Development, implementation and impact of Phlebotomy training on blood sample rejection and Phlebotomy knowledge of primary health care workers at selected primary health care facilities in Cape Town: A quasi-experimental study design.

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Declaration

I, MUMTAZ ABBAS, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. This work has not been published prior to registration for the abovementioned degree. I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

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PART A: THE PROTOCOL

The development and implementation of a phlebotomy training session for primary health care workers and evaluating whether it is associated with a decrease in the rejection rate of blood samples sent to the laboratory.

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TABLE OF CONTENTS

1. Abstract 5
2. Introduction 7
   2.1. Literature review 7
   2.2. Motivation for study 10
   2.3. Research question 11
   2.4. Aim 12
   2.5. Objectives 12
3. Methodology 12
   3.1. Study design 12
   3.2. The intervention 13
   3.3. Study setting 13
   3.4. Study population 13
   3.5. Sampling 14
      3.5.1. Inclusion criteria 14
      3.5.2. Exclusion criteria 14
   3.6. Recruitment 15
   3.7. Data collection and management 15
   3.8. Timeline 16
4. Statistical and data analysis 17
   4.1 Sample Analysis 17
   4.2 Data Analysis 17
5. Ethical and legal considerations 17
6. Limitations 18
7. Resources 19
   7.1. Available resources 19
   7.2. Budget 20

8. Reporting and implementation of results 20

References 21

Annexures

1. Abstract

Background:

There is an increasing amount of blood sample rejection at primary level health care facilities which impacts negatively on the staff, facility, patient and laboratory and resulting in escalating financial costs. The result of a pilot audit has shown that this rejection is predominantly related to incorrect phlebotomy technique.

Purpose:

To develop an effective sustainable intervention that will contribute in decreasing the rejection rate of blood samples by the laboratory in four different community health centres (CHCs) in Cape Town.

Objectives:

1. To conduct a pre training audit investigating the rejection rate of all routine blood samples and reasons for blood sample rejection taken at four different CHCs in Cape Town.
2. To implement a training programme with appropriate sustainable interventions that will ultimately benefit the staff, patient, facility and the laboratory.
3. To conduct a post training audit investigating the rejection rate and reasons for blood sample rejection at four different CHCs in Cape Town.
4. Study participants will complete the same phlebotomy questionnaire pre and post training to assess whether knowledge regarding phlebotomy has improved post training.

Study Design:

Two components: retrospective cross sectional and before-after study design.

Study Setting:

Multi-centre study conducted at four CHCs in Cape Town, two 24- hour facilities and two 8-hour facilities. The CHCs include Mitchells Plain, Hanover Park, Heideveld and Maitland.

Study Population:

The population groups that will be used in the three components of the study include:

1. Pre-training audit: The study population will include all routine blood samples (adults and children) taken, sent and rejected at the four CHCs over the audit period.
2. Intervention: 6 -10 staff members involved in phlebotomy will be invited to attend the training session and the members will be selected by convenience sampling. Members will be asked to complete a piloted pre and post training phlebotomy questionnaire.
3. Post-training audit: The study population will include all routine blood samples (adults and children) taken, sent and rejected at the four CHCs following the training session.

Study Sample:

Consecutive sampling of blood samples, convenience sampling of staff members to the intervention.

Data Collection Methods:

The NHLS database will be used to determine the rejection rate and reasons for blood sample rejection. A closed- ended questionnaire will be used pre and post training.

Statistical Methods:

Basic statistics, including proportions and corresponding confidence intervals will be determined.

2. Introduction

2.1 Literature Review

Patient care and safety has become increasingly more important in laboratory medicine.[1]Clinical governance is a system where healthcare organisations are responsible for continuously improving the quality of services that positively impacts on patient care.[1,2] It is described as "a framework through which organisations are accountable to continue to improve the quality of the service and safeguard high standards of care by creating an environment in which excellence in clinical care would flourish". [3]

Clinical laboratories are striving to decrease the rejection rate of unsuitable blood samples and to provide an excellent level of care with increasing attention paid to patient care and safety.[2] The International Organization for Standardisation defines laboratory error as "failure of a planned action to be completed as intended, or use of a wrong plan to achieve an aim, occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them".[4]

The National Health Laboratory Service (NHLS) is the provider of laboratory services to all public sector hospitals in South Africa and certain requirements are necessary before a sample can be successfully processed. Majority of blood samples are rejected as a result of pre-analytical errors and this accounts for up to 70% of laboratory errors.[5] Pre-analytical laboratory measures includes the following:[1,2]

- Patient identification (labelling errors, no test specified on request form, illegible request).
- Sample collection (clotting, insufficient volume, inappropriate sample container, haemolysis).
- Sample transport (storage conditions i.e. temperature, sample lost or not received by laboratory).

The absolute prevalence of pre-analytical problems ranged between 0.2% - 0.75% in a review on risk management, with the most common errors being haemolysis, clotting, insufficient blood volume, wrong sample tube and misidentification.[6] There was a 6.4%-12% chance of inappropriate care due to laboratory errors, with up to 30% of errors

resulting in patient discomfort, escalating financial costs as well as subjecting patients to repeat blood tests.[6] Risk reduction in the pre-analytical phase is essential in improving quality and patient satisfaction as this is one of the most important phases to impact on patient outcomes and healthcare costs.

In a recent retrospective audit conducted at Tygerberg hospital in Cape Town, investigating the rejection rate of blood samples, the reasons for blood sample rejection and the clinical impact on patient care, it was shown that 481 samples out of a total of 32 910 were rejected during the two week study period with a rejection rate of 1.46%. [1]The two main reasons for sample rejection were clotting (30%) and inadequate sample volume (22%).[1] Haemolysis account for 40-70% of all unsuitable blood samples sent to the laboratory and is much higher than any other causes such as clotted samples, incorrect blood volume, and incorrect sample tubes used. [7]The low frequency and delay in repeating the blood sample is also a concern as laboratory results can influence clinical decisions.[8]

A critical value is defined as a "result suggestive of imminent danger to the patient unless appropriate therapy is promptly initiated". An awareness of the clinical and economic impact of blood sample rejection can be created by communication between clinicians and laboratory staff, using the current guidelines available on specimen sampling and education of staff.[10]

The evaluation of the reasons for blood sample rejection and its impact on healthcare costs as well as costs to the staff and most importantly to the patient is a form of health systems research. Health systems research is a form of research that aims to provide information which will improve the functioning of a health system, which will lead to improved health status.[11]

The Commission on Health Research for Development identified international health research partnerships as vital to advancing health in developing countries and promoting global health equity.[12]The World Health Organisation (WHO) and global ministerial summits have subsequently linked health research to achieving the United Nations Millenium Development Goals (MDG's).[13,14] Stronger health systems are vital to achieving improved health outcomes.[14]

Strengthening health systems in developing countries is essential in improving healthcare globally and in reaching the MDG's. Most developing countries fall short of the requirements to implement the goals suggested by the WHO.[16] The following are important components, proposed by the WHO, in strengthening health systems and in achieving an effective public health system: service delivery, financing, governance, the health workforce, information systems and supply management systems.[17]

One of the main goals in strengthening health systems should be improving clinical and public health laboratories[13] and this includes reducing the rejection of blood samples sent to the laboratory. A recent conference evaluating a program for strengthening laboratory management was held in Africa in 2009. The highlights of this conference was to "act now, act collectively and act differently to ensure sustainability of global health efforts to enhance laboratory networks and systems"[18.]

Acting now involves addressing the 3 pillars for disease prevention, control, and patient management which include public health, clinical medicine, and laboratory medicine. The most neglected pillar in developing countries is laboratory medicine and this is important in clinical decision making. The increase in funding for global health development[19,20] provides a good opportunity to end the neglect of laboratory systems and services in global health in developing countries. Quality laboratory services and systems is important in strengthening health systems as laboratory medicine provides critical information that aids in clinical decision making.[18]Acting collectively involves addressing laboratory strengthening in a holistic way and to form partnerships to support developing countries to strengthen laboratory systems. Acting differently involves recognising the importance of clear indicators in order to monitor progress in strengthening laboratory systems.[18]

The first international conference of the African Society for Laboratory Medicine (ASLM) was held in Cape Town, South Africa in December 2012. The focus of the conference was to strengthen national laboratory health systems. The outcomes of this conference was that it aimed to meet the following targets by the year 2020: "certification of 30,000 laboratory staff, the harmonisation in the regulation of diagnostics in Africa's five economic regions, the international accreditation of 250 laboratories, and the strengthening of an African Network of National Public Health Reference laboratories in 30 countries."[21]

The National Health Insurance (NHI) is a financing system that will ensure that all South Africans have access to essential healthcare irrespective of their employment status. The NHI will be piloted in 10 districts over a 5 year period with an audit being conducted of all public health facilities in the country. During the first 5 years of NHI, the focus will be on strengthening the health system in the following areas: management of health facilities, quality improvement, development of infrastructure, medical equipment, management of human resources, information management and systems support and development of an NHI fund.[22] The NHI will contribute to strengthening laboratory health systems and reduce the escalating financial costs of rejected blood samples at primary level.

2.2 Motivation for study:

The motivation for this study was based on the results of a pilot audit conducted by the principal investigator in 2012 at Vanguard Community Health Centre (CHC).

A CHC is a public health care facility funded by the government. It focusses on providing primary health care by covering a range of health promotion, disease prevention, curative and rehabilitative services to the community. [23,24]

An uncontrolled non-validated pilot audit was conducted by the principal investigator in August 2012 at Vanguard CHC. In this audit, it was found that 81 blood samples out of a total of 1117 were rejected in the two week audit period which correlated to a rejection rate of 7.3%. The most common reasons for sample rejection were haemolysis (46%), followed by no sample tube received by the laboratory (26%). Only adult blood samples that were taken, sent and rejected were included in this audit.

Other costs of blood sample rejection at the CHC include costs to the staff, patient, facility and the laboratory. The costs to the staff include having to request the folder and either call the patient back or post a letter to the patient's home. This then resulted in one less doctor seeing patients in the clinic and thus a delay in the flow of patients. A delay in obtaining urgent results compromises patient care as important clinical decisions cannot be made during the current hospital visit. The costs to the patient include financial strain (borrowing money or using own money for public transport to access the CHC), a day off work and

being pricked again for another blood sample. The cost to the facility includes paying for the phlebotomy equipment. Costs to the laboratory include paying for the rejected blood samples, the sample tubes and the paper and ink used to print the rejected results to the facility.

Following the results of the audit at Vanguard CHC, interventions were put in place in order to decrease the rejection rate at the facility. The results of the audit were presented to the staff of Vanguard CHC. The results were also presented at the combined University of Cape Town (UCT) and Metro District Health Services (MDHS) workshop.

Interventions included posters highlighting which samples tubes to use for the requested blood test and the volume of blood required per blood test, education of staff regarding criteria for sample acceptability, a poster highlighting the modified criteria for sample acceptability was put up on the wall in the phlebotomy room for nurses to use as a guide, checking of samples on a daily basis and the nurse responsible for checking the samples to sign the "daily sample checklist", which is handed to the facility manager on a weekly basis, record keeping of all samples drawn as well education and training of staff regarding correct phlebotomy technique. Additional phlebotomy equipment were also ordered to reduce the risk of haemolysis as a cause for sample rejection.

A formal phlebotomy training session was held at Vanguard CHC on 4 April 2013, 28 members of the facility attended the training session which included doctors, nurses and students. The training was conducted by a qualified phlebotomist employed at the NHLS Greenpoint laboratory. At this training session all the basic principles of good phlebotomy technique was highlighted with a practical demonstration. Each member received a copy of the "specimen sampling manual" which outlines all the principles of phlebotomy.

2.3 Research question

Is training of staff regarding phlebotomy associated with a decrease in rejection rate of blood samples by the laboratory, as compared to no training?

2.4 Aim

To develop an effective sustainable intervention that will contribute in decreasing the rejection rate of blood samples by the laboratory in four different CHCs in Cape Town.

2.5 Objectives:

1. To conduct a pre training audit investigating the rejection rate of all routine blood samples and reasons for blood sample rejection at four different CHCs in Cape Town.
2. To implement a training programme with appropriate sustainable interventions that will ultimately benefit the staff, patient, facility and the laboratory.
3. To conduct a post training audit investigating the rejection rate and reasons for blood sample rejection at four different CHCs in Cape Town.
4. Study participants will complete the same phlebotomy questionnaire pre and post training to assess whether knowledge regarding phlebotomy has improved post training.

3. Methodology

3.1 Study Design:

This study will consist of two components: Firstly, a retrospective cross-sectional study design will be used to determine the rejection rate and reasons for blood sample rejection at four CHCs in Cape Town. The laboratory information system of the NHLS DISALAB will be used to extract the number of routine blood samples that was performed and rejected over the audit period as well as the reasons for blood sample rejection.

Secondly, a before-after study design will be used to determine the rejection rate before and after the intervention.

This section was conducted in five steps:

1. Pre-training audit at each of the four identified CHC's to determine the rejection rate and reasons for blood sample rejection.

2. Training of staff in one session at each of the identified CHCs with the same pre and post training phlebotomy questionnaire.
3. Post-training audit at each of the four CHCs that received training.
4. Analysing the data of the audit pre and post training.
5. Analysing the data of the pre and post training questionnaire.

3.2 The Intervention

See Annexure 2

3.3 Study Setting

A multi-centre study at four CHCs in Cape Town, two 24 hour facilities and two eight hour facilities. The CHCs include Mitchells Plain, Hanover Park, Heideveld and Maitland.

