Research Article

Pre-Analytical Phase Awareness Amongst Doctors of a Tertiary Care Hospital - A Cause for Concern

Noor-ul-Ain Waheed[1], Mohammad Suleman Bajwa[2], Sumair Anwar[3], Hamza Ali[4]

[1]Assistant Professor, Department of Biochemistry, King Edward Medical University, Lahore; [2,4]3rd Year, MBBS Student, King Edward Medical University, Lahore; [3]Professor, Department of Community Medicine Department, Gujranwala Medical College, Gujranwala

Abstract

Background & Objective: Errors in the pre-analytical phase constitute about 68% of all lab diagnostic errors and they occur mostly during specimen collection phase. The aim of our study was to assess awareness of resident and internee doctors regarding pre-analytical errors during venous blood sampling and handling.

Methodology: This cross-sectional questionnaire-based study was conducted at Mayo Hospital, Lahore. One hundred and eighty residents and internees were included, whereas doctors working solely in Emergency & Pathology departments were excluded. Data were collected through questionnaire consisting of 29 questions.

Results: A mean ± SD of correct responses was 10.61 ± 3 was found in total sample of 180 participants out of 25 selected questions. Higher mean values were observed in residents as compared to internees, in Pediatrics subjects as compared to other specialties and in graduates from outside Pakistan, as compared to local graduates. Amongst the questions with the lowest correct answer ratio were: forceful pulling of plunger of syringe (36.1%), awareness regarding evacuated tubes system (30%), vials used for hematological tests (5.6%), glucose estimation tests (4.4%) and plasma electrolytesestimation (0.0%).

Conclusion: Study shows a lack of awareness of stages of pre-analytical phase, and thus of possible errors in this phase. This directly influences quality of lab results, compromising the time, finances and health of patients. Therefore, the situation demands prompt correction.

Received | 05-06-2018: **Accepted** | 25-03-2019

Corresponding Author | Dr. Noor-ul-Ain Waheed, Assistant Professor, Department of Biochemistry, King Edward Medical University, Lahore. **Email:** noorwaheed80@gmail.com

Keywords | Pre-analytical phase, Phlebotomy, Specimen handling, Awareness

Introduction

Venous blood sampling, the most commonly performed invasive procedure in patient care[1], has a chief role in the quality of lab reports and becomes one of the causes of medical errors. Medical errors are costly in terms of time, patient discomfort and compounded medical expenses[2]. About 60–80% of important decisions in patient management depend upon laboratory results. Therefore, correct test results may augment patient safety and improve healthcare economy.[3] Laboratory errors represent quality failures in the pathway from selection of test to produce an appropriately interpreted result.[4] During medical lab testing process, errors occur in pre-analytical, analytical & post-analytical phases. Presently, errors in the pre-analytical phase constitute about 68% of all lab diagnostic errors[5], and mostly due to incorrectly performed venous blood specimen collection.[3] The pre-analytical stage encompasses patient

preparation, sampling, handling and transport of samples. Sample hemolysis is a common pre-analytical error.[6] The factors that contribute to pre-analytical errors include poor understanding of the possible errors, insu cient training in standard operating procedures (SOPs) and an underestimation of the importance of SOPs.[7] Outside of Pakistan, ground is being made in reducing pre-analytical errors through the wide dissemination of guidelines and recommendations, such as those of WHO[8], Clinical & Laboratory Standards Institute[9] (CLSI), and establishment of working groups European Federation for Clinical Chemistry and Laboratory Medicine(EFLM).

This study attempts to assess the awareness of pre-analytical errors, compliance to guidelines[8,9] and quality of practice of phlebotomy amongst those non-phlebotomists who perform it, and thus, endeavors to support our hypothesis, that there is an acute lack of awareness of pre-analytical lab diagnostic procedure amongst local doctors due to inadequate training.

