

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

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Comment [HM1]: The title is incomplete. Quality management of the preanalytical phase of what????????????

Background: - Laboratory testing is a complex process comprising three phases that includes the preanalytical, analytical and the post analytical phase of total laboratory testing process. Pre-analytical phases represent the most error prone vulnerable phase of the laboratory testing process. Consequently, many problems arise mostly at pre-analytical phase of non-laboratory settings which are outside the control of laboratory before the analysis of the submitted specimens.

Objectives: - To evaluate the monitoring and control of errors in the non-laboratory preanalytical related pre-analytical phase of the total testing process.

Methods: - A literature review. Please, provide details of how you synthesized and distilled your literature. Simply put, how can someone replicate this research using your methodology

Results: - The prevalence of preanalytical errors is approximately 70% of all errors that occurred in laboratory diagnostics. Many of the variables are outside the traditional laboratory areas. Errors in the pre-analytical phase can result in misdiagnosis and mismanagement and consequently compromise harm for patients safety. Errors presentation at this stage requires good communication and co-operation among all health professionals involved in the total testing process from the time a laboratory request is made until the sample is ready for testing.

Conclusion: - In non-laboratory settings cContinuous monitoring and control of the initial phase of the total testing process is critical in order to will allow reduce the decrease of pre-analytical errors so that the laboratory can achieve an accurate and reliable results. adequate performance level. Non-laboratory errors in pre-analytical phase can be monitored and controls by timely and effective coordination of health care professionals for improved patients safety and reliable testing outputs. Impact of error on patient outcomes can be prevented by the timely and effective action of health professionals.

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

Introduction

The tTotal laboratory testing process includes three phases: the preanalytical, the analytical and the post analytical phase. The pre-analytical phase is the most complex of the total testing

Comment [HM2]: The introduction is incomplete without talking of the other phases and their impact / error rates according to literature before you focusing on the pre-analytical. This will make a reader understand the various phases of the laboratory total testing process.

33 | process as pre-analytical errors are estimated to account for approximately 70% of all ~~errors that~~
34 | ~~occurred mistakes made~~ in laboratory diagnostics [1,2] Studies have shown that more than 60-
35 | 70% of the most important decisions on admission, discharge and medication are based on
36 | laboratory test results indicating the high degree of influence and the importance of the quality of
37 | laboratory testing and reporting [3,4]. The pre-analytical phase consists of two categories, the
38 | “pre”-pre-analytical phase and the “conventional” pre-analytical phase [5, 6]. The management
39 | of quality in medical laboratories today is generally subject to national or international guidelines
40 | for good clinical laboratory practice [7]. The International Organization for Standardization
41 | ~~International Standard Organization~~ (ISO) 15189:2012 standard for medical laboratories –
42 | particular requirements for quality and competence, ~~which~~ provides a framework for the design
43 | and improvement of laboratory process-based on quality management systems [8]. Laboratory
44 | service is a highly dynamic sector of healthcare. The implementation of a quality management
45 | systems is a major issue for patient safety both inside and outside the walls of the medical
46 | laboratory [9]. Some important pre-analytical phase of laboratory process ~~are~~ generally held
47 | outside the medical laboratory environment, which are not under total control of laboratory
48 | management. [10]. Therefore, ~~the~~ active monitoring and control of all possible defects that are
49 | ~~could occurred carried among by~~ non-laboratory personnel is essential in order to incorporate
50 | actions outside the laboratory in the laboratory quality assurance plan. This article discussed the
51 | monitoring and control of pre-analytical errors in non-laboratory ~~for settings for~~ continuous
52 | quality improvement in laboratory testing.

53 | **Pre-analytical Errors**

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

57 | The pre-analytical phase can be classified into two namely the “Pre”-pre-analytical constituting
58 | (46-68%) and the “true” or “conventional” pre-analytical phase (3-5%).[14,15] The “Pre” pre-
59 | analytical phase refers to the time between the tests ordering until samples receiving time by the
60 | laboratory [16] while the “conventional” pre-analytical step involves the process required to
61 | make sample suitable for analysis which included:- centrifugation, aliquoting, diluting and
62 | sorting specimens into batches for their introduction into automated analyzers [17,18].

