CLIA Corner

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Quality Assessment Introduction

The Clinical Laboratory Improvement Amendments (CLIA) interpretive guidelines define quality assessment (QA) as an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations where testing is performed. QA extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the other non-laboratory areas or departments of the facility of which it is a part.

Subpart K of the CLIA regulations is divided into four quality systems: general laboratory, preanalytic, analytic, and postanalytic. Laboratories performing nonwaived testing must establish and follow policies and procedures that implement and monitor all four quality systems. The laboratory's QA process must include a component that ensures continuous improvement of the laboratory's performance and services through ongoing mechanisms to monitor, assess and, when indicated, correct problems. The QA policies and procedures should include: a review of the effectiveness of corrective action taken to resolve problems, the revision of policies and procedures necessary to prevent recurrence of problems and a discussion of the QA reviews with the appropriate staff. CLIA does not define the specific QA monitors or the frequency for monitoring. It is the laboratory's responsibility to have a written comprehensive QA plan that covers the four quality systems, and then follow the written plan.

This edition of the CLIA Corner will focus on QA of the Post-analytic System and give examples of possible QA monitors.

Fourth CLIA Quality System – Post-analytic

The Post-analytic System is related to test reports. The laboratory's QA plan should include processes to monitor, assess and, if necessary, revise procedures in these areas.

Test Report - Delivery

- The laboratory must have a manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes:
  1. Results reported from calculated data.
  2. Results and patient-specific data electronically reported to network or interfaced systems
  3. Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

QA Examples:

- Monitor periodically the transmission of test reports for:
  - Legibility;
  - That information received at the final destination is the same data sent by the laboratory; and

- If the laboratory uses a laboratory information system (LIS), electronic health record (EHR) or facsimile; check the security of the system(s) to ensure that the transmitted reports go directly from the device sending reports only to the authorized individual, their location or electronic system.

- Assess the competency of laboratory personnel who are responsible for manually entering test results into a LIS or EHR.
- Monitor the accuracy of manual entries by personnel into a LIS or EHR.

Test Report – Content:

The test report must indicate the following:

- Either the patient's name and identification number or unique patient identifier and identification number for positive patient identification.
- Name and address of the laboratory location where the test was performed.
- Test report date.
- Test performed.
- Specimen source, when appropriate.
- Test result and, if applicable, the units of measurement or interpretation or both.
- Any information regarding the condition of and disposition of specimens that do not meet the laboratory's criteria for acceptability.

QA Examples:

- Monitor test reports for completeness and accuracy, including manual entries into a LIS or EHR.
- Verify the accuracy of calculated data.
- Verify the test report is updated and accurate when a new test or test method is introduced (i.e. units of measurement or interpretation or both).
- If the laboratory has multiple sites, monitor that the test reports identify at which site the testing was performed.

Test Report – Information to be available to authorized person

- Pertinent "reference intervals" or "normal" values must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.
- The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory.
- Information that may affect the interpretation of test results must be provided upon request.
- Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

QA Examples:

- Monitor periodically the information sent to the clients to ensure it is current with the testing performed (i.e. list of test methods, interpretation of test results, normal ranges).
- Verify when test methods are changed or added that the clients are notified of the changes or additions.

Test Report – Notification/release of test results

- Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.
- The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.
- When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

QA Examples:

- Review and evaluate the procedures for notification or reporting of test results, including:
  - Verbal orders, including the process to confirm patient identification (e.g. patient's first and last name and birth date) and ensure that results are heard correctly (e.g. recipient repeats results).
  - Process for reporting (verbal and written) results on patients with multiple laboratory encounters to ensure that the exact name, date, time and identification of the specimen is conveyed to the authorized person.
  - Criteria for reporting abnormal, panic and critical test results, including documentation of who reported the results, who received the results, and time and date of notification; and
  - Process for verification and release of test results through LIS.
- Monitor and evaluate turn-around time criteria (e.g. routine, STATS, specific hospital nursing units/ department).
- Review and evaluate the alternate method utilized by the laboratory for testing and reporting patient test results when a test system, LIS or EHR is down and the delay of reporting test results could impact patient care.

Test Report – Referral of patient specimens for testing

- The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.
- The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce the exact duplicate of the testing laboratory's report.
- The authorized person who orders a test must be notified by the referring laboratory of the name and

address of each laboratory location where the test was performed.

QA Examples:

- Monitor and evaluate the system for tracking patient specimens sent to a reference laboratory for testing to ensure the reference laboratory sends test reports in an accurate and timely manner.
- Monitor the CLIA certificate of the reference laboratory to ensure that it is current.

Test Report – Retention and retrieval

- Test report information maintained as part of the patient's chart or medical records must be readily available to the laboratory.
- All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

QA Examples:

- Review procedures for retention and retrieval of test reports. Ensure test reports are retained and retrievable for the minimum time for all regulatory agencies (i.e. CLIA, Medicare, Medicaid, insurance carriers, etc.)
- If using a LIS or EHR, monitor that the date of the test report is the date test results are generated as a final report and ensure that the date does not change on copies generated at a later date.
- If using a LIS or EHR, monitor the laboratory's system for backing-up information (i.e. daily, weekly, monthly).

Test Report – Corrected Reports

When errors in the reported patient test results are detected, the laboratory must do the following:

- Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.
- Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.
- Maintain duplicates of the original report, as well as the corrected report.

QA Examples:

- Monitor and evaluate the system to ensure prompt notification to the authorized person, prompt issuance of the corrected report, and maintenance of both the corrected and original test reports.

Laboratory Information Systems (LIS) and Electronic Health Records (EHR)

QA Examples:

- Monitor the patient information confidentiality and security (e.g. password changes, personnel accessibility, personnel authorization levels, etc.)

- Monitor and evaluate the laboratory's backup system for requesting patient tests and reporting test results during scheduled and/or non-scheduled downtime of the LIS and EHR.
- Ensure that the laboratory makes the necessary updates or changes to the LIS or EHR when a new test or test method is introduced (i.e. different reference or normal ranges, calculations, control ranges).
- Verify or validate the LIS and/or EHR when major updates or repairs are made to the system(s).
- Ensure that procedures are available to all operators. Guidelines should identify individual(s), either by name or position, to notify if the LIS or EHR goes down or if a system error occurs.

Correction Process

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. It is the laboratory's responsibility to identify, investigate and resolve the error or problem. All pertinent laboratory staff must be involved in the assessment process. The laboratory must then develop policies and procedures to prevent recurrence of the problem. New policies developed due to QA monitors must be written, as well as communicated with the laboratory personnel and all other necessary staff. Over time, the laboratory must monitor the corrective action(s) taken to ensure that the recurrence of the original error or problem has been prevented.