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Microorganisms cultured from laryngoscope blades in an academic hospital following implementation of a new decontamination technique

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in Anaesthesiology

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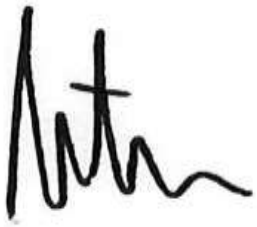
Examiner's Reports

All amendments made are highlighted in yellow.

1. Page 31 and page 32: Paragraphs added discussing a series of studies conducted by Samuel et al in KwaZulu Natal.
2. Page 34: Paragraph added discussing the SASA Guidelines for Infection Control in South Africa 2014.
3. Page 40: 3.6.4.1 Statement added "At the time of developing this protocol, SASA had not yet published their guidelines."
4. Page 53, paragraph 1: Removed reference to Table 4.8, "Table 4.8 illustrates these agents".
5. Page 53, paragraph 3: Removed reference to Table 4.9, "In Table 4.9 antimicrobials with resistance and sensitivity to the viridans group of streptococci are listed".
6. Page 53, paragraph 5: Addition of comparison to the Venter study.
7. Page 57: 5.2.4 Main findings: Correction to disinfectant solution utilised in study.
8. Page 65: Correction made to reference 103.

Declaration

I, Maria Fourtounas, declare that this Research Report is my own work. It is being submitted for the Degree of Master of Medicine in Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.



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Signature

Signed on the 30th day of June 2015

Signed at Johannesburg

Abstract

Background

Laryngoscopy is a commonly performed invasive procedure in hospitals, especially in theatre. Lack of formal guidelines and variation of utilised decontamination techniques have resulted in a breach of ensuring patient safety in hospitals. Multiple international and local studies have found microorganism contamination of laryngoscope blades.

Aim

The aim of this study was to describe the effectiveness of a newly implemented decontamination protocol for reusable laryngoscope blades at Helen Joseph Hospital.

Method

A prospective, contextual, comparative, descriptive study design was used. A single area on the size 4 blades in the two emergency theatres was swabbed in an aseptic manner. After transport to the laboratory, the samples were inoculated onto petri film and blood agar plates. Following 48 hours of aerobic incubation, plates were examined for colonies with subsequent enumeration and identification of microorganisms. The samples were collected over a two month period.

Results

Five control samples were collected, all of which had no microorganism growth. Of the 73 samples collected, four samples were misplaced by the laboratory with no results recovered. Positive quantitative counts were reported on eight (11.6%) samples, with only two (2.9%) samples having positive microorganism growth and identification and 67 (97.1%) samples reporting no microorganism growth. The two microorganisms isolated were *Chryseobacterium indologenes* and *Streptococcus salivarius*. This showed the effectiveness of the new decontamination technique, with a p-value < 0.0001.

Conclusion

The reduction in positive microorganism contamination by high-level disinfection with Cidex®OPA will improve patient safety and decrease the potential risk of cross infection. Formal decontamination protocols using a high-level disinfectant should be implemented at all hospitals.

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Abbreviations and Acronyms

AAGBI:	Association of Anaesthetists of Great Britain and Ireland
AANA:	American Association of Nurse Anesthetists
AORN:	Associated Perioperative Registered Nurses
APIC:	Association for Professionals in Infection Control and Epidemiology
CDC:	Centre for Disease Control
CFU:	Colony forming units
***E. coli*:**	*Escherichia coli*
FDA:	Food and Drug Administration
HAIs:	Healthcare-associated infections
HBV:	Hepatitis B virus
HIV:	Human immunodeficiency virus
HJH:	Helen Joseph Hospital
MHRA:	Medicines and Healthcare products Regulatory Agency
MRSA:	methicillin-resistant *Staphylococcus aureus*
NHLS:	National Health Laboratory Services
NSW:	New South Wales
OPA:	*Ortho*-phthalaldehyde
spp:	species
vCJD:	variant Creutzfeldt-Jakob disease
Wits:	Witwatersrand
WHO:	World Health Organisation

Chapter 1: Overview of study

1.1 Introduction

This chapter will contain an overview of the background of the study, problem statement, aim, objectives, research assumptions, demarcation of the study field, ethical considerations, research methodology, significance of the study, validity and reliability, overview of the study and a summary.

1.2 Background

Laryngoscopy is an invasive procedure commonly performed in all hospital settings (1). In order to intubate a patient using a rigid laryngoscope, a reusable laryngoscope blade is placed in the patient's oral cavity with contact made between the blade and the surrounding mucous membranes, including any secretions and blood present. It is this contact that may allow for the transmission of infections if the blades, and handles, are not adequately decontaminated (2-5).

The Centre for Disease Control (CDC) advises that laryngoscope blades be cleaned prior to high-level disinfection, pasteurisation or sterilisation (2). Most institutions employ their own guidelines as to the decontamination technique for laryngoscope blades. The guidelines of the American Association of Nurse Anaesthetists (AANA) 2012 state that high-level disinfection followed by sterilisation is required for semicritical instruments, including laryngoscope blades (6). The New South Wales (NSW) Health Department Infection Control Policy and the Association of Anaesthetists of Great Britain and Ireland (AAGBI) classify laryngoscope blades as critical instruments requiring sterilisation (7, 8).

Several studies have been conducted worldwide identifying microbial growth on laryngoscope blades and identifying the decontamination techniques employed at various institutions (2, 9-12). Both pathogenic and non-pathogenic microorganisms have been cultured from laryngoscope blades and handles (4, 12, 13). The concern is the transmission of pathogenic microorganisms resulting in cross infection of various harmful pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA), *Klebsiella* species (spp), *Escherichia coli (E.*

coli), *Pseudomonas* spp and Group A *Streptococci* (2, 4, 12, 13). A study conducted in England raised a further concern about the possible transmission of prion disease, such as variant Creutzfeldt-Jakob disease (vCJD). This is a major concern as prions can withstand customary sterilisation techniques. (14)

In 1974, Carstens (15) reported bacterial growth on laryngoscope blades at Baragwanath Hospital, Johannesburg. The concern raised was the possibility of transmitting infection via the laryngoscope blades (15). After obtaining positive cultures from all the blades that were swabbed, a new sterilisation technique was implemented at the hospital (15). Unfortunately, no follow-up study could be found assessing the effectiveness of the new sterilisation technique.

Laryngoscope blade decontamination was shown to be ineffective in a recent prospective, descriptive study conducted in the Department of Anaesthesiology, University of Witwatersrand (Wits) at Helen Joseph Hospital (HJH) (16). A total of 110 samples were examined for bacterial growth, of which 57.3% were positive for microorganism growth. This study was in accordance with the previously conducted international studies, depicting the growth of non-pathogenic and pathogenic microorganisms on the ready-to-use laryngoscope blades. Organisms isolated were diphtheroids, viridans streptococci, *Micrococcus* spp, coagulase-negative staphylococci, *Candida albicans*, *Bacillus* spp, *Arcanobacterium haemolyticum*, *Enterobacter* spp and *Acinetobacter baumannii*. (16)

1.3 Problem statement

It is important to assess the effectiveness of a newly implemented decontamination protocol to identify any potential risks to patient safety and identify any flaws. Assessing the effectiveness of the decontamination protocol utilised is important as the World Health Organisation (WHO) has acknowledged patient safety as an important goal (17, 18). Adequate decontamination of hospital equipment is paramount to patient safety.

Evident from the literature was that laryngoscope blades are a potential source of cross infection and that decontamination techniques differ immensely in different institutions. The recently conducted study at HJH showed that the

decontamination technique employed was ineffective (16). These findings prompted the need to implement a new decontamination protocol and then assess its effectiveness.

1.4 Aim

The aim of this study was to describe the effectiveness of a newly implemented decontamination protocol for reusable laryngoscope blades at HJH.

1.5 Objectives

The objectives of this study were to:

- describe the identity and quantity of microorganisms isolated from five blades (control samples) immediately after high-level disinfection with a newly implemented decontamination protocol;
- describe the identity and quantity of the microorganisms isolated from blades on the anaesthesia tabletop after implementation of a new decontamination protocol;
- evaluate the effectiveness of the newly implemented decontamination protocol by comparing microbial growth on blades to those from a historical control group from HJH.

1.6 Research assumptions

The following definitions were used in this study.

