

Assessment of phlebotomy errors by direct observation of sample collection procedure in a NABL Accredited Hospital: An Observational study

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Abstract: *Background:* Preanalytical phase is largely dependent on phlebotomist. The most frequently encountered preanalytical errors are hemolysis, incorrect patient identification, clotted specimens and insufficient sample volume. These errors can mostly be attributed to faulty phlebotomy procedure. *Objective:* To assess phlebotomy errors by direct observation of laboratory professionals-patients interaction during phlebotomy procedure. *Material and methods:* This study used the real time observations of patient-laboratory staff interactions to collect first-hand data on phlebotomy errors. Five different phlebotomists were directly observed while performing phlebotomy procedure on 200 patients. A checklist was used to collect data on the phlebotomy procedure and errors. *Results:* During the observation period, 200 blood samples were drawn into 457 tubes by 5 phlebotomists and none of the procedures could meet all the quality criteria of good and safe phlebotomy practice as described by WHO. *Conclusion:* There is urgent need for standard operating protocols to standardize phlebotomist-patient interaction. Phlebotomy errors can damage the institution's reputation, diminish confidence in healthcare services and contribute to increase in total operating costs, both for the hospital and laboratory. While it is understood that human errors cannot be completely eliminated, compliance with best practices for blood collection may help in minimizing the errors.

Keywords: Preanalytical phase, laboratory professionals, phlebotomy, hemolysis

Introduction

The term phlebotomy comes from ancient Greek, and literally means "lancing a vein". Venipuncture is a more recent term for phlebotomy; it refers to the practice of drawing blood (by penetrating the vein's wall with a needle rather than cutting it with a lancet) for collection and analysis. With advancement in medical science, "blood collectors" have been trained as professional "Phlebotomists" to reduce faulty venipuncture procedure and other errors during sample collection in a clinical laboratory. Phlebotomy is one of the most common invasive procedures in health care. During the phlebotomy procedure the health workers and patients are exposed to risk from blood borne pathogens like Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV) etc. From the simplest blood tests to the most complex oncology and molecular diagnostic solutions, laboratories around the

world have become an indispensable part of the healthcare system.

In the clinical laboratory, the preanalytical phase errors accounts for up to 60-70 % of total laboratory errors; 26% of these may have detrimental effects on patient care, which leads to unnecessary investigations or inappropriate treatment, increase in lengths of hospital stay ultimately can result in patient's dissatisfaction with healthcare services [1]. The preanalytical phase has been described as the "dark side of the moon" in laboratory medicine [2-3]. Phlebotomy error constitute more than 60% of these preanalytical errors [4].

Preanalytical phase is largely dependent on phlebotomist. The most frequently encountered preanalytical errors are hemolysis, incorrect patient identification,

clotted specimens and insufficient sample volume. These errors can mostly be attributed to faulty phlebotomy procedure. Satisfactory skills and a relevant and good level of knowledge and experience are essential to collect a quality sample that will generate anticipated and accurate results. Phlebotomy errors represent a serious public health problem and pose a threat to patient safety. The three major issues arising from an incorrect phlebotomy procedure are haemoconcentration, spurious hyperkalemia and spurious haemolysis. Faulty phlebotomy causing pseudohyperkalaemia have been highlighted in previous studies [5].

A study of medical errors published in the New England Journal of Medicine showed that 11% patients received potentially harmful care and that 46% of patients did not receive the recommended care [6]. These numbers could be significantly high in developing countries like India. The cost of phlebotomy errors and their impact on efficiency can also be assessed by the hours lost as a result of required redraws and delayed follow-up care. These errors damage the institution's repute, loss of confidence in healthcare services and lead to increase in total operating costs, both for the hospital as well as laboratory. With rising healthcare expenses and financial constraints, it is the utmost responsibility of hospital and laboratory administrators to prevent or reduce the incidence of these errors.

There has been a lot of automation in the analytical phase of the clinical laboratories leading to a significant decrease in analytical errors over the last decade. But still the preanalytic part is the least automated one hence prone to many random errors because of lack of regular monitoring. There may be many laboratory and non-laboratory professionals involved in the blood collection process, presenting even more incidence for errors to occur. There is scarcity of data on direct observation of phlebotomy errors in the clinical laboratory therefore this study was planned to assess the phlebotomy error by direct observation of laboratory professionals-patient interactions at the time of phlebotomy procedure .

