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Inspection of selected medical device routine cleaning procedures: detection of residual proteins in the clinical setting in Gauteng hospitals

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CHAPTER ONE

OVERVIEW OF THE STUDY

1.1 INTRODUCTION

This chapter provides an overview of what was covered in this study. The background regarding the importance of medical device decontamination was discussed. The problem statement, purpose of the study, research questions, research objectives and the significance of this study were clarified. The research assumptions and methodology were also discussed. Likewise, the ethical considerations, validity and reliability of this study were reviewed in this chapter.

1.2 BACKGROUND REGARDING MEDICAL DEVICE DECONTAMINATION

The background to this study includes an introduction to the concept that an improperly cleaned medical device is potentially able to transmit disease. The importance of proper cleaning of a medical device in order to facilitate disinfection and/or sterilisation of that device was discussed, as device cleaning incorporates a number of different steps. The factors that influence effective medical device decontamination and methods that can be used to verify that a medical device is clean were described.

Historically a medical device was regarded as clean if no soil or foreign material was macroscopically seen on the device, but that is no longer the case (Association for the Advancement of Medical Instrumentation, 2011). A number of changes have been made to the cleaning and sterilisation guidelines over the last 15 years (Cobbold & Lord, 2012). These changes have come about mainly due to two healthcare concerns according to

Cobbold & Lord (2012), namely the research surrounding variant Creutzfeldt-Jakob's disease and the growing problems with health care associated infections.

The potential transmission of pathogenic micro-organisms (disease causing micro-organisms) such as hepatitis B, hepatitis C, *Serratia marcescens*, *Pseudomonas aeruginosa*, *Salmonella*, carbapenem-resistant *Klebsiella pneumoniae, Mycobacterium tuberculosis* and atypical mycobacteria have been reported in a variety of published studies (Birnie et al., 1983, Bronowicki et al., 1997, Jones et al., 2000, Orsi and Venditti, 2013, Spach et al., 1993). These microorganisms can cause life threating infections for hospitalised patients undergoing surgical procedures and, it is therefore critical that medical devices are properly cleaned and appropriately disinfected or sterilized before they are used on patients (AAMI, 2011). A health care associated infection (HCAI) is defined as an infection that is acquired by a patient receiving care in a hospital or other health-care facility which was not present or incubating at the time of admission but appeared after discharge (World Health Organization, 2011). In the World Health Organisation's (WHO) report on the burden of endemic HCAI worldwide it is stated that surgical site infections are the most frequent type of HCAI in low and middle income countries (WHO, 2011). The WHO also states that between 1.2 to 23.6 % per 100 patients undergoing surgical procedures develop surgical site infections in lower and middle income countries (WHO, 2011).

In 1957 Spaulding established guidelines to help hospital staff understand to what extent medical devices need to be cleaned, disinfected and/or sterilized (Alfa & Jackson, 2001). These guidelines are still used today (McDonnell & Burke, 2011). Spaulding proposed that all medical devices can be divided into three groups. The extent to which medical devices need to be cleaned, disinfected and/or sterilised depends on which group they fall under (McDonnell & Burke, 2011). Medical devices can therefore be grouped as non-critical, semi-critical or critical. Medical devices that come into contact with intact skin are

classified as non-critical devices. Medical devices that come into contact with intact mucous membranes and non-intact skin are classified as semi-critical devices. Medical devices that come into contact with blood and the vascular system are classified as critical devices (McDonnell & Burke, 2011).

Non-critical devices are low-risk devices (i.e. there is little chance that the devices will transmit infection) these devices must undergo low-level disinfection (Rutala & Weber, 2008). Semi-critical medical devices are an intermediate risk; these devices must at least undergo high-level disinfection. Medical devices that have undergone high-level disinfection should be free from most microorganisms but not necessarily free from bacterial spores (AAMI, 2011). Critical devices are high risk devices and must undergo sterilization (Rutala & Weber, 2008). Medical devices that have undergone sterilization should be free from all viable microorganisms including bacterial spores (AAMI, 2011).

Before medical devices are disinfected or sterilized they must first be cleaned (McDonnell, 2006). Cleaning is defined as a process that removes contamination from an item (AAMI, 2011). For cleaning to be effective, three things are needed; correct type of detergent, water and friction (McDonnell & Sheard, 2012). Friction can be produced by manually scrubbing a medical device or mechanically by the force of water spray (McDonnell & Sheard, 2012).

When medical devices are used on patients they can come into contact with organic and non-organic soils (McDonnell, 2006). Organic soils that could be found on medical devices include proteins, carbohydrates, lipids and microorganisms (McDonnell, 2006). Non organic soils that could be found on medical devices include minerals, salts, detergents and rust (McDonnell, 2006). If these soils are not removed they can impair successful disinfection or sterilization of that device (McDonnell, 2006).

Contamination according to McDonnell and Sheard refers to a device that is dirty or soiled, and therefore decontamination is a process that makes the device safe to handle or ready for use on a patient (McDonnell & Sheard, 2012). Decontamination often involves cleaning to remove soil, disinfection and/or sterilization (McDonnell & Sheard, 2012). In order to achieve effective decontamination a number of steps needs to be taken when reprocessing medical devices. These steps are outlined in the National Health Services of the United Kingdom (NHS) life cycle model seen below (Veerabadran & Parkinson, 2010).

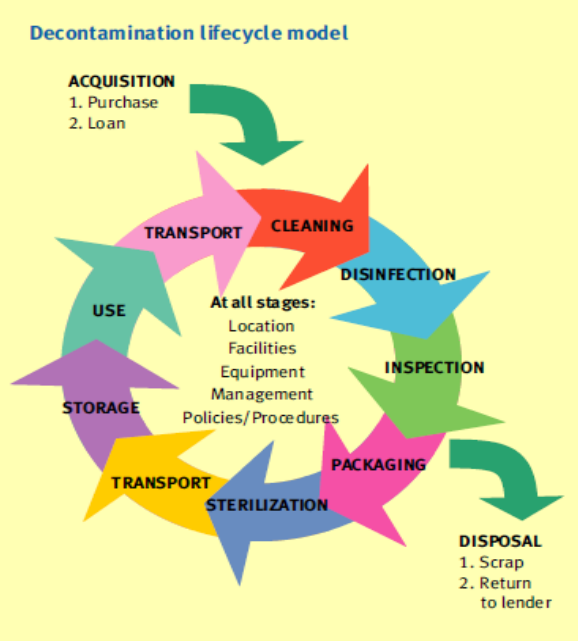


Figure 1.1: Decontamination lifecycle model

The main steps in the process outlined in the model are as follows; use of medical device on a patient, transport, cleaning, disinfection, inspection, packaging, sterilization, transport, storage until use of the device again on a patient.

A variety of factors influence effective decontamination, they are as follows:

1.2.1 Manual and automated cleaning methods

Medical devices can be cleaned manually (by hand) or in an automated washer-disinfector (Association for the Advancement of Medical Instrumentation, 2010). However latest guidelines recommend that medical devices be cleaned using an automated washer-disinfector and not manually (Welsh Health Technical Memorandum 01-01, 2013). The Welsh decontamination guidelines also state that medical devices should only be cleaned manually if the medical device in question cannot be processed in a washer (WHTM01-01, 2013). Mechanical cleaning is preferred because the cleaning is performed by a machine which is a reproducible process, unlike manual cleaning which relies on the performance of the individual doing the cleaning (AAMI, 2011).

There are three main types of washer-disinfectors. Each is designed and manufactured to clean different kinds of medical devices. Firstly there are washer-disinfectors that clean flexible endoscopes, secondly washer-disinfectors that clean surgical instruments and thirdly washers that clean human waste containers (bedpans and urinals) (International Standards Organisation 15883-1, 2006). The manufacture and performance of all these washer-disinfectors should conform to the relevant sections of the ISO standard 15883, for washer-disinfectors (ISO15883-01, 2006). The performance (efficacy) of a washer-disinfector can and should be monitored (ISO15883-01, 2006). The washer-disinfector (depending on the cycle parameters and the cycle selected) is also able to disinfect medical devices, rendering them safe for the staff to handle (McDonnell & Sheard, 2012). In order to ensure effective cleaning the washer-disinfector should be correctly loaded, and appropriate instrument trays should be used (WHTM01-01, 2013). The instrument trays containing soiled instruments should not be overloaded (WHTM01-01, 2013).

1.2.2 Standard operating procedures for cleaning

The Association for the Advancement of Medical Instrumentation (AAMI, 2011) recommends that all healthcare institutions should develop Standard Operating Procedures (SOP) for cleaning of medical devices. Those procedures should be based on cleaning (disinfection and sterilization) instructions provided by device manufactures, and validated procedures. The cleaning procedures should be audited on a regular basis to ensure compliance with the SOP (AAMI, 2011).

1.2.3 Education and training

In the Centres for Disease Control's (CDC), Guideline for Disinfection and Sterilization in Healthcare facilities, it is mentioned that healthcare institutions in the United States of America don't always comply with established guidelines for decontamination (Rutala and Weber, 2008). If healthcare institutions don't comply with recommended guidelines outbreaks of infection can occur (Rutala and Weber, 2008). An example of such an outbreak was described recently in the American Journal of Infection Control, where there was an outbreak of carbapenem-resistant *Klebsiella pneumoniae* which was attributed to a contaminated endoscope (Alrabaa, Nguyen, Sanderson, et al., 2013).
One of the ways to prevent such an outbreak is to ensure that hospital staff are well trained or educated in their field (AAMI, 2011). According to AAMI (2011) it is the responsibility of the healthcare institution to train their staff, and the training should be based on various manufacturers' instructions for decontamination. Device manufacturers can also assist healthcare institutions by providing in-service education and training materials (AAMI, 2011).

The task of device decontamination is performed under direct or indirect supervision of the registered nurse and/or enrolled nurse, in the South African context. The actual

decontamination of medical devices however may be performed by registered nurses, enrolled nurses, enrolled nursing assistants, technicians or even non healthcare workers. The ultimate responsibility for decontamination of medical devices in a CSSD (Central Sterile Services Departments) in a hospital setting falls under the registered nurse responsible for the operating theatre. Devices may be decontaminated in other departments in the hospital and would then fall under the responsibility of the registered nurse in charge of that particular department for example the intensive care unit, or the gastroenterology unit. Medical device decontamination falls within the scope of practice of a registered nurse whose responsibility it is to prevent disease, facilitate healing of wounds (incorporates preventing the patient developing an infection from a contaminated medical device), and to prepare for and assist with operative and diagnostic procedures to be performed on a patient (SANC, 1991).

1.2.4 Medical device design

The efficacy of cleaning, disinfection and sterilization is affected by the design of a device and where the microorganisms are on the device (Rutala and Weber, 2008). Complex medical devices and instruments must be dissembled as far as possible, so that detergent and the germicide can have direct contact with the microorganisms (Rutala and Weber, 2008). The shape, design and geometry of a medical device will affect the ability to clean it (Quality Task Group, 2011). Specific aspects of a devices design that influence cleaning include gaps, crevices, joints, threads and types of surfaces (QTG, 2011).

Various guidelines state that it is important to verify that the methods used to clean medical devices are effective (AAMI, 2010, McDonnell, 2006). Verification of cleaning can be done by visually inspecting the device, by testing the device for residual soils or testing the device for the presence of microorganisms (McDonnell, 2006). Microbial detection as

a method to test cleaning efficiency is not routinely used, as it requires microbial laboratory facilities and it takes 24-72 hours to get the test results (McDonnell, 2006). All devices should at least be visually inspected for residual soils before undergoing disinfection or sterilization (AAMI, 2011). However not all soils are visible to the naked eye, and it is not possible to visualise the lumens of certain medical devices (AAMI, 2011). Visual inspection is not a reliable method for checking cleaning efficacy according to McDonnell (2006). An effective way to check cleaning efficacy would be to test or measure the levels of residual soils that remain on a medical device after it has been cleaned (AAMI, 2011).

Residual soil detection includes testing medical devices for haemoglobin, blood, protein, salts, glucose and enzymes (McDonnell, 2006). The most common method used for evaluating cleaning efficacy is testing medical devices for residual proteins (McDonnell, 2006). Protein is the most common element found in the types of soils medical devices come into contact with (McDonnell, 2006). Protein residual tests are based on a reaction of protein and peptides with a reagent (McDonnell, 2006). The reagents and tests commonly used include Biuret, amino black ink, Bradford's, ninhydrin and ortho-phthalic dialdehyde (McDonnell, 2006). The reaction of the protein and the reagent generally results in some form of colour change which denotes the presence of protein (McDonnell, 2006). Protein detection tests are able to detect protein levels below that which can be detected visually (McDonnell, 2006). Cleaning verification tests should be easy to use, give a rapid result, be sensitive, be repeatable and produce accurate results (AAMI, 2011). In addition to this the ideal test should not damage the medical device or require that the device needs to be re-cleaned after the test has been performed (AAMI, 2011).

1.3 PROBLEM STATEMENT

In South Africa medical devices are not always cleaned following validated cleaning procedures. Medical devices are also not routinely visually inspected after cleaning. Complex medical devices and devices with lumens are difficult, if not impossible to inspect for cleanliness (AAMI, 2011). Therefore it can be said that visual inspection is not a reliable method of establishing if a device is clean. Cleaning efficacy should be verified using a biochemical process (Rutala & Weber, 2008), which is not done in South Africa.

1.4 RESEARCH QUESTIONS

- Do five hospitals in Gauteng (three private hospitals and two public hospitals) have SOP's for cleaning of medical devices?
- Do the routine cleaning procedures at five hospitals in Gauteng comply with international validated cleaning procedures as recommended by guidance documents?
- Do protein residuals remain on selected medical devices after routine cleaning procedures?
- Which method of cleaning produces cleaner medical devices, manual or automated cleaning in five hospitals in Gauteng?
- Is it feasibly possible to verifying cleaning efficacy using a ninhydrin residual protein test and an artificial soil test?

1.5 PURPOSE OF THE STUDY

The purpose of the pilot study was to inspect selected medical device routine cleaning procedures in one hospital in Gauteng, and to establish if those devices tested positive for

residual proteins post routine cleaning. The purpose the pilot study was also to evaluate if the data collection tool (structured observation check list) would adequately enable the researcher to record all pertinent research data.

The purpose of the main study was to inspect selected medical device routine cleaning procedures in five hospitals in Gauteng, and to establish if those devices tested positive for residual proteins post routine cleaning.

1.6 RESEARCH OBJECTIVES

- To establish if five hospitals in Gauteng (three private hospitals and two public hospitals) have SOP's for cleaning of medical devices.
- To assess if routine cleaning procedures at five hospitals in Gauteng comply with international validated cleaning procedures as recommended by guidance documents like American National Standard (AAMI, 2010) for example.
- To determine if protein residuals remain on selected medical devices after routine cleaning procedures.
- To establish which cleaning method, manual or automated produces cleaner medical devices.
- To assess the feasibility of verifying cleaning efficacy using a ninhydrin residual protein test and an artificial soil test.

1.7 SIGNIFICANCE

The significance of this study is that in South Africa there are no guidelines or recommendations that describe how medical devices should be cleaned. Countries like America and Wales have decontamination guidelines that incorporate cleaning guidelines.

(AAMI 2010, WHTM01-01, 2013). These international guidelines also recommended that hospitals create SOP's that clearly outline how medical devices should be cleaned and sterilised (AAMI, 2010). The SOP's should be based on the medical device manufacturers' guidelines (AAMI, 2010). Manufacturers' guidelines are derived by inoculating a medical device with a known amount of pathogen, cleaning the device and then measuring the device after cleaning for residual pathogens. The recommended procedures are therefore validated procedures (AAMI, 2010).
International guidelines like the American National Standard (AAMI, 2010) and International Standard for Washer-disinfectors, Part 1: General requirements, terms, definitions and tests (ISO15883-1, 2006), recommend that the efficacy of medical device cleaning should be verified using a scientific test method. One such test method is to test medical devices for residual proteins. As no such guidelines exists in South Africa it is possible that medical devices are not being cleaned correctly and may indeed have residual proteins on them.

If a patient develops a HCAI, from being treated with an incorrectly decontaminated (cleaned) medical device, the length of stay in the hospital is increased, additional medication and treatment is required, and the patient is often unable to return to work as expected (Centers for Disease Control , 2013). According to McDonnell & Sheard, (2012) the risk of contracting an infectious disease is increased when the body is compromised. A patient with a predisposed infection like human immunodeficiency virus (HIV) or tuberculosis (TB) who undergoes a medical or surgical procedure with a poorly decontaminated instrument will therefore, have an even greater chance of developing a HCAI. According to the South African National strategic plan for HIV, STI and TB, 10% of the South African population has HIV (South African National Aids Council, 2011). It is also noted that the HIV epidemic is driving the TB epidemic in South Africa with estimates that 1% of the population will develop TB every year. South Africa has the third highest TB rate in the world (SANAC, 2011). Given the prevalence of HIV and TB in South Africa, it is

critical that medical devices are properly cleaned in order to prevent patients from developing HCAI from contaminated medical devices.

The findings of this study could therefore be used to help establish South African national guidelines for cleaning and decontamination of medical devices. Therefore this study is significant for the following groups:

- Patients who undergo surgical procedures in South Africa
- All hospitals and medical institutions
- The nursing staff who manage wards and units especially operating theatres and decontamination departments (CSSD)
- Infection prevention and control personnel (doctors and nurses)
- Nursing educators responsible for continuous professional development

1.8 RESEARCHER ASSUMPTIONS

1.8.1 Meta-Theoretical Assumptions

Theoretical assumptions are assumptions that can be regarded as being accurate or truthful (George, 2002). According to Meleis, meta theoretical assumptions are aspects that a particular scientific community shares, and these aspects or assumptions are not meant to be tested (Meleis, 2005). Four meta-theoretical assumptions of nursing were discussed in this study namely; the person, the environment, nursing care and health.

The Person

Florence Nightingale was one of the first nursing theorists who developed the environmental nursing model (George, 2002). In Nightingale's environmental nursing

model the person is defined in relationship to the environment that they are in, as well as how that environment impacts on them (George, 2002).

The person in this study refers to the patient undergoing a surgical procedure on whom a medical device is being used. The patient undergoing surgery may be at great risk of developing a HCAI, and this risk is even greater for a patient who is immuno-compromised. This study aims to protect the patient (person) by decreasing the chances of developing a HCAI whilst undergoing surgery.

Environment

In her writings Florence Nightingale focused on the physical environment and its impact on the patient (George, 2002). Nightingale was particularly concerned with sanitation, and ensuring that the patient's environment was clean (George, 2002). In this study medical devices and the cleanliness of these devices can be regarded as the physical environment that could directly impact on the patient's health care outcomes. Some medical devices have long thin lumens, complex designs, narrow joints and rough surfaces making them difficult to clean. The device and its cleanliness (the environment) could negatively impact on the patients' healthcare outcomes.

Nursing

Florence Nightingale also believed that a nurse can manipulate the patient's environment to ensure that the patient and his environment are balanced (George, 2002). In this study nursing can be regarded as carrying out the task of cleaning or ensuring that medical devices are clean to facilitate a balance between the patient and the environment. According to Nightingale if a patient's environment is not balanced the patient will need to expend unnecessary energy (George, 2002). In this case the patient would need to expend energy fighting off potential infections from contaminated medical devices.

Health

From Florence Nightingale's environmental nursing theory perspective, prevention of illness is as important, as nursing an ill patient back to health (George, 2002). When a patient undergoes a surgical procedure he is compromised and the risk of contracting a HCAI is increased (McDonnell & Sheard, 2012). The goal in healthcare is thus for nurses to prevent the patient from acquiring a HCAI. Therefore in this study health would refer to a patient that has not contracted a HCAI whilst undergoing a surgical procedure with a medical device.

If procedures are performed on patients with medical devices that are not clean, the patients' health outcomes would be adversely affected.

1.8.2. Theoretical Assumptions

Theoretical assumptions refer to concepts underpinning this study such as those defined below:

1.8.2.1 Definition of terms for the purpose of this study

Case Study: A research method that studies phenomena in the context of real life (Yin, 2009).

Cleaning: Removal of contamination from a medical device to the extent needed for further processing or for the intended use (AAMI, 2011).

Contaminated: State of having been actually or potentially in contact with microorganisms (AAMI, 2010).

Crile's Forceps: A clamping medical device with a box joint, used in this research to represent a process challenge device.

CSSD: Central sterile services departments (McDonnell & Sheard, 2012).

CSSD Technician: For the purposes of this research this term refers to an **i**ndividual allocated to work in the CSSD who has received some form of training on medical device decontamination.

Decontamination: The use of chemical or physical methods to remove or destroy pathogens on an item to the point where the pathogens are no longer capable of transmitting infectious particles (AAMI, 2011).

Detergent: Cleaning chemical that can be classified based on type of chemistry, classified as enzymatic (contains enzymes) or non-enzymatic, an alkaline based cleaning chemistry for example (McDonnell & Sheard, 2012).

Diathermy forceps: Medical device which when attached to an electro surgical unit and is used to cauterise human tissue.

Disinfection: Process that kills most pathogenic and other micro-organisms but not necessarily bacterial spores, this can be by physical or chemical means (AAMI, 2011).

Endoscope: A generic term used to describe medical devices that are inserted into a cavity to facilitate viewing, an example of which is a gastroscope.

Enrolled nurse: A person educated to practice basic nursing in a manner and to the level prescribed (SANC, 2005).

Enrolled nursing assistant: A person educated to provide elementary nursing care in a manner and to the level prescribed (SANC, 2005)**.**

Gastroscope: Medical device used to perform diagnostic and therapeutic procedures when passed via the mouth and oesophagus into the stomach.

Hawthorne effect: An accomplishment or deed that results from the mere fact of being under observation (Merriam-Webster, 2014a).

Healthcare associated infection: An infection occurring in a patient during the process of care in a hospital or other health-care facility which was not present or incubating at the time of admission but appearing after discharge (WHO, 2011).

Laryngoscope blade: Medical device which is attached to a handle and inserted into the mouth to facilitate the insertion of an endotracheal tube.

Lumen: Is a channel within a tube (AAMI, 2011).

Medical device: Any instrument or apparatus designed by the manufacturer to be used on human beings for the purpose of diagnosis, monitoring or treatment of disease or injury (AAMI, 2011).

Micro-organism: An entity so small it can only be seen under a microscope for example bacteria, protozoa and fungi (AAMI, 2011).

Needle Holder: Medical device used in surgery when suturing human tissue

Non-healthcare worker: For the purposes of this research this term refers to an individual who works in a hospital environment or doctors rooms who has been delegated the task of cleaning medical devices, who has had no training in medical device decontamination and may include a receptionist or cleaner.

Prions: Transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals including for example Creutzfeldt-Jakob disease in humans (AAMI, 2011).

Registered Nurse: A person who is qualified and competent to independently practice comprehensive nursing in a manner and to the level prescribed who is capable of assuming responsibility and accountability for such practice (SANC, 2005).

Residual Protein: Contamination which occurs on a reusable medical device that is partly or fully made of proteinaceous material (ISO15883-1, 2006).

Reusable medical device: Device intended for repeated use on different patients that is appropriately decontaminated between uses (AAMI, 2011).

Standard Operating Procedure: Prescribed methods to be followed when performing specific tasks or when in specific types of situations (Merriam-Webster, 2014b)

Sterilisation: A validated process that when used will produce an item that is free from viable micro-organisms (AAMI, 2011).

Surgical Instrument: Medical device used to perform surgery which is used to dissect, grasp, hold, retract, ligate, clamp or cut tissue (McDonnell & Sheard, 2012).

Test Soil: A preparation designed as a substitute for soil or debris typically found on a medical instrument after clinical use and used as part of the procedure to validate a cleaning process (AAMI, 2011).

Vaginal Speculum: Medical device inserted in the vagina to facilitate access to the cervix.

Validation: Documented procedure for obtaining, recording and interpreting results required to establish that a process will reliably or consistently comply with predetermined specifications (AAMI, 2011).

User Verification: Documented procedure, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined requirements or specifications have been met (AAMI, 2011).

Yankhauer suction: A medical device used to aspirate blood and fluid when performing surgery.

1.8.3 Methodological Assumptions

Research methodology refers to options available to a researcher for instance whether to conduct research using a qualitative or quantitative approach (Remenyi, 2012). This can be further described as techniques that can be used to structure research as well as to collect and analyse information relating to the research (Polit & Beck, 2012).

The methodology that was used in this research is case study methodology. A case study according to Bell *"is an umbrella term for a family of research methods having in common the decision to focus on an enquiry around a specific instance or event"* (Remenyi, 2012:4) Case studies therefore use multiple research methods (Remenyi, 2012).

Case study methodology can also be described as *" a research method involving a thorough, in-depth analysis of an individual, a group or a social unit"* (Polit & Beck, 2012:721). Based on this definition, it can be said that case study research involves in depth analysis.

According to Yin (2009:18) case study research methodology is *"empirical inquiry that investigates contemporary phenomenon in depth, within its real life context, especially when the boundaries between phenomenon and context are not clearly evident*". Yin (2009) thus also states that case study research is in depth, but furthermore Yin adds that case study methodology is used to study phenomena in the real life context.

1.9 OVERVIEW OF RESEARCH METHODOLOGY

A brief description of the research methodology is provided. A detailed version is provided in Chapter 3. The research design and research methods including population, sample, sampling method, data collection, and the data collection instrument is briefly described.

1.9.1 Research Design

A descriptive, multiple case study design consisting of two phases a pilot study and a main study, was utilised in this study, in order to understand the phenomenon of medical device cleaning within its real life context, in five hospitals in Gauteng South Africa.

1.9.2 Research Method

Case study research is defined by Yin (Remenyi, 2012:2) as *"an empirical enquiry that investigates a contemporary phenomenon within its real life context, when boundaries between phenomenon and context are not clearly evident, and in which multiple sources of evidence are used".*

1.9.3 Pilot Study Phase 1

A pilot study was first undertaken in one private hospital in Gauteng that uses six selected medical devices on their patients: namely gastroscopes, Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blade and vaginal specula.

The cleaning of selected medical devices was observed and documented. Following cleaning the selected medical devices was tested for residual proteins using a commercially available ninhydrin test kit. Two types of residual protein tests were used, one test is performed using a brush that is inserted down a lumen of a device and the other is a swab test which is performed on the surface of a device. A brush test was performed on ten gastroscopes. A brush test and a swab test were performed on ten Yankhauer suctions. A swab test was performed on ten needle holders, ten diathermy forceps, ten vaginal specula and ten laryngoscope blades. In addition the cleaning of one Crile's forceps inoculated with test soil was observed and the forceps were swab tested for residual proteins. A total of seventy one residual protein tests were performed.

The aforementioned data was collected using a structured observation check list called SOCL: P1. The data collected included the following:

- Existence of medical device cleaning standard operating procedures
- Audit of routine cleaning methods
- Results of macroscopic visual inspection
- Results of residual protein test

The data for the pilot study was collected over six months.

During the pilot study the researcher recognised that it would be more effective to use one structured observation checklist for collecting data pertaining to gastroscopes and a separate document capturing data relating to the remaining five medical devices namely; Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blades and vaginal

specula. Therefore two structured observation check lists were used in main phase of the research.

1.9.4 Population

Research for the main study (phase 2) was undertaken in five selected Gauteng hospitals. The five hospitals were not randomly selected. They were purposively selected to represent hospital groups in Gauteng that employ different cleaning methods. The hospitals selected (3 private and 2 public) included one hospital from each large private hospital group, and two public hospitals. Each hospital selected used the six selected medical devices on their patients. The six selected medical devices were gastroscopes, Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blade and vaginal specula.

1.9.5 Sample and sampling

In this research the cleaning of selected medical devices was observed and documented. Following that the medical devices were tested for residual proteins using a commercially available ninhydrin test kit. Per hospital, brush tests were performed on five dirty gastroscopes and five clean gastroscopes. A swab test was performed on ten Yankhauer suctions, on ten needle holders, ten diathermy forceps, ten vaginal specula, and ten laryngoscope blades. Two swabs were taken from the ten vaginal specula. In addition the cleaning of one Crile's forceps inoculated with test soil was observed and the forceps were swab tested. A total of seventy one tests were performed at each hospital. This process was repeated at the five hospitals, so a total of three hundred and fifty five residual protein tests were performed in main study.

1.9.6 Data Collection

In the main study (phase 2), data was collected using two separate structured observation check lists called SOCL: P2 (Gastro) and SOCL:P2 (Devices)

The data collected included the following:

- Existence of medical device cleaning standard operating procedures
- Audit of routine cleaning methods
- Results of macroscopic visual inspection
- Results of residual protein test

1.9.7 Structured observation check list (Instrument)

As mentioned two structured observation check lists were used in main study (phase 2) of the research. The contents of the both structured observation check lists were based on the cleaning procedures recommended in the American National Standard: Association for Advancement of Medical Instrumentation (AAMI): Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities and in the Centres for Disease Control and Prevention (CDC): Guideline for Disinfection and Sterilization in Healthcare Facilities (AAMI, 2010, Rutala and Weber, 2008).

1.9.8 Data Analysis

The same data analysis method was applied for both the pilot study and the main study. The data collected was captured on an excel spread sheet and analysed by means of descriptive statistics and pattern matching. Aspects that were calculated included the number of swabs done and what proportion of these tested positive for protein residues. This was calculated per hospital and per medical device type. Pattern matching was done to establish if specific cleaning methods produced visibly clean medical devices and/or

devices free from protein residuals. Pattern matching according to Yin (2009) compares an empirically based pattern with a predicted pattern, thus comparing what was observed, what actually happened, and what was thought would happen.

1.10 VALIDITY AND RELIABILITY OF THE STUDY

An overview of the reliability and validity of the study is provided. A pilot study was conducted to enhance the validity and reliability of the study. The observations and data collection in the pilot and the main study were carried out by the researcher which would further enhance the reliability of the research. The structured observation check list was based on expert opinion as presented in the American National Standard: Association for Advancement of Medical Instrumentation (AAMI): Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities and in the Centres for Disease Control and Prevention (CDC): Guideline for Disinfection and Sterilization in Healthcare Facilities (AAMI, 2010, Rutala and Weber, 2008). The validity of the structured observation check list was strengthened by conducting a pilot study. A detailed discussion regarding validity and reliability can be found in chapter three.

1.11 ETHICAL CONSIDERATIONS

An overview of the ethical considerations is provided. A detailed discussion can be found in chapter three.

Ethical clearance was obtained from the Human Research Ethics Committee of the University of the Witwatersrand (appendix I). Ethical clearance was also obtained from relevant private group's ethics committee's (appendix J, K and L). A coding system was used when raw data was collected to ensure the anonymity of the hospitals concerned. Access to this data was restricted to the researcher and the researcher's supervisors.

1.12 SUMMARY

Chapter one provided an outline of what was covered in this research. The background to the importance of medical device decontamination was discussed. The pilot study, the problem statement, purpose of the study, research questions, research objectives and the significance of this study were outlined. The methodological assumptions and the research methodology were described. The ethical considerations, validity and reliability of this study were also briefly reviewed.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

This chapter reviews known cases of disease transmission from contaminated medical devices causing HCAI, the impact of HCAI on the healthcare systems, and the various methods that can be used to verify that medical devices were properly cleaned.
It is critical to ensure that medical devices used on patients are properly cleaned or else they could transmit disease from one patient to another, causing HCAI, which in turn places a huge burden on the healthcare system. In the literature there are a number of methods that can be used to ensure that medical devices are properly cleaned.

2.2 BACKGROUND

If medical devices are not properly cleaned, disinfected and sterilised they could be a possible vector for the transmission of diseases from one patient to another (McDonnell, Dehen, Perrin, et al., 2013). Cleaning refers to the removal of contamination from a medical device. Disinfection means the device will be free from most pathogenic microorganisms, whereas a sterilised device will be free from all viable microorganism including bacterial spores (AAMI, 2011). A number of steps must be taken to properly clean a medical device, but numerous factors can affect the efficacy of medical device cleaning (AAMI, 2010).
As an improperly cleaned medical device can pose a high risk to a patient's health, it is critical to verify that the medical device has been effectively cleaned (AAMI, 2011). This can be done using a variety of test methods including visual inspection of a medical device for residual proteins (AAMI, 2011).

2.3 TRANSMISSION OF DISEASE VIA CONTAMINATED MEDICAL DEVICES

Medical devices used on patients become contaminated with microorganisms (AAMI, 2010). All microorganisms encountered in a hospital setting should be regarded as potentially pathogenic, meaning that they are harmful to the patient (AAMI, 2010). The ability of a microorganism to cause an infection in a patient depends on; how virulent it was, how many were present, how susceptible the patient was and if there was a portal of entry into the patient (AAMI, 2010). A contaminated medical device could facilitate a portal of entry for a pathogenic microorganism.

It has been shown in laboratory settings and in clinical practice that prion disease can be transmitted through patient tissues on surgical devices (McDonnell et al., 2013). Prions cause diseases known as transmissible spongiform encephalopathies (TSEs), like Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease (vCJD) (McDonnell et al., 2013). In one particular incident intra-cerebral electrodes became contaminated with prions from a patient infected with CJD. The disease was transmitted to two younger patients even though the electrodes had been cleaned and sterilised. The infected patients died within 18 months after being exposed to the contaminated electrodes (McDonnell et al., 2013). It is believed that at least another four cases of transmission of CJD disease has occurred through contaminated neurosurgical instruments (McDonnell et al., 2013).

Similarly, in 1995 a 55 year old man and his 54 year old wife reported symptoms of hepatitis. Both patients tested positive for hepatitis C and both had undergone colonoscopies on the same day in the same hospital (Bronowicki, Venard, Botté,et al., 1997). The 55 year old man was the second patient on the list and his wife was third. Between the procedures the biopsy suction channel of the colonoscopy was not thoroughly cleaned with an appropriate brush (Bronowicki et al., 1997). It was concluded

that hepatitis C was transmitted from the patient first on the list who had a known hepatitis infection to the two patients who underwent colonoscopies to follow, the 55 year old man and his wife (Bronowicki et al., 1997).

In addition to the above cases an outbreak of *Serratia marcescens* in two neonatal intensive care units was reported in the Journal of Hospital Infection in 2000 (Jones Gorman, Simpson, et al., 2000). In this incident 17 babies were infected with *S. marcescens* and 2 babies died from the infection (Jones et al., 2000). The outbreak occurred initially at one hospital and was spread to another. Two babies were transferred between these hospitals. Laryngoscope blades and breast pumps were identified as the possible vectors for transmission of the *S. marcescens* infections (Jones et al., 2000).

The transmission of infection via gastrointestinal endoscopy and bronchoscopy was reviewed in a paper published in 1993 (Spach, Silverstein, Stamm, 1993). The objective of this review was to evaluate reports on the transmission of infections by flexible gastrointestinal scopes and bronchoscopes to determine common infecting microorganisms and circumstances of transmission. Spach determined that 281 infections had been transmitted by gastrointestinal endoscopy's and 96 infections had been transmitted by bronchoscopy's (Spach et al., 1993). Infectious agents that were transmitted included *P. aeruginosa, M. tuberculosis*, atypical mycobacteria *Pseudomonas* and *Salmonella* species (Spach et al., 1993). Spach concluded that the transmission of infections via contaminated endoscopes resulted predominately from three things: improper cleaning and disinfection of endoscopes, contamination of endoscopes by mechanical washers and the difficult design of valves and endoscope channels (Spach et al., 1993).

Outbreaks of infection due to contaminated ureteroscopes are seldom reported, however an outbreak of urinary tract infections caused by ertapenem-resistant

Enterobacter cloacae has occurred in a teaching hospital in Taiwan (Chang, Su, Lu et al., 2013). Fifteen patients contracted a urinary tract infection from a contaminated ureterscope (Chang et al., 2013). The reasons for this could possibly have been; a build-up of biofilm in the scope which impeded effective decontamination, and the second reason could have been that the microorganisms on the ureterscope became resistant to the disinfectant used (Chang et al., 2013).

In the above mentioned scenarios the patients acquired infections in in a healthcare setting, which can be regarded as HCAI (WHO, 2011).

2.4 THE BURDEN OF HEALTHCARE ASSOCIATED INFECTIONS

If a patient develops a HCAI it places a significant burden on the healthcare system (WHO, 2011). It will affect the patient's length of stay in hospital, which could result in increased medical costs for the patient and his family, and it could cause long term disabilities or death of the patient (WHO, 2011).

