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Questionnaire-based Study of Preanalytical Errors in Laboratory Testing – A Much needed Learning for Health care Personnel's

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Abstract

Background and Objectives: The present study was conducted to find out proficiency in preanalytical phase of laboratory procedures by questionnaire-based method at a tertiary care centre.

Methods: Questionnaire based study was done during the period January 21 to July 21 and 100 junior residents and interns were included in the study. 15 multiple choice questions (MCQ) were included in the questionnaire; out of which four were perspective based, hence were not included in the analysis. The respondents were supposed to mark the most suitable response. This would help us to identify the topics that need special attention in the up-skilling program.

Statistical analysis: Observations were analyzed on Excel operations in Microsoft with a basic spreadsheet to evaluate the data.

Results: 100 responses from interns (75) and junior residents (25) were obtained. 'Pre-analytic mistakes' were 60%. Formal phlebotomy teaching was observed in 8% participants. Correct answers of Questions related to coagulation tests, optimal fasting period, blood mixing and sequence of draw were obtained among less than 40% participants, which signified that further training is much needed.

Conclusions: In the time of confirmation-based medicine, quality results of Laboratory are necessary. This calls for automation and robotics technology which will help in reducing the mistakes and improve precision of results. Major mistakes were observed during

preanalytical phase, which were mainly due to lack of rational abilities. Hence regular training of employees (i.e., Lab Technicians, nurses & trainees' physicians) should be executed to up-skill them.

Keywords: Questionnaire, automation, preanalytical error.

Introduction

The clinical diagnosis is mainly dependent on reliable laboratory data. Advances in sample collection, transport, automation and dispatch of reports have augmented the major improvement in laboratory performances[1]. A vital role is played by the medical laboratories in the decision making by physicians. Major clinical decisions about management of patient are based on laboratory results. The quality of laboratory test results is vital as they play a large role. The processing of blood sample can involve errors at any phase [2]. Laboratory errors can be categorized as preanalytical, analytical, and post analytical. Pre-analytical phase is an important part of laboratory medicine [3, 4]. Pre-analytical phase consist of all the steps that occur before the sample is actually processed [4]. It includes sample [5] collection, managing and processing variables, physiological variables & endogenous variables. Certain pre-analytical variables, namely, specimen variables can be controlled; whereas knowledge of uncontrollable variables needs to be well understood in order to separate their effects from disease related changes affecting laboratory results. The rejection criteria during pre-analytical phase are [6,7] ordering tests on the wrong patient, misidentifying the patient, ordering the wrong test, missing sample and/or test request, wrong or missing identification, contamination from infusion route, hemolyzed, clotted, and insufficient samples, inappropriate containers, improper labeling of containers, inappropriate blood to anticoagulant ratio, and inappropriate transport and storage conditions [8,9].These pre-analytical errors lead to the burden of incorrect reporting on the laboratories. Diagnostic errors can be [5] reduced with the recent progression in technology and beginning of automation in hematology laboratories. Although automation has been introduced in hematology, the laboratory results can be influenced by many factors [10]. The Central Pathology Laboratory (CPL) is routinely functional throughout the year. Correctly collected blood sample is vital for superior performance by the Laboratory. Whole blood is used for hematological testing. Hence, the laboratory data & reliability entirely depends on submitted samples if they are adequate, labeled, and properly transported to the laboratory with in time as per the required protocol. Therefore, the present questionnaire-based study was [11] conducted with the objective to analyze the knowledge base of common laboratory practices among medical interns and residents in a tertiary medical college hospital. It will help us to plan training programs with lesser-known topics, so as to improve laboratory test quality [12].