Methodology

This cross-sectional study was done at the clinical departments of Mayo Hospital Lahore, where patients are admitted for treatment and health care providers including doctors and nurses both perform phlebotomy. The study involved both Residents in post-graduate training as well as Internee doctors doing their house job. A WHO & CLSI-guidelines[8,9] - based, pretested, structured, expert-validated questionnaire was developed. It was then piloted to post-graduate & internee doctors with experience in the pre-analytical phase. Purposive sampling technique was used for recording response from 180 residents and internee doctors using 95% confidence level, 5% absolute precision with expected percentage of awareness about exact definition of a factor causing pre-analytical error as 93%.[10] Respondents working solely in Accident& Emergency department, all specialties of Pathology and Interns who had been working for less than 3 months at the time of filling of questionnaires were excluded from this study.

Data were collected by the principal investigator herself after the approval from IRB of KEMU. Written consent was taken from the study participants. The finalized close ended questionnaire included questions regarding background characteristics (5 questions) and qualitative variables (29 questions). Among these multiple choice questions, 25 had only one possible correct answer, regarding lab test requisition (1 question), 17 questions on phlebotomy procedure, sample labeling, handling, transport, processing & potential outcomes of collection errors (13 in table 1), and 7 questions on the type of vacutainers recommended for a particular laboratory blood test (6 in table 2). The remaining 4 were related to patient preparation and identification (2 questions), need for training and use of checklist (2 questions).

Data were analyzed by SPSS 21. Descriptive statistics were applied to determine frequency & percentages of the variables consisting of correct and incorrect responses against the questions asked. Data regarding their rank (either resident or internee), department of their training and place of graduation were also recorded. Departments of subjects were categorized into Medicine, Surgery, Pediatrics, Eye and Other specialties. Place of graduation was categorized into KEMU and other Pakistani medical institutes of public sector, private sector and outside Pakistan. Frequency of correct responses, total scores, their mean for each category, and cross-tabulation were determined. Chi-square test was applied to find out the association between total score against correct responses with their ranks, or department of their training and place of graduation. p-value < 0.05 was considered significant.

Results

Of a total of 180 respondents, 58.3% (n=105) were residents and 41.7% (n=75) internees. Respondents belonged to the clinical departments of Medicine (27%, n = 49), Surgery (22.8%, n=41), Pediatrics (14.4%, n = 26), Ophthalmology (7.2%, n=13), Pulmonology, Oncology, Orthopedics, Gynecology, Urology and Plastic surgery. Almost half (n=94) of the subjects were graduates from KEMU, followed by 19.4% (n=35) from private sector, 19% (n=34) from other public sector institutions and 9.4% (n=17) from foreign institutions. Regarding year of residency, first year residents (n=34) were greatest in number, followed by second year (n=29), third year (n=24) and fourth year (n=18).

Only 1/3rd subjects used to write patient's probable diagnosis on request form sent to lab for tests. 1/4th subjects used to advise microalbuminuria test for every diabetic patient even with less than 7% HbA1c value.

Minimum and maximum values of total score of correct responses against the 25 selected questions were 2 & 19 respectively with mean ± SD of 10.61 ±3. Figure 1 revealed higher mean values in residents as compared to internees, in Pediatrics subjects (both residents & interns) as compared to other specialties and in graduates from outside Pakistan, as compared to local graduates. However, minimum score was recorded from graduates of national private sector institutions.

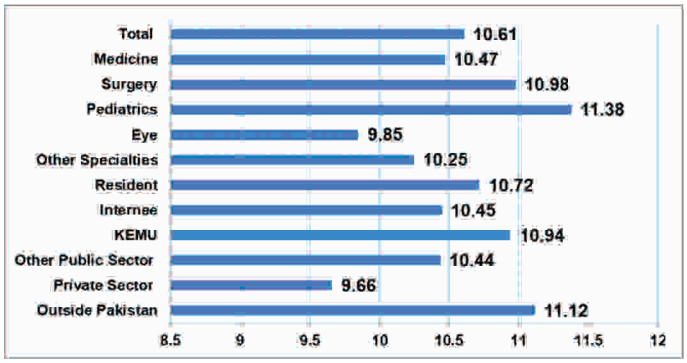

Figure 1: *Comparison of Mean of Total Score of Correct Responses in Subjects (N=180)*

On comparison of total scores of postgraduate residents & internees, we observed slightly higher mean and less SD for residents as compared to internees (figure 2).