The global burden of HCAI is difficult to estimate because it is difficult to obtain reliable data (WHO, 2011). HCAI data is obtained by using HCAI surveillance systems. HCAI surveillance is complicated and is mostly done in many high-income countries and not in many low and middle-income countries (WHO, 2011). In the WHO (World Health Organisation's) report on the burden of endemic HCAI worldwide it was stated that surgical site infections are the most frequent type of healthcare associated infections in low and middle income countries (WHO, 2011). The WHO also stated that between 1.2% to 23.6 % per 100 patients that undergo surgical procedures develop surgical site infections in lower and middle income countries (WHO, 2011) . According to the published literature reviewed by Rothe, the prevalence of HCAI in sub-Saharan Africa is much higher (between 6,7% and 28%) than in Europe (7.1%) (Rothe, Schlaich, Thompson, 2013).

In the 2011 WHO report, it was noted that HCAI infections cause 16 million extra days of hospital stay and cost approximately € 7 billion per annum (WHO, 2011). In a paper published in 2013 it was concluded that the total annual costs for the five major infections (central line infections, urinary tract infections, ventilator associated infection, *C difficile* infections and surgical site infections) was $ 9.8 billion (Zimlichman, Henderson, Tamir, et al., 2013). Surgical site infections contributed the most to the overall costs making up 33.7% of the total (Zimlichman et al., 2013). The effect of HCAI is worse in resource poor countries with a high burden of community acquired infections (Rothe et al., 2013). South Africa has a high burden of community acquired infections especially HIV and TB (SANAC, 2011).

HCAI also play a role in the increased resistance of microorganism to antimicrobials (WHO, 2011). The CDC (Centres for Disease Control and Prevention) estimates that every year in the United States of America more than 2 million people contract an antimicrobial resistant infection, and at least 23 000 people per annum die as a result of such an infections (CDC, 2013). The CDC published a report in 2013 titled 'antibiotics resistance threats in the United States' to increase the awareness of seriousness of the health threat of antibiotic resistance and encourage immediate action to address this threat (CDC, 2013). Duse (1999) reiterates the fact that a number of environmental factors can contribute to the increase of HCAI including the emergence of certain pathogens resistance to antibiotics and contamination of inanimate objects like equipment.

2.5 WHY IS MEDICAL DEVICE CLEANING SO IMPORTANT

Cleaning of a medical device is the first step in the decontamination process (Desbuquois et al., 2010). If medical devices are not properly cleaned before they are disinfected or sterilised there can be a number of consequences, namely the residual soils on the

medical device can hamper effective sterilisation, the device itself could be damaged, the residual soils could cause the device to rust, which could cause the device to malfunction and result in an adverse patient reaction (Desbuquois, Richard, Khammo, et al., 2010).

This sentiment is reiterated by Nugent who states that '*inadequate cleaning of instruments to remove blood and tissue residues reduces the efficacy of subsequent sterilisation and high level disinfection*' (Nugent, Modi, Mcleod et al., 2013: 60).
It can be said that medical device cleaning is very important because a device that is not properly clean can never be sterile leading to the transmission of microorganisms (McDonnell et al., 2013).

2.6 FACTORS THAT AFFECT MEDICAL DEVICE CLEANING

2.6.1 Manufacturer's instructions for use (MIFU)

According to the American National Standard, manufacturers of reusable medical devices must ensure that the devices they sell can be properly cleaned and sterilised (AAMI, 2010). The manufactures must provide written and validated reprocessing instructions (AAMI, 2010). This means that the manufacturer must be able to prove that if the decontamination instructions were followed explicitly the device would indeed be thoroughly cleaned and sterilised at the end of the process. The validation of cleaning and sterilisation is a process that may require microbiological, engineering, toxicological and clinical evaluation of the medical device (AAMI, 2010).

Knudson (Knudson, 2014:C1) explains that the *"increasing complexity of surgical instruments has complicated instrument cleaning processes".* Minimally invasive surgical approaches have led to the continuous development of complex surgical devices (Knudson, 2014).

Manufacturer's instructions are detailed and will inform the reprocessor what critical reprocessing elements must be followed (Knudson, 2014). The instructions will stipulate for example what type of cleaning solution should be used, what type of brush should be used and what the temperature of the water should be (Knudson, 2014). It is critical that written instructions of the device manufacturer are followed when processing devices (AAMI, 2010).

Not all medical devices are cleaned and sterilized in exactly the same manner, which is why it is important to follow the MIFU (manufacturer's instructions for use) (Duro, 2013). If the MFIU are not followed correctly it could result in direct harm to the patient and could also result in damage to the device itself (Duro, 2013). Some medical devices require more reprocessing steps than others which could include the reprocessing instructions for brushing, flushing and ultrasonic cleaning for example (Duro, 2013).

Before purchasing, borrowing or trialling a reusable device, a hospital should obtain a written copy of the MIFU (Knudson, 2014). If the MIFU are obtained after the device has already been purchased the hospital may find that they cannot reprocess the device adequately as they may not have the necessary cleaning and sterilisation accessories needed (Knudson, 2014).

One way to ensure that staff reprocesses reusable medical devices correctly, is to have the MIFU available in the unit (Duro, 2013). The most common mistake made when reprocessing devices is to either not have the MFIU available or to not follow the instructions (Knudson, 2014). In the USA, national survey organisations like the Joint Commission will audit a hospital to assess its compliance with manufactures instructions for use (Knudson, 2014). Some hospitals in the United States of America however report that it is sometimes difficult to secure a copy of MIFU and to interpret them as they lack standardisation (Knudson, 2014).

According to the American National Standard, it is also important that a hospital is capable of implementing the device manufactures' instructions (AAMI, 2011). The MIFU should therefore understand or be aware of what facilities and accessories are commonly available for decontamination of medical devices in a hospital setting (AAMI, 2011). National guidelines like AAMI TIR 30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices, discuss cleaning agents, equipment and procedures commonly used in hospitals in the United States of America (AAMI, 2011).
The MIFU must be practical, feasible and minimise occupational exposure to blood borne pathogens and toxic chemicals (AAMI, 2011).

To the best of my knowledge MIFU are not provided as a norm in South Africa and are therefore not followed.

2.6.2. Policies and Procedures

According to the American National Standard, comprehensive guide to steam sterilization and sterility assurance in health care facilities, all hospitals should develop their own policies and procedures for the decontamination of reusable medical devices that are based on the manufacturer's instructions (AAMI, 2010). These policies should be detailed, comprehensive and provide step by step instructions (AAMI, 2011). Even though the device manufacturer may provide validated reprocessing instructions, the outcome of cleaning depends on the individual performing the cleaning (AAMI, 2011). Step by step instructions (in a language understood by the reprocessor) are necessary to ensure reprocessing steps are followed accurately and variations don't occur (AAMI, 2011). If there are no step by step instructions or standard operating procedures (SOP's) it is possible that medical devices will not be properly cleaned.

2.6.3 Education and Training of Staff

According to the American national standard, it is the responsibility of the hospital to ensure that staff who decontaminate medical devices are properly trained (AAMI, 2011). Device manufacturers can assist hospitals with training, this can be done by providing, clear written reprocessing instructions, in-service training and instructional videos (AAMI, 2011).

In-service education should include a demonstration of how to reprocess a device by a company representative; following which the hospital staff should then be able to demonstrate the correct procedure to the company representative (AAMI, 2011). Training videos can also be used to train staff that were unable to attend the in-service sessions, to train new staff or to revise training on an annual basis or however often required (AAMI, 2011).

In a paper published by Taneja, Gill, Biswal et al (2010:245) it is noted that "*nurses working in operating theatres showed average knowledge levels regarding sterilisation and disinfection principles*". It is known that a contaminated medical device (one that has not been properly cleaned, disinfected and sterilised can transmit disease from one patient to another (McDonnell et al., 2013). It is therefore important that all nurses and relevant hospital staff (theatre, CSSD, ICU, accident and emergency staff) are suitably trained and educated in decontamination. In South Africa it appears that medical device decontamination is performed by various categories of nursing staff or CSSD technicians who are overseen by or fall under the responsibility of a registered nurse. By definition a registered nurse is *"a person who is qualified and competent to independently practice comprehensive nursing in the manner and to the level prescribed and who is capable of assuming responsibility and accountability for such practice*" (SANC, 2005:34). In order to assume responsibility the registered nurse must be suitably trained in medical device decontamination.

According to Cobbold the entire aim of educating staff in the decontamination of reusable medical devices is to reduce the incidences of HCAI (Cobbold & Lord, 2012) . The knowledge level regarding HCAI in developing countries according to Taneja (2010) is low, and there is an urgent need to rectify this.

Cobbold & Lord (2012, 383) advocates that education regarding decontamination should be standardised and be "*in-line with clinical practice and evidence based research*".

2.6.4 Keeping instruments moist

It is not always possible to clean medical devices immediately after use as surgical procedures can take many hours and sterilising units are faced with increased workloads (Secker, Hervé, & Keevil, 2011). How devices are managed during and after surgical procedures may affect the level of tissue proteins left on them after cleaning as well as the efficacy of the subsequent disinfection and sterilisation processes (Secker et al., 2011).

In 2011, Secker contaminated stainless steel discs with proteins and exposed some of discs to dry conditions, some discs were kept moist (Secker et al., 2011). The discs were then cleaned using an enzymatic detergent and the level of proteins remaining on the discs was measured (Secker et al., 2011). It was much easier to remove the proteins from the discs that were kept moist, and Secker concluded that keeping medical devices moist until they can be cleaned could improve decontamination of devices, possibly reduce the time it takes to decontaminate them, as well as the cost to decontaminate (Secker et al., 2011).

Both the American National Standard and the Technical Information Report advocate that devices should be kept moist, whilst being transported, until they can be cleaned (AAMI, 2010, AAMI, 2011). Devices can be kept moist by wrapping them in a towel moistened with water, or by spraying them with transport gels or foams intended for this use (AAMI, 2010, AAMI, 2011).

2.6.5. Design of Instruments

Certain design features of medical devices can make them more difficult to clean (AAMI, 2011). Specific design features that make medical device cleaning difficult include valves, crevices, luer locks, hinges, fittings with close tolerances, devices with long flexible lumens, rough surfaces that can entrap patient soils, clamps that cannot be fully opened and overlapping joints (AAMI, 2011). Minimally invasive surgical approaches are growing in popularity and have led to the continuous development of complex medical devices that are required to perform this type of surgery (Knudson, 2014). According to Duse (1999) the need for closer collaboration between device manufacturers and infection prevention is important to ensure that medical devices are designed in a fashion that facilitates proper cleaning and decontamination.

On the 19th of February 2015 the FDA (Food and Drug Administration) in the United States of America issued a safety communication titled, Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning (FDA, 2015). The reason for the alert according to the FDA was to *"raise awareness among health care professionals, including those working in reprocessing units in health care facilities, that the complex design of ERCP endoscopes (also called duodenoscopes) may impede effective reprocessing"* (FDA, 2015, 1). The complex nature of the design of the scope has made it difficult to decontaminate as may not be possible to access certain parts of the scope (FDA, 2015).

Possible disease transmission associated with complex medical devices namely; flexible gastroscopes, Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blades and vaginal specula are discussed.

2.6.5.1 Flexible gastroscopes (a type of endoscope)

Outbreaks of infections have been associated with flexible endoscopes, as they come into contact with high levels of soil (bioburden) because of where they are inserted into the body (Rutala & Weber, 2004). The highest levels of bioburden have been found in the suction/biopsy channel (Rutala & Weber, 2004). An audit of provincial gastroenterology services in the Western Cape was conducted in 2008 and the findings of the audit state that reprocessing of flexible endoscopes was "*haphazard*" (Watermeyer, Van Wyk, & Goldberg, 2008:71) Ofstead, Dirlam, Mueller, Tosh, & Wetzler (2013:735) stated that "*nearly all endoscope associated infections have resulted from failure to adequately clean and disinfect endoscopes*. Ofstead also states that there are ongoing, widespread reports of incidents of lapses in endoscope reprocessing (Ofstead et al., 2013). The risk of transmission of infection is higher when there are lapses in reprocessing versus when endoscopes are reprocessed correctly (Ofstead et al., 2013). It is known that "*contaminated endoscopes are linked to more healthcare associated infections than any other medical device*" (Ofstead et al., 2013:734).

In 2010 a multisite, observational study of gastrointestinal scope reprocessing was conducted (Dirlam Langlay et al., 2013). Only 48% of the 183 endoscopes were correctly reprocessed (Dirlam Langlay et al., 2013).

A study published in 2010 examined the impact of human factors and automation on endoscope reprocessing (Ofstead et al., 2010). It was noted in this study that not all reprocessing steps were performed consistently, for example the endoscopes were disassembled in 100% of cases, leak test was performed in clear water in 77% of cases, endoscopes were completely submerged in detergent in 99% of the cases, but all endoscope channels and components were brushed only in 43% of the cases (Ofstead et al., 2010).

In the top 10 health technology hazard for 2014 report by the ECRI institute (a non-profit organisation that uses applied scientific research to improve patient care), inadequate reprocessing of endoscopes and surgical instruments is ranked as the 6th highest health

technology hazard (ERCI, 2013). According to Ofstead et al. (2013) that the current estimate of risk of transmission of infection during endoscopy in the USA is inaccurate and outdated.

2.6.5.2 Yankhauer Suctions

As Yankhauer suctions are lumened devices they can be difficult to clean. A lumened device is a device with a channel within a tube (AAMI, 2011). It is important to flush devices with lumens when cleaning them, as according to Alfa, Olson, & Al-Fadhaly (2010:174) *"if there is no directed fluid flow into a lumen device, there will be no removal of organic material despite being exposed to sonification and a fully automated cleaning cycle*".

A hospital in the United States of America undertook a quality improvement programme that focused on the cleaning of Yankhauer suction tips because "*they are used in most surgical procedures, are exposed to high levels of organic debris and are difficult to clean*" (Azizi et al.,2012:152). The Yankhauer suction tips were first cleaned using a manual process of rinsing and brushing, and following that they were washed in an automated washer in accordance with the manufacturer's instructions (Azizi et al., 2012). After cleaning was performed the lumens of the suction tips were visually inspected using a fibre optic bronchoscope (Azizi et al., 2012). Debris was visible in all 144 suction tips inspected (Azizi et al., 2012). In the study it was noted that it was difficult to clean Yankhauer suction tips as the suction gets narrower as it gets closer to the tip and that the interior lumen had ridges grooves and other tooling marks which seemed to contribute to the build- up of debris in the suction lumen (Azizi et al., 2012).

Despite following manufacturer's instructions Yankhauer suctions remain difficult to clean.

2.6.5.3 Needle Holders

A needle holder is a medical device that is used during surgery to suture with. It has a complex joint design known as a box joint (McDonnell & Sheard, 2012). An instrument with a box joint is likely to have a greater amount of soil adhering to it, which means it is a greater challenge to clean (Lipscomb, Pinchin, Collin et al., 2006c).

In 2007 a study was published in the Journal of Hospital Infection comparing the efficacy of visually inspecting instruments for residual soil versus microscopic inspection of instruments for residual soils (Lipscomb Sihota, & Keevil, et al., 2008). Simple and hinged instruments (instruments with a box joint) were inspected for residual proteins. 41% of the hinged instruments were deemed to be visibly soiled and only 31% of the simple instruments were visibly soiled (Lipscomb et al., 2008).

In a study published by Murdoch, Taylor, Dickinson, et al. (2006), two hundred and six (ready for use) instruments were tested for residual proteins. Of the needle holders tested, 20% of them had protein residuals on them high enough to pose a risk for direct transmission of possible infections (Murdoch et al., 2006).

2.6.5.4 Diathermy Forceps

Diathermy forceps are used to cauterise bleeding blood vessels in all types of surgery including neurological surgery (Lipscomb, Sihota & Keevil et al., 2006b). Eight clean and sterilised diathermy forceps were collected from various hospitals in the United Kingdom and inspected for residual soils (Lipscomb et al., 2006b). Large amounts of residual contamination (soils) were found on the tips of the forceps (Lipscomb et al., 2006b). These findings indicate that diathermy forceps could be a potential reservoir for the transmission of prion diseases and that the residual materials on diathermy forceps could protect and prevent the inactivation of pathogenic microorganism (Lipscomb et al., 2006b).

2.6.5.5 Laryngoscope Blades

Laryngoscope devices are made up of two parts, a blade and handle. The laryngoscope is held by the handle and the blade is inserted into the mouth to facilitate tracheal intubation (Negri de Sousa, Levy & Freitas, 2013). Laryngoscope blades are complex in design as they have grooves and recesses that are difficult to clean thoroughly, which may result in the accumulation of residual organic soils on them. This is potentially harmful to the patient and to the healthcare workers handling the devices (Negri de Sousa et al., 2013). Laryngoscope blades are commonly exposed to blood and saliva when intubating a patient (Negri de Sousa et al., 2013). A study was performed by Negri de Sousa et al, to evaluate evidence available in literature with reference to the risk of laryngoscope blades and handles transmitting disease (Negri de Sousa et al., 2013). This study noted that the cleaning phase of laryngoscope blades decontamination had previously been underestimated and that cleaning was indeed very important (Negri de Sousa et al., 2013). Laryngoscope blades are a risk for transmitting disease (Negri de Sousa et al., 2013). Neonatal deaths have also been associated with the use of incorrectly decontaminated laryngoscope blades (Jones et al., 2000).

2.6.5.6 Vaginal Specula

Following an inspection of vaginal specula at a general practitioners practice in 2003 it was noted by an infection control nurse that debris was visible on vaginal specula that had been decontaminated and were ready for use on patients (Wilkins, Kerr & Milne , 2006). It was difficult to assess the possible risk of transmission of sexually transmitted disease and blood borne pathogens, but it was decided that there was a risk of transmission and patients had to be informed. Over four hundred patients were offered screening for possible chlamydia and hepatitis B and C infections (Wilkins et al., 2006). An outbreak of

viral haemorrhagic fever has also been associated with vaginal specula (Fisher-Hoch, S, 2005).

2.6.6. Manual and Automated Cleaning

According to the American National Standard and published research, medical devices should be cleaned using an automated washing process (AAMI, 2011, Alfa et al., 2010). When devices are cleaned manually instead of using an automated process, the efficacy of cleaning depends on the nurse or hospital staff member doing the cleaning, and that person may not follow the reprocessing steps accurately each time (AAMI, 2011).

Automated cleaning on the other hand is reproducible, meaning the exact same process is repeated each time; there is no variation (AAMI, 2011). Automated cleaning is more thorough than manual cleaning (Alfa et al., 2010). In addition automated cleaning is preferred because nursing staff and relevant hospital staff are less exposed to harmful microorganisms and chemicals, productivity is increased and devices can be cleaned using higher water temperatures (AAMI, 2011). Medical devices should be loaded correctly into an automated washer-disinfector, or else they will not be effectively cleaned (Draghici, Gauer, Michels et al., 2005). It is possible that incorrect loading will shield the wash jets preventing effective cleaning (Draghici et al., 2005). Surgical instruments for example must be placed into mesh baskets with the hinge joints opened as wide as possible, and then loaded in an automated washer, as the water spray must come into contact with the entire instrument including the joints (Draghici et al., 2005). Solid instrument baskets will therefore impede the water jet. The cleaning efficacy of an automated washer should also be tested at least weekly but preferably daily (AAMI, 2010).

2.7 HOW TO VERIFY CLEANING WAS DONE EFFECTIVELY

As an improperly cleaned medical device can pose a high risk to a patient, it is critical to verify that medical devices have been effectively cleaned (AAMI, 2011).
The most common method used to verify if medical devices are clean is to visually inspect them for residual soils (AAMI, 2011). In addition to visual inspection verification of cleaning can be by testing medical devices for residual soils (McDonnell, 2006) Residual soil detection includes testing medical devices for haemoglobin, blood, protein, salts, glucose and enzymes (McDonnell, 2006) The most common test method used for evaluating cleaning efficacy is testing medical devices for residual proteins (McDonnell, 2006)
Test methods used to verify efficacy of cleaning should be; easy to perform, provide rapid results, be sensitive, accurate, repeatable, free of interfering substances and robust (AAMI, 2011).

2.8 VISUAL INSPECTION

Once medical devices have been cleaned they should be visually inspected for any visible residual soils (AAMI, 2011). This inspection should be done carefully, and would be enhanced if a magnifying glass was used (AAMI, 2011). It would be easier to identify residual soils using magnification than with the naked eye (AAMI, 2011). However some medical devices have complex designs, overlapping joints and lumens which cannot be effectively visually inspected for residual soils (AAMI, 2011). In a study published by Rothe & Michels (2005) there was a discrepancy between soils that could be visibly seen on instruments and how much protein was detected on instruments with joints, likely because of the inability to see inside a joint.

In addition to this, it is not possible to detect microorganisms, endotoxins or chemical residuals on instruments by visual inspection (AAMI, 2011).
Body fluids like human cerebral spinal fluid are colourless and odourless and will not be detected on a medical device by visual inspection alone (Lipscomb et al., 2006c). It has been shown that human cerebral spinal fluid is a carrier of prion disease (Lipscomb et al., 2006c).

A series of instruments were visually inspected for residual soils in a study done by Fengler, Pahlke, Bisson et al. (2001) it was noted that 92% of the instruments were deemed to be clean and 6% were contaminated, the reaming 2% were not visually inspected. The same instruments were subjected to a protein residual test. Only 32, 5% of the instruments were found to be clean and 67, 5% were contaminated (Fengler et al., 2001). Visual inspection of the instruments was not an accurate reflection of how clean they were.
If only visual inspection is used to verify cleaning “highly dangerous and robust biological agents may remain infectious and undetected” (Lipscomb et al., 2006a). It can be said that visual inspection of medical devices for cleanliness is “*fraught with possible error*” (Lipscomb et al., 2008:52).

Current guidelines state that it is sufficient to verify that endoscopes have been adequately cleaned by visually inspecting them (Visrodia, Ofstead, Yellin et al., 2014). However Australian and European guidelines recommended that outer surfaces and channels of endoscopes are routinely cultured for microorganism (Visrodia, Ofstead, Yellin et al., 2014). Due to the long incubation period required for cultures, the results are only received after the endoscopes have been used on subsequent patients (Visrodia et al., 2014). It is inadequate to rely only on visual inspection only to verify effective endoscope cleaning as it is not possible to see inside the internal channels of an endoscope (Visrodia et al., 2014). Therefore interest has been shown recently in using

rapid indicator tests that detect organic residuals like blood, adenosine triphosphate or proteins that provide immediate feedback regarding cleaning efficacy (Visrodia et al., 2014).

2.9 PROTEIN RESIDUAL TESTS

Three protein residual tests methods are described in the ISO standard for washer-disinfectors part 1 general requirements, terms, definitions and tests (ISO15883-1, 2006). They are the ninhydrin method, the modified ortho-phthalic dialdehyde (OPA) method and the biuret method (ISO15883-1, 2006).

2.9.1 Ninhydrin Method

The ninhydrin method is a swab test method, that provides a qualitative pass fail test that is highly sensitive to proteins and amino acids (ISO15883-1, 2006). Ninhydrin reacts with the primary amino group of amino acids creating a purple colour reaction known as Ruhemann's purple (Nayuni et al., 2013). A commercially available Ninhydrin test kit (Browne Ltd, UK) was deemed to measure a sensitivity level of 9.µg of protein (Lipscomb et al., 2006c). The ninhydrin test method is routinely used in test laboratories and healthcare facilities to test for residual proteins on re-usable surgical instruments as specified in the ISO standard, however according to (Nayuni, Cloutman-Green, Hollis, et al., 2013) some publications advocate that more sensitive protein detection methods are needed. Nayuni (Nayuni et al., 2013) also suggests that the ninhydrin test kits are not able to detect all types of protein, and that it is difficult to remove protein from instrument surfaces using the swab method. It may also be difficult to remove proteins from medical devices with indentations, polished or mirrored surfaces, surfaces that are pitted or scratched, when using a swab test (Lipscomb et al., 2006a). In my experience these tests are not routinely performed in South Africa.

2.9.2 Modified ortho-phthalic dialdehyde (OPA) method

The modified OPA method provides a quantitative test for free primary amino groups of proteins (ISO15883-1, 2006). OPA in the presence of a reagent and amino acids reacts to form a highly fluorescent blue colour. A spectrophotometer can be used quantify the amount of protein present (McDonnell, 2006). The OPA method can be associated with the false-positive detection of proteins (Mc Donnell, 2014).

2.9.3 Biuret Method

The Biuret method is a semi-quantitative method that tests for two or more peptide bonds (ISO15883-1, 2006). When proteins are exposed to an alkaline sulphate reagent a colour change occurs from blue to purple. The more proteins present the darker the purple colour change is, and this can be measured using spectrophotometer provided a semi-quantitative test (McDonnell, 2006).

2.10 SUMMARY

This chapter described the fact that numerous contaminated medical devices have been associated with possible disease transmission from patient to patient, via contaminated medical devices. As this creates a burden on the healthcare system, it is vital that this is prevented by ensuring that medical devices are properly cleaned after use on patients. A number of methods can be employed to prevent transmission of disease via contaminated medical devices including visual inspection and verification of cleanliness using residual protein detection tests. The next chapter describes the research design.

CHAPTER THREE

RESEARCH DESIGN AND RESEARCH METHODS

3.1 INTRODUCTION

This chapter describes the research methodology used in this study. The pilot study, the research population, the sample, the data collection method and the instrument used will be explained in detail. In addition to this the validity and reliability and ethical considerations of the study were also described.

3.2. RESEARCH METHODOLOGY

Research methods can be defined as "*the techniques researchers use to structure a study and to gather and analyse information relevant to the research question*" (Polit & Beck, 2012:741). This can be further described as techniques that can be used to structure research, as well as collect and analyse information relating to the research (Polit & Beck, 2012).

3.3 RESEARCH DESIGN

The research design can be described as '*the overall plan for obtaining answers to research questions*" (Polit & Beck, 2012: 741). There are many ways to classify and describe research designs (Brink, 2006). One way is to classify research designs as qualitative, quantitative and non-traditional (Brink, 2006). Non-traditional research methods according to Brink (2006) include case studies, historical research and meta-analysis.

In this study a descriptive, multiple case study design (consisting of two phases, phase one a pilot study and phase two the main study) was utilised in order to understand the phenomenon of medical device cleaning within its real life context in five hospitals in the province of Gauteng, South Africa. The five hospitals represent the major hospital groups in Gauteng (three private and two public). The circumstances and medical device cleaning may be different in the private sector versus the public sector, and from one private hospital group to another. Therefore research was conducted at three private hospitals each one representing the three major groups of private hospitals in South Africa, and two different sized public hospitals.

3.3.1 Descriptive Research

According to Polit & Beck (2012) descriptive research is non experimental research. The aim of descriptive research is to watch events unfold, and to then describe and record what is seen (Polit & Beck, 2012). The purpose of using a descriptive research design in this study was to observe, describe and record aspects of medical device cleaning within its real context.

3.3.2 Case Study

Case study research is further defined by Yin (Remenyi, 2012:2) as *"an empirical enquiry that investigates a contemporary phenomenon within its real life context, when boundaries between phenomenon and context are not clearly evident, and in which multiple sources of evidence are used".* Empirical enquiry means that case study research, is research that is objectively obtained (Polit & Beck, 2012). Case study research is in-depth as the data that is collected pertains to the problem being researched as well to relevant situational factors (Polit & Beck, 2012). Case study research therefore aims to understand and analyse the situational factors as well (Polit & Beck, 2012). A case study cannot be

conducted in an environment that the researcher can manipulate or control, it is conducted in the real life context (Remenyi, 2012). Another important factor is that case studies make use of multiple sources of evidence (Remenyi, 2012).

According to Remenyi (2012) case study research should not be regarded as qualitative or quantitative in nature, as all relevant data can be used in case studies.

In this research multiple sources of evidence or data were analysed which included the existence of medical device cleaning standard operating procedures, an audit of routine cleaning methods, results of macroscopic visual inspection and results of residual protein detection tests.

3.3.2.1 Types of case study designs

There are a variety of case study designs, such as single holistic, single embedded, multiple holistic and multiple embedded. For first part of this research, the pilot study, a single embedded case study design was used, as the research in this phase was conducted at one hospital only, but did focus on numerous units of analysis. A single case study design can be used when the case in question is rare, unique or representative of a typical case, and a single case study can also be used for a pilot study, but should not be consider a study unto itself (Yin, 2009).

Embedded single case study designs have advantages in that they allow the researcher to examine a wide range of aspects which could enhance the research's findings (Yin, 2009). A wide range of aspects of routine cleaning of medical devices were examined in both the pilot and the main study, including for example where medical devices were cleaned, who cleaned them and how they were cleaned. The disadvantage of an embedded design is that the researcher could focus too much attention on the sub units of analysis (the wider range of aspects) and lose sight of the original research (Yin, 2009).

For the main study, a multiple case, embedded case study design was utilised. Each hospital (3 private and 2 public) represented one case study. At each hospital the

following aspects of importance were evaluated; did the hospital have a cleaning standard operating procedure (SOP), were the six selected medical devices (gastroscopes, Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blades, and vaginal specula) routinely cleaned using methods in line with recommended guidance documents, did the six selected medical devices test positive for residual proteins after routine cleaning. Each of these aspects and each type of medical device is a unit of analysis. The outcome of these aspects (units of analysis) were evaluated and compared, hospital to hospital, i.e. from one case study to the next (Yin, 2009). A multiple case study involves more than one case (Polit & Beck, 2012). Multiple case studies can be equated to doing multiple experiments, as the evidence from these studies can strongly be regarded as being more believable (Yin, 2009). As the evidence from a multiple case study is stronger it is more convincing (Yin, 2009). Each case study should therefore be carefully selected so that it either predicts similar or dissimilar results but for predictable reasons (Yin, 2009). In the main study each hospital or case, employed similar and different cleaning techniques as some devices were cleaned manually and some were cleaned in an automated wash process. In instances where the case studies selected are expected to produce similar results, literal replication has been applied, when the case studies selected are expected to produce different results (for predictable reasons) then theoretical replication logic has been applied (Yin, 2009).

In this research more than one hospital used automated cleaning methods, meaning that literal replication has been applied as these hospitals were expected to produce similar cleaning results.

Theoretically the percentage of devices cleaned in an automated washer versus those cleaned manually should have less residual proteins, as according to Alfa et al. (2010) an automated cleaning process is more thorough. Therefore theoretical replication logic has been applied in this case study research design as some hospitals used automated cleaning methods and are expected to produce different results to those hospitals that cleaned medical devices manually.

Case study research employs replication logic not sampling logic (Yin, 2009). Sampling logic requires a form of calculation to find a representative number or subset on which research should be performed (Yin, 2009). Replication logic however looks for subsets to research that are similar to each other or different to each other (Yin, 2009). Replication logic was applied in this research, as the research was carried out in hospitals that employed both similar and different cleaning methods.

3.4 PILOT STUDY

A pilot study was conducted prior to the main study. A pilot study is a *"small scale version or trial run, done in preparation for a major study"* (Polit & Beck, 2012:737). According to Yin (2009) the selection for the site of a pilot study may be based on convenience, ease of access or geographical proximity. The scope of the pilot study can also be broader than the final data collection plan (Yin, 2009). The pilot study report should detail the lessons learnt regarding the research design and the data collection field procedures (Yin, 2009). The pilot study performed in this research, was a small scale simulation of the main study. It was conducted at one hospital. The hospital was purposively chosen based on geographical location, ease of access and access to the six selected medical devices. The pilot data collection methodology was similar to the main study data collection methodology. The swabbing technique was slightly different, as the pilot study was used to refine the data collection methods. An attempt was made during the pilot study to perform a protein residual brush test on the lumens of the Yankhauer suctions but this was ineffective so it was not done in the main study. In addition it was decided that protein residual swab tests be performed on both the superior and inferior blades of the vaginal speculum, resulting in two swabs per device instead of just one swab as done in pilot study. This was done as the researcher noticed in pilot study that potentially both blades could contain or harbour residual proteins.

3.4.1 Research setting

The research setting for pilot study (phase one) and the main study (phase two) was the same within the hospital complex, however phase one was conducted at one hospital and phase two was conducted at five hospitals.

3.4.2 Population

The population for the pilot study (phase one) consisted of the six selected medical devices at one hospital and the healthcare worker who is allocated to clean those devices. The six selected medical devices were; gastroscopes, Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blades and vaginal specula.

3.4.3 Sample and sampling

The pilot study was performed at one selected hospital that was representative of one of the major hospital groups. This hospital was chosen for a pilot study because; of its accessibility, geographically convenience and because it utilised the six selected medical devices (gastroscopes, Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blades, vaginal specula) routinely on its patients.

3.4.3.1 Sample size

For the pilot study, cleaning of selected medical devices was observed and documented. Following that the devices were tested for residual proteins using a commercially available Browne Ltd, UK ninhydrin test kit. The intention was to perform protein residual test on ten gastroscopes (which included ten brush tests and ten swab tests), ten Yankhauer suctions (which included ten brush tests and ten swab tests), and ten needle holders, ten

diathermy forceps, ten vaginal specula, and ten laryngoscope blades. In addition to the above, the cleaning of one Crile's forceps inoculated with a protein based test soil was observed and swab tested. A total of seventy one tests were to be performed during the data collection as illustrated in the **table 3.1.**

Table 3.1 Sample size pilot study

Gastroscopes	10
Yankhauer lumens	10
Yankhauer	10
Needle holder	10
Diathermy forceps	10
Vaginal speculum	10
Laryngoscope blade	10
Crile's forceps	1
Total tests	71

3.4.4 Data collection

All data and test results were collected and recorded on a structured observation check list (SOCL). For the pilot study one structured observation checklist named SOCL: P1 was used.

3.4.5 Structured Observation Checklist (SOCL) tool for data collection

Data collected on this SOCL in pilot study included; date, name of hospital, type of medical device in question, whether there was a cleaning SOP, if the device was cleaned according to the SOP, where the device was cleaned, the designation of the person who cleaned the device, if the medical device was kept moist until it was cleaned, if it was dismantled, if it was cleaned manually or in an automated washer, what detergent type was used, specific points relating to manual and automated cleaning, whether the device

was macroscopically visually clean, and the result of protein residual test at five minutes, thirty minutes and sixty minutes.

A copy of this document can be found in Appendix D.

3.4.6 Data collection procedure

The researcher entered the setting where routine cleaning of the selected medical devices is carried out. A testing station was set up by the researcher in the area where routine cleaning takes place. Negative and positive ninhydrin protein detection, control tests were performed, and incubated at 57°C for 1 hour, as per the manufacturer (Browne Ltd, UK) instructions.

The researcher established if the hospitals had a medical device cleaning standard operating procedures. The researcher observed and documented how specific medical devices were routinely cleaned (namely; flexible gastroscope, Yankhauer suction nozzle, needle holder, diathermy forceps, laryngoscope blades and vaginal specula). Those devices were then macroscopically visually inspected for soil and photographed.

A marked (traceable) Crile's forceps provided by the researcher was soiled with the Browne Ltd, UK soil test (artificial test soil). This process was required to create a positive control test as the quantity of organic soil will vary on the different medical devices which could possibly result in a false negative. The Crile's forceps was then subjected to routine cleaning. The forceps were then macroscopically visually inspected for soil and photographed.

The Crile forceps and the aforementioned six medical devices were then swabbed with a sterile swab that had been moistened with four drops of sterile water, in keeping with the technique described by Lipscomb (2006c). That swab was tested for protein residues with a ninhydrin protein residue test. The results of the test were photographed and recorded on the structured observation check list at five minutes, thirty minutes and sixty minutes. If

the swab showed a purple colour change the test was said to be positive. This is illustrated in **figure 3.1.** Refer to **figure 3.14** for the data collection flow chart.



Figure 3.2 Purple colour change

Residual protein test technique pilot study (phase one)

The technique for the residual protein tests were performed, following manufacturer's instructions as follows:

- **Gastroscope**

A DispoClean (Odon Life Technology supplied by Browne Ltd, UK), endoscope cleaning brush was passed through the biopsy channel of the gastroscope. The tip of the brush was removed, and placed in the gel filled ninhydrin vial provided (as illustrated in **figure 3.2, 3.3, 3.4, and 3.5**). In addition a test swab was moistened with four drops of sterile water and inserted into the biopsy port illustrated in **figure 3.2**. The test swab was inserted into the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The vial was observed for colour change after five minutes and then again at thirty minutes and finally at sixty minutes. If the brush tip changed to a purple colour the device will have

tested positive for protein. The results were documented on the structured observation check list.

