Journal of Health and Rehabilitation Research 2791-156X JHRR

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Original Article

Observational Study on Adherence to Modified Clinical and Laboratory Standard Institute H3-A6 Guidelines on Blood Sampling Procedures

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Conflict of Interest: None.

Rana MZ., et al. (2024). 4(1): DOI: https://doi.org/10.61919/jhrr.v4i1.404

ABSTRACT

Background: The accuracy of clinical laboratory results is paramount for effective patient diagnosis and treatment. However, errors in the pre-analytical phase, particularly during phlebotomy, significantly impact the reliability of laboratory data. With the Clinical and Laboratory Standards Institute (CLSI) guidelines serving as a benchmark for best practices in blood collection, adherence to these standards is crucial for minimizing errors.

Objective: This study aimed to assess compliance with modified CLSI guidelines in phlebotomy procedures within a healthcare setting and identify the most prevalent errors in the pre-analytical phase that could compromise patient safety and the integrity of laboratory results.

Methods: Conducted at the Combined Military Hospital Lahore from January to March 2023, this observational study scrutinized phlebotomy practices across three distinct healthcare settings: emergency department, outpatient department, and clinical wards. A structured checklist, adapted from the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) guidelines and aligned with local modifications, was employed to evaluate compliance in 20 specific areas of phlebotomy practice. A total of 285 phlebotomies were observed by specialized staff, with data analyzed using SPSS version 25 to compare error frequencies and compliance rates across different settings and among various healthcare professionals.

Results: The study revealed an overall compliance rate of 88% for identified request forms, 76% for patient identification according to local guidelines, and 66% for proper hand sanitization. However, significant errors were identified in checking for potential complications of venipuncture (34% compliance), with tubes being clearly under or overfilled (46% compliance), and in verifying that patients were prepared for phlebotomy (46% compliance). The error frequency varied across settings, with the highest discrepancies observed in the emergency department. Differences in compliance rates between laboratory staff and nurses were statistically significant in key areas, including patient identification ($p<0.001$) and tube labeling ($p=0.081$).

Conclusion: The study highlights a critical need for improving adherence to CLSI guidelines within phlebotomy practices to enhance patient safety and the accuracy of laboratory results. Targeted educational and training interventions are essential for addressing the identified gaps in compliance, particularly in patient identification, sample volume control, and verification of patient preparation for phlebotomy.

Keywords: Phlebotomy, CLSI Guidelines, Pre-analytical Errors, Laboratory Medicine, Patient Safety, Compliance.

INTRODUCTION

In the context of clinical decision-making, laboratory data play a pivotal role, with evidence suggesting that up to 70% of medical decisions are influenced by test results (1). This underscores the critical importance of minimizing errors within laboratory processes, especially given the potential for medical errors to rank as the third leading cause of death in the United States if classified as a disease (2). Despite advancements in laboratory automation that have significantly mitigated analytical errors, the pre-analytical

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phase—particularly the blood collection process—remains fraught with challenges. Studies indicate that as much as 75% of laboratory errors originate in this phase, which can have dire consequences for patient diagnosis and treatment (3,4).

The inconsistency in the training of phlebotomy personnel across Europe, coupled with a disregard for the standards set by the Clinical and Laboratory Standards Institute (CLSI) and the International Organization for Standardization (ISO), raises significant concerns. The ISO 15189:2012 guidelines underscore the need for detailed instructions on patient preparation and sample transportation to mitigate phlebotomy-related issues (5). Guidelines from the CLSI (2007), national societies, and the World Health Organization (2010), as well as recommendations from the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE), emphasize the importance of routine phlebotomy quality monitoring (6,7). However, the diverse nature of errors associated with phlebotomy, ranging from patient/sample misidentification, prolonged tourniquet application, and inadequate patient preparation to insufficient blood collection volumes and compromised healthcare worker safety, highlights the complexity of enforcing quality control (4). These challenges are exacerbated by a lack of awareness about the consequences of improper techniques, reluctance to adhere to protocols due to increased workload, time constraints, insufficient training, unfamiliarity with guidelines, and a lack of interdepartmental support in hospital settings (8).

