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 the 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 Preanalytic System and give examples of possible QA monitors.

SECOND CLIA QUALITY SYSTEM - PREANALYTIC

The Preanalytic System is related to test requests and specimen submission, handling and referral. The laboratory's QA plan should include processes to monitor, assess and, if necessary, revise procedures in these areas.

Test Request –

- A written or electronic request for patient testing from an authorized person must be obtained by the laboratory. If the laboratory accepts verbal requests, ensure that the laboratory solicits a written or electronic authorization within 30 days of the verbal request.
- The test requisition requires the following information:

1. Name and address (or suitable identifier) of the authorized person requesting the test or the laboratory submitting the specimen.
2. Patient name or unique identifier.
3. Sex and age or date of birth of the patient.
4. Test(s) to be performed.
5. Source of the specimen, when appropriate.
6. Date and, if appropriate, time of specimen collection.
7. For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment or biopsy.
8. Any additional information relevant or necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

- If the laboratory transcribes or enters test requisitions or authorization information into a records system or a laboratory information system (LIS), the laboratory must ensure the information is transcribed or entered accurately.

QA Examples:

- Review written policy for standing orders, including description of which tests may be covered by standing orders and at what interval standing orders should be reconfirmed.
- Monitor test requisitions for completeness. Identify clients who repeatedly complete requisition forms improperly and document the laboratory's efforts to reduce the recurrence.
- Monitor that a written test request is received for verbal orders within 30 days, or if no order has been received, that the laboratory has documentation of its attempt to obtain.
- Assess the competency of laboratory personnel who are responsible for manually entering test request information into a LIS.
- Monitor the accuracy of manual entries by personnel into a LIS.

Specimen Submission, Handling and Referral –

- The laboratory must establish and follow written procedures for the following:

1. Patient preparation.
2. Specimen collection.
3. Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.
4. Specimen storage and preservation.
5. Conditions for specimen transportation.
6. Specimen processing.

7. Specimen acceptability and rejection.
8. Specimen referral.

- The laboratory must document the date and time it receives a specimen.
- The laboratory must refer specimens for testing only to a CLIA-certified or CMS-approved laboratory.
- If the laboratory accepts referral specimens, written instructions must be available to clients and must include the items listed above in this section.

QA Examples:

- Review procedures and policies periodically to ensure they are up-to-date with the current laboratory practices, including instructions for patient preparation.
- Assess the competency of laboratory personnel who are responsible for specimen collection and processing.
- Monitor the frequency of specimen collection and handling problems (such as the use of an improper blood collection tube, inadequate mixing of blood specimens with anticoagulant after collection, mislabeled or unlabeled specimens).
- Identify clients who repeatedly refer unacceptable specimens and document the laboratory's efforts to reduce the recurrence.
- Monitor the transport of specimens to the reference laboratory for delays and timeliness.

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.

Watch the next two issues of CLIA Corner for information on the remaining quality systems: Analytic and Postanalytic!

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