ASSESSING ADHERENCE TO INFECTION PREVENTION AND CONTROL STANDARD OPERATING PROCEDURES IN PHLEBOTOMY AMONG HEALTH LABORATORY PRACTITIONERS IN DAR ES SALAAM REGIONAL REFERRAL HOSPITALS.

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MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

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ASSESSING ADHERENCE TO INFECTION PREVENTION AND CONTROL STANDARD OPERATING PROCEDURES IN PHLEBOTOMY AMONG HEALTH LABORATORY PRACTITIONERS IN DAR ES SALAAM REGIONAL REFERRAL HOSPITALS.

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October, 2024

CERTIFICATION

The undersigned certify that he has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation titled: "*Adherence to Infection Prevention and Control Standard Operating Procedures in Phlebotomy among Health Laboratory Practitioners in Dar Es Salaam Regional Referral Hospitals*", in fulfilment of the requirements for the degree of Master of Science in Project Management Monitoring and Evaluation in Health of Muhimbili University of Health and Allied Sciences.

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DECLARATION AND COPYRIGHT

I, Shekha Yusuf Silim, declare that this dissertation is my original work and that it has not been presented and will not be presented to any other university/institution for a similar or any other degree award

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DEDICATION

This work is dedicated to my family, starting with my late father, Mr. Yusuf Silim, who would have been very proud if he was still with us. It also honors my mother, Salma Mohamed, my wonderful husband, Dr. Hamis Abdallah, my sisters, Sakina Yusuf and Ilham Yusuf, and my sons, Ahyan Hamis, Adyan Hamis, Alyan Hamis and Ahlam Hamis, as well as my friends, who have provided me with unwavering support emotionally and physically.

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ABSTRACT

Background: Infection prevention and control (IPC) is a systematic approach to reduce healthcare-associated infections (HAI). HAI accounts for 90% of admissions in developing nations annually while healthcare-associated infections range from 2.5% to 14.8% in Africa. Tanzania introduced IPC Standard Operating Procedures in 2020 to ensure worker safety and quality health services. However, there are limited studies specifically evaluating the compliance of health laboratory practitioners with safe phlebotomy practices as per IPC standard operating procedures to determine not only the level of compliance but also explanatory individual and organizational facilitators and barriers.

Objective: To evaluate health laboratory practitioners' adherence to safe phlebotomy procedures as per Infection Prevention and Control standard operating procedures (IPC SOPs) at Dar es Salaam Regional Referral Hospitals**.**

Methods: The researcher conducted a cross-sectional descriptive study involving laboratory managers and practitioners at Dar es Salaam RRHS. The study involved 303 patient observations in a quantitative approach using an observation checklist as a tool, and 12 participants in a qualitative approach using in-depth interviews, convenient and purposive sampling were employed

Results: Only 8.6% of health laboratory practitioners adhered **to** the IPC SOPs. There was minimal compliance with the recommendations to use gloves 59.7%, disinfection of venipuncture sites 13.5%, and before and after procedure hand hygiene 19.5% and 4.3% consecutively, the study show the significant relationship between training, designation and adherence to IPC SOPs (P value<0.05). Experience of the personnel, availability of IPC SOPs, and QMS made it easier to follow safe phlebotomy protocols. Poor attitude of personnel, poor working environment, insufficient supplies, and a high workload were among the obstacles toward adherence to safe phlebotomy procedures.

Conclusion: The study has revealed low adherence to safe phlebotomy practices, suggesting a serious need for training and behavioral change interventions at different health care facility levels.

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ABBREVIATIONS

CDC	Centers for Disease Control and Prevention
CHMT	Council Health Management Team
CLSI	Clinical Laboratory Standards Institute
COVID 19	Corona Virus Disease of 2019
HAIs	Health **Associated** Infections
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HCW	Health Care Worker
IPC	Infection Prevention and Control
MoHCDGEC	The Ministry of Health Community Development, Gender, Elderly and Children
PPE	Personal Protective Equipment
QMS	Quality Management System
REAIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance
RHMT	Regional Health Management Team
SOPs	Standard Operating Procedures
TB	Tuberculosis
WHO	World Health Organization

OPERATION DEFINITION

Infection Prevention and Control: A scientific approach and practical solution designed to prevent harm caused by infection to patients and health workers.

Phlebotomy: The act of removing blood from a patient using a needle.

Health laboratory practitioner: Includes a health laboratory scientist, health laboratory technologist, and health laboratory assistant.

Health laboratory scientist: A Health laboratory practitioner who has a bachelor's degree in medical laboratory sciences.

Health laboratory technologist: A Health laboratory practitioner who has a diploma in medical laboratory sciences.

Health laboratory assistant technologist: A Health laboratory practitioner who has a certificate in medical laboratory sciences.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Infection prevention and control (IPC) is a methodical approach to reduce the negative impacts of infections on patients and healthcare staff. It includes practices like hand hygiene, PPE use, and proper medical waste management (1).

Globally, 3 million healthcare workers face blood-borne infections, with developing nations accounting for 90% of these cases annually (2). Healthcare-associated infections (HAIs) afflict 10-30% of all admissions, affecting 1.4 million patients (3). In developing countries, the prevalence is often underestimated due to diagnosis complexity and insufficient resources. In Africa, healthcare-associated infections range from 2.5% to 14.8%, with healthcare professionals experiencing two to four needle-stick injuries annually (2).

The Ministry of Health-Tanzania Mainland has been working to improve infection prevention and control guidelines and standards in health facilities since 2004, in laboratory settings, phlebotomy is among the departments where healthcare-associated infections are more likely to occur (4).

Phlebotomy, derived from ancient Greek, involves extracting blood from veins using a needle to puncture the vein's wall. Phlebotomists undergo specialized training to improve precision. This invasive procedure in healthcare exposes healthcare personnel and patients to blood-borne infections like HIV and HBV. Laboratories provide diagnostic services, including basic blood tests and advanced oncology and molecular diagnostics (5).

Health Laboratory practitioners play a vital role in the healthcare system, contributing to disease identification by conducting a diverse range of examinations on various samples, including blood, tissues, urine, stool, and other bodily fluids (6). These professionals face the risk of acquiring infections directly from infected patients during sample collection, especially when their duties involve tasks like phlebotomy and sample collection (7).

Direct interaction between health laboratory practitioners and patients during sample collection increases the likelihood of transmission between the health Laboratory

practitioners and infected patients and vice versa. Furthermore, health laboratory practitioners regularly come into contact with diverse bodily fluids that may harbor infectious agents, leading to potential contamination of laboratory surfaces and equipment during sample processing (8).

Contaminated gloves can increase infection risk when they touch the eyes, nose, or mouth, emphasizing the need for regular surface disinfection and consistent hand-washing/sanitization practices (9). Additionally, various laboratory processes can generate aerosols or droplets that may reach the eyes, mouth, and nose, or be inhaled (10). The use of face shields/goggles and masks serves to reduce the risk of infection through this route (11). Adherence to these guidelines can be influenced by diverse factors, including the individual's level of education, training in laboratory safety, and years of professional experience (12).

In 2018, Tanzania's health, community development, gender, the elderly, and children ministry enacted national infection prevention and Control(IPC) guidelines for healthcare services (13). The aim is to decrease healthcare-associated infections among healthcare personnel and patients. The guidelines are directed toward policymakers, health managers, administrators, program officers, healthcare providers, trainers, and health facilities (14).

The IPC SOPs are comprehensive, step-by-step protocols implemented in healthcare settings to reduce infection risks and prevent the transmission of diseases. These SOPs ensure that healthcare workers, patients, and visitors adhere to standardized practices for effective infection prevention and control.

The MoHCDGEC introduced Standard Operating Procedures for IPC in Tanzania in 2020, guiding healthcare providers in high-risk procedures, and ensuring worker safety and quality services (15). As a result, since laboratory practitioners engage in most hospital sample collection and management, it is critical to assess health laboratory practitioner adherence to safe phlebotomy practices by infection prevention and control standard operating procedures at Dar es Salaam Regional Referral Hospitals.

1.2 Problem statement

Addressing Infection Prevention and Control (IPC) standards presents a significant global challenge, particularly in low- to middle-income countries. Non-compliance with IPC standards and operating procedures has been associated with a 15% infection rate, by which Africa ranges from 2.5% up to 14.8% as reported by the World Health Organization in 2011 (16). Inadequate infection prevention and control practices, including healthcare worker transmission, contaminated equipment, procedures, and environment, significantly increase patients' risk of healthcare-associated infections (HAIs) through direct contact (17).

Globally, An observational study was conducted in 12 European countries to assess the level of compliance with the Clinical Laboratory Standards Institutes (CLSI) guidelines indicating that there were 26.9% non-compliance to guidelines (18). There was a study that evaluated phlebotomist performance and identified significant sources of errors during diagnostic blood collection that reported a 60% deviation rate in phlebotomy operations(19). In Sub-Saharan Africa, The study conducted in Kenya, the investigation found that none of the blood collection processes followed all of WHO's standard operating procedures for phlebotomy protocol, which could impact both patient and healthcare worker safety (20).

Research conducted in Tanzania in Songwe region showed the overall compliance rate of 22.5% for IPC criteria exceeding 80%, which is a low compliance rate, this study identified predictors of healthcare workers' compliance with IPC standards precautions, which include: years of work experience and having experienced a needle stick injury (21). However, these previous studies were narrowly focused on individual factors. Exploration of contextual factors explaining poor adherence to infection prevention and control standard precautions is scarce.

Notably, there are limited studies specifically evaluating the compliance of health laboratory practitioners with safe phlebotomy practices as per IPC standard operating procedures with a view of determining not only the level of compliance but also explanatory individual and organizational facilitators and barriers. Therefore, this process evaluation study assessed the adherence to safe phlebotomy practices as per IPC SOPs in Dar es Salaam Regional Referral Hospitals, where to the best of our knowledge no similar study has been conducted.

1.3 Conceptual framework

The RE-AIM framework is a comprehensive evaluation framework designed to assess the public health impact and the potential for translation of research interventions into real-world practice. It was created by Russell Glasgow and his colleagues in the 1990s. The term "RE-AIM" stands for Reach, Efficacy, Adoption, Implementation, and Maintenance. Each component of the framework represents an important dimension for assessing the effectiveness and sustainability of health interventions. The study was focused on the Implementation domain only, which relates to the extent to which an intervention is given as intended (22). The goal of this framework was to evaluate the fidelity with which healthcare personnel adhere to specified guidelines when implementing safe phlebotomy practices. It analyzed phlebotomist compliance with standard operating procedures, as well as the individual factors (facilitators and barriers) and organizational factors (facilitators and barriers) in safe phlebotomy practices as per IPC SOPs in the health system (23).