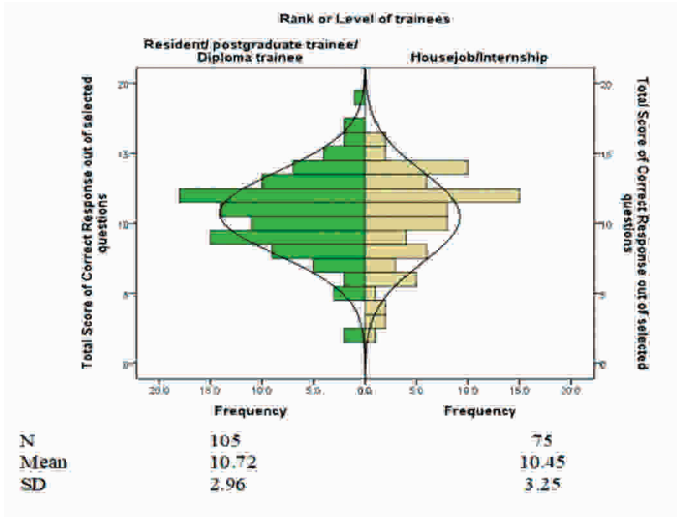

Figure 2: *Comparison of Total Score of Correct Responses: Postgraduate Residents Versus Internees (N=180)*

Twenty-two percent subjects did not confirm fasting state for lipid test. Only 6.6% selected apron & gloves as adequate aseptic measures during high workload besides hand washing, showing their unsafe practice of phlebotomy. Almost one-third subjects knew the standard method of sample identification of matching through numbering present on vial pasted on request form. Two - third subjects responded that they observed the practice of pushing the plunger of the syringe forcefully when transferring its contents to the vial showing undesired attitude that accounts for in vitro hemolysis. When asked about standardized equipment being used for venipuncture, one-third subjects were aware of evacuated tubes system as correct response.

Table 1 reveals the frequency of correct responses, ranging from 29% to 65.5% for rest of the questions related to phlebotomy procedures, potential errors, and sample transportation. Higher percentages in residents were noted as compared to internees with statistically significant di erences about correct order of draw of sample from septicemic patient (p= 0.003, calculated by χ^2 test), nominal volume required for a sample (p=0.001, calculated by χ^2 test) & opaque sample a ecting reliability of a specific parameter (p=0.004, calculated by χ^2 test). We observed higher percentages of correct responses of participants in pediatrics (regarding six questions) as compared to Medicine, Surgery & Eye (regarding 3 questions each) amongst di erent specialties. However, maximum subjects from pediatrics (54%) correctly identified the waiting time for the alcohol swab to dry and di erence is statistically significant (p=0.02, calculated by χ^2 test).

In table 2, frequency of correct responses was highest 74.4% for calcium estimation followed by 39% for biochemistry & serology tests, 29.4% for HbA1c estimation, 10.6% for coagulation tests, but very low 5.6% & 4.4% for commonly required hematological and glucose estimation tests. Moreover, not a single subject identified correct vial for plasma electrolytes estimation.