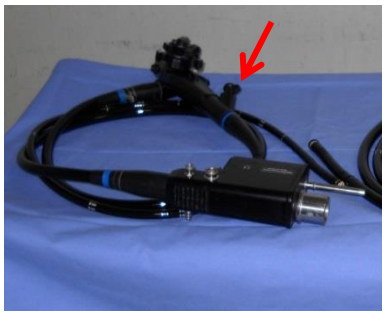


Figure 3.2 Gastroscope biopsy port

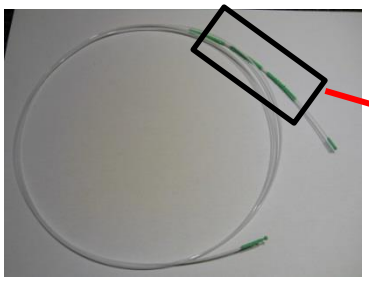


Figure 3.3 Brush tip



Figure 3.4 Tip of brush in vial



Figure 3.5 Vial in incubator

- **Yankhauer suction**

The rose tip of the suction nozzle was removed. A DispoClean endoscope cleaning brush was passed through the lumen of the Yankhauer suction (Yankhauer suction depicted in **figure 3.7**). The tip of the brush was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The vial was observed for colour change after five minutes and then again at thirty minutes and finally at sixty minutes. The results were observed and documented in the structured observation check list.

A test swab was moistened with four drops of sterile water. The test swab was run over the outer surface of the suction nozzle and run over the inside of the rose tip. The tip of the swab was broken off and was placed in the gel filled ninhydrin vial, depicted in **figure**

3.8. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.



Figure 3.6 Yankhauer suction

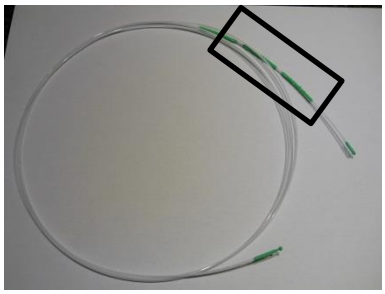


Figure 3.7 DispoClean brush

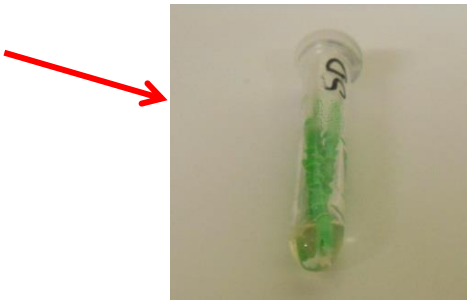


Figure 3.8 Tip of brush in vial

- **Needle Holder**

A test swab was moistened with four drops of sterile water. The test swab was run over the outer surfaces and inner surfaces of the needle holder (needle holder depicted in figure 3.9), including the box joint. The tip of the swab was broken off and was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.

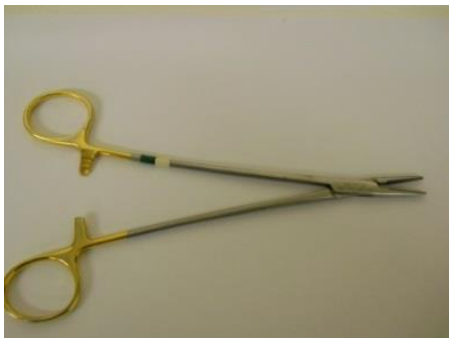


Figure 3.9 Needle holder

- **Diathermy Forceps**

A test swab was moistened with four drops of sterile water. The test swab was run over the outer surfaces and inner surfaces of the diathermy forceps (diathermy forceps depicted in below **figure 3.10**), including the serrated tip. The tip of the swab was broken off and was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.



Figure 3.10 Diathermy forceps

- **Laryngoscope Blade**

A test swab was moistened with four drops of sterile water. The test swab was run over the outer surfaces and inner surfaces of the laryngoscope blade (illustrated in **figure 3.11**), including the tip. The tip of the swab was broken off and was placed in the gel filled

ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.



Figure 3.11 Laryngoscope blade

- **Vaginal speculum**

A test swab was moistened with four drops of sterile water. The test swab was run over the outer surfaces and inner surfaces of the vaginal speculum (illustrated in **figure 3.12**). The tip of the swab was broken off and was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.



Figure 3.12 Vaginal speculum

- **Crile forceps (Control)**

A test swab was moistened with four drops of sterile water. The test swab was run over the outer surfaces and inner surfaces of the Crile's forceps (illustrated in **figure 3.13**),

including the box joint. The tip of the swab was broken off and was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.



Figure 3.13 Crile's forceps

3.5 RESEARCH SETTING

The research setting is the *"physical location and conditions in which data collection takes place in a study"* (Polit & Beck, 2012:743).

In this study data was collected in the department (area) where a particular medical device was cleaned (soil was removed to prepare the device for further processing).

Gastroscopes may be cleaned in the operating room, intensive care unit, a hospital ward or in a specialised gastroenterology unit. Within these units the gastroscopes may be cleaned in a specially designated area or next to the patients ICU or ward bed, next to the patient in the actual operating theatre or gastroenterology unit.

Data pertaining to dirty gastroscopes was collected at the point (in the room) where the gastroscopes were used on patients.

However in the case of cleaned gastroscopes, data was collected at the point where they were cleaned, in that particular hospital.

Vaginal specula are used in the operating rooms, gynaecological surgeon's rooms, and gynaecological clinics. They may be cleaned in the department (area) where they are used or they may be sent the central service sterilising department (CSSD) to be cleaned. A CSSD is an area in a hospital specifically designed and appropriately equipped for cleaning, disinfection and sterilization of medical devices. CSSD's may be adjacent to operating theatres, or they may be housed somewhere within the hospitals building. Data in this study was collected for vaginal specula at the point where they were cleaned at the hospital in question.

The researcher collected data from the CSSD area where needle holders, diathermy forceps, Yankhauer suctions, Crile's forceps were cleaned.
Laryngoscopes blades may be cleaned in CSSD, intensive care, or the scrub rooms adjacent to operating rooms, data was collected in the department (area) where they were cleaned for that particular hospital.

3.6 POPULATION

The population in phase two of this study consisted of the six selected medical devices, the five selected hospitals and the healthcare worker who is allocated to clean those devices. The six selected medical devices were; gastroscopes, Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blades and vaginal specula.
These six medical devices are commonly used devices with complex designs that are known to be difficult to clean or have been associated with disease transmission. The devices were purposively selected for the aforementioned reasons, they are commonly used, are known to be difficult to clean and have been associated with disease transmission.

In this study a health care worker is anyone assigned to cleaning the medical devices in question and can include nursing staff, cleaning staff, technicians and assistants working in doctors' rooms.

3.7. SAMPLE AND SAMPLING

Sampling can be defined as *"the process of selecting a portion of the population to represent the entire population"* (Polit & Beck, 2012:742).
For this study purposive sampling was used. Purposive sampling can be defined as *"nonprobability sampling in which the researcher selects participants based on personal judgement about which ones will be most informative"* (Polit & Beck, 2012:739).

The main study (phase two) was conducted at five additional hospitals in Gauteng. The five hospitals were not randomly selected; they were purposively selected to represent the major hospital groups (private and public) in Gauteng and to represent hospitals that employ different cleaning methods. The hospitals selected included one hospital from the large private hospital groups, and two from the public sector.

In purposive sampling the researcher can employ variation sampling, homogenous sampling, typical case sampling and extreme case sampling (Polit & Beck, 2012).
In this study samples selected (hospitals) employ different cleaning methods so a variation sampling method was applied, however the selected hospitals also represent typical cleaning methods, so typical case sampling was also used.
In terms of variation sampling the researcher looks for subjects that are as different from each other as possible (Polit & Beck, 2012). An advantage of variation sampling is that if common patterns are seen despite the variations in the sample, those patterns can be

said to be of value (Polit & Beck, 2012). For typical case sampling the researcher looks for subjects that are typical or represent the norm (Polit & Beck, 2012).

3.7.1 Sample size

For the main study (phase two), the cleaning of selected medical devices was observed and documented. Following this the devices were tested for residual proteins using a commercially available ninhydrin test kit. Brush tests were to be performed on ten gastroscopes (five clean and five dirty), swab tests were to be performed on ten Yankhauer suctions, ten needle holders, ten diathermy forceps, ten vaginal specula (superior and inferior blades), and ten laryngoscope blades. In addition the cleaning of one Crile's forceps inoculated with test soil was observed and the forceps was swab tested. A total of seventy one tests were to be performed at each hospital. The residual protein tests were carried out at five hospitals; therefore a total of three hundred and fifty five tests were to be performed for the main study, as illustrated in **table 3.2.**

Table 3.2 Sample size main study

	Number of instruments tested	Number of Hospitals	Total number of Tests
Gastroscopes Clean	5	5	25
Gastroscopes Dirty	5	5	25
Yankhauer	10	5	50
Needle holder	10	5	50
Diathermy forceps	10	5	50
Vaginal speculum superior	10	5	50
Vaginal speculum inferior	10	5	50
Laryngoscope blade	10	5	50
Crile's forceps	1	5	5
Total tests			355

3.8 DATA COLLECTION

Data collection is described as *"the gathering of information to address a research problem"* (Polit & Beck, 2012:725). For this research a case study protocol was used to guide the researcher when doing the data collection. According to Yin (2009) a case study protocol describes the rules and procedure's the researcher must follow whilst collecting data as well containing the as the data collection instrument or tool. A case study protocol is "*essential if you are doing a multiple case study*" (Yin, 2009: 79). The case study protocol can be found in appendix A.

All data and test results were collected and recorded on a structured observation check list (SOCL). For the main study (phase two), two structured observation checklists named SOCL: P2 Gastroscopes and SOCL: P2 Medical Devices were used.

Structured observation is a method used to observe and document specific behaviours or actions (Polit & Beck, 2012). In order to conduct structured observation, the researcher or observer should make use of a formal instrument/tool and protocols that specify what behaviours must be observed (Polit & Beck, 2012). The structured observation check list therefore guided the researcher in terms of what specific medical device cleaning procedures needed to be observed and recorded on the tool.
A category system was also used in this study which allowed the researcher to document specific behaviour, and to express the observed behaviours in a numeric format (Polit & Beck, 2012). For example if a device tested positive for residual proteins it was designated by the numerical symbol 1, if the device did not test positive it was designated by the numerical symbol 0.

3.8.1 Structured Observation Checklist (SOCL) tool for data collection

The data collection tool/instrument used in this research was called a structured observation check list as it guided the researcher in terms of the medical device cleaning processes that needed to be observed, the tests that needed to be performed, as well as documenting the results.

The cleaning steps for gastroscopes and the remaining medical devices differ considerably, and could not be easily captured on one document. A single document was too cumbersome to use and therefore two separate structured observation check lists were created, one for gastroscopes and one for the remaining medical devices.

SOCL: P2 Gastroscopes

This structured observation checklist (gastroscopes) was used when the researcher captured data pertaining to gastroscopes.

Using this document the following data was collected; date, hospital, hospital code, instrument code, type of medical device in question, whether there was a cleaning SOP, if the device was cleaned according to the SOP, where the device was cleaned, the designation of the person cleaning the device, if the device was cleaned manually or in an automated washer, what detergent type was used, whether a leakage test was conducted prior to cleaning the device, specific points relating to manual and automated cleaning, the time the protein residual test was incubated, and the result of protein residual test at five minutes, thirty minutes and sixty minutes.

A copy of this document can be found in Appendix E.

SOCL: P2 Medical Devices

This check list was used when the researcher was capturing data pertaining to the remaining five selected medical devices namely; Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blades and vaginal specula.

Using this document the following data was collected; date, name of hospital, hospital code, instrument code, type of medical device in question, whether there was a cleaning SOP, if the device was cleaned according to the SOP, where the device was cleaned, the designation of the person cleaning the device, if the medical device was kept moist until it was cleaned, if it was dismantled, cleaned manually or in an automated washer, if the device was pre-cleaned before being placed into the automated washer, what detergent type was used, specific points relating to manual and automated cleaning, whether the device was macroscopically visually clean, the time the protein residual test was incubated, and the result of the protein residual test at five minutes, thirty minutes and sixty minutes.

A copy of this document can be found in Appendix F.

3.8.2 Validity and reliability of the structured observation checklist (Instrument)

Instrument or data collection tool validity refers to *"the degree to which an instrument measures what it is intended to measure"* (Polit & Beck, 2012:336).

The pilot study was conducted to increase the validity and reliability of the structured observation check list (instrument/tool used for data collection).

The researcher realised after the pilot study that the data collection tool (SOCL) used did enable not sufficient data collection which is why two separate data collection tools were created for main study.

The observations and data collection were carried out by the researcher only; this further enhanced the reliability of this study. Instrument or data collection tool reliability refers to *"the degree of consistency or dependability with which an instrument measures an attribute"* (Polit & Beck, 2012:331).

The structured observation check lists, or aspects observed and document on the document were based on expert opinion (AAMI, 2010,Rutala & Weber 2008).

3.8.3 Data Collection Procedure

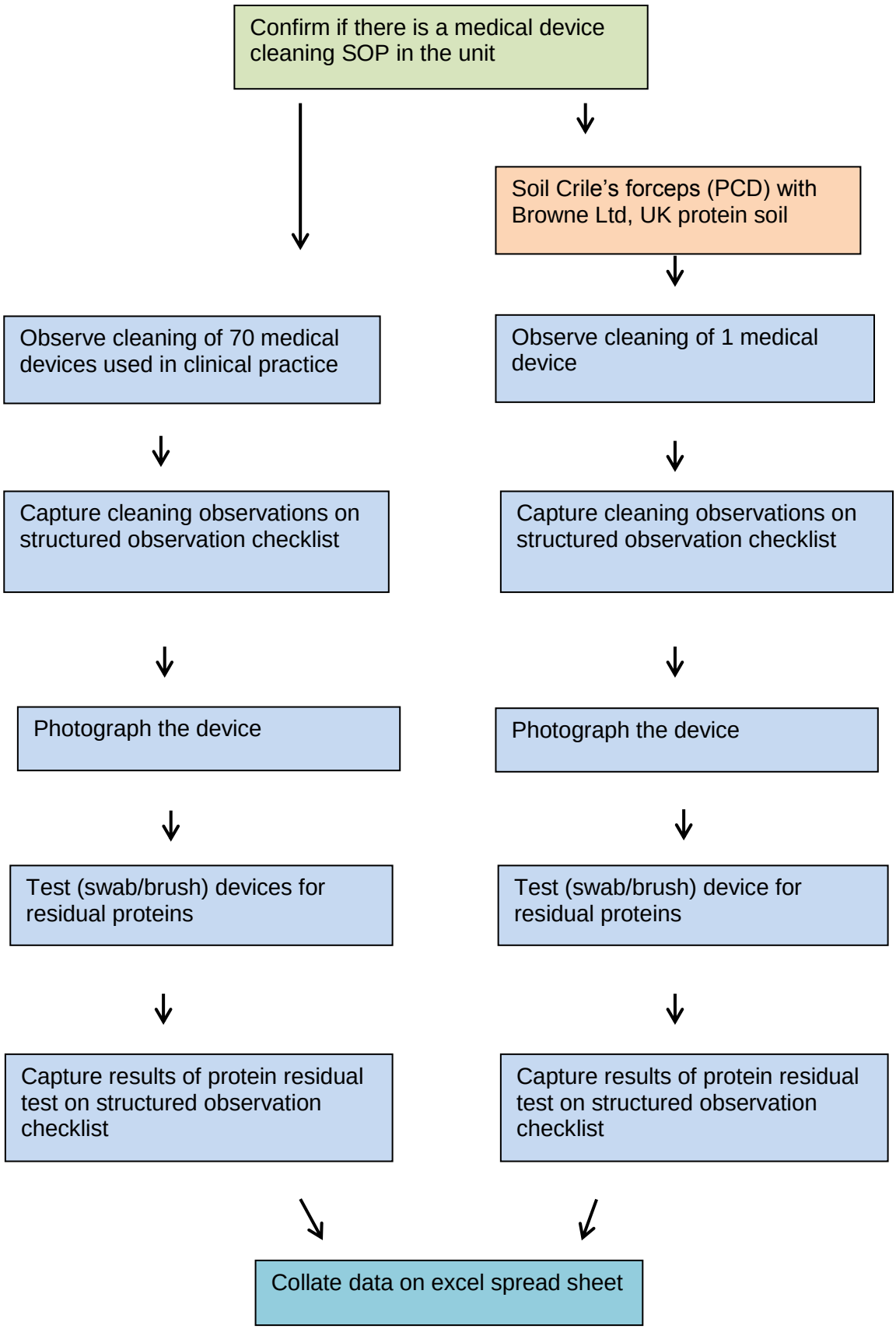


Figure 3.14 The data collection procedure flow chart: pilot study and main study

The researcher entered the setting where routine cleaning of the selected medical devices was carried out. A testing station was set up in the area where routine cleaning takes place. Negative and positive ninhydrin protein detection control tests were performed, and incubated at for 1 hour, as per the manufacturer instructions.

The researcher established if the hospitals had medical device cleaning standard operating procedures. How specific medical devices were routinely cleaned was observed by the researcher for the following devices namely; flexible gastroscope, Yankhauer suction nozzle, needle holder, diathermy forceps, laryngoscope blades and vaginal specula. The above devices were then macroscopically visually inspected for soil and photographed.

A marked (traceable) Crile's forceps provided by the researcher was soiled with Browne Ltd, UK soil test (artificial test soil). This process is required to create a positive control test as the quantity of organic soil will vary on the different medical devices which could possibly result in a false negative. The Crile's forceps was then subjected to routine cleaning. The forceps were then macroscopically visually inspected for soil and photographed.

The Crile forceps and the aforementioned 6 medical devices were then swabbed with a sterile swab and that swab was tested for protein residues with a ninhydrin protein residue test. The results of the test were photographed and recorded on the structured observation check list at five minutes, thirty minutes and sixty minutes. Refer to **figure 3.1** for the data collection flow chart.

Residual protein test technique: Main study

The swabbing and brushing technique for the residual protein test was performed as follows:

- **Gastroscope**

A DispoClean endoscope cleaning brush was passed through the biopsy channel of the gastroscope, as illustrated in **figure 3.15**.

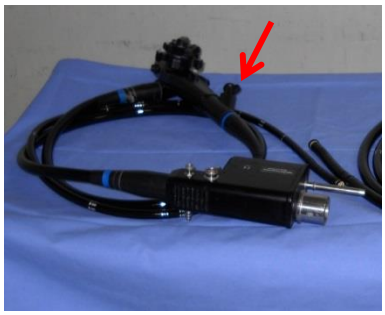


Figure 3.15 Gastroscope biopsy port

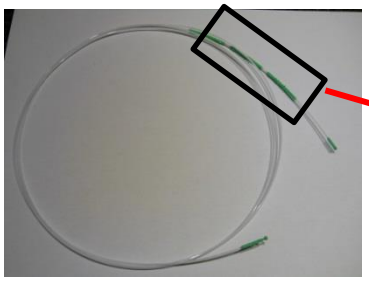


Figure 3.16 Brush tip



Figure 3.17 Tip of brush in vial



Figure 3.18 Vial in incubator

The tip of the brush was removed, and placed in the gel filled ninhydrin vial provided. The vial was incubated at 57°C for 1 hour. The vial was observed for colour change after five minutes and then again at thirty minutes and finally at sixty minutes. If the brush tip changed to a purple colour the device would have tested positive for protein. The results were documented on the structured observation check list. This test was performed on clean and dirty gastroscopes.

- **Yankhauer suction**

The rose tip of the suction nozzle was removed. A test swab was moistened with four drops of sterile water. The test swab was inserted into the lumen of the tip of the suction, and the lumen was swabbed, then the rose tip cap was swabbed with the same swab, as depicted in **figure 3.19**.

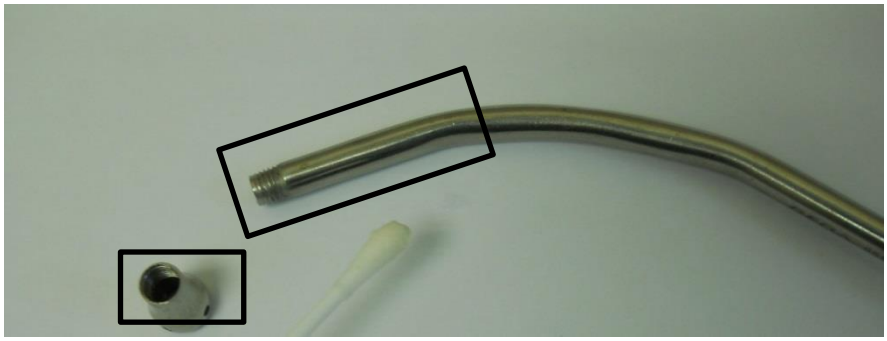


Figure 3.19 Portion of Yankhauer suction swab tested for residual protein

The tip of the swab was broken off and was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.

- **Needle Holder**

A test swab was moistened with four drops of sterile water. The test swab was run over all sides of the instrument tips ending at and including the box joint, as depicted in **figure 3.20**.

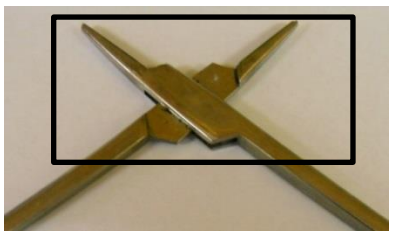


Figure 3.20 Portion of needle holder swab tested for residual protein

The tip of the swab was broken off and was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.

- **Diathermy Forceps**

A test swab was moistened with four drops of sterile water. The test swab was run over all the surfaces of the diathermy forceps serrated tip ending at the insulation, as depicted in **figure 3.21**.

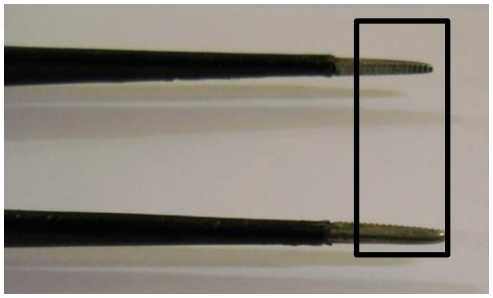


Figure 3.21 Portion of diathermy forceps swab tested for residual protein

The tip of the swab was broken off and was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.

- **Laryngoscope Blade**

A test swab was moistened with four drops of sterile water. The test swab was run over the superior surface of the laryngoscope blade ending at and including the portion where the light bulb is inserted, as depicted in **figure 3.22**.

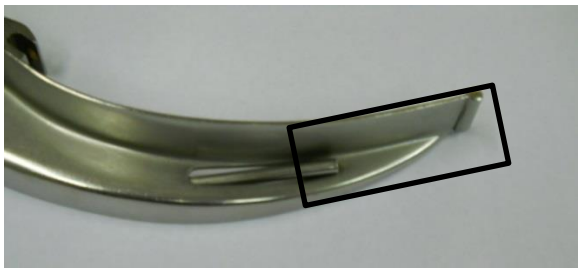


Figure 3.22 Portion of laryngoscope swab tested for residual protein

The tip of the swab was broken off and was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.

- **Vaginal speculum**

A test swab was moistened with four drops of sterile water. The speculum mouth was opened. A test swab was run over the superior inner first third surfaces of the vaginal speculum. Another test swab was moistened and then run over the inferior inner first third of the vaginal speculum, as depicted in **figure 3.23**.

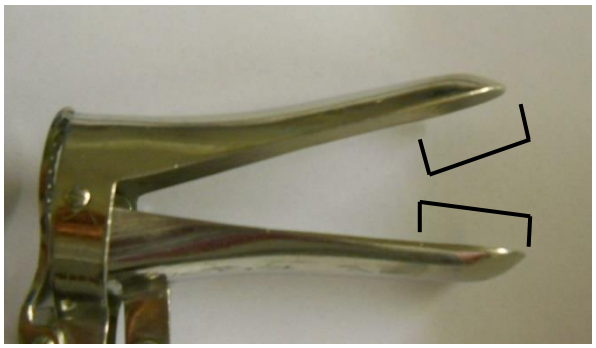


Figure 3.23 Portion of vaginal speculum swab tested for residual protein

The tip of the swabs was broken off and was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.

- **Crile forceps (Control)**

A test swab was moistened with four drops of sterile water. The test swab was run over all sides of the instrument tips ending at and including the box joint, as depicted in **figure 3.24** below.

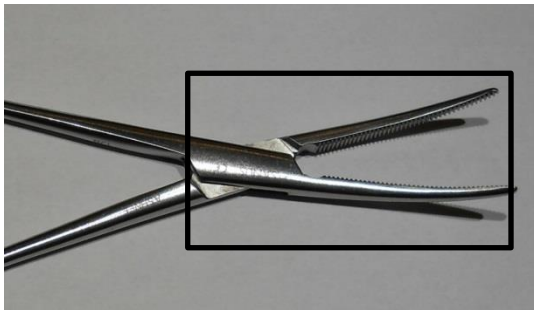


Figure 3.24 Portion of Crile's forceps swab tested for residual protein

The tip of the swab was broken off and was placed in the gel filled ninhydrin vial. The vial was incubated at 57°C for 1 hour. The results were observed and documented on the structured observation check list.

3.9 VALIDITY AND RELIABILITY OF STUDY

The validity of a study refers to how accurate the conclusions or suppositions made in the study actually are (Polit & Beck, 2012).
When using case study methodology the researcher can focus on construct validity, internal validity and external validity (Yin, 2009).

3.9.1 Construct Validity

Construct validity is concerned with ensuring that the right aspects for a particular study are being researched (Yin, 2009). Various techniques can be used to improve the

construct validity according to Yin, including using multiple sources of evidence during data collection and by establishing a chain of evidence (Yin, 2009). The types of evidence that can be used includes; documentation, archival records, interviews, direct observations, participant observation and physical artefacts (Yin, 2009).

In this study multiple sources of evidence were used. The sources of evidence included the following:

- Documentation: checking if the unit has written standard operating procedures to guide the cleaning of the selected medical devices.
- Macroscopic visual inspection: of the medical devices (results recorded on the structured observation check list).
- Photograph: of the visually inspected medical device.
- Direct Observation: of cleaning methods using a structured observation check list.
- Protein test: a test performed by the researcher to test if the selected medical devices are positive for residual proteins. This is a measure of cleaning efficacy.

3.9.2 Internal Validity

A tactic that can be used to address internal validity when using a case study research design according to Yin, is to make use of pattern matching when analysing the data (Yin, 2009).

In this research, the researcher used pattern matching to establish if specific cleaning methods produce medical devices free from protein residuals. All data captured was filtered on a excel spread sheet to ascertain what percentage of medical devices cleaned manually and cleaned in an automated washer tested positive for proteins. Data was also filtered to establish if more of the devices that were kept moist tested positive for proteins than those that are not kept moist.

3.9.3 External validity

External validity is concerned with being able to generalise the results of the study to circumstances beyond this immediate case study (Yin, 2009).
Typically single case studies are less suited to generalizing (Yin, 2009), therefore in this research a multiple case study design was used. Having said that, this research was conducted on a small scale and the results may reflect a snap shot of medical device decontamination in the South African context, but does not enable the researcher to generalise beyond this immediate case study. This highlights the need for additional research in this area.

3.9.4 Reliability

According to Yin (2009) in the past case study research procedures were not well documented, and as a result the critics tend to be suspicious of the reliability of the case study research design. If the research process is not well documented, even the researcher would not be able to repeat his own research (Yin, 2009).
One way to increase a studies reliability is to make use of a case study protocol (Yin, 2009). A case study protocol will guide the investigator / researcher when carrying out the data collection (Yin, 2009). A case study protocol is more than just a data collection instrument, but it should also contain the data collection instrument (Yin, 2009). A case study protocol was written and followed in this research. A copy of the case study protocol can be found in appendix A.

3.10 ETHICAL CONSIDERATIONS

According to Burns & Grove (2001) nursing research requires expertise, diligence along with honesty and integrity. Ethical research is needed to produce knowledge for practice

whilst protecting the rights of the humans who are subjects of research. Ethical assessment and clearance is critical in research to ensure that there is balance between the risks and benefits of a particular study as well as to prevent any wrong doing or misconduct.

The following steps were taken to address ethical considerations in the proposed study:

- The research proposal and structured observation check list were submitted to the Postgraduate committee (Faculty of Health Sciences) of the University of the Witwatersrand for permission to undertake research. Permission was obtained. Appendix M.
- The research proposal and structured observation check list were submitted to the Committee for Medical Research on Human Subjects of the University of the Witwatersrand for permission. Permission was obtained and the committee issued a clearance certificate. Clearance certificate number: M130345. Appendix I
- Permission to conduct research was obtained from appropriate Hospital Management personnel of the 2 public sector and 3 private hospitals. Appendix G, H, J, K and L.
- Written consent was obtained from each individual being observed and each was provided with an information letter explaining the study procedure.
- The names of the individuals being observed were not recorded only their designation, to ensure confidentiality and protect anonymity.
- Each hospital was allocated a code/unique identification thereby ensuring hospital anonymity, and protecting confidentiality.
- Confidentiality of hospitals was further protected as only the researcher and supervisor had access to this study's raw data.
- Participants were protected from any discomfort whilst being observed as they were guaranteed that no negative relationships would develop between them and the researcher if they chose not to participate in the study.

- Consent was obtained to conduct research from the ethics committee at a private healthcare group which was subject to a privacy and confidentiality agreement.

3.11 SUMMARY

In this chapter the research design, the research setting and the research population were described. Following that, the research sample and sampling method, data collection, pilot study, validity and reliability and ethical considerations of the study was also described

CHAPTER FOUR

DATA ANALYSIS AND RESULTS

4.1 INTRODUCTION

In this chapter the approach used to analyse the data and the results was described. The results were described using descriptive statistics and pattern matching. The result from the pilot study (phase one) and the main study (phase two) where presented. The research findings were also discussed.

4.2 APPROACH TO DATA ANALYSIS

The data collected was captured on an excel spread sheet and analysed by means of descriptive statistics, pattern matching and MICROSOFT EXCEL + ANALYSE IT ®, Version 2013, standard edition. Aspects that were calculated include number of tests done and what proportion of the tests was positive for protein residues. This was calculated per hospital and per medical device type.

Pattern matching was done to establish if specific cleaning methods produced medical devices free from protein residuals. Pattern matching logic according to Yin (2009) compares an empirically based pattern with a predicted pattern, thus comparing what was observed, what actually happened, and what was thought would happen. All data captured was filtered on a excel spread sheet to ascertain what percentage of medical devices cleaned manually tested positive for proteins, and what percentage cleaned in an automated washer tested positive for proteins i.e. using pattern matching. Theoretically less of the medical devices washed in an automated washer should have positive for proteins, as an automated cleaning process is more thorough than manual cleaning (Alfa

et al., 2010). Data was also filtered to establish if more of the devices that were kept moist tested positive for proteins then those that are not kept moist.

4.3. RESULTS OF THE PILOT STUDY

4.3.1 Research setting

Research was conducted in a variety settings or hospitals that represented both the private sector and the provincial sector. For the pilot study all of the research 100% was conducted in one private hospital (n=1/1. Findings are shown in **figure 4.1.**

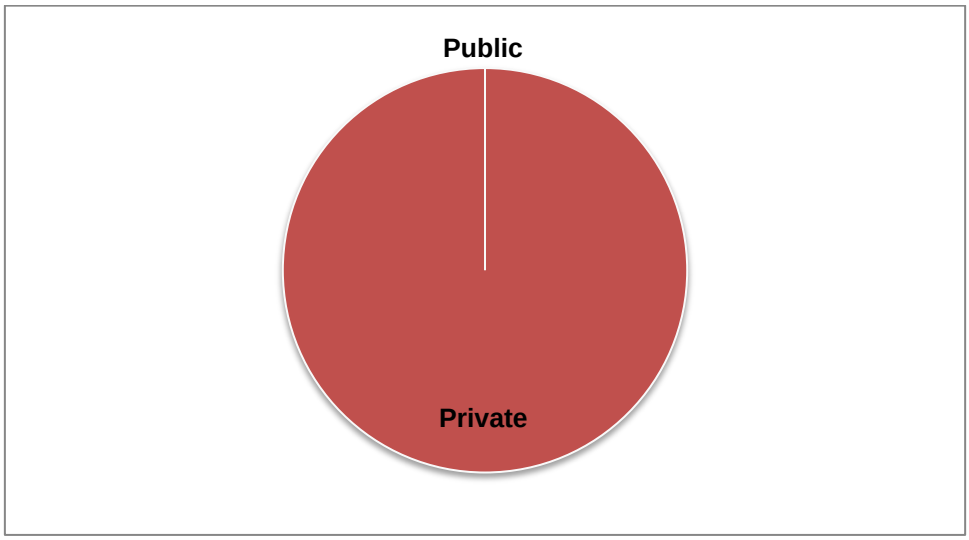


Figure 4.1 Research setting

4.3.2 Number of protein residual tests done at 1 hospital

The researcher observed the cleaning of medical devices and performed protein residual tests on 119 medical devices, at one hospital for the pilot study

As research was performed at only one hospital, the researcher cannot reflect the findings for number of residual protein tests done per hospital as was done in the findings for main study.

The researcher intended to observe the cleaning of and to perform 71 protein residual tests on six types of medical devices. The six types of medical devices were as follows; Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blades, vaginal specula, Crile's forceps and gastroscopes.

The pilot study was used to refine the test taking method and the structured observation check list that was used for data collection called SOCL: P1. As a result additional protein residual tests were required, a total of 119 tests were performed whereas it was intended to perform 71 tests.

The researcher had also intended to perform protein residual **brush** tests on the Yankhauer suctions, but this was not done as the design of the instrument did not facilitate the use of a brush test.

The intended and actual numbers of protein residual test performed per medical device are outlined in **Table 4.1.**

Table 4.1: Number of residual protein tests done per medical device

Medical device	Number of intended tests	Number of tests performed
Yankhauer Brush	10	0
Yankhauer Swab	10	21
Needle holder	10	22
Diathermy	10	13
Laryngoscope	10	32
Vaginal Speculum	10	18
Crile's forceps	1	1
Gastroscopes	10	12
Total	71	119

4.3.3 Cleaning observed or described

The researcher intended to observe and record how medical devices were cleaned. In some instances it was not possible to observe the cleaning process, so the process was describe to the researcher by the individual who did the cleaning.

The researcher was able to observe 39% of the participants in this study cleaning the medical devices (n=46/119), and the remaining participants described the cleaning method used in 61% of the cases (n=73/119). The findings are shown in **figure 4.2.**

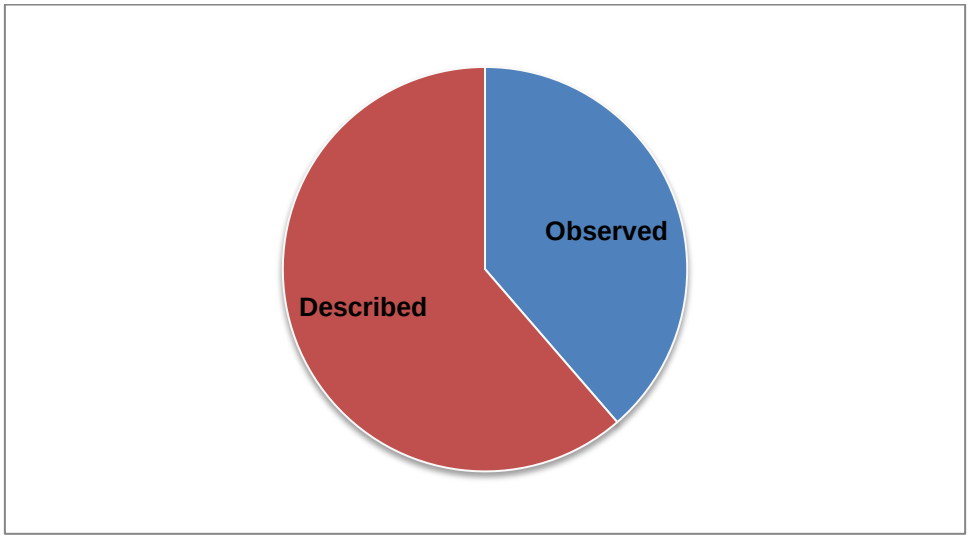


Figure 4.2: Percentage of medical device cleaning observed vs. described pilot study

4.3.4 Where devices were cleaned

The researcher had to record on the SOCL where in the hospital the various medical devices were cleaned. The researcher recorded that 50% of the medical devices were cleaned in the CSSD (n=60/119), 28% were cleaned in the operating theatre (n=33/119), 13% in doctors rooms (n=15/119) and 9% in the intensive care unit (ICU) (n=11/119). These findings are shown in **figure 4.3.**

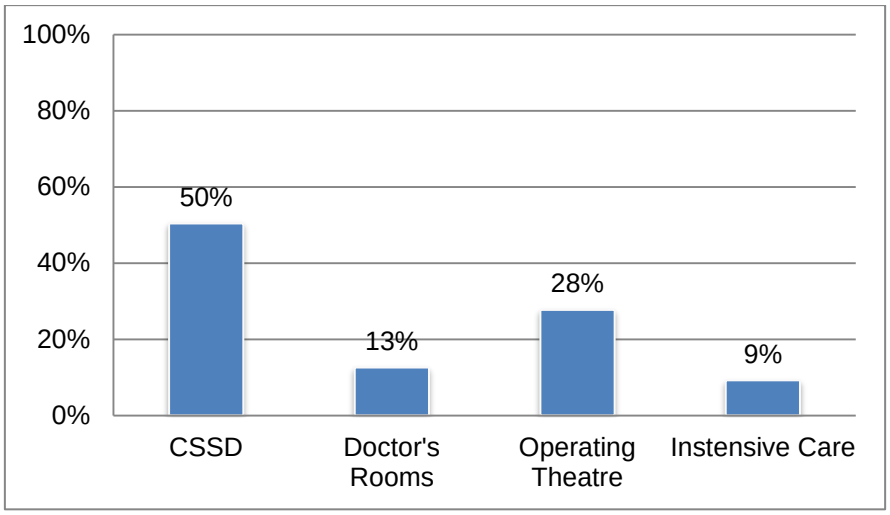


Figure 4.3 Where in the hospital medical devices were cleaned pilot study

4.3.5 Designation of the person cleaning

The researcher needed to ascertain and record the designation of the individual cleaning the medical device in question. This was done by asking the individual doing the cleaning what their designation was, and recording this on the SOCL.