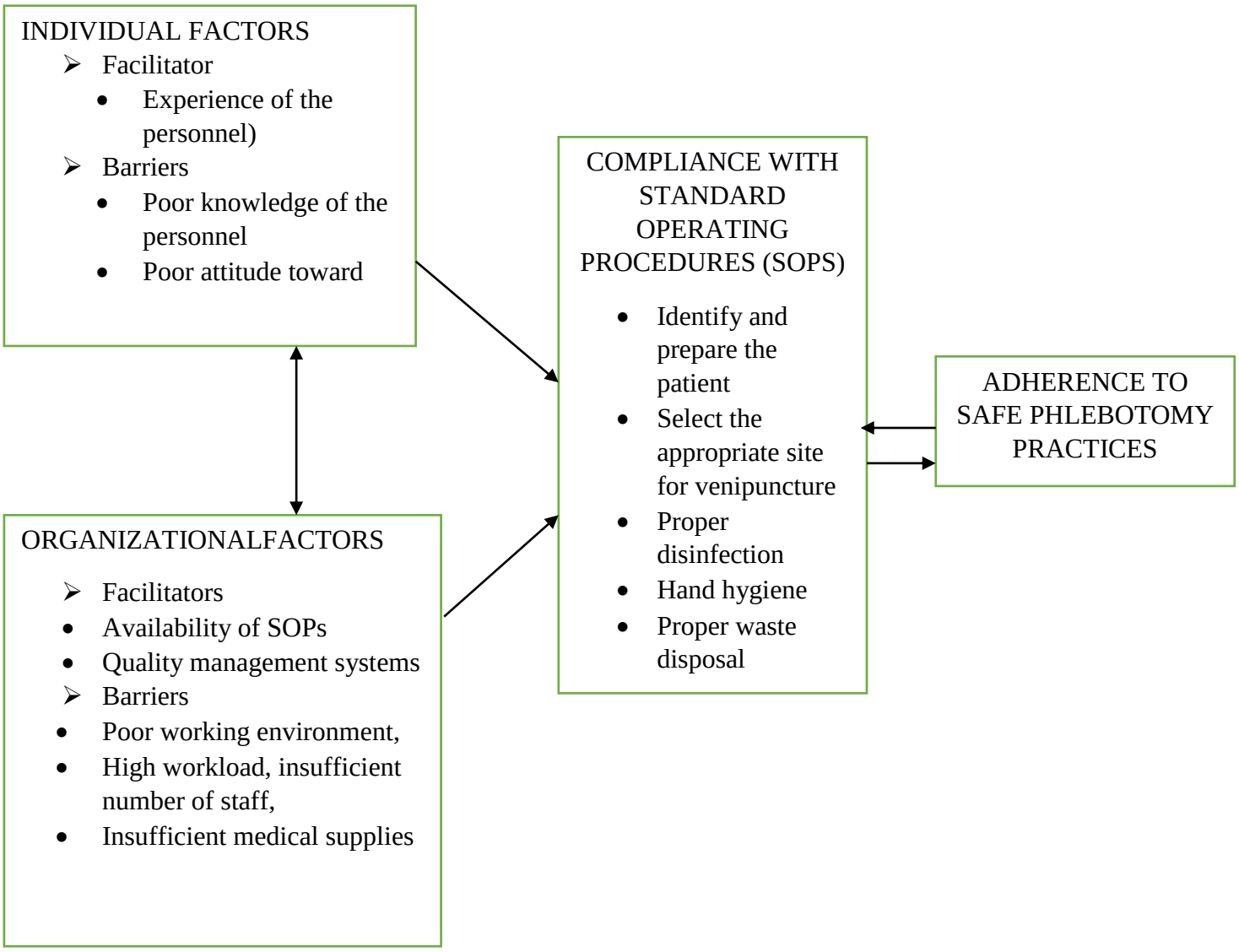


Figure 1. Conceptual framework-

(REAIM frame work - adapted implementation domain only)

(Source: Researcher's construct)

1.4 Research rationale

This study aimed to assess adherence to infection prevention standard operating procedures during sample collection and identify potential deficiencies in regional referral hospitals in Dar es Salaam. The findings will help health practitioners enhance their methods and contribute to a safer working environment. The study is crucial for hospital management, highlighting deficiencies in aseptic techniques during sample collection. Addressing these concerns promotes a safer hospital environment, minimizing infection risks for healthcare personnel and patients which could reduce the health care cost to the patients and improve patient's health care outcomes. The findings will inform policymakers and other stakeholders about improving training programs and standardized protocols and enhancing safety in phlebotomy laboratories. The research is important for scholars, and researchers as it facilitates research and promotes discussions aimed at improving and refining best practices within healthcare organizations.

1.5 Evaluation questions

1.5.1 Main evaluation question

How well do health laboratory practitioners at Dar es Salaam Regional Referral Hospitals adhere to safe phlebotomy practices as per Infection Prevention and Control standards operating procedures (IPC SOPs)?

1.5.2 Specific Evaluation Questions

i. To what extent do the health laboratory practitioners comply with IPC SOPs?
ii. What individual factors influence adherence to safe Phlebotomy practices among health laboratory practitioners as per IPC SOPs?
iii. What organizational factors influence adherence to safe Phlebotomy practices among health laboratory practitioners as per IPC SOPs?

1.6 Evaluation objectives

1.6.1 Main evaluation objective

To evaluate health laboratory practitioners' adherence to safe phlebotomy methods as per Infection Prevention and Control standard operating procedures (IPC SOPs) at Dar es Salaam Regional Referral Hospitals**.**

1.6.2 Specific evaluation objectives

i. To determine the level of compliance with Standard Operating Procedures among health laboratory practitioners as per IPC SOPs.
ii. To assess the individual factors influencing the adherence to safe Phlebotomy practices among health laboratory practitioners as per IPC SOPs.
iii. To assess the organizational factors influencing the adherence to safe Phlebotomy practices among health laboratory practitioners as per IPC SOPs.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

This section discusses the theoretical review relevant to this study of assessing adherence to safe phlebotomy practices as per Infection Prevention and Control standards among health laboratory practitioners in Dar es Salaam Regional Referral Hospitals in connection with the research objectives.

2.2 Compliance with IPC SOPs among health laboratory practitioners.

Research was undertaken in Pakistan to assess the Knowledge, Attitudes, and Practice of Standard Operating Procedures by Phlebotomists. Among the 75 volunteers questioned by the phlebotomist, the findings showed that 42% were trained phlebotomists. 71% of them worked for 8 to 10 hours every day. 37% of them received immunization 1-3 years before 25% of the individuals did not wear a lab coat, and 60% of them changed their lab coat in the laboratory. A majority of phlebotomists, namely 73%, did not use gloves. 77% of individuals were provided with suitable equipment and supplies.70% of the participants used a tourniquet for 1 minute, whereas 27% used it for 2 minutes. 5% of individuals neglected to use any antiseptic to cleanse the skin region before blood extraction. 54% neglected to sanitize blood spills on the table 14% of the population used a solution containing 1% hypochlorite. Among the phlebotomists, just 1% correctly disposed of their gloves in biohazard containers, while 17% discarded them in regular trash bins, each of them successfully conveyed the sample (24).

The study was conducted in 12 European countries to assess the adherence to the Clinical laboratory standards institute criteria. 12 European states participated in a total of 336 audits. The median number of audits per nation was 33, with a range of 18 to 36. The overall median error rate for the whole phlebotomy procedure was 26.9% (with a range of 10.6% to 43.8%), indicating a low degree of compliance with the recommended standards. The key issues about guidelines were identified as patient identification and test tube labeling, which have the highest possibility and potential for causing injury. The administrative staff neglected to

adhere to patient identification rules during phlebotomy, while the physicians failed to adhere to the policy of labeling test tubes. The adherence of phlebotomy procedures to the Clinical and laboratory standards institute criteria in 12 European countries was found to be very insufficient (18).

Research was undertaken in Sweden to investigate the relationship between workplace affiliation and phlebotomy methods, specifically in regard to patient identification and test request processing processes at primary healthcare centers. The study observed consistent and significant median odds ratios (MOR) in two patient identification outcomes. These MOR values were steady in both the empty model and the modified complete model, which accounted for individual and workplace characteristics. Our data indicate that the differences among phlebotomy personnel may be mostly attributed to their association with primary healthcare centers, even after considering individual and workplace demographic variables. Analyses indicated that phlebotomy personnel at medium and large primary healthcare centers had a higher likelihood of adhering to criteria compared to those at small centers. In addition, employees who work for a shorter duration at the job are more likely to adhere compared to those who work for a longer duration. Those who performed phlebotomy less often, such as once a week or fewer, were more likely to adhere to the protocol compared to those who performed phlebotomy daily (25).

2.3 The individual factors influence the adherence to safe Phlebotomy practices among health laboratory practitioners as per IPC SOPs.

Research was conducted on the techniques used in blood collection in Kenya. A total of 283 blood samples were collected, with 194 being venous draws carried out by 72 healthcare workers (HCWs) and 89 being capillary draws done by 33 HCWs. This research was conducted in 8 healthcare institutions throughout 4 regions of Kenya, using a cross-sectional observational design. Out of the 194 observed phlebotomies, none of them satisfied the criterion based on 12 predetermined quality-related criteria. A total of 91 healthcare workers (HCWs) received training in phlebotomy. The average knowledge gain between the pre-and post-training tests was 41%, with a range of 39% to 45% (95% confidence interval, 29.3%–53.5%; $P < .001$) (19).

Furthermore, a study was undertaken in Sweden to investigate the personnel's encounters with Phlebotomy practices after their involvement in educational programs. The findings indicate that EIPs can elicit contemplation, particularly in larger study cohorts, regarding phlebotomy procedures. Enhanced understanding of phlebotomy procedures, coupled with feedback from participants, enhances the potential to refine and optimize the quality of EIPs by incorporating pertinent information. The study participants had gained knowledge about potential dangers and had made advancements in their clinical practice due to the EIP. They also felt confident and comforted by the training. The areas requiring additional attention include the patient identification protocol, environmental distractions, and information transfer. It is important to consider this when creating and executing EIPs (26).

Evaluation of the extent of infection prevention and control knowledge among healthcare staff in Saudi Arabia (27). Healthcare staff have a good understanding of infection prevention and control (IPC), including traditional precautions, hand hygiene, and urinary catheter management. However, there are gaps in knowledge about occupational vaccines, transmission mechanisms, and infection risk from needle sticks and sharps injuries. The paper identifies factors contributing to noncompliance with IPC standards and recommends improving adherence. Leadership engagement is crucial for ensuring adherence to IPC standards in all healthcare institutions, including labs.

A qualitative study conducted at Kenya reported that health laboratory practitioners had poor knowledge toward these IPC SOPs, practitioners who didn’t follow all the procedures required was due to not recalling all the procedures during phlebotomy, also a negative attitude toward compliance of SOPs was reported as the factor that influence the adherence of IPC SOPs, among of the practitioners they viewed these guideline as a burdensome task(28)**.**

2.4 The organizational factors influence the adherence to safe Phlebotomy practices among health laboratory practitioners as per IPC SOPs.