Objective of the study: To assess phlebotomy errors by direct observation of laboratory

professionals-patients interaction during phlebotomy procedure.

Implication of the study: Finding of this study could be implicated in decreasing phlebotomy errors in the clinical laboratory setting, thereby benefiting patients

Material and Methods

This study used the real time observations of patient-laboratory staff interactions to collect first-hand data on phlebotomy errors. Five different phlebotomists were directly observed while performing phlebotomy procedure on 200 patients. Phlebotomies observed during the study were performed by the trained laboratory staff. A checklist was used to collect data on the phlebotomy procedure and errors. The observation checklist for quality control of phlebotomy was constructed based on the previous studies and adjusted to local procedures [7].

Statistical analysis: Data were entered into Microsoft Excel. Descriptive statistics such as number and percentage were used to present the data.

Results

During the observation period, 200 blood samples were drawn into 457 tubes by 5 phlebotomists and none of the procedures could meet all the quality criteria of good and safe phlebotomy practice as described by WHO. We observed that in 184 phlebotomies (92%), patient was identified as per CLSI guidelines [7]. In routine practice it was seen that in 16 phlebotomies (8%), patient was asked for the prescription given by the physician and name, age was noted done from there. In majority of 180 procedures (90%) the phlebotomist followed proper hand hygiene and other safety protocols including use of face mask. The phlebotomist put on clean gloves prior to the blood sampling procedure but in 20 (10 %) of cases they did not perform the correct disinfection procedures in the collection of blood sampling.

Single-use of the holder and the tourniquet were not used in our setup for the blood drawing procedures. In 170 (85%) patients it

was assured that the patient was properly prepared as per instruction (e.g. fasting). In all 200 patients venipuncture site was located and disinfected properly and gently. In 176 (88%) of the venipuncture procedures venipuncture device and vacutainers were kept ready before application of the tourniquet, however tourniquet was not tied at proper place in 140 venipunctures (70%) but it was not to loose or tight in all the phlebotomies performed. Patient was instructed to clench the fist in 180(90%) of the phlebotomies but it was observed that request was not done for repeated clenching of the fist in 196(98%) patients.

Alcohol was not allowed to evaporate in 128 patients (64%). Phlebotomy site was touched before venipuncture in 160 (80%) procedures. Appropriate tourniquet time and release were not

applied in 168(84%) of the procedures. The order of citrated and EDTA tubes was wrong in 4% and 16% of the drawings, respectively. Sample tubes were not immediately and appropriately mixed with the inversion (5-6 times) in 148 (74%) phlebotomies.

The fill volume was evaluated in the observation period. The fill volume error was seen in 8(4%) of samples. In 4 of the vacutainers the fill volume was <75%, and in 2 of the gel tubes the fill volume was <50%. The hemolysis was observed in one sample. However labeling of the tubes, correct disposal of needles & other used products were done properly in 200(100%) of the procedures. All the above observations are depicted in table 1.

Table-1: Checklist for observation of phlebotomy procedures showing results in numbers and percentages		
Observations	Yes	No
1. Was the patient identified as per CLSI Guideline?	184(92%)	16(8%)
2. Did the phlebotomist follow proper hand hygiene and other safety protocols including face mask?	180(90%)	20(10%)
3. Was it assured that the patient was properly prepared as per instruction (e.g. Fasting)?	170(85%)	30(15%)
4. Was the venipuncture site located and disinfected properly and gently?	200(100%)	0(0%)
5. Was appropriate venipuncture device used and kept ready before application of tourniquet?	176(88%)	24(12%)
6. Was the tourniquet placed in proper place?	60(30%)	140(70%)
7. Was the tourniquet too tight?	0(0%)	200(100%)
8. Was the patient asked to clench his/her fist repeatedly?	4(2%)	196(98%)
9. Was the alcohol allowed to evaporate from the site before venipuncture?	72(36%)	128(64%)
10. Was the site untouched before venipuncture?	40(20%)	160(80%)
11. Was the tourniquet released immediately after venipuncture?	32(16%)	168(84%)
12. Was the tourniquet tied for more than 1 minute?	168(84%)	32(16%)
13. Was the correct order of vacuum tubes used?	160(80%)	40(20%)
14. Were the blood tubes filled properly and adequately?	184(92%)	16(8%)
16. Was the blood in tubes containing anticoagulant or clot activating additives properly mixed after sampling?	148(74%)	52(26%)
17. Was the syringe/needle and other used products disposed immediately?	200(100%)	0(0%)
18. Were the tubes labeled properly before the patient left?	200(100%)	0(0%)