Blade: this refers to a conventional reusable non-fibreoptic laryngoscope blade that has been decontaminated and is considered “ready-to-use”.

Sample: specimens collected in a specific manner during the study, by swabbing the blade, were sent to the lab for isolation of microorganisms.

Aseptic technique: precautions, such as sterile gloves and instruments, are added to a healthcare procedure to prevent contamination of a person, object or area by microorganisms. (19)

Decontamination: the removal of pathogenic microorganisms from objects so they are safe to handle, use, or discard (20). The four-step process implemented to remove pathogenic microorganisms from the laryngoscope blades including cleaning, disinfecting, rinsing and drying.

Cleaning: the removal of visible soil or foreign material from objects and surfaces (20) by the use of an enzymatic detergent.

Disinfection: a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects (20). This step was achieved by immersing the laryngoscope blades in Cidex®OPA solution.

Sterilisation: the complete destruction of all living microorganisms, accomplished by physical methods (dry or moist heat), chemical agents, radiation or mechanical methods. (20, 21)

Microbial contamination: presence of microorganisms on an item for use in the medical care of patients (21). As per the definitions used in the previous study at HJH, a quantitative count of the microorganisms was stated as colony forming units (CFUs) per 1 ml of ¼ Ringers Lactate solution. The contamination levels were described as low if a count of 1 to 99 microorganisms were isolated; intermediate if the count was between 100 and 300; and high if more than 300 microorganisms per sample were isolated. (22)

1.7 Demarcation of the study

The study was conducted at HJH, Johannesburg. Two operating theatres were used, theatres 6 and 11. These are the emergency theatres at HJH; theatre 6 is mainly for general surgery related cases and septic cases and theatre 11 for orthopaedic emergencies.

HJH is a 485 bed regional academic hospital affiliated to the University of the Witwatersrand (23).

1.8 Ethical considerations

Approvals to conduct the study were obtained from the relevant authorities. This study was conducted in accordance with the Declaration of Helsinki (24) and Good Clinical Research Practice and Good Clinical Laboratory Practice (25).

1.9 Research methodology

1.9.1 Study design

A prospective, contextual, comparative descriptive study design was used.

1.9.2 Study population

The study population will consist of the blades utilised in the theatres of HJH.

1.9.3 Study sample

Sample size

In consultation with a biostatistician, it was anticipated that approximately 25% of the blades would be contaminated. A sample of 73 blades estimated the contaminated proportion to an accuracy of within 10% with 95% confidence.

Sample method

A convenience sampling method was followed in this study.

Eligibility criteria

“Ready-to-use” size four blades from theatres 6 and 11 will be included in this study.

Exclusion criteria:

- any infringement of the aseptic technique during sample collection
- any infringement of the accepted transport technique.

1.9.4 Study method

1.9.4.1 Current decontamination technique for blades employed at HJH theatres

A new decontamination protocol for laryngoscope blades was implemented at HJH. At the beginning of every case, a clean paper towel and clean “ready-to-use”

airway equipment including laryngoscope blades and handle, artery forceps, Magill forceps, face masks and a syringe are placed on the anaesthesia machine tabletop. After successful intubation, the anaesthesia machine tabletop is kept as clean as possible by not placing any dirty/used items on it. The blade is placed in the packet of the endotracheal tube and the handle is given to the anaesthetic sister to clean with an alcohol-soaked swab.

The decontamination process involves four steps: cleaning, disinfecting, rinsing and drying. The blade is placed in a container of enzymatic detergent solution and then rinsed thoroughly with water, ensuring all macroscopic soiling has been removed. Excess moisture is removed and the blade is then placed in a container with Cidex®OPA, a high-level disinfectant. The lid of the container needs to be securely fitted and the entire blade covered by the solution. The blade is immersed for five minutes, removed and thoroughly rinsed with water. A total of three rinses lasting one minute each are required to prevent toxicity. The blade is then dried with a paper towel and placed on the anaesthesia tabletop for use.

1.9.4.2 Data collection

Samples from the blades were collected using a standardised technique to avoid any further contamination. Samples were collected from the two emergency theatres at HJH. Only a single area of the blade was swabbed using an aseptic technique.

Swabbing

The researcher was responsible for sampling and transporting the specimens to the laboratory. If the researcher was unavailable, an assistant was trained to perform the standardised sampling technique and to transport specimens. This was not required.

Labelling of samples

A standard National Health Laboratory Services (NHLS) request form was used to enter each specimen's differentiating information. A unique study number was assigned to each specimen depending on the date the specimen was collected and the theatre from which it was collected. This number was generated in a

standardised manner. The unique detachable barcode from the NHLS form was placed on the data collection sheet for recovery of the results.

Storage and transport of samples

Samples were collected at HJH during the course of the day and delivered to the Infection Control Services Laboratory at the Department of Clinical Microbiology and Infectious Diseases of the Witwatersrand School of Pathology, University of the Wits Medical Campus. Sample collection was mostly performed once a day. On some days, a second sample collection was conducted at a different time of the day to allow a variety of collection times. Samples collected were stored in the fridge at 4 °C and transported to the laboratory at Wits Medical Campus at the earliest possible time thereafter. These samples were transported in a cooler box maintained at 4 °C using ice packs and were delivered by the researcher to the final destination.

Processing of samples at laboratory

The samples were processed and the culture and isolation of microorganisms was performed by trained laboratory personnel using standard microbiological techniques. The sample was incubated for 48 hours aerobically and the colonies examined, tallied and detailed.

1.10 Significance of study

Several studies conducted worldwide, including the two studies in South Africa, have repeatedly concluded that ready-to-use laryngoscope blades are contaminated with a wide range of microorganisms, of which numerous are pathogenic microbes that could result in morbidity and mortality. (2, 12, 13, 15, 16, 26)

The previously conducted study at HJH confirmed that the blades were contaminated and that the decontamination technique utilised may have been ineffective in eliminating microorganisms, including pathogenic microbes. This is a concern, especially in South Africa, as a large proportion of our patients are

immunocompromised and particularly susceptible to opportunistic infections (27, 28).

Following the results of the study conducted at HJH, a new decontamination protocol was instituted (Appendix A); blades are now disinfected with Cidex®OPA. It is important to assess the effectiveness of this newly implemented decontamination protocol to identify any potential risks to patient safety and identify any flaws. Assessing the effectiveness of the decontamination protocol utilised is important as WHO has acknowledged patient safety as an important goal (17, 18). Adequate decontamination of hospital equipment is paramount to patient safety.

1.11 Validity and reliability

Measures were taken to ensure the validity and reliability of this study.

1.12 Overview of study

The chapters in this study include:
An overview of the study was provided in chapter one. Chapter two contains a review of the relevant literature available. The research methodology is discussed in detail in chapter three. The results of the study and a discussion thereof are presented in chapter four. Chapter five contains a summary, the limitations of the study, recommendations and the conclusion of the study.

1.13 Summary

This chapter gave an outline of the background of the study, problem statement, aim, objectives, research assumptions, demarcation of the study field, ethical considerations, research methodology, significance of the study, reliability and validity, overview of the study and a summary. The next chapter will contain the literature review.

Chapter 2: Literature review

2.1 Introduction

Invasive procedures, such as laryngoscopy, pose a potential source of cross infection. After performing laryngoscopy, both the laryngoscope blade and handle are deemed to be contaminated (5, 6). Decontamination, if performed according to the guidelines, prevents this. A recent literature review found that current cleaning techniques for anaesthesia equipment are ineffective (9). This chapter will explore patient safety, the decontamination guidelines available, the decontamination techniques employed in different institutions and the effectiveness of these techniques, healthcare-associated infections (HAIs) and the relationship to reusable laryngoscope blades, the various microorganisms that have been cultured on laryngoscope blades and handles in a variety of settings, the previous study conducted at HJH will be discussed and infection control practices that can be utilised to diminish the risk of cross infection.

