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Pre-analytical errors, percent occurrence and rectification strategies at a tertiary case hospital based clinical Biochemistry laboratory

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Abstract *Background*: Pre-analytical errors necessitate specimen rejection or refusal which causes delay in timely treatment and management and thus risking patient's safety. *Aim:* We report comprehensive date of frequency and types of pre-analytical errors in clinical chemistry lab services. Moreover, factors leading to specimen rejection and its impact on reporting and management were explored and reported. *Materials and Methods*: Various influencing pre-analytical errors that can deviate our QC and QM for pledged and guaranteed patients' services were identified with help of daily assessment Liver function test and thyroid function profiles out of around 800 patients (1500-1700 sample tubes) and 5500 parametric tests requested for a period of one year (Jan 2019 to Dec 2019). An estimated 288,000 blood samples were routinely collected from both indoor and OPD patients for Clinical Biochemistry labs at LNH during a year. *Results:* Most common pre-analytical error or reason for rejection was noted to be hemolyzed and lipimic samples, followed by delays in delivery, insufficient quantity or samples not on ice and incorrect sample identification. Moreover, Patient (Preparation for collection, Daily clinical variation), Sample containers (insufficient quantity, Lab-codes, Request Slips (Missing tests request or un-related, Missing or incorrect Lab-codes, Missing time of request/dispatch, Patient's file (Missing tests request or un-related, Missing or incorrect Lab-codes, Missing time of request/dispatch), Receiving Register for samples, Data logging and Entry Register, Barcode, Samples, Data logging were errors that were noted in detail and documented. *Conclusion:* Incidence of pre-analytical errors is defective for clinical laboratory services. To avoid it, continual revalidating (checklist, audits, and trainings) and harmonizing (standardization of collection, transport and storage) existing practices of health care professionals are the actual remedies. This continual exertion ensures deliverance of standardized, proficiency tested, optimized services for patient care, which always guarantees maximum patients' confidence.

Keywords Pre-analytical errors, Standardized, IFCC, Harmonized

Introduction

Pre-analytical errors are known to affect the entire outcome of clinical laboratory testing [1-3]. Moreover, quality of the entire process that leads to a Clinical laboratory final report can affect the assessment of patient's status and might results in inappropriate clinical decisions [4,5]. It is documented that two types, out of three (pre-intra-post), i.e. pre-analytical and post-analytical errors are a major quandary of all clinical laboratory deviations in reporting. Commonly, pre-analytical phase includes patient preparation, specimen collection and transportation and storage;

and strikingly majority of clinical laboratories, whether independent or attached with a hospital, notified errors at either pre-analytical phase or post-analytical phase [1-3,5]

Pre-analytical errors, if and when noted and documented, necessitate then and there specimen rejection; causes delay in timely treatment and management and thus risking patient's safety [5-7]. Data analyzed and reported showed a high prevalence of pre-analytical errors in all sections of clinical laboratories, surrounding inappropriate handling of samples, either before or during collection, requisition, transport of storage [6-8]. This also hinders or delays in stat reporting, which comprise 35% of the total volume, 24/7 in a tertiary care hospital lab. Undoubtedly, it was argued and advocated that pre-analytical is the most vital phase and surprisingly, the most hardest to regulate and monitor. Reasons were involvement of too many variables such as professionals (physicians, specialists of laboratory medicine, nurses, laboratory technicians and phlebotomists) and administrative entities (requisitions, filing, transport, storage) [6,7]. Since clinical laboratories are responsible for expeditious analysis and accurate reporting, thus burden of quality, most of the time, given to labs ONLY. However, pre-analytical errors are mostly related to Non-labs entities, mostly sample collection, requisitions and transport, and revolve around human errors. Nonetheless, introduction of Quality control (QC) and Quality Management (QM) in pre-analytical, analytical and post-analytical phases in clinical laboratories is an important entity for providing patient-friendly, cost-effective, quality controlled diagnostic services.

In this study, we present a comprehensive date of frequency and types of pre-analytical errors in clinical chemistry lab services. Objective was to explore the factors leading to specimen rejection and its impact on reporting and management.

Methods and Study Protocols

Various influencing pre-analytical errors that can deviate our QC and QM for pledged and guaranteed patients' services were identified with help of daily assessment Liver function test and thyroid function profiles out of around 800 patients (1500-1700 sample tubes) and 5500 parametric tests requested for a period of one year (Jan 2019 to Dec 2019). An estimated 288,000 blood samples were routinely collected from both indoor and OPD patients for Clinical Biochemistry labs at LNH during a year. Occurrence of pre-analytical phase errors for Hepatic (Bilirubin, Alanine aminotransferase ALT, gamma glutamyl transpeptidase gGT, Alkaline phosphatase, ALP), Urea, creatinine and thyroid (tri-iodothyronine T3, tetra-iodo thyronine T4, Free tri-iodothyronine FT3, tetra-iodo thyronine FT4) hormone function tests were assessed and each sample was scrutinized from the time of blood collection in wards/OPDs to receiving in clinical biochemistry lab counter. 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 collection/handling, requisition generation 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 (Roche Cobas e501) and 5 Immunoassay iECL analyzers (Cobas, Roche e411, Abbott iSR and Beckman Coulter Access2), including a pre-analytical phase p591. 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)
  - Case Number, dates, ward/OPD
  - Selected Blood tubes
  - 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.

