

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 sites. 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

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 use 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 |

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

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 |

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).

Table 4 Major errors observed during phlebotomy

| Error | Phlebotomist (n = 24) | | P |
|---|----------------------------|----------------------------|-------|
| | Public laboratory (n = 18) | Private laboratory (n = 6) | |
| 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 |

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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Audit du système de phlébotomie dans les laboratoires médicaux de la ville de Port-Soudan (Soudan)

Résumé

Contexte : La phlébotomie est l'une des techniques de médecine de laboratoire et de soins de santé les plus délaissées. Il s'agit d'une pratique complexe nécessitant de vastes connaissances et des compétences de haut niveau. Des erreurs en phlébotomie peuvent influencer les résultats des analyses de laboratoire (diagnostic) et avoir une incidence sur la prise en charge des patients.

Objectifs : Évaluer la pratique des phlébotomistes ainsi que le degré de conformité avec les lignes directrices et déterminer la fréquence des erreurs commises dans les laboratoires hospitaliers de Port-Soudan (Soudan).

Méthodes : Entre août et septembre 2017, une étude d'observation transversale a été menée dans huit hôpitaux publics soudanais à l'aide d'un système d'observation structuré. Un questionnaire structuré a été utilisé pour évaluer les procédures de ponction veineuse. Lors de chaque session, cinq prélèvements de sang différents effectués par chacun des phlébotomistes ont été observés. On a surveillé 120 prélèvements de sang effectués par 24 phlébotomistes, 16 (66,7 %) étant des hommes et 8 (33,3 %) femmes, dont l'âge moyen était de 31,1 ans.

Résultats : Trois des huit sites de phlébotomie n'étaient pas couverts par des modes opératoires normalisés. De plus, les phlébotomistes ne disposaient pas de plans de formation adéquats. Dans 33,3 % des sessions, les phlébotomistes ne portaient pas du tout de gants, et dans 69,2 % des sessions, ils ne portaient pas de nouveaux gants pour chaque patient. Une forte corrélation a été observée entre l'expertise des phlébotomistes et la durée d'application du garrot.

Conclusion : La présente étude met en évidence la non-disponibilité de modes opératoires normalisés dans certains sites de phlébotomie. Les phlébotomistes ne suivaient pas les lignes directrices du *Clinical and Laboratory Standards Institute*. L'évaluation continue et l'amélioration des procédures sont essentielles pour garantir le bon fonctionnement du service de phlébotomie.

مراجعة نظام فصد الدم في المختبرات الطبية في مدينة بورتسودان في السودان

بشير عبدالرحمن بشير، أحمد عبد ربه

الخلاصة

الخلفية: إن فصد الدم هو إحدى أكثر التقنيات التي تعاني من الإهمال في طب المختبرات والرعاية الصحية. وهو من الممارسات المعقدة التي تتطلب معرفة واسعة ومهارات رفيعة المستوى. وقد تؤثر الأخطاء التي تحدث أثناء فصد الدم على نتائج الفحوص المختبرية (التشخيص)، مما يؤثر بدوره على الرعاية المقدمة للمرضى.

الأهداف: هدفت الدراسة إلى تقييم ممارسة أخصائيي فصد الدم وتقدير مدى امتثالهم للمبادئ التوجيهية، وتحديد وتيرة حدوث الأخطاء في مختبرات المستشفيات في بورتسودان، السودان.

طرق البحث: أجريت دراسة رصدية مقطعية باستخدام خطة رصد منظمّة في 8 مستشفيات عامة في السودان في الفترة بين أغسطس/ آب وسبتمبر/ أيلول 2017. واستخدم استبيان مُنسق لتقييم مستوى إجراءات بزل الوريد. كما رُصدت خمس عمليات لجمع الدم قام بها كل فرد من أخصائيي الفصد. ورصدنا 120 عملية لجمع الدم قام بها 24 أخصائي فصد، 16 منهم من الذكور (66.7%)، و8 من الإناث (33.3%)، وكان متوسط عمرهم 31.1 عاماً.

النتائج: لم تشمل إجراءات التشغيل الموحدة ثلاثة من مواضع فصد الدم الثانية. وعلاوة على ذلك، لم تتوافر الخطط التدريبية الملائمة لأخصائيي فصد الدم. وفي 33.3% من الجلسات، لم يرتد أخصائيو الفصد قفازات على الإطلاق، كما أنهم في 2, 69% من الجلسات، لم يرتدوا زوجاً جديداً من القفازات لكل مريض. وتبين وجود ترابط وثيق بين خبرة أخصائيي الفصد ومدة وضع العاصبة.

الاستنتاج: توضح هذه الدراسة عدم توافر إجراءات التشغيل الموحدة بشأن بعض مواضع فصد الدم، وعدم اتباع أخصائيي الفصد للمبادئ التوجيهية الخاصة بمعهد المعايير السريرية والمختبرية. وعليه، فإنه لا غنى عن تقييم الإجراءات وتحسينها باستمرار لضمان تشغيل خدمات فصد الدم بفعالية.

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