Auditing of the phlebotomy system in medical laboratories in Port Sudan City, Sudan

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Abstract

Background: Phlebotomy is one of the most ignored techniques in laboratory medicine and health care. It is a complicated practice that requires wide knowledge and high-level skills. Mistakes in phlebotomy can influence laboratory results (diagnosis) and affect patient care.

Aims: To appraise phlebotomists' practice and assess the extent of compliance with the guidelines and determine the frequency of errors in hospital laboratories in Port Sudan, Sudan.

Methods: A cross-sectional observational study was conducted using a structured observation scheme in 8 Sudanese public hospitals between August and September 2017. A structured questionnaire was used to assess the venepuncture procedures. Five diverse blood collections by each phlebotomist were observed at each session. We monitored 120 blood collections by 24 phlebotomists, 16 (66.7%) male, and 8 (33.3%) female, with a mean age of 31.1 years.

Results: Three of 8 phlebotomy sites were not covered by standard operating procedures (SOPs). Furthermore, phlebotomists lacked appropriate training plans. At 33.3% of the sessions, phlebotomists did not wear gloves at all, and in 69.2% sessions, they did not use new gloves for each patient. There was a significant correlation between phlebotomists' expertise and the duration of tourniquet application.

Conclusion: This study demonstrates that SOPs were not available in some phlebotomy districts. Phlebotomists did not follow Clinical and Laboratory Standards Institute guidelines. Ongoing assessment and improvement of procedures are fundamental to ensure that the phlebotomy service operates effectively.

Keywords: phlebotomy, Port Sudan, standard operating system, tourniquet, venepuncture

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Introduction

Phlebotomy is a technique of blood drawing in which the needle is temporarily inserted into a suitable vein (*1*). Phlebotomy is an ancient procedure, dating back for 3500 years to the time of ancient Egypt. The word phlebotomy is derived from Greek phlebo from phleps (vein), and tomy from tomia (to make an incision) (2). Today, phlebotomy is available primarily for enhancing diagnosis and monitoring patients' disease status. It calls for rigorous adherence to test procedures and guidelines to ensure patient safety and integrity of blood samples (*3*). Previously, medical technicians were responsible for blood sample collection, but in recent decades, this practice has changed and the responsibility is now shared with other health professionals (*4*).

Compliance in phlebotomy is challenging because there are many errors associated with the procedure (*5*). Quality control in the laboratory includes 3 main phases: preanalytical, analytical, and postanalytical. The preanalytical phase is the most important for phlebotomists. Every laboratory makes efforts to ensure that the routine procedure produces reliable results and that service quality is maintained (*6*). Agency accreditation is motivating laboratories to go beyond the standardization and quality required for pre-and postanalytical quality control to minimize errors (*7*). For that, most of the effort in laboratory medicine has been to raise quality and improve patient safety (*8*). The accreditation system of clinical laboratories based on ISO 15189 has been implemented in many countries to improve quality and competence (*9*). Bolenius et al. (*10*) and Saurav et al. (*11*) reported that the preanalytical phase had 46–68% of the total laboratory errors, and most of those errors were encountered during blood sample collection. In the preanalytical stage, venous blood collection is critical because it affects laboratory results. Many errors affect patient safety and health, such as patient identification, incorrect equipment use, lack of knowledge of tourniquet usage, improper skin puncturing, and no disinfectant use (*12*). Many factors are likely to influence the laboratory outcome, including phlebotomy education, understanding anatomy, training, and inspection of infection control procedures (*13*).

To the best of our knowledge, assessment of phlebotomy services in Sudan has not been reported. In this study, we aimed to assess the feasibility of phlebotomy by focusing on phlebotomists' practice and identifying the most frequently encountered errors during venous blood collection in public hospital laboratories in Port Sudan City.

Methods

Study design

This was a hospital-based, cross-sectional observational study conducted during August to September 2017. A structured questionnaire was used (Table 1) (*14*) for assessment of the phlebotomy service practice. The layout of the questionnaire was intended to be simple to read with a limited number of pages, to ensure that it could be completed within the shortest possible time. The data collection was qualitative and quantitative. Confidentiality was maintained and data were solely for research purposes. Results were reported as yes/no for all phlebotomists in each setting.

Study area and population

The Red Sea Province has 16 hospitals, and 8 were chosen for this study: 4 government sector hospitals (Port Sudan Teaching Hospital, Police Hospital, Prince Osman Digna Hospital, and Seaport Corporation Hospital), 3 private sector hospitals, and a national blood bank.