A set of questions (six) were also asked (mentioned below, modified from Cornes *et al*. 2016 [6] to further assess QC and control of pre-analytical errors.

1. How do you count requests? a. Each sample has a separate accession number b. Each request has a separate accession number
2. How do you record errors? a. Manual reporting b. LRS or HIMS based data collection
3. What analytical platform do you use? a. Roche b. Abbott c. Siemens d. Vitros e. Beckman f. Other? Please state
4. Do you use automated hemolysis, icterous, and lipemic (HIL) indices? a. Yes b. No
5. Do you currently routinely monitor any pre-analytical markers, such as hemolysis, non received samples, insufficient samples, booking errors, etc.? a. Yes b. No
6. If you already monitor pre-analytical markers, what do you measure (check all that apply)? a. Illegible requests b. Percentage of samples where tests were not requested first time

Table 1A: Pre-analytical errors Description Daily Chart

Errors	e.g. Frequency per 100 samples	Percentage %
Hemolyzed/Lipimic sample	03	3%
Insufficient sample	02	2%
Incorrect sample tube/vaccutainers	00	--
Sample not on ice	01	1%
Incorrect sample identification	01	1%
Delay in sample transportation	03	3%
Sample mix-ups	00	--

Table 1B: Definition of Pre-analytical errors [5]

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

Results

Foremost and commonest pre-analytical error or reason for rejection was noted to be hemolyzed and lipimic samples, followed by delays in delivery, insufficient quantity or samples not on ice and incorrect sample identification. Table 2 summarized the errors that had been recognized during assessment of pre-analytical errors during the period Jan 2019 to Dec 2019. Data was collected from request for Urea, creatinine, Hepatic (Bilirubin ALT, gGT, ALP) and thyroid (T3, T4, FT3, FT4) function tests. More detailed Pre-analytical errors are presented in Table 3 with its specificities, such as Patient (Preparation for collection, Daily clinical variation), Sample containers

(insufficient quantity, Lab-codes, Request Slips (Missing tests request or un-related, Missing or incorrect Lab-codes, Missing time of request/dispatch, Patient's file (Missing tests request or un-related, Missing or incorrect Lab-codes, Missing time of request/dispatch), Receiving Register for samples, Data logging and Entry Register, Barcode, Samples, Data logging.

Organizations such as International Federation of Clinical Chemistry (IFCC) or AACC (American Association of Clinical Chemists) and/or UKAS/ISO 9001:2015 system recognize these pre-analytical errors and its implication, if not controlled or corrected. Nonetheless, strictly following Standard Operation Procedures (SOPs), corrective actions, abide by checklists and quality assurance tools (e.g trainings), can provides baseline to avoid and rectify these errors.

Table 2: Percent Occurrence of Various Errors in Pre-Analytical Phase: (Patients approximately 700, per 24 hrs, samples (tubes) 1500 per 24 hrs)

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

Discussion

Recent studies [1,2,4] showed frequency and occurrence of pre-analytical errors, somewhat similar to ours, and rejection of samples mostly due to hemolysed, clotted, inappropriate volumes and patients' identifications errors. Moreover, errors and rejections were more frequent in indoor (wards) samples than OPD patients, parallel to our findings. Remedy to overcome such pre-analytical errors has been linked to continual checks and trainings. In a recent study, percent occurrence of pre-analytical errors was decreased from 0.42% to 0.32%, when training and questionnaire interventions were introduced [1]. Rejected samples were the highest rated category where intervention was introduced and rectified. In an another study by same institute, overall rate of pre-analytical errors was 0.40%, after interventions, corrections, trainings, this percent occurrence was reduced to 0.36% within a year [2]. Commonest errors noted were improper volume and undue clotting, and percent wise more regularly occurring in inpatients as compared to OPDs [2]. Our data also exhibited similar pattern and interventional strategies, trainings, periodic audits, to overcome pre-analytical errors were always been successful.

It is well reported and factual that the pre-analytical phase is dependent on patient, sample collection, transport, preliminary treatment of sample (processing) and preparation of the sample for analysis [9,10]. Recent and past studies have shown that up to 70% of analytical errors reflect in the pre-analytical phase [1,2,4,5,7,9,10]. It was noted that all factors, reasons, deviations related to rejection of samples, due to pre-analytical errors, could be resolved by training and quality assurance measures such as Quality Management system tools and its implementation such as ISO certifications, College of American Pathology surveys, Audits and 3rd party regular inspections. Nonetheless, all standard operation procedures and policies, specific to specimen collection, transportation, and preparation need to be strictly followed by all health care professional to avoid daily deviations [5,8]. It was acknowledged that frequent but preventable medical errors could have serious adverse effect on patient safety and treatments, in addition to wasted resources [11]. Surprisingly, several researchers related to Clinical Laboratory contended that post- and pre-analytical errors were neglected worldwide, and ONLY in last decade focus shifted on the importance of the pre-analytical phase to obtain accurate lab results [11].

Conclusion

It is concluded that occurrence of pre-analytical errors is defective for clinical laboratory services and avoiding it through revalidating (checklist, audits, and trainings) and harmonizing (standardization of collection, transport and storage) the existing practices are the only renewable and doable solutions and remedy, especially those associated with tertiary care hospital. This continual activity and standardization of SOPs will ensure deliverance of standardized, proficiency tested, optimized services for prompt and better patient care that will guarantee maximum patients' confidence.

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