It was noted that 51% of the medical devices were cleaned by CSSD technicians (n=61/119), the remaining medical devices 36% were cleaned by nurses (registered or enrolled) RN/EN (n= 43/119) and 13% were cleaned by non-healthcare workers (n=15/119). The findings are shown in **figure 4.4.**

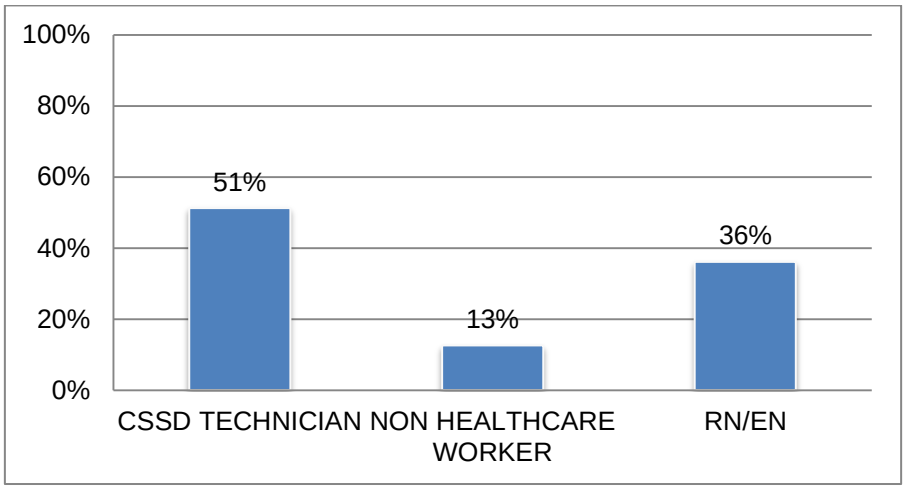


Figure 4.4 Designation of the person cleaning

4.3.6 Cleaning SOP

The researcher needed to ascertain if the individual cleaning the medical device was aware of any SOP describing how medical devices must be cleaned.

100% of the participants were **not aware** of any medical device cleaning SOP in their respective hospital units (n=119). The findings are shown in **figure 4.5.**

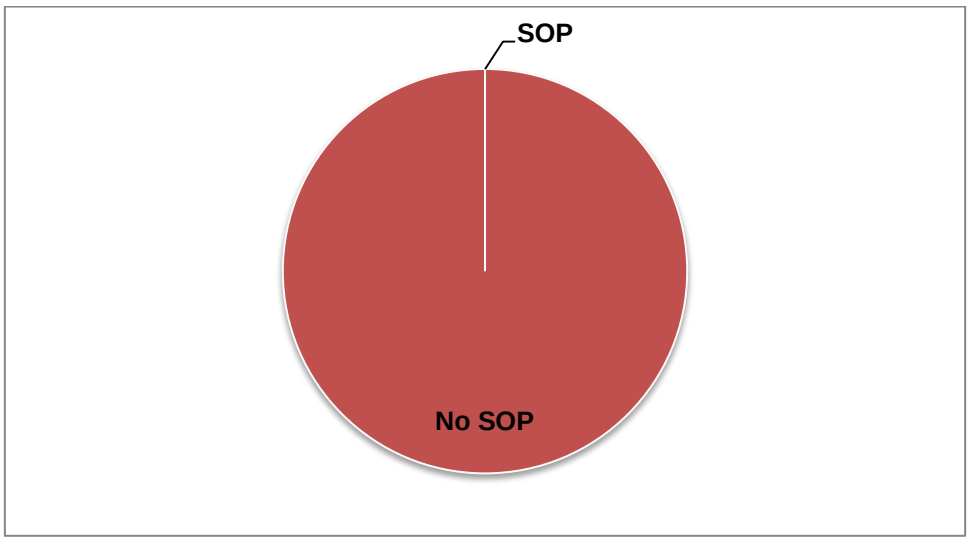


Figure 4.5 Percentage not aware of medical device cleaning SOP's

4.3.7 Cleaning Method: Manual or Automated

Medical devices can be cleaned using manual or automated cleaning methods. The researcher needed to ascertain if medical devices were cleaned manually or using an automated process.

The researcher found that 100% of the medical devices in the pilot study were cleaned manually (n=119). The findings are shown in **figure 4.6.**

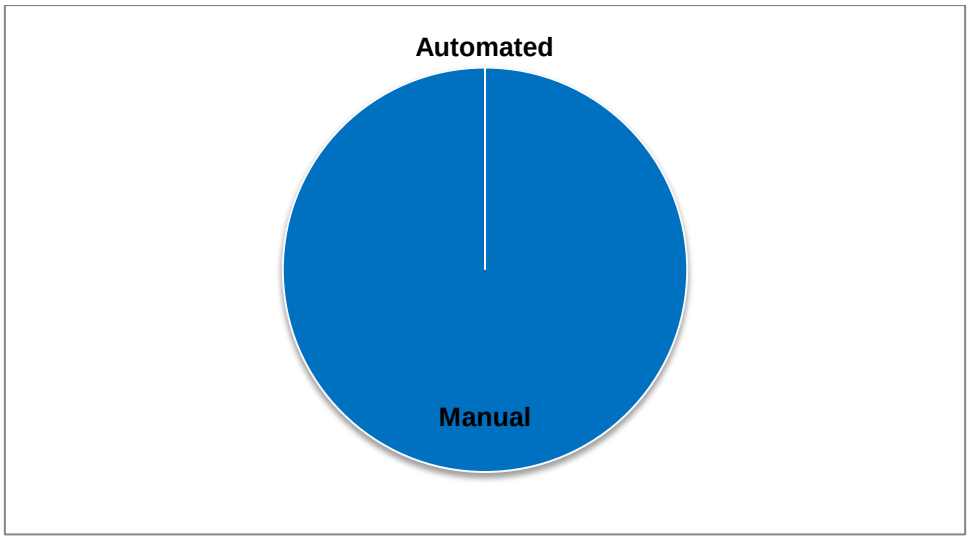


Figure 4.6: Percentage of devices cleaned manually vs. automated cleaning pilot study

4.3.8 Type of Detergent

The researcher had to ascertain what type of detergent was used to clean the medical devices in question.

The researcher found that 68% of the medical devices were cleaned with an enzymatic detergent (n=81/119) and the remaining 32% of the devices were cleaned with hand soap, not designed to clean medical devices (n=38/119). The findings are shown in **figure 4.7.**

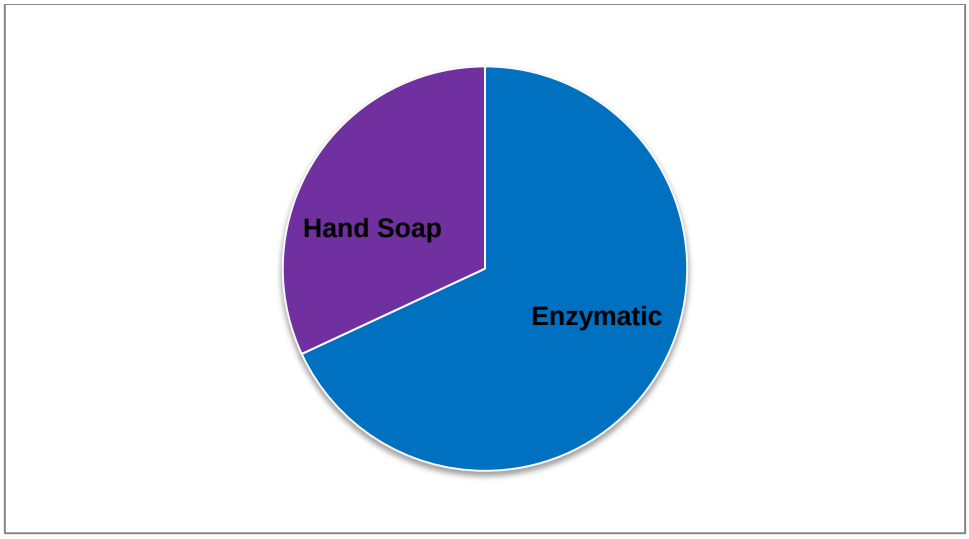


Figure 4.7: Type of detergent used to clean medical devices pilot study

4.3.9 Dilution of Detergent and Water

Medical devices are cleaned in a dilution of detergent and water. The researcher ticked yes on the SOCL if the detergent was diluted correctly, according to MIFU, and no if it was not.

The researcher found that in 92% of the cases (n=110/119) the detergent used to clean medical devices was **not** diluted according to the MIFU. The findings are shown in **figure 4.8.**

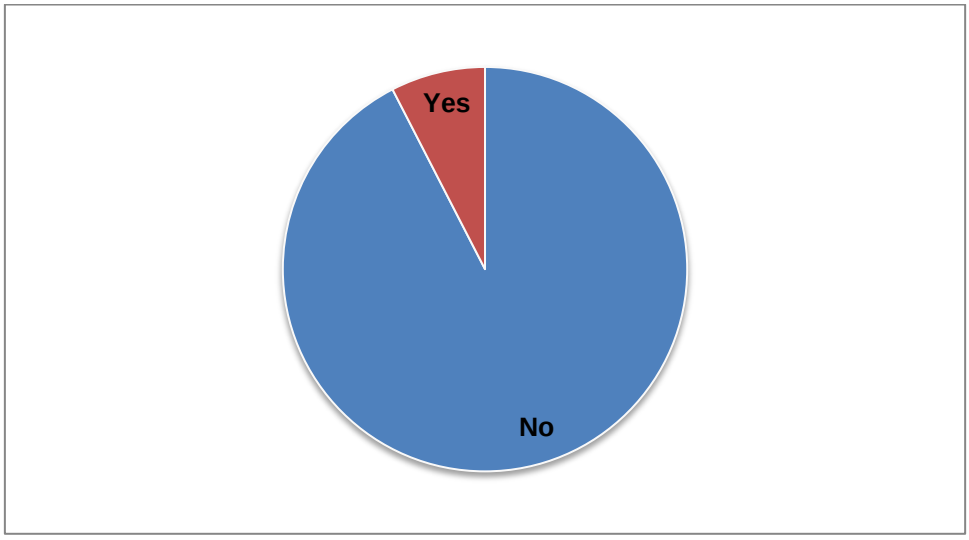


Figure 4.8: Detergent diluted according to MIFU pilot study

4.3.10 Kept Moist

The researcher needed to ascertain and record if medical devices were kept moist until such time as they were cleaned.

The researcher found that medical devices were kept moist in 69% of cases until they were cleaned (n=74/107) and were not kept moist in 31% of the cases (n=15/33). The findings are shown in figure **4.9.**

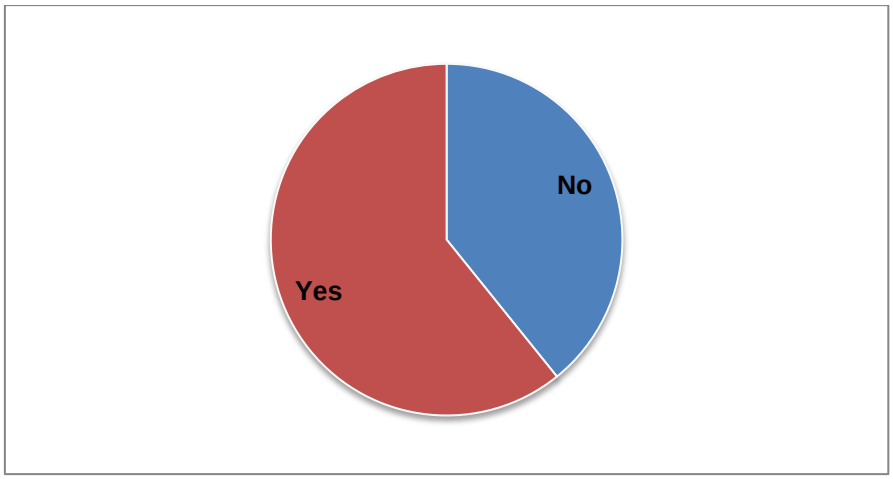


Figure 4.9 Medical devices kept moist until cleaned

As all medical devices were cleaned manually in the pilot study, the researcher cannot report any findings with regards to the factors associated with automated cleaning namely; pre clean, washer manufacture, correct tray, shadowing or overloading.

4.3.11 Friction

The researcher needed to ascertain and record if friction was applied to the medical devices during the cleaning process.

The majority of medical devices 89% were placed in a detergent water solution and cleaned by applying friction with a cleaning accessory (n=95/107). The remaining 11% of medical devices were placed in the detergent, water solution but no friction was applied during the cleaning process (n=12/107).

The findings are shown in **figure 4.10**.

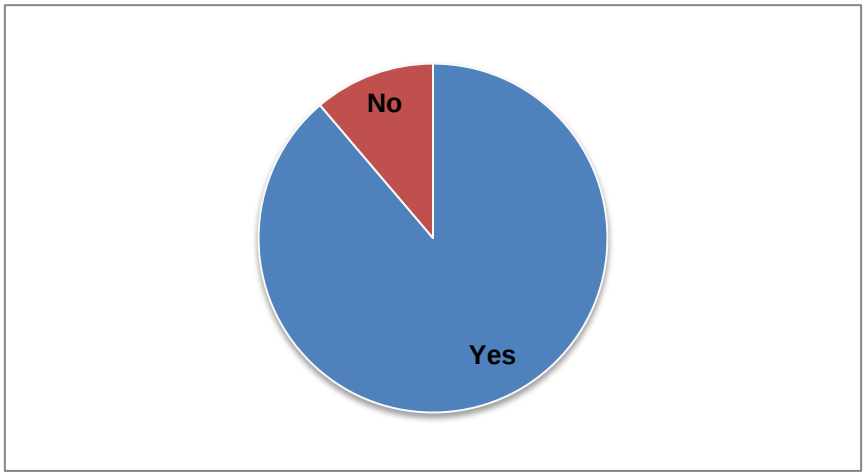


Figure 4.10 Medical devices cleaned using friction

4.3.12 Cleaning accessories

When cleaning medical devices, friction is applied using a cleaning accessory. A number of different cleaning accessories can be used.

The researcher found that during the pilot study medical devices were cleaned using a brush in 89% of the cases (n=95/107). The findings are shown in **figure 4.11.**

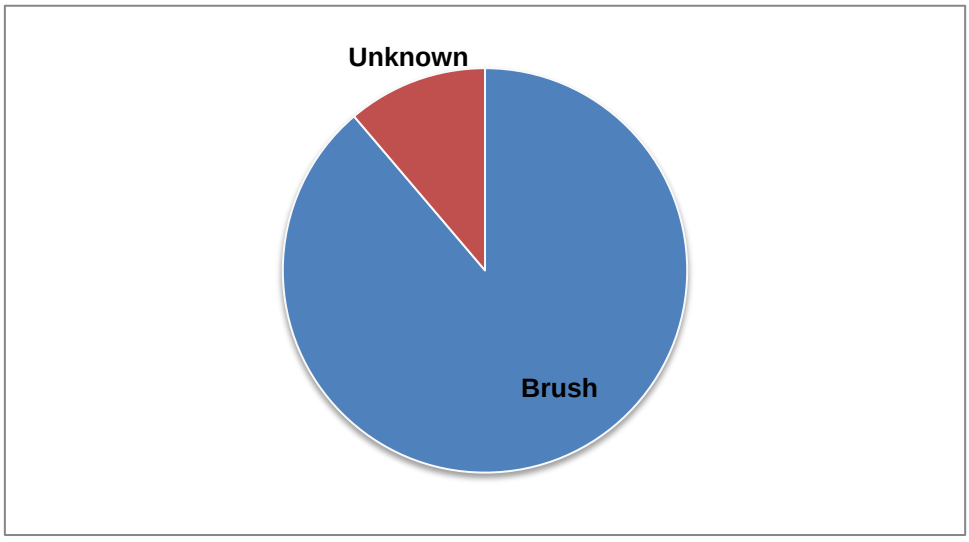


Figure 4.11 Cleaning accessories

4.3.13 Flush lumen manual cleaning

The researcher needed to ascertain if the lumens of the Yankhauer suctions were flushed during the cleaning process. The researcher found that the lumens of the Yankhauer suctions were flushed in 62% of the cases (n=13/21) and not flushed in 38% of the cases (n=8/21). The findings are shown in figure **4.12.**

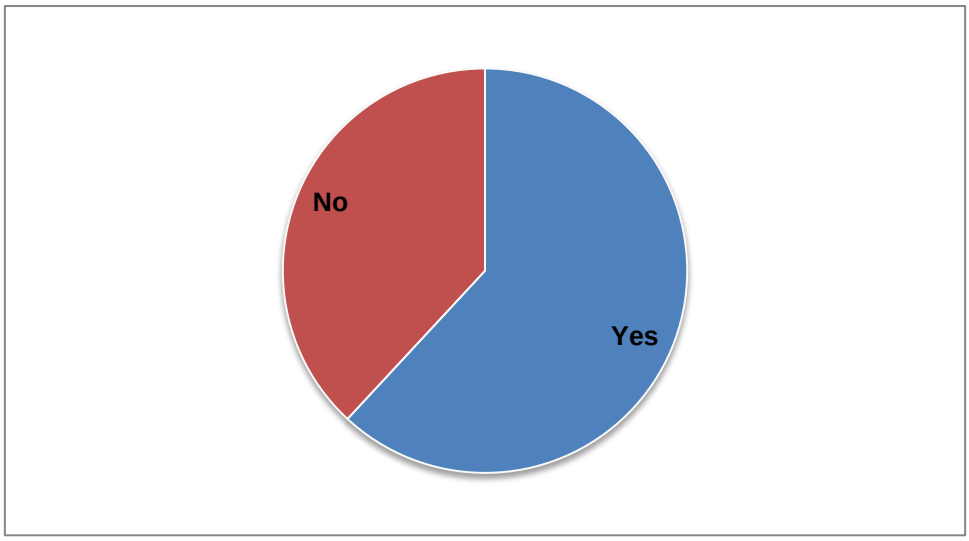


Figure 4.12: Percentage of lumens of Yankhauer suction flushed

As all Yankhauer suctions were cleaned manually the researcher cannot report in findings regarding lumen flush, automated cleaning.

4.3.14 Macroscopically Visually Clean

The cleaned medical devices were macroscopically visually inspected by the researcher (using a naked eye) for residual soils and findings were recorded.

The **cleaned** medical devices appeared to be macroscopically visually clean in 37% of the cases (n=40/107) and visually dirty in 63% of the cases (n=67/107). The findings are shown in **figure 4.13.**

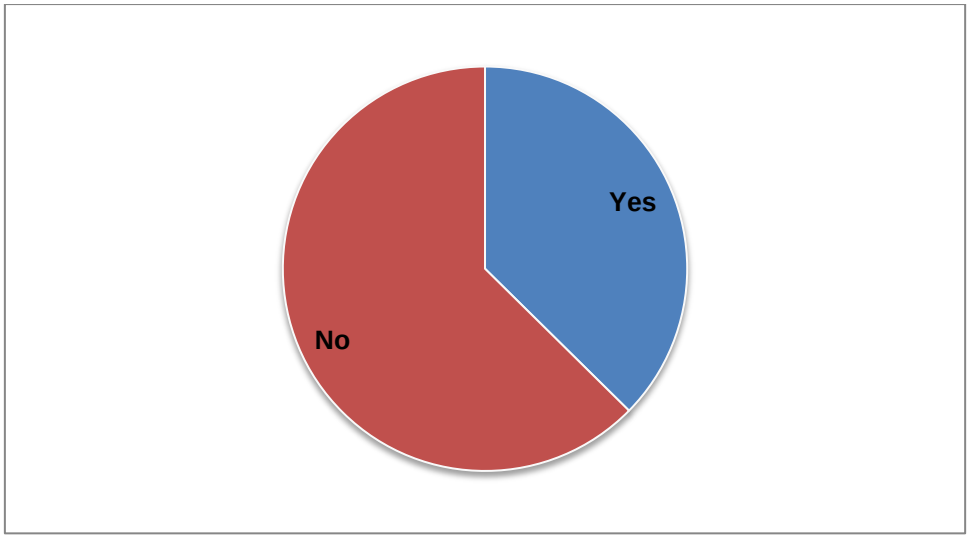


Figure 4.13: Percentage of devices visually clean

4.3.15 Gastroscopes

The cleaning of gastroscopes was neither thoroughly observed, nor documented by the researcher during the pilot study. This was because the structured observation check list (SOCL: P1) was not adequately designed for this purpose. No findings could be reported in the pilot study with regards to; leak test available, leak test performed, gastroscope cleaning steps performed, clean-time, cleaning method, dirty scopes that tested positive for proteins. Only cleaned gastroscopes were tested for residual proteins in the pilot study.

Because this test yielded low results it was decided (on consultation with the supervisor) to test both dirty and cleaned gastroscopes for residual proteins main study, to establish if this test method was suitable for testing gastroscopes for residual proteins.

4.3.16 Cleaned gastroscopes tested positive for residual proteins

The researcher found that 8% of the cleaned gastroscopes (n=1/12) tested positive for residual proteins. Findings are shown in **figure 4.14.**

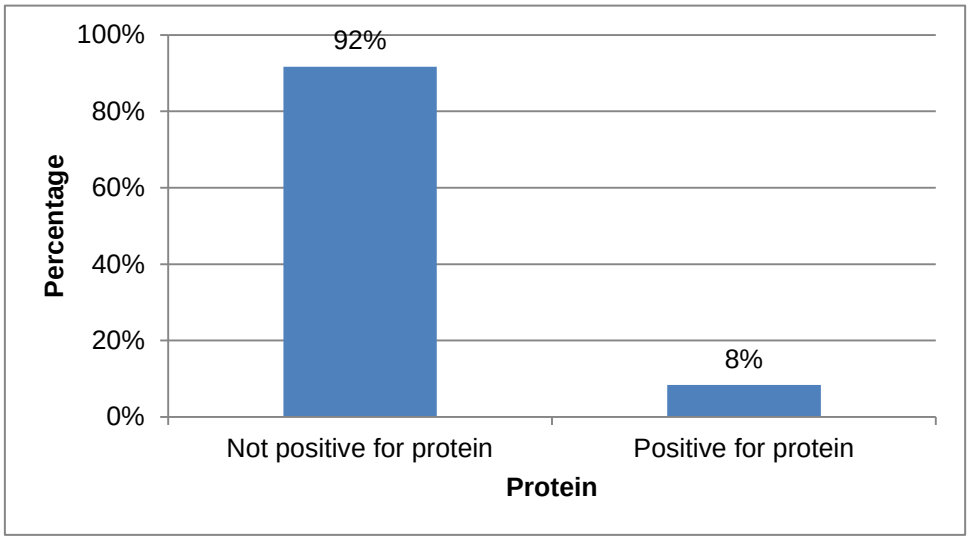


Figure 4.14 Cleaned gastroscopes tested positive for protein

As mentioned previously only **cleaned** gastroscopes were tested for residual protein in the **pilot study**. In the main study, cleaned and purposively dirty gastroscopes were tested for residual proteins.

The researcher is therefore not able to provide findings for pattern matching of gastroscope cleaning time versus gastroscopes positive for residual proteins, as this was not observed in the pilot study. As previously mentioned the data collection instrument/tool referred to as SOCL: P1 was not suitable for collecting this type of data.

4.3.17 Medical devices positive for residual proteins overall

Of all the medical devices tested for residual proteins in the pilot study 28% were positive for proteins (n=33/119) and 72% were not (n=86/119). The findings are shown in **figure 4.15**.

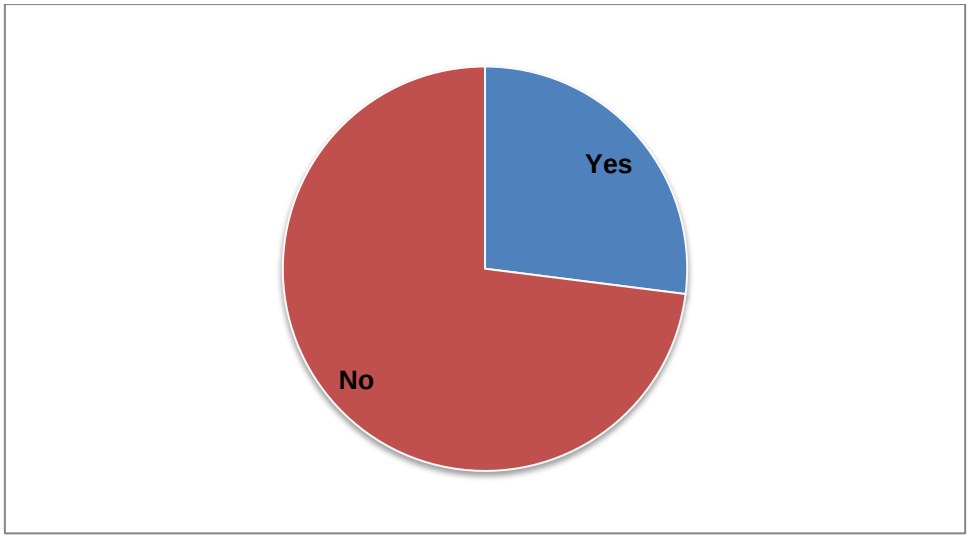


Figure 4.15: Overall percentage of devices positive for proteins pilot study

4.3.18 Positive for proteins, per device

The researcher found that certain types of medical devices have a higher percentage of residual proteins than other types of devices.

The Crile's forceps was the medical device with the highest percentage 100% positive for proteins (n=1/1), laryngoscopes blades were the next highest at 41% positive for proteins (n=13/32) and Yankhauer suction nozzles were the third highest scoring at 33% positive for proteins (n=7/21). These findings as well as the number of devices tested are shown in **table 4.2.**

Table 4.2: Number of medical devices tested positive per device pilot study

Medical Device	Number tested	Number positive	Percentage
Needle Holders	22	4	18%
Vaginal Speculum	18	4	22%
Laryngoscope	32	13	41%
Diathermy	13	2	15%
Yankhauer	21	7	33%
Gastroscope	12	1	8%
Crile's forceps	1	1	100%
ALL	119	32	27%

4.3.19 Positive protein test reaction time

According to the manufacturer of the commercially available residual protein test (Browne Ltd, UK) used in this research, there is a relationship between the amount of residual protein detected and the time it takes for the swab to react (turn purple). The higher the protein the quicker the protein will react to the ninhydrin reagent. Therefore the researcher observed the protein test for a colour change at five minutes, thirty minutes and sixty minutes, although the MIFU state to incubate the test for 60 minutes and then observe for the colour change.

The researcher noted that 56% (n=18/32) of the residual protein tests reacted in five minutes. 41% (n=13/32) reacted after 30 minutes and 3% (n=1/32) reacted after sixty minutes. The findings are shown in **figure 4.16.**

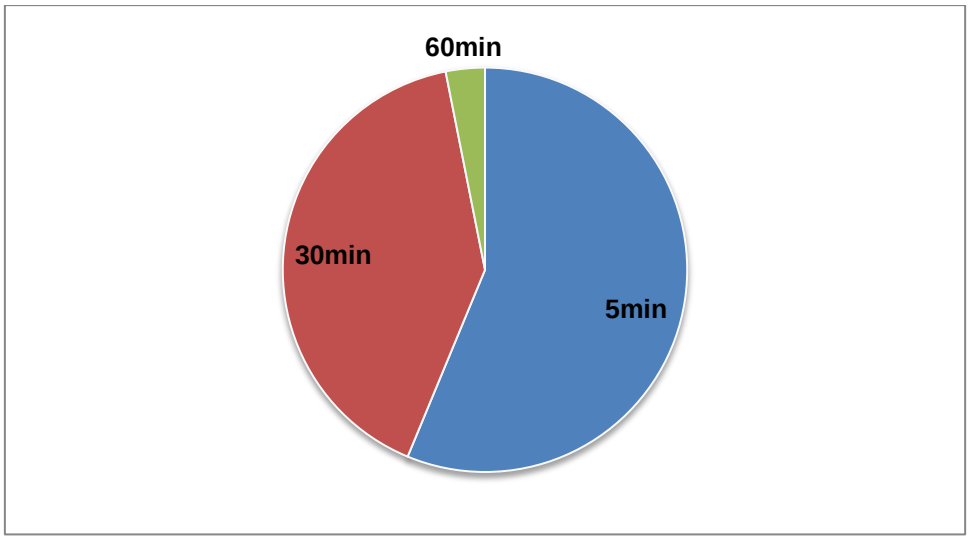


Figure 4.16: Positive protein test reaction time pilot study

4.3.20 Pattern matching: Positive for proteins: washed manually

Pattern matching was done to establish if specific cleaning methods produced medical devices free from protein residuals. Pattern matching logic according to Yin (2009) compares an empirically based pattern with a predicted pattern, thus comparing what was observed, what actually happened, and what was thought would happen.

The research data was filtered to determine what percentage of medical devices that were washed in a manual cleaning process tested positive for proteins.

The researcher found that 28% (n=33/119) of the medical devices cleaned manually were positive for proteins. The findings are shown in **figure 4.17**.

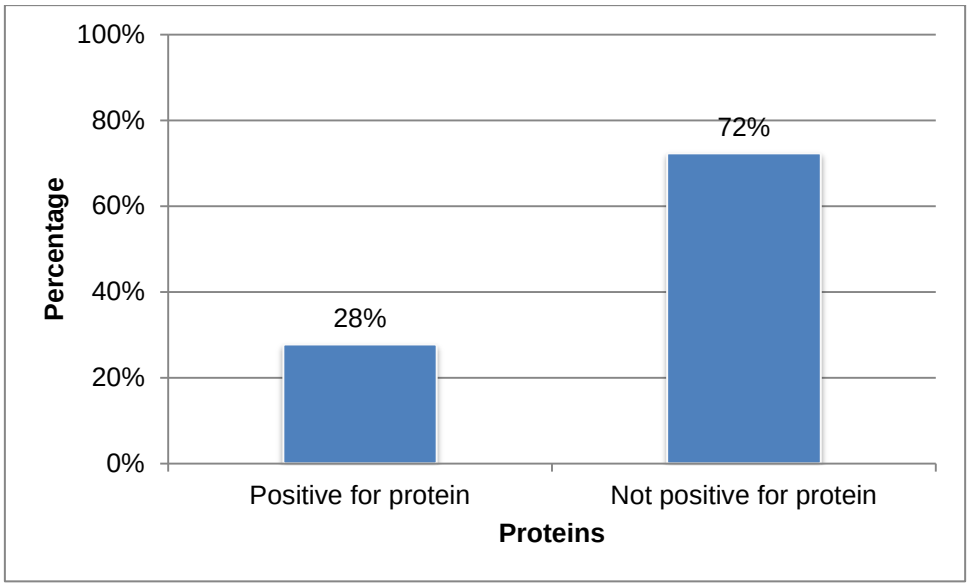


Figure 4.17 Washed manually positive for proteins pilot study

As all the medical devices in pilot study were washed manually the researcher was not able to produce findings for the number of devices cleaned in an automated cleaning process that tested positive for proteins, as was done in the main study.

4.3.21 Pattern matching: Positive for proteins: kept moist

The researcher filtered the data captured in the pilot study to ascertain what percentage of the medical devices that were kept moist was positive for residual proteins.
The researcher found that when the medical devices were kept moist until they were cleaned, the devices had less residual proteins on them than those that were not kept moist.

Only 23% (n=17/74) of the medical devices that were **kept moist** tested positive for residual proteins.
Whereas 45% (n=15/33) of the medical devices that were **not** kept moist tested positive for residual proteins.
Findings are shown in **figure 4.18**.

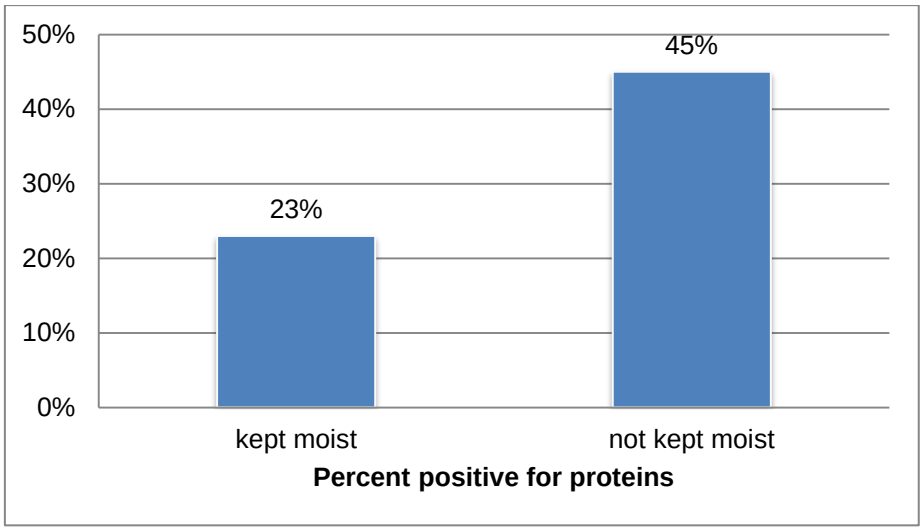


Figure 4.18: Percentage of devices kept moist positive for proteins pilot study

4.3.22 Pattern Matching: Positive for proteins: Yankhauer suction lumen flushed vs. not flushed

The research data was filtered to determine what percentage of Yankhauer suction nozzles flushed during the cleaning process tested positive for residual proteins.

The researcher found that less of the Yankhauer that **were flushed** during the cleaning process 23% (n=3/13) were positive for residual proteins whereas more of the Yankhauer suctions 50% (n=4/8) that were **not flushed** during the cleaning process tested positive for residual proteins. Findings are shown in **figure 4.19.**

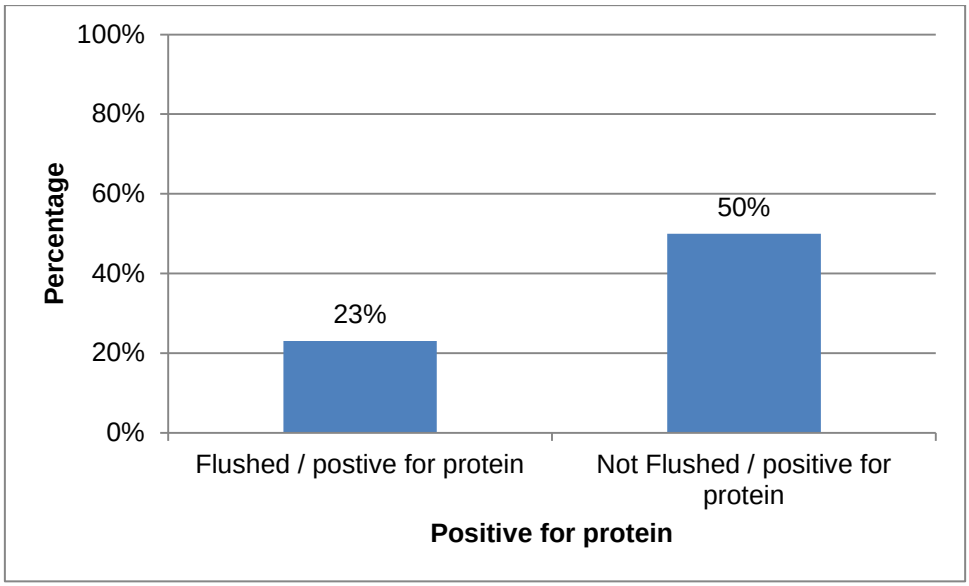


Figure 4.19 Percentage of Yankhauer suction nozzles positive for proteins: lumen flushed vs. lumens not flushed

4.3.23 Pattern Matching: Visually Clean: Positive for proteins

The research data was filtered to ascertain what percentage of the medical devices that appeared to be macroscopically visually clean tested positive for residual protein, meaning they were **not** actually clean.