On comparing ranks of subjects, we observed statistically significant di erence in case of biochemistry &

Table 1: *Frequency of Correct Responses Against Questions Asked for Pre-Analytical Errors of Blood Tests (N=180)*

Questions related to errors occurred in phlebotomy procedure, collection and transportation		Correct responses									P value^
		Total	Medicine	Surgery	Pediatrics	Eye	Other specialties*	P value^	Residents	Internee*	
Phlebotomy procedure	**Desired Response**	**% (n)**	**% (n)**	**% (n)**	**% (n)**	**% (n)**	**% (n)**		**% (n)**	**% (n)**	
1-Parameter affected by repeated fist 'pumping' in venipuncture	Blood potassium	39 (70)	34.7 (17)	**58.5** (24)	46.1 (12)	23 (3)	27.4 (14)	NS	43 (45)	33.3 (25)	NS
2-Minimum time to wait for the alcohol swab to dry	30 seconds	29 (53)	30.6 (15)	29.2 (12)	**54** (14)	7.7 (1)	21.5 (11)	0.02	35.2 (37)	21.3 (16)	NS
3-Tourniquet application time	Up to 1 minute	38 (68)	36.7 (18)	**41.5** (17)	34.6 (9)	15.4 (2)	43.1 (22)	NS	40 (42)	34.6 (26)	NS
4-Correct order of draw of sample from septicemic patient	Blood Culture followed by Biochemical test & hematological test at the end	49.4 (89)	**57.1** (28)	44 (18)	38.5 (10)	54 (7)	51 (26)	NS	55.2 (58)	41.3 (31)	0.003
5-Volume required for a sample	Up to Nominal Volume	65.6 (118)	**81.6** (40)	68.2 (28)	50 (13)	61.5 (8)	57 (29)	NS	57 (60)	77.3 (58)	0.001
6-Mixing of additive	Gently inverting the vial 3-5 times	31 (56)	26.5 (13)	**39** (16)	31 (8)	23 (3)	31.8 (16)	NS	34.2 (36)	26.6 (20)	NS
7-Parameter reliability affected in opaque sample	Triglycerides	39 (70)	**51** (25)	39 (16)	19.2 (5)	46.1 (6)	35.3 (18)	NS	37 (39)	41.3 (31)	0.004
Collection	**Desired Response**										
8-Parameter affected by prolonged venous stasis	Proteins	49.4 (89)	49 (24)	44 (18)	50 (13)	**54** (7)	53 (27)	NS	53.3 (56)	44 (33)	NS
9-Parameter affected by blood sample taken from I/V infusion site	Decreased Serum Sodium levels	63.3 (114)	63.2 (31)	63.4 (26)	**88.5** (23)	54 (7)	53 (27)	NS	65 (68)	61.3 (46)	NS
10-Reduced chance of hemolysis	Usage of appropriate bore needle	32.2 (58)	24.5 (12)	26.8 (11)	**46** (12)	38.5 (5)	35.3 (18)	NS	33.3 (35)	30.6 (23)	NS
11-Parameters affected by haemolysed sample	Potassium, LDH, AST	44.4 (80)	41 (20)	51.2 (21)	**54** (14)	**54** (7)	35.3 (18)	NS	42 (44)	48 (36)	NS
Transportation	**Desired Response**										
12-Mandatory use of Icepack for transportation of sample	For Ammonia estimation	65 (117)	60 (29)	68.2 (28)	**88.5** (23)	69.2 (9)	55 (28)	NS	66.6 (70)	62.6 (47)	NS
13-Transport of sample for Bilirubin estimation	Avoid exposure to light	63 (113)	55 (27)	65.8 (27)	**77** (20)	**77** (10)	57 (29)	NS	66.6 (70)	57.3 (43)	NS
	Total	**180**	**49**	**41**	**26**	**13**	**51**		**105**	**75**	

*Pulmonology, Oncology, Orthopedics, Gynecology, Urology, Plastic surgery etc^ Chi-square test

serology tests only, p=0.008 calculated by χ^2 test (Table-2). Likewise, we found higher percentages of subjects identifying correct vials from Pediatrics (regarding calcium estimation & biochemistry/ serology test), and Medicine (regarding coagulation, hematological and glucose estimation tests). However, maximum (46.3%) subjects from Surgery correctly identified desired vial for HbA1c estimation, p = 0.04 calculated by χ^2 test. Most of the participants (86%) had not received any training in proper lab sampling techniques within last year.79% subjects responded that 'Standard Checklist' if