2.2 Patient safety

The incidence of HAIs is increasing globally (17). Infections acquired in-hospital lead to increased hospital stay, complicate patient care, increase morbidity and mortality and increase the financial burden on patients, their family and the healthcare system. WHO launched the “Clean Care is Safer Care” campaign based on the patient safety goal of *“Primum non nocere”* – “First, do no harm”. This campaign centres on preventing HAIs. This involves promoting hand hygiene, blood safety, injection and immunisation safety, safer clinical practices and safer water, sanitation and waste management. Hand washing is advocated as one of the critical aspects in preventing the transmission of infection between patients and to healthcare workers. It is these basic principles that should be applied at all times to all aspects of healthcare, such as the use of “safe” laryngoscope blades, as patient safety – “doing no harm” – should be a priority. (17, 18)

2.3 Decontamination guidelines

Procedures utilising reusable medical or surgical instruments that come in contact with a patient’s sterile tissue or mucous membranes are performed daily in the

hospital setting. These instruments require proper decontamination prior to reuse. Any inattention to the correct decontamination technique can lead to possible cross infection (20, 29).

The CDC (20) and Medicines and Healthcare products Regulatory Agency (MHRA) (30) define the concepts of decontamination, cleaning, disinfection and sterilisation. Decontamination is the combination of these processes comprising of cleaning, disinfection and sterilisation. It is “the removal of pathogenic microorganisms from objects so they are safe to handle, use, or discard”. The term cleaning is the removal of visible soil or foreign material from objects and surfaces. Disinfection is “a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects”. This is further subdivided into low- and high-level disinfection. Sterilisation is defined as “a process that destroys or eliminates all forms of microbial life”. This process can be performed using either physical or chemical methods. (20, 30, 31)

The proposed use of a reusable item and the associated risk of pathogen transmission will determine the technique chosen. The Spaulding classification refers to Earle Spaulding’s grouping of medical and surgical instruments and the approach to their disinfection and sterilisation (20). This classification, comprised of three categories, was developed in 1968 and it still forms the cornerstone of the CDC’s disinfection and sterilisation guidelines. It also forms the basis of the guidelines of the Association for Professionals in Infection Control and Epidemiology (APIC) (32), and the Occupational Safety and Health Administration (20).

Spaulding’s classification comprises critical, semicritical and noncritical items. Critical items are those that come in contact with sterile tissue or the vascular system. These items pose a high risk of transmission of infection and therefore require sterilisation. Such items include surgical instruments, cardiac and urinary catheters, implants and ultrasound probes for use in sterile body cavities. These items can either be purchased sterile or sterilised prior to use. (6-8, 11, 20, 29)

Semicritical items come into contact with nonintact skin or mucous membranes. The CDC recommends, as a minimum requirement, high-level disinfection using chemical disinfectants, but sterilisation is preferred if possible (6, 9, 16, 20). High-level disinfection allows small numbers of bacterial spores to remain on the item. Laryngoscope blades fall into this category. Other semicritical items include respiratory therapy and anaesthesia equipment, oesophageal manometer probes and cystoscopes. Some authorities, such as the NSW Health Department (7), state in their infection control policy that laryngoscope blades are classified as critical items and require sterilisation. This is supported by the AAGBI guidelines (8) . The AANA recommend that laryngoscope blades require both high-level disinfection and sterilisation prior to being considered “ready-to-use” (6). The Joint Commission and Centres for Medicare and Medicaid Services further recommend that after blades have undergone high-level disinfection, they should be individually wrapped for storage in order to prevent contamination prior to reuse (33). The blades at HJH are not individually wrapped after decontamination.

The South African Society of Anaesthesiologists (SASA) compiled guidelines for infection control practices in 2014: SASA Guidelines for Infection Control in Anaesthesia in South Africa 2014. These guidelines recommend the use of disposable laryngoscope blades as the preferred option. Alternatively, reusable laryngoscope blades should be sterilised as there are significant concerns regarding the use of high-level disinfection in our setting. (34)

Items that come into contact only with intact skin are classified as noncritical items. Decontamination by low-level disinfection is adequate as the risk of cross infection through noncritical items is minimal (9, 16, 20). Examples are blood pressure cuffs, stethoscopes and arm boards. (6, 20, 29)

Environmental surfaces include surfaces and objects that do not come into contact with the patient and are therefore classified as noncritical items. Adequate decontamination can be achieved with cleaning and low- or intermediate-level disinfectants. (6, 20)

The MHRA makes use of a different classification in their guidelines on sterilisation, disinfection and cleaning of medical equipment. This classification also contains three categories: high, intermediate and low risk items (30, 35). This classification can be correlated with the Spaulding classification (30). High risk items are either introduced into a sterile body area or come into contact with nonintact skin or nonintact mucous membranes. The recommended technique for decontamination is sterilisation. Items in the intermediate risk group have come into contact with mucous membranes, were previously used on immunocompromised patients or have been contaminated with virulent microorganisms. Sterilisation or disinfection is required. If items have come in contact with healthy skin or have not come in contact with the patient, they are placed in the low risk category and cleaning is considered adequate. (30)

However, there is no consensus between the various organisations' guidelines on rigid laryngoscope decontamination. Whereas most of these organisations, such as the AANA and CDC, agree on the classification of laryngoscope blades and handles as semicritical items and requiring high-level disinfection as a minimum prior to reuse, the guidelines of the Associated Perioperative Registered Nurses (AORN) classify the laryngoscope blade as a semicritical item and the handle as a noncritical item requiring only low-level disinfection (36, 37). This is a worrisome discrepancy from the other guidelines as Williams et al (3) clearly demonstrated that the handle can be as contaminated as the blade (3). High- and low-level disinfection achieve immensely different levels of decontamination. High-level disinfection will eradicate vegetative bacteria, mycobacteria, viruses, fungi and some bacterial endospores; whereas, low-level disinfection does not achieve this (36, 37).

2.3.1 Decontamination techniques

2.3.1.1 Cleaning

After manually or mechanically removing all visible organic matter by cleaning the instruments, a further process may be commenced to achieve the desired level of disinfection or sterilisation. Thorough cleaning is important as the presence of organic and inorganic material that remains on the instruments interferes with the next process, rendering it less effective or inactivating the chemical germicides

utilised in the next process (6, 20). If soiled instruments are not adequately rinsed and cleaned, the soiling can dry or bake onto the instruments making removal far more difficult thereafter. Cleaning is usually performed by rinsing with water and a detergent or enzymatic product and then thoroughly rinsing and drying the instruments (8, 20). Alternative techniques include friction cleaning by using a brush to scrub the soiled area or fluidics, where debris can be removed using fluids under high pressure (20). Cleaning is the least effective method in decontaminating instruments (38) but is the first important step that decreases the quantity of microorganisms on instruments and equipment (20).

2.3.1.2 Disinfection

Disinfection reduces the number of microorganisms present on an item, but most disinfectants are not sporicidal. However, by prolonging the exposure time of some disinfectants, spores may be destroyed. It is important to note that microbial contamination is not decreased to levels obtained by sterilisation (30). There are three levels of disinfection: low, intermediate and high. Low-level disinfection eradicates most vegetative bacteria, some viruses and fungi, but has no effect against mycobacteria, endospores and the lipid viruses e.g. human immunodeficiency virus (HIV), hepatitis B (HBV) and herpes. Sodium hypochlorite or 70% alcohol and chlorhexidine are low-level disinfectants (8). Smaller viruses e.g. polio and coxsackie, and most fungi are destroyed by intermediate-level disinfection. Mycobacteria are destroyed by high-level disinfection, however, not all endospores, fungi and viruses are destroyed by this process (6, 20, 30). By increasing the contact time, to several hours, high-level disinfectants may produce sterilisation (8) . Preventing the transmission of infection, via the laryngoscope blade, should be achieved by cleaning and then high-level disinfection, as per the CDC's guidelines. (20)

Types of disinfectants

There are a large variety of disinfectants but they do not all achieve the same level of disinfection. Chemical disinfectants are used to achieve high-level disinfection required for semicritical items. Disinfectants can be used alone or in combination. Examples include alcohols, chlorine and chlorine compounds, paracetic acid, glutaraldehyde, formaldehyde, hydrogen peroxide, *ortho*-phthalaldehyde,

iodophors, quaternary ammonium compounds and phenolics (6, 20). Several of these chemicals are toxic and hazardous and personnel exposed to them should always adhere to universal precautions (20). The different disinfectants will be discussed briefly, with the main focus on the Cidex® products, as Cidex®OPA was the solution used in the new decontamination protocol implemented.