The researcher found that 14% (n=7/51) of the medical devices that appeared to be macroscopically visually clean tested positive for residual proteins.

Findings are shown in **figure 4.20.**

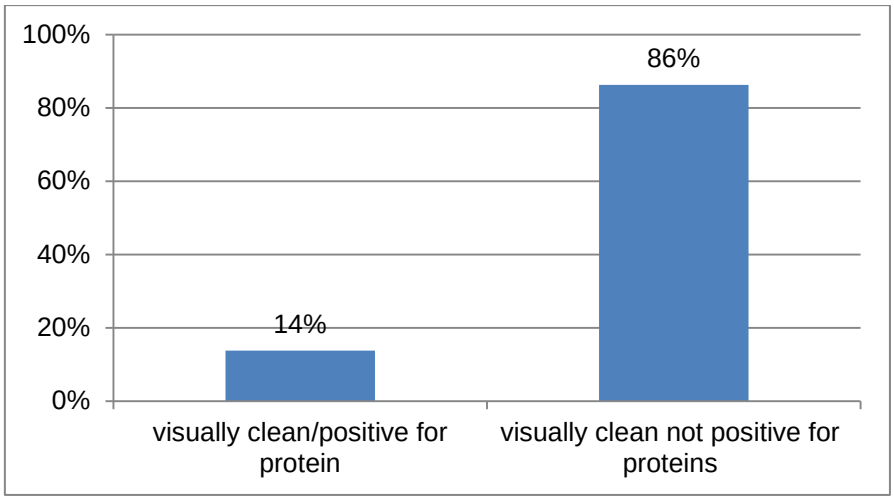


Figure 4.20 Visually clean but positive for proteins

4.3.24 Pattern Matching: Visually Dirty: Positive for proteins

The research data was filtered to ascertain what percentage of the medical devices that appeared to be macroscopically visually dirty actually tested positive for residual protein. The researcher found that of 38% (n=26/68) of the medical devices that appeared to be macroscopically visually dirty tested positive for residual proteins. Findings are shown in **figure 4.21.**

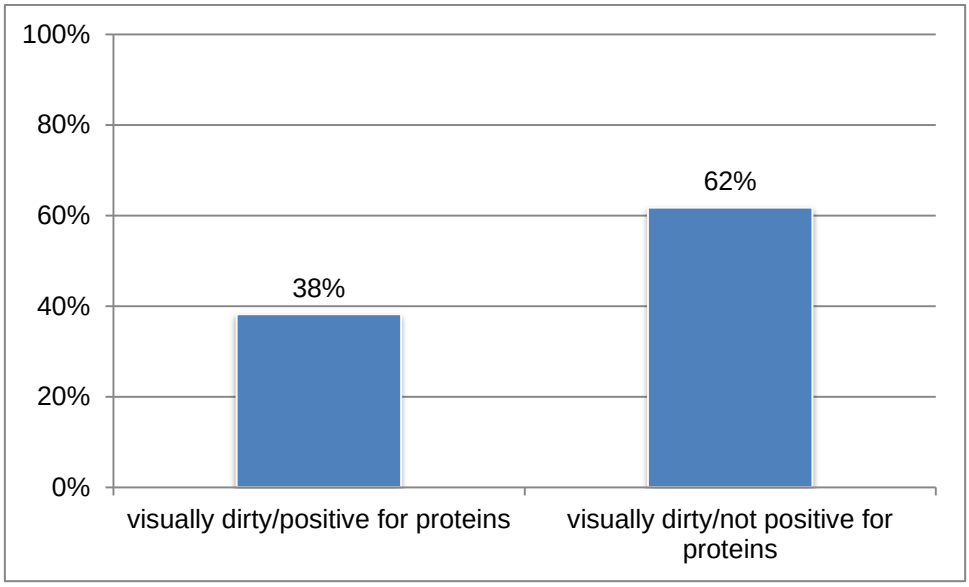


Figure 4.21 Visually dirty but positive for proteins

4.4 RESULTS OF MAIN STUDY

4.4.1. Research Setting

This research was conducted in a variety settings or hospitals that represented both the private sector and the provincial sector. In the main study the majority of research 60% (n=3/5) was conducted at private hospitals and 40% (n=2/5) was conducted in public hospitals. Findings are shown in **figure 4.22.**

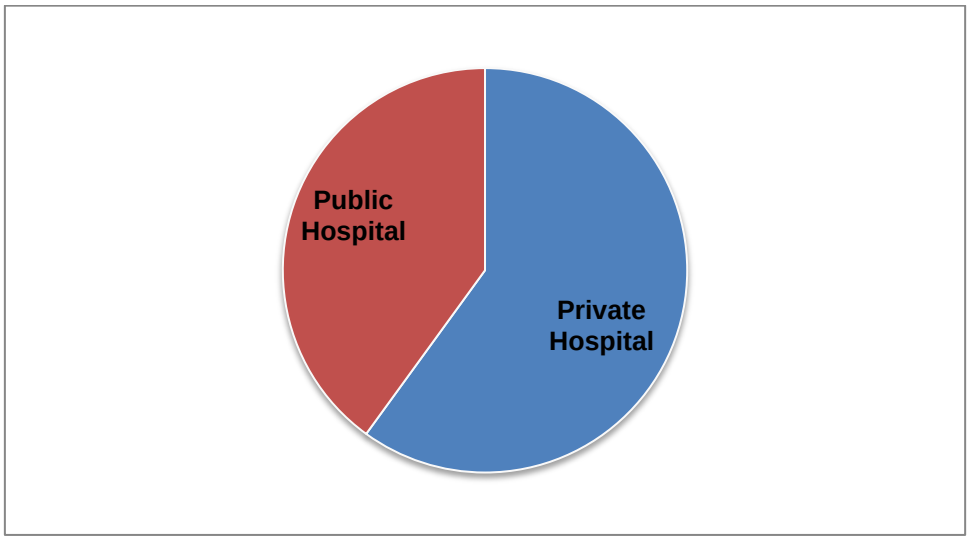


Figure 4.22 Research setting main study

4.4.2 Number of Protein Residual Tests done per hospital

The researcher observed the cleaning of medical devices and performed protein residual tests on 328 medical devices at five hospitals, namely hospitals A, B, C, D and E, for the main study. At hospitals A and B 71 tests were performed. At hospital C 57 tests, hospital D 67 tests and at hospital E 62 residual protein tests were performed. Findings are shown in **figure 4.23.**

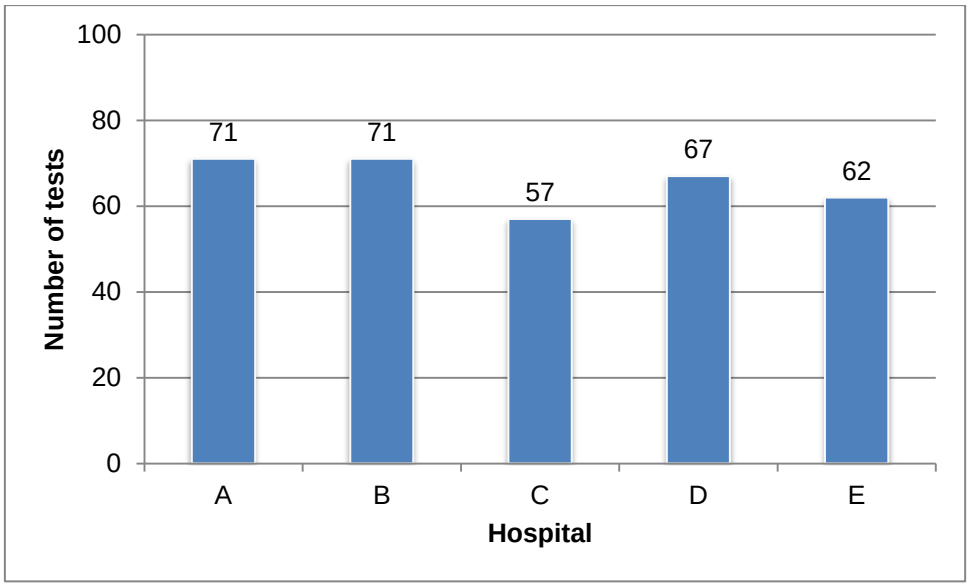


Figure 4.23 Number of residual protein tests done per hospital main study

4.4.3 Number of Protein Residual Tests done per hospital; per device

The researcher intended to observe the cleaning of medical devices and perform protein residual tests on 355 medical devices i.e. ten Yankhauer suction nozzles, ten needle holders, ten diathermy forceps, ten vaginal specula (anterior and posterior blades, i.e. twenty tests), and ten laryngoscope blades, one Crile's forceps and ten gastroscopes per hospital.

One hospital however had converted to using single use, disposable diathermy pencils instead of diathermy forceps, and two hospitals made use of single use, disposable vaginal specula. This meant that the researcher was not able to test the intended 355 medical devices at three of the five hospitals. The researcher was able to test a total 328 medical devices at the five hospitals as outlined in **table 4.3**.

Table 4.3: Number of residual protein tests intended vs. actual tests done per device per hospital

	Intended	**Actual tests done per hospital**				
Instrument Type	Intended per Hospital	Hospital A	Hospital B	Hospital C	Hospital D	Hospital E
Yankhauer	10	10	10	10	10	10
Needle Holder	10	10	10	10	10	10
Diathermy	10	10	10	10	10	1
Laryngoscope	10	10	10	10	10	10
Vaginal Speculum	20	20	20	6	16	20
Criles (PCD)	1	1	1	1	1	1
Gastroscope Clean	5	5	5	5	5	5
Gastroscope Dirty	5	5	5	5	5	5
Total per Hospital	**71**	**71**	**71**	**57**	**67**	**62**

4.4.4 Cleaning observed or described

The researcher intended to observe and record how medical devices were cleaned. In some instances it was not possible to observe the cleaning process, so the process was describe to the researcher by the individual who did the cleaning.

The researcher was able to observe 69% of the participants in this study cleaning the medical devices (n=210/303), and the remaining participants described the cleaning method in 31% of the cases (n=93/303). The findings are shown in **figure 4.24.**

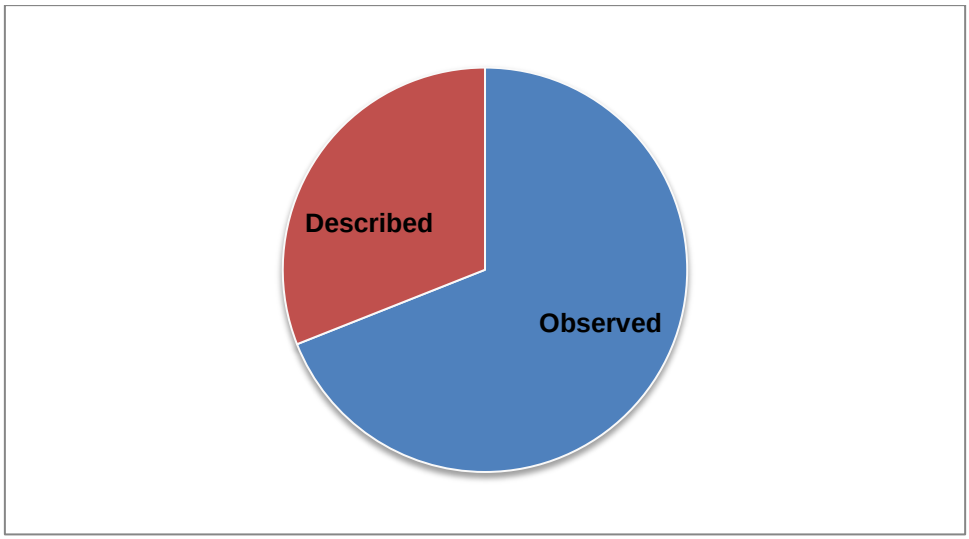


Figure 4.24 Percentage of medical device cleaning observed vs described main study

4.4.5 Where devices were cleaned

The researcher had to record on the SOCL where in the hospital the various medical devices were cleaned.

The researcher found that the majority of medical devices 61% were cleaned in the CSSD (n=186/303), 16% were cleaned in the operating room (n=48/303), 11% were cleaned in doctor's rooms (n=32/303), 8% in the gastroenterology unit (n=23/303), 3% in the gynaecology clinic (n=10/303) and 1% were cleaned in the ICU (n=4/303).

The findings are shown in **figure 4.25.**

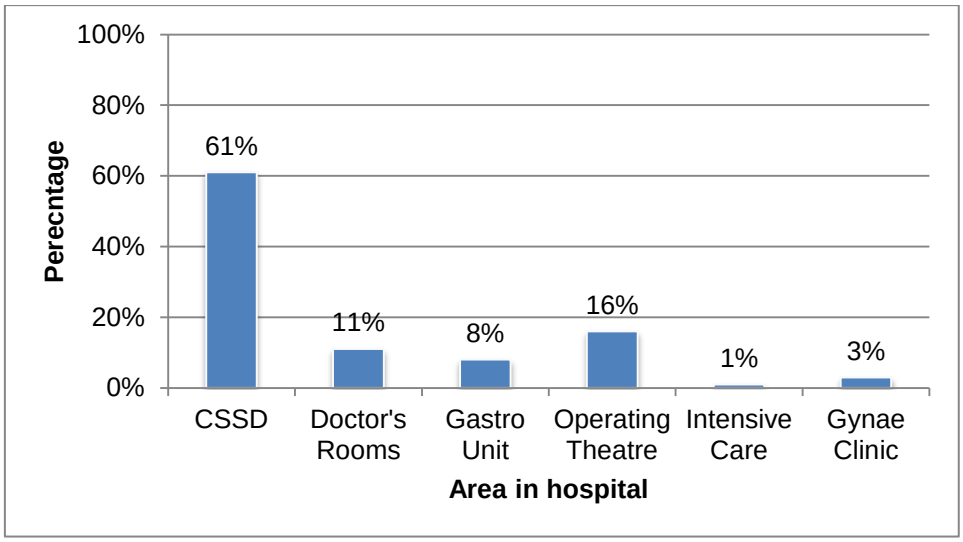


Figure 4.25: Area in the hospital where medical devices were cleaned main study

4.4.6 Designation of the person cleaning

The researcher needed to ascertain and record the designation of the individual cleaning the medical device in question. This was done by asking the individual doing the cleaning what their designation was, and recording this on the SOCL.

The researcher found that in the main study 50% of medical devices were cleaned by CSSD technicians (n=153/303), and 23% were cleaned by non-healthcare workers (n=71/303). The remaining devices were cleaned by nurses of which 21% were cleaned by RN/EN (n=64/303), 3% were cleaned by student nurses (n=10/303) and 2% were cleaned by ENA's (n= 5/303).

The findings are shown in **figure 4.26**.

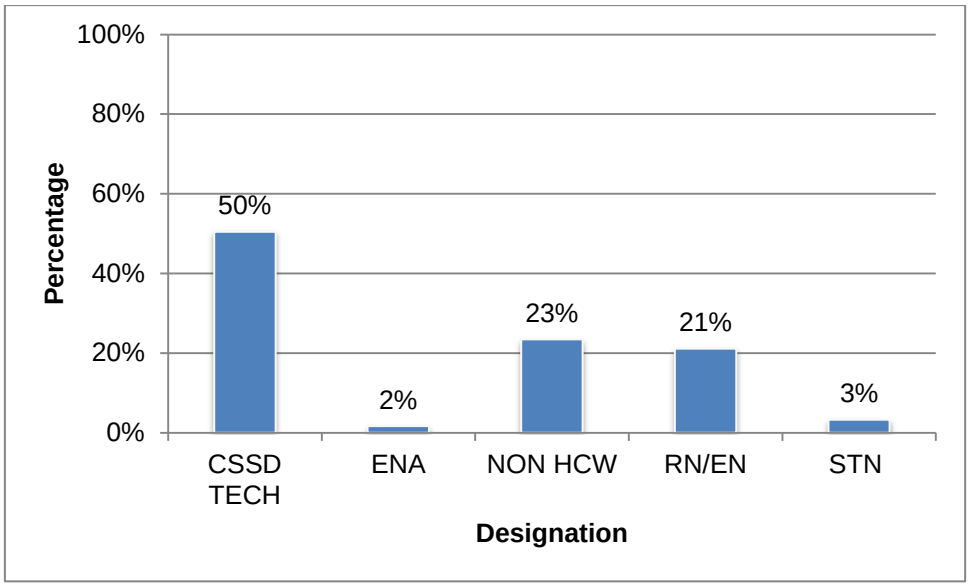


Figure 4.26 Designation of the staff cleaning medical devices main study

4.4.7 Cleaning SOP

The researcher needed to ascertain if the individual cleaning medical devices was aware of any SOP describing how medical devices must be cleaned. Of the individuals responsible for cleaning of medical devices 3% were aware of SOP's for cleaning of medical devices in their respective hospital units (n=10/303). Findings are shown in **figure 4.27.**

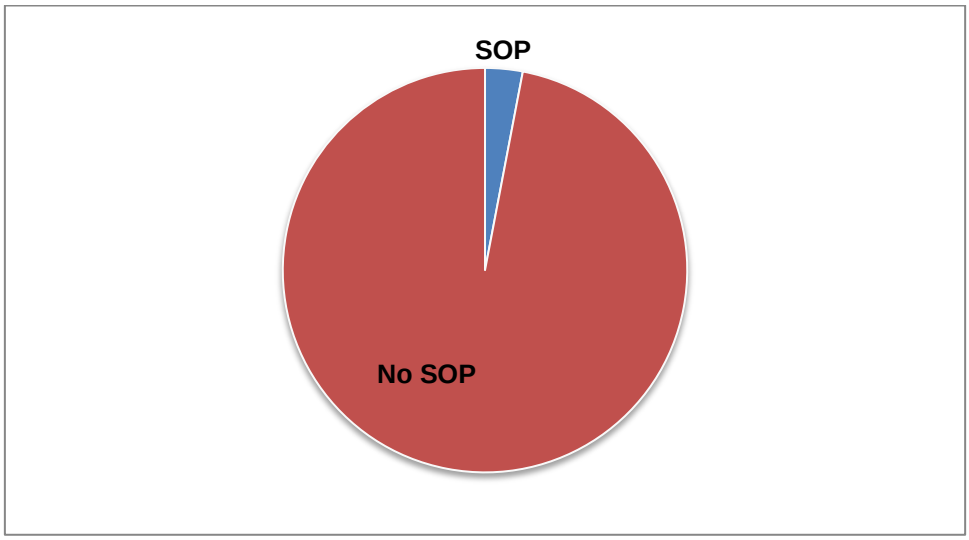


Figure 4.27 Percentage **aware** of a cleaning SOP main study

4.4.8 Cleaning Method: Manual or Automated

Medical devices can be cleaned using manual or automated cleaning methods. The researcher needed to ascertain if medical devices were cleaned manually or using an automated process.

The researcher found that medical devices were cleaned manually in 51% of the cases (n=154/303), an in an automated washer in 49% of the cases (n=149/303). The findings are shown in **figure 4.28.**

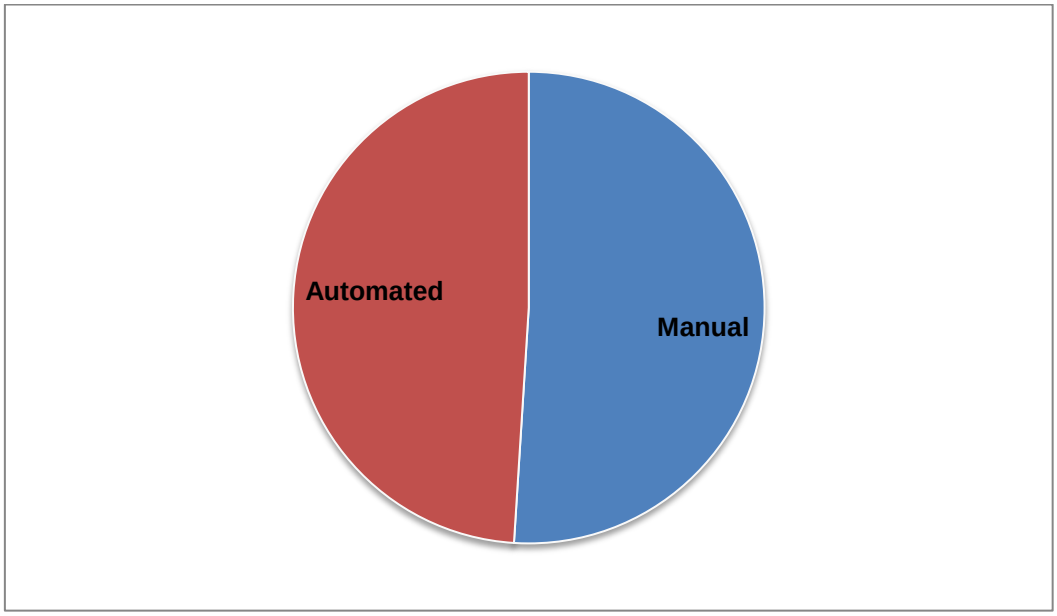


Figure 4.28: Percentage of devices cleaned manually vs. automated cleaning main study

4.4.9 Type of Detergent

The researcher had to ascertain what type of detergent was used to clean the medical devices in question.

The researcher found that medical devices were cleaned with an alkaline detergent in 32% of the cases (n=98/303), with an enzymatic detergent in 27% of the cases

(n=81/303), with hand soap in 27% of the cases (n=82/303) and with hand soap mixed with and enzymatic detergent in 14% of the cases (n=42/303). Findings are shown in **figure 4.29.**

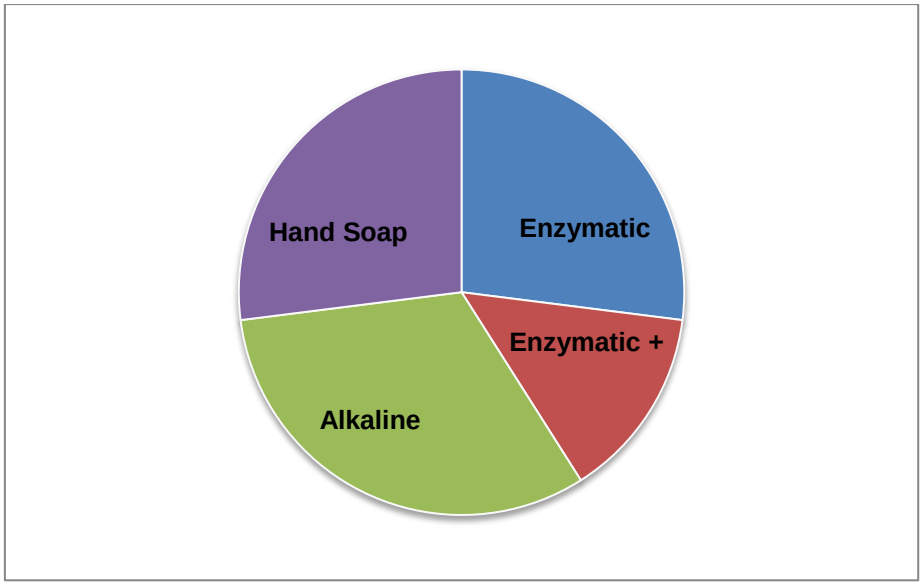


Figure 4.29: Type of detergent used to clean medical devices main study

4.4.10 Dilution of Detergent and Water

Manufacturers of medical device detergents provide manufacturer instructions for use (MIFU) that specify how the detergent should be diluted (mixed) with water. The researcher ticked yes on the SOCL if the detergent was diluted correctly, according to MIFU, and no if it was not.

The researcher found that detergents were diluted according to the MIFU 55% of the cases (n=167/303), therefore in 45% of the cases the MIFU were not followed (n=136/303).

The findings are shown in **figure 4.30.**

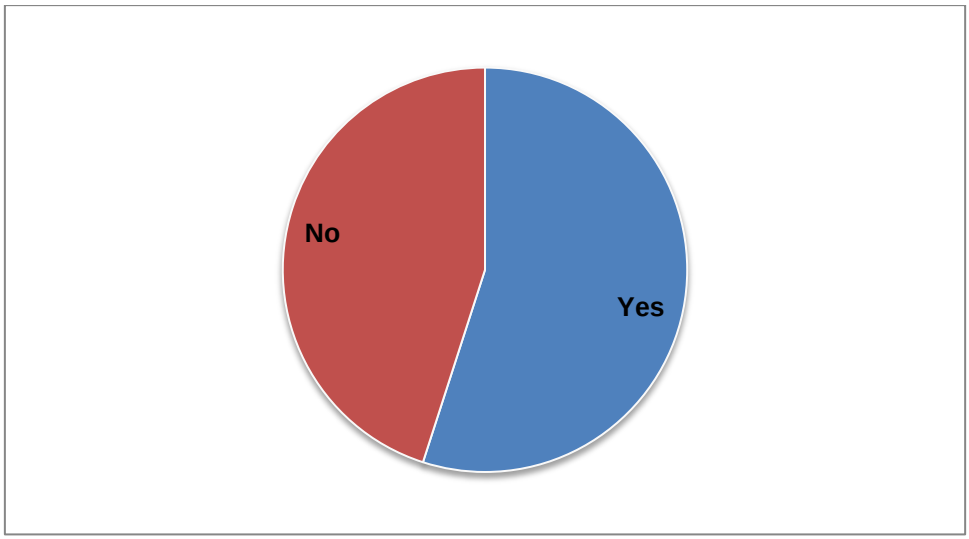


Figure 4.30 Detergent diluted according to MIFU main study

4.4.11 Kept Moist

The researcher needed to ascertain and record if medical devices were kept moist until such time as they were cleaned.

The researcher found that medical devices were kept moist until they were cleaned in 34% of cases (n=95/278) and not kept moist in 66% of the cases (n=183/278). The findings are shown in **figure 4.31**.

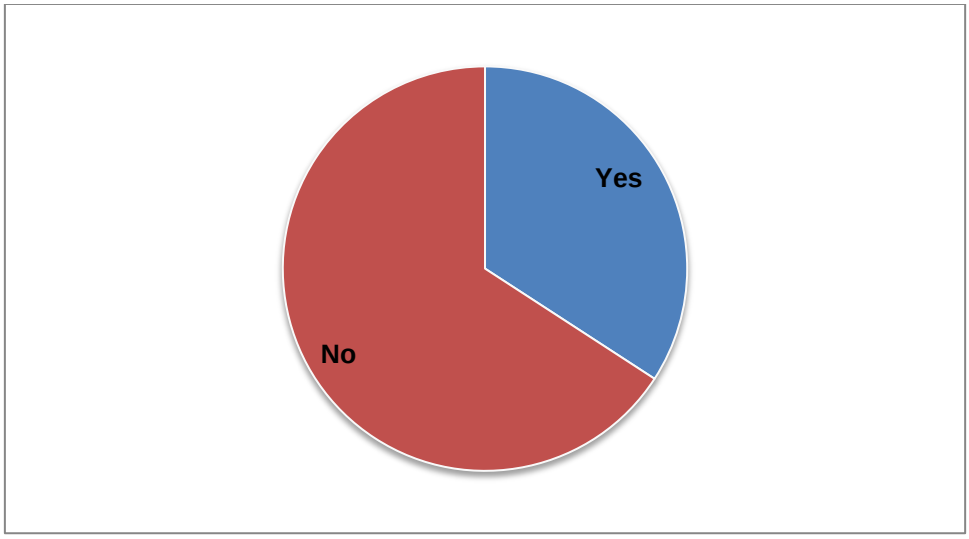


Figure 4.31 Percentage of medical devices kept moist until cleaned main study

4.4.12 Automated Cleaning: Pre clean

The researcher had to ascertain if the medical devices washed in an automated wash process where manually pre cleaned. The researcher found that 55% of the medical devices washed in an automated process were pre-cleaned (n=82/149) and 45% were not (n=67/149). The findings are shown in **figure 4.32.**

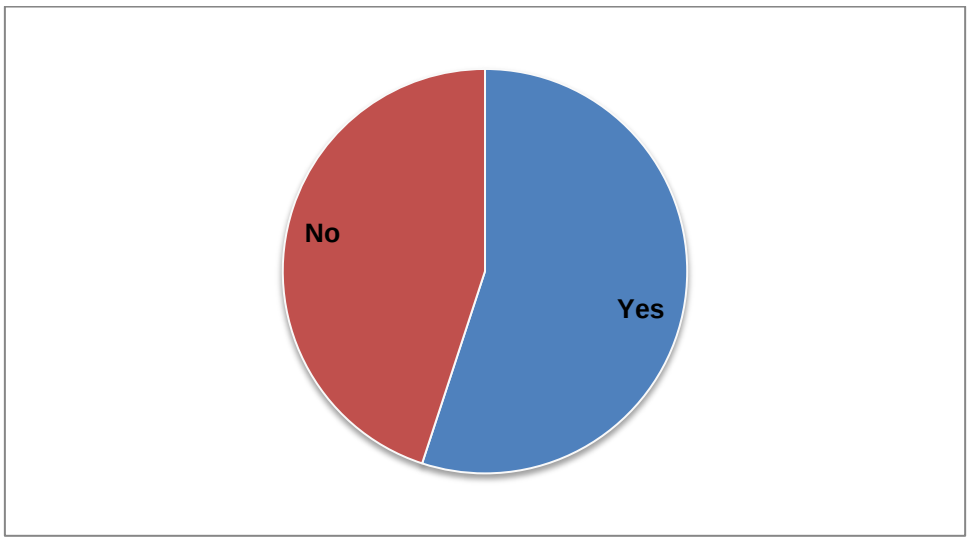


Figure 4.32: Percentage of devices pre cleaned prior to automated cleaning

4.4.13 Washer Manufacturer

The medical devices in this research also classified as surgical instruments were washed in washer-disinfectors manufactured by four different manufacturers, they were called manufacturer A, B, C and D.

A total of 40% of the devices (excluding gastroscopes) were washed in washers manufactured by company A (n=57/144), 32% by company B (n=46/144), 23% by company C (n=33/144) and 5% by company D (n=8/144).

These findings are shown in **figure 4.33.**

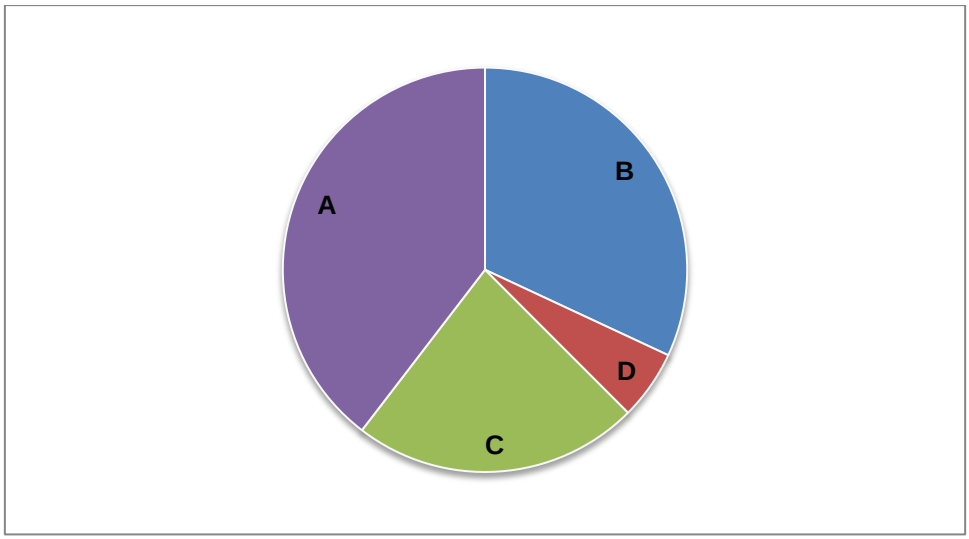


Figure 4.33 Automated washer manufacturers

4.4.14 Correct Tray

The research had to observe and record if the medical devices (excluding gastroscopes) were loaded into the washer-disinfector in a suitable (correct) instrument tray. The researcher found that medical devices were loaded into a tray suitable for use in a washer-disinfector in 75% of the cases (n=108/144) and an unsuitable tray was used in 25% of the case (n=36/144). The findings are shown in **figure 4.34.**

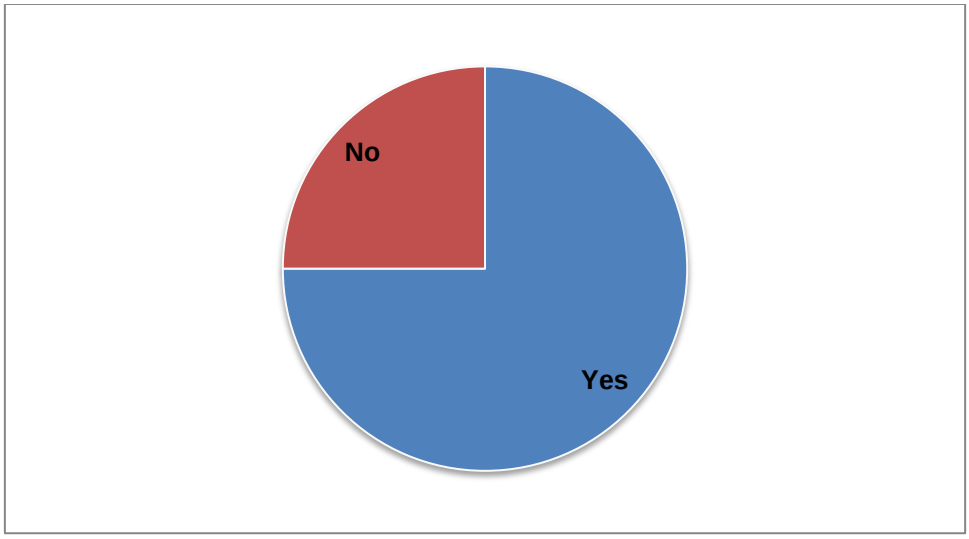


Figure 4.34 Percentage of time correct trays were used in automated washer

These findings exclude gastroscopes as they are loaded directly into the washer, not into an instrument tray.

4.4.15 Shadowing

The researcher had to observe and record if medical devices were loaded into the washer-disinfector in a manner that the devices being cleaned shadowed or cover each other. When devices shadow over each other they ‘cover’ each other which prevents contact with the water jet spray. The researcher found that the washer-disinfector was loaded in such a manner that the devices being cleaned shadowed over each other in 60% of the cases (n=86/144) and did not shadow in 41% of the cases (n=58/144).

This excludes gastroscopes, as they loaded individually in the washer and therefore cannot shadow other devices from being cleaned.

Findings are shown in **figure 4.35.**

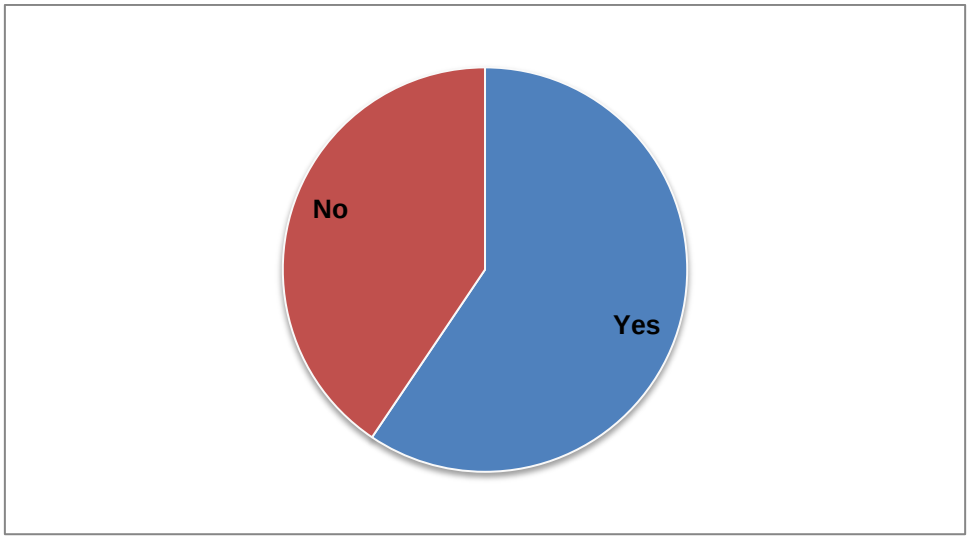


Figure 4.35 Percentage of medical device shadowed in the automated washer

4.4.16 Overloaded

The researcher had to observe and record when the instrument washer-disinfector was loaded with too many devices i.e. overloaded. The researcher found that the washer-disinfector was overloaded in 60% of the cases (n=86/144) and not overloaded 40% of the cases (n=58/144).