Table 2: *Frequency of correct responses against questions asked for pre-analytical errors related to selection of appropriate vacutainers for blood sampling (N=180)*

	Correct responses									
		Specialties						Rank		
	Total	Medicine	Surgery	Pediatrics	Eye	Others specialties*	P value^	Residents	Internee	P value^
Types of Tests	% (N)	% (n)	% (n)	% (n)	% (n)	% (n)		% (n)	n% (n)	
1-Calcium Estimation	74.4 (134)	71.4 (35)	80.5 (33)	**92.3** (24)	69.2 (9)	64.7 (33)	NS	76(80)	72 (54)	NS
2-Biochemistry & Serology Tests	39 (70)	32.6 (16)	41.5 (17)	**57.7** (15)	23 (3)	37.2 (19)	NS	48.6 (51)	25.3 (19)	0.008
3-HbA1c estimation	29 (53)	22.44 (11)	**46.3** (19)	27 (7)	7.7 (1)	29.4 (15)	0.04	32.4 (34)	25.3 (19)	NS
4-Coagulation Tests	10.6 (19)	**12.24** (6)	4.9 (2)	11.5 (3)	7.7 (1)	13.7 (7)	NS	11.4 (12)	9.3 (7)	NS
5-Hematological Tests	5.6 (10)	**6.12** (3)	4.9 (2)	0	0	9.8 (5)	NS	6.6 (7)	4 (3)	NS
6-Glucose Estimation	4.4(8)	**8.16** (4)	4.9 (2)	0	0	3.9 (2)	NS	6.6 (7)	1.3 (1)	NS
	180	49	41	26	13	51		105	75	

*Pulmonology, Oncology, Orthopedics, Gynecology, Urology, Plastic surgery etc^ Chi-square test

available to them, would have been useful to recall and then follow the recommended steps of venipuncture procedure.

Discussion

Most errors in laboratory medicine are the result of human elements prior to analysis of the samples in the laboratory. Our review of literature has revealed that a very few surveys assessing awareness of pre-analytical errors amongst doctors have been performed in our country. We conducted this study to uncover significant variations in knowledge of pre-analytical errors amongst doctors of di erent departments, ranks and places of graduation, as well as to suggest components of the pre-analytical phase in which education is mandatory. Likewise, an Indian study explored inadequate knowledge of their interns and residents regarding pre-analytical phase of laboratory testing.[11] Schulenburg-Brand D concluded that incorrect ordering of tests by the doctors may be the consequence of inadequate knowledge about correct use of a test.[12] To assess the practice of doctors in requesting lab tests correctly, they were questioned regarding their decision to request a microalbuminuria test in all diabetic patients. Higher mean values of total score of correct responses in residents were observed compared to interns, a likely result of their having more experience. Respondents from the departments of Pediatrics and of Medicine obtained higher score amongst other specialties, in agreement with an awareness study.[13] Regarding the place of graduation of study subjects, we observed the highest scores were attained by foreign graduates and the lowest by local graduates of private medical institutions. This suggests substantially inadequate training of graduates of Pakistan, including private medical institutions. It is noteworthy that 78% of our subjects responded correctly in questions to patient preparation for lipid profile test. Improper patient preparation begets lipemic samples as evident from survey in UK,[14] which can interfere with the analysis of calcium, phosphorus, bilirubin, and enzymes ALT, AST, & gamma glutamyl-transferase levels.[15] It has been observed that a dangerous 93% of our subjects perform unsafe venous puncture by not using complete personal protective equipment (PPE). According to CLSI guidelines, using PPE is essential and may even reduce pre-analytical error rate.[16]