Alcohol disinfectants are not considered high-level disinfectants. Ethyl alcohol and isopropyl alcohol are rapidly bactericidal against vegetative bacteria; they are also tuberculocidal, fungicidal and virucidal. However, they do not destroy bacterial spores and are not able to destroy hydrophilic viruses, such as poliovirus and coxsackie virus. Medical and surgical items should not be sterilised with alcohol as it lacks the ability to penetrate protein-rich materials. (20)

Chlorine and chlorine compounds, more commonly known as household bleach, have a broad spectrum of antimicrobial activity. Chlorine in higher concentrations is effective against *Mycobacterium tuberculosis*. (20)

Paracetic, or peroxyacetic, acid has rapid action against all microorganisms. Another advantage is that its decomposition compounds are not harmful. The removal of organic matter is enhanced and it is sporicidal. Gram-negative and gram-positive bacteria, fungi and yeasts can be neutralised rapidly. (20)

Formaldehyde can be used in its liquid and gaseous phase for disinfection and sterilisation. Formalin is the water-based solution of formaldehyde. This aqueous solution is effective against bacteria, fungi, viruses and spores, and is also tuberculocidal. However, it is a potential carcinogen linked to lung cancer. (20)

Hydrogen peroxide has activity against bacteria, yeasts, fungi, viruses and spores. It produces hydroxyl free radicals that attack cell components such as the membrane lipids and DNA resulting in destruction. (20)

Iodophors have not been cleared by the Food and Drug Administration (FDA) as high-level disinfectants. Iodine solutions are commonly used as skin antiseptics as

they are bactericidal, mycobactericidal and virucidal. In order to be fungicidal and sporicidal, prolonged contact times are required. (20)

Quaternary ammonium compounds are capable of destroying bacteria, fungi and viruses, including the lipophillic, or nonenveloped, viruses. As such, they are widely used disinfectants. However, reports of HAIs from contaminated used quaternary ammonium compounds are of concern. (20)
Phenol derivatives can be used to disinfect environmental surfaces and noncritical items. They are not cleared by the FDA as high-level disinfectants and should not be used for semicritical items. They can, however, be used in the cleaning process prior to high-level disinfection or sterilisation. These disinfectants are bactericidal, virucidal, fungicidal and tuberculocidal. (20)

Cidex®

Cidex® is a high-level disinfectant used for medical and surgical instruments. It is fast acting and effective and is available in three formulations: Cidex®14-Day, Cidex®Plus 28-Day, Cidex®OPA (39).

Cidex®14-Day is a 2.4% alkaline glutaraldehyde solution. At 25 °C, it reportedly kills 99.8% of *Mycobacterium tuberculosis* if the instrument is immersed for 45 minutes (39). Glutaraldehyde, a high-level disinfectant, is normally available in an acidic solution. This solution requires activation by the addition of alkalinating agents in order to render it sporicidal (20). This particular formulation can be reused for 14 days (39).

Cidex®Plus 28-Day contains a higher concentration of glutaraldehyde. It is a 3.4% alkaline solution that is used to achieve high-level disinfection. It destroys microorganisms within 20 minutes at 25 °C. This formulation can be reused for 28 days. (39)

Glutaraldehyde is a saturated dialdehyde used as a high-level disinfectant and chemical sterilant. Glutaraldehyde is normally available in an acidic aqueous solution that is not sporicidal. In order to achieve sporicidal activity, a pH of 7.5-8.5 must be obtained by using an alkalinating agent. Glutaraldehyde possesses the

advantage of being noncorrosive and can therefore be used to decontaminate endoscopic equipment, rubber or plastic equipment, spirometry tubing, transducers, thermometers and anaesthesia and respiratory equipment. A buffered solution of at least 2% glutaraldehyde is effective in destroying vegetative bacteria in less than two minutes. An immersion time of 10 minutes will destroy *Mycobacterium tuberculosis*, fungi and viruses. However, much longer immersion times of three hours are required to destroy *Bacillus* and *Clostridium* spores. (20) Extensive resistance to glutaraldehyde by some microorganisms has been reported:

- Some mycobacteria e.g. *Mycobacterium avium* complex, can result in extensive morbidity in immunocompromised patients and is often resistant to standard tuberculosis treatment (40).
- *Methylobacterium mesophilicum* is an opportunistic infection in immunocompromised patients. It is a gram-negative rod forming pink colonies and is found in environmental surroundings (41).
- *Trichosporon* spp, classified as yeasts, are also associated with disseminated infection in immunocompromised patients and a high mortality rate (40, 42).
- *Cryptosporidium* spp, which are found in the gastrointestinal and respiratory epithelium, can cause malabsorption states and chronic diarrhoea in immunocompromised patients (40, 43).

It is of vital importance that instruments be thoroughly cleaned prior to placement in glutaraldehyde, as any organic matter still present will bind to the surface of the instrument (2, 20). Prolonged exposure can cause unwanted side effects in healthcare workers, such as skin and mucous membrane irritation, asthma, rhinitis and epistaxis. (20)

Cidex®OPA, unlike the other two Cidex® formulations, uses an *ortho*-phthalaldehyde solution. No mixing or activation is required prior to use. This formulation can be used on a wide range of medical devices. In 12 minutes at 20 °C, it is effective against *Mycobacterium tuberculosis* (20). The FDA has cleared Cidex®OPA as a high-level disinfectant with immersion times as short as 12 minutes at 20 °C and five minutes at 25 °C. The advantage of the short soak time enabled its use in an combined study between an emergency department and

emergency medical services (44). The short soak time makes it ideal for time-restricted situations.

Ortho-phthalaldehyde (OPA), a high-level disinfectant, is a clear pale blue solution. It is comprised of 0.55% 1,2-benzenedicarboxaldehyde and has excellent antimicrobial activity. It is effective against spores and a wide range of bacteria. Its effectiveness against mycobacteria is far superior to glutaraldehyde and it is also effective against glutaraldehyde-resistant mycobacteria. One of the advantages of OPA is a safer profile when compared to glutaraldehyde; it lacks the irritation to the nasal passages and eyes. A disadvantage is that proteins stain gray which is problematic if it is handled with unprotected skin. (20)

Johnson and Johnson, manufacturer of Cidex®, reports effectiveness against the following microorganisms: *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Mycobacterium bovis*, *Salmonella* serotype *Choleraesuis*, Poliovirus type 1, Adenovirus type 2, Cytomegalovirus, Influenza virus and HIV-1, among others. (39)

2.3.1.3 Sterilisation

Sterilisation is an absolute condition – a yes or no state (20, 29). This is the most effective method for the reduction of bacterial growth (38). Sterilisation destroys all microorganisms on the surface of an item, however, the effectiveness against prions is poor (8, 14, 20). Sterilisation is reserved for critical items. Various techniques are available: steam sterilisation, flash, ethyl oxide gas, hydrogen peroxide gas, paracetic acid, etc. Manufacturer recommendations should be read prior to sterilisation as some items are not heat resistant and therefore will not tolerate heat sterilisation, such as steam. (20)

Protocols employed at institutions should be based on the guidelines from the CDC but should also incorporate the manufacturers' instructions depending on the equipment used as these can vary significantly.

2.3.2 Factors influencing disinfection and sterilisation

The decontamination technique selected is dependent on a multitude of other factors in addition to the classifications mentioned above.

