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Quality audit on venous blood sample processing in laboratories of governmental hospitals in Gamo Gofa zone, southern Ethiopia

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Abstract: Back ground: Pre-analytical activities persist to pose significant amount of uncertainties in clinical laboratories causing adverse impacts on patient health and the entire healthcare system. Venous blood sample (VBS) processing that has many error prone activities is one of the pre-analytical procedures performed in the laboratory. The objective of our survey was to identify, in Ethiopian Hospital laboratory set-up, the major activities in the processing of VBS in which undesirable practices that may result in errors are executed. Methods: We have conducted institution based cross-sectional survey supplemented with non-participatory type observational study from February 2012 to September 2012 in laboratories of three governmental hospitals of Gamo Gofa zone, Southern Ethiopia. Pre-tested questionnaire and check list were used for data collection. Analysis of the data was performed using Medcalc® version 12.1.4 software. Results: A total of 19 laboratory professionals working in the three governmental hospitals were included in this survey. The activities possessing highest proportions of undesirable practices were related to establishment and adherence to serum/plasma/whole blood rejection criteria, measures taken when produced serum/plasma is too small for analysis, speed and duration of centrifugation. Low proportion of undesirable practices were found in activities related to capping test tubes before centrifugation, maximum allowed time before analysis of unpreserved serum/plasma/whole blood samples and balancing during centrifugation. None of the socio-demographic and background information of participants we assessed was associated with undesirability of VBS processing activities. Conclusion: From this study, we concluded that the VBS processing in the laboratories involved many undesirable practices that might lead to erroneous results. We identified that the gearing problem to the undesirable practices was absence of laboratory documents regarding VBS processing activities. Therefore, establishment and strict adherence to laboratory documents for every activity in VBS processing by every laboratory personnel would avoid many of the undesirable practices.

Keywords: Venous Blood Sample Processing, Undesirable Practice, Pre-Analytical Error, Standard Operating Procedure

1. Introduction

In spite of great improvements in the performance and analytical quality of clinical laboratory testing in the last four decades, clinical laboratories and professionals continue facing challenges to ensure credibility of their laboratory results due to the significant amount of persisting errors [1, 2]. Especially, the errors emanating from the pre-analytical phase were found to be responsible for a significant amount of uncertainties (up to 80% of total laboratory errors) in clinical laboratories [3, 4]. These errors can cause an adverse impact on patient health and on the entire healthcare system [5] regardless of how well clinical laboratories are equipped with state of the art instruments or are having qualified and experienced personnel [6].

Venous blood sample (VBS) processing is one of the major pre-analytical activities performed in the laboratory; and like other pre-analytical practices, it has many error prone activities. Even though, there are many reports on sources of errors of VBS processing, the majority could not explain the situation in developing countries including Ethiopia. This is because the reports were from studies conducted in accredited laboratories equipped with relatively more experienced and qualified professionals [2-5].

The objective of this survey was to identify, in Ethiopian

Hospital laboratory set-up, the major steps in the processing of VBS in which undesirable practices that may result in errors are executed. Moreover, this study aimed to determine association of the undesirable practices with socio-demographic and backgrounds of participants.

2. Methods and Materials

Institution based cross-sectional survey was conducted from February 2012 to September 2012 in laboratories of three governmental hospitals of Gamo Gofa zone, Southern Ethiopia. These hospitals were Arbaminch general hospital, Chencha district hospital and Sawula district hospital.

A questionnaire and check list were prepared by critically reviewing similar studies in other parts of the world and standard practices developed by the Clinical and Laboratory Standards Institute (CLSI) on Procedures for the Handling and Processing of Blood Specimens; Approved Guideline-Third Edition (H18-A4, 2010) [7]. Both tools were pre-tested and appropriate corrections, modifications and improvements were made. Then, all of the laboratory professionals in the three hospitals were interviewed regarding their practice in VBS processing using the pre-tested questionnaire. Additionally, a non-participatory type observational survey was conducted using the pre-tested check list to collect information regarding practices that cannot be surveyed using the questionnaire and to ascertain real practices in the study sites.

