value		
Result Date		
Ordering Facility		
Ordering Provider		
LOINC and/or SNOMED-CT Code(s)		
Local Test Description		
Specimen type		
Specimen Source Type		
Specimen Collection Date		
Timeliness[1]		
Lab Ordering Provider Name		
Lab Ordering Provider Address		
Lab Ordering Provider City		
Lab Ordering Provider Zip Code		
Lab Ordering Provider County		
Lab Ordering Provider Phone		

[1]North Carolina will use the following equation: difference between investigation report date (i.e., last date the lab released an ELR for this specimen) and investigation date last modified (i.e. the date the last ELR for this specimen was imported into NC EDSS) <= 24 hours.