The nature of contamination refers to the quantity of organic and inorganic soiling and the type and level of microbial contamination present on the instruments, which will determine the decontamination technique chosen and the time required to ensure adequate decontamination. The greater the contamination, the more extensive the cleaning required and the longer the time required to destroy the microorganisms by chemical disinfection. (20, 29)

Thoroughly cleaning the instruments prior to disinfection and sterilisation is important as it removes organic matter present which can interfere with the next process. The presence of organic and inorganic matter can inactivate some of the chemical disinfectants, rending the process ineffective. (20, 29)

The processing time and concentration of disinfectant influences the level of disinfection obtained. Higher concentrations of disinfectant can achieve a higher level of disinfection and may even shorten the exposure time necessary to be equally efficacious. (20, 29)

Resilience of the object to heat, pressure, moisture and chemicals will determine the technique chosen; disinfection or sterilisation and the chemicals utilised. High temperatures, moisture and certain chemicals can damage some items. The manufacturer’s recommendations should always be checked prior to exposing items to decontamination procedures. (20, 29)

The shape, size and texture of instruments can affect the efficacy of the decontamination technique employed. Objects placed in a chemical disinfectant require surfaces to be in direct contact with the chemical agent in order to be disinfected. Crevices and channels may not obtain adequate disinfectant contact resulting in inadequate disinfection. (20, 29)

Microorganism resistance to disinfectants is one of the most important factors influencing the chemical disinfectant chosen. In a similar manner that bacteria develop resistance to antibiotics, they may show a level of resistance to disinfectants. This is due mainly to an intrinsic mechanism rather than developing the resistance; spores have an outer coat and cortex barrier that protects them against the disinfectant and the waxy cell wall of mycobateria acts as a defence mechanism. The highest level of resistance to chemical disinfectants is exhibited by prions, followed by bacterial spores, coccidia, mycobacteria and the non-lipid viruses. Vegetative bacteria are among the most susceptible. (20, 29) Temperature, pH and water hardness need to be taken into consideration. As temperature increases, most disinfectants will have an increased activity. However, if the temperature increase is too large, the disinfectant can degrade and as a consequence weaken its activity and become a health hazard to healthcare workers handling the chemical. Glutaraldehyde exhibits an improvement in its antimicrobial activity if there is an increase in pH. Insoluble precipitates develop when hard water interacts with the disinfectant, thus decreasing the rate of elimination of microorganisms. (20, 29)

Not all healthcare facilities will have the same processing equipment available, therefore, the processing equipment available to the facility will determine the technique used. The manufacturer's recommendations should always be checked prior to subjecting an item to a decontamination technique to avoid damaging the item. Some of the chemical disinfectants pose a health risk to the healthcare workers handling the chemicals. They can be toxic and some have been linked to terminal diseases e.g. formaldehyde has been linked to lung cancer. (20, 29, 30)

2.4 Decontamination techniques utilised in practice for laryngoscope blades

Studies done in several countries have shown a wide variation in the techniques employed for the decontamination of laryngoscopes (1, 2, 45, 46). Bucx et al (45) used a structured telephonic questionnaire in the Netherlands and found substantial differences between the decontamination methods utilised in Dutch hospitals. In addition, these methods were different to the standards of the CDC

and APIC – only 19.4% of the hospitals met the CDC and APIC standards in full. After performing this survey, the decontamination procedure was changed at the hospital conducting the survey; mechanical cleaning and steam sterilisation were chosen as the protocol. (45)

Esler et al (46) carried out a postal questionnaire in the United Kingdom surveying the cleaning methods used for laryngoscope blades. A wide range of techniques were found and the majority of units questioned, 60%, had no guidelines for laryngoscope decontamination between patients. The interesting finding from this survey was that approximately 30% of responders were not prepared to place a randomly chosen laryngoscope blade into their own mouth. A survey conducted in India by Telang et al (2) asked the same question regarding placement of the blade into one's own mouth and received a uniformly negative response from the anaesthesiologists (2). No surveys could be found that were conducted in South Africa and no formal guidelines could be sourced.

2.5 Healthcare-associated infections

The incidence of HAIs is escalating globally, and South Africa is no exception (17, 47). It is, however, difficult to ascertain a direct link between contaminated anaesthesia equipment and HAIs (11, 48). These infections can have a significant impact on the health system and economy and therefore prevention should be the main objective. Some of these microorganisms may cause a high incidence of morbidity and mortality (9). Patients who are particularly vulnerable to HAIs are those with immunosuppressive diseases e.g. cancer and HIV, and those receiving immunosuppressive therapy (48). Other risk factors include the elderly, diabetics, obesity and poor nutritional status (48). A multitude of studies have shown that some decontamination techniques, employed for anaesthetic airway equipment, are ineffective and that the potential for cross infection exists. This raises a public health concern (5, 12, 13, 45, 46, 49-51).

HAIs are spread in three different ways. Contact spread entails the direct physical transfer of various microorganisms between patients via the healthcare worker, usually with skin-to-skin contact or through inert objects. This transmission of

microorganisms can be reduced by hand washing and adequately cleaning items used on multiple patients. Laryngoscope blades and handles are implicated in contact spread. Respiratory droplets can spread pathogens through coughing, sneezing and talking which is termed droplet spread. Airborne spread is similar to droplet spread, except that the droplets are smaller and can remain suspended in the air for longer periods of time. (47)

Cleaning of the blade may be difficult due to the shape and grooves, where matter can become embedded in small cracks and behind the bulb (26).

Foweraker (50) and Neal (52) described the neonatal laryngoscope as a potential source of cross infection after *Pseudomonas aeruginosa* was cultured from a laryngoscope blade after an outbreak of *P. aeruginosa* in the neonatal intensive care unit. Although transmission from the blade could not be proven, it places a high index of suspicion on the source of the infection. (50, 52)

Although no evidence has shown a direct link between poorly decontaminated blades and an infection, the most likely infections that could occur from the use of a contaminated blade are upper respiratory tract infections and pneumonia. Nosocomial, or hospital-acquired, pneumonia is defined as a pneumonia that occurs more than 48 hours after a patient has been admitted to the hospital and provided that the pneumonia was neither present nor incubating at the time of hospital admission (47). Bacteria implicated in nosocomial pneumonia have been cultured on laryngoscope blades and handles in several studies. These pathogens include:

- *Streptococcus pneumoniae*
- methicillin-resistant *Staphylococcus aureus*
- *Escherichia coli*
- *Klebsiella* spp
- *Pseudomonas* spp
- *Acinetobacter* spp. (2, 4, 12, 47)

Another important factor to consider is that the laryngoscope blade is not the only source of contamination in the anaesthesia workplace. Laryngoscope handles can become contaminated, indirectly, when the tip of the blade touches the handle when the laryngoscope is folded closed and when the anaesthetist touches the handle with contaminated gloves (1, 9, 53). Studies by Ballin (13), Call (49) and Simmons (4) all show high levels of bacterial contamination on the laryngoscope handles; this despite disinfection in some cases. Blood, visible and occult, has also been reported (11, 54). Laryngoscope handles, although attached to the blade, are not routinely disinfected between patients and as such pose a risk for transmission of microorganisms (3).

Consensus is lacking regarding the classification of the laryngoscope handle as semicritical or noncritical items. Although, as per the definition of the Spaulding classification, the laryngoscope handle corresponds to the noncritical category and the CDC states in their guidelines that noncritical items “do not necessitate disinfection between uses on different patients unless grossly soiled” (20, 29), growth of microorganisms and the presence of occult blood have been extensively reported on laryngoscope handles (3, 4, 11, 49, 54). One study demonstrated that the maximum growth on the handle was at the contact point, where the tip of the blade makes contact with the handle when in the closed “off” position (3). This contact point is situated in the middle of the handle; the portion that the anaesthetic healthcare worker makes maximum contact with during intubation. Williams et al (3) found that the most abundant organism cultured was coagulase-negative staphylococcus, most likely contamination from the hands of staff utilising and cleaning the equipment (3). This finding further emphasises the need for adequate universal precautions and correct handling and storage of equipment. An appropriate cleaning technique for the handle would be employing a germicidal solution to clean the entire handle with, after removing visible organic matter (49).

The level of contamination on anaesthesia equipment cannot be accurately assessed by visual inspection (9, 11, 54); instruments that appear clean may not be ready for use. Another important item responsible for contamination is the tabletop and the rotameter dials of the anaesthetic machine (55). It is important to note that airway equipment is placed on this tabletop and the same monitoring

equipment is used throughout the day on different patients which can result in the transmission of microorganisms between patients and equipment. Pathogenic microorganisms cultured from the tabletop included *Acinetobacter*, *Staphylococcus aureus* and other gram-negative rods, which can cause respiratory infections (55). Perry et al (54) detected occult blood in 32.7% of the samples obtained from the ventilator control dials and the vaporiser dials on the anaesthetic machine, electrocardiograph (ECG) cables, pulse oximeter probes and noninvasive blood pressure cuffs (54). Similar findings were reported by Hall in 1994 (51). Perry et al (54) suggest using disposable monitoring equipment or the equipment should undergo high-level disinfection prior to reuse (54). Disposable equipment is not a feasible option in resource limited settings. Asepsis in operating theatres is considered of paramount importance in the prevention of cross infection (2). Surgical staff are expected to adhere to a five-minute hand-washing technique followed by donning sterile surgical gowns and gloves, the patient is covered with sterile drapes and autoclaved surgical instruments are used. Less emphasis is placed on the sterility required for some invasive procedures performed by the anaesthetists e.g. laryngoscopy (2). A few infection control techniques for anaesthesia personnel are described later.

