IJISET - International Journal of Innovative Science, Engineering & Technology, Vol. 4 Issue 5, May 2017
ISSN (Online) 2348 – 7968 | Impact Factor (2016) – 5.264
www.ijiset.com

Occurrence and Rectification of Pre-Analytical Errors in Clinical Chemistry Profile Requests from Accident and Emergency Services at Tertiary Care Health Institute.

[1]Junaid Mahmood Alam, [1]Amna Salman, [2]Farah Ashraf, [1]Ishrat Sultana,

[1]Department of Biochemistry Lab services and Chemical Pathology, [2]School of Diagnostic laboratory Sciences, Liaquat National Hospital and Medical College, Karachi-74800. Pakistan

[Corresponding author; dr_jmalam@hotmail.com]

Abstract: Clinical laboratories play a crucial role in providing much needed diagnostic tests results to physicians to impart timely management of the disease. Nevertheless, any deviation in from entire process from requesting or collection of blood or testing samples that leads to Clinical laboratory reports, can affect the evaluation of patient's status. Present study details a comprehensive assessment of the frequency and types of pre-analytical errors in clinical chemistry profile during request, collection and dispatch from Accident and Emergency department. We documented the occurrence of pre-analytical phase errors for Accident and emergency (AED) clinical chemistry profiles such as Urea, Creatinine, Chloride, Sodium, Potassium, Bicarbonate, Calcium, Magnesium, Phosphorus, and Troponin I 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). In cases of AED clinical chemistry profile, some of the foremost pre-analytical errors or reason for delays were hemolyzed and icteric samples, followed by delays in delivery, none-sufficient quantity or missing/later addition, one or two parameters and no clinical history. It is concluded that revisiting, revalidating, upgrading and harmonizing the existing practices, policies of pre-analytical steps should be executed and implemented by all clinical laboratories, in addition to end-user as well; especially those associated with tertiary care hospital and cater major emergency department services. A standardized and validated service, ensured with deliverance of homogeneous, proficiency tested, optimized testing profile for prompt and better patient care, will guarantee maximum patients' confidence.

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

1. Introduction

Clinical laboratories play a crucial role in providing much needed diagnostic tests results to physicians to impart timely management of the disease [1-4]. However, any deviation in the quality of the entire process from requesting or collection of blood or testing samples that leads to Clinical laboratory reports, can affect the evaluation of patient's status. Adherence to established Quality control (QC) and Quality Management (QM) system and standard operating procedures (SOPs) in pre-analytical, analytical and post-analytical phases is an important step for providing patient-friendly, cost-effective, quality controlled diagnostic services [1].

Studies carried out during last one and half decades established that Pre- and post-analytical errors are major predicament of all clinical laboratory errors; most importantly the pre-analytical phase [1,5-7]. In this regard, usage and deployment of international and national guidelines and periodical audits of adherence to it, ensures proper abiding of all steps in pre-analytical phase including patient preparation, specimen transportation, specimen collection and storage [1,2]. Clinical laboratories all around the world, whether independent or attached with a hospital, reports pre-analytical, analytical or post-analytical phase errors and present it as major hurdle, whether as low as 1%, in providing 360^{o} timely and proper reporting to its customers. Research studies and published data showed that 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 [1,5,6]. Thus as a result, pre-analytical errors results in frequent specimen rejection or delays in reporting; consequently affecting patient safety and delays in timely treatment and management [5]. In the present study, we report the comprehensive assessment of the frequency and types of pre-analytical errors in clinical chemistry profile during request, collection and dispatch from Accident and Emergency department. Our purpose was to investigate the factors leading to specimen rejection and its impact on reporting and management.

2. Methods and Study design:

Samples and data collection: Various influencing factors for QC and QM were identified with help of daily assessment of around 250 patients and 2500 parametric tests requested for a period of one year (May 2016 to April 2017) from Accident and Emergency department (AED). An estimated 90,000 blood samples were routinely collected from AED for Biochemistry labs at LNH during a year. We documented the occurrence of pre-analytical phase errors for Accident and emergency (AED) profiles such as Urea, Creatinine, Chloride, Sodium, Potassium, Bicarbonate, Calcium,

Magnesium, Phosphorus, and Troponin I 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).

Methodology: Department of Clinical Biochemistry Lab services at LNH is comprised of 3 fully automated chemistry and 3 electrolyte analyzers, in addition to three immunology equipments. 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.

3. Results:

In cases of Urea, Creatinine, Chloride, Sodium, Potassium, Bicarbonate, Calcium, Magnesium, Phosphorus, Tropinin I, some of the foremost pre-analytical errors or reasons for rejection were hemolyzed and icteric samples, followed by delays in delivery, none-sufficient quantity or missing one or two parameters and without clinical history. Table 1 and 2 summarized the errors that had been recognized during assessment of pre-analytical errors during the period May 2016 to April 2017.

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) one can provides these baseline components to avoid and rectify these errors.