Two-thirds of respondents were insu ciently aware of requirements for properly labeling samples. Mislabeling of samples is a main identification problem that accounts for pre-analyticalerrors[17]. Almost two-thirds of respondents reported their practice of pushing syringe plungers forcefully, a

cause of hemolysed samples, to which 75% of total pre-analytical errors have been attributed[18]. We observed an obvious lacuna in their awareness of causes of hemolysed samples, as indicated by correct response frequency almost 50%. This is consistent with a study that demonstrated reduced hemolysis rates when the task of phlebotomy was reallocated from untrained physicians to trained nursing sta .[19]

Selection and acquisition of the best blood collection system is important, influencing the measured concentration of analytes less often and thus assuring quality & e ciency of testing process.[20] The highest frequency (74.4%) was found in choosing the correct vacutainer for calcium estimation. However, frequency of correct selection of vacutainers for all 7 other tests is far less promising, ranging from 0-39% of correct answers. Moreover, the frequency of correct responses regarding possible errors in collection of blood samples was identified as almost 50%, except amongst respondents of the Pediatrics department. Correct responses regarding samples transportation was recorded up to 65% in our subjects showing their relatively better understanding in this regard. This has also been demonstrated by Kulkarni et al observing less percentage of errors due to transportation of sample.[21] We found that 79% respondents were keen to acquire some standard checklist for phlebotomy procedure so as to recall & follow the required steps. Moreover, our 86% subjects did not receive any training on blood sampling techniques in the recent past. This observation mirrors that of a local study that showed extremely low percentage of subjects who acquired recent education in blood sampling.[22] This, along with the recording of dangerously low awareness of the proper vacutainers to use for tests, amongst other findings mentioned, should provoke us to identify the key problems, and work to inculcate ideal phlebotomy practice in our system by regularly educating and training healthcare providers.

Our local studies demonstrated that errors in pre-analytical phase contribute significantly to total lab errors and this might be due to lack of education & training in proper techniques.[5,22] A study of developed country showed better knowledge scores of doctors in venipuncture as compared to phlebotomists.[23] However, improvement in phlebotomy practices after training was reported by some developed countries.[19]

This study is limited to a single centre. To broadly judge the awareness of local non-phlebotomists, it should be repeated on a wider scale with randomly selected sample, so that its finding can be generalized.

Conclusion

Inadequate awareness of standard procedure in the pre-analytical phase amongst doctors actively involved in venous blood sampling, working in one of the country's largest tertiary care hospitals, is an austere reality. Devoid of adequate training & education, residents and internee doctors are significantly uninformed in proper phlebotomy techniques and possible errors in every stage of the pre-analytical phase.

Ethical Approval: Given
Conflict of Interest: None
Funding Source: None

References

1. Van Dongen-Lases EC, Cornes MP, Grankvist K, Ibarz M, Kristensen GB, Lippi G, et al. Patient identification and tube labelling–a call for harmonisation. Clin Chem Lab Med. 2016;547:1141-5.
2. Dorotić A, Antončić D, RadišićBiljak V, Nedić D, Beletić A. Hemolysis from a nurses' standpoint – survey from four Croatian hospitals. Biochem Med (Zagreb). 2015;253:393-400.
3. Bölenius K, Nilsson K. Variations in the system influencing venous blood specimen collection practices: sources of pre-analytical errors. J Lab Precis Med. 2018;3:39.
4. Restelli V, Taylor A, Cochrane D, Noble MA. Medical laboratory associated errors: the 33-month experience of an on-line volunteer Canadian province wide error reporting system. Diagnosis (Berl). 2017; 4(2):79-86.
5. Naz S, Mumtaz A, Sadaruddin A. Pre-analytical errors and their impact on tests in clinical laboratory practice. Pak J Med Res. 2012; 511:27.
6. McCaughey EJ, Vecellio E, Lake R, Li L, Burnett L, Chesher D, et al. Key factors influencing the incidence of hemolysis: A critical appraisal of current evidence. Crit Rev Clin Lab Sci. 2017; 541:59-2.
7. Shymko M, Shymko T. Understanding the Causative Issues of Pre-Analytic Hemolysis in the Health Care Setting. Journal of Continuing Education Topics & Issues.2018;20(1):4-8.
8. World Health Organization. WHO guidelines on drawing blood: best practices in phlebotomy.2010.