The proposal of this study was ethically approved by the Institutional Ethical Review Committee (IRC) of Arbaminch University. Moreover, the hospitals were asked providing with the letter of ethical approval, for permission to use their health facility to conduct this research. Written informed consents from each study participants were also obtained after clear explanation about the objective and purpose of the survey.

Determination of desirability and undesirability of the activities in VBS processing was done by setting operational definitions from the same source used to prepare the questionnaire and check list [7].

2.1. Operational Definitions

Desirable Practices

Cross-checking the information on test tubes with the information provided on request papers before the beginning of VBS processing on regular basis

Waiting for at least 30 minutes before centrifugation to produce serum

Separating cells from plasma/serum within 2 hours of venipuncture

Centrifuging duration of 10-15 minutes when separating serum/plasma from cells

Centrifuging speed of 1000-1500 RCF when separating serum/plasma from cells

Requesting new sample/re-centrifuging when serum/plasma is insufficient

Analyzing serum/plasma/whole blood samples within 8 hours of venipuncture unless preserved

Mixing well whole blood samples with anticoagulants prior analysis with gentle inversions of 8-10 times

Establishing and strictly adhering to sample rejection criteria

Undesirable Practices: The respective deviations of the practices listed in the above section (from i-ix).

The data was cleaned and entered in a Microsoft Excel sheet and exported to Medcalc® version 12.1.4 software for analyses. Data summary was presented by using tables, and Chi-square test and Fisher's exact test were used to determine associations between socio-demographic variables and the practice of venous blood sample processing. P value of less than 0.05 was considered as statistically significant.

3. Results

3.1. Socio-Demographic and Background Information of Study Participants

A total of 19 laboratory professionals working in the three governmental hospitals were included in this survey (table 1). The median age of the participants was 25 years (IQR= 23.3-27 years). The median years of experience among participants was 3 years (IQR= 2-5 years).

Table 1. *Socio-demographic characteristics of study participants (n=19).*

	Frequency	Percentage
Working site		
Arbaminch general hospital	10	52.6
Chencha district hospital	5	26.3
Sawula district hospital	4	21.1
Gender		
Male	15	78.9
Female	4	21.1
Age group		
≤ 25 years	9	47.4
> 25 years	10	52.6
Qualification		
Diploma	14	73.7
First degree	5	26.3
Experience		
≤ 3 years	10	52.6
> 3 years	9	47.4
Education on VBS processing		
Yes	19	100
No	0	0
Training on VBS processing		
Yes	5	26.3
No	14	73.3

VBS= venous blood sample.

All of them responded that they have got an education about VBS processing during their stay in Colleges/Universities. Only 26.3% (n=5) of the participants reported that they have got an on-job training on VBS processing.

3.2. Venous Blood Sample (VBS) Processing Practice

Among Participants

As presented in table 2, the highest proportion of undesirable practice reported by participants was related to establishment and adherence to serum/plasma/whole blood rejection criteria (n=19, 100%) followed by measures taken when produced serum/plasma is too small for analysis (n=17, 89.5%), speed (n=14,73.7%) and duration of centrifugation (n=13,68.4%), minutes waited before centrifugation during serum preparation (n=9,47.4%), maximum allowed time before separation of serum/plasma from cells (n=9,47.4%), cross-checking information on test tube with that of on request paper (n=2,10.5%), mixing of whole blood samples with anticoagulants prior analysis (n=1,10.5%), maximum allowed time before analysis of unpreserved serum/plasma/whole blood samples (n=1,5.3%), capping test tubes during centrifugation (5.3%), balancing during centrifugation (n=1,5.3%).