Study sample

The Kish formula was used to determine the sample size for the cross-sectional study (*15*). We included 24 phlebotomists (16 male, 8 female), with a mean age of 31.1 years (range 19–48) years. Only permanently registered phlebotomists employed at the laboratory were considered for inclusion. There were 3 phlebotomists from each of the 8 hospitals. Sixteen phlebotomists had the experience [mean 6.6 (5.3) years] and competence to gain patient confidence in the venepuncture process. The checklist had 24 criteria that the phlebotomists conducted during venepuncture. The sociodemographic characteristics are summarized in Table 2. Five different venepuncture collection sessions were assessed for each phlebotomist, giving a total of 120 venous blood collections.

Study performance

Phlebotomy performance was assessed in patients who received the service after verbal consent was obtained from phlebotomist volunteers participating in the study. According to Clinical and Laboratory Standards Institute (CLSI) recommendations (7), phlebotomists were monitored for 5 different blood sample collection practices. The remarks were reviewed by independent expert evaluators and scored against a criterion-based CLSI checklist to identify preanalytical technical errors made by the phlebotomists.

Study dependents

To assess the phlebotomists' venepuncture practice performed in the laboratory, the dependents were: identification of patients; usage of tourniquet (application, and time); sterilization of the puncture sites; correct use of anticoagulant tube during blood collection; mixing blood samples for the correct time; and labelling of samples.

Statistical analysis

The findings were presented as mean (standard deviation, SD). The observational variables were estimated stepwise by comparing means by Student's *t* test and χ^2 test. $P \leq 0.05$ represented the minimum level of significance. Major errors were compared by χ^2 test using SPSS version 24. Two independent expert evaluators used the same criterion-based observational evaluation checklist before and after venepuncture, to assess the phlebotomist-recorded remarks. The total scores referred to compliance with the procedural standards. Feedback from the performing laboratory on the quality of all samples collected during the study period provided additional quality control.

Ethical approval

Permission for the study was granted by the Department of Hematology, Port Sudan Ahlia College and approval was obtained from the Ministry of Health, Red Sea State, Sudan (Letter No. 44/b/1- date: 25 September 2017) and the health laboratories administration. Informed consent was obtained from all study respondents.

Results

In 5 of 8 (62.5%) hospitals, the phlebotomy area had enough space for phlebotomists to carry out their work and met the minimum requirements for the materials needed. Unfortunately, during the study period, the standard operating procedures (SOPs) were not considered a part of quality control in 3 of the 8 (37.5%) phlebotomy sites. Furthermore, most of the phlebotomists were not specialized according to their education. They worked by shift system and had no plan for future training.

Findings before venepuncture session

Sixteen of the 24 (66.6%) phlebotomists received in-service training and 8 were untrained (according to the mean experience). Eleven of the 16 (68.8%) trained phlebotomists worked in the government sector and 5 (31.3%) worked in the private sector. Seven of the 8 (87.2%) untrained phlebotomists worked in the government sector. This indicated that phlebotomists working in government hospitals had fewer skills and needed an intensive training programme. Nine of the 16 (56.2%) trained phlebotomists were married and the remainder were single. This indicated that marital status had a psychological effect on the work ($P < 0.042$). Nineteen of 24 (79.2%) phlebotomists had some idea of how to use the tourniquet (time and

application), but 5 (20.8%) of them did not know the time of tourniquet application. Twenty-three of 24 (99.2%) phlebotomists knew about the types of specimens and anticoagulants used.

Table 3 highlights the findings of 24 phlebotomists performing 5 venepuncture procedures. In 53 of 120 (44.2%) sessions, phlebotomists did not use 70% alcohol disinfectant. In 40 (33.3%) sessions, phlebotomists did not wear gloves at all. In 83 (69.2%) sessions, phlebotomists did not renew their gloves for each patient ($P< 0.042$). In 45 (37.5%) sessions, 9 phlebotomists collected blood samples using a tourniquet for an inappropriate time (CLSI recommends 1 minute). In 75 (62.5%) sessions, 15 phlebotomists used a tourniquet based on CLSI recommendations. The mean (SD) tourniquet time was 59.22 (14.37) seconds. There was a significant correlation between phlebotomists' expertise and duration of tourniquet application ($P< 0.011$).

Findings during venepuncture

Ninety-eight (81.7%) of 120 blood specimen collection tubes were labelled before collection and checking the patients (Table 3). The procedure for collecting blood specimens varied among the hospitals. In 108 (90%) of 120 sessions, phlebotomists used a syringe to collect the blood and transferred it to vacutainer tubes. In 66 (55%) of 120 sessions, phlebotomists used multisampling needles and holders with evacuated tubes. In 72 (60.8%) of 120 sessions, phlebotomists released the tourniquet when blood appeared in the syringe or test tube, demonstrating full awareness of the use of the tourniquet.