This excludes gastroscopes, as they were loaded individually in the washer and therefore the scope washer could not be overloaded. Findings are shown in **figure 4.36.**

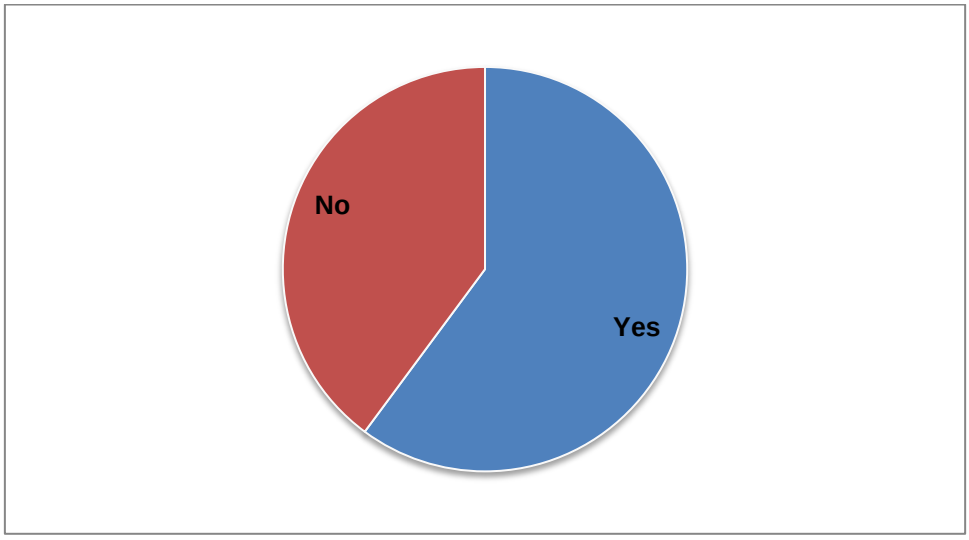


Figure 4.36: Percentage of devices washed in overloaded automated washer

4.4.17 Friction

The researcher needed to ascertain and record if friction was applied to the medical devices during the cleaning process.

The majority of medical devices 82% were placed in a detergent water solution and cleaned by applying friction with a cleaning accessory (n=110/134). The remaining 18% of

medical devices were placed in the detergent, water solution but no friction was applied (n=24/134)

The findings are shown in **figure 4.37.**

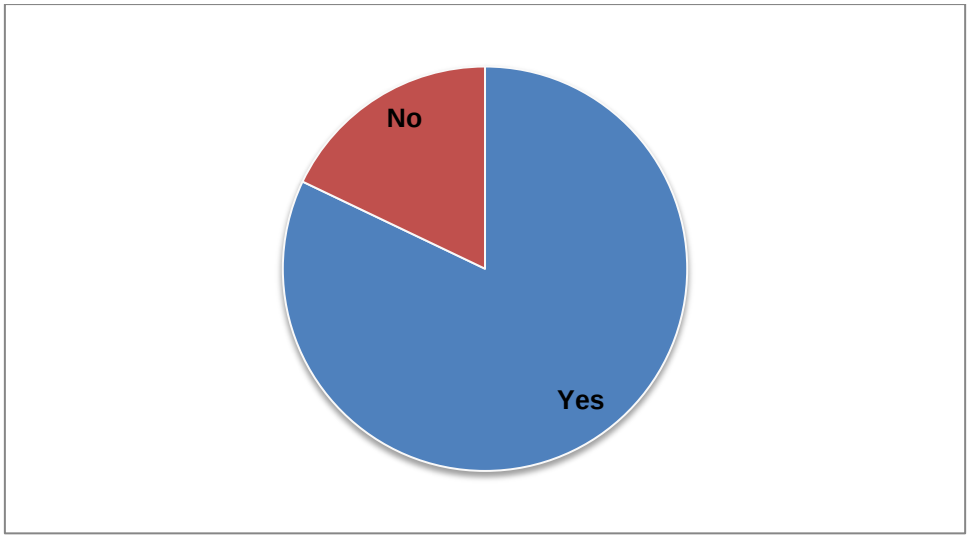


Figure 4.37 Percentage medical devices cleaned using friction main study

4.4. 18 Cleaning accessories

When cleaning medical devices, friction is applied using a cleaning accessory. A number of different cleaning accessories can be used.

The researchers found that of the medical devices cleaned manually they were cleaned with a household sponge 22% of the cases (n=24/110), a brush in 68% of the cases (n=75/110) and cloth in 10% of the cases (n=11/110).

The findings are shown in **figure 3.38.**

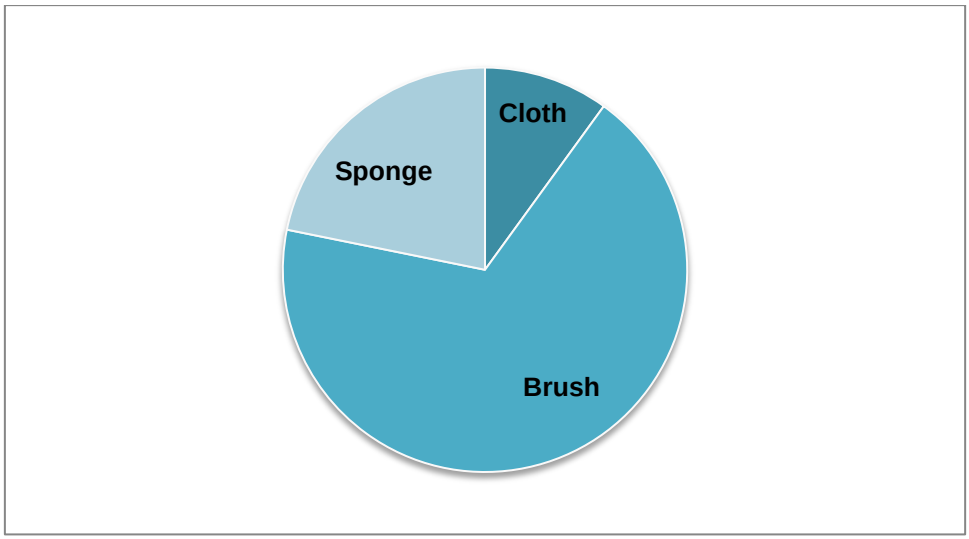


Figure 4.38 Cleaning accessories used in main study

4.4.19 Flush lumen manual cleaning

The lumens of Yankhauer suction nozzles should be flushed during cleaning. The researcher found in this research **none** of lumens of the Yankhauer suctions (100%) washed manually were flushed (n=10/10). Findings are shown in **figure 4.39.**

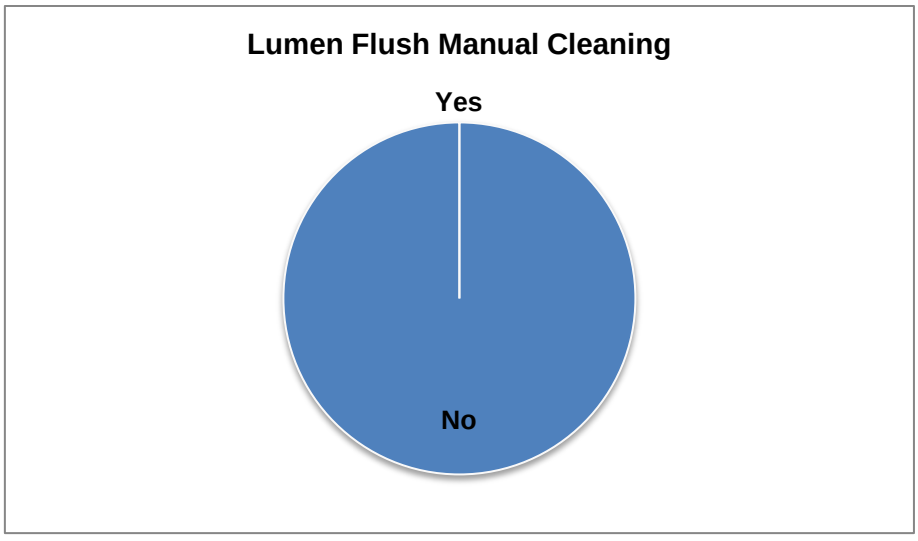


Figure 4.39: Percentage of lumens of Yankhauer suction flushed during **manual** cleaning main study

4.4.20 Flush lumen automated cleaning

The researcher found that the lumens of the Yankhauer suction nozzles were flushed in 22% of the cases (n=9/40) and not flushed in 78% of the cases (n=31/40) when the Yankhauer suction nozzles were washed in an automated cleaning process. The findings are shown in **figure 4.40.**

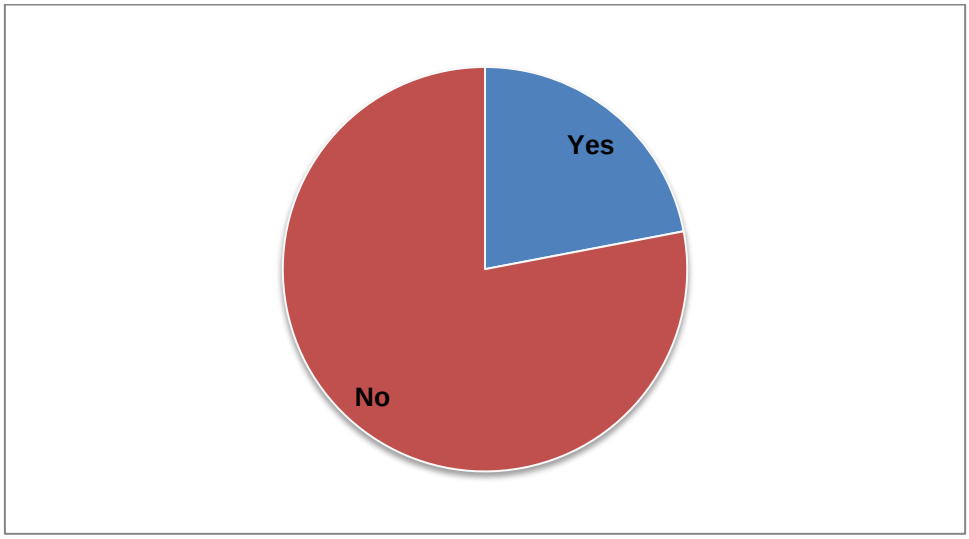


Figure 4.40: Percentage of lumens of Yankhauer suction flushed during **automated** cleaning main study

4.4.21 Macroscopically visually clean

It is impossible to visualise the lumens of a gastroscopes with the naked eye, therefore they were excluded from these findings.

The remaining cleaned medical devices were macroscopically visually inspected by the researcher (using a naked eye) for residual soils and findings were recorded.

The researcher found that 46% of the medical devices appeared to be macroscopically visually clean (n=128/278), and 54% appeared to be dirty (n=150/278). Findings are shown in **figure 4.41.**

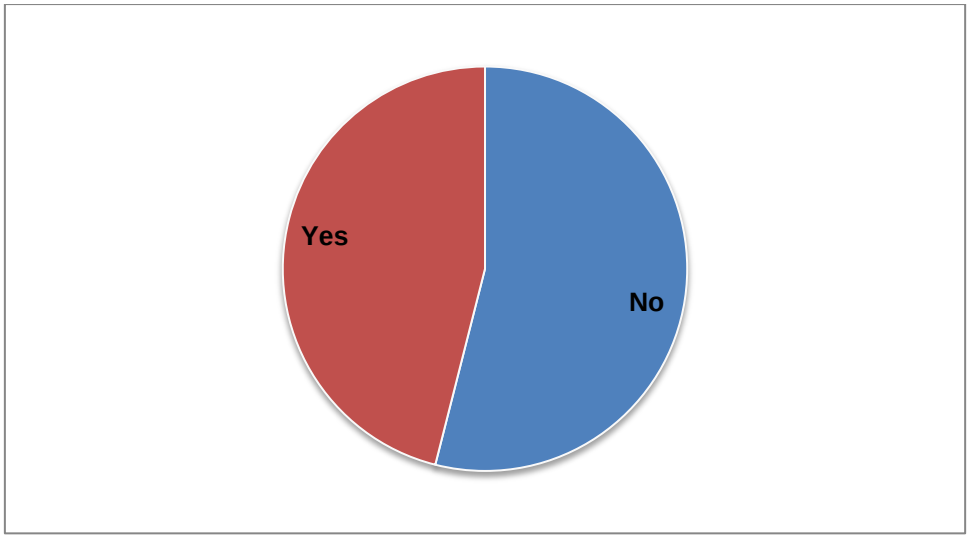


Figure 4.41 Percentage of devices visually clean main study

4. 4.22 Cleaning of gastroscopes: leak test available

The researcher observed the various cleaning steps performed when cleaning gastroscopes.

The researcher found that a standalone leakage tester was available for use in 20% of the cases (n=5/25) and not available for 80% (n=20/25).

Findings are shown in **figure 4.42.**

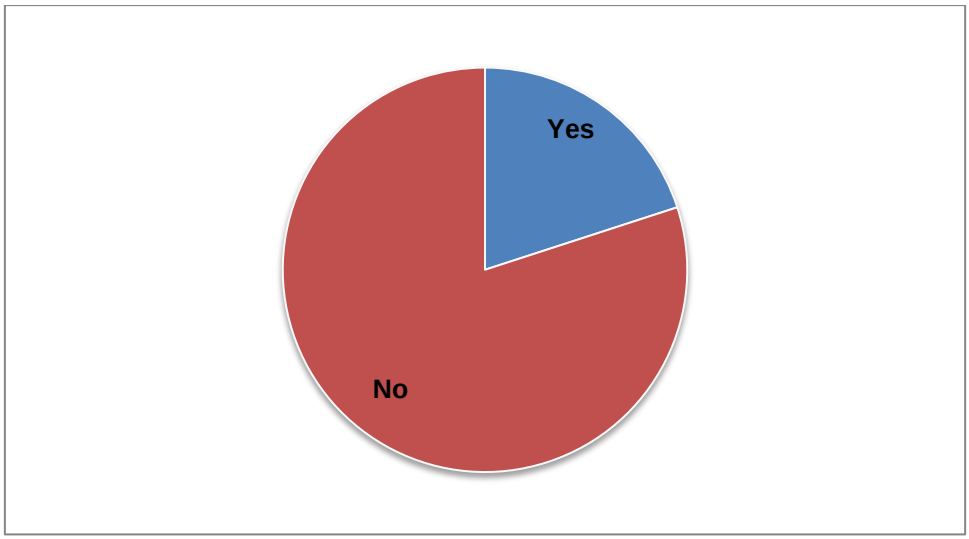


Figure 4.42 Percentage of times leakage test available

4. 4.23 Cleaning of gastroscopes: leak test performed

The researcher observed the various cleaning steps performed when cleaning gastroscopes. The researcher found that leakage tests were performed as part of the automated cleaning process in 20% of the cases (n=5/25), and that no leakage tests were performed when the gastroscopes were cleaned manually in 80% of the cases (n=20/25). Findings are shown in **figure 4.43.**

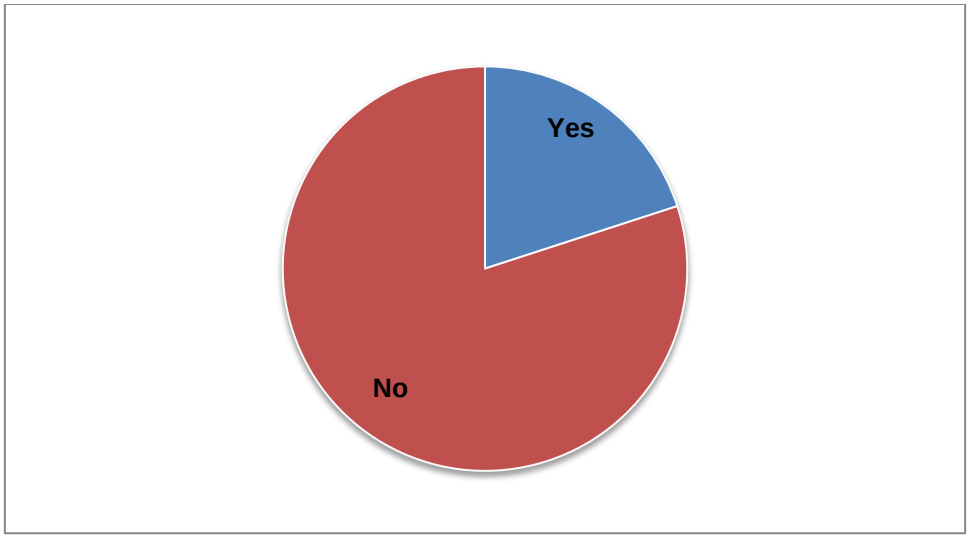


Figure 4.43 Percentage of time leakage test performed

4. 4.24 Cleaning of gastroscopes: cleaning steps performed when cleaning manually

The researcher observed the various cleaning steps performed when cleaning gastroscopes.

The researcher found that the cleaning step rinsing of the outer tube of the gastroscope post cleaning was the **only** step performed 100% of the time (n=20/20).

The air water and suction valves were only removed and brushed 25% of time (n=5/20).

The cleaning accessories were attached to the gastroscope 25% of the time (n=5/20).

The entire gastroscope was submerged 50% of the time (n=10/20).

The outer tubes were washed 80% of the time (n=16/20) and the biopsy channel was brushed 95% of the time (n=19/20).

The findings are shown in **figure 4.44.**

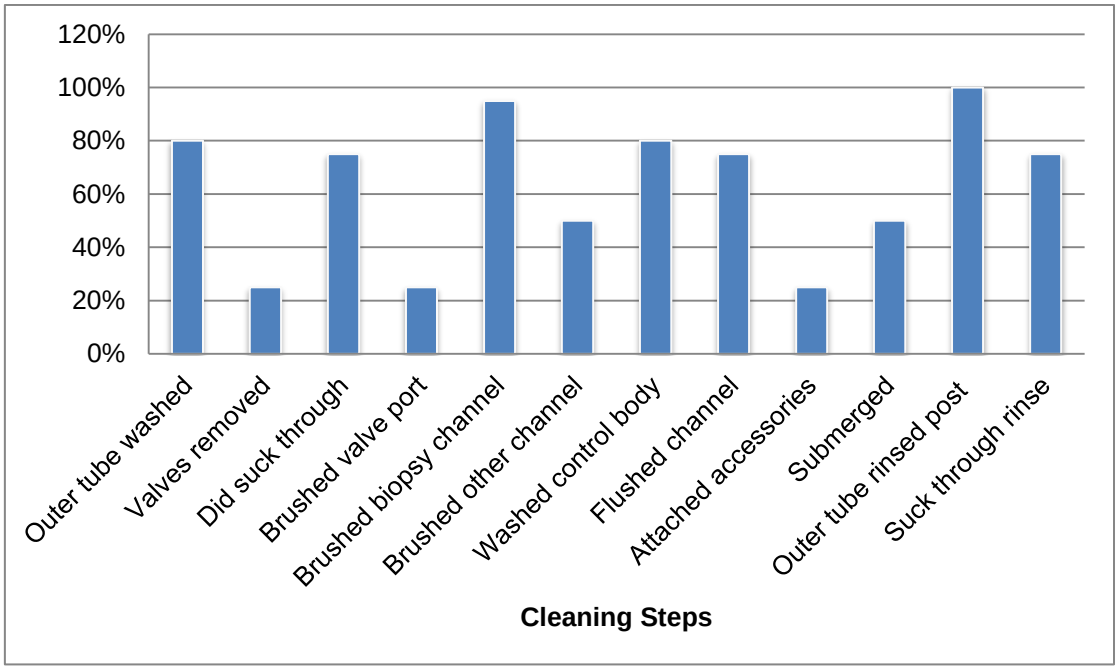


Figure 4.44 Percentage of times scope cleaning steps performed for manual cleaning

4.4.25 Cleaning of gastroscopes: manual clean-time

The researcher observed the various cleaning steps performed when cleaning gastroscopes. The researcher noted whether the cleaning process was performed in less than one minute, in two to three minutes or in three to five minutes. The researcher found that 50% of the gastroscopes were cleaned in two to three minutes (n=10/20), 25% were cleaned in less than one minute (n=5/20) and the remaining 25% (n=5/20) were cleaned in three to five minutes.

The findings are shown in **figure 4.45.**

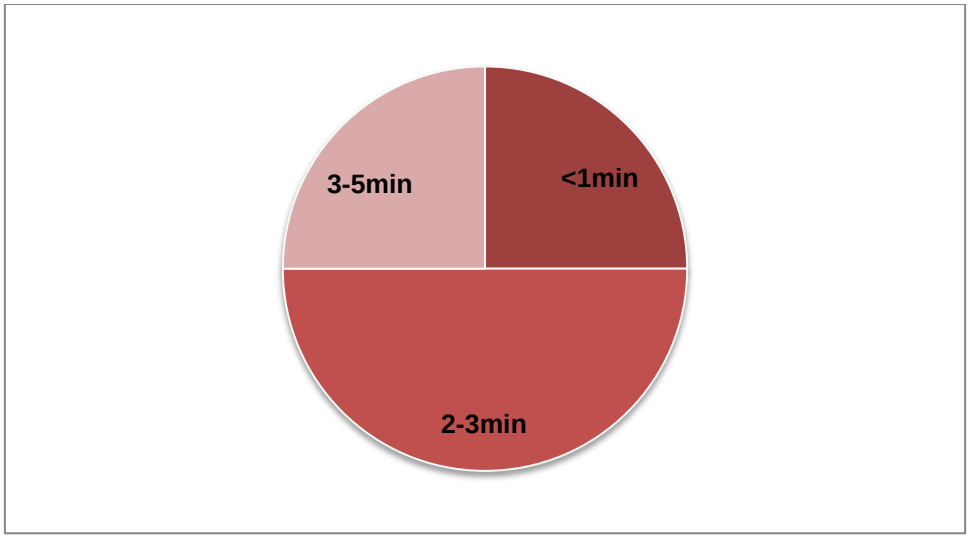


Figure 4.45: Time taken to clean gastroscope manually

4.4.26 Cleaning of gastroscopes: manual vs. automated

The researcher observed the various cleaning steps performed when cleaning gastroscopes. The researcher noted whether the gastroscopes were cleaned manually or in an automated scope washer-disinfector. Only 20% gastroscopes were cleaned in an automated wash process (n=5/25), and 80% were cleaned using a manual cleaning process (n=20/25). Findings are shown in **figure 4.46.**

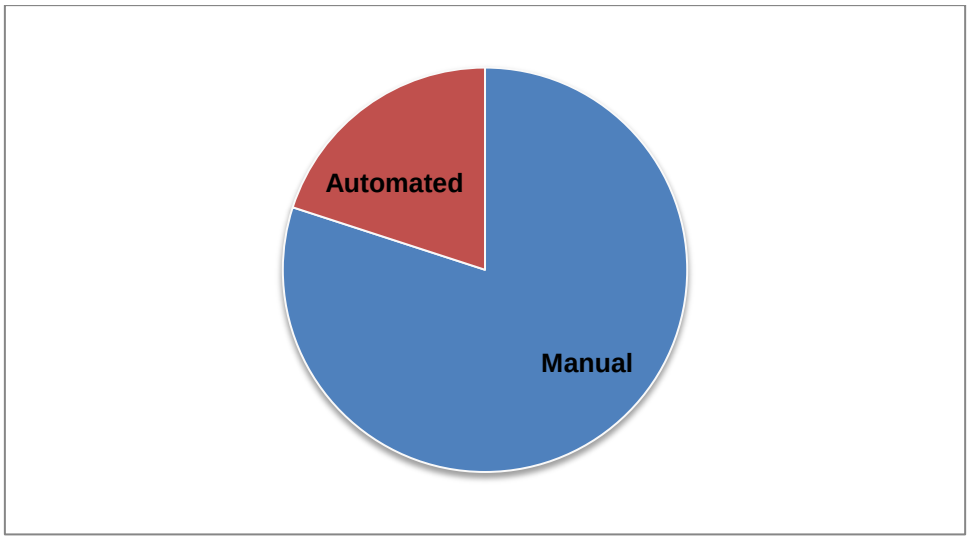


Figure 4.46: Number of gastroscopes cleaned manually and in an automated washer

4.4.27 Dirty gastroscopes tested positive for residual proteins

The researcher purposefully tested dirty gastroscopes (before they were cleaned) for residual proteins. The researcher found that the ninhydrin residual protein test was able to pick up residual proteins on 76% of the dirty scopes (n=19/25).

The findings are shown in **figure 4.47.**

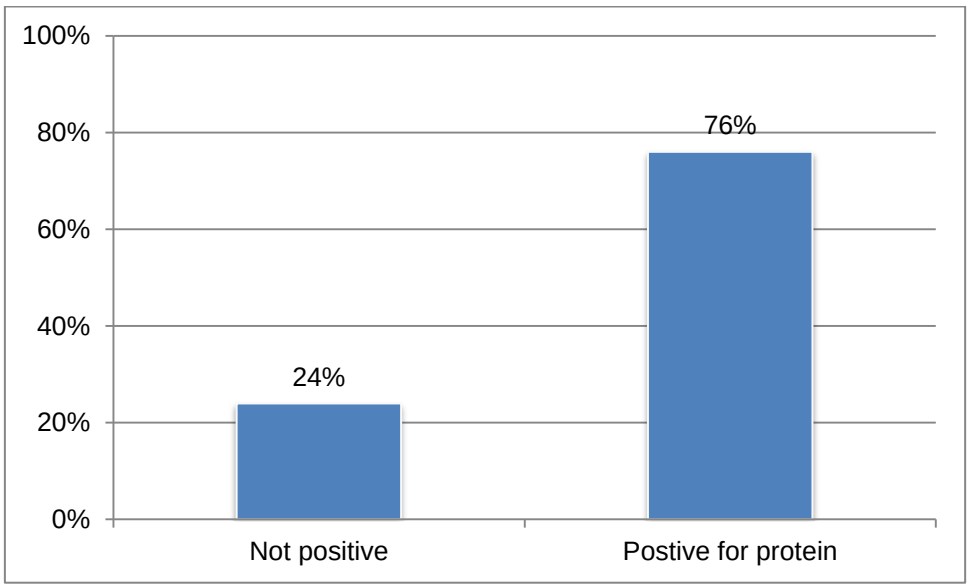


Figure 4.47 Number of dirty gastroscopes tested positive for proteins

4.4.28 Cleaned gastroscopes tested positive for residual proteins

The researcher tested cleaned gastroscopes for residual proteins.

The researcher found that 8% of the cleaned gastroscopes tested positive for residual proteins (n=2/25). Findings are shown in **figure 4.48.**

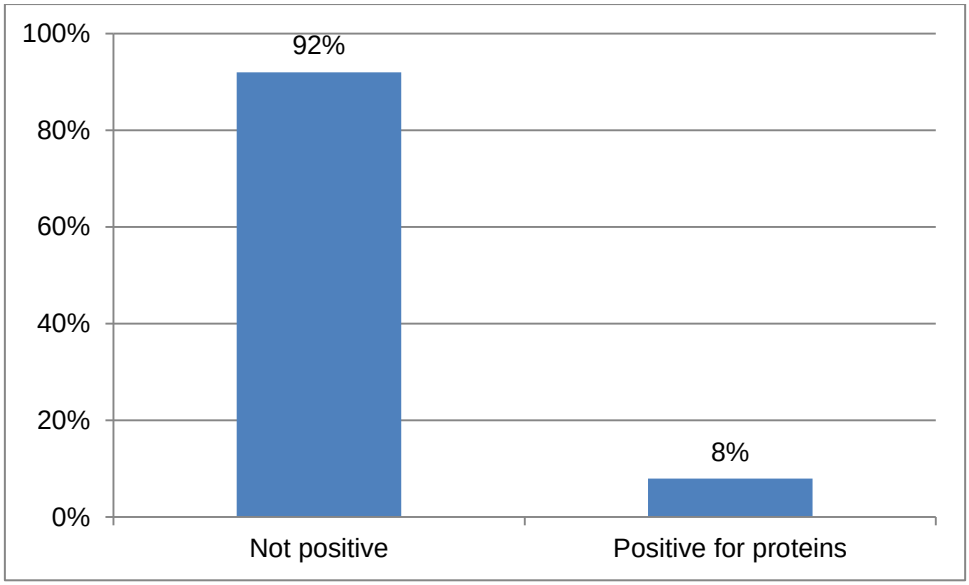


Figure 4.48: Number of cleaned gastroscopes tested positive for proteins

4.4.29 Pattern matching gastroscopes: positive for proteins: washed manually

The researcher filtered the gastroscope cleaning data and found that of the gastroscopes cleaned manually 10% were positive for proteins (n=2/20), and 90% were negative (n=18/20).

Findings are shown in **figure 4.49.**

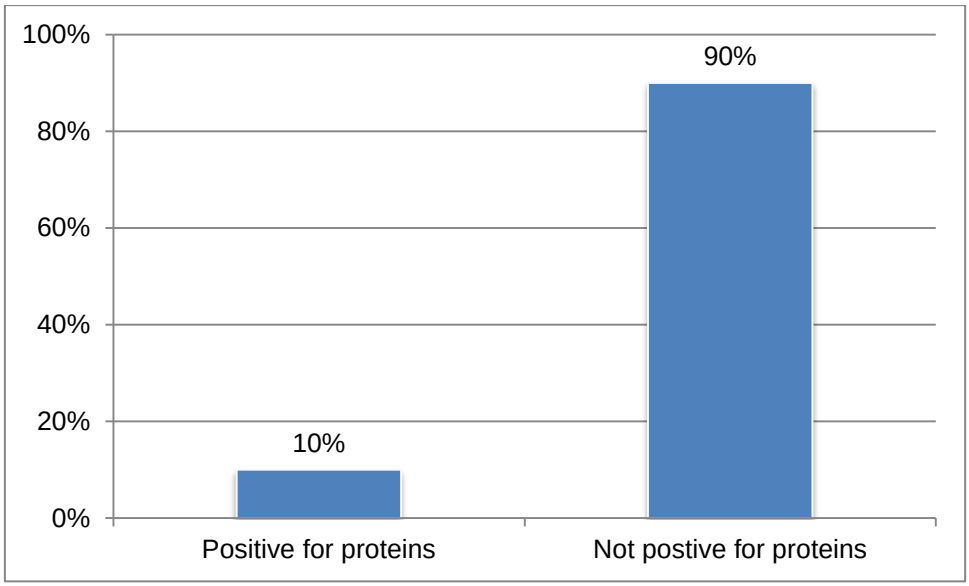


Figure 4.49 Gastroscopes washed manually positive for proteins

4.4.30 Pattern matching gastroscopes: positive for proteins: washed in automated washer

The researcher found that of the gastroscopes cleaned in an automated washer **none** 0% were positive for proteins (n=0/5), and 100% were negative (n=5/5).

Findings are shown in **figure 4.50.**

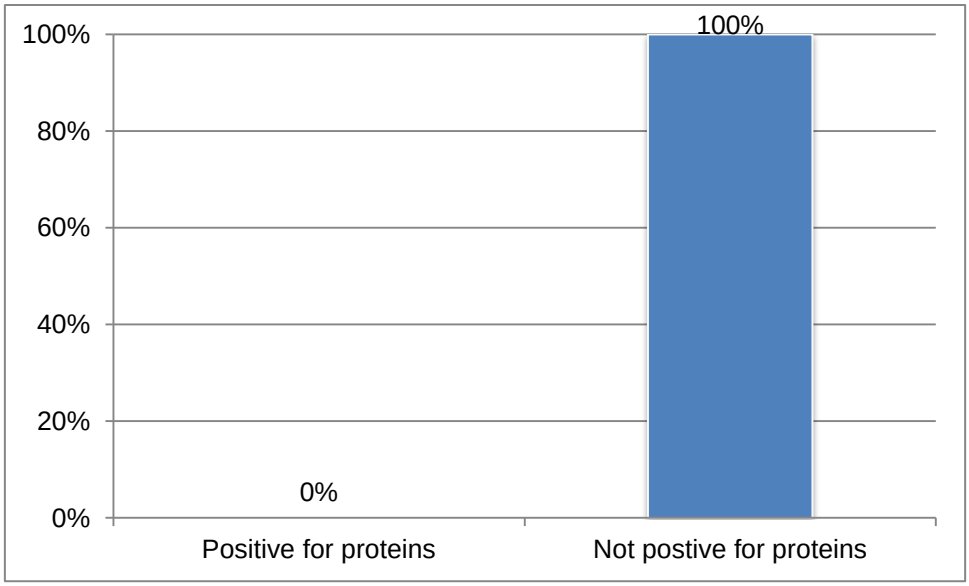


Figure 4.50 Gastroscopes washed in an automated washer positive for proteins

4.4.31 Pattern matching gastroscopes: clean-time positive for proteins

The researcher filtered the gastroscope cleaning data and found that, of the gastroscopes cleaned in under 1 minute, 40% of them (n=2/5) tested positive for residual proteins.

Findings are shown in **figure 4.51.**

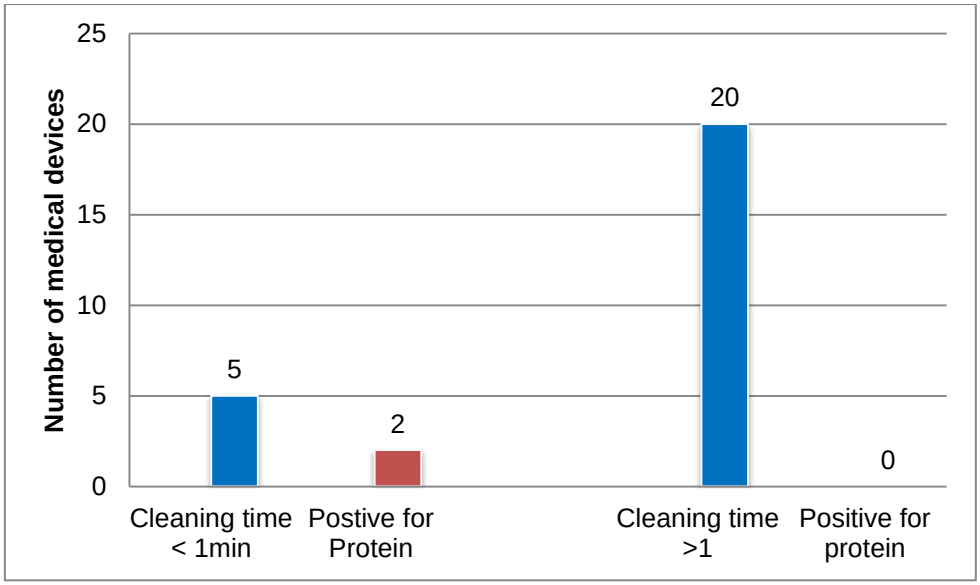


Figure 4.51: Number of gastroscopes positive for proteins when cleaned for less than one minute and greater than one minute

4.4.32 Medical devices positive for residual proteins overall

The researcher found that overall 16% of medical devices tested positive for residual proteins (n=47/303).

Findings are shown in **figure 4.52.**

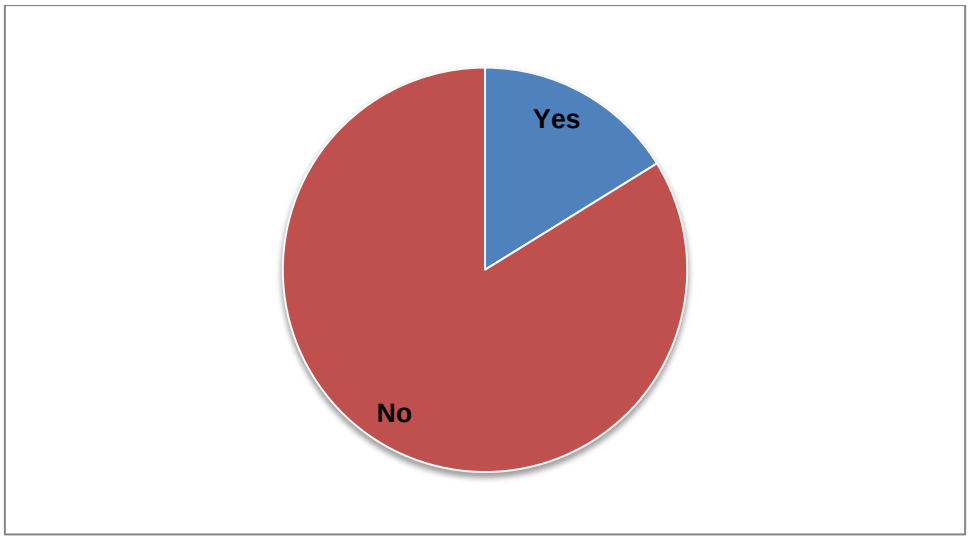


Figure 4.52: Overall percentage of device positive for proteins main study

4.4.33 Overall average positive for proteins per hospital

The researcher found that hospital's A and B had the highest percentage of medical devices positive for proteins both at 21% (n=14/66). Hospital C had the next highest at 13% (n=7/52), hospital E 12% (n=7/57) and hospital D had the lowest percentage of devices positive for proteins at 8% (n=5/62). Findings are shown in **figure 4.53**.

