CLINICAL LAB ERRORS:

A First Step Towards Quality Improvement

Before the 1990s, most articles published about errors in laboratory medicine focused on the analytical phase of the total testing process (TTP). Since then, diagnostic companies and laboratories have greatly improved and standardized analytic techniques, investing in more sensitive and accurate assays with performant automation systems and analyzers and implementing internal quality controls and external quality assessments. These measures drastically decreased the number of analytical errors. Likewise, improvements in the pre-analytic and post-analytic phase of the TTP also reduced mistakes. In fact, most medical lab errors take place in the pre-pre-analytical and post-post-analytical stages of the testing process, which are outside the control of laboratory personnel. However, there are still steps you can take to reduce the chance of error both within and outside the lab.

ADOPTING STRATEGIES USED BY THE MANUFACTURING INDUSTRY

Although improvements in laboratory settings have been impressive, companies could reduce errors even further if they adopted a more systemic approach to improving the lab environment. Even though mistakes made by humans ultimately cause all clinical lab errors, trying to change human nature is pointless — staff members are not machines that you can program to repeat and reproduce the same task with the same result. It's far more effective to create a system with stringent metrics that will improve the conditions under which lab technicians work. This requires knowing each step of your TTP down to the smallest detail so you can identify the critical points and weaknesses and then improve the process and implement good quality indicators.

Many diagnostic laboratories have adopted tools like Lean Six Sigma, HACCP (Hazards Analysis and Critical Control Points) and FMEA (Failure Mode and Effects Analysis). These tools were first used by the food processing and manufacturing industries to optimize processes and reduce operational costs. Although the connection between laboratories and manufacturing companies may not be obvious, workers in both industries process raw material into finished products using quality criteria. Whether it's a cheese wheel, a car or a laboratory result, if the raw material is of poor quality, the finished product will also be of poor quality. That's why the process should be rigorously followed, allowing for quick identification and efficient management of all samples that do not meet quality criteria. You should also implement a robust control phase that includes quality indicators for assessment to ensure improvements are sustained over time.

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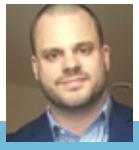
Based on the projects I've collaborated on, the benefits of systematically improving the lab process are indisputable. For starters, you will create a safer work environment and your employees will see a reduction in their workload. Adopting one of the above-mentioned tools can also reduce:

- Alarms and errors on the automation line
- Downtime and unscheduled maintenance
- Manual remediation and exception handling that will slow down the process
- Turnaround time (as you will increase the throughput on the automation line)
- The cost per test

IMPROVING ACTIVITIES BEYOND THE LAB

Of course, even if you implement optimal processes within your lab, it won't affect what happens outside of the lab where most errors occur. To reduce errors that take place in hospitals or medical clinics, the entire health care system must be involved in improving the total testing process. It's crucial that clinicians and other health care professionals collaborate and cooperate with laboratory staff and that they clearly understand what type of errors can occur and the impact this may have on patients' health. Health care professionals need to be trained about appropriate test selection as well as correct blood collection, labelling, handling, storage and transportation procedures. Make sure these procedures are clearly written down, regularly updated and easily accessible. Keep in mind that health care providers will likely be more receptive to training if you have invested time in building good working relationships with them.



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THE FIVE PHASES OF THE TOTAL TESTING PROCESS

The total testing process (TTP) is based on the familiar nine-step brain-to-brain loop described by George Lundberg in 1981. In this concept, the first step begins in the brain of the clinician who chooses a specific laboratory test for a patient, and the final step is the ordering physician's therapeutic decision based on the test result. Traditionally, the testing process has been divided into three phases: pre-analytic, analytic and post-analytic. However, in the last decade, some professionals have brought even more precision to the nomenclature by adding pre-pre-analytical and post-post-analytical phases.

1. Pre-pre-analytical phase

The highest number of errors — 46 to 68.2 per cent* — take place in the pre-pre-analytical phase. A variety of factors can adversely affect the testing process, including:

- Selection of the incorrect test
- Order entry errors
- Patient/specimen misidentification
- Contamination from infusion routes
- Interference due to hemolysis
- Choosing the wrong collection container
- Time delay from specimen collection to analysis
- Failure to store specimens in the correct environment (e.g. at the wrong temperature)
- Improper transportation of the specimen

2. Pre-analytical phase

The pre-analytical phase occurs in the lab setting. Only 3 to 5.3 per cent of errors occur in this stage, and they mostly involve incorrect specimen preparation, centrifugation, aliquot preparation, pipetting and sorting.

3. Analytical phase

The analytical phase encompasses the diagnostic procedures, processes, and products that provide lab results. This stage accounts for 7 to 13 per cent of errors, which are often related to sample mix-ups, procedures that are not followed or equipment malfunction.

4. Post-analytical phase

The post-analytical phase of the testing process, which accounts for 12.5 to 20 per cent of errors, also occurs in the lab. Typical errors include delays in delivering results, reporting to the wrong health care provider, or transcribing the wrong information.

5. Post-post-analytical phase

In this phase, which involves the release of results to clinicians, 25 to 45.5 per cent of errors occur. Typical errors include incorrectly interpreting test results or failing to inform patients of clinically important results or to order additional tests.

**All statistics come from Plebani M. Exploring the iceberg of errors in laboratory medicine. Clin Chim Acta 2009;404:16–23 https://www.ncbi.nlm.nih.gov/pubmed/19302995*