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Frequency Assessment of Pre-Analytical Errors in Tertiary Care Clinical Laboratories Services.

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Abstract: It is reported that pre-analytical phase is the most vital and hardest to regulate and monitor because of the involvement of too many professionals. Review of available data and its analysis showed a significant prevalence of errors the pre-analytical phase. In the present study, we report the comprehensive assessment of the frequency and types of pre-analytical errors. Our purpose was to investigate the factors leading to specimen rejection and its impact on reporting and management. Various influencing factors for QC and QM were identified with help of daily assessment of around 800 patients and 5500 parametric tests requested for a period of one year (Jan 2016 to Dec 2016). We documented the occurrence of pre-analytical phase errors for Hepatic (Bilirubin, Alanine aminotransferase ALT, gamma glutamyl transpeptidase gGT, Alkaline phosphatase, ALP) and thyroid (tri-iodothyronine T3, tetra-iodo thyronine T4, Free tri-iodothyronine FT3, tetra-iodo thyronine FT4) hormone function tests. Some of the foremost pre-analytical error or reason for rejection was hemolyzed and lipimic samples, followed by delays in delivery, incorrect sample identification, insufficient quantity or without clinical history. It is concluded that by using checklist, audits, and trainings in addition to standardization of collection, transport and storage mechanisms, the existing practices of pre-analytical steps should be executed by all clinical laboratories, especially those associated with tertiary care hospital. This will provide deliverance of standardized, proficiency tested, optimized services for prompt and better patient care.

Key words: Pre-analytical errors, Revalidation, Standardized, IFCC, Harmonized

1. Introduction

This is an established fact that the quality of the entire process leading to Clinical laboratory reports can affect the evaluation of patient's status and may cause repercussions on clinical decisions. The introduction of Quality control (QC) and Quality Management (QM) in pre-analytical, analytical and post-analytical phases is an important entity for providing patient-friendly, cost-effective, quality controlled diagnostic services.

Pre- and post-analytical errors have been recognized as a major predicament of all clinical laboratory errors, most importantly the pre-analytical phase [1-3]. Generally, the pre-analytical phase includes patient preparation, specimen transportation, specimen collection and storage. A majority number of clinical laboratories, whether independent or attached with a hospital, depict errors at either pre-analytical phase or post-analytical phase. Arguably, pre-analytical phase is the most vital and hardest to regulate and monitor because of the involvement of too many professionals, such as physicians, specialists of laboratory medicine, nurses, laboratory technicians and phlebotomists [1,2]. Pre-analytical errors necessitate specimen rejection; negatively affect patient safety and delays timely treatment and management [2]. Review of available data and its analysis showed a high prevalence of improper sample handling during the pre-analytical phase, either in clinical chemistry, microbiology, hematology or molecular pathology, which comprised a large chunk of stat reporting.

In the present study, we report the comprehensive assessment of the frequency and types of pre-analytical errors. Our purpose was to investigate the factors leading to specimen rejection and its impact on reporting and management.

2. Materials and Methods:

Various influencing factors for QC and QM were identified with help of daily assessment of around 800 patients and 5500 parametric tests requested for a period of one year (Jan 2016 to Dec 2016). An estimated 288,000 blood samples were routinely collected from both indoor and OPD patients for Biochemistry labs at LNH during a year. We documented the occurrence of pre-analytical phase errors for Hepatic (Bilirubin, Alanine aminotransferase ALT, gamma glutamyl transpeptidase gGT, Alkaline phosphatase, ALP) and thyroid (tri-iodothyronine T3, tetra-iodo thyronine T4, Free tri-iodothyronine FT3, tetra-iodo thyronine FT4) hormone function tests and each sample was followed from the time of blood withdrawal to testing equipment. Each step of laboratory processing was evaluated as a part of our ISO 9001:2015 Quality Management System daily checks and monthly audits. Phlebotomy techniques, patient preparation, sample handling, instrument handling and maintenance were evaluated where and when needed for assessment of maintainability of standard operating procedures (SOP).

Department of Clinical Biochemistry Lab services at LNH is comprised of 3 fully automated chemistry and 3 electrolyte analyzers, in addition to three immunology These equipment have inbuilt calibration traceability and internal quality controls (QC). In addition to routine usage of QC protocols of PNU (normal control) and PPU (Pathological control), external quality surveys of College of American Pathology (CAP) were also an integral part of QMS at our Clinical Laboratory services.

Frequent and occasional errors in each factor were noted and tabulated accordingly pre-analytical phase such as mentioned in Table 1. Other factors that may influence are listed as follows;

Pre-analytical phase of QC:

- For Patients
  - Identification (name)
  - Preparation for collection
  - Treatment with drugs

- Feeding
- Daily clinical variation

- Each item and its error was rechecked and calculated with respect to factor
- The results (i.e. errors) are expressed as percentage [%] error for each influencing factor.

3. Results:

Table 1A: Pre-analytical errors Description Daily Chart

Errors	**e.g. Frequency per 100 samples**
Hemolyzed sample	03
Insufficient sample	02
Incorrect sample tube/vaccutainers	00
Sample not on ice	01
Incorrect sample identification	01
Delay in sample transportation	03
Sample mix-ups	00

In cases of Hepatic (Bilirubin ALT, gGT, ALP) and thyroid (T3, T4, FT3, FT4) function tests, some of the foremost pre-analytical error or reason for rejection was hemolyzed and lipimic samples, followed by delays in delivery, incorrect sample identification, none-sufficient quantity or without clinical history. Table 2 summarized the errors that had been recognized during assessment of pre-analytical errors during the period Jan 2016 to Dec 2016.