Findings after venepuncture

In 105 (87.5%) of 120 sessions, phlebotomists applied cotton or an adhesive bandage to the blood collection site (Table 3) and 85.8% of them, especially the trained were careful in recapping the needles or syringes ($P< 0.001$), which considerably minimized exposure to needle injury. In 119 (99.2%) sessions, phlebotomists immediately gently mixed the blood samples after collection. In 12 (10%) sessions, after collecting blood, phlebotomists placed the samples in a rack without mixing or with an unacceptable mixing time. The major errors demonstrated during phlebotomy are shown in Table 4.

Discussion

Poor performance of phlebotomy has adverse effects on patient safety and health. Thus, this research was conducted to assess phlebotomy practice and identify the major errors during venepunctures in public laboratories in Port Sudan City.

Phlebotomy is one of the most neglected procedures, particularly in Red Sea State. It is reported that 80% of errors occur in the preanalytical stage in clinical laboratories

(*4*,*17*,*18*). The present study showed that phlebotomists working in government hospitals had fewer skills and needed an intensive training programme. This finding agrees with Ernst (*19*), who proposed that the phlebotomist is stressed during work. Importantly, this study revealed that lack of planning and continuous training of the phlebotomists has a negative impact, and this may limit their career prospects. WHO also emphasized the significance of training and regular evaluation of venepuncture techniques because ineffective training and evaluation increases mistakes and lawsuits (*20*). Therefore, training is indispensable and motivates phlebotomists to become experts in their field committed to lifelong learning, caring for their patients, and ensuring high-quality blood specimen collection. ISO 15189 accreditation has been accepted by the laboratory personnel, because it is an internationally approved standard of laboratory medicine (*21*). Accreditation systems have only recently started in Red Sea State, due to a shortage of resources.

We found that 62.5% of phlebotomists had sufficient space to perform their work, which is similar to a study by Mekonon et al. (*17*), and both studies agree with the WHO phlebotomy guidelines (*20*). Regrettably, SOPs were developed in only 5 of 8 laboratories and this led to poor quality.

General safety measures should be present throughout all laboratory work, including venepuncture (*7*). In our study, in 40 of 120 sessions, phlebotomists did not wear gloves at all, and in 83 (69.2%) sessions, phlebotomists did not renew their gloves for each patient. In 53 (44.2%) sessions, venous blood collections were performed without using 70% alcohol or any disinfectant agent. These findings are not in accordance with the CLSI guidelines and other previous studies (*7*,*17*). In 80 of 120 (66.7%) sessions, phlebotomists requested the patient to clench their fist. This finding is inconsistent with Lima-Oliveria et al. (*18*), who have argued that this practice could contribute to changes in electrolyte concentration and skin pH. WHO guidelines recommend that the blood puncture site must be compressed to inhibit bleeding (*20*); this action was achieved in 105 (87.5%) sessions by applying an adhesive bandage. Lack of knowledge is considered to be a risk for errors. Twenty-three of 24 (99.2%) phlebotomists knew about the types of specimens and anticoagulants used. However, they did not have full knowledge of the order in which to collect the samples, according to the CLSI guidelines (*7*).

Blood samples collected in tubes containing anticoagulant should be mixed by inverting gently several times to create homogeneity of anticoagulant and blood (*7*). In the present study, 10% of blood samples were inappropriately mixed, although this was less than the average reported by Mekonon et al. (*17*) and Lima-Oliveria et al. (*18*).

Our study highlights the errors made by phlebotomists during venepuncture. These errors included not wearing new gloves for each patient, not using 70% alcohol for cleaning the puncture site, retouching the cleaned site, collecting blood samples prior to alcohol drying, and applying tourniquets for a prolonged time, thereby not complying with CLSI guidelines. However, similar findings were observed in previous studies (*22–24*). The duration of tourniquet application of 59.2 (14.4) seconds in our study was within the recommended time. Our finding is consistent with that of Mekonon et al. [51.6 (12.5) seconds] (*17*), but not with that of Lima-Oliveria et al. [84.4 (14.1) seconds] (*18*).

The current study has some limitations. We had difficulty finding literature on phlebotomists' performance of venepuncture. Moreover, we were unable to find any studies on phlebotomy in laboratories in Sudan. Eventually, we recommended a longitudinal intervention study to assess phlebotomy practice before and after an in-service training programme. We also recommend establishing a regular standardized training programme within the fields of anatomy and pathology to develop practical skills and implement the CLSI and ISO 15189 guidelines in some public hospital laboratories and expand the training gradually to other laboratories in Red Sea State.