3.4 Study Population:

The population groups that will be used in the three components of the study include:

1. Pre-training audit: The study population will include all routine blood samples (adults and children) taken, sent and rejected at the identified four different CHCs over the audit period.
2. Intervention: 6 -10 staff members will be invited to attend the training session and the members will be selected by convenience sampling.
3. Post-training audit: The study population will include all routine blood samples (adults and children) taken, sent and rejected at the identified four different CHCs following the training session.

3.5 Sampling:

Sampling of blood samples: Consecutive sampling will be done from the number of blood samples sent to the NHLS by the four facilities. No random allocation to the intervention will be done.

Sampling of staff for training (intervention): Convenience sampling of staff members to the intervention will be done on the day of training. The comparison will be time based (before and after the intervention).

3.5.1 Inclusion Criteria:

The study will include the following routine blood samples and staff members.

Blood samples:

- All blood samples including children and adults of all ages.
- Bloods drawn via any phlebotomy technique i.e. needle and syringe, needle and bull dog and butterfly needle and syringe.
- Bloods drawn from any site on the body i.e. arm, leg etc
- Arterial and venous blood.
- Bloods drawn by any member of the health care team including doctors, nurses, medical students, nursing students, interns, community service doctors and locum nurses or doctors will be included.
- Bloods drawn from any area of the CHC which includes emergency department, injection room, INR room, doctors consultation room, club room.

Staff members:

Approximately 6-10 staff members involved in phlebotomy at the CHC who are available on the day of training will be invited to participate in the study.

3.5.2 Exclusion criteria:

- All blood samples that are not drawn at the four CHCs where the audit will be conducted.
- Urine, stool, sputum, pleural fluid, ascitic fluid, FNABS and PAP smears.
- Staff that are not involved with phlebotomy e.g. admin staff, cleaners.

3.6 Recruitment

Participants for the phlebotomy training session will be recruited by sending an email to the facility managers and family physicians at the four CHCs. Posters will also be put up on the walls at the CHCs.

3.7 Data Collection and Management

The data for this study will be extracted from the NHLS DISALAB at the data warehouse in Johannesburg. This information will be emailed to me in the form of an excel document. The list of variables to be collected/extracted includes the total number of routine blood samples performed and rejected blood samples over the audit period, the name of the tested that was rejected e.g full blood count and the reason for the blood sample being rejected e.g. clotted sample. Illegible or inconsistent entries will be excluded from the study and reported on. No patient details will be provided as this is not required for the purpose of the study. The data collection tool will be a data capture sheet (see Annexure 1).

Data from the data capture sheets will be captured onto Microsoft Excel, where it will be backed up on external USB storage devices which will only be accessible to the principal investigator and supervisors of this study, members of the University of Cape Town and the Department of Family medicine as well as staff at the NHLS. The data will also be encrypted and password protected within Microsoft Excel to limit access to the principal investigator and supervisor upon request.

The same pre and post training questionnaire will be completed by all staff attending the training session. It is a closed ended questionnaire comprising of 20 questions and will be translated into one other language Afrikaans. The questionnaire was developed based on the NHLS phlebotomy training manual 2013. The questionnaire will be piloted by staff ordering blood investigations or involved in phlebotomy at Vanguard CHC.

3.8 Timeline

2013	**Mar - July**	• Formulation of research proposal
	Aug	• Submission to UCT Human Research Ethics Committee
	Sept - Nov	• Approval by UCT Human Research Ethics Committee
	Dec - Feb	• Data collection from data warehouse at NHLS in Johannesburg
2014	**Mar**	• Data capturing
	Apr- May	• Training of staff
	Jun - Aug	• Data collection from data warehouse at NHLS in Johannesburg after intervention introduced
	Sept	• Data capturing
	Oct	• Data Analysis
	Nov	• Article write-up and submission – Study supervisors
	Dec	• Feedback from study supervisors and apply corrections
2015	**Jan**	• Final submission for grading
	Feb – Apr	• Feedback • Dissemination of research findings to study participants and CHCs

4 Statistical and Data Analysis

4.1 Sample Analysis

The primary analysis method in this study will be the calculation of the proportion and corresponding confidence interval for the rejection rate from the retrieved data from NHLS. The required sample size was based on this proportion and achieving the desired precision in the 95% confidence interval. The power of the study will be set at 90% and the α value will be set at 0.05. A sample size of 742 is needed using the above power and α value and using the rejection rate of 7.3% from the pilot audit. Consecutive sampling of blood samples will be done to reach a minimum number of 742 samples. The number of rejected samples and subsequent rejection rate will be determined from this sample.

4.2 Data Analysis

Microsoft Excel™ will be used to capture the data and STATISTICA™ version 10 will be used to analyse the data.

The primary objective of the study is to determine whether training of staff is associated with a decrease in the rejection rate of adult blood samples in four CHCs in Cape Town.

A p-value of < 0.05 will represent statistical significance in hypothesis testing and 95% confidence intervals will be used to describe the estimation of unknown parameters.

5 Ethical and Legal Considerations

Patient/participant confidentiality will be maintained throughout the study. For the pre and post training audit, a waiver of consent will be requested as no patients will be directly involved or contacted. A study identity without any external meaning will be allocated to each record. Written consent will be obtained from all staff participating in the training programme (Annexure 3). Each participant in attendance at the training will complete the same pre and post training questionnaire and a number will be allocated to each questionnaire to protect the identity of the participant completing the questionnaire. All

staff participating in the study will be informed of the background, aims and objectives of the study. Permission will be obtained from the data warehouse of the NHLS in Johannesburg to obtain the number of samples received and rejected and reasons for blood sample rejection at the four CHC's in Cape Town. This information will only be provided once the study has gained ethics approval from the Human Research Ethics Committee (HREC) at the University of Cape Town.

6 Limitations

The study is limited by its retrospective design based on pre-collected records that may be incomplete. The study is only investigating the rejection rate and reasons for blood sample rejection at four CHCs in Cape Town and the interventions will only be instituted at these four facilities. The study will also be limited to CHCs and no district, secondary or tertiary hospitals will be included. The private sector will be excluded from the study.

All staff involved in phlebotomy might not have been exposed to the intervention as they may have been absent or sick on the days that training was done. The recruitment process of participants into this study as well as illegible or inconsistent results from NHLS may affect internal validity.

The training session will be done in English. The participant information leaflet and the study questionnaire will be made available in two languages, English and Afrikaans. A non – validated closed-ended questionnaire will used.

7 Resources

7.1 Available Resources

	Description	Source
1.	Statistical services	Centre for Statistical Consultation, University of Cape Town
2.	Travel Services	Principal Investigator
3.	Telephone Services	Principal Investigator
4.	Internet access and email facilities	Principal Investigator
5.	Access to Microsoft excel and Microsoft word	Principal Investigator
6.	Printing and copying	Principal Investigator

7.2 Budget

STUDY BUDGET				
March 2013 – December 2014				
Item	**Description**	**Unit cost**	**No. of units**	**Total cost**
1. Communication	Phone, internet, email	R100/month	8	R800.00
2. Travel to sites	Travel cost	R3.61/km	200	R722.00
3. Office supplies, printing, laminating, photos for posters	Printing	R0.40/page	1000	R400.00
4. Juice and snacks for Training	Eatables	R150	4	R600.00
5. Specialised services	Bio statistical services	No cost	10	
	Phlebotomist assisting with training	No cost		
	Dummy IV arms	R3100.00	1	R3100.00
	Phlebotomy equipment for demonstration	No cost		
TOTAL				R5622.00

8 Reporting and Implementation of Results

Once the study has been completed, the results of the study will be made available to all participants and members of the four CHCs where the study was conducted, members of the NHLS and the UCT division of Family Medicine as well as key provincial members responsible for decision making in the metro-district health services. The study will be published as a journal article and contribute to evidence based medicine and will serve as a platform for further research into strengthening laboratory health systems.

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ANNEXURE 1

DATA CAPTURE SHEET

No	No request form	Date& time of sample collection	No test specified on request form/ Illegible request	Patient Details	No specimen received by laboratory	Incorrect sample tube colour	Incorrect specimen type for test requested	Unlabelled specimen	Incorrect blood volume	Patients name on form and specimen not matching	Haemolysis	Age of specimen (>3 days)	Clotted specimen	Expired tube	Storage conditions	Other
1																
2																
3																
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ANNEXURE 2

THE INTERVENTION

Background:

Phlebotomy refers to the process of making an incision in a vein. It is associated with venipuncture which is the practice of collecting venous blood samples.[1]

Phlebotomy training is important as it provides the trainee with the necessary theoretical and practical knowledge in phlebotomy which will enable you to carry out your task effectively and confidently. The training also highlights the health and safety measures of phlebotomy. The training teaches the trainee the proper venipuncture technique to draw blood, the right way to control and handle materials including blood samples as well as phlebotomy equipment such as needles and syringes. [2]

The training session for the study will be approximately one to two hours long and will be conducted at each of the four identified CHCs (Mitchells Plain, Hanover Park, Heideveld and Maitland) at a pre-determined time which will be most convenient for the staff. It will be based on the "NHLS Western Cape Regional Laboratories Specimen Sampling Manual 2013". The manual is used as a guide to everyone involved in taking specimens that are sent to the NHLS. The diagnostic information from the laboratory is dependant on the adequacy and quality of the sample and request form received. All staff members who attends the training session will receive a copy of the "NHLS Western Cape Regional Laboratories Specimen Sampling Manual 2013".

A pre and post training questionnaire will be completed by each staff member who attends the training to see if their knowledge has improved post training.

Purpose:

The purpose of the phlebotomy training session is to equip nursing students, doctors and nurses in proper phlebotomy technique. It is not meant to teach trainees phlebotomy from scratch as trainees do have prior experience and many have been working at the CHCs for many years. It is meant to advise on proper technique, to address problems and concerns,

to add to existing knowledge and to strengthen skills. The content includes performance of safe and efficient work practices in obtaining adequate and correct blood specimens by venipuncture on adults[3], maintaining the integrity of the specimen in relation to the test to be performed, labelling specimens accurately and completely, promoting the comfort and well-being of the patient while performing blood collecting, checking the request form and phlebotomy equipment prior to drawing blood.

Exit level outcomes:

After completion of the training programme, the trainee should be able to correctly complete a sample request form and demonstrate the skills and knowledge to perform phlebotomy.

Specific outcomes:

On completion of this phlebotomy training programme, the trainee will be able to:

1. Understand the importance of correct completion of the sample request form.
2. Understand the equipment used for phlebotomy.
3. Demonstrate skills and knowledge necessary to perform phlebotomy.
4. Implement the “Criteria for specimen acceptability” with every blood sample drawn.

Lesson Plan:

Module: Phlebotomy training

Topic: Strengthening knowledge and skills related to phlebotomy

Venue: Flat carpeted room at community health centre

Facilitators: Dr M. Abbas; Phlebotomist from NHLS

Learning Aids:

1. Laptop
2. Projector screen
3. Table for snacks and drinks
4. Chairs for staff
5. "Dummy IV arms"
6. Phlebotomy equipment: request forms, sample tubes, syringes, needles, butterfly needles, luer adaptors.
7. Copy of "specimen sampling manual 2013" for each member in attendance.

Programme:

07:30 -08:00: Welcome staff, Introduction, discussion on common problems that staff are experiencing at CHC regarding anything related to phlebotomy. Interactive session to address concerns. Obtain informed consent for participation in study.

08:00 – 08:10: Very brief PowerPoint presentation. Background on why phlebotomy training is important and results of pilot audit at Vanguard CHC.

08:10- 08:25: Pre training questionnaire

08:25- 09:15: Training. Interactive session including opportunity to practice technique on "dummy IV arms". Address questions and concerns.

09:15 – 09:30: Questions and post training questionnaire

09:30: Snacks and closure

Assessment Criteria:

Trainees will be assessed using the same questionnaire pre and post training. There will be no pass mark. The score pre and post training will determine whether knowledge around phlebotomy has increased. Trainees will have an opportunity to practice their skills on the "dummy IV arms".

Instructors guide:

The training session will cover the following areas related to phlebotomy:[4]

1. **Introduction and general instructions**

   1.1. Equipment check before proceeding with venepuncture

   - correct request form for a CHC, enquire where the request forms are kept
   - butterfly needles, 23G best to use
   - green and black needles
   - 5ml and 10ml syringes
   - Webcols to clean skin
   - Luer adaptors
   - "bull dogs" with adaptors
   - Samples tubes of different colours
   - Sharps container
   - Tape and cotton wool for application to site of venepuncture
   - Gloves
   - Tourniquet

   1.2. Sample collection times by driver of NHLS

   Staff need to be aware of the daily collection times of blood samples and if there is a driver that collects samples after hours. Is the collection time documented by staff?

1.3. Sample storage conditions

Samples should be stored at room temperature at 15 - 30^{o}C, out of direct sunlight. All Purple top samples should reach the laboratory within 24 hours.

Full blood count (FBC), Potassium , Creatinine, INR and CD4 samples must be sent to the laboratory within 24 hours and can be kept in the fridge on a hot day while awaiting transport. Potassium must be processed by the laboratory within 8 hours from the time of sample collection to prevent a falsely elevated potassium reading. The fridge temperature must be set at a maximum temperature of 2-8^{o}C and samples should not be kept close to the freezer. Do not pour blood from one sample tube into another as this will also result in incorrect blood results.