A study named "Management Practices for Leaders to Promote Infection Prevention: Lessons" was undertaken, focusing on qualitative research methods, three essential management practices were recognized as pivotal determinants in the prevention of healthcare-associate infections (HAIs) across many institutions and according to interviewees: active participation of senior leadership, effective interchange of information; and mentorship of managers (29). Research suggests that the presence of prominent executives, clear communication, and frequent chances to exchange and promote knowledge derived from feedback are key elements in supporting and sustaining initiatives to prevent healthcare-associated infections (HAIs).

In the United States, researchers analyzed institutional practices for reducing phlebotomy-related percutaneous injuries in hospital settings. The study involved nine hospitals. There were 126 phlebotomy operations observed. Most observed operations were carried out by healthcare workers utilizing devices equipped with safety features. Observance of approved phlebotomy protocols for handling needles after usage ranged from 42% to 92%.The level of adherence varied according to device kind, job, and facility PI rate. During 23 interviews and 9 focus groups, participants identified a variety of factors that contributed to PI avoidance. These determinants included the presence and usage of safety-equipped equipment, adherence to suggested practices for properly handling needles, and the provision of phlebotomy training inside the institution (30).

A study was conducted to evaluate the adherence of healthcare workers to infection prevention and control strategies in several healthcare sectors in Qatar-Doha during the COVID-19 pandemic (31). From November 2020 to January 2021, a nationwide online survey was performed, with a focus on healthcare professionals working in the government, semi-government, and commercial healthcare sectors. The main obstacles that were frequently noted were the high labor needs and the scarcity of personal protective equipment (PPE) and hand hygiene products.

A qualitative Research examined the barriers that impede the execution of infection prevention and control protocols at teaching hospitals in the Amhara area (32). Ten distinct obstacles were identified, encompassing limited facility availability, inadequate material supply, insufficient facility, and equipment maintenance, high patient influx, lack of experience, emergency situations, healthcare worker behavior, healthcare workers' knowledge about infection prevention, low awareness among patients and visitors, and overcrowding of families and visitors at the hospital. To successfully implement infection prevention measures, it is crucial to analyze obstacles from the perspectives of the organization, healthcare personnel (HCWs), and patients and visitors.

A qualitative study conducted in Kenya reported that there were facilitating factors toward the adherence of IPC SOPs in phlebotomy like the availability of a Quality management system, this system included the quality team which is responsible for assessing all activities in phlebotomy (33)**.**

The studies above from different settings revealed that there was poor adherence to Infection prevention and control standards in phlebotomy which gaps identified were a lack of formal training, poor facility maintenance, and lack of active engagement by leadership.

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Study design

The study used a descriptive cross-sectional study design because it was simple to conduct and cost effective, also a process evaluation was employed by which an audit evaluation design was adopted because the study aim to assess health laboratory practitioners if they implement the IPC SOPs as recommended by the guideline.

In this study, both qualitative and quantitative approaches were used to assess adherence to safe phlebotomy practices as per Infection Prevention and Control standard operating procedures among health laboratory practitioners in Dar es Salaam Regional Referral Hospitals because a mixed approach could give a comprehensive understanding by providing detailed insight and validation of the results through data triangulation.

3.2 Study Area

The research was carried out in the Dar es Salaam region, at the laboratories of three regional referral hospitals: Amana, Mwananyamala, and Temeke. Since Dar es Salaam was the only region with more than one regional referral hospital, it was ideal to choose the area because apart from these laboratories being better equipped in terms of both personnel and material resources the results would give a comprehensive understanding of the issues, because all those three hospitals included in the study. The study's goal was to provide a comprehensive picture of healthcare settings in the region.

3.2 Study population

The study involved the health laboratory practitioners from Mwananyamala, Amana, and Temeke regional referral hospitals. These respondents were chosen because they can provide the required information regarding safe phlebotomy adherence practices as per IPC standard operating procedures as they work within the laboratories at their respective hospitals.

3.3 Sample size and sampling technique

3.3.1 Sample size

The quantitative part: sample size considered the number of phlebotomy procedures on 303 patients conducted by health laboratory practitioners that were available during the data collection, performance of laboratory phlebotomists was observed and documented on an observation checklist.

Where the sample size for the study population was calculated using the Kish &Leslie formula as follows:

Where, n = Estimated sample size

Z 2 = standard normal deviate corresponding to 95% confidence interval (1.96)

P = 22.5 % obtained from a study on (21)

d = desired level of precision 0.05

Therefore, n= (1.96) 2 * 0.23(1-0.23) / (0.05) 2 = 273 phlebotomy procedure conducted by health laboratory practitioners

ASSUMPTION:

For the response rate, 90% R is equal to 0.9.

Therefore, Adjusted sample size (n) = 1/R*sample size for phlebotomy procedures conducted by Health laboratory practitioners

n= 1/0.9*273

n= 303

Each hospital had a maximum number of observation phlebotomy procedures of 101, equally distributed

The sample size of the study for 90% response was 303.

In the qualitative part, the study used a sample size of 12 participants, until the saturation level reach of the information collected. The level at which new data collection ceases to provide additional insights. It meant that additional data collection was unlikely to yield new or significant information that adds to the depth of understanding. The rationale behind choosing this particular sample size was rooted on the principles of in-depth investigation,

the acquisition of comprehensive and valuable information, as well as limitations imposed by available resources. The researcher concluded that a sample size of 12 participants strikes a harmonious equilibrium between acquiring substantial data and adhering to the limitations imposed by the study (34).

3.3.2 Sampling technique

In the qualitative part; the study used purposive sampling (35). This method was employed to select laboratory managers and health laboratory practitioners from the three regional referral hospitals in Dar es Salaam (Mwananyamala, Temeke, and Amana). The rationale for employing that sampling technique lay in its guarantees of deliberate incorporation of persons possessing specialized expertise in infection prevention and control in phlebotomy, therefore providing invaluable insights essential for enhancing the comprehensiveness and precision of the study and participants had rich information about IPC SOPS in phlebotomy.

In the quantitative part; the study used convenience sampling, this sampling was chosen because it was time and cost-effective, with no need to wait for specific participants at the time of data collection until the sample size was reached. It involved the participants who were accessible and available during data collection.

3.4 Inclusion and exclusion criteria

3.4.1 Inclusion criteria

Health Laboratory Practitioners:

- Employed in the phlebotomy department of Dar es Salaam Regional Referral Hospitals (Amana, Mwananyamala, and Temeke).
- Willing to participate in the study and provide informed consent.

Hospital: Regional Referral Hospitals (Amana, Mwananyamala, and Temeke).

3.4.2 Exclusive criteria

- Health Laboratory Practitioners:
- On leave or absent from work during the study period.
- Refuses to participate in the study or provide informed consent.
- Newly employed with less than six months of experience in phlebotomy.

3.5 Variables

3.5.1 Dependent variable

Adherence to safe phlebotomy practices as per infection prevention and control standards operating procedures among health laboratory practitioners in Dar es Salaam Regional Referral Hospitals. A compliance score of 80% or higher was considered the desired level of adherence this was due to the National guidelines for recognition of the implementation status of quality improvement initiatives in health facilities by the ministry of Health(36).

3.5.2 Independent variables

Compliances to infection prevention and control standard operating procedures with constructs such as personnel training, availability of equipment, patient identification, site selection, hand hygiene, proper disinfection, proper use of gloves, and proper disposal of waste. Another independent variable was individual factors (barriers and facilitators) and organizational factors (barriers and facilitators) influencing adherence to safe phlebotomy practices.

3.6 Data collection tool and technique

3.6.1 Quantitative approach

A direct observational technique was employed to collect quantitative data from 303 phlebotomy procedures conducted by health laboratory practitioners from 3 regional referral hospitals through an Observation checklist. This approach enables researchers to directly witness the activities of laboratory personnel, thereby minimizing the reliance on verbal reports of their actions. The observational checklist was adapted from Tanzania Ministry of Health Community Development, Gender, Elderly, and Children, The National Infection Prevention and Control Standards for Hospitals in Tanzania August 2020(4).

3.7.2 Qualitative approach

The in-depth interview was used to collect data through conversation by conducting face-to-face in-depth interviews with the health laboratory practitioners at their convenience. An interview guide with a list of open-ended questions was used.

3.8 Validity and reliability of the study

For the quantitative objective, the study ensured the validity and reliability by the following

3.8.1 Validity of the study

The experienced and knowledgeable person reviewed the observational checklist to ensure the content validity of the tools fitted for the study

3.8.2 Reliability of the study

The researcher checked the reliability of the checklist tools during the pretest and provided similar results when administered to the different health providers, this was performed during the pre-test of the study.

3.9 Trustworthiness of the study

Trustworthiness relates to the level of confidence in the data, interpretation, and procedures that were employed to assure the study's quality. Lincoln and Guba proposed four criteria, which were applied. These are credibility, dependability, conformability, and transferability.

3.9.1 Transferability

Transferability is the degree to which the findings of a qualitative study can be utilized or translated to other settings or situations.

In this study, the researcher explored generalizability by employing various methodologies (direct observations and in-depth interviews) for data collection. Additionally, participants were selected at different time points to assess the extent to which the findings can be generalized.

3.9.2 Conformability

Conformability refers to how much the participants and circumstances shape the conclusions rather than the researchers' biases, viewpoints, or prejudices.

The researcher evaluated adherence by performing an audit of all activities related to the study's objective, with a specific focus on how well laboratory technicians in Tanzania comply with the Infection Prevention and Control requirements for safe phlebotomy.

3.9.3 Credibility

Credibility refers to the believability and trustworthiness of the study's findings.

This was ensured by data triangulation whereby more than one data collection method was applied

3.9.4 Dependability

Dependability refers to the stability and consistency of data over time and between researchers or study contexts. Ensured that assessment methods and procedures are consistent and reliable. This involved employing standardized and consistent protocols for data collection and analysis.

3.10 Data Processing and Analysis

3.10.1 Quantitative approach

The first particular evaluation objective was to evaluate the level of compliance with standard operating procedures among laboratory personnel. Data were assessed statistically, using descriptive analysis using frequency tables, percentages, and graphs. SPSS was used in data analysis because it can handle vast amounts of data. The analysis was performed, and categorical variables such as gender were shown. The univariate analysis stage was undertaken using a frequency distribution table and a percentage. The bivariate variable analysis was carried out with a binary chi-square.

3.10.2 Qualitative approach

For the second and third objectives, in-depth taped interviews were verbatim transcribed and translated from Kiswahili to English. Supplemental field notes were prepared immediately using a word processor. A thematic analysis using the Nvivo software approach was used in qualitative data, and the study's findings were evaluated in precise steps (37). Initially, transcripts and field notes were carefully examined several times to identify patterns of experience or shared thoughts. Data relating to recognizing patterns was then sorted and organized properly. The second phase entails studying patterns of experience to identify parallels and variances in their meanings concerning the research question. Finally, these patterns of experience were merged into study themes that signify a higher level of patterned

response or relevance in the dataset (38). These themes were prominently featured in the introductory segment of the results section.

3.11 Data management

In the quantitative approach, standardized checklists were fed in Online Data Kit (ODK), where ODK was used to collect data, Ms. Excel (Excel spreadsheet) was used to export data from ODK, and SPSS software was used to analyze data, and MS word was used to write the report.