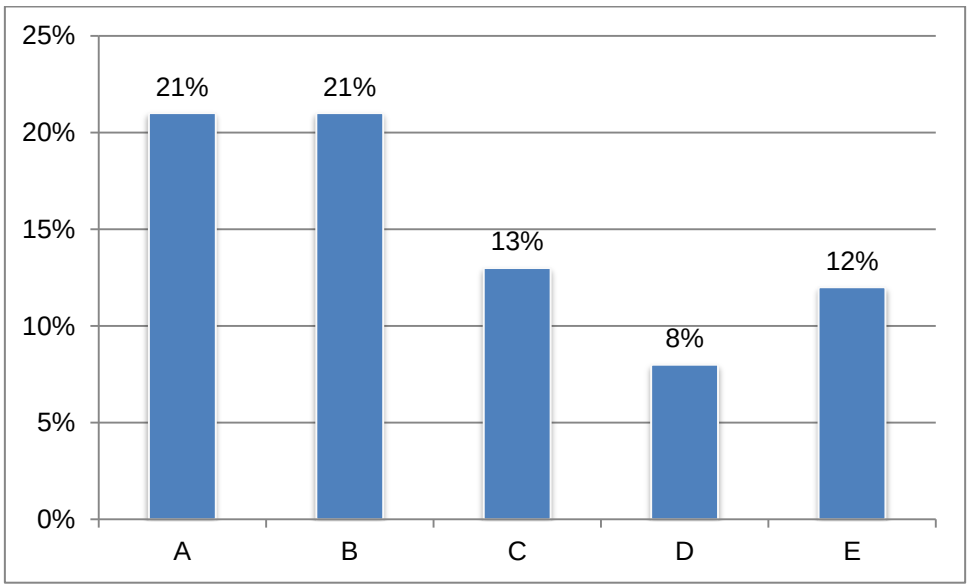


Figure 4.53 Overall percentage of device positive for proteins, per hospital main study

4.4.34 Positive for proteins, per device

The researcher found that certain types of medical devices have a higher percentage of residual proteins than other types of devices.

Crile's forceps, needle holders and Yankhauer suctions were the worst cleaned medical devices as they had the highest percentage of residual proteins at 60%, 26% and 24% respectively. Findings are shown in **table 4.4.**

Table 4.4: Number of medical devices tested and number positive for proteins per device

Medical Device	Number Tested	Number Positive	Percent Positive
Needle Holders	50	13	26%
Vaginal Speculum	82	9	11%
Laryngoscope	50	5	10%
Diathermy	41	3	7%
Yankhauer	50	12	24%
Gastroscope	5	3	8%
Crile's forceps(PCD)	25	2	60%
Overall	303	47	16%

4.4.35 Positive Protein Test Reaction Time

According to the manufacturer of the commercially available residual protein test (Browne Ltd, UK) used in this research, there is a relationship between the amount of residual protein detected and the time it takes for the swab to react (turn purple). The higher the protein the quicker the protein will react to the ninhydrin reagent. The research found that the majority, 62% of protein tests showed a positive result in five minutes (n=29/47), 28% in thirty minutes (n=13/47) and 10% reacted after sixty minutes (n=5/47).

Findings are shown in **figure 4. 54.**

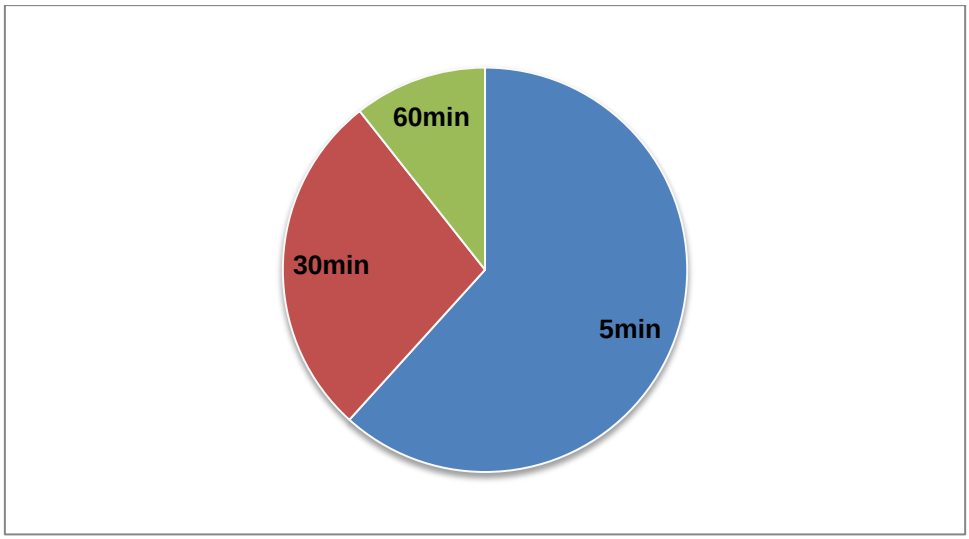


Figure 4.54 Positive protein test reaction time main study

4.4.36 Pattern Matching: Washed manually: positive for residual proteins

Pattern matching was done to establish if specific cleaning methods produced medical devices free from protein residuals. The research data was filtered to determine what percentage of medical devices that were washed in a manual cleaning process tested positive for proteins. The researcher found that 12% of the medical devices that were washed manually (n=19/154) tested positive for residual proteins and 88% did not (n=135/154). Findings are shown in **figure 4.55.**

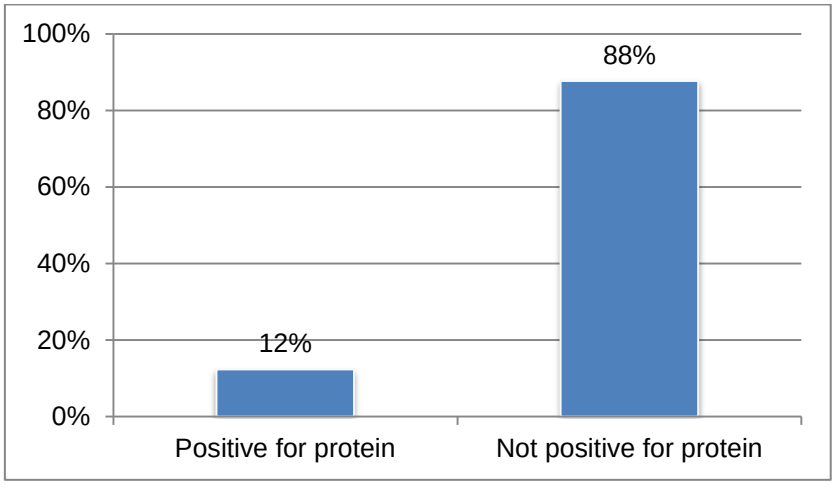


Figure 4.55 Washed manually positive for proteins main study

4.4.37 Pattern Matching: Washed in an automated washer: positive for residual proteins

The researcher found that 19% of the medical devices washed in an automated wash process (n=28/149) tested positive for residual proteins and 81% did not (n=12/149). Findings are shown in **figure 4.56.**

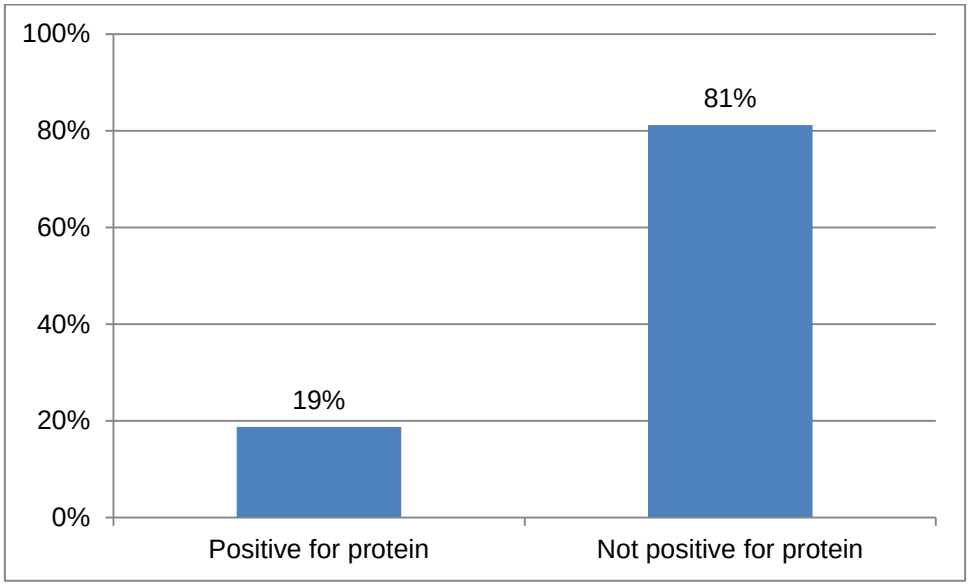


Figure 4.56 Washed in automated washer: positive for proteins

4.4.38 Pattern Matching: Positive for proteins: kept moist

The researcher filtered the data captured in the main study to ascertain what percentage of the medical devices that were kept moist was positive for residual proteins.
The researcher found that when the medical devices were kept moist until they were cleaned, the devices had less residual proteins on them than those that were not kept moist.

Only 12% (n=11/95) of the medical devices that were **kept moist** tested positive for residual proteins.

Whereas 19% (n=34/183) of the medical devices that were **not** kept moist tested positive for residual proteins. Findings are shown in figure **4. 57.**

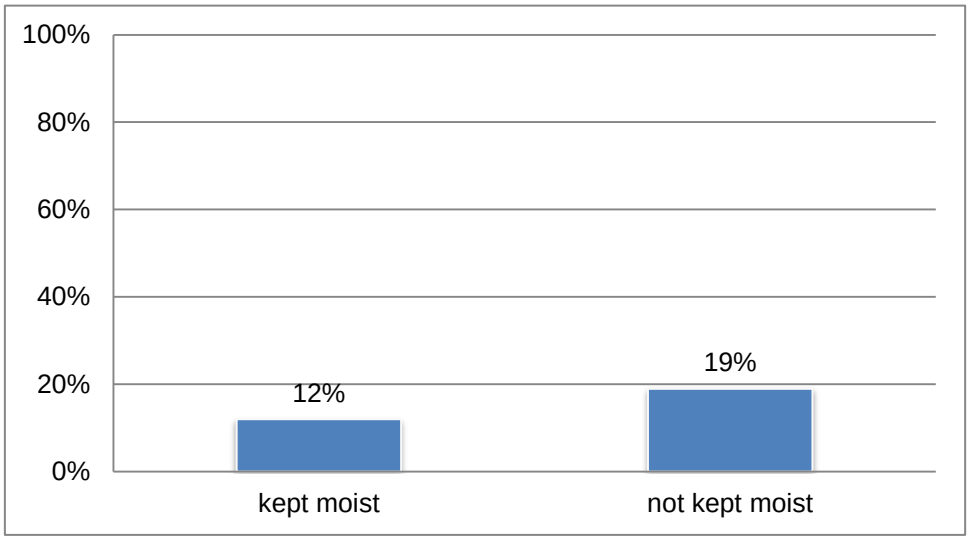


Figure 4.57: Percentage of devices kept moist positive for proteins main study

4.4.39 Pattern Matching: Positive for proteins: Yankhauer suction lumen flushed vs. not flushed

The research data was filtered to determine what percentage of Yankhauer suction nozzles flushed during the cleaning process tested positive for residual proteins.
The researcher found that less of the Yankhauer that **were flushed** during the cleaning process 22% (n=2/9) were positive for residual proteins whereas more of the Yankhauer suctions 24% (n=10/41) that were **not flushed** during the cleaning process tested positive for residual proteins.
Findings are shown in **figure 4.58.**

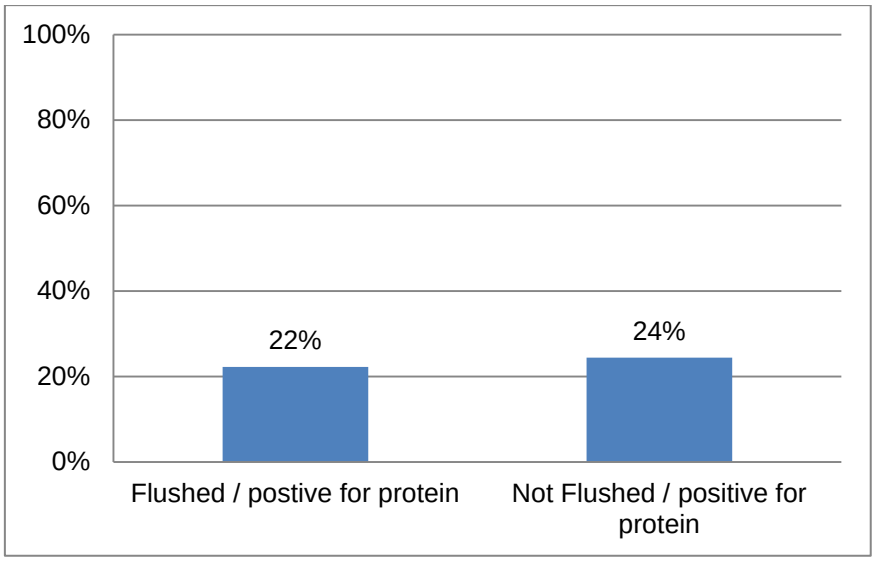


Figure 4.58 Percentage of Yankhauer suctions flushed and not flushed positive for proteins

4.4.40 Pattern Matching: Visually Clean: Positive for proteins

The research data was filtered to ascertain what percentage of the medical devices that appeared to be macroscopically visually clean tested positive for residual protein, meaning they were **not** actually clean. The researcher found that 4% (n=5/128) of the medical devices that appeared to be macroscopically visually clean tested positive for residual proteins. Findings are shown in **figure 4.59.**

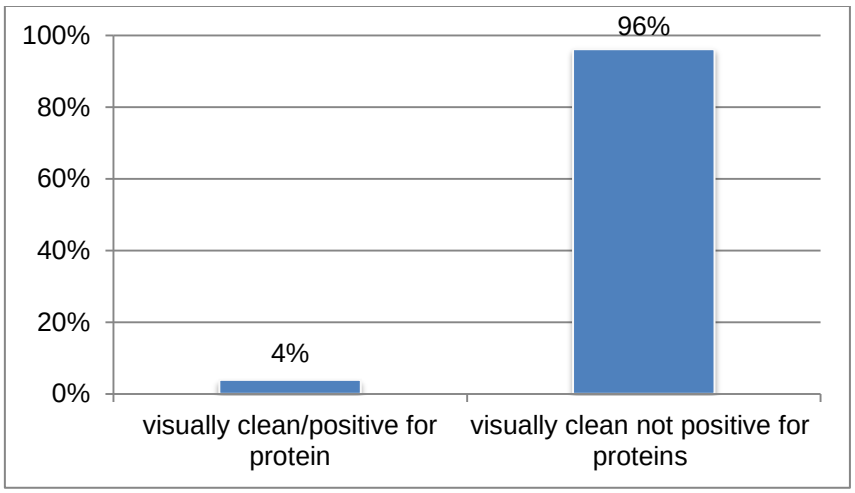


Figure 4.59: Medical devices that were visually clean but tested positive for proteins

4.4.41 Pattern Matching: Visually Dirty: Positive for proteins

The research data was filtered to ascertain what percentage of the medical devices that appeared to be macroscopically visually dirty actually tested positive for residual protein. The researcher found that of 27% (n=40/150) of the medical devices that appeared to be macroscopically visually dirty tested positive for residual proteins

Findings are shown in **figure 4.60.**

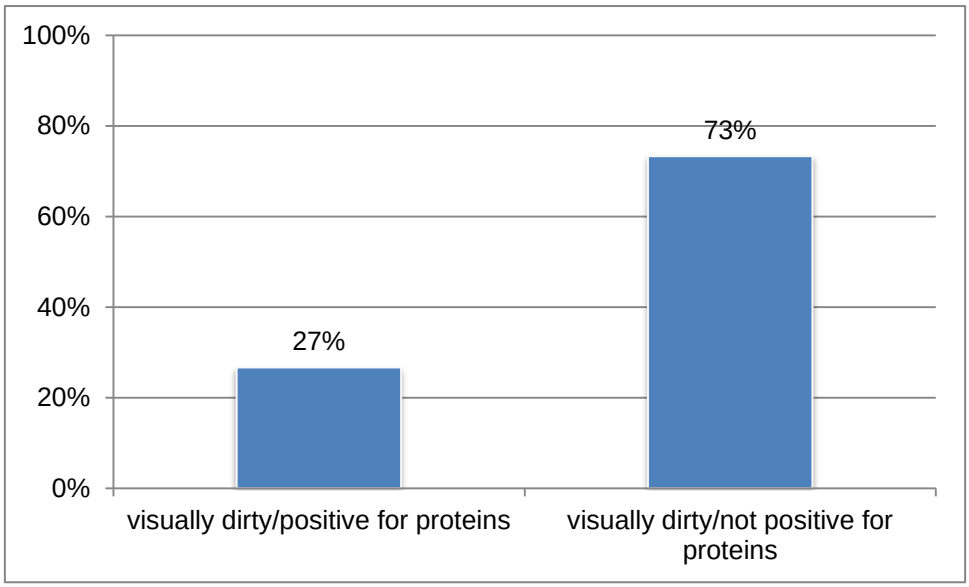


Figure 4.60 Medical devices that were visually dirty but tested positive for proteins

4.5 SUMMARY

In this chapter the approach used to analyse the data and the results was described. The results were described using descriptive statistics and pattern matching. The result from the pilot study (phase one) and the main study (phase two) were presented. The research findings were also discussed.

CHAPTER FIVE

SUMMARY LIMITATIONS RECOMMENDATIONS AND CONCLUSIONS

5.1 INTRODUCTION

In this chapter a summary of the whole study was provided, various findings and conclusions deduced from the research results were discussed. The limitation of the study was examined and recommendations regarding the potential future use of protein residual tests were discussed.

5.2 PURPOSE OF THE STUDY

The purpose of this study was to establish if five hospitals in the province of Gauteng had SOP's for cleaning medical devices, if medical devices were cleaned following internationally validated procedures, whether medical devices had protein residuals on them after routine cleaning procedures, to establish which cleaning method, i.e. manual or automated cleaning produced cleaner instruments and whether it was feasible to verify cleaning efficacy using a commercially available ninhydrin residual protein test.

5.3 RESEARCH OBJECTIVES

- To establish if five hospitals in Gauteng (three private hospitals and two public hospitals) have SOP's for cleaning of medical devices.

- To assess if routine cleaning procedures at five hospitals in Gauteng comply with international validated cleaning procedures as recommended by guidance documents like American National Standard (AAMI, 2010) for example.
- To determine if protein residuals remain on selected medical devices after routine cleaning procedures.
- To establish which cleaning method, manual or automated produces cleaner medical devices.
- To assess the feasibility of verifying cleaning efficacy using a ninhydrin residual protein test and an artificial soil test.

5.4 METHODOLOGY

In this study a descriptive, multiple case study design (consisting of two phases a pilot and a main study) was utilised in order to understand the phenomenon of medical device cleaning in its real life context in five hospitals in the province of Gauteng, South Africa. The five hospitals represent the major hospital groups in Gauteng (three private and two public) that employ different cleaning methods.

Case study methodology was used or this research, as it is the preferred method when the researcher examines contemporary events in a real life context, but has no control over behaviours and is utilising multiple sources of evidence (Yin, 2009). The multiple sources of evidence that were used in this study included five Gauteng based hospital's standard operating procedures, observations of cleaning methods used in those hospitals and results of ninhydrin residual protein test done on selected medical devices (this data was collected using a structured observation check list) .

5.5 SUMMARY OF THE MAIN FINDINGS

The main findings from this research are presented as follows:

- Medical devices were being **cleaned in various departments** in the hospital, 61% were cleaned in the CSSD, 16% were cleaned in the operating room, 11% were cleaned in doctor's rooms 8% in the gastroenterology unit 3% in the gynaecology clinic and 1% were cleaned in the ICU. In order to effectively clean (and sterilise) medical devices a number of steps must be followed and to perform these steps, staff need ample space and cleaning equipment (ECRI, 2013). As CSSD's are designed and equipped for this process it stands to reason that cleaning of medical devices should be done in this dedicated area, and it is unlikely that intensive care units, operating theatres, doctor's rooms and gynaecology clinics have the required space, or equipped to effectively clean medical devices. Yet in this research only 61% of medical devices were cleaned in the CSSD.

- Medical devices **were cleaned by staff of various designations**, of which 50% were cleaned by CSSD technicians, and 23% by non-healthcare workers. The remaining devices were cleaned by nurses, 21% by RN/EN, 3% by student nurses and 2% were cleaned by ENA's. According to Taneja et al. (2010) the knowledge and expertise of staff (even with regards to routine procedures) should never be presumed. One cannot therefore assume that a medical device will be better cleaned by a nurse with a higher theoretical qualification. In research conducted in India the staff in CSSD showed a higher level of knowledge with regards to sterilisation and disinfection than those working in the operating room Taneja et al., 2010). Knudson (2014:C1) also explains that the *"increasing complexity of surgical instruments has complicated instrument cleaning processes"*

- Very few of the individuals responsible for cleaning of medical devices that is to say, 3% were aware of **SOP's for cleaning** in their respective hospital units. According to the American National Standard, comprehensive guide to steam sterilization and sterility assurance in health care facilities, all hospitals should develop their own policies and procedures for the decontamination of reusable medical devices that are based on the manufacturer's instructions (AAMI, 2010). These policies should be detailed, comprehensive and provide step by step instructions (AAMI, 2011). If the MFIU are not followed correctly it could result in direct harm to the patient and could also result in damage to the device itself (Duro, 2013). Some medical devices require more reprocessing steps than others which could include the reprocessing instructions for brushing, flushing and ultrasonic cleaning (Duro, 2013).

- Fifty one percent of medical devices were **cleaned manually**. According to the American National Standard and published research, medical devices should be cleaned using an automated wash process (AAMI, 2011, Alfa et al., 2010). When devices are cleaned manually instead of using an automated process, the efficacy of cleaning depends on the nurse or hospital staff member doing the cleaning, and that person may not follow the reprocessing steps accurately each time (AAMI, 2011). **Automated cleaning** is more thorough than manual cleaning (Alfa et al., 2010). In addition automated cleaning is preferred because nursing staff and relevant hospital staff are less exposed to harmful microorganisms and chemicals, productivity is increased and devices can be cleaned using higher water temperatures (AAMI, 2011). It was found that only 49% of medical devices were cleaned in an automated washer in this research despite the fact that international guidelines advocate that automated wash procedures are more effective. There are however no applicable South African guidelines in this regard.

- Forty one percent of medical devices were cleaned with an **inappropriate detergent** or combinations of detergents, not necessarily compatible with medical devices. Various types of detergents can be used to clean medical devices but those detergents must be compatible with the device in question (AAMI, 2011). Enzymatic and alkaline detergents used in the correct concentrations are advocated for the cleaning of medical devices. The consequence of using an inappropriate detergent could be ineffective cleaning, as well as damage to medical devices. It is equally as import to **dilute detergents** used to clean medical devices correctly, according to Duro (2013) it is important to follow MFIU when diluting detergents which was only done 55% of the time in this research. If too much detergent is used, it may be difficult to rinse off the medical device completely, and if too little is used the detergent will be ineffective.

- Sixty six percent of medical devices were **not kept moist** until such time as they were cleaned. It is not always possible to clean medical devices immediately after use as surgical procedures can take many hours and sterilising units are faced with increased workloads (Secker et al., 2011). International guidelines, like the American National Standard and the Technical Information Report both advocate that devices should be kept moist whilst being transported until they can be cleaned (AAMI, 2010, AAMI, 2011). How devices are managed during and after surgical procedures may affect the level of tissue proteins left on them after cleaning, this can also affect the efficacy of the subsequent disinfection and sterilisation processes (Secker et al., 2011).

- Medical devices were loaded into a tray suitable for use in a washer-disinfector in 75% of the cases when medical devices were being washed in an automated washer-disinfector. In a paper published by Draghici et al., (2005) it was noted that instruments should be placed in suitable standardised sieve baskets when being

placed in a washer-disinfector, as the type of baskets used in a washer can affect the cleaning of medical devices. This sentiment is further enhanced by Roth & Michels (2005) who state that perforated tin baskets don't allow the water spray in an automated washer to adequately come into contact with the medical devices should not be allowed. In this research 25% of medical devices processed in automated washer-disinfector were loaded in an unsuitable**, incorrect** type of **instrument tray**.

- Instrument trays placed in the washer-disinfectors were **overloaded** and the medical devices were **shadowing** over each other which can severely hamper cleaning efficacy. When instrument trays are overloaded or loaded in such a way that instruments are shadowed, it is technically impossible for the detergent and water spray to reach the medical devices in the tray (Roth & Michels, 2005).

- Medical devices cleaned manually were cleaned with a household sponge in 22% of the cases, a brush in 68% of the cases and a cloth in 10% of the cases. When cleaning medical devices, friction is applied using a **cleaning accessory**. A number of different cleaning accessories can be used. Manufacturer's instructions are detailed and would inform the reprocessor what critical reprocessing elements must be followed (Knudson, 2014). The instructions will stipulate for example what type of cleaning solution should be used, what type of brush should be used and what the temperature of the water should be (Knudson, 2014). It does not seem that MIFU are always followed in South Africa as cleaning accessories are used haphazardly. Household sponges (used in 22%) of the cases would not be recommended in MFIU as they have scours that will scratch and damage medical devices.

- Eighteen percent of the **lumens of Yankhauer** suction nozzles were flushed whether the suction was cleaned manually or in an automated wash process. As Yankhauer

suctions are lumened devices they can be difficult to clean. It is important to flush devices with lumens when cleaning them as, according to Alfa et al. (2010:174) *"if there is no directed fluid flow into a lumen device, there will be no removal of organic material despite being exposed to sonification and a fully automated cleaning cycle"*. Despite this fact very few, of the lumens of Yankhauer suctions were flushed whether the suction was washed manually or in an automated washer.

- Forty six percent 46% of the medical devices macroscopically visually inspected the after they had been cleaned appeared to be **visually clean** and 54% appeared to be dirty. The most common method used to verify if medical devices are clean is to visually inspect them for residual soils (AAMI, 2011). This inspection should be done carefully, and would be enhanced if a magnifying glass was used (AAMI, 2011). However for the purposes of this research the medical devices in question were inspected macroscopically with the naked eye to reflect common clinical practice, as not all CSSD's have magnifying glasses. With just using the naked eye 54% of them did not appear to be clean.

- When the various **gastroscope cleaning steps** were performed a standalone leakage tester was available for use and a **leakage test** was performed in 20% of the cases. These findings are in-line an audit conducted in 2008 of the provincial gastroenterology services in the Western Cape where it was noted that "*leakage testing equipment was available at all endoscopy units but was only used routinely were trained nursing staff was available"* (Watermeyer et al., 2008:70). In this research leakage tests were only performed when gastroscopes were cleaned in an automated washer, as part of the wash process. The **cleaning step** rinsing of the outer tube of the gastroscope post cleaning was the only step performed 100% of the time; the air water and suction valves were only removed and brushed 25% of time. The cleaning accessories were attached to the gastroscope 25% of the time and the entire

gastroscope was submerged 50% of the time. In addition the outer tubes were washed 80% of the time and the biopsy channel was brushed 95% of the time. The results of this research are in line with findings of the audit conducted in provincial gastroenterology services in the Western Cape in 2008, that state that reprocessing of flexible endoscopes was "*haphazard*" (Watermeyer et al., 2008:71). In contrast in a study published by Ofstead et al. (2010) it was noted that endoscopes were completely submerged in detergent in 99% of the cases, and scopes were disassembled (water air and suction valves removed) in 99% of the cases. Ofstead et al. (2013:735) states that "*nearly all endoscope associated infections have resulted from failure to adequately clean and disinfect endoscopes*. Ofstead also states that there are ongoing, widespread reports of incidents of lapses in endoscope reprocessing (Ofstead et al., 2013). The risk of transmission of infection is higher when there are lapses in reprocessing versus when endoscopes are reprocessed correctly (Ofstead et al., 2013). It is known that "*contaminated endoscopes are linked to more healthcare associated infections than any other medical device*" (Ofstead et al., 2013:734).

- Fifty percent of gastroscopes were cleaned in two to three minutes 25% in less than one minute and the remaining 25% were cleaned in three to five minutes. In research conducted in the USA in 2008 through to 2009 (Ofstead et al., 2010), it was noted that 65% of the staff spent 1-2 minutes brushing each endoscope, and 18% of the time they spent longer than 2 minutes brushing the scopes (Ofstead et al., 2010). In contrast in this research it was found that the entire scope cleaning process was performed in almost the **same amount of time** that was spent on just brushing the scope in the research conducted by Ofstead et al. (2010). In this research 50% of the gastroscopes were cleaned in two to three minutes 25% in less than one minute and the remaining 25% were cleaned in three to five minutes.

- Twenty percent of gastroscopes were cleaned in an **automated wash** process and 80% were cleaned using a **manual cleaning** process It has been noted that staff do not adhere to cleaning guidelines (more so) when cleaning scopes using a manual process versus when cleaning using an automated scope washer (Dirlam Langlay et al., 2013). Yet despite this only 20% of gastroscopes in this research were cleaned using an automated washer.

- The commercially available **Ninhydrin** test kit (Browne Ltd, UK) was used in this research to test medical devices for residual proteins was able to pick up residual proteins on 76% of the dirty scopes. This test was deemed to measure a sensitivity level of 9.µg of protein (Lipscomb et al., 2006c). The researcher purposefully tested **dirty gastroscopes** (before they were cleaned) for residual proteins. The ninhydrin test method is routinely used in test laboratories and healthcare facilities to test for residual proteins on re-usable medical devices as specified in the ISO standard, (15883) however according to Nayuni et al. (2013) some publications advocate that more sensitive protein detection methods are needed. As the test was not able to pick up residual proteins on 100% of the dirty scopes the findings suggest that the ninhydrin test method may not be ideal (or possibly sensitive enough) for testing gastroscopes. In this research 8% of the **cleaned gastroscopes** tested positive for residual proteins. As the test method used does not appear to be sensitive enough to pick up residual proteins on dirty gastroscopes this result may not be accurate and the percentage of cleaned gastroscopes positive for residual proteins may have been underestimated.

- Ten percent of gastroscopes cleaned manually were positive for proteins, whereas none of gastroscopes cleaned in an automated wash process tested positive for residual proteins. Although a limited number of gastroscopes were tested for residual proteins in this research, these findings support the concept that **automated cleaning**

is more thorough than manual cleaning (Alfa et al., 2010). These findings in this research also suggest that **the quicker a gastroscope** is cleaned the greater the likelihood that it will not be clean and will therefore test positive for residual proteins, as 40% of the cleaned in under 1 minute tested positive for proteins. It also stands to reason the quicker a gastroscope is cleaned the greater the chance that all the cleaning steps were not performed.

- **In total** 16% of all medical devices tested were **positive for residual proteins**. In research similar to this de Bruijn, Orzechowski, & Wassenaar et al (2001) tested 190 medical devices from two CSSD's for residual proteins using the ninhydrin residual protein test method. Twenty six percent of the medical devices tested positive for residual protein. De Bruijn et al's. (2001) overall findings of the percentage of medical devices that tested positive for residual proteins was higher (26%) than those found in this research (16%), however de Bruijn' s research (2001) was conducted at only 2 hospitals and 190 medical devices were tested versus 5 hospitals and 278 medical devices in this research. Similarly in the research conducted by de Bruijn (2001) the percentage of medical devices that tested positive for residual proteins **per hospital** differed. Eleven percent tested positive at hospital 1 and 43% tested positive hospital 2. In this research the percentage of medical devices that tested positive per hospital ranged from 8% to 21%.

- Certain **types of medical devices** have a higher percentage of residual proteins than other types of devices. Crile's forceps, needle holders and Yankhauer suctions had the highest percentage of residual proteins at 60%, 26% and 24% respectively. These results are not surprising as needle holders and Crile's forceps both have box joints. Instruments with **box joints** are likely to have a greater amount of soil adhering to them, which means they are a greater challenge to clean (Lipscomb et al., 2006c).

Similarly in a study published by Murdoch et al. (2006), two hundred and six (ready for use) instruments were tested for residual proteins. Of the **needle holders** tested, 20% of them had protein residuals on them high enough to pose a risk for direct transmission of possible infections (Murdoch et al., 2006).

- Twenty four percent of the Yankhauer suction nozzles tested positive for residual proteins. A study published by Azizi et al. (2012) states that it is difficult to clean a **Yankhauer** suction tip because the suction gets narrower as it gets closer to the tip and that the interior lumen has ridges grooves and other tooling marks which seemed to contribute to the build- up of debris in the suctions lumen. The findings in this research substantiate this point, as 24% of the Yankhauer suction nozzles tested positive for residual proteins.

- The percentage of **diathermy forceps** that tested positive for proteins was surprisingly low at just 7%. Large amounts of residual contamination (soils) were found on the tips of the forceps by Lipscomb et al (2006b), it was expected that this result would be higher. It may be possible that the results for the diathermy forceps were lower than expected because it is indeed difficult to remove proteins from medical devices using a wetted swab as advocated by Nayuni et al. (2013) and Baxter, Baxter, Campbell, et al. (2006).

- The majority, i.e. 62% of protein tests showed a positive result in five minutes, 28% in thirty minutes and 10% reacted after sixty minutes. According to the manufacturer of the commercially available residual protein test (Browne Ltd, UK) used in this research, there is a relationship between the amount of residual protein detected and the time it takes for the **swab to react** (turn purple). The higher the protein the quicker the protein will react to the ninhydrin reagent.

- Twelve percent of the medical devices **washed manually** tested positive for **residual proteins**, and 19% of the medical devices washed in an **automated** process tested **positive for proteins**. It was expected that medical devices that were washed manually would yield more medical devices positive for proteins then devices washed in an automated washer. It is possible that the personnel cleaning medical devices manually were influenced by the Hawthorne effect as was noted in research published by Ofstead et al. (2010). The staff knew they were being observed, and as a result, manual cleaning may have been done more thoroughly than usual. However according to Alfa et al. (2010) automated cleaning is more thorough than manual cleaning but medical devices must be loaded correctly into an automated washer, or else they will not be effectively cleaned (Draghici et al., 2005). It is possible that incorrect loading will shield the wash jets preventing effective cleaning (Draghici et al., 2005). It has already been noted in this research that incorrect instrument trays were used 76% of the time, they were overloaded in 60% of the cases and medical device were shadowed in 60% in of the cases. It therefore was not surprising that more medical devices washed in an automated washer were positive for proteins than those washed manually.

- Only 12% of the medical devices that were **kept moist** tested positive for residual proteins, whereas 19% of the medical devices that were **not** kept moist tested positive for residual proteins. These findings are aligned with a paper published by Secker et al. (2011) who contaminated stainless steel discs with proteins and exposed some of the discs to dry conditions, and some discs were kept moist. The discs were then cleaned using an enzymatic detergent and the level of proteins remaining on the discs was measured (Secker et al., 2011). It was much easier to remove the proteins from the discs that were kept moist, and Secker et al. (2011) concluded that keeping medical devices moist until they can be cleaned could improve decontamination of

devices, possibly reduce the time it takes to decontaminate them, as well as the cost to decontaminate.

- Of the Yankhauer suctions that were flushed during the cleaning process in this research, 22% were positive for residual proteins, and of the Yankhauer suctions that were **not flushed** 24% tested **positive for residual proteins**. This data is in accordance with findings from Alfa et al. (2010:174) which state that "*if there is no directed fluid flow into a lumen device, there will be no removal of organic material despite being exposed to sonification and a fully automated cleaning cycle*".