Table 2. *Summary of proportion of desirable and undesirable practices among participants (n=19) in major steps of VBS processing.*

	Frequency	**Percentage**
Cross-checking information on test tube with that of on request paper		
Desirable	17	89.5
Undesirable	2	10.5
Establishment and adherence to serum/plasma/whole blood rejection criteria		
Desirable	0	0
Undesirable	19	100
Minutes waited before centrifugation during serum preparation		
Desirable	10	52.6
Undesirable	9	47.4
Maximum allowed time before separation of serum/plasma from cells		
Desirable	10	52.6
Undesirable	9	47.4
Duration of centrifugation		
Desirable	6	31.6
Undesirable	13	68.4
Speed of centrifugation		
Desirable	5	26.3
Undesirable	14	73.7
Capping test tubes during centrifugation		
Yes	18	94.7
No	1	5.3
Balancing during centrifugation		
Yes	18	94.7
No	1	5.3
Measures taken when produced serum/plasma is too small for analysis		
Desirable	2	10.5
Undesirable	17	89.5
Maximum allowed time before analysis of unpreserved serum/plasma/whole blood samples		
Desirable	18	94.7
Undesirable	1	5.3
Mixing of whole blood samples with anticoagulants prior analysis		
Yes	17	89.5
No	2	10.5

VBS= venous blood sample.

Many of the undesirable practices were also evidenced during our observational study. None of the laboratories were having nor applying sample rejection criteria, standard operating procedures (SOPs) for VBS processing activities and other laboratory documents such as laboratory policy and quality manuals.

We have also noted that when they get insufficient serum after spinning, they use an applicator stick to agitate the sample. Workload driven centrifuge speed and time adjustments were also seen in the laboratories. It seemed that when there is lower workload, samples would be left on benches without preservation for longer durations beyond the maximum allowed time for separation of serum/plasma from cells.

Even though many of the participants responded that they cross-check information on test tube with that of on request paper, we have noticed that much information was provided on the request papers than on test tubes. Test tubes were usually labeled with hospital number of the patient, name of the patient or non-systematic numbers given by the sample collector. Legibility of the labels was also a problem in some occasions.

The undesirable practice noted with regard to mixing whole blood samples with anticoagulants prior analysis was the method used to mix (vigorous shaking rather than gentle inversions) in addition to failure to mix samples at all.

The association between socio-demographic and background information of participants with venous blood sample processing practices is summarized in table 3.

Table 3. *Association between socio-demographic and background information of study participants with VBS processing practices.*

	Gender*	Age group*	Working site§	Qualification*	Years of Experience*	Training on VBS processing*
Cross-checking information on test tube with that of on request paper	1.000	0.474	0.366	0.468	0.211	1.000
Minutes waited before centrifugation during serum preparation	1.000	0.656	0.056	1.000	1.000	0.628
Maximum allowed time before separation of serum/plasma from cells	0.087	0.179	0.187	0.628	0.070	0.628
Duration of centrifugation	1.000	0.057	0.055	1.000	0.141	0.128
Speed of centrifugation	1.000	1.000	0.287	0.084	0.628	0.570
Capping test tubes during centrifugation	1.000	1.000	0.622	1.000	0.474	1.000
Balancing during centrifugation	1.000	1.000	0.622	1.000	0.474	1.000
Measures taken when produced serum/plasma is too small for analysis	1.000	1.000	0.477	0.468	1.000	1.000
Maximum allowed time before analysis of unpreserved samples	1.000	1.000	0.622	0.263	0.474	0.263
Mixing of whole blood samples with anticoagulants prior analysis	1.000	1.000	0.622	0.468	1.000	1.000

** P values from Fisher's exact test, § P values from Chi square test, VBS= venous blood sample.*

4. Discussion

In spite of previous reports that focused on type and magnitude of errors in VBS processing, our study was centered at identifying the activities which act as sources of the errors in VBS processing and to identify the so cio- demographic and background variables associated with the undesirable way of VBS processing by laboratory personnel [2-5].