In the qualitative approach, an audio recorder was used to record the audio conversation through an in-depth interview during data collection, MS Word was used to write transcripts (transcribe from audio to words), and from those transcripts, the NVIVO software was used to analyze the transcripts and later the report was extracted in MS word, from the report different pattern was formed by which later form themes.

Both quantitative and qualitative data were kept in a safe place where no other people could access them to maintain confidentiality.

3.12 Ethical consideration

Ethical approval was obtained from the institutional review board at Muhimbili University of Health and Allied Sciences (MUHAS IRB). Additionally, permission to perform the study was sought from Temeke, Mwananyamala, and Amana Regional Referral Hospitals. The forthcoming study addresses a delicate subject matter. When engaging with the respondent, it was essential to uphold their dignity, rights, safety, privacy, and well-being.

Hence, the research adhered to four primary ethical standards, as outlined by Alan Bryman (39), to safeguard the safety and well-being of all participants. These principles encompass refraining from inflicting any harm to participants, obtaining their informed consent, ensuring their privacy, and abstaining from any form of deception. In addition, the researcher provided the participants with information about the goal and benefits of the study to obtain their agreement, furthermore, a summary report was created to alert relevant authorities.

CHAPTER FOUR

4.0 RESULTS

4.1 Overview

This chapter explains the presentation of results that assessed the adherence to infection prevention and control standard operating procedures in phlebotomy among health laboratory practitioners in Dar es Salaam regional referral hospitals.

The chapter presents results on the level of compliance with Standard Operating Procedures among health laboratory practitioners as per IPC SOPs, the individual factors influence adherence to safe phlebotomy practices among health laboratory practitioners as per IPC SOPs which include barriers and facilitators and the organizational factors influence adherence to safe phlebotomy practices among health laboratory practitioners as per IPC SOPs which also include barriers and facilitators.

The following section presents the results of the study according to the research objectives.

4.2 Demographic characteristics

Social demographic characteristics of the participants were very important and helped to identify the characteristics of the population where the study was conducted. This section highlights on age, gender, level of education, and working experience.

4.2.1 Demographic Characteristics of the qualitative sample

Health laboratory practitioners who participated in this in-depth interview were 12 participants. Most of the participant's ages range from 30 years to 60 years. Females were 10 while males were 2. Their level of education was as follows firstly, the degree holder (health laboratory scientist) was four 1 male and 3 females, the diploma holder (Health laboratory technologist) was 7, 1 male and 6 females and the certificate holder (health laboratory assistant) was 1 who was female. Lastly the working experience of the participant were greater than 5 years of experience.

4.2.2 Demographic Characteristics of the quantitative sample

A Total of 303 phlebotomy procedures were observed as per inclusion criteria and took part in the study. The distribution was evenly between those 3 regional referral hospitals which included 101 observation phlebotomy procedures for each hospital.

The majority of procedures observed were performed by males which account for 180 (59.4%). The procedures observed were mostly performed by the age group of greater than 40 age which was 196 counts (64.7%). Furthermore, most phlebotomy procedures observed were performed by Health laboratory scientists and health laboratory technologists which count for 116 (38.3%), and 113 (37.3%) respectively. Moreover, the procedures observed were mostly performed by practitioners with more than 10 years of experience. Last but not least most of the phlebotomy procedures were performed by practitioners with between 1-4 phlebotomy procedures training which counts for 202 (66.7%).

Table 1: Demographic characteristics of quantitative samples

Variable	Frequency	Percentage
Sex (n=303)		
Female	123	40.6
Male	180	59.4
Age group (n=303)		
40 years or less	107	35.3
More than 40 years	196	64.7
Designation (n=303)		
Health laboratory assistance	74	24.4
Health laboratory scientist	116	38.3
Health laboratory technician	113	37.3
Years of experiences (n=303)		
10 years or less	128	42.2
more than 10 years	175	57.8
Attended trainings (n=303)		
1 to 4	202	66.7
5 or more	101	33.3

4.3 To determine the level of compliance with Standard Operating Procedures among health laboratory practitionersas per IPC SOPs.

According to WHO standards, practitioners have adhered to safe phlebotomy practices if they comply with IPCs SOPs in the implementation of the guideline and score at least 80%.

The compliance with the standard operating procedure among health laboratory practitioners as per IPC SOPS was found to be low, and critically low in the step of repeating hand hygiene and checking the insertion site if it's not bleeding after blood collection.

The guidelines for safe phlebotomy procedures were found in the laboratory area during the observation but some of the practitioners were not familiar with the guidelines. In this study, the health laboratory scientist was found to be highly compliant with the standard operating procedures more than other categories which may show the need to have more health laboratory scientists for better compliance with the IPC SOPs.

Furthermore, most of the practitioners had less than 4 trainings in safe phlebotomy practices which was not sufficient for them to be updated with the guidelines, and hence contributed much on poor adherence to safe phlebotomy practices as per IPC SOPs.

During the observation some practitioners were found to reuse gloves, they used the same gloves for more than one client, which was against the standards, also there were a some practitioners who did not wear gloves during the procedure which increased the risk of infection transmission from one person to another.

Furthermore during the observation the practitioner did not disinfect the site according to guidelines and this may led to contamination of the area of venipuncture which might cause bacteria to migrate from the skin to the blood system during venipuncture and may cause bacteria systemic infection.

Also even after disinfecting the site most of the practitioners did not allow the site to air dry before venipuncture as the procedure want, this might cause the chemical found in the alcohol swab to penetrate the blood vessel during the venipuncture.

Moreover, during the observation, poor communication was observed between clients and practitioners, most of the practitioners were observed not introducing themselves to their clients and they did not give proper details of the procedure which were about to be performed some of the steps required the practitioner to instruct the patients but practitioners did not instruct them like instruct clients to hold dry gauze or cotton and request the client to refrain from bending their arms after removing the needle from venipuncture site.

The results indicated a prevalence of 8.6%, which implies very poor adherence of health laboratory practitioners to IPCs SOPs.

Table 2: Adherence to IPCs SOPs

Adherence of health practitioners to IPCs SOPs (n=303)	**Frequency**	**Percentage (%)**
Adhered	26	8.6
Not adhered	277	91.4

Possible replies in this study were: 1) yes; 2) no; and 3) not applicable (NA). The favorable answer (compliance) for most of the study checklist questions was yes. If the reply was no, it was considered evidence for non-compliance with the procedure except for item No. 2

Table 3: Level of compliance with standard operating procedures among health laboratory practitioners

Variable	Frequency	Percentage (%)
1.Put on new non-sterile gloves sterile gloves (n=303)		
yes	181	59.7
No	122	40.3
2. Reused gloves (n=303)		
Yes	108	35.6
No	195	64.4
3.Use of well-fitted sterile gloves (n=303)		
Yes	303	100
No	0	0
4.Single use of blood sampling instrument (n=303)		
yes	301	99.3
No	2	0.7
5.Atourniquet (n=303)		
Yes	303	100
No	0	0
6.Alcohol swabs for skin disinfections (n=303)		
Yes	303	100
No	0	0
7.Gauze/cotton wool applied over the puncture site (n=303)		
Yes	303	100
No	0	0
8.Use of leak-proof transportation bags/containers as per IPC guidelines (n=303)		
yes	303	100
No	0	0
9.Ensures correct identification by matching patient details (n=303)		
Yes	287	94.7
No	16	5.3
10.Apply a tourniquet about 4-5 finger width (n=303)		
Yes	275	90.8
No	28	9.2
11.Hands should be washed with Soap, Water and Dried with a single-use towel (n=303)		
Yes	59	19.5
No	244	80.5
12.Use of alcohol swab (n=303)		
yes	287	94.7
No	16	5.3
13.Begin cleaning from the centre of the venepuncture site (n=303)		
Yes	41	13.5
No	262	86.5
14.Allow the site to dry (n=303)		
Yes	127	41.9
No	176	58.1

Variable	Frequency	Percentage (%)
15.Ask the patient to make a fist for veins to be more visible (n=303)		
yes	261	86.1
No	42	13.9
16.The needle should enter the vein quickly at a 30-degree angle or less (n=303)		
Yes	270	89.1
No	33	10.9
17.Release the tourniquet once the blood has been collected (n=303)		
yes	285	94.1
No	18	5.9
18.Use a clean gauze or dry cotton wool ball to gently apply pressure to location (n=303)		
yes	185	61.1
No	118	38.9
19. Instruct the patient to hold gauze or cotton wool in place (n=303)		
yes	65	21.5
No	238	78.5
20.Requests that the patient refrain from bending their arm (n=303)		
yes	51	16.8
No	252	83.2
21.Fill the tube with one hand or use a needle shield to prevent needle sticking (n=303)		
yes	298	98.4
No	5	1.6
22.Use moderate and steady pressure to pierce the tube stopper (n=303)		
Yes	267	88.1
No	36	11.9
23.Do not press the syringe plunger as it raises the risk of haemolysis (n=303)		
yes	265	87.5
No	38	12.5
24.Do not remove the stopper because it will release the vacuum (n=303)		
yes	267	88.1
No	36	11.9
25.Do not recap and remove the needle (n=303)		
Yes	270	89.1
No	33	10.9
26.Invert tubes as recommended by the ISP guidelines before sending them (n=303)		
Yes	208	68.7
No	95	31.3
27.Remove used gloves and dispose in a proper waste container (n=303)		
Yes	167	55.1
No	136	44.9
28. Repeat hand hygiene (n=303)		
yes	13	4.3
No	290	95.7

Variable	Frequency	Percentage (%)
29. Check the insertion site to ensure it is not bleeding (n=303)		
yes	21	6.9
No	282	93.1

Figure 2; Adherence to IPC SOPs of safe phlebotomy procedures among health laboratory practitioners in regional referral hospitals in %.