Sample tubes (before blood is drawn) must NOT be kept in the fridge as this causes the red blood cells to rupture causing haemolysis when warm blood enters the cold sample tube.

1.4. Samples sent to different laboratories

If you are drawing blood which will be processed by two or more laboratories e.g. haematology (FBC) and chemical pathology (HBA1c), which both require purple top tubes then send two samples as specimens can get lost between laboratories or one sample tube might not have enough blood to process two tests. The test may then be rejected by the laboratory as “insufficient specimen” or “specimen not received by lab”

1.5. Record of bloods drawn and rejected

Does the facility keep a record of daily bloods drawn and rejected? How is this documented and what measures have been taken to improve the current system?

2. Technique for venepuncture and specimen handling:

2.1. Patient identification

Greet the patient and identify yourself and ensure that you are taking the correct patients blood.

2.2. Criteria for sample acceptability, the Modified "Abbas Tool" (see attached)

2.3. Order of draw of samples

Blood samples have to be drawn in the following order to avoid cross-contamination of additives between tubes.

- blood culture (this is not done at the CHC)
- yellow top
- blue top
- grey top
- purple top

2.4. Venepuncture site collection

The veins of choice are the median cubital and cephalic veins of the arm. Veins on the wrist and hands can also be used.

<u>Areas to avoid during venepuncture</u>:

- Scars from burns and previous surgery.
- Upper extremity on the side of a previous mastectomy as test results may be affected by lymphoedema.
- Haematoma – if this develops then choose another site or go distal to the haematoma.
- Intravenous therapy (IV) or blood transfusions – fluid dilutes the specimens and alters the test result. Samples should be collected from the opposite arm. Samples may be drawn below the IV site as follows:
    - Turn off IV for 2 minutes before venepuncture
    - Place tourniquet below IV site
    - Choose a suitable vein but not the vein where the IV is inserted.
    - Draw 5ml of blood from the selected vein and discard the blood.
    - Then draw the blood required for the sample tubes.
- Oedematous extremities – fluid in the tissues also alters test results.

Procedure for vein selection: if superficial veins are not easily seen or felt, massage the arm from wrist to elbow to force blood into the vein. Tapping the vein with one or two fingers and placing a warm damp cloth onto the vein for 5 minutes, lowering the extremity over a bed or chair also allows the veins to fill.

2.5. Performance of a venepuncture

The patient should be approached in a friendly manner, make the patient comfortable and explain what you are about to do.

- Ensure that blood is being drawn on the correct patient.
- Complete the request form correctly
- Position the patient correctly: patient should sit in chair, lie down or sit up in the bed. The arm should be hyperextended.
- Apply the tourniquet 3-4cm above the puncture site. Do not apply the tourniquet too tight. Do not leave the tourniquet on for more than 2 minutes.
- Use an alcohol preparation like webcol to prepare the patient's arm and clean in a circular manner, starting at the site and moving outward, allowing the area to air dry.
- Draw the patient's skin taut with your thumb and stabilise the vein. Ensure that the needle forms a 15-30 degree angle with the surface of the arm and insert the needle through the skin and into the lumen of the vein. Avoid trauma and probing.
- Release the tourniquet when the last sample tube is filling.
- The needle should be removed from the patient's arm in a swift backward motion
- Once the needle is removed, apply gauze pressing down firmly to avoid a haematoma.
- Do not ask the patient to bend the arm as the tension of the two muscles causes bruising.
- Dispose of all sharps in the sharps container

- Mix the tubes gently and label correctly placing the patient's sticker length wise on the tube and not over the cap. Do not pre-label sample tubes.
- Place collected samples in the appropriate collection box for collection by the driver to the NHLS.

2.6. Additional considerations.

2.6.1 Preventing a haematoma

- Only puncture the upper most wall of the selected vein.
- Remove the tourniquet before removing the needle.
- Use the major superficial veins.
- The needle must penetrate the upper most wall of the vein as partial penetration will cause blood to leak into the soft tissue surrounding the vein.
- Adequate pressure should be applied to the site of venepuncture.

2.6.2. Preventing haemolysis

- Mix tubes gently 8-10 times by gentle inversion, do not shake as this will cause haemolysis. Failure to mix adequately can result in the formation of a clot which may render the sample unsuitable for analyses.
- Do not draw blood from a haematoma.
- Do not draw the plunger back too forcefully when using a syringe and needle and avoid frothing the sample.
- Do not force blood into the sample tube, but allow the blood to run into the tube spontaneously when using a needle and syringe.
- When using a butterfly needle to draw blood, discard the butterfly needle and attach a new needle to the syringe and then transfer the blood into the sample tube.
- In patients with small veins, one can also use a butterfly needle with a luer adaptor and use the "bull dog" to obtain blood.
- Ensure that the site of venepuncture is dry.

- Avoid a traumatic venepuncture or probing.

2.6.3 Haemoconcentration

Factors that result in an increased concentration of larger molecules and formed elements in the blood include:

- Prolonged tourniquet time of more than 2 minutes.
- Massaging, squeezing or probing a site.
- IV therapy
- Sclerosed or occluded veins

2.7. Troubleshooting guidelines

Incomplete blood sample collection or no blood obtained:

- This is corrected by changing the position of the needle, moving it forward (needle might not be in lumen)or backwards (needle might have penetrated too far).
- Adjust the angle as the bevel of the needle may be against the wall of the vein.
- Loosen the tourniquet to ensure that there is no obstruction to blood flow.
- Use another sample tube as the previous one may have no vacuum.
- Re-stabilise the vein as it may have moved from the point of the needle and puncture site.

If blood stops flowing into the tube:

- This can occur if the vein collapses, re secure the tourniquet to increase venous filling.
- If this is unsuccessful then remove the needle and redraw from a different site.
- The needle may also have pulled out of the vein while switching sample tubes. The equipment should be held firmly with fingers against the patient's arm, the flange to be used as leverage when withdrawing and inserting tubes.

Other problems:

- If a hematoma forms under the skin at the puncture site, immediately release the tourniquet and withdraw the needle and apply firm pressure.
- If arterial blood is drawn instead of venous blood then apply pressure for 5 minutes.

References for intervention:

1. Phlebotomy. Available from: en.wikipedia.org/wiki/Phlebotomy. [Accessed 10 July 2013]

2. Importance of phlebotomy training. Available from: http://www.phlebotomycertification.co.uk/importance-of-phlebotomist-training/.[Accessed 10 July 2013]

3. Zivkovic C. Instructors guide for training phlebotomists. 2006. Available from: www.pte.idaho.gov/pdf/health/curriculum/phlebotomycurriculum.pdf

4. Quality Managemnet working group. The National Health Laboratory Service Specimen Sampling Manual 2013, version 7.

MODIFIED ABBAS TOOL:
Criteria for Specimen Acceptability

1. REQUEST FORM

- Name of facility
- Diagnosis
- Name of requesting doctor
- Date and time of sample collection
- Person who took specimen
- Test specified on request form
- Legible request
- Patient's details (first name & surname, folder no, age/DOB, sex)
- Correct specimen type for test requested
- Doctor's signature
- INR sample – working contact number of patient or doctor

2. SAMPLE

- Tube not expired (check expiry date on tube)/cracked
- Correct colour tube
- Labelled specimen (sticker placed lengthwise, NOT covering cap): First name and surname, folder no OR sticker if available
- Do not pre-label before drawing blood
- Patient's name on form and specimen matching
- Correct volume of blood (check volume required on tube)
- Gentle mixing of sample 8-10 times
- Sample tubes kept at room temperature, NO direct sunlight
- Samples kept at room temperature, IN FRIDGE if after hours

3. SAMPLE TRANSPORT

- Sealed packet
- Blood sample/s and request form of index patient in one packet

References:

1. Jacobsz LA, Zemlin AE et al. Chemistry and haematology sample rejection and clinical impact in a tertiary laboratory in Cape Town. Clin Chem Lab Med. 2011: 49(12): 2047-2050.
2. Lab informants: Anthony Williams, Sr. Petersen, Mogamed Davids, Almaree Kline at NHLS (August/September 2012).

Compiled by: Dr. M. Abbas (Family medicine registrar)

Supervised by: Dr. M. Namane (Senior Family Physician, Vanguard CHC)

ANNEXURE 3

PHLEBOTOMY QUESTIONAIRE 2013

DEMOGRAPHIC DATA:

Age:……..

Occupation:…….

Rank:…….

Years of experience in phlebotomy:……..

Read each question carefully and choose the correct answer. Make a "x" in the correct box.

1. It is important to check your phlebotomy equipment before proceeding with drawing blood.
   - ◯ True
   - ◯ False

2. Please circle the number that represents your confidence in drawing blood at your facility.

Not confident at all Very confident

1 2 3 4 5 6

3. A blood sample, if refrigerated should be stored at the following temperature to preserve the sample integrity.
   - ◯ 5 - 10^{o}C
   - ◯ 2 - 8^{o}C
   - ◯ 1 - 10^{o}C
   - ◯ 37 – 38 ^{o}C

4. Blood sample tubes should ideally be kept in the fridge.
   - ◯ True
   - ◯ False

5. CD4 blood samples once drawn should be kept in the fridge

◯ True

◯ False

6. The correct order of draw of blood samples are as follows:

◯ purple, yellow, blue, grey

◯ purple, blue, yellow, grey

◯ blue, purple, yellow, grey

◯ yellow, blue, grey, purple

7. Choose the correct option.

The following areas should be avoided when drawing blood except:

◯ scars from burns and previous surgery

◯ veins from the antecubital fossa

◯ blood from a haematoma

◯ site where an intravenous line is placed

◯ oedematous extremities

8. If a superficial vein is not easily seen/felt, you can:

◯ Ask the patient to elevate their arm for a few seconds

◯ Wash the patient's hand with cold water

◯ Tap the vein with one/two fingers and place a warm damp cloth onto the vein

◯ Gently massage the arm from the shoulder to the wrist

9. When drawing blood, the tourniquet should be placed:

◯ 1-2cm from the puncture site

◯ 5cm from the puncture site

◯ 3-4cm from the puncture site

◯ 6-8cm from the puncture site

PHLEBOTOMY QUESTIONAIRE 2013

10. The tourniquet should not be left on the arm for more than:

◯ 2 minutes

◯ 10 minutes

◯ 5 minutes

◯ 30 seconds

11. The angle of insertion of the needle into the patient's arm should be:

◯ 45^{o}

◯ $15 - 30^{o}$

◯ 90^{o}

◯ $10 - 20^{o}$

12. When should the tourniquet be released?

◯ while the first tube is filling

◯ 1 min after the last tube is filling

◯ when the last tube is filling

◯ immediately after the last tube is filled

13. Choose the correct option:

◯ Blood samples should be mixed vigorously atleast 8 times

◯ Blood samples should be mixed gently 8 -10 times

◯ Blood samples should be inverted atleast once

◯ Blood samples should be shaken to ensure adequate mixing of the sample

14. Factors that result in haemoconcentration include all of the following:

prolonged tourniquet time, squeezing a puncture site, intravenous therapy

◯ True

◯ False

15. A haematoma can be prevented by:

◯ Applying pressure to the puncture site

◯ Forcefully drawing back the plunger of the syringe until the blood starts frothing

◯ Removing the needle before removing the tourniquet

16. Which of the following results in blood sample rejection:

◯ Haemolysis

◯ No facility name on request form

◯ Cracked sample tube

◯ Some of the above

◯ All of the above

17. Haemolysis can be prevented by the use of a luer adaptor attached to a butterfly needle.

◯ True

◯ False

18. Samples should be transported in a sealed packet with one specimen per packet.

◯ True

◯ False

19. Blood samples should be kept out of direct sunlight.

◯ True

◯ False

20. Look at the blood sample and request form.

Would this sample be accepted or rejected by the laboratory?

◯ Accepted

◯ Rejected

[A completed request form and an expired sample tube will be provided, the correct answer to the question above will be: rejected as a result of an expired tube]

The staff are expected to know that they need to check the expiry date on the tube.

ANNEXURE 4

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: The development and implementation of a phlebotomy training session for primary health care workers and evaluating whether it is associated with a decrease in the rejection rate of blood samples sent to the laboratory.

REFERENCE NUMBER:	**ABBMUM001**
PRINCIPAL INVESTIGATOR:	**Mumtaz Abbas**
ADDRESS:	**University of Cape Town – School of Public Health and Family Medicine**
CONTACT NUMBER:	**082 491 9048/ 021 633 3250**

Good Day

My name is Dr. Mumtaz Abbas. I am a postgraduate student in the Department of Family Medicine at the University of Cape Town.

I would like to invite you to participate in a research project. Please read the information presented here and feel free to ask any questions. Also, your participation is entirely voluntary and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the Human Research Ethics Committee (HREC) at the University of Cape Town (HREC REF: 549/2013). The HREC is located at Room E52-24 Groote Schuur Hospital, Old Main Building, Observatory 7925. Contact no: 021 406 6338.

What is the research study all about?

There are many blood samples that are rejected at primary health care facilities, the cause of these rejections are related to phlebotomy technique. This study aims to

look at whether phlebotomy training is associated with a decrease in the rejection rate of blood samples sent to the laboratory.

This study will consist of a phlebotomy training session of approximately 2 hours and a pre and post training questionnaire, comprising of 20 questions which will evaluate your knowledge and experience of phlebotomy. The questionnaire will take 10-15 minutes to complete.

Will you benefit from taking part in this research?