We revealed that there was no mechanism in place in the studied hospital laboratories to reject inappropriate VBS since none of the laboratories were having established specimen rejection criteria. However, it has been described that determining acceptability of samples for requested analyses is one of the pre-analytical requirements of paramount importance [8]. The studied laboratories lost the multi-faceted benefits of saving cost and time that could be attained by establishing and adhering to sample rejection criteria [9, 10]. The absence of the criteria also may lead to subjective judgments on the quality of VBS. Therefore, the laboratories need to prepare sample rejection criteria and enforce strict adherence by the laboratory personnel.

This study also indicated that there was high proportion of undesirable practice of delayed separation of plasma/serum from cells after centrifugation. It has been documented in literature that prolonged contact of the serum/plasma with the cells might cause hemolysis and/or an alteration in some biochemical analytes [11, 12]. In cases where a delay in analysis is required, utilization of test tubes with gel barriers would be essential. In such tubes, the serum/plasma could be stable at room temperature for 8 hours and up to 48 hours at 2-4 °C after spinning [7].

We have calculated relatively low proportion of undesirable practice among participants with regard to information cross-checking on test tubes with request papers. However, the information on which the cross-checking is made was inappropriate since the labels were bearing either hospital number of the patient only, name of the patient only or non-systematic numbers given by the sample collector. Moreover, legibility of the labels was also a problem in some occasions. All these could result in misidentification of samples during analyses. Hence, inspecting test tubes up on arrival to the laboratory whether they are bearing firmly attached label with at least the following information is of paramount importance: the patient's first and last names, an identification number, the date and time of collection and the identification of the person collecting specimen [13].

In our study, failure of mixing whole blood samples col-

lected with an anticoagulant prior analysis and mixing with vigorous shakings was noted. Failure and inadequate inversion of test tubes with anticoagulants might lead to clotting of the blood sample, which constitutes an important part of pre-analytical errors [5, 14]. Hemolysis of samples as a result of improper inversion was also found to be a source of pre-analytical error [15]. Thus, laboratories need to incorporate statements on how to mix whole blood samples before analysis in their laboratory documents.

The maximum delay time before analysis of unpreserved samples, capping and balancing test tubes during centrifugation were the activities in which we found the lowest proportions of undesirability. However, these also need to be improved more since improper centrifugation techniques, in addition to causing hemolysis, might be responsible for tube breakage and splashes within the centrifuges (account for 0.6% of all errors in total testing process) [3]. These could be possible by establishing and strictly adhering to SOPs.

None of the socio-demographic and background information of participants showed statistically significant associations with undesirability of VBS processing practices. Hence, the undesirability of practices was randomly distributed among outcomes of studied socio-demographic and background information of participants. Establishing and adhering to laboratory policy, quality manual and SOPs for every activity of VBS processing would avoid the undesirable practices detected thereby minimizing the chance of pre-analytical errors. Furthermore, the education given in Colleges/Universities about VBS processing need to be standardized and improved in a way that emphasize the effect of any undesirable practice on the overall laboratory test result. Periodic on-job refresher trainings are also critical for laboratory personnel who commit many undesirable practices and/or who are fund to be deficient on the area during performance appraisals.

5. Conclusion

From this study, we concluded that the VBS processing in the laboratories involved many undesirable practices that might lead to erroneous results. We identified that the gearing problem to the undesirable practices was absence of laboratory documents on the VBS processing activities. Thus, we recommend the establishment and strict adherence to laboratory documents for every activity in VBS processing. In addition, emphasis should be given to enhance the knowledge and practice of laboratory professionals with regard to VBS processing during pre-service educations and/or in-services trainings.

Author's Contributions

MM has conceived and designed the study. MM, AG, and TT have participated in acquisition of data and observational study. MM, AG, and TT have participated in preparing and critically reviewing the draft manuscript. All authors have read and approved the final manuscript.

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Competing Interests

The authors declared that they have no any relevant competing interest to disclose in this research.

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