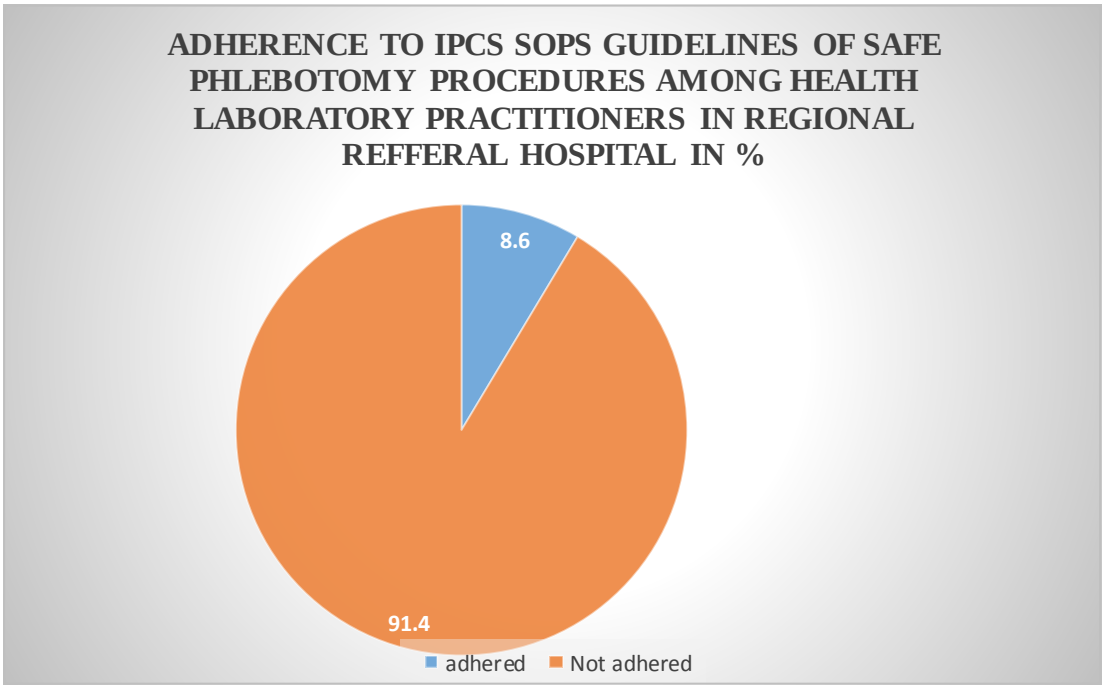
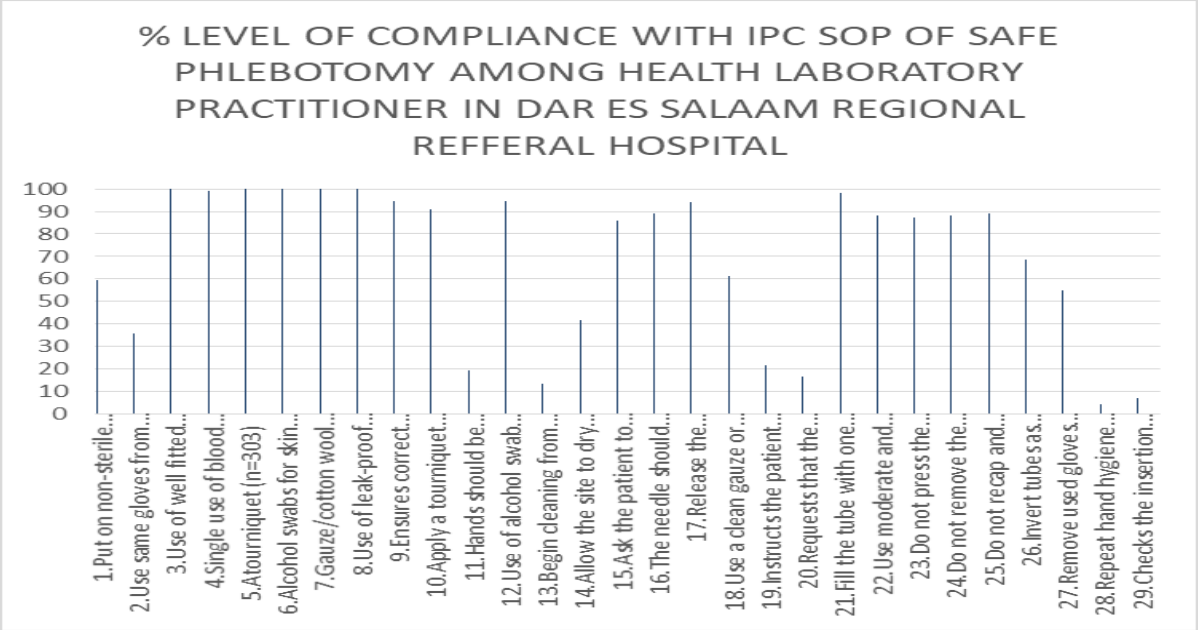


Figure 3: Level of compliance with IPC SOP of safe phlebotomy procedures among health laboratory practitioners in Dar es Salaam Regional Referral Hospital



4.4 Bi-variate analysis

The results implied the significant relationship (association) between adherence (compliance) to IPCs SOPs and the type of designation of health laboratory practitioners. Health laboratory scientists and health laboratory technicians were more likely to adhere to IPCs SOPs (12.1% and 9.7% respectively) as compared to health laboratory assistants (1.4%).

Health laboratory practitioners who attended more than 4 trainings were more likely to adhere (13.8%) to IPCs SOPs as compared to practitioners who attended 4 or fewer trainings (5.9%).

Male health practitioners were more likely to adhere to the IPCs SOPs as compared to female practitioners. However, the results were not significant at a 5% level of significance. No significant association was also found in terms of the age of health practitioners. However, health practitioners with 40 years of age or less indicated higher adherence as compared to practitioners with more than 40 years of age.

Table 4: Bivariate Analysis:

Compliance with Standard Operating Procedures among laboratory technicians as per IPC SOPs.

	Adherence		
Variable	**frequency**	**percentage**	**P-value**
Sex			
Female (n=123)	6	4.9	
Male (n=180)	20	11.1	0.057
Age			
40 years or less (n=107)	12	11.2	
More than 40 years (n=196)	14	7.1	0.226
Designation			
Health laboratory assistance (n=74)	1	1.4	
health laboratory scientist (n=116)	14	12.1	
Health laboratory technician (n=113)	11	9.7	0.031**
Years of experiences			
10 years or less (n=128)	11	8.6	
More than 10 years (n=175)	15	8.6	0.995
Attended training			
1 to 4 trainings (n=202)	12	5.9	
5 or more trainings (n=101)	14	13.8	0.020**

Table 5: Summary of Findings of Qualitative Data

CODES	SUB THEMES	THEMES
-Years of experience of the personnel -Confidence - Efficiency	-Length of service of the practitioner - Competency in practices	**Individual factors to the adherence of IPC SOPs** -Experience of the practitioners.
-Lack of comprehensive trainings. -Insufficient practical sessions.	-Limited exposure to IPC protocols. -Absence of hand on experience.	-Poor knowledge of IPC SOPS of the practitioners/personnel.
-Perceived inefficiency -Lack of commitment	-Perception of procedures as burdensome and time consuming. -Lack of personnel responsibility	-Poor personnel attitude toward the IPC SOPs adherence
-Location of SOPs - Clear instruction from SOPs	-Present of printed SOPs -Easily accessible location -Understandable language	**Organizational factors to the adherence of IPC SOPs** -Availability of IPC SOPs
-Presence of competency assessments -Education program -Adoption of Quality Management System QMS	-Skill development -Continuous education (CME) -Compliance with regulatory requirements (ISO)	-Availability of Quality Management System (QMS)
-Poor ventilation in the phlebotomy area -Insufficient working space	-Poor physical environment of the phlebotomy area.	-Poor infrastructures
-Inadequacy of supplies -Inadequate material	-Un availability of necessary supplies and materials	-Insufficient supplies
-Patient volume -Time management	-Efficiency in handling patients -Management of workload timely	- High workload
-Staffing ration	-Inadequacy personnel	-Insufficient number of staff

4.5 The individual factors influence the adherence to safe phlebotomy practices among laboratory technicians as per IPC SOPS.

4.5.1 Facilitators to the adherence of IPC SOPS in individual factors.

4.5.1.1 Experience of the Personnel

Most of the participants had more than five years of experience in phlebotomy. Some of the participants reported that their extensive experience in phlebotomy enhanced their adherence to Infection Prevention and Control Standard Operating Procedures (IPC SOPs). They explained that because they practice phlebotomy procedures more frequently than others, their continuous practice has led to a higher level of proficiency and precision in these procedures. Consequently, their repeated practice has ingrained these protocols into their routine, resulting in more rigorous and consistent application procedures as per IPC SOPs guidelines.

*"I work at the blood bank as a phlebotomist, drawing blood from people by performing phlebotomy. By frequently performing these procedures, I adhere strictly to Standard Operating Procedures (SOPs) because my regular practice in my section reinforces these protocols." (*IDI 10/Health Laboratory Technologist/Female /Aged 31).

Study findings showed that some of the health laboratory practitioners gained phlebotomy experience over time, and the requirements and procedures of the IPC SOPs became ingrained in their workflow. This consistent attention made sure that infection prevention and control protocols were adhered to, which improved process efficiency and safety. Thus, their vast experience guaranteed a strong dedication to the strict implementation of IPC SOPs, which is essential for upholding high standards of patient care and infection control. It also boosted their technical abilities.

4.5.2 Barriers to the adherence to IPC SOPS in individual factors.

4.5.2.1 Poor knowledge of personnel

Safe phlebotomy techniques involved a series of steps that some practitioners found challenging to remember and implement. Observations revealed that some did not follow the procedures as outlined by IPC SOPs guidelines, and among of them were unable to provide the researcher with a detailed list of all required steps in a phlebotomy process when

questioned. This highlights a gap in their adherence to protocols, potentially compromising the safety and effectiveness of their procedures. The difficulty in recalling and articulating these critical steps indicates a need for further training and reinforcement of best practices to ensure consistent compliance with safe and effective phlebotomy procedures among all practitioners.

"*First, I ensure the patient and their tests are based on their history, and I tie the tourniquet to make sure I've found the vein. I hold it and make sure it's the right vein, then I take my cotton and put the spirit on the swab, and once it's dry, I take the needle and do the process*"(IDI 8/Health Laboratory scientist/Female/Aged 37)

These findings showed that there was a notable lack of compliance with IPC SOPs, as evidenced by the difficulties some practitioners have remembering and following safe phlebotomy procedures. This discrepancy highlights the necessity of more thorough monitoring, ongoing education, and improved training to guarantee that all practitioners consistently adhere to safe and efficient phlebotomy protocols. Sustaining high levels of patient care and infection control requires addressing these concerns.

4.5.2.2 Negative attitude toward compliance of IPC SOPs.

A noticeable disregard for IPC SOPs guidelines during procedures, such as hand hygiene and glove changes, was observed among practitioners. Instead of viewing these guidelines as essential to patient and practitioner safety, they seemed to treat them as optional or burdensome tasks. This negative attitude, characterized by a disregard for infection prevention and control measures, led to a casual and inattentive approach, compromising the integrity of the safe phlebotomy process and increasing the risk of infection transmission**.**

"*I am frequently required to perform phlebotomy and adhere to patient service standards. While I strive to prioritize practicality while caring for patients, it's not always feasible to meet every criterion. For example, washing hands frequently before attending to each patient is often impractical given the demands of the workload and time constraints*". (IDI 8 /Health laboratory scientist /Female/Aged 37).

The result of this study showed that the IPC protocols offer a safety net, which is compromised when these crucial precautions are disregarded. Practitioners unintentionally raise the risk of illness transmission by neglecting precautions like hand cleanliness and changing gloves. This conduct jeopardizes the safety of medical staff members and puts patients' health at risk by exposing them to possible illnesses. When professionals believe that IPC SOPs are not important, their level of compliance declines dramatically. Because the precautionary procedures meant to avoid infection are not being implemented consistently, this decrease in adherence directly jeopardizes safety.