2.6 Microorganisms identified from anaesthetic equipment

Several studies conducted worldwide have repeatedly concluded that laryngoscope blades are contaminated with a wide range of microorganisms, of which numerous are pathogenic microbes, that could result in transmission of infection (2, 12, 13). Pathogens cultured include *Streptococcus* spp, *Staphylococcus* spp and MRSA, *Serratia marcescens* and *Pseudomonas aeruginosa* (1, 4, 10-13, 46, 56, 57).

2.6.1 Bacteria

The variety of bacteria cultured on anaesthesia equipment is summarised in Table 2.1.

Of the pathogenic organisms mentioned in Table 2.1, some are implicated in the development of nosocomial pneumonia.

These pathogens include:

- *Klebsiella* spp
- methicillin-resistant *Staphylococcus aureus*
- *Escherichia coli*
- *Pseudomonas aeruginosa*
- *Acinetobacter* spp
- *Streptococcus pneumoniae.*

Table 2.1 Microbial growth on anaesthetic equipment

Sample size	Microorganisms		Author, Year (Reference)
	Commensals	Pathogens	
Laryngoscope blades			
50	*Bacillus* spp Coagulase-negative staphylococci	*Klebsiella* spp *E. Coli* *Pseudomonas* spp Group A Streptococci *Streptococcus pneumoniae*	Telang et al, 2010 (2)
162	Positive culture with condom 13.3%	Positive culture without condom 88.6%	Chen et al, 2006 (26)
112	Diphtheroids Viridans streptococci *Micrococcus* spp Coagulase-negative staphylococci *Candida albicans* *Bacillus* spp	*Arcanobacterium haemolyticum* *Enterobacter* spp *Acinetobacter baumannii*	Venter , 2012
30	Viridans streptococci *Staphylococcus epidermidis* *Streptococcus pyogenes* (can be pathogenic)	*Streptococcus faecalis* (now *Enterococcus faecalis)* *Neisseria catarrhalis*	Carstens, 1974 (15)
20	Viridans streptococci *Bacillus* spp	Methicillin-resistant *Staphylococcus aureus* (MRSA)	Beamer, 1999 (12)
Laryngoscope blades and handles			
100	Coagulase-negative staphylococci	α-haemolytic streptococci	Ballin et al, 1999 (13)
Laryngoscope handles			
64 handles 192 specimens	*Bacillus* spp Coagulase-negative staphylococci Viridans streptococci (can be pathogenic)	Enterococci Methicillin-susceptible *Stapylococcus aureus* (MSSA) *Klebsiella* spp *Acinetobacter* spp	Williams et al, 2010 (3)
60	Coagulase-negative staphylococci *Bacillus* spp	*Enterococcus* spp *Staphylococcus aureus* Corynebacteria α-haemolytic streptococci	Call et al, 2009 (49)
20	*Staphylococcus epidermidis*	*Staphylococcus aureus* *Citrobacter* spp *Pseudomonas aeruginosa* Enterococci	Simmons, 2000 (4)
120 (ICU setting)	Coagulase-negative staphylococci *Bacillus* spp *Micrococcus* spp	Corynebacteria *Staphylococcus aureus*	Qureshi et al, 2008 (58)
Anaesthesia machine tabletop			
	Coagulase-negative staphylococci *Bacillus* spp	*Acinetobacter* spp *Staphylococcus aureus* Gram-negative rods α-haemolytic streptococci	Maslyk, 2002 (55)

Klebsiella spp

Klebsiella species, a group of gram-negative rods, are known to cause a variety of HAIs, such as pneumonia, surgical site infections, bacteraemia and meningitis. A resulting bronchopneumonia can cause chronic destructive lesions and abscesses in the lungs. These organisms are notorious for their extensive resistance to antibiotics and their ability to readily acquire resistance to other antibiotics. *Klebsiella pneumoniae* produces the enzyme carbapenemase which renders the carbapenems ineffective. This is a major concern as the carbapenems are usually reserved for use against the gram-negative bacteria resistant to conventional antibiotics. (59, 60)

Methicillin-resistant *Staphylococcus aureus* (MRSA)

Beamer et al (12) sampled 20 laryngoscope blades at the end of a routine theatre day with one blade showing a positive culture of MRSA (12). This study revealed yet another potential vector for the transmission of MRSA, a particularly virulent microorganism endemic in hospitals worldwide causing bacteraemia, respiratory tract, bone and joint infections. MRSA also possesses resistance to multiple antibiotics. (40, 60)

Escherichia coli (E. coli)

E. coli is part of the commensal flora in the gastrointestinal tract; they are found wherever faecal contamination has occurred. It is the most common cause of uncomplicated, acute urinary tract infections but is also implicated in hospital-associated urinary tract infections. Quaternary ammonium compounds, phenolics and hypochlorites can eliminate *E.coli* within 30 seconds. (60)

Pseudomonas aeruginosa

These gram-negative bacteria can cause severe HAIs and may be resistant to several antibiotics. They pose an even greater threat as they are adaptable and are able to remain viable after disinfection (20, 60). Infections acquired by in-hospital patients are usually localised but may become generalised in the immunocompromised population e.g. HIV, leukaemia and patients treated with immunosuppressive drugs and corticosteroids. Septicaemia and necrotising pneumonia have a high mortality rate in immunocompromised patients. (40, 60)

***Acinetobacter* spp**

Acinetobacter spp may be commensal flora of moist areas of human skin. A wide spectrum of infections is associated with *Acinetobacter baumannii*, including pneumonia, septicaemia, meningitis and wound infections. These organisms survive well in hospital environments and patients at high risk are those in the intensive care units. They display resistance to many antimicrobial agents. (60)

Streptococcus pneumoniae

Streptococcus pneumoniae, also referred to as pneumococcus, is part of the oropharyngeal flora. It can cause infections in the middle ear, paranasal sinuses and is the most common cause of pneumonia. Aspiration of the pneumococci from upper airway secretions into the lower respiratory tract results in pneumonia. (60)

2.6.2 Viruses

Of great concern regarding viruses is the survival of HBV and HIV on dry instruments and equipment. HBV can survive for a week on these surfaces (9). Both these infections contain an initial asymptomatic period during which the patient may be unaware of the presence of disease (54, 61). The CDC recommends high-level disinfection for semicritical devices contaminated by Hepatitis B and C and HIV (20). Johnson and Johnson claim that Cidex®, a high-level disinfectant, eliminates HIV-1 (39).

2.6.3 Protein deposits and prion diseases

This is perhaps the greatest concern regarding the transmission of infections through reuse of laryngoscope blades as the number of people incubating prion diseases is unknown and prions are resistant to sterilisation techniques (56). The most commonly known prion disease is vCJD which was first reported in 1996 in the United Kingdom (62). It belongs to a class of diseases known as transmissible spongiform encephalopathies (62). The interval between onset of symptoms and death is a mere 14 months (14, 63).

These misshapen prion proteins are resistant to the routine sterilisation techniques employed and therefore the risk of transmitting the disease to non-infected patients through the use of a reusable laryngoscope blade is an alarming reality

(64). Furthermore, the use of chemical disinfectants on inadequately cleaned instruments can result in the coagulation and fixation of the protein to the instrument (56).

Miller et al (56) found that 82% (50 of 61) of laryngoscope blades stained positive for protein deposits after being autoclaved (56). Lymphoid tissue contamination was found on 30% of the laryngoscope blades by Hirsch et al (14), eliciting the concern that contaminated reusable blades are a possible vector for the transmission of vCJD. Neither of these studies mentioned the possible transmission rate of vCJD from the use of reusable blades. The first report of iatrogenic transmission of CJD was in 1974 through a corneal transplant (65). In 2006, the WHO reported 363 deaths from iatrogenic CJD (66). Reported mechanisms of transmission include: blood transfusion, use of pituitary-derived hormones, human dura mater grafts, corneal transplants, neurosurgical instruments and depth electrodes (65-67). Zobeley et al (68) described the transmission of vCJD from a medical electrode used in the brain of an infected patient which was then inserted in the brain of another patient after routine sterilisation (68). To date, the route of infection has been parenteral with no infections from walls or countertops (65, 69).