Materials and Methods

A cross sectional study was carried out in hematology section to a medical college and Hospital during January 2021 to July 2021. The data was collected from questionnaire [12]. The participants who volunteered were MBBS interns and junior residents. A hard paper copy containing 15- item, multiple-choice questionnaire (MCQ) with questions related to common laboratory practices was given to assess the knowledge base of 100 participants. These MCQs consisted of the questions which focused on preanalytical variables like patient preparation (fasting and postprandial), sample collection, minimum amount of the sample required, various anticoagulants used in

various analysis, etc. Question numbers 1, 2, 3 and 4 were subjective and opinion-based, while the remaining questions were objective & analyzed for correct answer. Responses were analyzed as percentages of correct answer and most commonly given answer. These responses were further categorized as less than 40% with correct answer, 40 to 80% with correct answer, and more than 80% with correct answer for our convenience. By making these categories, specific technical knowledge points were identified which could be stressed upon in designing training programs. All the data collected was entered in Microsoft Excel and analyzed in percentages using a simple calculator.

Results

A total of 100 students participated in this cross-sectional observational study. Of these, 75 were medical interns who had just passed their final MBBS examination, and 25 were Junior residents who had taken admission for PG course in various specialties.

Table 1 shows question-wise response of participants. Most of participants 91% were happy with laboratory results (Question 1), with only 6% saying faulty laboratory results are very frequent. Seven participants did not opine on the accuracy of laboratory results. The term “preanalytical error” was known to 60% participants. A large number of participants (92%) said that they did not receive formal training in phlebotomy. Few commonly performed tests require fasting condition for, at least, specific durations, for example, lipid profile and blood sugar testing. Ideal fasting duration for lipid profile testing is 9 to 12 hours, while that for blood sugar is 6 to 8 hours.[13] when participants were asked question about lipid profile, only 34% replied correctly, while most of them thought it is 6 to 8 hours, which is clearly inadequate fasting time for lipid profile. When we asked about the type of bulb (Lypholysed ready to use tube) used for blood collection, 97% participants knew about bulb use, while only 3% did not respond. For routine adult blood collection, needle with gauze number, 22 while for pediatric, small bore needle number 24 is preferred. About 48% and 69% participants responded with right answer for blood collection, respectively. Most interns and residents responded correctly (question 7:89% and question 9:63%) about amount of blood collected for routine testing in adult and pediatric patients, respectively.

Most respondents got it wrong (correct response: 27%) when asked about citrate bulb blood: anticoagulant ratio. Proper technique for mixing blood involves inversion technique for 8 to 10 times in a slow constant manner.[14] Plain bulb must be kept steady and upright for serum separation. Many participants knew about plain bulb handling (67% correct response), while only 40% participants correctly knew about the mixing technique of anticoagulant bulbs. When asked about the accepted time interval for pro- thrombin time testing, only 24% trainee doctors out of 100 knew about the importance of time interval and accepted limits in coagulation testing. A large number of participants (24%) were unaware of the term “order of draw” and its importance. When asked about preference of site for blood collection in IPD patients, half of the trainee doctors (48%) knew the preferred site is the opposite arm if IV catheter is inserted in one arm.

Table -2 & Fig- 1: shows categorization of topics based on questions which received maximum right answers to minimum right answers. Most participants

gave wrong answers to question numbers 4, 10, 13 and 14 (less than 40% correct answers), while only question number 7 received more than 80% correct response. Other questions received mix response (40–80% correct response).

S.N.	Questions (Correct answer)	Correct Response	Most Common Response	No Response
01.	What is the frequency of faulty result?	Frequent: 6 %)	Few: 91%	do not know :3%
02.	Do you knowledge of pre analytical error?	Yes : 60%	-	No: 40%
03.	Have you been trained in Phlebotomy?	Yes : 8%	-	No: 92%
04.	Mention the type of collecting tube? (Lypholysed ready to use)	Lypholysed ready to use tube :97%	In house prepared:00%	Do not know:03%
05.	What is minimum fasting duration for lipid profile? (9–12hours)	34%	57 %(6-8hours)	9%
06.	Which size of needle is used in adult for venepuncture? (22g)	48%	NA[b]	14%
07.	What is the adequate volume of blood for hematological/biochemical test in adult? (5–7ml)	89%	NA	1%
08.	Which size of needle is used in pediatric for venepuncture? (24g)	69%	NA	7%
09.	What is the adequate volume of blood for? Hematological/biochemical tests in pediatric? (2–5ml)	63%	NA	2%
10.	What is the anticoagulant to blood ratio in citrate bulb? (1:9)	27%	NA	14%
11.	What is the mixing process of EDTA tube? (Inversion and Rotational movements8–10times)	40%	NA	2%
12.	What is done after collecting blood in plane tube? (Let it stand)	67%	NA	3%
13.	What is the optimum time for coagulation profile estimation? (Four hours)	24%	58 % (3hours)	18%
14.	What is the order of draw for transport of blood sample? (citrate)	24%	50 % (EDTA)	6%
15.	What is the procedure of blood sample collection during IV transfusion? (Any other vein from the other arm)	48%	NA	7%