4.6 The organizational factors influence the adherence to safe phlebotomy practices among health laboratory practitioners as per IPC SOPS.

4.6.1 Facilitators to the adherence to IPC SOPs in organizational factors.

4.6.1.1 Availability of IPC SOPs for safe phlebotomy practices.

During the data collection, it was observed that the guidelines and standard operating procedures were readily available. Also, the manual like sample collection manual and safety manual were available. Practitioners said that the guidelines were available and visibly displayed for consultation whenever needed. These documents were strategically placed in locations easily visible to all, ensuring every practitioner could refer to them to refresh their memory or seek clarification on procedures. For instance, the hand hygiene procedures were prominently positioned on the wall adjacent to the hand washing basin, serving as a constant reminder for practitioners to adhere to proper hand hygiene practices as per IPC SOPs guidelines. Some of the participants reported to say that,

"The guidelines are available, including the sample collection manual prepared by the laboratory's quality section. This manual outlines how each sample should be collected, providing concise Standard Operating Procedures (SOPs) for all necessary procedures and serves as a helpful reminder in case I forget any procedures."(IDI 4/health laboratory technologist/female/Aged 35).

Results of this study showed that by highlighting best practices, the availability and thoughtful placement of guidelines and SOPs immediately aided in the observance of IPC standards. These steps improve overall compliance with IPC SOPs and help create a safer

healthcare environment by ensuring that practitioners have access to the information they need and are routinely reminded of the proper practices.

4.6.1.2 Availability of Quality Management System.

Practitioners reported that they had systems used to assess any IPC and quality-related issues in the laboratory called a quality management system (QMS), a quality management system comprised of the quality management team, which is responsible for assessing all phlebotomy practices adhere to regulatory requirements and standards related to infection prevention and control. This includes compliance with national regulations, guidelines from health authorities, and accreditation standards (e.g., ISO 15189 for medical laboratories). Some of the practitioners reported that the quality management team normally performs laboratory assessments and during the assessment, they took corrective measures in the case of deviation from any standards.

"*Aah, in the laboratory, assessments are conducted by the quality team, and the same applies to external assessments. However, there's no specific assessment team, it varies. From internal assessment mostly they're from within the facility. Some assessments are conducted from outside the region and aren't limited to the hospital*" (IDI 5 /Assistant Lab Manager/ Health Laboratory Scientist /Female/Aged 38).

Also, other participants reported that the quality management team regularly conducts continuous education per schedule within a specified time helping practitioners be reminded frequently about the standard operating procedures which made them recall the procedures.

"*mmh I don't remember exactly how many times, training is not frequent but we have clinical meetings (CME) where we update each other regarding different procedures in the laboratory including phlebotomy procedures-related issues"* (IDI 8/Health laboratory scientist/ Female-Aged 37)

From the findings in this study, it show that the quality management team's ongoing education and frequent assessments guarantee that phlebotomy procedures always adhere to infection prevention control guidelines. In addition to quickly identifying and resolving

deviations, this proactive approach upholds a culture of compliance and ongoing improvement in the laboratory. This consequently improves patient care outcomes by enabling practitioners to maintain high levels of safety and quality in their phlebotomy operations.

4.6.2 Barriers to the adherence to IPC SOPs in organizational factors.

4.6.2.1 Poor Infrastructure.

The criteria for a standard Phlebotomy area include well-equipped phlebotomy, sufficient space to accommodate patients, staff, and equipment comfortably, adequate lighting to perform procedures accurately, and proper ventilation to ensure a comfortable environment that reduces the risk of airborne contamination. Among of issues observed during the data collection were poor ventilation and Air conditioners not working in the phlebotomy area in some of the hospitals. Some of the participants said that they did not adhere to phlebotomy IPC SOP guidelines because of a poor working environment characterized by a small phlebotomy area with poor ventilation, sometimes they were supposed to bypass some steps to get ventilation outside which diminished their working morale.

"…….*Unfortunately, our area does not have any windows, and we rely solely on the air conditioning. When the air conditioning breaks down, it becomes problematic, and we have to work quickly to get outside and get some fresh air."* (IDI 6 /Health laboratory technologist/Female/Aged 50).

This study reveal that the morale of practitioners and their adherence to IPC SOPs can be severely impacted by working circumstances such as small areas and poor ventilation. These discomforts have the potential to undermine desire to adhere to procedures, resulting in a decline in morale and discouragement, which in turn can lower IPC SOPs compliance.

4.6.2.2 High workload

Additionally, other participants reported facing a high workload, which often forced them to rush and skip some of the procedures. They also mentioned that, at times, they had to serve two patients simultaneously in a single room, compromising patient privacy in the phlebotomy area. This practice not only undermined the confidentiality and comfort of the

patients but also increased the risk of procedural errors due to the hurried pace and divided attention of the practitioners. Some of the practitioner reported that

"Mmmmh, firstly, handling a high patient workload is indeed challenging because when you have many patients, it can be mentally taxing and following all steps needed to perform safe phlebotomy procedures would be very difficult. This hospital, being a referral center, helps by accommodating many patients. The influx of patients seeking specialized care adds to the pressure, as we strive to provide the best possible treatment and attention to each individual." (IDI 6 /Health laboratory technologist/Female/Aged 50).

Furthermore, other practitioners reported that they were supposed to serve two patients simultaneously in a single room due to the high number of patients they served.

"In some circumstances, practitioners serve two patients at the same time due to the high workload. Ideally, every patient should receive service privately to ensure confidentiality and comfort. However, the overwhelming number of patients often necessitates simultaneous care, compromising the standard of individualized attention." (IDI 11/Health laboratory scientist/Female/ Aged 37).

Findings from this study showed that the excessive workload of practitioners sometimes causes them to speed through procedures, missing crucial stages in the Standard Operating Procedures for Infection control and Control (IPC SOPs). This impairs infection control measures and raises the possibility of cross-contamination between patients. This hurried approach also neglects glove changes and hand cleanliness, putting patients at risk for illnesses linked to healthcare and raising the possibility of procedural mistakes

4.6.2.3 Insufficient supplies

Some of the practitioners, some reported experiencing insufficient supplies in the hospital, including insufficient gloves. This scarcity forced them to reuse gloves for more than one patient, despite the recommended procedures strictly advising against the reuse of gloves. This practice not only contravened infection prevention and control guidelines but also posed significant risks to both patients and practitioners.

"The shortage of supplies, such as gloves, sometimes led to the use of a single pair of gloves for even three patients". (IDI 5 /Assistant lab manager/Health laboratory scientist/Female/Aged 38).

Furthermore, other participants reported the same issue of re-use of gloves due to scarcity of the gloves.

"I don't change gloves frequently because we serve many patients. If we were to change gloves every time, we would end up using up to fifty boxes a day across all departments, including laboratory staff and reception. Therefore, we minimize usage, fearing that gloves might run out" (IDI 3/Health laboratory scientist/Male/Aged 50).

Results in this study reveal that the practitioners are at risk of reusing gloves due to supply shortages, which undermines IPC protocols and exposes them to potential healthcare-associated infections. This compromises patient safety and poses occupational health hazards. Adherence to IPC SOPs is crucial for ethical responsibility and professional integrity in healthcare settings.

4.6.2.4 Insufficient number of staff

Health laboratory practitioners in these hospitals were reported to experience high workloads that did not match the staff available, some of the phlebotomies gave service to a high number of clients from different hospital departments a day, and mostly the staff were few, so it was difficult to adhere to standards. Some of the participant reported that:

*"There are not enough staff; we are understaffed. The high number of patients leads me to skip some of the steps and also mix up infectious waste" (*IDI 11 /Health laboratory scientist/Female/Aged 37).

Study finding showed that Hospital staff shortages often lead to healthcare workers rushing through tasks, neglecting infection prevention control guidelines, and causing mistakes. This can increase the risk of spreading infections. Additionally, fatigue and busyness can cause

workers to overlook important infection control procedures, making it harder for them to perform their jobs safely, potentially putting patients at risk.

CHAPTER FIVE

5.0 DISCUSSION OF FINDINGS

5.1 Overview

This chapter deals with a discussion of the study findings in line with the study objectives. The chapter is structured under the following areas; the level of compliance with standard operating procedures among health laboratory practitioners as per IPC SOPs, the individual factors that influence the adherence to safe phlebotomy practices among health laboratory practitioners as per IPC SOPs, and the organizational factors that influence the adherence to safe phlebotomy practices among health laboratory practitioners as per IPC SOPs.

5.2 The level of compliance with standard operating procedures among health laboratory practitioners as per IPC SOPs.

With just an 8.6% adherence rate of the observed procedures fulfilling the IPC SOPs, this suggests a poor compliance rate, most often appearing in hand hygiene, venipuncture disinfection, and proper use of gloves. A low proportion like this suggests widespread non-adherence, which poses serious problems for patient safety and infection management. Due to the high degree of non-compliance, patients and healthcare professionals are at greater risk of infection and other problems. This is because the great majority of operations did not follow fundamental infection prevention measures.

The previous study agreed with the current study which showed that the compliance level was low, Poor adherence to IPC SOPs was discovered by researchers in healthcare settings, endangering patient safety and bringing to light structural difficulties in upholding and enforcing IPC standards, a pervasive problem that is comparable to the findings of this study (18). Another Study reveals that healthcare professionals do not always follow proper hand hygiene and blood sample methods, even though these practices are vital to infection control strategies (40). Furthermore the previous study accord with current finding on improper use of gloves which increase the risk of infection transmission from one person to another (41).

To enhance adherence to IPC SOPs, the study emphasizes the critical necessity for focused interventions. This entails developing a culture of safety and compliance, as well as strengthening training programs and resource availability.

5.3 The individual factors influence adherence to safe phlebotomy practices among health laboratory practitioners as per IPC SOPS.

This section discussed the individual factors of adherence to safe phlebotomy practices among health laboratory practitioners as per IPC SOPs which include barriers and facilitators to the adherence of IPC SOPs. Facilitator found was the experience of the personnel in the phlebotomy section while barriers found were poor knowledge of the personnel and poor attitude toward adherence to safe phlebotomy procedures.

Facilitators identified within the individual factors were the experience of the health laboratory practitioner in phlebotomy; the more experience the practitioners have, the more they comply with IPC standards because practitioners would get to use those procedures frequently, which helped with adherence to IPC standards. This current study's findings are supported by previous research, which shows similar results of the personnel's experience contributing to the adherence to IPC standards. The study showed that the practitioner's experience directly affected the adherence to IPC standards (21). Another piece of paper accords with current study findings showed that the practitioner's expertise directly impacts compliance with IPC standards, this study indicated length of clinical experience had a positive correlation with compliance to the IPC standards (42). Regular competency assessment can help to identify gaps in compliance with IPC SOPs in phlebotomy, not only but also the allocation of tasks based on the practitioner's level of experience while less experienced staff take the responsibilities as they gain experience gradually.

