LabGuide 70

Quality Assessment

This LabGuide pertains to QSE Continual Improvement and all phases of the Path of Workflow.

What is Quality Assessment?

Quality Assessment (QA) is a planned, ongoing review process that observes and evaluates the quality of all laboratory-related processes and activities. All non-waived laboratories are required to perform quality assessment. However, laboratories of all complexities, including waived labs, can benefit from effective Quality Assessment since it increases the quality of the laboratory's performance and services by identifying, evaluating, correcting, and preventing test system problems.

The basics of QA are:

- Setting goals.
- Evaluating current policies, processes, and procedures to see if they are effective and are being followed by all staff.
- Identifying activities that have the potential for problems that can impact the quality of lab test results.
- Detecting and keeping track of errors over time.
- Making corrections and improvements, and evaluating the effectiveness of those changes in meeting goals.
- Reducing errors, and preventing the same errors from happening again.

Quality Assessment is a planned, ongoing review of all laboratory processes.

Continuous quality improvement focuses on improving processes and activities even when no problems are identified.

Quality Systems

The updates that were made to the Clinical Laboratory Improvement Amendments (CLIA) in 2003, describe a quality systems approach to laboratory operations. Quality systems are all of the laboratory's policies, processes, procedures, and resources that are needed to achieve consistently high quality testing and customer service. The quality systems approach focuses on comprehensive and coordinated efforts to achieve accurate and reliable test results. Quality Assessment is an integral part of the quality systems approach, and allows you to provide accurate and reliable test results through high quality testing while improving patient care and customer service.

Quality Assessment is about carefully observing and examining what you do every day. This allows you to gather data over time to perform an in-depth evaluation of your laboratory activities, and to look for patterns of events that could be handled more effectively or efficiently. Quality Assessment is not just a routine check to see that required activities were performed. It goes to the next level to assess how all activities related to laboratory testing are performed and how they can be improved.

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The Path of Workflow

The laboratory path of workflow is the sequence of activities that take place to produce test results.

Quality assessment monitors how things are done at every step in the path of workflow, from:

- The order for the test,
- To the collection of the specimen,
- Through the actual test performance,
- To the report that is given to the healthcare provider.

The path of workflow includes all laboratory processes, and is categorized into four phases:

- General phase – processes that are administrative, that continue through more than one phase, or that relate to all phases;
- Pre-analytic phase – processes that occur before testing begins;
- Analytic phase – processes that occur during testing or are related to test performance;
- Post-analytic phase – processes that occur after testing is performed.

Since each phase in the path of workflow has an impact on the quality of your test results, your QA Plan must detail how you will evaluate each phase.

Here are examples of some of the processes that should be evaluated in each phase:

General		
Personnel, Proficiency Testing, Laboratory Information Systems (LIS), Safety, Communication, and Complaints		
Pre-analytic	Analytic	Post-analytic
Test ordering	Equipment calibration and maintenance	Result reporting
Specimen collection and labeling	Quality control	Record retention
Specimen transport, processing, and storage	Test performance	Specimen retention, if applicable
	Result review and interpretation	

The Path of Workflow consists of four phases:

- ***Pre-analytic***
- ***Analytic***
- ***Post-analytic***
- ***General***

A problem with any activity in the path of workflow can adversely affect the outcome. You must assess your laboratory activities to identify and correct problems at every point in the process, from order to report. You must be constantly aware of what is happening in your laboratory, during all testing phases, so you can incorporate quality assessment into your daily routine.

Developing a QA Plan

There isn't a hard and fast rule for how to perform Quality Assessment, but CLIA regulations state that you must have a written Quality Assessment plan, and that you must implement the plan by performing QA reviews.

Begin by thinking about who, what, when, and how. Then, follow these basic steps to start developing your QA plan:

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1. State the purpose of your plan, and list your goals.
2. Describe what you will review, (Think about the path of workflow and all of your quality systems.) the standards that you expect, and how you will collect data to assess your laboratory activities.
3. Describe how you will implement the plan, and schedule and perform reviews.
4. Describe how you will respond to identified problems, methods for corrective action, and how follow-up reviews will be scheduled and performed.
5. Develop forms for documenting observed problems, collecting data, performing reviews, and documenting all QA activities.
6. Describe how you will share findings with your Laboratory Director, staff, and other appropriate parties.