Table: 1 Results of questionnaire, n=100

Note

: The use of bold numbers indicates that the most popular answer to a question is an improper response.

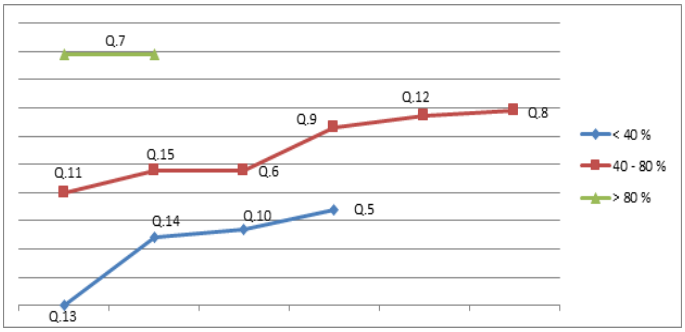
: Question1, 2, 3, and 4 are observation and are not included in this study.

: NA[b] when the most popular answer is the right response stands for not suitable.

Table 2: Category wise percentages of correct answers

Parameters	Percentages of accurate answers		
	Less than 40%	40 to 80%	More than 80%
Question Numbers	5,10,13,14	6,8,9,11,12,15	7
Topics Related Questions	Fasting time for lipids Citrate ratio with blood Coagulation testing time Order of draw.	Phlebotomy needle size in adult, Phlebotomy needle size in pediatric, Adequacy of pediatric sample, Mixing procedure of EDTA sample, Procedure of Plane tube sample, Procedure of sample collection in IV patient,	Adequacy of adult sample,

Figure.1 Categorywise % of Correct Answers according to Table No.2



Discussion

As most of respondents (91%) were contented about laboratory results, it shows strong trust between clinician and laboratory staff, which helps in reduced double checking of results and timely management. Awareness of preanalytical process plays a very important role in quality assurance of laboratory test results. In our study, although the term "preanalytical error" was known to participants (60%), efforts should be made to increase this number. Studies by Plebani et al[15] and Da Rin[16] concluded that preanalytical errors are the key reason behind erroneous laboratory results. Specific training programs for interns, junior residents and others who are mainly involved in clinical sample collection should be performed every so often to reduce these errors. Also, Standard Operating Procedure manuals, illustrative charts and guidelines about standard sample collection method and transport are to be made available in the wards and OPDs beside laboratory.

Correct phlebotomy procedure is vital and an important step in the preanalytical process. Our study showed only 8% of respondents received proper training in phlebotomy, hence phlebotomy training needs emphasis in the medical curriculum. Lima-Oliveira et al supported that proper training is necessary to improve the quality of laboratory results significanty.[17] Few tests require fasting condition for, at least, specific durations, for example, lipid profile and blood sugar testing. For lipid profile testing, the ideal fasting duration is 9 to 12 hours whereas for blood sugar it is 6 to 8 hours.[13] 66% participants were of the opinion that fasting duration for lipid profile is 6