The barriers identified were due to the poor knowledge of the personnel, practitioners were supposed to follow all the steps required for safe phlebotomy procedures, but most of them didn’t recall all the steps for safe phlebotomy procedures. The current study showed that their knowledge of safe IPC in phlebotomy procedures was poor. There was a study that concurred with the current results of health laboratory practitioners who didn’t follow all the procedures required due to not recalling all the procedures during phlebotomy (43). Another study

argues that knowledge alone cannot contribute to the adherence to IPC standards; there are other factors, like the attitude of personnel, which have a significant contribution to the adherence to IPC standards (42). Moreover, a poor attitude of personnel toward the compliance of IPC SOPs was observed as the barrier to adherence to IPC SOP guidelines in the current study which led to poor adherence to IPC guidelines, instead of viewing these guidelines as essential to patient and practitioner safety, they seemed to treat them as optional or burdensome tasks. Previous studies agreed with the current study findings, which showed that the attitude of personnel had a direct impact on the compliance of the IPC standards (42) (33). Comprehensive training programs are essential to improve knowledge and attitudes towards IPC guidelines, ensuring safe phlebotomy practices and enhancing adherence to IPC standards.

5.4 The organizational factors influence the adherence to safe phlebotomy practices among health laboratory practitioners as per IPC SOPS.

This section discussed the organizational factors influencing the adherence to safe phlebotomy practices among health laboratory practitioners as per IPC SOPs in Dar es Salaam Regional Referral Hospital. Facilitators identified were the availability of SOPs and quality management systems while Barriers found were poor working environment, high workload, insufficient number of staff, and insufficient medical supplies.

Facilitators of the adherence to IPC SOPs identified were the availability of standard operating procedures for safe phlebotomy practices. In this study, guidelines like IPC guidelines, safety manuals, and sample collection manuals were reported to be available, which means that whenever practitioners needed to revise or clarify the procedures of phlebotomy, the SOPs and guidelines were there, which helped them understand more about the procedure. There was a study that agreed with current findings that the availability and understanding of standard operating procedures facilitate adherence to safe phlebotomy practices(26)(27). Furthermore, presence of Quality management system, study have also underscored the importance of a robust QMS in maintaining high standards of infection prevention and control (IPC). These systems serve as comprehensive frameworks that monitor and manage all aspects of laboratory operations, from sample collection to analysis

and reporting (33). Ensuring the comprehensive maintaining of quality management system that will help in monitoring IPC standards adherence in each step in phlebotomy also increase dissemination of IPC SOPs to all practitioners.

Barriers identified in this study were poor working environments characterized by several challenges, these included a small phlebotomy area and non-functional air conditioning (AC), these factors collectively contributed to a challenging and uncomfortable working environment for the practitioners. Similar findings have been documented in other studies, highlighting common barriers to safe phlebotomy practices stemming from inadequate working conditions, such conditions not only impact the physical comfort of healthcare providers but also potentially compromise patient care and safety (33). Moreover, the health laboratory practitioners in the current study reported insufficient supplies in the hospital, like a shortage of gloves, which made them re-use gloves for more than one client regardless of the procedure recommended not to re-use gloves. Their previous studies highlight similar issues as in our study (32)(33). In the current study, health laboratory practitioners in those hospitals reported facing substantial workloads that were not adequately supported by available staffing, similar findings have been documented in previous studies, underscoring a recurring issue across healthcare facilities. These studies consistently highlight the strain imposed by high patient volumes and insufficient staffing on adherence to clinical standards, such conditions not only place considerable stress on healthcare professionals but also compromise the quality and safety of patient care (33). Addressing obstacles in phlebotomy procedures, such as improving the physical working environment, ensuring resource availability, and allocating sufficient manpower, can enhance patient care and safety hence adherence to safe phlebotomy practices.

5.5 Study Limitation and Mitigation

A descriptive cross-sectional study identified the adherence rate of IPC SOPs but did not explain why practitioners do or don't follow IPC SOPs, this challenge was mitigated by incorporating with qualitative approach like an in-depth interview to gain insight into the reason for adherence to IPC SOPs. Also, a mixed approach needs specialized skills and multiple skill sets, this limitation was mitigated by consulting specialized personnel and using software tools like Nvivo and SPSS to simplify the process.

Moreover, convenience sampling leads to a biased sample, which was mitigated by choosing participants from different settings, also purposive sampling uses a small sample size which was mitigated by incorporating a quantitative approach

Further studies could be done at lower-level healthcare settings like health centers and dispensaries to get more pictures of adhering to these IPC SOPs at lower level health facilities, also follow up study may be conducted to observe for consistency on adherence to these guideline.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

IPC guidelines were introduced to minimize the rate of infections from one person or point to another. The findings in this study show that the adherence to safe phlebotomy practices as per IPC SOPs was 8.6% which was very low, no health laboratory practitioner complies with all steps on an IPC SOPs. Barriers identified in this study included poor knowledge, negative attitudes attitude of personnel toward the adherence to IPC SOPs, poor infrastructures, insufficient supplies, shortage number of staff, and high workloads.

The findings of this study, implicate the serious need for intervention at multiple levels in health care facilities. These barriers could be addressed through improved training, better working conditions, adequate resources, and effective workload management to enhance adherence to safe phlebotomy practices. Also, the correlation between training and adherence to IPC SOPs was found, so training could be used to increase compliance with IPC SOPs.

6.2 Recommendations

From the barriers identified in this study, there are things to be done by the management of hospitals, policymakers, the Ministry of Health, and other stakeholders. Barriers identified were a shortage of supplies, poor working environment, high workload, and poor personnel knowledge and attitude toward the adherence to safe phlebotomy practices as per IPC SOPs among health laboratory practitioners in Dar es Salaam regional referral hospitals. From the above conclusion, the recommendations are as follows

1. The Ministry of Health, hospital management together with other stakeholders should conduct training regularly regarding safe phlebotomy procedures and their importance in the transmission of infections, both internal and external training are very important, and most of the pieces of training conducted are too general regarding IPC issues, the training should be specific to safe phlebotomy for the phlebotomist to gain insight into the procedures in detail, and from there the practitioners will get to know the important to follow each step accordingly. Through those trainings,

practitioners might change their negative attitudes toward adherence to safe phlebotomy practices as per IPC SOPs.

2. Hospital management encourage a culture of safety by praising and rewarding employees who follow IPC procedures on a regular basis. Also hospital management should establish a system of routine supervision visits where management or assigned IPC officers watch staff procedures, offer comments, and quickly address risky conduct. This can support learning and guarantee that SOPs are followed.

3. Hospital management should ensure the availability of medical equipment and supplies like gloves which the practitioners did not comply with SOP due to a shortage of supplies like gloves. The person responsible for ordering equipment and supplies must order supplies that align with the population of patients served.
4. Hospital management should improve the working environment by increasing the ventilation to the phlebotomy area, maintenance should not take too long. Also increase hiring staff to accommodate the workload experienced by the health laboratory practitioners since those are regional referral hospitals, receiving a high number of patients is inevitable.

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8.0 APPENDICES

8.1 Appendix I: consent forms for IDI: English Version

GREETINGS: MADAM / SIR

My name is Shekha Yusuf Silim. I am a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing a Master of Project Management, Monitoring, and Evaluation in Health. As part of the prerequisite for the issuance of a Master's degree, I am needed to do research and provide valuable results. The goal of this study is to evaluate adherence to infection prevention and control standard operating procedures during sample collection and identify any inadequacies in a regional referral hospital in Dar es Salaam.

The consented health laboratory practitioner will be interviewed with open-ended semi-structured questions. All information I collect will be confidential and used solely for improved care and treatment, medical research information, and to enable professionals to improve patient care.

Participation is voluntary, and you have the right to withdraw from the study at any time.
Shekha Yusuf Silim

Investigator.

I _____

Have understood the above information, and willingly I agree to take part in this study

Participant Name_____ _____Signature_____

Date: _____

Investigator _____Signature _____

Date: _____

8.2 Appendix II: fomu ya ridhaa: Dodoso la Kiswahili

HABARI YA SAA HIZI:

Naitwa Shekha Yusuf Silim. Mimi ni mwanafunzi wa Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili (MUHAS) nasoma Shahada ya Uzamili ya Usimamizi wa Miradi, Ufuatiliaji na Tathmini katika Afya. Kama sehemu ya sharti la utoaji wa digrii ya Uzamili, ninahitajika kufanya utafiti na kutoa matokeo muhimu. Lengo la utafiti huu ni kutathmini ufuasi wa taratibu za uendeshaji wa udhibiti wa maambukizi wakati wa ukusanyaji wa sampuli na kubaini mapungufu yoyote katika hospitali ya rufaa ya mkoa wa Dar es Salaam.

Mfanyikazi wa maabara aliyeidhinishwa atahojiwa na maswali ya nusu-muundo wazi. Taarifa zote nitakazokusanya zitakuwa za siri na zitatumika kwa ajili ya huduma bora na matibabu pekee, taarifa za utafiti wa kimatibabu na kuwawezesha wataalamu kuboresha huduma ya wagonjwa.

Kushiriki ni kwa hiari, na una haki ya kujiondoa kwenye utafiti wakati wowote.

Shekha Yusuf Silim……. Mtafiti.

Mimi _____

Nimeelewa maelezo hapo juu, na kwa hiari yangu ninakubali kushiriki katika utafiti huu

□ Mshiriki _____ Sahihi_____

□ Tarehe _____

□ Mtafiti _____ Sahihi _____

□ Tarehe _____

8.3 Appendix III: Interview Guided Questions

DEMOGRAPHIC INFORMATION

1. Please tell me about your (Age, sex, level of education, title, duration, and roles)?
2. Kindly tell me what you understand about Infection Prevention Control in general

Probe for:

- *IPC practices (i.e. (Sterile instruments and devices, hand hygiene, vaccinations, cleaning, safe injection practices, importance of scrubs, waste management)*

3. How would you describe the current training for safe phlebotomy procedures, and if they have any gaps

Probe for:

- *If they receive any training on safe phlebotomy procedures*
- *Frequency of training*
- *When, where, and content of training*

4. Please explain how you follow the guidelines during phlebotomy procedures

Probe for:

- *If they follow SOPs (i.e. arrange all necessary equipment on a tray, identify and prepare the patient, select an appropriate site (for venepuncture), practice PPE, Use a clean gauze or dry cotton wool after withdrawing the needle, instruct the patient to hold the gauze while arm uplifted, Requests that the patient refrains from bending their arm as this can result in a hematoma, fills the laboratory sample tubes properly, remove gloves and repeat hand hygiene, prepared sample for transit*

5. In your opinion, what factors facilitate your day-to-day implementation of safe phlebotomy procedures in your health facility?

Probe for:

- *Working Environment*
- *Equipment and supplies*

- *Availability of SOPs/guidelines*

6. 6. In your opinion, what factors hinder your day-to-day implementation of safe phlebotomy procedures in your health facility?