Performing Reviews

The purpose of QA reviews is to produce a positive impact for your laboratory that is truly worth the effort. While it is good to periodically review all laboratory activities; creating a list of activities, assigning one to each month, and evaluating for that one short period of time doesn't really tell you a lot about how you operate on an ongoing basis. Quality Assessment should detect errors over time, allowing you to implement corrective actions with an emphasis on preventing those errors from happening again. It is not just about fixing the initial problem, but creating an opportunity for problem reduction and prevention, so the error does not become repetitive. QA also allows you to improve your processes when no errors exist so your laboratory performs at peak efficiency. To do this, review key areas more frequently, evaluate your performance over time, not just at one particular point in time, and implement and monitor process improvements before errors occur.

Develop a mindset of continuous quality improvement in your lab.

Think about those areas in your laboratory where if something went wrong it would have the most impact. Choose a "high-impact" laboratory activity to review and evaluate for each phase (general, pre-analytic, analytic, and post-analytic). You will want to evaluate that activity multiple times throughout the year because multiple reviews are needed to determine if your performance is improving, is declining, or is stable and at a consistently acceptable level across time.

Responding to Problems

When problems are found, continue periodic ongoing reviews that concentrate on the same problematic issues. This will allow you to compare performance over time, looking for differences based on changes in workload, staffing levels, or other factors that can influence the problem. Being aware of the impact of these factors can help identify the root cause of a problem as you dig deeper to uncover what is really wrong and how it can be fixed.

Making Improvements

Develop corrective actions and make the necessary changes and improvements to resolve the problem and prevent a recurrence. When you develop corrective actions, continue your ongoing assessments to determine if the solutions really work, and ensure that fixing one problem does not cause a new problem. Ongoing reviews also help make sure that the corrective actions are long-lasting so that a new mindset of continuous quality improvement develops in your lab.

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How Do We Begin?

COLA suggests that you get staff together for an open discussion about the processes you perform during each of the phases in the path of workflow. Create a list of the most problematic areas for your lab in each phase, and commit to assessing performance in these areas throughout the coming year. If you don't have a lot of readily apparent problems, great! However, you should still select areas to observe and evaluate in each phase to discover opportunities for improvement as well as any hidden weaknesses that could lead to problems.

Sound like a lot of work? COLA offers a Quality Assessment plan for purchase, *Quality Assessment Plan: A Simplified Approach* that may be beneficial to you. This plan is designed to meet the Quality Assessment requirements of CLIA and COLA, and may also meet the requirements of other laboratory accreditation organizations. The plan is easily customized to fit your facility and then adopt as your own. It can be purchased through LabUniversity at the following link: www.labuniversity.org/?page_id=454.

Remember that having a QA plan is only the first step. You must implement your plan by:

- Evaluating your laboratory activities in all phases of the path of workflow;
- Performing reviews that identify problems and areas of weakness;
- Resolving problems and making needed improvements;
- Assessing the effectiveness of those improvements;
- Sharing the findings and learning from the process;
- Documenting all QA activities.

Any Quality Assessment plan is a plan of action – it won't work unless you implement it and get everyone involved, including your Laboratory Director and all testing personnel.

Effective Quality Assessment leads to improved patient care.

What are the Benefits of Effective QA?

Quality Assessment is not just a regulatory requirement. You will discover that effective Quality Assessment will help you improve patient care. It is inevitable that mistakes and oversights may occur, complaints may be made (by patients, staff, and/or physicians), or communication breakdowns may happen. If you have a process to uncover these problems, and you work to find the cause and prevent recurrences, you can improve your laboratory operations. In addition, you may identify and prevent potential problems before they occur by regularly evaluating your processes and activities in each phase in the path of workflow. You may also discover ways to improve efficiency and economy by examining your day-to-day operations.

References

CLIA Brochure # 7: Laboratory Director Responsibilities

Quality Assessment Plan: A Simplified Approach COLA ©2008

COLA Accreditation Criteria QA 1 to QA 22

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