63 | The commonest causes of errors in the ‘Pre’ pre-analytical phase include inappropriate test
64 | request, order entry, patient/specimen mis-identification, sample collected from infusion route,

65 sample collection (hemolysis, clotting, insufficient volume etc), inappropriate container,
66 handling, storage and transportation. [19] The sources of error in the ‘conventional’ pre-
67 analytical phase includes sorting and routing, aliquoting, pipetting, centrifugation (time and/or
68 speed) [20]. In laboratories, analytical errors are mostly all alike: every method has some amount
69 of analytical error in the form of systematic and random error, however with pre-analytical, each
70 laboratory has pre-analytical errors in their own way. (Citation) While the analytical process is
71 essentially the same in each laboratory (the instrument and methods are designed to perform the
72 same process), the path that the patient specimen takes to reach the instrument is unique to each
73 healthcare setting- (Citation). Accordingly, since the problems tend to be unique, the solutions
74 must often be customized. There is no standardized list of errors upon which all laboratories and
75 regulators agree. It is ~~important~~ therefore important for each laboratory to perform a systems
76 analysis of its own laboratory testing system to identify these areas where errors are likely to
77 occur. There are seemingly unlimited ways by which a specimen can go wrong before it reaches
78 the laboratory and the analytical system. Once the processes have been documented, the
79 processes that are most susceptible to error should be identified and should receive the most
80 attention [21, 22].

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

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

- 85 1. Correct Ordering of tests – Careful monitoring of test request and their appropriateness is
86 likely to increase in importance and the laboratory will likely have a role in identifying
87 situations in which test utilization can be optimized. Delayed and lost test requisitions,
88 specimens and reports have been major problems for the laboratories (table 1)
- 89 2. Patient Preparation – The patient must be informed of any pretest preparations such as
90 fasting or medical restrictions. Proper patient preparation is essential for the test results to
91 be meaningful. Specific enquiry should be made regarding patient preparation before
92 specimens are collected and efforts should be made to correct noncompliance.
93 Compliance is monitored directly when the laboratory employs its own phlebotomists
94 [23].

3. Correct Identification of the patient by the phlebotomist- The name and identification on the collection sample and the request form must match each other and must also match the correct patients [24].

4. Proper specimen collection- The specimen must be collected in the correct container and under conditions specified by the test procedure.

The techniques used to acquire a specimen affect many laboratory tests. Improper containers and incorrect preservation greatly affect test results and make them inappropriate [25].

5. Specimen Transportation – The stability of specimen during transport from the patient to the laboratory is seldom monitored, however, this aspect may be critical for some tests when performed locally and for most tests when sent to regional centers and commercial laboratories. In controlling specimen transport, the essential feature is the authority to reject specimens that arrive in the laboratory in an obviously unsatisfactory conditions. [26].

6. Specimen separation and aliquoting – Separating and aliquoting blood specimens are more directly under the control of the laboratory. The main variables are the centrifuges, the containers used and the personnel for QC purposes, centrifuges should be monitored by checking the speed timer and personnel [27,28].

Unfortunately, these procedures cannot be verified or monitored by statistical procedures, the indication that there has been a lapse in quality in this area—which usually reaches the laboratory in the form of a complaint or a report of a quality compromising event. The possible compromise in quality is then evaluated by a formalized process that defines the indicator of the possible lapse in quality, standards of performance for the indicator, and mechanism for and monitoring the performance. Most pre-analytical quality assurance monitoring procedures, take this problem-oriented approach to ensure quality (Citation).

Quality management systems

Quality management ~~has~~ systems 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 (Citation).

126 | Quality management ~~_involves~~ systems involves the policies, processes and procedures that are
 127 | needed to organize implement and support laboratory testing (Citation). Quality assurance is the
 128 | outcome of this quality management process. It takes well-planned and well managed activities
 129 | of every step taken from the test ordering to the point of analysis of sample in the laboratory to
 130 | achieve quality. Standard ~~o~~Operating ~~p~~Procedures (SOPs) are the starting point in managing
 131 | quality. Medical laboratories must implement systematic processes that are performed in the
 132 | same way by all ~~personnel~~ personnel. ~~Efforts~~ —We must also be made toward increased
 133 | education and training of efforts with laboratory personnel, particularly in the minute details of
 134 | these critical processes. This is an area where accreditation guidelines (ISO) and standards for
 135 | clinical best laboratory practice (CLSI, ISO) ~~do~~ detail with the practical needs of the laboratory.
 136 | These institutions require well-defined and detailed procedures and manuals. It is essential that
 137 | the laboratory analysts have the correct instructions, ~~if if he or she we~~ must want them to perform
 138 | ~~the _procedures~~ laboratory procedures correctly. In addition, competent and well trained
 139 | personnel who would ensure errors free and reliable testing ~~Then with better trained staff, we~~
 140 | ~~make fewer errors~~ [30]

141 | **Table 1**

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

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
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Adapted from [7]

Table 2

Types and Description of most common prep-analytical errors

Pre-analytical errors	Description
Hemolyzed samples	Presence of pink to red tinge in serum or plasma
Insufficient sample	Serum obtained not enough for requested test
Incorrect sample tube	Most samples received should not be in anticoagulated tubes
Sample not on ice	Samples for arterial blood gases analysis not transported on ice
Incorrect sample identification	Mismatch between name on sample and request form
Tube broken in centrifuge	The use of different tube sizes for sample collection
Delay in sample transportation	Samples were not sent to the laboratory on

	time
Expired reagents	Some reagents expired before use
Sample mix up	Samples intended for other laboratories were sent to the biochemistry lab

Adapted from [35]

The most common pre-analytical errors include inappropriateness of test order, patient identification error, timing errors in sampling and preparation, hemolysis and lipemic blood samples, inappropriate transport and inadequate and inappropriate sample collection tube (table 2).