International Federation of Clinical Chemistry (IFCC) or AACC (American Association of Clinical Chemists) standardization recognizes these pre-analytical errors and through corrective actions, checklists and tools (e.g trainings), it provides baseline to avoid and rectify these errors.

Table 1B: Definition of Pre-analytical errors (Reference[2])

Hemolyzed sample	Presence of pink to red tinge in serum Plasma
Insufficient sample	Serum obtained not enough for requested Tests
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
Delay in sample transportation	Samples were not sent to the laboratory on Time
Sample mix-ups	Samples intended for other laboratories were sent to the biochemistry laboratory

4. Discussion:

The application of QM to clinical laboratory testing requires that all steps of the diagnostic process to be managed to reduce or eliminate all defects in the process. The pre-analytical phase is dependent on patient, sample collection, transport, preliminary treatment of sample (processing) and preparation of the sample for analysis. The analytical phase of QC is composed of preparation of reagents, pippetting of reagents and samples, incubation and measurement (analysis). Post-analytical phase depends on calculation, calibration, documentation and transcription, expression of units, reporting and distribution. This study outlined various types of factors that influence pre-analytical phase of QC and QM and the errors, which may influence the results and reports. Laboratory testing is roughly divided into three phases: a pre-analytical phase, an analytical phase and a post-analytical phase [1-4]. Most analytical errors have been attributed to the analytical phase. However, recent studies have shown that up to 70% of analytical errors reflect the pre-analytical phase. The pre-analytical phase comprises all processes from the time a laboratory request is made by a physician until the specimen is analyzed at the lab [3-6]. Specimen rejections in a clinical chemistry laboratory during a 1-year period were reviewed retrospectively and analyzed for frequency, cause, circumstances, and impact.

It was noted that all factors related with rejection due to pre-anaytical errors can be remediable by training and quality assurance measures such as Quality Management system (QMS, ISO, CAP) implementation. Furthermore, all policies and procedures specific to specimen collection, transportation, and preparation need to be strictly followed [1]. This was also argued that frequent, preventable medical errors can have an adverse effect on patient safety and quality as well as leading to wasted resources [3]. Moreover, it is a known fact that in clinical laboratory processes, errors can occur at any stage of sample processing; pre-analytical, analytical, and post analytical stages. Coincidently, evidence shows most of the laboratory errors occur during the pre-analytical stage, inclusive of receipt and processing of specimens, which is one of the main steps in the pre-analytical stage. Errors in this stage could be due to mislabeling, incorrect test entry and entering the wrong location, among other reasons [3]. Interestingly several Clinical Laboratory researchers argued that post- and pre-analytical errors were neglected worldwide, and in last decade focus shifted on the importance of the pre-analytical phase to obtain accurate lab results [3]. In this regard an American pathologist program conducted a study enrolling 660 laboratories and showed that order error rate from outpatient centers was 4.8% [2,5,6]. Similarly the College of American Pathologists, including 120 labs, concluded that mis-identification is a common laboratory error [2,6]. However, a Danish study on laboratory errors showed that 81% of lab errors were pre-analytical, while only 10% of lab errors were analytical [2].

5. Conclusion:

It is concluded that revalidating (checklist, audits, and trainings) and harmonizing (standardization of collection, transport and storage) the existing practices of pre-analytical steps should be executed by all clinical laboratories, especially those associated with tertiary care hospital. This is will ensure deliverance of standardized, proficiency tested, optimized services for prompt and better patient care that will guarantee maximum patients' confidence.

6. References:

1. Cao L, Chen M, Phipps RA, Del Guidice RE, Handy BC, Wagar EA, Meng QH.Causes and impact of specimen rejection in a clinical chemistry laboratory. Clin Chim Acta. 2016; 458:154-8.
2. Najat, D. Prevalence of Pre-Analytical Errors in Clinical Chemistry Diagnostic Labs in Sulaimani City of Iraqi Kurdistan. PLoS ONE 2017; 12(1): e017021
3. Saleem NA, Al-Surimi K Reducing the occurrence of errors in a laboratory's specimen receiving and processing department. BMJ Quality Improvement Reports 2016; 1-4
4. Bonini P., et al., Errors in laboratory medicine. Clinical chemistry, 2002. 48: 691–698.
5. Szecsi PB, Ødum L. Error tracking in a clinical biochemistry laboratory. Clin Chem Lab Med. Walter de Gruyter; 2009; 47(10):1253-1257.
6. Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. Arch Pathol Lab Med., 1999; 123(12):1145-1150.

TABLE 2:
PERCENT (%) OCCURRENCE OF VARIOUS ERRORS IN PRE-ANALYTICAL PHASE:

Factors:	% Occurence
Patient:	
➢ Preparation for collection	02
➢ Daily clinical variation	03
Sample containers:	
➢ Insufficient quantity	02
➢ Lab-codes	01
Request Slips:	
➢ Missing tests request or un-related	02
➢ Lab-codes	01
➢ Missing time of request/dispatch	02
Patient's file:	
➢ Missing tests request or un-related	02
➢ Lab-codes	01
➢ Missing time of request/dispatch	02
Receiving Register for samples:	
➢ Missing or un-related test request	01
➢ Case numbers	02
➢ Lab-codes	02
➢ Missing time of request/dispatch	02
Data logging and Entry Register:	
➢ Missing un-related test request	01
➢ Lab-codes	01
➢ Time of sample receiving	04
Samples:	
➢ Insufficient quantity	02
➢ Quality	
• Icteric	01
• Hemolysed	04
• Lipemic	03
• Turbid	02
Data:	
➢ Tests' requests	
• Additional	01
• Missing	01
➢ Checking	01
➢ Evaluation	00