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Pre-analytical workstations: A tool for reducing laboratory errors

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ABSTRACT

Laboratory testing, a highly complex process commonly called the total testing process (TTP), is usually subdivided into three traditional (pre-, intra-, and post-) analytical phases. The majority of errors in TTP originate in the pre-analytical phase, being due to individual or system design defects. In order to reduce errors in TTP, the pre-analytical phase should therefore be prioritized. In addition to developing procedures, providing training, improving interdepartmental cooperation, information technology and robotics may be a tool to reduce errors in specimen collection and pre-analytical sample handling. It has been estimated that >2000 clinical laboratories worldwide use total or subtotal automation supporting pre-analytic activities, with a high rate of increase compared to 2007; the need to reduce errors seems to be the catalyst for increasing the use of robotics. Automated systems to prevent medical personnel from drawing blood from the wrong patient were introduced commercially in the early 1990s. Correct patient identification and test tube labelling before phlebotomy are of extreme importance for patient safety in TTP, but currently few laboratories are interested in such products. At San Bassiano hospital, the implementation of advanced information technology and robotics in the pre-analytical phase (specimen collection and pre-analytical sample handling) have improved accuracy, and clinical efficiency of the laboratory process and created a TTP that minimizes errors.

1. Introduction

Laboratory testing is a highly complex process. The testing cycle, commonly called the total testing process (TTP), was well described several years ago by Lundberg [1]. In the performance of any laboratory tests, Lundberg described the brain-to-brain turnaround time as a series of nine steps consisting of: ordering, collection, identification, transportation, preparation, analysis, reporting, interpretation and action.

The laboratory testing process starts outside the laboratory with the physician ordering the test, followed by the nurse or phlebotomist obtaining the specimen, the courier delivering the specimen, and the laboratory personnel performing the test; the loop is completed when the laboratory delivers the correct result back to the physician, who may rely upon the laboratory's expertise and clear presentation to interpret the result [2].

Although TTP is usually subdivided into the three traditional (pre-, intra-, and post-) analytical phases, the pre-analytical phase can be further subdivided into the "conventional" pre-analytical phase, which occurs under the control of the laboratory, and pre-pre-analytical phase, which occurs outside the laboratory and consists of the selection of appropriate tests on the basis of clinical question, ordering, collecting and handling, transportation and reception of samples prior to testing. The "conventional" pre-analytical step involves the processes required to make a sample suitable for analysis: centrifugation, aliquotting, diluting and sorting the specimens into batches for their introduction into automated analyzers [3].

2. Errors in laboratory medicine

The laboratory service plays a key role in patient care, and laboratory data are estimated to affect 60–70% of the most important decisions on admission, discharge, and medication [4]. Consequently, laboratory testing is an important source of medical errors affecting patient safety. Moreover, errors can occur in each and every step of TTP. Of all errors in TTP, approximately one fourth have consequences for the patient [5–7], which include a delayed test result or new sample collection, but may also have a life threatening impact [8], and tragic consequences, such as the administration of unnecessary chemotherapy or the onset of coma [9].

Since the few studies available on laboratory errors are heterogeneous, the frequency of errors in clinical laboratories reported in the literature varies greatly, there being differences in definitions used, methods used to identify frequency and nature, and study design and setting (Table 1) [10].

3. Strategies for preventing errors

Although, most of the laboratory quality improvement efforts once focused on improving the analytic process, findings reported in the

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Table 1
Types and rates of error in the three stages of the laboratory testing process (modified from reference [10]).

Phase of TTP	Type of error	Rates
Pre-analytical (Outside the laboratory)	Inappropriate test request	46–68.2%
	Order entry errors	
	Misidentification of patient	
	Container inappropriate	
	Container improperly labeled	
	Sample collection and transport inadequate	
	Specimen collected from infusion route	
	Inadequate sample/anticoagulant volume ratio	
	Insufficient sample volume	
Pre-analytical phase (Within the laboratory)	Sorting and routing errors	
	Pour-off errors	
	Labelling errors	
	Biohazard exposure event	
Analytical phase	Equipment malfunction	7–13%
	Sample mix-ups/Interference	
	Undetected failure in quality control	
	Procedure not followed	
Post-analytical phase	Failure in reporting	18.5–47%
	Erroneous validation of analytical data	
	Improper data entry	
	Excessive turn- around time	

literature showed that pre-analytical factors call for an equally thorough consideration and investigation, and indicated that laboratories should implement a series of effective interventional measures to reduce pre-analytical errors, thereby enhancing patient safety.