Probe for:

- *Working Environment*
- *Equipment and supplies*
- *Availability of SOPs/guidelines*

7. Please explain how mentorship/supportive supervision has contributed to the performance of safe phlebotomy procedures in your facility

Probe for:

- *How frequently were internal/external assessments/supervisions conducted in the past year?*
- *How were assessments delivered (e.g., demonstration, friendly and simple language)?*
- *What is your opinion on mentorship/supportive supervision for safe phlebotomy procedures (if needs for any changes)?*

8. How does mentorship/supportive supervision contribute to the adherence to IPC standards during phlebotomy procedures?

9. What would you recommend to improve the implementation on safe phlebotomy procedures at your health facility?

Thank you for your participation

8.4 Appendix IV: Checklist for observation of phlebotomy procedures

A CHECKLIST FOR PERFORMING PHLEBOTOMY AS PER STANDARD OPERATING PROCEDURES (The tool adopted from Tanzania Ministry of Health Community Development, Gender, Elderly and Children standard operating procedures for infection prevention and control in Tanzania of 2020.)

DEMOGRAPHIC CHARACTERISTIC OF THE LABORATORY PRACTITIONERS

AGE:

SEX:

EDUCATION LEVEL:

YEARS OF EXPERIANCE:

NUMBER OF PHLEBOTOMY TRAININGS ATTENDED**:**

PERFORMANCE STANDARDS	**VERIFICATION CRITERIA**		**YES**	**NO**	**NOT APPLICABLE**
STANDARD 1 **The *National IPC Guidelines for Health Care Services in Tanzania* are available and Accessible.**	Verify by observation that:				
	1.	**One of the following documents is available: National IPC Standards, National IPC Guidelines, and National IPC SOPs**			
	2.	**One of the following documents is accessible: National IPC Standards, National IPC Guidelines and National IPC SOPs**			
STANDARD 2 **Standard Operating**	Ensure that Standard Operating processes (SOPs) for IPC practices and related processes are available and				

Procedures (SOPs) for IPC are available and accessible	accessible, whether developed by the MoHCDGEC or the facility:				
	1.	Performing phlebotomy for blood testing.			
STANDARD 3 Phlebotomy procedures are carried out as per the World Health Organization (WHO) best phlebotomy practice Guidelines.	Verify that				
	1.	The person(s) performing phlebotomy have been trained in the procedure.			
	2.	Providers should clearly specify the indications for blood sample in patient notes, laboratory forms, or written protocols.			
	The provider arranges all necessary equipment on a tray or trolley for convenient access and visibility during the process. According to the indicators, these goods include:				
	3.	Supply of laboratory sample containers and slides			
	4.	Well-fitting, non-sterile gloves			
	5.	Single-use blood-sampling instruments, such as safety needles and syringes.			
	6.	A tourniquet			
	7.	Alcohol swabs for skin disinfection			
	8.	Gauze or cotton-wool ball to be applied over puncture site			

	9.	Use leak-proof transportation bags and containers as per IPC guidelines (red for highly infectious waste, yellow for infection waste, and black/blue for non-infectious trash).			
	The provider identifies and prepares the patient appropriately: (Only relevant for aware patients)				
	10.	Introduces oneself to the patient and asks for their complete name.			
	11.	Ensures correct identification by matching the patient's details to the laboratory form.			
	Provider selects an appropriate site:				
	12.	Apply a tourniquet about 4-5 finger widths above a visible, straight, and clear vein. Re-examine the vein.			
	13.	Blood cannot be collected via a pre-existing peripheral venous access site (only relevant for inpatients).			
	The provider practices hand hygiene and puts on gloves:				
	14.	Hands should be washed with soap and water, dried with single-use towels, or air-dried.			

		To clean hands that are not obviously dirty, use an alcohol rub...			
	15.	After hand hygiene, put on non-sterile gloves that fit well.			
	Provider performs proper disinfection of the site:				
	16.	Uses alcohol swab.			
	17.	Begin cleaning from the center of the venepuncture site and work downwards and outwards to cover at least 2 cm. Apply hard but mild pressure for approximately 30 seconds.			
	18..	Allows the site/area to dry.			
	Provider performs venepuncture as follows:				
	19.	Asks the patient to make a fist so that the veins are more visible			
	20.	The needle should enter the vein quickly at a 30 degree angle or less and be guided along the vein at the easiest angle.			
	21.	Once enough blood has been collected, release the tourniquet.			

	Before withdrawing the needle.				
	22	Use a clean gauze or dry cotton-wool ball to gently apply pressure to the location after withdrawing the needle.			
	23.	Instructs the patient to hold the gauze or cotton wool in place with their arm extended and lifted.			
	24.	Requests that the patient refrain from bending their arm as this can result in a hematoma.			
	The provider fills the laboratory sample tubes properly.				
	25.	Fill the tube with one hand, or use a needle shield to prevent needle sticking.			
	26.	Use moderate and steady pressure to pierce the tube stopper from above.			
	27.	Do not press the syringe plunger as it raises the risk of hemolysis.			
	28.	Does not remove the stopper because it will release the vacuum.			
	29.	Does not recap and remove the needle.			

	30.	Before sending the tubes containing additives, invert them as recommended by the local laboratory.			
	31.	Repeats hand hygiene.			
	32.	Checks the insertion site to ensure it is not bleeding;			
	Samples are properly prepared for transit.				
	33.	Laboratory samples are properly packed in a leak-proof plastic bag with an exterior pocket for the request form. Placing the requisition on the outside minimizes contamination.			

8.5 Appendix V: Ethical Clearance

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/2063 Date: 26/02/2024

MUHAS-REC-02-2024-2063
SHEKHA YUSUF SILIM
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: ASSESSING ADHERENCE TO INFECTION PREVENTION AND CONTROL STANDARD OPERATING PROCEDURES IN PHLEBOTOMY AMONG HEALTH LABORATORY PRACTITIONERS IN DAR ES SALAAM REGIONAL REFERRAL HOSPITALS, AN OBSERVATIONAL STUDY.

Reference is made to the above heading,

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 26/02/2024
EXPIRATION DATE OF APPROVAL: 26/02/2025

STUDY DESCRIPTION:
Purpose:

The purpose of this observational cross-sectional study is to evaluate health laboratory practitioners' adherence to safe phlebotomy methods as per Infection Prevention and Control standard operating procedures (IPC SOPs) at Dar es Salaam Regional Referral Hospitals.

- The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014554.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain Data Transfer Agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain Material Transfer Agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country.
8. Apply for and obtain permission to publish the results from National Institute for Medical Research. The application should be before submitting to a publisher and not concurrently through the email publications@nimr.or.tz.
9. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.





Dr. Nahya Salim Masoud,

CHAIRPERSON, MUHAS RESEARCH AND ETHICS COMMITTEE

8.6 Appendix VI: Permission letter –Temeke

JAMHURI YA MUUNGANO WA TANZANIA
WIZARA YA AFYA.
HOSPITAL YA RUFAA YA MKOA YA TEMEKE
Baruapepe:temekerh@afya.go.tz,S.L.P 45232 Dar es Salaam,Simu 0222856007

Kumb. Na. TRRH/RSC/9/9/02/84 **Tarehe: 04/04/2024**

Ndg. Shekha Yusuf Silim
Muhimbili University of Health and Allied Science
S.L.P 65001
DAR ES SALAAM.

YAH: OMBI LA KUFANYA UTAFITI "ASSESSING ADHERENCE TO INFECTION PREVENTION AND CONTROL STANDARD OPERATING PROCEDURS IN PHLEBOTOMY AMONG HEALTH LABORATORY PRACTITIONERS AT TEMEKE REGIONAL REFFERAL HOSPITAL" (RESEARCH)

Tafadhali husika na somo tajwa hapo juu.

2. Nimepokea barua yako ya tarehe 8 March, 2024 kuhusu ombi lako la kufanya Utafiti (Research) katika Taasisi yetu, kuhusu **"Assessing Adherence to Infection Prevention and Control Standard Operating Procedures in Phlebotomy Among Health Laboratory Practitioners at Temeke Regional Referral Hospital"**

3. Ombi lako limekubaliwa, utatakiwa kulipa ada kiasi cha **Tshs.100,000/=**. Hivyo *wasiliana* na mhasibu wa mapato wa Hospitali **Ndg. Lusajo Nsajigwa** kwa namba ***0717 959495*** *ili* akupatie control Number kwa ajili ya malipo ya ada hii ili uweze *kuruhusiwa kufanya utafiti.*

4. *Asante kwa ushirikiano.*

Dkt. Husna Msangi
Kny: MKURUGENZI
HOSPITALI YA RUFAA YA MKOA YA TEMEKE

Nakala: CSCO/PSY - ***Tafadhali hakikisha taarifa ya utafiti inabaki hospitalini***

8.7 Appendix VII: Permission letter Mwananyamala

JAMHURI YA MUUNGANO WA TANZANIA
WIZARA YA AFYA

Anwani ya simu "AFYA".
Simu ya Mdomo 022-2760500

(Unapojibu Tafadhali Taja)

Hospitali ya Rufaa ya Mkoa.
Mwananyamala.
S.L.P 61665.
Dar es Salaam.

Tarehe: 5/04/2024

Kumb. Na. MA. 240/341/01/20

Shekha Yusuf Silim,
S.L.P 6768,
DAR ES SALAAM.

YAH: MAOMBI YA UTAFITI KATIKA HOSPITALI A MWANANYAMALA

Tafadhali rejea mada tajwa,

2. Ofisi imepokea barua yako ya tarehe 14/03/2024, iliyohusu kuja kufanya utafiti Hospitali ya Rufaa ya Mkoa Mwananyamala kwa kichwa cha habari " *Assessing adherence to infection prevention and control standard operating procedures in phlebotomy among health Laboratory practitionrs in Dar es Salaam- Tanzania An Observational study*"

3. Kwa barua hii napenda kukutaarifu kuwa nafasi ipo, na utalipia kiasi cha shiling 50,000/=

Asante.

Dkt. Mkiwa Akida
KNY: MGANGA MFAWIDHI
HOSPITALI YA RUFAA YA MKOA MWANANYAMALA

Nakala:
Mkuu wa Idara ya Maabara - Kwa taarifa
Shekha Yusuf Silim - Kwa taarifa

8.8 Appendix VIII: Permission letter Amana

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

AMANA REGIONAL REFERRAL HOSPITAL

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P.O. Box 25411
DAR ES SALAAM
Phone: 022—2861903

Date: 12/04/2024

Director, Postgraduate Studies,
MUHAS,
P.O. B ox 65001,
DAR ES SALAAM.

Re: PERMISSION FOR DATA COLLECTION

Refer to your letter dated 8th March, 2024 which requested us to allow Shekha *Yusuf Silim to conduct research and collect* data in our institution.

We are here to acknowledge your request with the following conditions, that he must submit the results of his research after completion of analysis in order the hospital to make use of data's to solve hospital problems.

Regards.

For: MEDICAL OFFICER I/C
AMANA REGIONAL REFERAL HOSPITAL
P. O. Box 25411
DAR ES SALAAM

Dr. Rose Ntambuti
FOR: MEDICAL OFFICER INCHARGE
AMANA REGIONAL REFERRAL HOSPITAL