Hirsch et al (14) recommend the use of disposable laryngoscope blades as this is the only completely safe technique to prevent the transmission of prion diseases (62). This recommendation is endorsed by the WHO (18).

2.6.4 Blood

A number of studies have confirmed the presence of occult blood on laryngoscope blades and handles that are considered “ready-to-use” (11, 13, 54, 57, 70). Up to 50% of handles and 20% of blades tested positive for occult blood (11, 57). However, no studies were found that correlated this presence with the risk of cross infection (9). Laryngoscope blades and handles can easily become contaminated with blood during laryngoscopy. Phillips et al (11) examined 65 laryngoscope blades and 65 handles and found that 20% of the blades and 40% of the handles were positive for occult blood (11). There was a larger number of blades that tested positive in the afternoon than in the morning, implying that the

contamination worsened through the day (11). Morrell et al (57) conducted a similar study at a university hospital and a community hospital and found that up to 50% of the handles and 10.5% of blades tested positive for occult blood (57). The recommendation from the authors was the use of more meticulous decontamination, the use of disposable handle and blade covers or the use of disposable equipment (57). Ballin et al (13) showed that both laryngoscope blades and handles were contaminated with blood and microbes (13). Occult blood was found on 38% of the handles with only 5% exhibiting no microbial growth (13). The blades were found to have less occult blood, only 2%, but 80% had microbial contamination (13).

The presence of blood on anaesthesia equipment would suggest that the equipment has not been thoroughly cleaned and adequately disinfected which poses a risk for transmission of microorganisms, particularly blood-borne pathogens. Perry et al (54) tested anaesthesia and monitoring equipment for the presence of occult blood. A total of 336 pieces were tested and 32.7% tested positive for occult blood. The most heavily contaminated surfaces were the ECG cables (52.9%) and the rotameter dials (41.2%) followed by the ventilator controls (23.5%) (54). The authors recommended using disposable monitoring equipment including the pulse oximeter probe, ECG cables and the blood pressure cuff. Due to the poor feasibility of this option, an alternative recommendation is high-level disinfection of such equipment before reuse (54).

2.7 Studies conducted in South Africa

Two studies conducted in South Africa were found determining the contamination of laryngoscope blades. Carstens (15) reported in 1974 that positive bacterial cultures were obtained from all the laryngoscope blades swabbed in the study (Table 2.1) conducted at Baragwanath Hospital, Johannesburg. The most commonly cultured organism was viridans streptococci (73%), a member of the oropharyngeal flora and important in preventing the colonisation of many pathogens (60). This was followed by *Neisseria catarrhalis* (50%), now classified as *Moraxella catarrhalis*. This study concluded that the decontamination technique employed during the study was ineffective and subsequently a new technique was

implemented with the intention of retesting the laryngoscope blades to assess its effectiveness. Unfortunately, this follow-up study could not be located.

Venter (16) conducted a similar study at HJH, Johannesburg in 2012. The findings showed a wide range of microorganisms (Table 2.1) from the 57.3% positive samples (16). Diphtheroids were the most common organism cultured followed by *Staphylococcus epidermidis*. Only a limited number of microorganisms were fully identified to species level due to financial constraints. Two areas on the blade were compared which were believed to have the most contact time with the patient's mucosal surfaces. Area 1 was the area on the left lateral aspect of the blade which is used to push the tongue out the way on entering the oral cavity and area 2 was the flange of the blade, the part that lies on the tongue during intubation, depicted in Figure 2.1. There was no statistically significant difference in growth between the two areas – area 1, 55.5% samples had positive growth and area 2, 60% were positive for growth (p = 0.563).

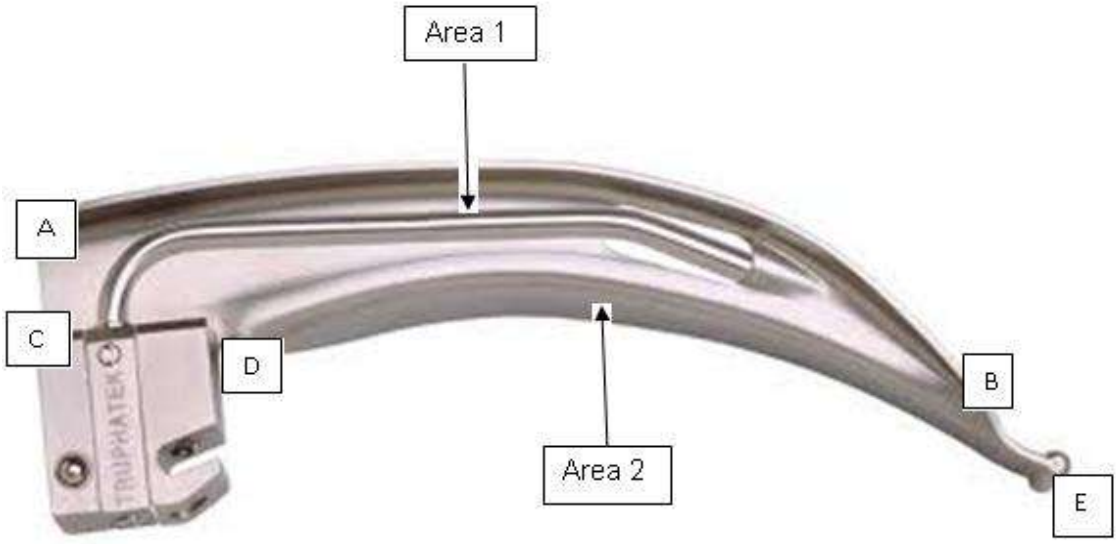

Figure 2.1: Area 1 and 2 for sample taking (22)

The growth on the blades before the first endotracheal intubation of the day was performed, was compared with that after the last intubation. A minimal difference was found, 60.7% of the samples were positive for growth before the first

intubation of the day with 53.7% having positive growth after the last intubation; the p-value of 0.457 showed no statistically significant difference. (16)

Two operating theatres were compared. These were the two emergency theatres at HJH, one theatre for orthopaedic emergencies and the other for general surgical cases. No statistical significant difference was found in the microbial growth on the blades between the two theatres. Theatre 6, the general surgical emergencies, had a positive growth rate of 60.7%; theatre 11, the theatre for orthopaedic emergencies, had 53.7% samples positive for growth (p = 0.457). (16)

Comparing the Venter (16) study to the international studies (2, 3, 26, 49, 55) conducted, several microorganisms have been consistently cultured: *Bacillus* spp, viridans streptococci, *Staphylococcus epidermidis*, diphtheroids and *Candida albicans* at various levels of contamination. Although commensal microorganisms were usually found to be in the high-level contamination group, this can still pose a threat of HAI, especially in the immunocompromised population (16).

At the time of the study, the practice of decontaminating laryngoscope blades at HJH was to place the used blade in a container of chlorhexidine in 70% alcohol. This informal protocol did not state the minimum immersion time. The blade was then removed from the container, scrubbed with Bioscrub™ under running tap water and then dried with non-sterile paper towel and thereafter placed on the anaesthetic work surface for reuse. (16)

The study conducted at HJH demonstrated that the decontamination technique utilised was not adequate in eliminating microorganisms from the blades. Venter (16) described alternative methods that could be employed to achieve high-level disinfection in compliance with international guidelines. A choice of two high-level disinfectants was recommended namely Cidex®OPA, available at HJH, and Cidex®Plus (16).

A recent observational study was conducted in KwaZulu Natal (KZN) in 2012 to determine equipment contamination at regional, tertiary and central hospitals. Equipment examined included laryngoscope blades and handles, Magill's forceps, nasopharyngeal temperature probes and suction bowls. These items were first

inspected for visible contamination and those without visible contamination were then tested for occult blood. Eighty percent of laryngoscope blades were contaminated. (71)

In this series of studies regarding infection control in anaesthesia in KZN by Samuel et al, the anaesthesia nurses responsible for decontaminating the equipment were interviewed regarding the hospital's infection control practices for these items. It was found that the current infection control practices for decontamination were poor. With regards to decontamination practices for laryngoscope blades, 67% of the hospitals did not meet the minimum recommended practice. (72)

2.8 Infection control

The presence of protein traces on sterilised reusable laryngoscope blades and the risk of transmission of other microbial pathogens necessitate an alternative to conventional reusable blades. Several options are available to decrease the risk of transmitting microorganisms between patients. Simple infection control techniques such as the double-glove technique described by Gadalla (73) and the two-table technique can be employed. Disposable sheaths are available that are placed over the blade and/or handle and the option of disposable, or single-use, laryngoscope blades are indicated in certain settings.