A comprehensive plan to prevent pre-analytic errors has five interrelated steps [11–13]:

1. Developing clear written procedures.
2. Enhancing healthcare professional training.
3. Automating functions, both for support operations and for executive operations.
4. Monitoring quality indicators.
5. Improving communication among healthcare professionals and fostering interdepartmental cooperation.

Written procedures should clearly explain how to reliably identify a patient, collect and label a specimen, and subsequently transport the specimen and prepare it for analysis. To ensure that written procedures are consistently followed, those who perform pre-analytic activities must understand not only what the proper procedures are, but also why these steps are important and how failure to correctly follow instructions can cause serious errors. This calls for ongoing training, beginning in the new employee orientation period and continuing in annual proficiency and competency assessments. Moreover, because many pre-analytic steps are often performed by non-laboratory personnel, the laboratory's program should include efforts to train them to properly follow collection procedures.

Modern technologies such as robotics and information management systems can also help reduce errors. Pre-analytical workstations allow the automation of some steps, thereby reducing both the number of people involved in the pre-analytic phase, and the number of manual steps required; moreover, barcodes simplify specimen routing and tracking. A computerized order entry systems (COES) that simplifies test ordering for the clinician obviates the need for a second person to transcribe the order.

The success of efforts made to reduce errors must be monitored in order to assess the efficacy of measures taken. Quality indicators, such as the rate of sample label errors, which focus on specific problems, should be used for assessment. It is also important to bear in mind that, as many pre-analytic activities are performed by non-laboratory personnel, interdepartmental cooperation is of crucial importance in avoiding errors. It is thus clear that the entire health care system is involved in improving the total testing process.

4. Pre-analytical procedures performed within the laboratory

Specimen preparation, which involves all the activities required to render a sample suitable for analysis, includes log-in, centrifugation, aliquotting, pipetting, dilution, and sorting specimens into batches for their introduction into automated analyzers. When performed by technologists unaided by automation, the pre-analytic tasks account for the most labor intensive phase of testing in the medical laboratory. The risk of human error in this phase is exacerbated by the fact that currently laboratories are handling ever-increasing workloads while experiencing a reduction in personnel: the consequent physical and mental fatigue also leads to errors.

The specimen preparation step, which contributes to approximately 19% of the overall cost of analyzing a single specimen, is also time-consuming (37% of time spent in producing a result) [10]. The manual handling of potentially infectious samples exposes laboratory staff to biohazards whenever samples are splashed or test tubes broken.

5. Pre-analytical workstations

The automation of the pre-analytical phase is therefore a means to preventing errors. In a paper on this issue, the use of automated pre-analytical robotic workstations effectively reduced the labor associated with specimen processing, and reduced the number of laboratory errors occurring on sorting, labeling, and aliquotting specimens; it was also found to improve the integrity of specimen handling throughout the steps of specimen processing [14].

Before choosing an automated pre-analytical workstation, laboratory professionals must establish specific quality goals: avoiding mistakes calling for new sample collection; reducing sample volume; ensuring secure patient and specimen identification; tracking throughout the process; achieving effective preservation; decrease sample handling; contain biohazards; minimize human labor and number of test-tubes used [15]. These quality goals may then be applied to various steps of sample handling, including sample log-in, sorting, centrifugation, detection and aliquotting. It should also be ensured that the system, on installation, will have no adverse effects on the working environment in terms of generation of excessive heat or noise, and that it will minimize occupational exposures; nor should it call for major renovations to fit into the available space. The available components/options for pre-analytical workstations and some of their advantages and disadvantages are shown below [16,17]

1. Sample specimen input area: a loading module where bar code-labeled specimens are introduced into the system. These input units often separate stat specimens from routine specimens, or specimens requiring centrifugation or decapping, into different trays or racks so the system's process control can determine the steps to be performed based on the specimen's loading location.
2. Sample identification: although all systems initially read the specimen bar code to identify the sample, there are two options for sample identification: (1) multiple linear bar code readers, and (2) radio-frequency identification (RFID) of specimen carriers combined with 1 or more bar code readers. The robustness of sample identification is critical; when specimens are identified by bar codes the sensitivity of the system to bar code-label quality and orientation is important and, when specimens are identified by RFID fixed in their carriers, it is of crucial importance to prevent the manual removal of tubes from the carriers in order to maintain the link between the tube bar code and the carrier's identification. Some systems have multiple bar code readers placed at critical locations in the processing system to track specimens and provide information for their proper routing to the various stations in the processing system.