Conclusion

Our study shows that there is a lack of SOPs in some phlebotomy practice in Port Sudan City. Also, there is some deficit in phlebotomists' skills. None of the phlebotomists undertook any training course or workshop and this reflects the extent of the negligence of phlebotomists by health administrations. However, the phlebotomists did not follow the CLSI guidelines. Ongoing assessment and improvement are fundamental to ensure that the phlebotomy service is effective. The shortage of resources is a major hurdle to improving health facilities and providing training to phlebotomy staff.

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Table 1. Questionnaire scheme used in this study

Evaluator		
Date		
Phlebotomist		
Specimen no.		
Age		
Graduation		
Sex		
Religion		
Marital status		
Type of sector		
Experience	Yes	No
Q1. Was the patient identified according to CLSI?		
Q2. Did the phlebotomist ask for permission before blood collection?		
Q3. Was the tourniquet placed correctly?		
Q4. Did the phlebotomist select a suitable venepuncture site?		
Q5. Did the phlebotomist know how to apply the tourniquet?		
Q6. Was the phlebotomist wearing gloves for each patient?		
Q7. Was the venepuncture site disinfected according to guidelines?		
Q8. Was alcohol allowed to evaporate before venepuncture?		
Q9. Did the venepuncture site remain untouched after disinfection?		
Q10. Did the phlebotomist ask the patient to clench their fists during collection?		
Q11. Was the tourniquet time within CLSI recommendations?		
Q12. Was the tourniquet released immediately after blood flow began?		
Q13. Were the tubes used labelled in the presence of the patient?		
Q14. Did the phlebotomist use a syringe to transfer blood to a vacutainer?		
Q15. Did the phlebotomist used vacutainer tubes with multisampling needles?		
Q16. Did the phlebotomist use a syringe to transfer blood to a vacuum tube by opening the cover?		
Q17. Did the phlebotomist mix the blood gently to avoid haemolysis?		

Q18. Did the phlebotomist have knowledge about sample kinds?		
Q19. Were the blood coagulation samples collected according to guidelines?		
Q20. Was a cotton or adhesive bandage placed over the venepuncture site after sampling?		
Q21. Did the phlebotomist recap the needles and syringes?		
Q22. Was the anticoagulated blood tube mixing time accepted or not?		
Q23. Was there any needle stick injury?		
Q24. Were syringes and needles disposed correctly after sampling?		

Table 2. Phlebotomists' characteristics

Characteristics	Phlebotomists (n = 24)
Age, mean (SD)	31.1 (8.1) yr
Sex	
Male	16
Female	8
Education, mean (SD)	2.79 (1.95)
Secondary school	12
Primary school	1
Graduated college	1
Diploma 2 years	10
Experience, mean (SD)	6.6 (5.3) yr
Trained	16
Untrained	8
Marital status	
Single	14
Married	10
Sector	
Government	18
Private	6
Training course	
Yes	0
No	24
Workshops	
Yes	0
No	24

Table 3. Checklist remarks of phlebotomists in venepuncture sessions

Steps	Yes (n = 120)	No (n = 120)
Phlebotomist easily identified patients	107	13
Phlebotomist asked permission before collecting blood	105	15
Wearing gloves	80	40
Wearing a new glove for each patient	37	83
Cleaning the puncture site with 70% alcohol	67	53
Collecting blood after alcohol drying	61	59
Retouching of the cleaned site	51	69
Request to clenching fist during collection	80	40
Labelling of test tube before collection	98	22
Using a syringe to transfer blood to test tube	108	12
Using multisampling needle with holder	66	54
Release the tourniquet when the blood starts flowing	73	47
Duration of tourniquet based on CLSI	75	45
Adding blood by opening the vacuum tube	72	48
Gentle mixing to avoid haemolysis	119	1
Mixing time of the specimen	108	12
Apply cotton or adhesive bandage	105	15
Collect the coagulation sample properly	92	28
Needle stick injury	11	109

Table 4. Major errors observed during phlebotomy

Error	Phlebotomist (n = 24)		
	Public laboratory (n = 18)	Private laboratory (n = 6)	*P*
Did not renew the glove for each patient	13 (72.2%)	4 (66.6%)	0.042
Did not use 70% alcohol for cleaning site of puncture	12 (66.6%)	1 (16.7%)	0.048
Retouching of the cleaned site	12 (66.6%)	3 (50.0%)	0.079
Collecting blood samples before alcohol, dried	8 (44.4%)	1 (16.7%)	0.238
Applying a tourniquet for prolonged time	9 (50.0%)	0 (0.0%)	0.037
Needle stick injury	4 (22.2%)	1 (16.7%)	0.634