to 8 hours which is incorrect. This can lead to faulty results. This knowledge should be added in the training curriculum. We use Lypholysed ready to use tubes which have reduced clotting of samples to a minimum. When we asked about this, 97% participants knew about the tube use, while only 3% failed to answer. The needle size selection varies with quantity of blood, age and superficial vein anatomy. Needle with gauze number 22 is used for routine adult blood collection whereas small bore needle number 24 is used for pediatric patients. 48% and 69% participants responded with right answer for blood collection, respectively. Choosing correct needle is very important to avoid double pricks and insufficient sampling. There is standard marking in all ready to use tubes.[18] most interns and residents responded correctly (question 7:89% and question 9:63%) about amount of blood collected for routine testing in adult and pediatric patients, respectively. Specifically designed tubes for pediatric patients are now available, which are adjusted for low-volume fill. Most respondents got it wrong (correct response–27%) when asked about citrate bulb blood: anticoagulant ratio. This proves that special emphasis has to be put on coagulation testing and its requirement under phlebotomy training. It revealed that haemolyzed samples received are unsuitable for testing and attributed to poor handling and mixing techniques. Haemolysis can be caused by rough shaking of bulbs for mixing of blood. Proper technique for mixing blood is required.[18]Many participants knew about plain bulb handling (67% correct response), while only 40% participants correctly knew about the mixing technique. Others were unaware of scientific methods & its consequences on laboratory results. Illustrative charts are the best method of improving knowledge and techniques. Medical interns and residents tend to send samples in bulk to the laboratory leading to variable time interval for blood sample collection and storage. Thus, coagulation test results are greatly affected due to variation in storage temperature and time interval. The recommendation laid down by the Clinical Laboratory and Standards Institute (CLSI) Guideline H21-A56 suggests that most coagulation parameters must be evaluated within 4 hours, except tests aimed at monitoring treatments with full-dose unfractionated heparin for whom the delay must not exceed 2 hours.[19] When asked about accepted time interval, only 48 (24%) trainee doctors out of 100 knew about the importance of time interval and accepted limits in coagulation testing. Often more than one tube is required for different blood tests. These blood tubes may contain different additives which may affect certain results should they contaminate another tube. For this reason, an order of draw was established.[20]

Cornes et al[20] in European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) stated that order of draw should start with blood culture tube (colour varies), followed by citrate tube (light blue), clot activator (red), heparin (green), EDTA (lavender), fluoride (Gray) in that order. 76% participants were unaware of this order of draw. WHO guidelines on best practices in phlebotomy mentioned few commonly occurring errors in patient with IV catheters.[21] While IV lines provide a means of direct vascular access for infusion fluids, collection of specimens through these lines and result in contamination of the specimen with the contains of the line. Whenever possible, specimens should be collected from the arm opposite the line to avoid

contamination. Specimens should not be collected distal to a catheter because fluids tend to pool in the periphery of the limb. Collection of samples proximal to a catheter will be diluted by the infusion fluid.[21] when vascular access is limited, a specimen may need to be collected from an IV line. This decision should only be made after weighing the risk of specimen contamination versus the risk of phlebotomy from another site. Before drawing a specimen from a line, the infusion fluid should be completely stopped for several minutes and an amount of blood equal to three or more times the dead space of the catheter should be discarded.[21]When asked about preference of site for blood collection in IPD patients, nearly half of trainee doctors (48%) knew the preferred site is the opposite arm if IV catheter is inserted in one arm.

As contamination or dilution of specimen can seriously affect laboratory test results, this error must be minimized by inclusion of these guidelines in every phlebotomy training program. Table 2 summarizes results of all questions according to percentages of correct responses. Less than 40% correct responses were received for questions 5, 10, 13 & 14. The reason for this is that topics such as coagulation testing are multifaceted, while others like variable fasting duration for sugar and lipids are complex. Order of draw is very new concept and vastly unknown to new interns and junior residents. These topics need special emphasis in the training program [12].

Limitation of Study

Preanalytical phase of laboratory test is strongly associated with proper knowledge as well as the skills of a person. However, our study did not take into consideration the "proficiency of manpower" part of preanalytical process and emphasized only on the knowledge part.

Conclusion

Preanalytical phase of laboratory testing plays a decisive role in quality assurance of test results, as maximum errors occur in this phase. Although most participants are aware of the term "preanalytical error" only 8% received informal training for phlebotomy. So it is necessary to increase awareness and introduce formal training in the medical curriculum. Use of vacutainer, selection of proper needle size for pediatric and adult patients, and adequate sample volume are well-understood topics among interns and residents. Topics like coagulation testing, ideal fasting duration and order of draw are very poorly known among interns and Junior residents (less than 40% responded correctly to questions). These topics need special importance in the training program.

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