You will benefit from the training by gaining additional knowledge and strengthening skills needed to conduct phlebotomy at primary health care facilities. Your patients will also benefit from the skills by improved phlebotomy technique and not having to return to the clinic for a repeat blood sample resulting in better patient and staff satisfaction.

Are there risks involved in your taking part in this research?

There are no risks involved if you take part in this study.

Who will have access to your study data?

The information obtained will be protected, and treated as confidential. The identity of all participants will remain anonymous. The only people who will have access to the data will be the three researchers: Dr Mumtaz Abbas, Dr Mosedi Namane and Dr Fidele Mukinda.

Will you be paid to take part in this study and are there any costs involved?

You will not be remunerated for participating in this study and will not incur any costs by participating in the study.

Declaration by participant

By signing below, I …… agree to take part in a research study entitled: **The development and implementation of a phlebotomy training programme for primary health care workers and evaluating whether it**

is associated with a decrease in the rejection rate of blood samples sent to the laboratory.

I declare that:

- I have read the information above and it is written in a language that I understand.
- I understand that my participation in this study is voluntary.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

Signed at (place) …… on (date) …….

…… ……..…..

Signature of participant **Signature of witness**

Dr. Mumtaz Abbas
Principal Investigator

ANNEXURE 5

INSTITUTION AUTHORISATION

TITLE OF THE RESEARCH PROJECT: **The development and implementation of a phlebotomy training session for primary health care workers and evaluating whether it is associated with a decrease in the rejection rate of blood samples sent to the laboratory.**

REFERENCE NUMBER:	**ABBMUM001**
PRINCIPAL INVESTIGATOR:	**Mumtaz Abbas**
ADDRESS:	**University of Cape Town – School of Public Health and Family Medicine**
CONTACT NUMBER:	**082 491 9048/ 021 633 3250**

To whom it may concern,

I …….. representing **Mitchells Plain / Heideveld / Maitland / Hanover Park / Vanguard Community Health Centre** in my capacity as **Family Physician** herewith authorize that this study be conducted in light of the principal investigator conducting a phlebotomy training session. I also herewith authorize the principal investigator to make use of patient records from the National Health Laboratory Service (NHLS) in order to obtain the rejection rate and reasons for blood sample rejection in order to conduct a audit to meet the aims and objectives of the research project.

It is accepted by the principal researcher that all legal and ethical aspects of this study will be considered and mitigated as outlined in the presented study proposal and adhered to at all times.

Signed at (*name of facility*) .....…….....…….On(date)…….....

....

Signature Print Name in full

ANNEXURE 6

RESEARCHER AND STAFF MEMBER CONFIDENTIALITY

TITLE OF THE RESEARCH PROJECT: The development and implementation of a phlebotomy training session for primary health care workers and evaluating whether it is associated with a decrease in the rejection rate of blood samples sent to the laboratory.

REFERENCE NUMBER:	**ABBMUM001**
PRINCIPAL INVESTIGATOR:	**Mumtaz Abbas**
ADDRESS:	**University of Cape Town – School of Public Health and Family Medicine**
CONTACT NUMBER:	**082 491 9048/ 021 633 3250**

I _____ understand and acknowledge that:

1. I shall respect and maintain the confidentiality of all discussions, deliberations, patient care records and any other information generated in connection with individual patient care, risk management and/or peer review activities.

2. It is my legal and ethical responsibility to protect the privacy, confidentiality and security of all medical records, proprietary information and other confidential information relating to the Provincial Government Western Cape Department of Health – The NHLS, the CHCs where the study will be conducted and its affiliates, including business, employment and medical information relating to our patients, members, employees and health care providers.

3. I shall only access or disseminate patient care information in the performance of my assigned duties and where required by or permitted by law, only with the express approval of my supervisor or designee. I shall make no voluntary disclosure of any discussion, deliberations, patient care records or any other patient care, peer review or risk management information, except to persons authorized to receive it.

4. I agree to discuss confidential information only in the work place and only for job related purposes and to not discuss such information outside of the work place or within hearing of other people who do not have a need to know about the information.

5. I understand that the law specially protects psychiatric and drug abuse records, and that unauthorized release of such information may make me subject to legal and/or disciplinary action.

6. My obligation to safeguard patient confidentiality continues after my termination of services with the principal investigator

I hereby acknowledge that I have read and understand the foregoing information and that my signature below signifies my agreement to comply with the above terms. In the event of a breach or threatened breach of the Confidentiality Agreement, I acknowledge that the University of Cape Town, its partners and affiliates involved in this study may, as applicable and as it deems appropriate, pursue disciplinary action via internal or external legal processes.

Signed at (*place*) .....…..…….. On ……...…….. 2013.

....

Signature Print Name in full

PART B: STRUCTURED LITERATURE REVIEW

a) Objectives of Literature Review

- To describe the role of health system performance in achieving millennium development goals
- To describe laboratory sample rejection rates and related-reasons
- To describe the impact of Phlebotomy Training on blood sample rejection

b) Literature Search Strategy

Databases include:

- Pubmed/Medline
- Scopus
- Ebsco
- Google Scholar

Keywords:

- Blood sample rejection, haemolysis, chemistry and haematology, rejection rate, Cape Town, Western Cape, South Africa, improving rejection rate
- Health systems research
- National Health Insurance, laboratory, rejected blood samples
- Millennium Development Goals
- Phlebotomy training

c) Literature Review

The role of laboratory medicine in achieving millennium development goals

The evaluation of the reasons for blood sample rejection and its impact on healthcare costs as well as costs to the staff and most importantly to the patient is a form of assessing health systems performance. This provides role players in the health system with policy options and practical information that can be used to improve the healthcare system performance. Role players vary from managers at primary care level to policy makers at a national level. Evaluation of health systems performance helps to improve the quality of health service delivery with the key feature being its link to decision making i.e. informing a decision within a health system in order to achieve its goal.[1]

The Commission on Health Research for Development identified international health research partnerships as vital to advancing health in developing countries and promoting global health equity.[2]The World Health Organisation (WHO) and global ministerial summits have subsequently linked health research to achieving the United Nations Millennium Development Goals (MDG's).[3,4]There is a lack of knowledge regarding the barriers in health systems that hinder the delivery of successful interventions and the strategies needed to overcome them.[5]Stronger health systems are vital to achieving improved health outcomes. A report by the WHO Task force on Health Systems Research says it is "essential to channel most resources to address the preparedness of health systems to delivering interventions".[5]

Strengthening health systems in developing countries is essential in improving healthcare globally and in reaching the MDG's. Most developing countries fall short of the requirements to implement the goals suggested by the WHO.[6] The following are important components, proposed by the WHO, in strengthening health systems and in achieving an effective public health system: service delivery, financing, governance, the health workforce, information systems and supply management systems.[7]

One of the main goals in strengthening health systems include improving clinical health laboratories[3] and this includes reducing the rejection of blood samples received by the laboratory.

A conference evaluating a programme for strengthening laboratory management was held in Africa in 2009. The highlights of this conference was to "act now, act collectively and act differently to ensure sustainability of global health efforts to enhance laboratory networks and systems"[8]Acting now involves addressing the 3 pillars for disease prevention, control, and patient management which include public health, clinical medicine, and laboratory medicine. The most neglected pillar in developing countries is laboratory medicine and this is vital in clinical decision making and for disease control. The increase in funding for global health development[9,10] provides an excellent opportunity to end the neglect of laboratory systems and services in global health in developing countries. Quality laboratory services and systems is important in strengthening health systems as laboratory medicine provides critical information that assists medical decision making for quality health care.[8]Acting collectively involves addressing laboratory strengthening in a holistic way and to form partnerships to support developing countries to strengthen laboratory systems. Acting differently involves recognising the importance of clear indicators in order to monitor progress in strengthening laboratory systems.[8]

The first international conference of the African Society for Laboratory Medicine (ASLM) was held in Cape Town, South Africa in December 2012. The focus of the conference was to strengthen national laboratory health systems. The outcomes of this conference was that it aimed to meet the following targets by the year 2020: "certification of 30,000 laboratory staff, the harmonisation in the regulation of diagnostics in Africa's five economic regions, the international accreditation of 250 laboratories, and the strengthening of an African Network of National Public Health Reference laboratories in 30 countries."[11]

Laboratory sample rejection, related-reasons and impact on patient care

Patient care and safety has become increasingly more important in laboratory medicine.[12]Clinical governance is a system where healthcare organisations are responsible for continuously improving the quality of services that positively impacts on patient care.[12,13] It is described as "a framework through which organisations are accountable to continue to improve the quality of the service and safeguard high standards of care by creating an environment in which excellence in clinical care would flourish".[14]

Clinical laboratories are striving to decrease the rejection rate of unsuitable blood samples and to provide an excellent level of care with more attention on patient care and safety.[13] The International Organization for Standardisation defines laboratory error as "failure of a planned action to be completed as intended, or use of a wrong plan to achieve an aim, occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them".[15]

The National Health Laboratory Service (NHLS) is the provider of laboratory services to all public sector hospitals in South Africa and certain requirements are necessary before a sample can be successfully processed. Majority of blood samples are rejected as a result of pre-analytical errors and this accounts for up to 70% of laboratory errors.[5]

Studies reported the following pre-analytical errors: Patient identification (labelling errors, no test specified on request form, illegible request, no ward specified); sample collection (clotting, insufficient volume or inadequate ratio of volume sample/anticoagulant, inappropriate sample container and haemolysis) and sample transport (storage conditions i.e. temperature, sample lost or not received by laboratory).[12,13]

The prevalence of pre-analytical problems ranged between 0.2% - 0.75% with the most common errors being haemolysis, clotting, insufficient blood volume, wrong sample tube and misidentification.[17] About 6.4% to 12% of patients received inappropriate care due to

laboratory errors, with up to 30% of errors resulting in patient discomfort, high hospital/healthcare costs as well as subjecting patients to re-sampling blood.[16]

In a recent retrospective audit conducted at Tygerberg hospital in Cape Town, 481 of 32 910 samples (1.46%) were rejected during the two week study period.[12]The main reasons for sample rejection were clotting (30%) and inadequate sample volume (22%).[12] Over half the samples were repeated. In the repeat sample, the average time for the sample to reach the laboratory was 5 days. Clinical impact of sample rejection on patient care was assessed in 30 patients whose hospital folders were randomly selected included: pre-operative unavailability of results, 4 of 30 (13.3%); delayed initiation of phototherapy, 2 of 30 (6.7%); delayed transfusion, 2 of 30 (6.7%), delayed laboratory evaluation of patient on admission, 3 of 30 (10%); no specific intervention, 18 of 30 (60%) and prolonged (unnecessary) treatment, 1 of 30 (3.3%).[12]

In the same audit discussed above, 98 out of 481 samples (20.3%) were rejected as a result of incorrect patient identification errors and 70 out of 481 samples (14.6%) were rejected as a result of sample transport errors.[12]

Haemolysis refers to the release of haemoglobin and intracellular components from erythrocytes into the surrounding plasma when the cell membrane is either damaged or disrupted.[18]Haemolysis account for 40-70% of all unsuitable blood samples sent to the laboratory and is much higher than any other causes such as clotted samples, incorrect blood volume, and incorrect sample tubes used. [18]Not all samples that are haemolysed are rejected by the laboratory, many samples can still be processed successfully except for electrolytes like potassium and other tests that are influenced by haemolysis.[18]

The low rate of repeating blood sample of rejected samples and delay in repeating the blood sample is also a concern as laboratory results can influence clinical decisions and inherent patient care.[19] Turnaround times in repeating rejected samples can improve with

access to the NHLS DISA Laboratory (DISALAB) on site where clinicians can check results during the current hospital visit.[12]

Critical values is defined as a "result suggestive of imminent danger to the patient unless appropriate therapy is promptly initiated".[20] Strategies need to be instituted in order to reduce pre-analytical errors. Promotion of an awareness of the significant clinical and economic impact of pre-analytical errors can help to improve this problem. An awareness can be created by communication between clinicians and laboratory staff, using the current guidelines available on specimen sampling and education of staff may increase the awareness of the problem at the facility we work.[21]

The impact of Phlebotomy Training on blood sample rejection

The quality of a service can be determined by evaluating the success with which a service is delivered.[22] Procedures that are deemed of high volume, high risk and expensive should be monitored by laboratories.[23]In primary health care centres, phlebotomy is considered a high volume and high risk procedure in terms of the volume of patients that require bloods drawn as well as the dangers of needlestick injuries to the healthcare provider and the consequences of incorrect phlebotomy technique as discussed previously. Phlebotomy can also be of high cost if blood samples are rejected due to various reasons. It has been shown that bloods drawn by trained laboratory personnel/phlebotomists have lower blood sample rejection rates when compared to health care workers who have not received training. Even with trained personnel; haemolysis, clotting and insufficient blood volume were the main causes for blood sample rejection.[21]

Laboratory medicine plays a vital role in everyday clinical practice as well as in the long term follow up of our patients. Only appropriate samples received by the laboratory can be analysed.[24] Programmes that evaluated laboratory quality has shown blood sample

rejection rates which vary from 0.3% in outpatient departments to 0.8% in hospital inpatients.[21]

A study conducted at a government hospital in Bhavnagar showed that incorrect phlebotomy technique was the main reason for blood sample rejection. In order to improve the quality of samples received by the laboratory, the authors of the above study suggest that phlebotomists and laboratory staff develop a manual on proper phlebotomy technique for provide health care providers.[24]

d) Summary or interpretation of literature

From the literature, it is clear that many blood samples are rejected in the pre analytical phase of laboratory testing with haemolysis and clotting being two of the main reasons for rejection. Patient identification errors and sample transport errors account for a minority of rejected blood samples. Many haemolysed samples are still processed by the laboratory despite this not being a good quality sample resulting in an underestimation of haemolysis as a cause for blood sample rejection. These reasons can be corrected by good phlebotomy technique which can be reinforced with a training manual and practical demonstration. It is important to reduce the rejection rate of laboratory blood in order to reduce the escalating costs to the laboratory, health care facility and the patient and to reduce patient discomfort.