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 well –and understood and made available to all staff. ~~But the procedures can't be just written down and forgotten or ignored.~~ In addition, all laboratory staff must be trained and periodic refresher training as needed is required for staff to be able to carry out relevant procedures correctly. You must train the staff and refresh their training periodically to do the correct procedures [31].

Quality management systems 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 (qQuality pPlanning (QP), qQuality Iaboratory pProcedure (QLP), qQuality control (QC), qQuality assurance (QA), qQuality improvement (QI) 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]. Review of the accreditation criteria, patient safety concerns and discussions in the literature indicate some clear areas for action for laboratories that wants to extend their quality attention outside the physical confines “outside the box” of the laboratory. The areas of highest priority in the pre-analytical phase are patient/sample identification. Laboratories can develop clear sample acceptance and rejection criteria which are linked to monitoring of the collection and transportation processes. Sample hemolysis and clotting are the commonest causes of unsuitable blood specimens and most laboratories have procedures to handle such specimen at sample receipt, but a more pro-active approach is extending this back to the point of collection [33,34].

177 The laboratories procedures regarding unlabeled or mislabeled specimens should be clear and
178 sample relabeling by laboratory personnel, clinical staff or third parties is strongly discouraged
179 [35,36]. Collection procedure, container, transport temperature/time/safety and within –
180 laboratory pre-analytical temperature/time/safety criteria should be stipulated and monitored.

181 Regular and periodic inspection of pre-analytical phase should be ~~are~~ carried out by teams of
182 practicing laboratory professionals using standard checklist which cover general laboratory
183 functions as well as specific disciplines. The standard checklist questions should be ~~are~~ explicit
184 in their intent and the required evidence or compliance (e.g., records, written procedures and
185 policies). More than 6,000 laboratories worldwide are college of American Pathologists (CAP)
186 accredited (Citation). The laboratory general checklist specifically refers to the monitoring of
187 pre-analytical quality and the CAP laboratory patient safety goals which requires the quality
188 management program to include monitoring important key indicators of quality including
189 patient/sample identification, test order accuracy and specimen acceptability.

190 **Summary**

191 The pre-analytical phase of the ~~t~~Total ~~t~~Testing ~~p~~Process is most prone ~~vulnerable~~ to errors. The
192 number of errors depend on the management of samples. The clinical laboratory must pay more
193 attention to good handling of samples. Preanalytical quality indicators include the
194 appropriateness of test selection, patient/samples identification, samples collected in
195 inappropriate containers or with insufficient volumes, hemolyzed or clotted samples, improperly
196 stored samples or samples damaged in transport. Preanalytical error prevention demands, good
197 communication and cooperation among all health professionals. The continuous education of
198 personnel involved in procedures for the collecting handling preparing and transporting
199 specimens is critically important for proper understanding of the effects of preanalytical
200 variables on specimen quality and the reliability of test results. Studies have shown that “pre”-
201 preanalytical errors predominated in the laboratory ranging from (46 – 68%), while the
202 conventional pre-analytical account for (3-5%) [5].

203 **Conclusion**

204 Preanalytical phase of total testing -processes are generally held outside the clinical laboratory
205 which are mostly ~~and~~ not under the total control of laboratory management. ~~Difficult to control~~
206 ~~P~~reanalytical phase is ~~errors prone stage and difficult to control may be is a possible reason for~~
207 ~~the high prevalence of errors in this phase. phase.~~ The implementation of ISO 15189:2012
208 quality management guidelines in the preanalytical phase should be adopted in order to prevent

209 or reduce errors to acceptable limit because the errors in this initial phase of the laboratory
210 testing are preventable since human factors involved are well understood and defined. Therefore,
211 inter departmental communication and cooperation of all stakeholders are crucial for effective
212 monitoring and quality control for continuous quality improvement. It is therefore
213 recommended that active monitoring and control systems of the errors that occurred in ~~caused~~
214 ~~the by~~ non-laboratory settings personnel should be monitored be and sustained to ensure
215 reliable testing. ~~The implementation of ISO 15189:2012 quality management guidelines in the~~
216 ~~preanalytical phase should be adopted in order to prevent or reduce errors, as errors in this initial~~
217 ~~phase of the laboratory testing are preventable if we understand the human factors involved;~~
218 ~~therefore, inter departmental communication and cooperation are crucial for effective quality~~
219 ~~control and continuous quality improvement.~~

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