Discussion

The study reveals a numbers of items like proper tying of the tourniquet, proper disinfection of the phlebotomy site and appropriate mixing of the

blood tubes containing anticoagulant or clot activating additives are in need of urgent attention. In our study patients were identified according to CLSI Guidelines in 184 phlebotomies while in 16 patients, identity

was noted down from the prescription. Carraro et al. observed high rates of patient identification errors at the time of blood sampling [8]. In another study, Carraro and Plebani shared their ten years of experience in a Stat laboratory, wherein they pointed out that the patient identification error (8.8%) was the second-highest type of error [9]. One of the most frequent errors that we observed in our study was improper placement of the tourniquet. The tourniquet should be applied at about 4-5 finger widths above the venipuncture site. This error may be attributed to the habitual procedures applied by the staff and failure to implement the written quality procedures.

Proper hand hygiene and disinfection of the venipuncture site was the second most commonly observed error in our study, this issue may be due deficit of alertness and lack of knowledge about the importance of hand hygiene. This is in corroboration with a study done by Linderberg et al [10] Venipuncture site was touched after disinfecting in 80% of the procedures which may lead to spread of infection at phlebotomy site. WHO guidelines recommend a one-step procedure for skin preparation. The skin should be cleaned with a combination of 2% chlorhexidine gluconate in 70% isopropyl alcohol, covering the whole area and ensuring that the skin area is in contact with the disinfectant for at least 30 seconds & then allowed it to dry completely for about 30 seconds.

Time of tourniquet application was another commonly observed error. Tourniquet was applied for more than one minute in 84% of the phlebotomies. Due to the tourniquet application inner pressure of the vein increases, prolonged or excessive application of this pressure can lead to vessel constriction raising the hydrostatic pressure and forcing the water into the outer connective tissue. Thereafter, the collected sample can show haemoconcentration, an activated pro-coagulant response, and an altered platelets function. The prolonged venous stasis, which also favors tissue hypoxia, produces a change in pH which locally affects the electrolytes balance, especially potassium [11-16]. Prolonged or repeated clenching of fist was also observed in few of the procedures, which can cause factitious elevation of plasma potassium by approximately 1.5 mmol/l due to potassium

entering venous effluent from the exercising forearm muscles. This occurs at all levels of plasma potassium [17-18]. The labeling of the tubes was done before blood collection or before the patient leaves the collection counter in 100% of the phlebotomies. One important finding was that tourniquet was not disposable neither it was disinfected which can lead to spread of infection. Tourniquets are a potential source of methicillin-resistant Staphylococcus aureus (MRSA), with up to 25% of tourniquets contaminated through lack of hand hygiene on the part of the phlebotomist or reuse of contaminated tourniquets [19].

We observed in the current study that correct order of tube filling was not used in 20% of the phlebotomies, 8% of the tubes were not filled and 26% of the samples were not mixed adequately. Incorrect order of fill, inadequate volume of sample and improper mixing can lead to sample contamination, hemolysis and insufficient sample for analysis. Atay et al. reported that the rejection rates for hemolysis, clotted specimen, and insufficient volume were 8%, 24%, and 34%, respectively [20].

It may be difficult to eliminate all errors but they can be minimized by following certain guidelines like Standard Operating Procedures (SOPs) which are required for each step or procedure. These should be written and be readily available to health workers. Education and training is necessary for all staff carrying out phlebotomy. It should include an anatomical knowledge, awareness about the risks infection from blood exposure and the consequences due to poor infection prevention and control. Further frequent assessment of the procedure is required in order to maintain quality compliance among the laboratory staff. Quality care in phlebotomy also involves cooperation of the patient; which will be mutually beneficial to both the health worker and the patient. Clear information preferably written should be available to each patient who undergoes phlebotomy

Limitations of the study: Observations of clinician and patient interaction was not taken into account. Future studies that address this gap will help to provide a comprehensive

understanding of the patient-practitioner interaction during hospital visit.

Conclusion

There is urgent need for standard operating protocols to standardize phlebotomist-patient interaction. Phlebotomy errors can damage the institution's reputation, diminish confidence in healthcare services and contribute to increase in

total operating costs, both for the hospital and laboratory. While it is understood that human errors cannot be completely eliminated, compliance with best practices for blood collection may help in minimizing the errors.

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