One of the goals in strengthening health care systems in South Africa is to improve the functioning of clinical laboratories. This can be done by ensuring that good quality samples reach the laboratory and that staff are adequately trained by laboratory personnel on all aspects of phlebotomy that is required to ensure a sample of good quality.

Needs for further research

Further research should assess the effect of phlebotomy training on blood sample rejection rate as well as the cost of rejected blood samples at primary health facilities. The impact of rejected blood samples on patient care should also be evaluated. Another aspect which would be very informative would be to train a group of health care providers on proper phlebotomy technique, and then follow this group up pre and post training to assess whether the blood sample rejection rate reduced post phlebotomy training. This will help to motivate for formal training of health care workers prior to allowing them to draw bloods on patients.

A survey looking at patients' experiences of phlebotomy will provide insight into what patients feelings, fears and anxieties are regarding phlebotomy. One could also gain insight into patients' positive experiences of phlebotomy at primary health care facilities, what worked well as well as areas they feel should be improved on.

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PART C: MANUSCRIPT

The effect of Phlebotomy training on blood sample rejection and Phlebotomy knowledge of primary health care providers in Cape Town: A quasi-experimental study.

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Supplementary Material: Phlebotomy Questionnaire 2013 (Appendix A)

Abstract

Background:

There is an increasing amount of blood sample rejection at primary health care facilities (PHCFs) impacting negatively on the staff, facility, patient and laboratory costs.

Aim:

The primary objective was to determine the rejection rate and reasons for blood sample rejection at four PHCFs pre and post phlebotomy training. The secondary objective was to determine whether phlebotomy training improved knowledge amongst primary health care providers (HCPs) and to develop a tool for blood sample acceptability.

Study Setting:

Two Community Health Centres (CHCs) and two Community Day Centres (CDCs) in Cape Town.

Methods:

A quasi-experimental study design

Results:

The sample rejection rate was 0.79% (n= 60) at CHC A, 1.13% (n= 45) at CHC B, 1.64% (n= 38) at CDC C and 1.36% (n= 8) at CDC D pre training. The rejection rates remained approximately the same post training ($p>0.05$).

The same phlebotomy questionnaire was administered pre and post training to HCPs. The average score increased from 63% (95% CI 6.97 - 17.03) to 96% (95% CI 16.91 - 20.09) at CHC A (p 0.039), 58% (95% CI 9.09 – 14.91) to 93% (95% CI 17.64 – 18.76) at CHC B (p 0.006), 60% (95% CI 8.84 – 13.13) to 97% (95% CI 16.14 – 19.29) at CDC C (p 0.001) and 63% (95% CI 9.81 – 13.33) to 97% (95% CI 18.08 – 19.07) at CDC D (p 0.001).

Conclusion:

There is no statistically significant improvement in the rejection rate of blood samples ($p>0.05$) post training despite knowledge improving in all HCPs

($p <0.05$).

Introduction

There is an increasing amount of blood sample rejection at PHCFs which impacts negatively on the staff, facility, patient and laboratory and results in high healthcare costs. Patient care and safety has become increasingly more important in laboratory medicine.[1] Clinical laboratories have a big role to play in the management and diagnosis of patients.[2] Clinical laboratories are striving to reduce the rejection rate of unsuitable blood samples and to provide an excellent level of care with more attention on patient care and safety.[3,4]

Approximately 70 to 80% of diagnoses are made in conjunction with laboratory tests. A delay in laboratory test results may result in delayed diagnoses, inappropriate or unnecessary treatment, increased risk to patient safety, high healthcare costs and time lost.[5] The National Health Laboratory Service (NHLS) provides laboratory services to all public sector hospitals in South Africa and certain requirements are necessary before a sample can be successfully processed. There are three main phases to the testing of blood samples at the laboratory and these include the pre-analytical, analytical and post analytical phase. The pre-analytical phase includes all steps from the time the clinician orders a test to the time the test is analysed; the analytical phase refers to the analysis of the sample and the post analytical phase refers to the reporting and interpretation of the test result.[6]

Studies reported the following pre-analytical errors: Patient identification (labelling errors, no test specified on request form, illegible request, no ward specified); sample collection (clotting, insufficient blood volume, inappropriate sample container, haemolysis) and sample transport (storage conditions i.e. incorrect temperature, sample lost or not received by the laboratory).[1,3]

Majority of blood samples are rejected as a result of pre-analytical errors and this accounts for up to 70% of laboratory errors.[7,8,9] The prevalence of pre-analytical problems ranged between 0.2% and 0.75% with the most common errors being haemolysis, clotting, insufficient blood volume, wrong sample tube and misidentification.[17] 6.4% to 12% of patients received inappropriate care due to laboratory errors, with up to 30% of errors resulting in patient discomfort, high hospital/healthcare costs as well as subjecting patients to re-sampling blood.[10]

A pilot audit at Vanguard CHC in August 2012 (unpublished) showed that blood sample rejection is predominantly related to incorrect phlebotomy technique. This contributes significantly to pre-analytical errors, as primary health care nurses do not receive formal phlebotomy training as part of their undergraduate training.

In a recent retrospective audit conducted at Tygerberg hospital in Cape Town, 481 of 32 910 samples (1.46%) were rejected during the two week study period.[1]The main reasons for sample rejection were clotting (30%) and inadequate sample volume (22%).[1] Over half the samples were repeated and the average time for the sample to reach the laboratory was 5 days.

Haemolysis refers to the release of haemoglobin and intracellular components from erythrocytes into the surrounding plasma when the cell membrane is either damaged or disrupted.[11] Haemolysis accounts for 40 to 70% of all unsuitable blood samples sent to the laboratory. [11] Not all haemolysed samples are rejected by the laboratory, many samples can still be processed successfully except for electrolytes like potassium and other tests that are influenced by haemolysis.[1]

The low rate of repeating blood samples of rejected samples and the delay in repeating the blood sample is also a concern as laboratory results can influence clinical decisions and inherent patient care.[12] Turnaround times in repeating rejected samples can improve with access to the NHLS DISA Laboratory (DISALAB) on site where clinicians can check results during the current hospital visit.[1]

The evaluation of the reasons for blood sample rejection and its impact on healthcare costs as well as costs to the staff and most importantly to the patient is a form of assessing health systems performance. This provides role players in the health system with policy options and practical information that can be used to improve the healthcare system performance.[13] One of the goals in strengthening health care systems in South Africa is to improve the functioning of clinical laboratories. [14]This can be done by ensuring that good quality samples reach the laboratory and that staff are adequately trained by laboratory personnel on all aspects of phlebotomy that is required to ensure a sample of good quality.

The quality of a service can be determined by evaluating the success with which a service is delivered.[15] Procedures that are deemed of high volume, high risk and expensive should be monitored by laboratories.[16] In primary health care centres, phlebotomy is considered a high volume and high risk procedure in terms of the volume of patients that require bloods drawn as well as the dangers of needle stick injuries to HCPs and the consequences of incorrect phlebotomy technique.

Phlebotomy can also be of high cost if blood samples are rejected due to various reasons. It was found that bloods drawn by trained laboratory personnel/phlebotomists have lower blood sample rejection rates when compared to

HCPs who have not received training (99.6% success vs 97.9%; p 0.002). Even with trained personnel; haemolysis, clotting and insufficient blood volume were the main causes for blood sample rejection.[17]

Laboratory medicine plays a vital role in everyday clinical practice as well as in the long term follow up of our patients. Only appropriate samples received by the laboratory can be analysed.[18] Programmes that evaluated laboratory quality has shown blood sample rejection rates vary from 0.3% in outpatient departments to 0.8% in hospital inpatients.[17]

A study conducted at a government hospital in Bhavnagar showed that incorrect phlebotomy technique was the main reason for blood sample rejection. In order to improve the quality of samples that reach the laboratory, the authors of the above study suggest that phlebotomists and laboratory staff develop a manual on proper phlebotomy technique for HCPs.[18]

Aims and Objectives

The aim was to assess the effect of phlebotomy training on blood sample rejection rate and knowledge among primary HCPs at four facilities in Cape Town.

The primary objective of this study was to determine the rejection rate and reasons for blood sample rejection at four selected primary health care facilities pre and post phlebotomy training. The secondary objective was to determine whether phlebotomy training improved phlebotomy knowledge among primary HCPs and to develop a tool for blood sample acceptability.

Study design and methods

Study design:

We performed a quasi-experimental study where we measured HCPs knowledge on phlebotomy technique and laboratory blood sample rejection rates before and after a phlebotomy training programme. All blood samples received and rejected by the NHLS during the month of May 2014 (pre training) and July 2014 (post training) were included in the study. Any sample processed by the laboratory that was not blood was excluded from the study.

Intervention:

The phlebotomy training programme was developed based on the "NHLS Western Cape Regional Laboratories Specimen Sampling Manual 2013". The programme was developed using the information in the manual regarding health and safety measures of phlebotomy, proper venepuncture technique, the correct way to handle blood samples and phlebotomy equipment such as needles and syringes, the correct storage and transport of blood samples as well as the correct completion of the NHLS sample request form.

Selected HCPs were assigned to receive phlebotomy training as our intervention of interest. The phlebotomy training session was approximately two hours long and was conducted at each of the four facilities (CHC A, CHC B, CDC C and CDC D) at a pre-determined day and time during the month of June 2014. All HCPs who attended the training session received a copy of the "NHLS Western Cape Regional Laboratories Specimen Sampling Manual 2013".

The same pre and post training questionnaire was completed by each HCP in attendance at the training to assess if their knowledge had improved post training. There was no pass mark however pre and post training scores determined whether knowledge around phlebotomy increased.

Setting:

The study was a multicentre study performed at four facilities in Cape Town, two 24 hour CHCs (CHC A and B) and two 8 hour CDCs (CDC C and D).

A community health facility (CHC and CDC) is a public primary health care facility funded by the government. It provides health care that covers a range of health promotion, disease prevention, curative and rehabilitative services to the community.[19,20]

The facilities included CHC A and B, which were large 24h hour facilities serving between 150 000 and 300 000 patients [21,22] and CDC C and D, which were smaller 8 hour facilities serving between 30 000 and 35 000 patients.[23]

Study population and sampling strategy:

The HCPs for the two hour phlebotomy training session were recruited by seeking their permission through the assistance of the facility managers and family physicians of the four facilities. Convenience sampling of HCPs were done, five HCPs from CHC A, seven from CHC B, seven from CDC C and four from CDC D. These HCPs were trained as trainers.

Data collection:

The data for May 2014 (pre training) and July 2014 (post training) were extracted from the NHLS DISALAB at the data warehouse in Johannesburg. The data was captured into Microsoft® Excel®. The variables extracted included the total number of routine blood samples performed, the number of blood samples rejected, the name of the test that was rejected (e.g full blood count) and the reason for rejected blood sample (e.g. clotted sample).

Data from the data capture sheets were captured onto Microsoft Excel, was backed up on an external USB storage device which was only accessible to the principal investigator and research team. The data was encrypted and password protected within Microsoft Excel.

A questionnaire with 20 closed ended questions (see Appendix A) was developed based on the NHLS phlebotomy training manual 2013 and input from experts working in PHCFs. The questionnaire was piloted by staff ordering blood investigations or involved in phlebotomy at Vanguard CHC and amended where necessary. The questionnaire was either in English or Afrikaans.

Data Analysis:

STATISTICA™ version 14 was used for data analysis. The summary statistics was used to describe the variables. A test of proportion was performed to assess the effect of the intervention on the rejection rate of blood samples before and after training. The pre and post training questionnaire scores were analysed using the

Wilcoxon signed-rank test for non-parametric paired data. A p-value of < 0.05 represented statistical significance

Ethical considerations:

This study has been approved by the Health Research Ethics Committee (HREC) of the University of Cape Town (HREC REF: 549/2013) as well as by the Provincial Government of the Western Cape (REF: 2013RP190). The study was conducted according to the Declaration of Helsinki.

Results

Approximately six to ten HCPs participated at these different sites. There were 23 study participants (Table 1) who attended the phlebotomy training session across all the facilities, mostly aged between 30 to 50 years. There was only one male participant and twenty two females. There were three student nurses, seventeen nurses and only three doctors. The phlebotomy experience across participants varied, with nine participants having less than five years' experience, five having five to ten years' experience and nine having more than 30 years' experience.

Box 1 describes the tool that was developed to facilitate the training listing all the criteria for laboratory blood sample acceptability.

Table 1: Demographic data of study participants across all four clinics

Category	Participants' n (%)
Rank	
- Student Nurse	3 (13)
- Nurse	17 (74)
- Doctor	3 (13)
Sex	
- Male	1 (5)
- Female	22 (95)
Age	
- <30 years	7 (30)
- 30 – 50 years	9 (39)
- >50 years	5 (22)
- Unknown	2 (9)
Phlebotomy Experience	
- <5 years	9 (39)
- 5 – 10 years	5 (22)
- >10 years	9 (39)

299 Box 1: ABBAS tool©

1. REQUEST FORM
• **Name of facility** • **Diagnosis** • **Name of requesting doctor** • **Date and time of sample collection** • **HCP who took sample** • **Test specified on request form** • **Legible request** • **Patient's details (first name & surname, folder no, age/DOB, sex)** • **Correct sample type for test requested** • **Doctor's signature** • **INR sample – working contact number of patient or doctor**
2. SAMPLE
• **Tube not expired (check expiry date on tube)/cracked** • **Correct colour tube** • **Labelled sample (sticker placed lengthwise, NOT covering cap): First name and surname, folder number OR sticker if available** • **Do not pre-label before drawing blood** • **Patient's name on form and sample matching** • **Correct volume of blood (check volume required on tube)** • **Gentle mixing of sample 8-10 times** • **Sample tubes kept at room temperature, NO direct sunlight** • **Samples kept at room temperature, IN FRIDGE if after hours**
3. SAMPLE TRANSPORT
• **Sealed packet** • **Blood sample/s and request form of index patient in one packet**

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301 ABBAS tool© compiled by: Drs Abbas, Namane and Mukinda

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The total number of blood samples included in the study during May 2014 (pre training): 7557 from CHC A, 3973 from CHC B, 2321 from CDC C and 589 from CDC D. The total number of blood samples included in the study during July 2014 (post training): 10218 from CHC A, 4114 from CHC B, 2279 from CDC C and 630 from CDC D.

During the month of May 2014 (Table 2): 60 of 7557 blood samples (0.79%) were rejected pre training at CHC A and 79 of 10218 blood samples (0.77%) post training (p 0.971). CHC A is the largest of the four facilities. Only eight of 589 blood samples (1.36%) were rejected pre training at CDC D and seven of 630 blood samples (1.11%) post training (p 0.696). CDC D is the smallest of the four facilities.

Table 2: Rejection rate of blood samples pre and post phlebotomy training

Pre Phlebotomy Training May 2014			**Post Phlebotomy Training July 2014**		
CHC/CDC	Blood Registrations	Blood Rejections n (%)	Blood Registrations	Blood Rejections n (%)	P value
A	7557	60 (0.79)	10218	79 (0.77)	0.876
B	3973	45 (1.13)	4114	48 (1.17)	0.886
C	2321	38 (1.64)	2279	37 (1.62)	0.971
D	589	8 (1.36)	630	7 (1.11)	0.696

The reasons for blood sample rejection were grouped into four main categories including technique related, knowledge related, request form related and unaccountable pre-analytical errors. Technique related errors include samples that were clotted or haemolysed. Knowledge related errors include errors due to incorrect blood volume or the incorrect blood sample tube used. Request form errors include any error in the completion of the request form such as no patient details

indicated, illegible requests, name on sample tube and request form unmatched, no test requested or an unlabelled sample. Unaccountable pre-analytical errors include all errors that are not accounted for by the above but that occur in the pre-analytical phase of laboratory testing of blood samples. These include samples with missing rejection reasons, samples older than three days, samples that leaked in transit as well as samples that were not received by the laboratory.

Table 3 provides a detailed summary of rejection rates and related-reasons by facility. At CHC A, many samples were rejected due to clotting, 20 (0.26%) were rejected pre training and 16 (0.16%) post training (Table 3). Request form errors improved post training from 11 (0.15%) pre training to eight (0.08%) post training. There was an increase in the rejection rate of samples due to unaccountable pre-analytical errors, 17 (0.22%) pre training to 27 (0.26%) post training (Figure 1).

At CHC B, knowledge related errors reduced from 16 (0.40%) rejected samples pre training to nine (0.22%). Twelve samples (0.16%) were rejected due to 'incorrect sample tube'. This was reduced by half (0.15%) post training. However all other reasons for blood sample rejection increased post training (Figure 2).

At CDC C, many samples were rejected due to clotting pre and post training with the rejection rate increasing post training. Knowledge related errors reduced from five (0.02%) rejected samples pre training to three (0.13%). Request form errors doubled from three (0.13%) rejected samples pre training to six (0.26%). Unaccountable pre-analytical errors, due to 'age of sample>3 days' also contributed to many of the sample rejection, 11 (0.04%) rejected samples pre training and seven (0.31%) post training (Figure 3).

CDC D is a smaller 8 hour facility compared to CDC C and only had four out of 589 (0.68%) samples rejected due to clotting pre training, which was reduced to two (0.32%). Unaccountable pre-analytical errors reduced by half post training. There were no request form errors pre or post training (Figure 4).

The overall rejection rate, irrespective of facility, showed an increase in the rejection rate post training, which was not statistically significant ($p > 0.05$) (Table 4).

370 Table 3: Rejection rate and reasons for blood sample rejection pre and post
371 phlebotomy training by facility

	Pre Phlebotomy Training May 2014 n (%)				**Post Phlebotomy Training July 2014 n (%)**			
Reasons for rejection	CHC A	CHC B	CDC C	CDC D	CHC A	CHC B	CDC C	CDC D
Technique related	**20 (0.26)**	**8 (0.20)**	**15 (0.65)**	**4 (0.68)**	**20 (0.20)**	**15 (0.36)**	**18 (0.79)**	**2 (0.32)**
- clotted	20 (0.26)	7 (0.18)	15 (0.65)	4 (0.68)	16 (0.16)	14 (0.34)	16 (0.70)	2 (0.32)
- haemolysed	0	1 (0.01)	0	0	4 (0.04)	1 (0.02)	2 (0.09)	0
Knowledge related	**12 (0.16)**	**16 (0.40)**	**5 (0.02)**	**0**	**24 (0.23)**	**9 (0.22)**	**3 (0.13)**	**3 (0.48)**
- incorrect blood volume	5 (0.07)	4 (0.10)	2 (0.09)	0	8 (0.08)	3 (0.07)	1 (0.04)	1 (0.16)
- incorrect sample tube	7 (0.09)	12 (0.30)	3 (0.13)	0	16 (0.16)	6 (0.15)	2 (0.09)	2 (0.32)
Request form errors	**11 (0.15)**	**11 (0.28)**	**3 (0.13)**	**0**	**8 (0.08)**	**12 (0.29)**	**6 (0.26)**	**0**
- name on form and sample unmatched	3 (0.04)	1 (0.03)	1 (0.04)		4 (0.04)	4 (0.10)	0	
- no patient details	1 (0.01)	0	0		0	0	0	
- no test requested	1 (0.01)	3 (0.08)	1 (0.04)		2 (0.02)	0	1 (0.04)	
- illegible request	1 (0.01)	0	0		0	0	0	
- unlabelled sample	5 (0.07)	3 (0.08)	0		2 (0.02)	5 (0.12)	3 (0.13)	
- no reason stated	0	4 (0.10)	1 (0.04)		0	3 (0.07)	2 (0.09)	
Unaccountable pre-analytical errors	**17 (0.22)**	**10 (0.25)**	**15 (0.65)**	**4(0.68)**	**27 (0.26)**	**12 (0.29)**	**10 (0.44)**	**2 (0.32)**
- no reason stated	11 (0.15)	0	0	0	18 (0.18)	0	0	1 (0.16)
- sample leaked	2 (0.03)	0	0	0	1 (0.01)	1 (0.02)	0	0
- no sample received	1(0.01)	2(0.05)	4(0.17)	4(0.68)	5 (0.05)	6 (0.15)	3 (0.13)	1 (0.16)
- age of sample >3 days	3 (0.03)	8 (0.20)	11 (0.04)	0	3 (0.03)	5 (0.12)	7 (0.31)	0

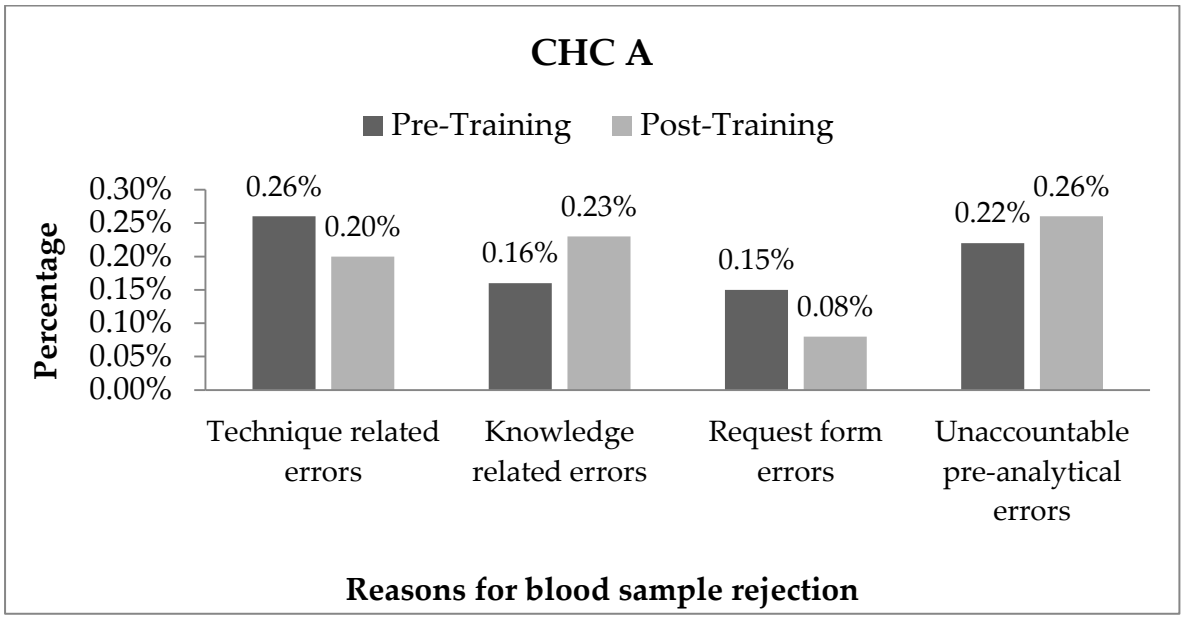

Figure 1: The rejection rate at CHC A

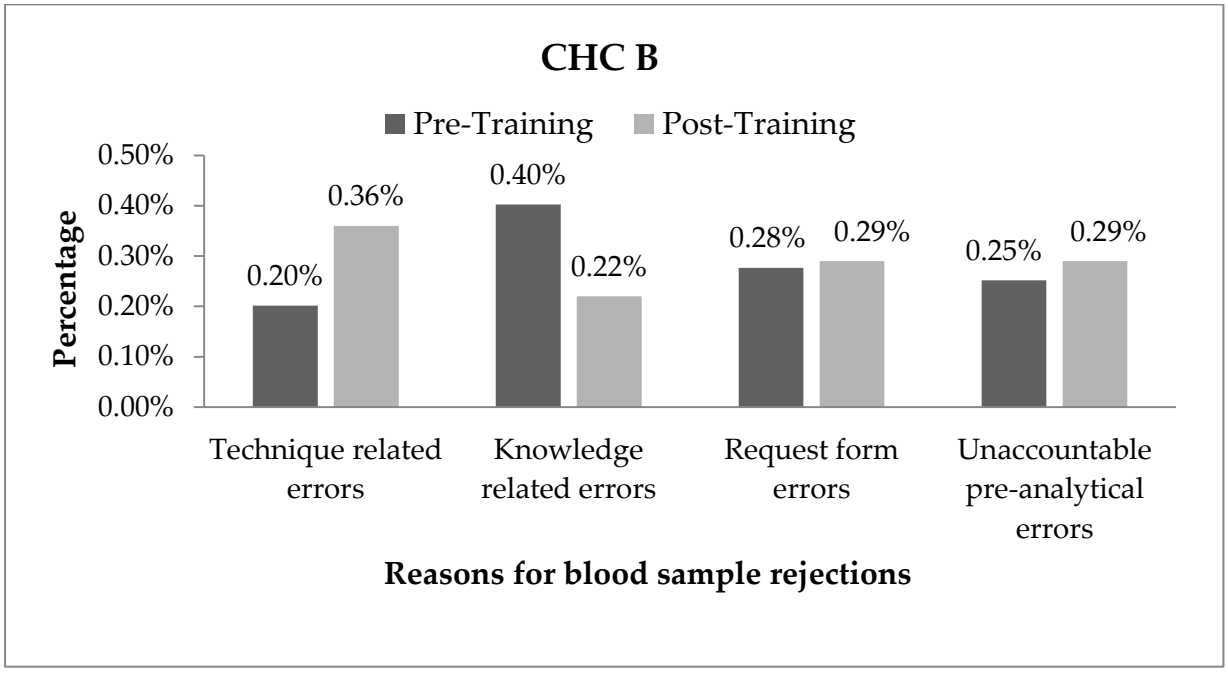

Figure 2: The rejection rate at CHC B

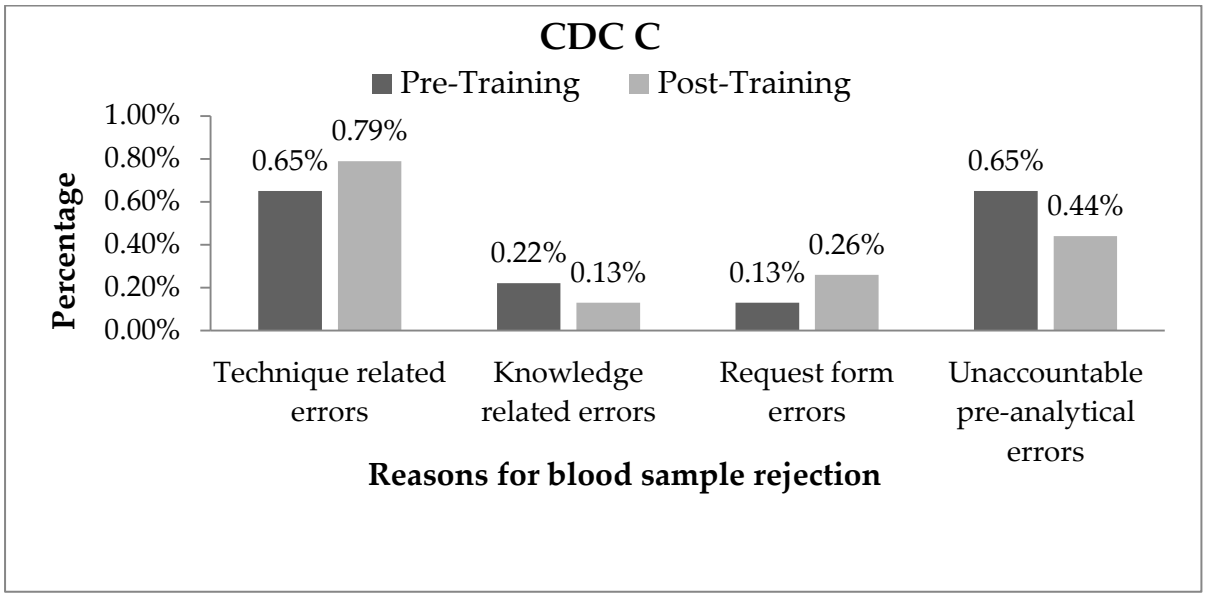

Figure 3: The rejection rate at CDC C

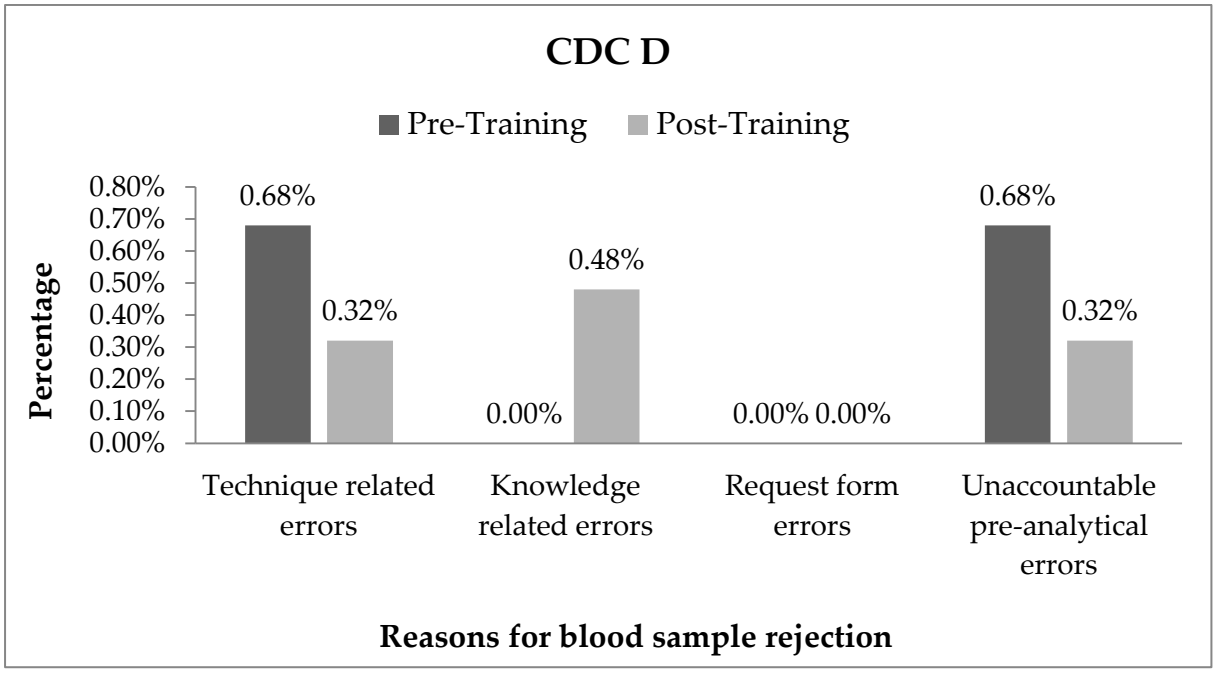

Figure 4: The rejection rate at CDC D

Table 4: Overall rejection rates and related reasons for all facilities combined

	Pre Phlebotomy Training May 2014	**Post Phlebotomy Training July 2014**		
Related reason for rejection	Rejection Rate n (%)	Rejection rate n (%)	P value	95% Confidence Interval
Technique related	47 (0.33%)	55 (0.32%)	0.38	-8 to 4
Knowledge related	33 (0.23%)	39 (0.23%)	0.74	-14.39 to 11.39
Request form errors	25 (0.17%)	26 (0.15%)	0.85	-4.23 to 3.73
Unaccountable pre-analytical errors	46 (0.32%)	51 (0.30%)	0.73	-11.59 to 9.09

The pre and post training questionnaire scores showed an improvement in Phlebotomy knowledge post training as the average percentage score increased across all clinics. The average score increased from 63% (95% CI 6.97 - 17.03) to 96% (95% CI 16.91 - 20.09) at CHC A (p 0.039), 58% (95% CI 9.09 – 14.91) to 93% (95% CI 17.64 – 18.76) at CHC B (p 0.006), 60% (95% CI 8.84 – 13.13) to 97% (95% CI 16.14 – 19.29) at CDC C (p 0.001) and 63% (95% CI 9.81 – 13.33) to 97% (95% CI 18.08 – 19.07) at CDC D (p 0.001).

Participants were asked to grade their level of confidence in phlebotomy on a Likert scale from 1 to 6, with 1 being 'not confident at all' and 6 being 'very confident'. All participants' level of confidence either remained the same or increased post phlebotomy training (Figure 5).

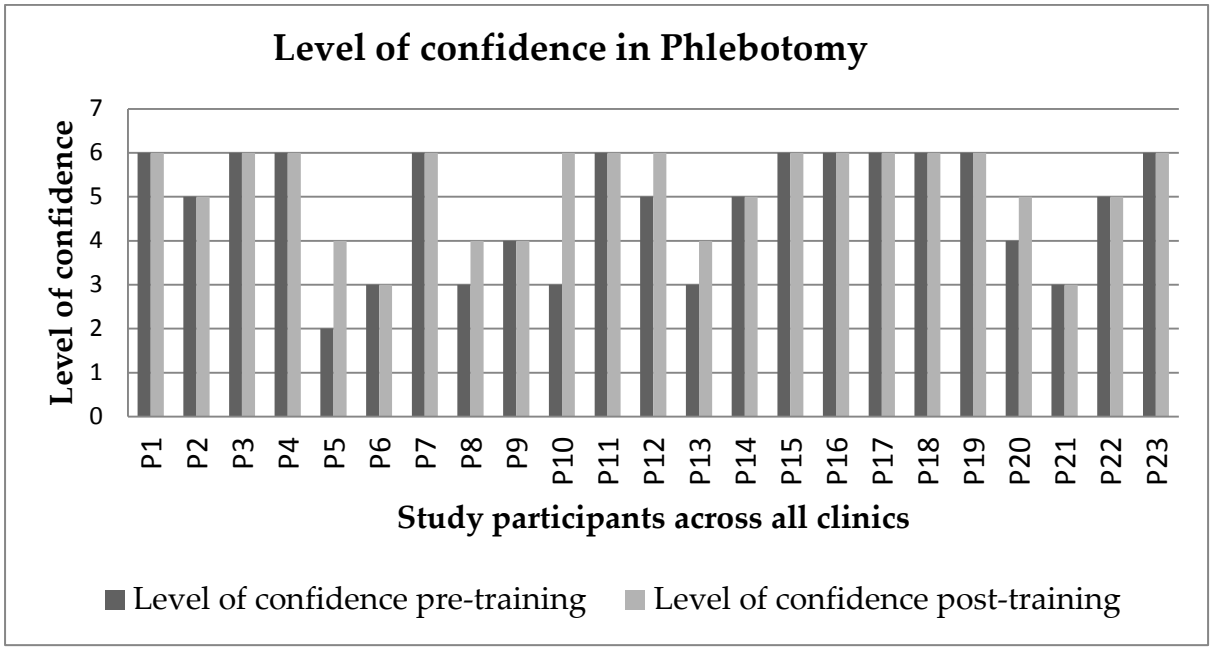

Figure 5: Level of confidence in Phlebotomy across all clinics pre and post training using a Likert Scale

Discussion

The study found that an appropriate intervention such as phlebotomy training has improved knowledge regarding phlebotomy ($p < 0.05$). The study results show no statistically significant improvement in the rejection rate of blood samples sent to the laboratory by each of the four PHCFs ($p > 0.05$) post phlebotomy training. The overall rejection rate also showed no statistical significance in the rejection rate post training ($p > 0.05$).

The sample rejection rate was 0.79% at CHC A, 1.13% at CHC B, 1.64% at CDC C and 1.36% at CDC D pre-training. The rejection rates remained approximately the same post training. This could possibly be explained by other factors not explored in this quasi-experimental study. These factors include the phlebotomy experience of the primary HCPs, the same group of participants who received training were not followed up and participants who did not receive training were involved in phlebotomy post training which may have affected the study results.

A large number of the blood samples in this study were rejected due to clotting which was also seen in a similar study in 2011 at Tygerberg hospital.[1]Pre-analytical errors is a major concern for laboratories accounting for up to 70% of laboratory errors[4] hence the need for a sustainable intervention to improve such errors. However, despite haemolysis being a leading cause of blood sample rejection accounting for up to 70% of unsuitable samples[11], this was not the leading cause of sample rejection in this study. From the overall rejection rates (Table 4), the leading cause of sample rejection was clotting which is related to phlebotomy technique, followed by unaccountable pre-analytical errors. It is difficult to correct unaccountable pre-analytical errors, since we do not always know why and how these errors occur.

Since approximately 60% of clinical decisions are influenced by laboratory results[12], an improvement in the rejection rate by improving pre-analytical errors should improve patient care. Apart from the impact that rejected blood samples has on patient care in terms of the patient's management, it also has a financial impact on the facility as well as causing pain and emotional harm to the patient.[24]

It was interesting that there was only 1 male participant out of the 23 participants. Only three out of 23 participants were doctors. This may be due to the high patient volumes and insufficient time to attend a two hour training programme, or they may not feel they will learn something new as phlebotomy training is part of the undergraduate training programme as a medical student. For each of the 23 participants, the pre and post training questionnaire scores improved. All participants' level of confidence had improved or remained the same.

Strengths and limitations

HCPs who did not participate in the training were involved in blood sample collection post training which may have adversely affected the study results. Reasons for some of the rejected blood samples were not provided in the NHLS database. There is also an underestimation of haemolysis as a cause of blood sample rejection as many haemolysed samples are still processed and only the potassium is rejected, therefore the rejection rate might be higher than reported on in this study.

Implications or recommendations

Increased knowledge in phlebotomy does not in itself influence practice. We recommend that primary HCPs receive phlebotomy training in order to reduce the rejection rate of laboratory blood samples and that any training at primary level facilities be accompanied by support from managers and that regular monitoring and evaluation of systems be done. The above recommendation is supported by similar audits conducted at other PHCFs.[25,26]

Conclusion

The study results show no statistically significant improvement in the rejection rate of blood samples sent to the laboratory by each of the four PHCFs ($p>0.05$) post phlebotomy training despite phlebotomy knowledge improving in all HCPs ($p < 0.05$).

Acknowledgments

The NHLS with special reference to Mr. Mogamed Davids and the Data Warehouse in Johannesburg for assisting with accessing data. Sister Petersen of the Cape Town NHLS is thanked for assisting with phlebotomy training. Dr Tasneem Allie and Dr Mireille Porter is thanked for their assistance with data analysis.

Competing interests

The authors declare that they have no financial or personal relationship(s) with the NHLS and the four study sites that may have inappropriately influenced them in writing this article.

Authors' contributions

MA (M.Med in Family Medicine student, University of Cape Town) was the principal investigator of the study and responsible for conception, data acquisition, data analysis and drafting of the manuscript. MN (University of Cape Town) was the main supervisor for the study. FKM (Stellenbosch University) was the co-supervisor for the study. All authors made substantial contributions to the

conception, design, data analysis and interpretation of the results. All authors read and critically revised the draft and approved the final manuscript.

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Appendix A

PHLEBOTOMY QUESTIONAIRE 2013

DEMOGRAPHIC DATA:

Age:……..

Occupation:…….

Rank:…….

Years of experience in phlebotomy:……..

Read each question carefully and choose the correct answer. Make a "x" in the correct box.

6. It is important to check your phlebotomy equipment before proceeding with drawing blood.
   - ◯ True
   - ◯ False

7. Please circle the number that represents your confidence in drawing blood at your facility.

Not confident at all Very confident

1 2 3 4 5 6

8. A blood sample, if refrigerated should be stored at the following temperature to preserve the sample integrity.
   - ◯ 5 - 10^0C
   - ◯ 2 - 8^0C
   - ◯ 1 - 10^0C
   - ◯ 37 – 38 ^{0}C

9. Blood sample tubes should ideally be kept in the fridge.
   - ◯ True
   - ◯ False

10. CD4 blood samples once drawn should be kept in the fridge

◯ True

◯ False

6. The correct order of draw of blood samples are as follows:

◯ purple, yellow, blue, grey

◯ purple, blue, yellow, grey

◯ blue, purple, yellow, grey

◯ yellow, blue, grey, purple

7. Choose the correct option.

The following areas should be avoided when drawing blood except:

◯ scars from burns and previous surgery

◯ veins from the antecubital fossa

◯ blood from a haematoma

◯ site where an intravenous line is placed

◯ oedematous extremities

8. If a superficial vein is not easily seen/felt, you can:

◯ Ask the patient to elevate their arm for a few seconds

◯ Wash the patient's hand with cold water

◯ Tap the vein with one/two fingers and place a warm damp cloth onto the vein

◯ Gently massage the arm from the shoulder to the wrist

9. When drawing blood, the tourniquet should be placed:

◯ 1-2cm from the puncture site

◯ 5cm from the puncture site

◯ 3-4cm from the puncture site

◯ 6-8cm from the puncture site

10. The tourniquet should not be left on the arm for more than:

◯ 2 minutes

◯ 10 minutes

◯ 5 minutes

◯ 30 seconds

11. The angle of insertion of the needle into the patient's arm should be:

◯ 45^0

◯ 15 - 30^0

◯ 90^0

◯ 10 -20^0

12. When should the tourniquet be released?

◯ while the first tube is filling

◯ 1 min after the last tube is filling

◯ when the last tube is filling

◯ immediately after the last tube is filled

13. Choose the correct option:

◯ Blood samples should be mixed vigorously atleast 8 times

◯ Blood samples should be mixed gently 8 -10 times

◯ Blood samples should be inverted atleast once

◯ Blood samples should be shaken to ensure adequate mixing of the sample

14. Factors that result in haemoconcentration include all of the following:

prolonged tourniquet time, squeezing a puncture site, intravenous therapy

◯ True

◯ False

15. A haematoma can be prevented by:

◯ Applying pressure to the puncture site

◯ Forcefully drawing back the plunger of the syringe until the blood starts frothing

◯ Removing the needle before removing the tourniquet

16. Which of the following results in blood sample rejection:

◯ Haemolysis

◯ No facility name on request form

◯ Cracked sample tube

◯ Some of the above

◯ All of the above

17. Haemolysis can be prevented by the use of a luer adaptor attached to a butterfly needle.

◯ True

◯ False

18. Samples should be transported in a sealed packet with one specimen per packet.

◯ True

◯ False

19. Blood samples should be kept out of direct sunlight.

◯ True

◯ False

20. Look at the blood sample and request form.

Would this sample be accepted or rejected by the laboratory?

◯ Accepted

◯ Rejected

[A completed request form and an expired sample tube will be provided, the correct answer to the question above will be: rejected as a result of an expired tube]

The staff are expected to know that they need to check the expiry date on the tube.

Instructions for Authors:

African Journal of Primary Health Care and Family Medicine (PHCFM)

Structure and style of your original research article

The page provides an overview of the structure and style of your original research article to be submitted to the *African Journal of Primary Health Care & Family Medicine*. An original article provides an overview of innovative research in a particular field within or related to the focus and scope of the journal, presented according to a clear and well-structured format (between 3500 and 7000 words with a maximum of 60 references).

When presenting your article in English. Please use British English, that is, according to the *Oxford English Dictionary*. Avoid Americanisms (e.g. use 's' and not 'z' spellings). Consult the *Oxford English Dictionary* when in doubt and remember to set your version of Microsoft Word to UK English.

- **Language:** Manuscripts must be written in British English or French.
- **Line numbers:** Insert continuous line numbers.
- **Font type:** Palatino
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- **General font size:** 12pt
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  - First headings: normal case, bold and 14pt
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  - Third headings: normal case, bold and 12pt
  - Fourth headings: normal case, bold, running-in text and separated by a colon.

Our publication system supports a limited range of formats for text and graphics. Text files can be submitted in the following formats only:

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The structure and style of your original article

Page 1

The format of the **compulsory cover letter** forms part of your submission, is on the first page of your manuscript and should always be presented in English. You should provide all of the following elements:

- **Full author details:** Provide title(s), full name(s), position(s), affiliation(s) and contact details (postal address, email, telephone and cellular number) of each author.
- **Corresponding author:** Identify to whom all correspondence should be addressed.
- **Summary:** Lastly, a list containing the number of words, pages, tables, figures and/or other supplementary material should accompany the submission.

Page 2 and onwards

Title: The article's full title should contain a maximum of 95 characters (including spaces).

Abstract: The abstract, written in **English and French**, should be no longer than 250 words and must be written in the **past** tense. The abstract should give a succinct account of the objectives, methods, results and significance of the matter. The structured abstract for an Original Research article should consist of six paragraphs labelled Background, Aim, Setting, Methods, Results and Conclusion. The journal can translate into French if this is difficult for you.

- **Background:** Summarise the social value (importance, relevance) and scientific value (knowledge gap) that your study addresses.
- **Aim:** State the overall aim of the study.
- **Setting:** State the setting for the study.
- **Methods:** Clearly express the basic design of the study, and name or briefly describe the methods used without going into excessive detail.
- **Results:** State the main findings.
- **Conclusion:** State your conclusion and any key implications or recommendations.

Do not cite references and do not use abbreviations excessively in the abstract.

The following headings serve as a guide for presenting your research in a well-structured original article. As an author you should include all first-level headings, but subsequent headings (second- and third-level headings) can be changed.

Introduction (first-level heading)
The introduction must contain your argument for the social and scientific value of the study, as well as the aim and objectives:

Social value: The first part of the introduction should make a clear and logical argument for the importance or relevance of the study. Your argument should be supported by use of evidence from the literature.

Scientific value: The second part of the introduction should make a clear and logical argument for the originality of the study. This should include a summary of what is already known about the research question or specific topic, and should clarify the knowledge gap that this study will address. Your argument should be supported by use of evidence from the literature.

Conceptual framework: In some research articles it will also be important to describe the underlying theoretical basis for the research and how these theories are linked together in a conceptual framework. The theoretical evidence used to construct the conceptual framework should be referenced from the literature.

Aim and objectives: The introduction should conclude with a clear summary of the aim and objectives of this study.

Research methods and design (first-level heading)
The methods should include:

Study design (second-level heading): An outline of the type of study design.

Setting (second-level heading): A description of the setting for the study; for example, the type of community from which the participants came or the nature of the health system and services in which the study is conducted.

Study population and sampling strategy (second-level heading): Describe the study population and any inclusion or exclusion criteria. Describe the intended sample size and your sample size calculation or justification. Describe the sampling strategy used. Describe in practical terms how this was implemented.

Intervention (if appropriate) (second-level heading): If there were intervention and comparison groups, describe the intervention in detail and what happened to the comparison groups.

Data collection (second-level heading): Define the data collection tools that were used and their validity. Describe in practical terms how data were collected and any key issues involved, e.g. language barriers.

Data analysis (second-level heading): Describe how data were captured, checked and cleaned. Describe the analysis process, for example, the statistical tests used orsteps followed in qualitative data analysis.

Ethical considerations (second-level heading): Approval must have been obtained for all studies from the author's institution or other relevant ethics committee and the institution's name and permit numbers should be stated here.

Results (first-level heading)
Present the results of your study in a logical sequence that addresses the aim and objectives of your study. Use tables and figures as required to present your findings. Use quotations as required to establish your interpretation of qualitative data.

All units should conform to the **SI convention** and be abbreviated accordingly. Metric units and their international symbols are used throughout, as is the decimal point (not the decimal comma).

Discussion (first-level heading)
The discussion section should address the following four elements:

Key findings: Summarise the key findings without reiterating details of the results.

Discussion of key findings: Explain how the key findings relate to previous research or to existing knowledge, practice or policy.

Strengths and limitations: Describe the strengths and limitations of your methods and what the reader should take into account when interpreting your results.

Implications or recommendations: State the implications of your study or recommendations for future research (questions that remain unanswered), policy or practice. Make sure that the recommendations flow directly from your findings.

Conclusion (first-level heading)
Provide a brief conclusion that summarises the results and their meaning or significance in relation to each objective of the study.

Acknowledgements (first-level heading)
If, through your study, you received any significant help in conceiving, designing or carrying out the work, or received materials from someone who did you a favour by supplying them, you must acknowledge their assistance and the service or material provided. **Authors should always acknowledge outside reviewers of their drafts and any sources of funding that supported the research.**

Competing interests (second-level heading): A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organisations that can potentially prevent you from executing and publishing unbiased research. Authors should disclose any financial competing interests but also any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript. **Where an author has no such competing interests, the listing will read as follows:** 'The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article.'

Authors' contributions (second-level heading): This section is necessary to give appropriate credit to each author, and to the authors' applicable institution. The individual contributions of authors should be specified with their affiliation at the time of the study and completion of the work. An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study. Contributions made by each of the authors listed can follow the example below (please note the use of authors' initials):

J.K. (University of Pretoria) was the project leader, L.M.N. (University of KwaZulu-Natal) and A.B. (Stellenbosch University) were responsible for experimental and project design. L.M.N. performed most of the experiments. P.R. (Cape Peninsula University of Technology) made conceptual contributions and S.T. (University of Cape Town), U.V. (University of Cape Town) and C.D. (University of Cape Town) performed some of the experiments. S.M. (Cape Peninsula University of Technology) and V.C. (Cape Peninsula University of Technology) prepared the samples and calculations were performed by C.S. (Cape Peninsula University of Technology).

References (first-level heading)
Begin the reference list on a separate page, and give no more than 60 references in all. The *African Journal of Primary Health Care & Family Medicine* uses the **Vancouver referencing style**, details of which can be downloaded from the journal website. **Note: No other style will be permitted.**

Systematic reviews

Systematic reviews should follow the same basic structure as other original research articles as described above. The aim and objectives should specific the focused clinical question that will be addressed in the review. The methods section should describe in detail the search

strategy, criteria used to select or reject articles, attempts made to obtain all important and relevant studies and deal with publication bias (including grey and unpublished literature), how the quality of included studies was appraised, the methodology used to extract and/or analyse data. Results should describe the homogeneity of the different findings, clearly present the overall results and any meta-analysis.

PART D: SUPPORTING DOCUMENTS

Please find the following supporting documents attached to “Part A: The Protocol” above:

1. Annexure 1: Data Capture Sheet
2. Annexure 2: The Intervention
3. Annexure 3: Phlebotomy Questionnaire 2013
4. Annexure 4: Participant information leaflet and consent form
5. Annexure 5: Institution Authorisation
6. Researcher and staff member confidentiality form

UNIVERSITY OF CAPE TOWN

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Website: www.health.uct.ac.za/research/humanethics/forms

10 September 2013

HREC REF: 549/2013

Dr M Abbas
c/o Dr M Namane
Public Health & Family Medicine
Falmouth Building

Dear Dr Abbas

PROJECT TITLE: THE DEVELOPMENT AND IMPLEMENTATION OF A PHLEBOTOMY TRAINING SESSION FOR PRIMARY HEALTH CARE WORKERS AND EVALUATING WHETHER IT IS ASSOCIATED WITH A DECREASE IN THE REJECTION RATE OF BLOOD SAMPLES SENT TO THE LABORATORY

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th September 2014

- Please add the UCT FHS HREC contact details.
- Please change the word from "Health" to "Human" (HREC) in the Informed Consent Form.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC. REF in all your correspondence.

Yours sincerely

pp T.Burgess

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

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UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30/09/2016
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	5/9/2015

Comments to PI from the HREC

MEDICAL RESEARCH ETHICS COMMITTEE
-4 SEP 2015
UNIVERSITY OF CAPE TOWN

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	4/9/2015		
HREC REF Number	548/2013	Current Ethics Approval was granted until	30/9/15
Protocol title	The development and implementation of a phlebotomy training session for primary health care workers and evaluating whether it is associated with a decrease in the rejection rate of blood samples sent to the laboratory		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes ☑ No		
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Dr Mumtaz Abbas		
Department / Office Internal Mail Address	mumtazabbas@ymail.com		

1.1 Does this protocol receive US Federal funding?	☐ Yes	☑ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	☐ No
1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	☐ Yes	☑ No

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REFERENCE: 2013RP190
ENQUIRIES: Ms Charlene Roderick

21 Duine Street

Rylands Estate

Athlone

7764

For attention: **Dr Mosedi Namane and Dr Fidele Mukinda**

Re: THE DEVELOPMENT AND IMPLEMENTATION OF A PHLEBOTOMY TRAINING SESSION FOR PRIMARY HELATH CARE WORKERS AND EVALUATING WHETHER IT IS ASSOCIATED WITH A DECREASE IN THE REJECTION RATE OF BLOOD SAMPLES SENT TO THE LABORATORY.

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted approval for your research. Please contact the following people to assist you with any further enquiries in accessing the following sites:

Vanguard	**L Mbanga**	**Contact No.: 021 695 8244**
Heideveld	**A Eksteen**	**Contact No.: 021 637 6686**
Hanover Park	**S Mc Cloen**	**Contact No.: 021 360 4022**
Maitland	**J Cilliers**	**Contact No.: 021 511 6272**
Mitchells Plain	**Z Xapile**	**Contact No.: 021 391 7991**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.

2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. The reference number above should be quoted in all future correspondence.

Yours sincerely

DR J EVANS pp

ACTING DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE: 23/09/2010

CC **P OLCKERS** **DIRECTOR: KLIPFONTEIN/ MITCHELL'S PLAIN**

K GRAMMER **DIRECTOR: SOUTHERN/ WESTERN**