Table 1: Pre-analytical errors Description Daily Chart in AED profile

Errors	Frequency per 100 samples
Hemolyzed sample	3-4
Insufficient sample	5
Incorrect sample tube/vaccutainers	00
Sample not on ice	02
Incorrect sample identification	01
Delay in sample transportation	04
Sample mix-ups	00

4. Discussion:

Emergency department is a crucial and integral part of any tertiary care hospital. Its time-line to manage and treat patients is fundamental in proper clinical services and patient satisfaction. In this regard, Clinical Laboratory services play a vital role in facilitating Emergency department in completing its task of timely patient management. Therefore any deviation or delay in reporting, due to either pre-analytical errors or otherwise, results in subsequent impediment in clinical decisions. Pre-analytical phase is dependent on patient, sample collection, transport, preliminary treatment of sample (processing) and preparation of the sample for analysis. 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. Recent studies have shown that up to 70% of analytical errors reflect the pre-analytical phase [1,3]. Previous studies confirmed that pre-analytical and post-analytical errors are related to most of total errors encountered in the laboratory. In recent years, since the advancement in clinical medicine, it is now crucial for clinicians to confirm their diagnosis through laboratory data than presumptive clinical presentations alone [1,3, 4]. One of the reasons suggested for continual commencement of pre-analytical errors was increase in work load as per sample volume and types of testing services in last one decade, which a clinical laboratory offers, without properly implementing trained manpower and clinical auditing practices.

Nonetheless, it was argued that all factors related with rejection or delays due to pre-analytical errors can be avoided or reverted by training and quality assurance measures such as Quality Management system (QMS, ISO, CAP) realization [1]. Additionally, all policies and procedures specific to specimen collection, transportation, and preparation that have been established and advocated by management needed to be followed [5]. Besides the induction of enormous volumes of sophisticated and automated clinical chemistry instruments, gadgets and pre-analytical processing equipments in last one decade all around the world, errors seems to crept in [1,4]. Thus clinical laboratory services, IF without proper implemented policies of sample collection and related co-factors, shall remain a source or errors that always manifest into delays in clinical decision and managements. Before offering any new test (or even existing testing services), Standard operating procedures (SOPs) for bio-sample collection, processing, storage and analysis, must be analyzed in detail every year to assess any loopholes or availability of advanced versions and strictly advise to follow by all stake holders. This will discourage bad practice in blood collections and shall facilitate clear, robust and standardized services that is build and sustained on international and national guidelines and practices [1,3].

Previous studies showed that most of the laboratories errors occur during the pre-analytical stage were receipt and processing of specimens [1]. Errors in this stage could be due to mislabeling, incorrect test entry and entering the wrong location, among other reasons [7]. 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 [7]. American pathologist program conducted a study enrolling 660 laboratories and showed that errors in order or request of tests from outpatient centers was 4.8% [6,9,10]. Moreover, College of American Pathologists, including 120 labs, reported that mis-identification is a common laboratory error [6,10], whereas a study on laboratory errors showed that 81% of lab errors were pre-analytical, while only 10% of lab errors were analytical [6].

5. Conclusion:

It is concluded that revisiting, revalidating (checklist, audits, and trainings), upgrading and harmonizing (standardization of collection, transport and storage) the existing practices, policies of pre-analytical steps should be executed and implemented by all clinical laboratories, especially those associated with tertiary care hospital and cater major emergency department services. A standardized and validated service, ensured with deliverance of homogeneous, proficiency tested, optimized testing profile for prompt and better patient care that will guarantee maximum patients' confidence.

6. References:

1. Alam, JM, Ali HH, Ashraf F, Sultana I. Frequency Assessment of Pre-Analytical Errors in Tertiary Care Clinical Laboratories Services. International Journal of Innovative Science, Engineering & Technology, 2017; 4 (4): 24-26
2. Gaye A, Peakman T, Tobin MD, Burton PR. Understanding the impact of pre-analytical variations in hematological and clinical chemistry analytes on the power of association studies. International J of Epidemiology. 2014; 43 (5): 1633-1644
3. Cornes M, van Dongen-Lases E, Grankvist K, Ibarz M, Kristensen G, Lippi G, Nybo M, Simundic AM. Order of blow draw: Opinion paper by the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) working group for the pre-analytical phase (WG-PRE). Clin Chem Lab Med., 2017; 55 (1): 27-31.
4. Sakyi AS, EF Laing, Ephraim RK, Asibey OF, Sadique OK. Evaluation of Analytical Errors in a Clinical Chemistry Laboratory: A 3 Year Experience. Ann Med Health Sci Res., 2015; 5 (1): 8-12
5. 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.
6. Najat, D. Prevalence of Pre-Analytical Errors in Clinical Chemistry Diagnostic Labs in Sulaimani City of Iraqi Kurdistan. PLoS ONE 2017; 12(1): e017021
7. 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
8. Bonini P., et al., Errors in laboratory medicine. Clinical chemistry, 2002. 48: 691–698.
9. Szecsi PB, Ødum L. Error tracking in a clinical biochemistry laboratory. Clin Chem Lab Med. Walter de Gruyter; 2009; 47(10):1253-1257.
10. 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 OF CLINICAL CHEMISTRY AED PROFILE

Factors:	% Occurence
Patient:	
➢ Preparation for collection	04
➢ Daily clinical variation	01
Sample containers:	
➢ Insufficient quantity	05
➢ Lab-codes	00
Request Slips:	
➢ Missing tests request or un-related	01
➢ Lab-codes	00
➢ Missing time of request/dispatch	03
Patient's file:	
➢ Missing tests request or un-related	01
➢ Lab-codes	00
➢ Missing time of request/dispatch	03
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	05
➢ Quality	
• Icteric	03
• Hemolysed	04
• Lipemic	01
• Turbid	01
Data:	
➢ Tests' requests	
• Additional	01
• Missing	00
➢ Checking	01
➢ Evaluation	00

ISSN (Online) 2348 – 7968 | Impact Factor (2016) – 5.264

www.ijiset.com