- Four percent of the medical devices that appeared to be macroscopically **visually clean** tested **positive for residual proteins**, and 27% of the medical devices that appeared to be macroscopically visually dirty tested positive for residual proteins. Similarly in a paper published by Fengler (2001) , it was noted that 92% of medical devices were visually deemed to be clean and 6% were contaminated. The same instruments were subjected to a protein residual test, and only 32, 5% of the medical devices were found to be clean and 67, 5% were contaminated (Fengler et al., 2001). Visual inspection of the medical devices was not an accurate reflection of how clean they were. The findings in this research are in-line with best practice guidelines that state all devices should at least be visually inspected for residual soils before undergoing disinfection or sterilization, but not all soils are visible to the naked eye, and it is not possible to visualise the lumens of certain medical devices (AAMI, 2011).

Objectives of this research have been achieved as the researcher was able to establish that:

- Only 3% percent of the staff at unit level was aware of medical device cleaning **SOP's**.
- Not all medical devices are cleaned in accordance with **internationally validated cleaning procedures**, as many devices are cleaned manually and not in an automated washer, with inappropriate, incorrectly diluted detergents.
- Overall 16% percent of medical devices in five hospitals in Gauteng, three private hospitals and two public hospitals were **positive for residual proteins post routine cleaning.**
- Overall in the South African context more medical devices washed in an automated washer tested positive for proteins then those **washed manually**, which may be due to the manner in which the washer-disinfector was loaded.
- The commercially available Ninhydrin test kit (Browne Ltd, UK) was able to **effectively detect residual proteins** on medical devices in this research to a similar degree found in previous research (Worthington et al., 2001). However the findings in this research suggest that ninhydrin test method may not be ideal (or possibly sensitive enough) for testing gastroscopes for residual proteins as the researcher was not able to pick up residual proteins on all dirty gastroscopes that had just been used on a patient.

5.6 LIMITATIONS OF THE STUDY

There were limitations in this study, they were as follows:

- This research was conducted at only five hospitals in Gauteng and this may not be representative of all hospitals in South Africa
- The researcher was not able to perform all 355 intended residual protein tests (only performed 278), as one hospital had converted to using single use only, disposable

diathermy pencils instead of diathermy forceps, and two hospitals made use of single use, disposable vaginal specula .

- The researcher used a ninhydrin residual protein detection test kit (Browne Ltd, UK) deemed to measure a sensitivity level of 9.µg of protein, which may not be sensitive enough to detect all forms of protein.
- Some medical devices stained the residual protein tests white swab tip in manner that made it difficult to see the purple colour change as depicted in figure 5.2.

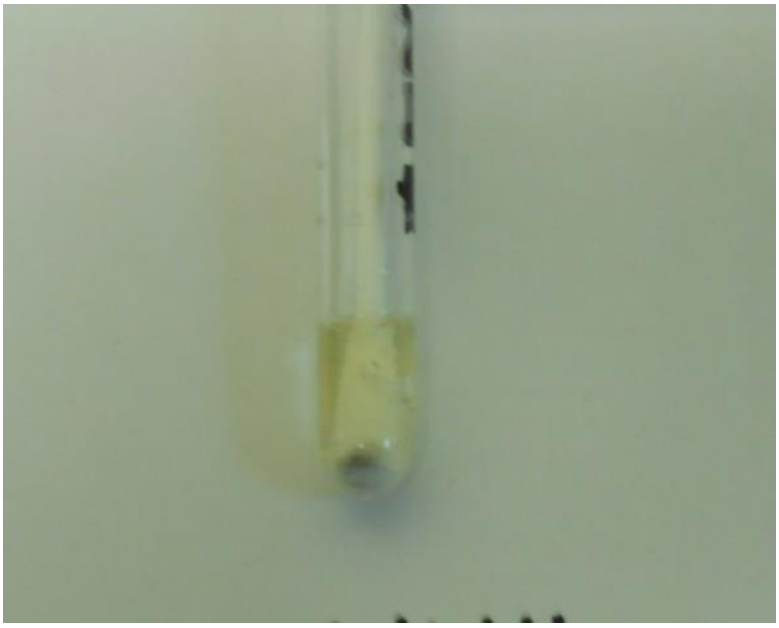


Figure 5.1: Stained swab

5.7 RECOMMENDATIONS

Based on the finding of this study the following is recommended:

5.7.1 Recommendations for healthcare education

The following healthcare education recommendations could be applicable to all healthcare practitioners using and/or cleaning medical devices in clinical practice.

- All healthcare staff should understand the importance of decontaminating medical devices.
- All healthcare staff should understand that it is possible to transmit disease from one patient to another via a contaminated medical device.
- All healthcare staff should understand the value and objectives of a SOP.
- Universities and nurse training institutions should include the topic of medical device decontamination in in-service training and theoretical teachings, as staff must understand the possible negative effects of using contaminated medical devices on patients with compromised immunities.
- Infection prevention nurses must be trained in medical device decontamination
- The South African Nursing Council should advocate continuous learning; CPD (continuous professional development points) should be allocated to this discipline of Nursing.

5.7.2 Recommendations for clinical practice

- All units/hospitals should have written SOP's for cleaning of medical devices based on the manufacturers validated instructions.
- All members of staff should be given in-service training on the existence of the SOP's and how to clean medical devices following the steps outlined in the SOP's.
- Compatible medical devices including all flexible endoscopes (for example gastroscopes) should be cleaned in an automated washer-disinfector.
- Medical devices should be loaded correctly into the washer-disinfector, in accordance with MIFU.
- Medical devices should be tested regularly by the CSSD unit manager under the supervision of the registered nurse responsible for the operating theatre, for residual proteins to check efficacy of cleaning techniques.

- Infection prevention nurses should monitor and audit medical devices cleaning processes.
- South African guidelines should be established for cleaning of medical devices that are in line with internationally validated procedures, MIFU and that advocate the use of protein residual tests to verify cleaning efficacy

5.7.3 Recommendations for further research

- Nation-wide extensive research should be conducted to understand the full extent of medical devices testing positive for residual proteins following routine cleaning procedures in the clinical setting, in South Africa and internationally.
- Nation-wide extensive research should be conducted using more sensitive residual protein detection tests to verify the efficacy of these test methods.
- Additional aspects that were not assessed in this research but should be included in future studies include; observing to what extent relevant medical devices were dismantled or opened when placed in a washer, understanding how many medical devices are processed in day so that a representative number of medical devices be tested for residual proteins.

5.8 CONCLUSION

Contaminated medical devices could play a role in transmitting infections from one patient to another, which could result in patients developing HCAI's. Ineffectively cleaned medical devices can never be properly sterilised as residual soils may hamper effective sterilization.

Medical devices should be decontaminated following clearly written hospital SOP's that are in-line with MIFU, in order for them to be cleaned effectively. Medical devices should

be cleaned following validated procedures and MIFU, as medical device decontamination can be a complex process that involves a number of different steps.

Where possible medical devices should be cleaned in an automated wash process, but the washer-disinfector should be loaded correctly ensuring that medical devices are not shadowed and washers are not overloaded, as this could hamper effective cleaning.
If medical devices are cleaned manually, appropriate correctly diluted detergents should be used, and the devices should be cleaned by applying friction using suitable cleaning accessories as stipulated by the MIFU.

Some medical devices are more difficult to clean than others because of the complex nature of their design and extra care should be taken when cleaning and inspecting these devices. Difficult to clean devices included those with lumens and box joints.

Medical devices should be kept moist until such time as they can be cleaned as medical devices with dried soils are more difficult to clean, and are more likely to test positive for residual proteins.

Medical devices should be visually inspected to verify if they are clean, but visual inspection alone is not an effective way to verify medical device cleanliness. Medical devices should therefore be tested regularly using suitably sensitive protein residual tests as recommended in the guidelines (AAMI; 2011, ISO15883, 2006).

South African guidelines should be established for cleaning of medical devices that are in line with internationally validated procedures, MIFU and that advocate the use of protein residual tests to verify cleaning efficacy.

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APPENDIX A

CASE STUDY PROTOCOL

1. BACKGROUND

Patients undergo surgical and medical procedures daily in hospitals and clinics in South Africa. Medical devices are used to perform these procedures. It is possible that dirty medical devices could transmit nosocomial infections, so it is critical that medical devices are cleaned, disinfected or sterilized according to validated procedures. Medical devices should be visually inspected to verify that they are indeed clean. Not all patient soils are visible to the naked eye so cleaning should be verified using additional methods. One such method is to test the device for protein residues.

The aim of this study is to establish if five hospitals in Gauteng have standard operating procedures for cleaning medical devices, if their cleaning procedures are based on international validated procedures and to investigate if medical devices have protein residuals left on them after undergoing routine cleaning procedures.

2. RESEARCH QUESTIONS

- Do South African hospitals have standard operating procedures for cleaning of medical devices?
- Do South African routine cleaning procedures comply with international validated cleaning procedures as recommended by guidance documents?
- Do protein residuals remain on selected medical devices after routine cleaning procedures?
- Which method of cleaning produces cleaner medical devices, manual or automated cleaning in five hospitals in Gauteng?

- Is it feasibly possible to verifying cleaning efficacy using a ninhydrin residual protein test and an artificial soil test?

3. STUDY DESIGN

A descriptive, multiple case study design is utilised in this study, in order to understand the phenomenon of medical device cleaning within its real life context in five hospitals in Gauteng.

3.1 CASE SELECTION

Research will be undertaken in five selected Gauteng hospitals. The five hospitals have not been randomly selected. They have been purposively selected to represent hospital groups in South Africa and to represent hospitals that that employ different cleaning methods that regularly use specific medical devices. The medical devices in question are Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blades, vaginal specula and flexible gastroscopes.
Data is to be collected at five hospitals

4. Case Study Procedures

4.1. Gain access

The researcher must establish who the applicable person is at each hospital, hospital group head office or doctor's rooms that is able to provide permission to conduct research. The researcher must complete the relevant application forms and obtain written permission to conduct research.

The researcher must report to the hospital management at each hospital with copies of the permission to conduct research and ask for permission to gain access to the relevant hospital departments to conduct research.

The researcher must report to the relevant department, provide the unit manager with a copy of the information letter and ask permission to be present in the various areas of the hospital where the selected medical devices are cleaned.

The researcher must establish where and when the selected medical devices are cleaned and make arrangements to be present for this process, with the unit manager.

Information Letter

The information letter outlines the proposed research, please see attached appendix B

Informed Consent

Before observing the cleaning of relevant medical devices the researcher should provide the individual who is to be observed with a copy of the information letter that describes the proposed research, explain the research, and then ask the individual to sign the consent form. If the individual to be observed gives verbal consent but is not comfortable to sign the consent form, the researcher should ask the individuals immediate supervisor to sign the consent form.

4.2 Preparation

- **Documentation**

The researcher should ensure that copies of the following documentation are on hand when arriving on site to conduct research

1. Structured observation check list for each medical device to be tested
2. Consent forms
3. Information letters

4. Copy of written permission obtained from the relevant heads of departments

- **Equipment**

The researcher must have a tool box with the following items when arriving at the department to conduct research:

1. Ninhydrin protein residual test kit
2. Sterile water
3. Incubator
4. Plug adaptor
5. Pen
6. Timer
7. Camera
8. Permanent marking pen
9. Blank paper
10. Gloves

- **Residual protein test preparation**

Plug in the incubator to warm up. Prepare testing kit; lay out swabs, sterile water, gloves, ninhydrin vials, Browne Ltd, UK soil test and camera. Perform positive control test as described in Browne Ltd, UK ninhydrin residual protein detection kit manufactures instruction for use insert.

4.3 Data Collection

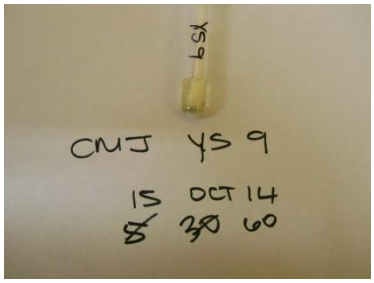
4.3.1 SOP

Ask the individual assigned to clean the relevant medical device if they are aware of an SOP (standard operating procedure) for cleaning of medical devices

4.3.2 Assign the device a code

The medical device and its corresponding protein residual test must be assigned a code. The code consists of the following; hospital code, medical device abbreviation and swab number.

The code is to be used when photographing the medical device and is to written on the relevant protein residual test vial. See examples below:





Medical device codes are as follows:

NH= Needle holder

VS= Vaginal speculum

LB= Laryngoscope blade

DF= Diathermy forceps

YS= Yankhauer suction

GS= Gastroscope

PCD= Process challenge device (Crile's forceps)

4.3.3 Observe cleaning

Where possible observe the relevant aspects of how the selected medical device was cleaned as outlined in the structured observation checklist. If is not possible to observe the cleaning of the medical device, ask the relevant person assigned to clean the device to describe how the device was cleaned. The selected medical devices to be observed and tested are Yankhauer suctions, needle holders, diathermy forceps, laryngoscope blades, vaginal specula and gastroscopes.

4.3.4 Record observations

Record the observations or descriptions on the structured observation checklist. There are two types of structured observation checklists, one for surgical instruments and one for gastroscopes. Ensure the correct structured observation check list is used.

4.3.5 Photograph device

Place the device on a blank piece of A4 paper. Record the device's code, the date and the hospital code on the piece of A4 paper and photograph the device, as per below example:



4.3.6 Test for residual protein

The technique for the residual protein test must be performed as follows:

- **Gastroscope**

A DispoClean endoscope cleaning brush is to be passed through the biopsy channel of the gastroscope, as illustrated below.



Biopsy channel



DispoClean brush

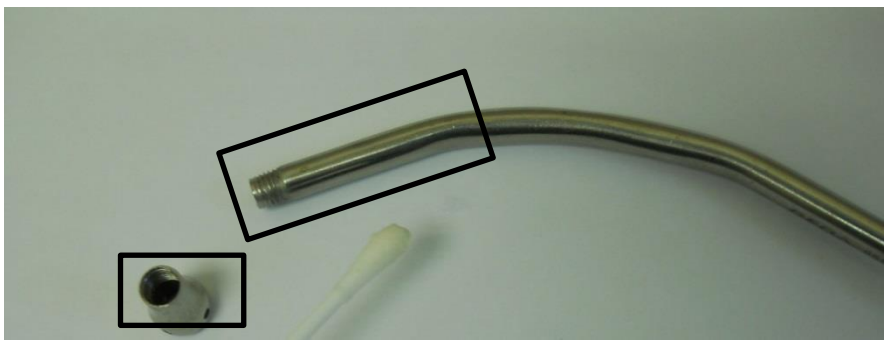


Tip of brush in vial

The tip of the brush must be removed, and placed in the gel filled ninhydrin vial provided. Incubate the vial at 57°C for 1 hour. The brush tip in the vial must be observed for colour change after five minutes and then again at thirty minutes and finally at sixty minutes. If the brush tip changed to a purple colour the device would have tested positive for protein. The results ate to be documented on the structured observation check list. This test is performed on clean and dirty gastroscopes.

- **Yankhauer suction**

The rose tip of the suction nozzle must be removed. Moisten a test swab with four drops of sterile water. Insert the swab into the lumen of the tip of the suction, swab the lumen and the rose tip cap with the same swab, as illustrated below.

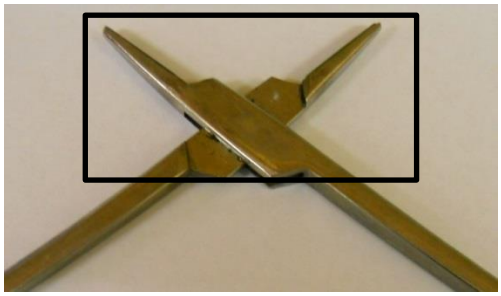


Portion of Yankhauer suction swab tested for residual protein

Break off the tip of the swab and place it in the gel filled ninhydrin vial. Incubate the vial at 57°C for 1 hour. Observe and document the results on the structured observation check list.

- **Needle Holder**

Moisten a test swab with four drops of sterile water. Run the test swab over all sides of the instrument tips ending at and including the box joint, as illustrated below:

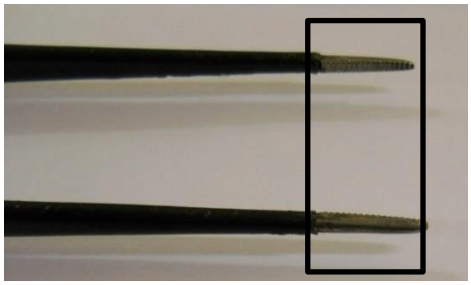


Portion of needle holder swab tested for residual protein

Break off the tip of the swab and place it in the gel filled ninhydrin vial. Incubate the vial at 57°C for 1 hour. Observe and document the results on the structured observation check list.

- **Diathermy Forceps**

Moisten a test swab with four drops of sterile water. Run the test swab over all the surfaces of the diathermy forceps serrated tip ending at the insulation, as illustrated below.

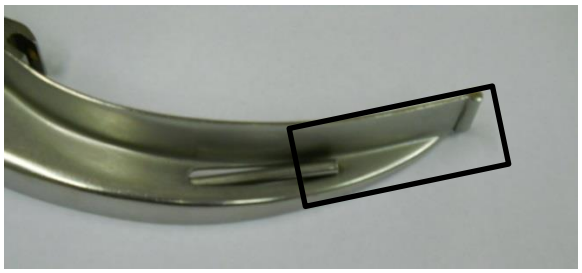


Portion of diathermy forceps swab tested for residual protein

Break off the tip of the swab and place it in the gel filled ninhydrin vial. Incubate the vial at 57°C for 1 hour. Observe and document the results on the structured observation check list.

- **Laryngoscope Blade**

Moisten a test swab with four drops of sterile water. Run the test swab over the superior surface of the laryngoscope blade ending at and including the portion where the light bulb is inserted, as illustrated below.

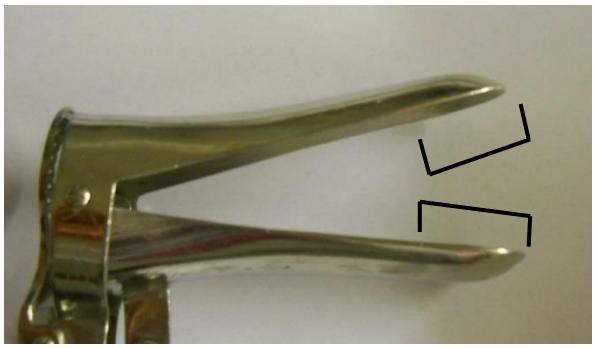


Portion of laryngoscope swab tested for residual protein

Break off the tip of the swab and place it in the gel filled ninhydrin vial. Incubate the vial at 57°C for 1 hour. Observe and document the results on the structured observation check list.

- **Vaginal speculum**

Moisten a test swab with four drops of sterile water. Open the mouth speculum mouth. Run a test swab over the superior inner first third surfaces of the vaginal speculum. Moisten another test swab and then run it over the inferior inner first third of the vaginal speculum, as illustrated below.

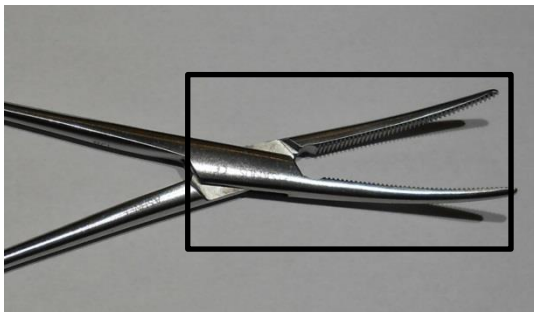


Portion of vaginal speculum swab tested for residual protein

Break off the tip of the swab and place it in the gel filled ninhydrin vial. Incubate the vial at 57°C for 1 hour. Observe and document the results on the structured observation check list.

- **Crile forceps (Control)**

Moisten a test swab with four drops of sterile water. Run the test swab over all sides of the instrument tips ending at and including the box joint, as illustrated below.

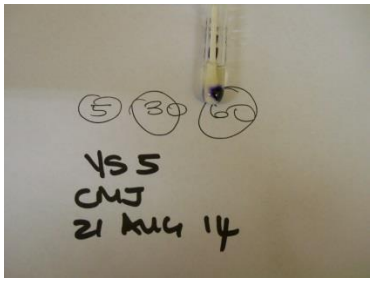


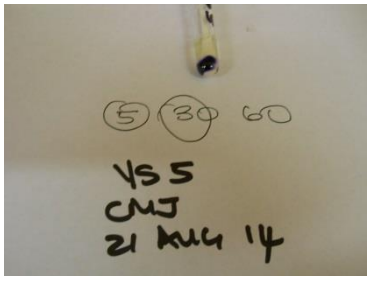
Portion of Crile's forceps swab tested for residual protein

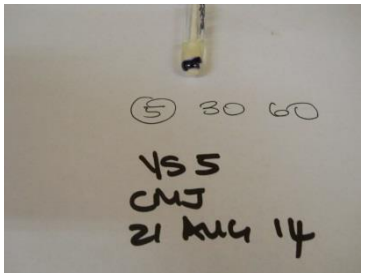
Break off the tip of the swab and place it in the gel filled ninhydrin vial. Incubate the vial at 57°C for 1 hour. Observe and document the results on the structured observation check list.

4.3.7 Photograph results

Results of the test (purple colour change) should be photographed at five, thirty and sixty minutes as illustrated below.







4.4 Sample size

The cleaning of seventy one medical devices should be observed, recorded and then the said medical devices should be tested for residual proteins at five hospitals as outlined in the table below.

Table :Sample size phase 2

	Number of instruments tested	Number of Hospitals	Total number of Tests
Gastroscopes Clean	5	5	25
Gastroscopes Dirty	5	5	25
Yankhauer	10	5	50
Needle holder	10	5	50
Diathermy forceps	10	5	50
Vaginal speculum superior	10	5	50
Vaginal speculum inferior	10	5	50
Laryngoscope blade	10	5	50
Crile's forceps	1	5	5
Total tests			355

5. Record Keeping

Photographs of medical devices and results of residual protein detection tests must be downloaded onto a computer. Observations and results recorded on the structured observation check list must be captured on an excel spread sheet under the following headings:

- Medical device code
- Date observations and test done
- Hospital code
- Visually clean (clean designated with the numeric symbol 0, dirty designated with the numeric symbol 1)
- Overall result (negative designated with the numeric symbol 0, positive designated with the numeric symbol 1)
- Results at 5 minutes, 30 minutes and 60 minutes
- Designation of the individual who cleaned the medical device
- Area in the hospital where the device was cleaned
- Was there an SOP for cleaning medical devices in the unit
- Device cleaned manually or automated (M=manual A= automated)
- Cleaning observed or described (OBS= observed DES= described)
- Type of detergent used
- Detergent mixed according to MIFU
- Device cleaned using friction
- Type of cleaning accessory
- Yankhauer suction lumen flushed (yes or no)
- Device kept moist (yes or no)
- Washer type
- Correct tray (yes or no)
- Tray overloaded (yes or no)
- Medical devices shadowed (yes or no)

APPENDIX B

INFORMATION LETTER FOR PARTICIPANTS

Dear Colleague,

My name is Susanne Jardine. I am currently studying for a Master's Degree in Nursing Science at the University of the Witwatersrand. I am conducting a study to to establish if hospitals have standard operating procedures for cleaning medical devices, if their cleaning procedures are based on international validated procedures and to investigate if medical devices have protein residuals left on them after undergoing routine cleaning procedures. The results of this study could be used to help establish South African medical device cleaning guidelines.

I would like to request permission to:

1. See your Standard Operating Procedures for cleaning medical devices.
2. To observe and document (using a structured observation check list) how specific medical devices are routinely cleaned (namely; flexible gastroscope, Yankhauer suction nozzle, needle holder, diathermy forceps, laryngoscope blades and vaginal speculum).
3. To visually inspect the aforementioned devices for soil (and photograph the device)
4. To paint a designated Crile's forceps (provided by the researcher) with an artificial soil test. This will provide a positive control test for the research. The Crile forceps will be then subjected to routine cleaning.
5. To visually inspected the Crile forceps for soil (and photograph).
6. To swab the aforementioned medical devices with a sterile swab, and test that swab for residual proteins with a residual protein residue test, which could indicate that cleaning is inadequate.

The test would be carried out by me. You have my assurance that I will treat your surgical instruments/medical devices with care.

Should you agree to participate, please signed the attached consent form.

Participation in the process is entirely voluntary. You may choose not to participate, or to withdraw from this validation process at any time. Confidentiality is guaranteed as only me and my supervisors will have access to your data.
I appreciate that you will not benefit directly from participation in this study; however, I hope that the results of the study will help to establish South African medical device cleaning guidelines.

The Faculty of Medicine Post Graduate Committee and the Ethics Committee of the University of the Witwatersrand have approved this study.

Should you wish to contact me, or require any further information, my cell number is 07161797939.
Thank you for taking the time to read this information letter.
Yours sincerely
Susanne Jardine

APPENDIX C

INFORMED CONSENT FORM

I Hereby confirm that I have been informed by the researcher Susanne Jardine (Xana) about the nature of her study entitled ‘Inspection of selected medical device routine cleaning procedures; detection of residual proteins in the clinical setting in Gauteng hospitals’.

I have received, read and understood the written information sheet regarding the study.

I am aware that the results of the study, including my designation will be anonymously processed into a study report and all the information will remain confidential.

I may at any stage, without prejudice, withdraw consent and participation in study.

I have had sufficient opportunity to ask questions and, of my own free will, declare myself prepared to participate in the study.

Participant

_____ _____ _____

Printed Name Signature Date and Time

APPENDIX D

STRUCTURED OBSERVATION CHECK LIST PHASE 1

Date:	Hospital:		Code:	
Instrument type				
Designation of person cleaning device				
Cleaning Area	Theatre	CSSD	Other	
Is there a cleaning SOP	Y	N		
Cleaned according to SOP	Y	N		
Instruments				
Kept moist	Y	N	Soak bowl	Spray
Dismantled / Opened	Y	N		
Cleaning Method Used	Manual	Auto		
Detergent	Alkaline	Enzymatic	Other	
Automated cleaning				
Washer	Type		Cycle	
Washer loaded correctly -correct tray -shadowing -attached to lumen flush	 Y Y Y	 N N N	 N/A	
Is washer ISO 15883 compliant	Y	N	Unknown	
Is washer cleaning validated using tests recommended in ISO 15883	Y	N	N/A	
Manual Cleaning				
MIFU followed when mixing detergent	Y	N	Not seen	

Friction Used	Y		N		Accessory Used Straight brush Round brush Other	
Lumen cleaned	Y	N	Fluid	Brush	Tap	Syringe
Post clean rinse with clean water	Y		N			
Gastroscope						
Outer tube washed	Y	N	Valves removed		Y	N
Suck through	Y	N	Brushed valve ports		Y	N
Brush biopsy channel	Y	N	Post clean suck/rinse with clean water		Y	N
Outer tube rinsed post cleaning with clean water	Y	N				
Result						
Visually clean	Y		N			
Purple colour change observed at	5 minutes		30 minutes		60 minutes	
	Y	N	Y	N	Y	N
Protein test result	Brush result		+ve	-ve	Swab result	+ve / -ve

APPENDIX E

STRUCTURED OBSERVATION CHECK LISTS PHASE 2 GASTROSCOPES

Date					
Hospital					
Code example Hosp:GS1C Hosp:GS1D					
Cleaning Area	Theatre		CSSD	Other	
Designation of person cleaning					
Is there a cleaning SOP	Y		N		
Cleaned according to SOP	Y		N		
Biopsy taken	Y		N		
Cleaning Method	Manual		Auto		
Detergent	Alkaline		Enzymatic	Other	
Automated cleaning					
Washer type			Cycle Type Time		
Point of use pre clean					
Manual Cleaning					
Leakage test available	Y	N	LT done pre clean	Y	N
Outer tube washed	Y	N	Valves removed	Y	N
Suck through	Y	N	Brush valve port	Y	N
Brush biopsy channel	Y	N	Brush other channel	Y	N
Wash control body	Y	N	Flush channel	Y	N
Attach accessories	Y	N	Submerge	Y	N
Outer tube rinsed post	Y	N	Suck through rinse	Y	N
Clean Time	< 1 min		>1 min <2 min	>2 min <5 min	
Result	Visually clean		Y	N	
Incubation time			Swab result 1=positive 0=negative		
5 min			1	0	
30 min			1	0	
60 min			1	0	

APPENDIX F

STRUCTURED OBSERVATION CHECK LISTS PHASE 2 MEDICAL DEVICES

Date					
Hospital					
Code / Instrument Hosp:NH1 Hosp:NH2	NH	VS	LB	DF	YS
Cleaning Area	Theatre		CSSD	Other	
Cleaning Observed	Y	N	Described	Y	N
Designation of person cleaning					
Is there a cleaning SOP	Y		N		
Cleaned according to SOP	Y		N		
Cleaning Method	Manual		Auto		
Detergent	Alkaline		Enzymatic	Other:	
MIFU followed when mixing detergent	Y		N	Not seen	
Kept Moist	Soak Bowl		Spray	N	
Automated cleaning					
Pre Clean	Y	N			
Washer type			Cycle		
Correct Tray	Y		N		
Shadowing	Y		N		
Overloaded	Y		N		
Attach to lumen flush	Y		N	NA	
Manual Cleaning					
Friction	Y		N		
Type	Brush		Cloth		
Flush lumen	Y		N	TAP H_2O	SYRINGE+D
Rinsed post wash	Y		N		
Result	Visually clean		Y	N	
Incubation time			Swab result 1=positive 0=negative		
5 min			1	0	
30 min			1	0	
60 min			1	0	

APPENDIX G

APPROVAL FROM GAUTENG PROVINCIAL HOSPITAL 1

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

[redacted]

[redacted]

06th February 2014

Ms. Susanne Jardine
Department of Nursing Education
University of Witwatersrand

Dear Ms. S. Jardine

RE: "Inspection of selected medical devises routine cleaning procedures; detection of Residual proteins in the clinical setting in Gauteng hospitals"

Permission is granted for you to conduct the above research as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in anyway incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the Head of Department and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Approved / ~~not approved~~

[redacted]

6/02/2014

APPENDIX H

APPROVAL FROM GAUTENG PROVINICIAL HOSPITAL 2

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

PERMISSION FOR RESEARCH

DATE: 24 OCT 2014

NAME OF RESEARCH WORKER: SJ JARDINE

CONTACT DETAILS OF RESEARCH (INCLUDE ALTERNATE RESEARCHER):
071 6797939
xanaCsafmed.co.za

TITLE OF RESEARCH PROJECT: Inspection of selected medical dence cleaning procedure detection of residual proteins

OBJECTIVES OF STUDY (Briefly or include a protocol): To see if we are cleaning medical denoes correctly (details in protocol)

METHODOLOGY (Briefly or include a protocol): Case study Nemodology

THE APPROVAL BY THE SUPERINTENDENT IS STRICTLY ON THE BASIS OF THE FOLLOWING:

(i) CONFIDENTIALITY OF PATIENTS MAINTAINED: Will be maintained
(ii) NO COSTS TO THE HOSPITAL: None
(iii) APPROVAL OF HEAD OF DEPARTMENT: Noted.
(iv) APPROVAL BY ETHICS COMMITTEE OF UNIVERSITY: in protocol

SUPERINTENDENT PERMISSION Seen.

Signature: [redacted] Date: 24/10/2014

SUBJECT TO ANY RESTRICTIONS: Financial impact on Hospital

[redacted] [redacted]

APPENDIX I

APPROVAL FROM HUMAN RESEARCH ETHICS COMMITTEE

M130345

R14/49 Miss SJ Jardine et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130345

NAME: (Principal Investigator)	Miss SJ Jardine et al
DEPARTMENT:	Department of Nursing Education CM Johannesburg Academic Hospital
PROJECT TITLE:	Inspection of selectedmedical device routine cleaning procedures, detection of residual proteins in the clinical setting in Gauteng Hospitals
DATE CONSIDERED:	05/04/2013
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Adriano Duse MT
APPROVED BY:	Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 08/07/2013

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX J

APPROVAL TO CONDUCT RESEARCH PRIVATE HEALTHCARE GROUP 1

RESEARCH OPERATIONS COMMITTEE FINAL APPROVAL OF RESEARCH

Approval number: UNIV-2014-0046

Ms X Jardine

E mail: xana@safmed.co.za

Dear Ms Jardine

RE: INSPECTION OF SELECTED MEDICAL DEVICE ROUTINE CLEANING PROCEDURES; DETECTION OF RESIDUAL PROTEINS IN THE CLINICAL SETTING IN GAUTENG HOSPITALS

The above-mentioned research was reviewed by the Research Operations Committee's delegated members and it is with pleasure that we inform you that your application to conduct this research at Private Hospital, has been approved, subject to the following:

i) Research may now commence with this FINAL APPROVAL from the Committee.

ii) All information regarding the Company will be treated as legally privileged and confidential.

iii) The Company's name will not be mentioned without written consent from the Committee.

iv) All legal requirements with regards to participants' rights and confidentiality will be complied with.

v) The Company must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from the Committee as well as a FINAL REPORT with reference to intention to publish and probable journals for publication, on completion of the study.

vi) A copy of the research report will be provided to the Committee once it is finally approved by the relevant primary party or tertiary institution, or once complete or if discontinued for any reason whatsoever prior to the expected completion date..

vii) The Company has the right to implement any recommendations from the research.

viii) The Company reserves the right to withdraw the approval for research at any time during the process, should the research prove

[redacted]

to be detrimental to the subjects' Company or should the researcher not comply with the conditions of approval.

iv) APPROVAL IS VALID FOR A PERIOD OF 36 MONTHS FROM DATE OF THIS LETTER OR COMPLETION OR DISCONTINUATION OF THE STUDY, WHICHEVER IS THE FIRST.

We wish you success in your research.

Yours faithfully



This letter has been anonymised to ensure confidentiality in the research report. The original letter is available with author of research

APPENDIX K

APPROVAL TO CONDUCT RESEARCH PRIVATE HEALTHCARE GROUP 2

[redacted] [redacted]

21 August 2013

ATTENTION: S Jardine

APPROVAL FOR RESEARCH STUDY
TITLE: Inspection of selected medical device routine cleaning procedures; detection of residual proteins in the clinical setting in Gauteng hospitals.

Our previous correspondence refers.

The Research Committee of the [redacted] has granted permission for your study.

We look forward to seeing the results of your research once it is completed.

Yours sincerely

[redacted]

APPENDIX L

APPROVAL FROM PRIVATE HEALTHCARE GROUP NO. 3

Appendix E

Inspection of selected medical device routine cleaning procedures; detection of residual proteins in the clinical setting in Gauteng hospitals

INFORMED CONSENT FORM FOR PARTICIPANTS

I Hereby confirm that I have been informed by the researcher Susanne Jardine (Xana) about the nature of her study entitled 'Inspection of selected medical device routine cleaning procedures; detection of residual proteins in the clinical setting in Gauteng hospitals'.

I have received, read and understood the written information sheet regarding the study.

I am aware that the results of the study, including my designation will be anonymously processed into a study report and all the information will remain confidential.

I may at any stage, without prejudice, withdraw consent and participation in study.

I have had sufficient opportunity to ask questions and, of my own free will, declare myself prepared to participate in the study.

Participant

[redacted] 1/10/14

Printed Name Signature Date and Time

Appendix F

Confidentiality Agreement

Between: [redacted]

And SJ Jardine Student number 699039

Date: 1/10/14

1. I agree to keep all institutional / hospital names and any other sensitive information strictly confidential.
2. No communication to third parties will be carried out unless agreed upon by both parties in writing.
3. Any information gained will only be used for post graduate research purposes and may be presented at a congress. The information will be presented in such a manner that persons, hospitals or institutions names or any other sensitive information will not be made public or disclosed to any third party.

Signed by:
Name: [redacted]

Signature:

Date: 30/10/14

AND

Researcher: SJ Jardine

Signature:

Date: 1/10/14

APPENDIX M

APPROVAL POSTGRADUATE COMMITTE

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax:
Tel: 027117172040

Reference: Ms Mpumi Mnqapu
E-mail: mpumi.mnqapu@wits.ac.za

17 April 2013
Person No: 699039
PAG

Miss SJ Jardine
P O Box 683
Bromhof
Johannesburg
2154
South Africa

Dear Miss Jardine

Master of Science in Nursing: Approval of Title

We have pleasure in advising that your proposal entitled *Detection of protein residues on medical devises after auditing routine cleaning in selected Gauteng Hospitals* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences