

QUALITY MANAGEMENT OF THE PRE-ANALYTICAL PHASE: MONITORING AND CONTROL

Abstract

Background: - Pre-analytical steps represent the most vulnerable phase of the Laboratory testing process. Consequently, many problems arise before the analysis of the submitted specimens.

Objectives: - to review the evaluation of the pre-analytical variables, monitor and control these errors.

Methods: - A literature review of an effective quality assurance and continuous quality improvement of the pre-analytical phase.

Results: - Many of the variables are outside the traditional laboratory areas. Monitoring pre-analytical variables requires the coordinated effort of many individuals and hospital departments each of which must recognize the importance of these efforts in maintaining high quality service.

Conclusion: - Continuous monitoring and control of the initial phase of the total testing process will allow the decreases of pre-analytical errors so that the laboratory can achieve an adequate performance level.

Keywords: Pre-analytical errors, quality management, monitoring and control.

Introduction

The pre-analytical phase is the most complex of the total testing process as pre-analytical errors are estimated to account for up to 70% of all mistakes made in laboratory diagnostics [1,2] Studies have shown that more than 60-70% of the most important decisions on admission discharge and medication are based on laboratory test results indicating the high degree of influence and the importance of the quality of laboratory testing and reporting [3,4].

The pre-analytical phase consists of two categories, the pre-pre-analytical phase the true or conventional pre-analytical phase [5, 6]. The management of quality in medical laboratories today is generally subject to national or international guidelines for good laboratory practice [7]. The ISO 15189:2012 standard for medical laboratories – particular requirements for quality and competence, provides a framework for the design and improvement of process-based quality management systems [8]. Laboratory service is a highly dynamic sector of healthcare. The implementation of a quality management system is a major issue for patient

33 safety both inside and outside the walls of the medical laboratory [9]. Pre-analytical processes
34 are generally held outside the medical laboratory and not under the control of laboratory
35 management. [10]. Therefore, the active monitoring and control of all possible defects that
36 are carried by non-laboratory personnel is essential in order to incorporate actions outside the
37 laboratory in the laboratory quality assurance plan. This article discussed the components of
38 an effective continuous quality improvement/quality assurance program in the pre-analytical
39 phase of the laboratory testing phase.

40 **Pre-analytical Errors**

41 The pre-analytical phase of the total laboratory testing process is where the majority of
42 laboratory error occur. Studies have shown that pre-analytical errors predominated in the
43 laboratory ranging from 31.6% to 75% [11, 12, 13].

44 The pre-analytical phase can be classified into two namely the “Pre”-pre-analytical
45 constituting (46-68%) and the “true” or “conventional” pre-analytical phase (3-5%). The
46 “Pre” pre-analytical phase refers to the time between the tests ordering until receiving time by
47 the laboratory [14,15,16] while the “conventional” pre-analytical step involves the process
48 required to make sample suitable for analysis: centrifugation, aliquoting, diluting and sorting
49 specimens into batches for their introduction into automated analyzers [17,18].

50 The commonest causes of errors in the ‘Pre’ pre-analytical phase include inappropriate test
51 request, order entry, patient/specimen mis-identification, sample collected from infusion
52 route, sample collection (hemolysis, clotting, insufficient value etc), inappropriate container,
53 handling, storage and transportation. The sources of error in the ‘true’ pre-analytical phase
54 include sorting and routing, pour-off aliquoting, pipetting and labeling centrifugation (time
55 and/or speed) [19,20]. In laboratories, analytical errors are mostly all alike: every method has
56 some amount of analytical error in the form of systematic and random error, however with
57 pre-analytical, each laboratory has pre-analytical errors in their own way. While the
58 analytical process is essentially the same in each laboratory (the instrument and methods are
59 designed to perform the same process), the path that the patient specimen takes to reach the
60 instrument is unique to each healthcare setting. Accordingly, since the problems tend to be
61 unique, the solutions must often be customized. There is no standardized list of errors upon
62 which all laboratories and regulators agree. It is important for each laboratory to perform a
63 systems analysis of its own laboratory testing system to identify these areas where errors are
64 likely to occur. There are seemingly unlimited ways by which a specimen can go wrong
65 before it reaches the laboratory and the analytical system. Once the processes have been

66 documented, the processes that are most susceptible to error should be identified and should
67 receive the most attention [21, 22].

68 **Components of an effective quality control monitoring**

69 The implementation and monitoring of quality indicators should be considered essential
70 components in continuous quality improvement program. Some components of an effective
71 pre-analytical quality control program include

- 72 1. Correct Ordering of tests – Careful monitoring of test request and their
73 appropriateness is likely to increase in importance and the laboratory will likely have
74 a role in identifying situations in which test utilization can be optimized. Delayed and
75 lost test requisitions, specimens and reports have been major problems for the
76 laboratories (table 1)
- 77 2. Patient Preparation – The patient must be informed of any pretest preparations such as
78 fasting or medical restrictions. Proper patient preparation is essential for the test
79 results to be meaningful. Specific enquiry should be made regarding patient
80 preparation before specimens are collected and efforts should be made to correct
81 noncompliance. Compliance is monitored directly when the laboratory employs its
82 own phlebotomists [23].
- 83 3. Correct Identification of the patient by the phlebotomist- The name and identification
84 on the collection sample and the request form must match each other and must also
85 match the correct patients [24].
- 86 4. Proper specimen collection- The specimen must be collected in the correct container
87 and under conditions specified by the test procedure.
88 The techniques used to acquire a specimen affect many laboratory tests. Improper
89 containers and incorrect preservation greatly affect test results and make them
90 inappropriate [25].
- 91 5. Specimen Transportation – The stability of specimen during transport from the patient
92 to the laboratory is seldom monitored, however, this aspect may be critical for some
93 tests when performed locally and for most tests when sent to regional centers and
94 commercial laboratories. In controlling specimen transport, the essential feature is the
95 authority to reject specimens that arrive in the laboratory in an obviously
96 unsatisfactorily conditions. [26].
- 97 6. Specimen separation and aliquoting – Separating and aliquoting blood specimens are
98 more directly under the control of the laboratory. The main variables are the

99 centrifuges, the containers used and the personnel for QC purposes, centrifuges
 100 should be monitored by checking the speed timer and personnel [27,28].

Phase	Possible Errors
Ordering	Sample without order Duplicate order Incorrect test Not readable Incorrect time/date Incorrect priority Typing error
Collection	Forgotten Failed Incorrect tube Lost tube Incorrect volume Incorrect temperature Incorrect treatment Patient state not appropriate (example: patient not fasting) Incorrect time/date Incorrect priority Tube missing Patient missing
Identification (this type of error can occur at any point throughout the total testing process	Insufficient clinical information Missing/incorrect patient ID Missing/incorrect physician ID Incorrect patient Incorrect labeling
Transportation	Forgotten/missing/lost Incorrect sorting Misrouted specimen (example sent to many lab) Incorrect packing

	Incorrect treatment during transport (example not refrigerated)
Sample preparation	Centrifugation Incorrect speed/time Too late Tube broken Label lost Incorrect temperature Insufficient centrifugation Pipetting Forgotten Too late Incorrect pipetting Freezing Forgotten Delayed freezing Incorrect temperature Sample stability exceeded Icterus Hemolysis Lipemia Delayed coagulation Coagulated Drug interference Antibody interference

101 These procedures cannot be verified or monitored by statistical procedures, the indication that
102 there has been a lapse in quality in this area usually reaches the laboratory in the form of a
103 complaint or a report of a quality compromising event. The possible compromise in quality is
104 then evaluated by a formalized process that defines the indicator of the possible lapse in
105 quality, standards of performance for the indicator, and mechanism for and monitoring the
106 performance most pre-analytical quality assurance monitoring procedures, take this problem-
107 oriented approach to ensure quality.

108

Quality management

Quality management has been described as the implementation of scientific method; or the Plan-do-check-Act cycle (PCDA) [29]. The PCDA cycle is represented by components for quality laboratory processes, quality control, quality assessment, quality improvement and quality planning- all of which have centered on the quality goals, objectives and requirements to be achieved by the medical laboratory.

Quality management involves the policies, processes and procedures that are needed to organize implement and support laboratory testing. Quality assurance is the outcome of this quality management process. It takes well-planned and well managed activities to achieve quality Standard operating procedure (SOPs) are the starting point in managing quality. Medical laboratories must implement systematic processes that are performed in the same way by all personnel. We must also increase education efforts with laboratory personnel, particularly in the minute details of these critical processes. This is an area where accreditation guidelines (ISO) and standards for best laboratory practice (CLSI, ISO) dovetail with the practical needs of the laboratory. These institutions require well-defined and detailed procedures manuals. It is essential that the laboratory analysts have the correct instructions, if we want them to perform the procedures correctly. Then with better trained staff, we make fewer errors [30]

Table 1

Error tracking in medical laboratory testing at the pre-analytical phase

Adapted from [7]

Getting everyone to do the same thing is a requirement if quality is to be managed anywhere in the laboratory and in any phase of the testing process. All of these instructions need to be documented in a clear format and made available to all staff. But the procedures can't be just written down and forgotten or ignored. You must train the staff and refresh their training periodically to do the correct procedures [31].

Quality system is defined as the organization, structure, resources, processes and procedures to implement quality management. Therefore, the PDCA cycle that we have adopted provides a quality management process and its components (QP, QLP, QC, QA, Q1) are sub-processes and procedures while there is a certain organization and structure to this model, it does not consider the management organization, laboratory structure, and laboratory resources that are necessary to support quality management in the laboratory [32].

Summary

The responsibility for accurate and timely test reports generally is with the laboratory, but many problems can arise before and after the analysis of the submitted specimen. To monitor and control these errors, it is essential to perform a system analysis of the laboratory and to identify the type of pre-analytical variable. The operation of the medical laboratory can be viewed as a series of processes, each of which has potential sources of error. Errors detection for pre-analytical errors includes visually checking for lipemia, hemolysis fibrin threads and short draws in anti-coagulated tubes. It may also include delta checks (comparing a patient's lab result with a previous lab result) and evaluating timeliness of the specimen.

When there are few ways to detect errors, more devices must be in place for error prevention. Strict guidelines in patient identification and collection processes must be followed. Quality management guidelines from ISO, CLSI and CLIA all identify the importance of the QC for process control and assurance of quality, but also recognized the need for many other essentials to support and sustain quality within the broader management and organization of a medical laboratory.

Conclusion

Comprehensive laboratory systems need to be defined and developed to account for the particular management and technical requirements of a medical laboratory. Sub-systems include pre-analytical, analytical and post analytical quality systems which in particular must address the technical requirements of a medical laboratory. Laboratories must develop quality systems that address the needs and characteristics of their own testing processes and their customer's requirements for quality.

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