Addressing these issues requires a comprehensive understanding of both barriers and facilitators to the effective implementation of phlebotomy guidelines. This knowledge is essential for developing strategies to enhance guideline adherence and improve the quality of blood collection practices. However, the quality of phlebotomy practices in Pakistan remains largely unknown, underscoring the need for this study. The study aims to assess the extent of compliance with CLSI guidelines among phlebotomy procedures in Pakistan and identify the most critical steps that require immediate attention and improvement. By doing so, it seeks to contribute to the improvement of phlebotomy practices, thereby reducing pre-analytical errors and enhancing the reliability of laboratory data for clinical decision-making.

MATERIAL AND METHODS

The methodology of this research was anchored in a comprehensive questionnaire derived from the pivotal issues underscored by the Clinical and Laboratory Standards Institute (CLSI) guidelines. Authorization to utilize this questionnaire was secured from the corresponding author of a seminal article (7), ensuring adherence to ethical standards for intellectual property. The investigation took place at the Combined Military Hospital Lahore, spanning from January to March 2023, where a systematic observation of phlebotomy practices was conducted across three different settings within the hospital.

During the three-month period, the research team observed a total of three phlebotomy sessions at each location, employing a structured checklist for data collection. This checklist was meticulously developed based on the guidelines provided by the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group, with adjustments made to align with local protocols and practices. These modifications were collaboratively decided upon by a team of quality control managers and phlebotomist training personnel, leading to the exclusion of nine items from the original 29-item checklist. The alterations included practices such as the non-recommendation of glove use, central verification of expiry dates, and the centralized assembly of necessary supplies, among others, resulting in a streamlined checklist comprising 20 items.

Observation sessions were characterized by stringent adherence to protocol, with particular emphasis on the accurate identification of patients, a critical step deemed mandatory for correct execution due to its potential for causing significant harm. Any discrepancies observed in patient identification were immediately corrected by the observer to maintain the integrity of the study and ensure patient safety. This approach underscored the observational nature of the study, with findings recorded as binary yes/no responses to assess compliance across the phlebotomists in the various settings.

Ethical considerations were paramount throughout the study, with all procedures conducted in accordance with the highest standards of research ethics, including the protection of participant confidentiality and the secure handling of data. The analytical phase employed Statistical Package for the Social Sciences (SPSS) version 25 for a detailed examination of the data. Responses were categorized as yes, no, or not applicable (NA), with compliance generally indicated by a yes. Exceptions were noted for specific questions where a no response denoted adherence to the recommended procedures. Notably, question 19's focus on sample volume accuracy and question 25's emphasis on post-phlebotomy labeling procedures were critical for evaluating procedural compliance.

The statistical analysis incorporated the $\chi 2$ test to explore differences across the three observational settings—laboratory, ward, and emergency department—with a significance threshold set at $p < 0.05$. Additional analyses for specific questions were tailored based on the applicability to the observed scenarios, such as outpatient-only analysis for question 6 and contingent analyses for questions 13 and 14 based on preceding responses. The results were presented as frequencies and percentages, offering a clear depiction of compliance levels and identifying areas for improvement. Through this rigorous methodological approach, the study aimed to

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provide valuable insights into the adherence to CLSI guidelines within the phlebotomy practices at the Combined Military Hospital Lahore, contributing to the ongoing efforts to enhance patient care and safety in clinical laboratory settings.

RESULTS

The study meticulously analyzed compliance with phlebotomy procedures across various healthcare settings and among different healthcare professionals, yielding insightful findings. In the emergency department, 65 audits were performed, constituting 22.54% of the total, while the outpatient department saw 119 audits, representing 41.19%, and clinical wards accounted for 101 audits, or 35.56%. When examining the distribution of phlebotomies by healthcare professionals, laboratory staff were responsible for 173 of the procedures, making up 60.92%, with nurses performing 111 procedures, accounting for 39.08%.

A closer look at the compliance with specific phlebotomy procedures revealed varied results. The compliance rate for having an identified request form was high at 88%, with a slightly higher likelihood of error in settings (p=0.005) and among professions (p=0.007). Patient identification compliance was 76%, indicating a significant area for improvement, particularly as the differences between both settings and professions were statistically significant (p<0.001 for both).

Hand sanitization had a 66% compliance rate, with differences observed between settings (p=0.013) and professions (p=0.027) suggesting specific areas for targeted interventions. Verification of patient preparation before phlebotomy had a lower compliance rate of 46%, with highly significant differences (p<0.001) indicating critical gaps in procedural adherence.

Tourniquet placement and venipuncture site selection demonstrated high compliance rates of 94% and 96%, respectively, although the differences between settings and professions (p ranging from 0.038 to 0.073) suggest room for minor improvements. Venipuncture site cleaning and drying procedures also showed strong compliance, at 90% and 62% respectively, but with considerable variability in adherence between different settings and professions.

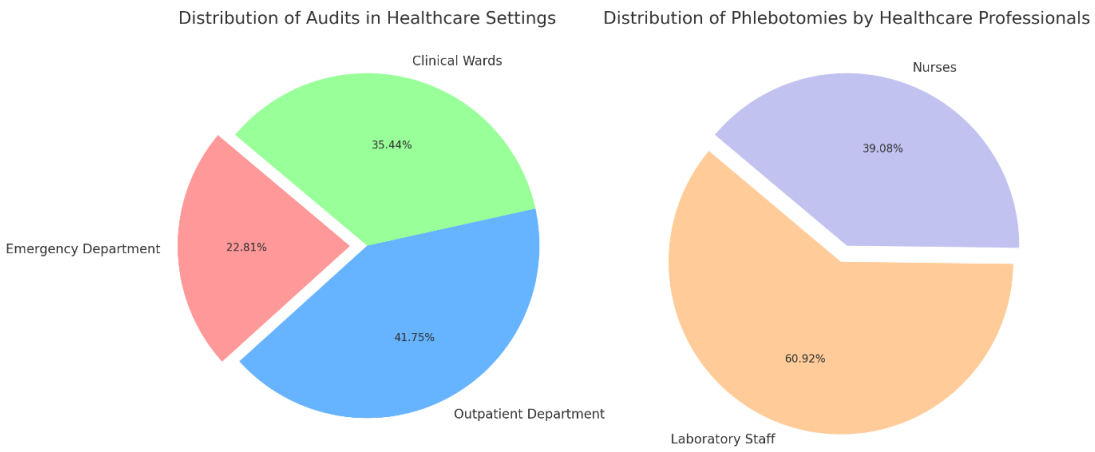

Figure 1 Distribution of Audits and Phlebotomies

Observations on post-cleaning site maintenance, fist release upon blood flow, and tourniquet release highlighted compliance rates ranging from 54% to 64%. Notably, the procedure for releasing the fist upon blood flow commencement exhibited the least consistency, with a compliance rate of 56% and significant discrepancies between settings (p=0.479) and professions (p=0.624).

Table 1 Error observed during phlebotomies and calculated differences between settings and professions

Question	EF	C (%)	Difference between (P Value)	
			Settings	Professions
1. Identified request form	12.0%	88%	0.005	0.007
2. Patient identification	24.0%	76%	<0.001	<0.001
3. Hand sanitization	34.0%	66%	0.013	0.027
4. Patient preparation verification	54.0%	46%	<0.001	<0.001
5. Tourniquet placement	6.0%	94%	0.038	0.046
6. Venipuncture site selection	4.0%	96%	0.073	0.045
7. Venipuncture site cleaning	10.0%	90%	0.165	0.295
8. Venipuncture site drying	38.0%	62%	0.081	0.273
9. Post-cleaning site untouched	46.0%	54%	0.197	0.086

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10. Fist release upon blood flow	44.0%	56%	0.479	0.624
11. Tourniquet release upon blood flow	36.0%	64%	0.358	0.974
12. Correct order of draw	34.0%	66%	0.256	0.715
13. Sample tube fill level	54.0%	46%	<0.001	0.005
14. Sample tube mixing	16.0%	84%	0.045	0.156
15. Gauze/cotton ball application	12.0%	88%	0.295	0.073
16. Needle/collection system disposal	38.0%	62%	0.273	0.165
17. Tube labeling in patient's presence	20.0%	80%	0.086	0.081
18. Successful collection from single venipuncture	8.0%	92%	0.045	0.184
19. Check for venipuncture complications	66.0%	34%	<0.001	0.009
20. Collector's ID recorded	8.0%	92%	0.075	0.023
EF: Error Frequency, C: Compliance (%)				

The correct order of draw had a 66% compliance rate, with differences indicating potential areas for standardization and training. Surprisingly, the procedure for checking potential complications of venipuncture had the lowest compliance rate at 34%, with stark differences between settings ($p<0.001$) and professions ($p=0.009$), underscoring a critical need for improvement.

DISCUSSION

The research undertaken revealed a concerning level of non-compliance with locally modified guidelines based on the Clinical and Laboratory Standards Institute (CLSI) recommendations, spotlighting the pre-analytical phase as a predominant source of errors and variability in laboratory testing. Historically, as early as the 1970s, the pre-analytical phase has been recognized as a critical juncture for errors in laboratory diagnostics, introducing terms such as "interference factors" and "influence" into the lexicon of clinical pathology (8). This phase has been consistently identified as the leading contributor to diagnostic inaccuracies across the testing continuum (9), with common errors including, but not limited to, patient misidentification, improper test tube labeling, specimen hemolysis, and inadequate sample volume. These errors not only compromise specimen integrity but also potentially lead to patient harm through unnecessary retesting, diagnostic delays, additional healthcare expenditures, misdiagnoses, and in severe cases, hospitalization or death.

In addressing these challenges, the study highlighted the historical focus of laboratory efforts on enhancing the analytical phase, with significant achievements in reducing analytical bias and variability. However, the externalization of phlebotomy from the direct supervision of laboratory personnel has perpetuated errors in the pre-analytical phase, which, despite being randomly distributed within the healthcare framework, are frequently overlooked, underreported, and inadequately managed, thus continuing to pose a risk to patient safety (10).

Clinical practice guidelines serve as critical instruments for improving the quality of care, reducing patient risk, and fostering procedural standardization across healthcare settings (11,12). The adoption of such guidelines by international health organizations, including the WHO, underscores the global consensus on best practices for clinical procedures (13). However, the study underscored the challenges inherent in the implementation of these guidelines, particularly in the context of venous blood specimen collection. The detailed and sequential nature of the recommended practices, as outlined in the CLSI H3-A6 guidelines and WHO recommendations, poses a significant recall challenge for phlebotomists, leading to inadvertent oversights and errors. The study's findings, particularly the identification of critical errors such as patient misidentification, improper tube filling, and failure in patient preparation verification, echo the vulnerabilities highlighted in previous research, including a cross-sectional comparative study in South Ethiopia, which reported similar issues (17).

The risk occurrence chart developed in this study, identifying key areas of concern (notably in patient identification, patient preparation verification, and specimen labeling), accentuates the gravity and frequency of these errors, particularly in high-pressure environments like emergency and outpatient departments. Such findings are corroborated by existing literature, which reports a distressingly high incidence of identification errors in routine practice (14-16).

Addressing these issues necessitates a dual focus on organizational and individual factors influencing guideline adherence. While recent studies have predominantly concentrated on organizational aspects, there is a palpable gap in understanding the personal risk factors that predispose healthcare professionals to overlook critical safety measures. This study, therefore, underscores the imperative for patient safety programs that balance systemic effectiveness with individualized practice interventions (20,21).

In reflecting on the strengths of the study, the comprehensive observational approach and the subsequent analysis provide a robust foundation for understanding the complexities of phlebotomy practice and guideline adherence. However, the study is not without

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limitations. The observational nature may have introduced an observer effect, potentially altering the behavior of healthcare professionals. Furthermore, the study's focus on a single healthcare institution may limit the generalizability of the findings.

Based on the insights garnered, recommendations for future research include expanding the scope to multiple institutions to enhance generalizability, exploring the impact of educational interventions on compliance rates, and investigating the personal and systemic barriers to guideline adherence. Additionally, there is a critical need for developing and implementing targeted patient safety programs that address the identified gaps in phlebotomy practice, thereby mitigating the risks associated with pre-analytical errors and enhancing overall patient care.

CONCLUSION

The study's findings highlight a significant concern regarding compliance with CLSI-based phlebotomy guidelines, specifically underscoring the pre-analytical phase as a critical source of error and variability in laboratory diagnostics. The recurrent issues of patient misidentification, improper sample volume, and inadequate patient preparation verification not only emphasize the enduring challenges within the pre-analytical phase but also reflect on the broader implications for patient safety and healthcare quality. These insights suggest an urgent need for targeted interventions, including enhanced training for healthcare professionals, implementation of stringent quality control measures, and the adoption of comprehensive patient safety programs. Addressing these issues requires a concerted effort from both organizational and individual levels within healthcare settings to mitigate the risk of pre-analytical errors. Ultimately, improving adherence to phlebotomy guidelines has the potential to significantly reduce diagnostic errors, decrease healthcare costs, and most importantly, improve patient outcomes. The study underscores the necessity for ongoing evaluation and adaptation of clinical practice guidelines to ensure they remain effective and practical in improving procedural standards and patient care.

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