Available at: whqlibdoc.who.int/publications/ 2010/ 9789241599221_eng. pdf (accessed 19 May, 2018).

9. Clinical and Laboratory Standards Institute. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition, December, 2010 Available from: http://96. 36.117.186/NewsLetter.pdf (accessed 19May, 2018)
10. Dorotić A, Antončić D, Biljak VR, Nedić D, Beletić A. Hemolysis from a nurses' standpoint–survey from four Croatian hospitals. Biochem Med (Zagreb). 2015;25(3):393–400.
11. Kumaran S, Ponniraivan K, Velayutharaj T, Sundhararajan NL. Laboratory Orientation Programme for Interns, A Need Based Training to Enhance Patient Care. South East Asian Journal of Medical Education. 2015;9(2):57.
12. Schulenburg-Brand D, Kumar N, Zouwali S. The impact of local guidelines on the tumour marker requesting patterns of a general surgery department. Ann Clin Biochem. 2013; 50: 438-442.
13. Ruhi M, Seema G. A survey for assessing the knowledge of transfusion medicine amongst resident doctors. J. Evolution Med. Dent. Sci. 2016;5(31): 1600-1605.
14. Cornes MP, Atherton J, Pourmahram G, Borthwick H, Kyle B, West J, et al. Monitoring and reporting of pre-analytical errors in laboratory medicine: the UK situation. Ann Clin Biochem. 2015;53(2):279-84.
15. Nikolac N. Lipemia: causes, interference mechanisms, detection and management. Biochem Med (Zagreb). 2014;24(1):57–67.
16. Sareen R, Kapil M, Gupta GN. Pre-analytical variables: Influence on laboratory results and patient care. Int J Clinicopathol Correl 2017; 1:31-4.
17. Plebani M, Sciacovelli L, Aita A, Padoan A, Chiozza-ML.Quality indicators to detect pre-analytical errors in laboratory testing. Clin Chim Acta. 2014; 432:44-8.
18. Begum F. A study of pre-analytical errors in a hospital based clinical biochemistry laboratory and formulation of measures for correction. Int J Bioassays. 2014; 3(09):3270-5.
19. Cadamuro J, von Meyer A, Wiedemann H, Felder TK, Moser F, Kipman U, et al. Hemolysis rates in blood samples: di erences between blood collected by clinicians and nurses and the e ect of phlebotomy training. Clin Chem Lab Med. 2016; 54(12):1987-92.
20. Lippi G, Cornes MP, Grankvist K, Nybo M, Simundic AM. EFLM WG-Preanalytical phase opinion paper: local validation of blood collection tubes in clinical laboratories. Clin Chem Lab Med. 2016; 54(5):755-60.
21. Kulkarni S, Ramesh R, Srinivasan AR, Silvia CW. Evaluation of Preanalytical Quality Indicators by Six Sigma and Paretos Principle. Indian J Clin Biochem. 2018; 33(1):102-7.
22. Zehra N, Malik AH, Arshad Q, Sarwar S, Aslam S. Assessment of preanalytical blood sampling errors in clinical settings. J Ayub Med Coll Abbottabad. 2016; 28(2):267-70.
23. Makhumula-Nkhoma N, Whittaker V, McSherry R. Level of confidence in venepuncture and knowledge in determining causes of blood sample haemolysis among clinical sta and phlebotomists. J Clin Nurs . 2015; 24(3-4):370-85.