2.8.1 Infection control techniques

Gadalla (73) described the two-glove technique for intubation. The individual intubating the patient wears two pairs of gloves and after endotracheal intubation is complete, removes the outer glove and encompasses the blade in the gloves. This allows a clean pair of gloves to remain on and the individual can then continue with setting the ventilator, etc. This technique prevents contamination of other surfaces and the hands of those using and cleaning the blade, but will not prevent patient-to-patient transmission if the blade is not decontaminated adequately. (73)

Neustein et al (74) proposed a two-table technique for the anaesthesia workspace. The front table is located on the anaesthesia machine and is the "dirty" table

whereby only items for the current case are placed on a sterile drape which is discarded and replaced with a clean drape after every case. The back “clean” table is on the anaesthesia cart where medication utilised throughout the day can be placed, such as the emergency drugs. (74)

2.8.2 Sheaths and protective barriers

Disposable sheaths are available that can be placed over the blade and/or handle and are discarded after every use. However, the blade still requires high-level disinfection thereafter as contamination cannot be eliminated with absolute certainty; contamination can occur during application or removal of the sheath or by contaminated hands (37).

In 1995, Tobin et al (75) suggested a small plastic bag, available from GEM Medical Industries, as a simple, cost-effective method for preventing laryngoscope handle contamination. The bag is placed over the handle and secured and removed and discarded after each use. (75)

So (76) reports the advantages of using a condom over the blade of a laryngoscope:

- readily available and inexpensive
- adequate transparency therefore does not interfere with light intensity
- accommodates any size blade
- easy to apply and remove
- good barrier against bacteria and viruses. (76)

However, no evidence was provided for determining these advantages.

Chen et al (26) assessed the effectiveness of latex condoms, a cheaper alternative barrier, as covers for laryngoscope blades. Two groups were compared, with or without the condom. There was a significant difference ($p<0.001$) in positive bacterial culture between the two groups; 13.3% in the study (condom) group and 88.6% in the control (no condom) group. In addition to the reduction of positive bacterial cultures in the study group, no occult blood was detected on these blades. No intervention is without its limitations. If those

responsible for the intubation are not careful, the condom may be torn by the patient's teeth rendering the barrier less effective. Transmission of microorganisms can be significantly reduced by employing this simple and inexpensive method. (26)

2.8.3 Disposable airway equipment

The evidence of residual bacteria and protein on anaesthetic equipment, the concern of potential cross infection of harmful pathogens and the deterioration in the reliability of the light intensity of reusable blades after thermal sterilisation (1, 77, 78) has lead to the recommendation of using single-use laryngoscope blades. This recommendation is dependent on the premise that these disposable blades are as efficient as the standard reusable blades (79). However, anaesthetic healthcare workers have portrayed mixed reviews about the use of and ease of intubation with single-use blades (80, 81).

Amour et al (82) compared disposable plastic blades with reusable metal blades during rapid sequence induction of anaesthesia and found that orotracheal intubation was significantly less successful with the disposable plastic blades on first attempt (82). A failure rate of 17% in the disposable plastic blade group was considerably worse than the reusable blade group, 3%, ($p<0.01$). The second attempt at intubation in the disposable blade group was performed using a reusable metal blade and all these intubations were successful with an improvement in the laryngeal view using the Cormack and Lehane classification. Furthermore, the increased failure rate with the disposable plastic blades was associated with an increase in complications: surface wounds in the oropharynx and oxygen desaturation. This significantly worse performance of single-use blades was confirmed by Twigg et al (83) in simulated cases. In addition, poorer visualisation of vocal cords and increased times to intubation were found (83, 84).

The study conducted by Galinski et al (79) employed adult patients presenting for elective surgery and excluding patients at risk of aspiration (79). This study compared reusable metal blades and two different manufacturers of disposable plastic blades, raising the question of whether a difference in performance exists between different types of disposable plastic blades. The findings confirmed a

worse performance for only one manufacturer of disposable plastic blades against the reusable metal blade (79).

Jabre et al (80) compared single-use plastic blades with reusable metal blades in the out-of-hospital setting where intubation circumstances can be appreciably more difficult (80). A success rate of 84% at the first intubation attempt was achieved with the metal reusable blade which was higher than with the single-use plastic blades; achieving a success rate of 76% ($p<0.002$) (80). Other factors assessed between the two types of blades were good laryngeal view, the reusable metal blades being superior with good visualisation achieved in 83% versus the 67% achieved with the single-use blades; and the need to use alternative airway techniques to ensure tracheal intubation, again, the reusable blades performing better with only 4% of intubations requiring other assistive airway devices compared to the 12% of the single-use group (80). The chief complaint reported regarding the single-use plastic blades was that the rigidity was less than that of the metal blades and requiring more force to assist with visualisation of the glottis (80, 85).

The poorer performance of disposable plastic blades has not been obtained in all studies. Asai et al (86) reported that there was no significant difference in visualisation of the glottis (86). Furthermore, not all the studies adhered to the same intubation assessment criteria, thereby making accurate comparison difficult (79).

The AAGBI updated their guidelines on Infection Control in Anaesthesia in 2008, clearly stating that preventative measures against the transmission of infections should be part of routine practice in anaesthesia. The guidelines recommend utilising single-use equipment wherever possible; this also eliminates the difficulties and discrepancies of decontamination techniques employed. (8)

2.9 Conclusion

Despite the potential risk of transmitting harmful pathogens to other patients and healthcare workers with inadequately decontaminated reusable laryngoscope blades, they still remain the customary apparatus for tracheal intubation (80). Disposable blades definitely have a place in some settings, such as patients with

prion disease, but these blades need to be thoroughly assessed prior to commencing their usage in the clinical setting (83). To prevent the transmission of cross infection via airway equipment, decontamination guidelines should be followed appropriately. Evidence suggests that high-level disinfection should be employed for decontaminating blades; this is accordance with the minimum recommendation of CDC guidelines. The research methodology utilised in this study is discussed in the next chapter.

Chapter 3: Research methodology

3.1 Introduction

This chapter will contain the problem statement, aim and objectives, ethical considerations, research methodology, validity and reliability and a summary.

3.2 Problem statement

It was important to assess the effectiveness of this newly implemented decontamination protocol to identify any potential risks to patient safety and identify any flaws. Assessing the effectiveness of the decontamination protocol utilised is important as WHO has acknowledged patient safety as an important goal (17, 18). Adequate decontamination of hospital equipment is paramount to patient safety.

Evident from the literature was that laryngoscope blades are a potential source of cross infection and that decontamination techniques differ immensely in different institutions. The recently conducted study at HJH showed that the decontamination technique employed was ineffective (16). These findings prompted the need to implement a new decontamination protocol and then assess its effectiveness.

3.3 Aim

The aim of this study was to describe the effectiveness of a newly implemented decontamination protocol for reusable laryngoscope blades at HJH.

3.4 Objectives

The objectives of this study were to:

- describe the identity and quantity of microorganisms isolated from five blades (control samples) immediately after high-level disinfection with a newly implemented decontamination protocol;
- describe the identity and quantity of the microorganisms isolated from blades on the anaesthesia tabletop after implementation of a new decontamination protocol;

- evaluate the effectiveness of the newly implemented decontamination protocol by comparing microbial growth on blades to those from a historical control group from HJH.

3.5 Ethical considerations

An ethical waiver was obtained from the Human Research Ethics Committee of the University of the Witwatersrand (Appendix B) as this study was a microbiological study and no humans or animals were involved. However, the identity of the anaesthesiology staff involved in the decontamination process of the laryngoscope blades will remain anonymous.

Permission to conduct the study was obtained from the Post Graduate Committee of the University of the Witwatersrand (Appendix C) and the HJH Senior Clinical Executive prior to commencement of the study (Appendix D).

The collected data will be stored for six years after completion of the study. This study was conducted in accordance with the Declaration of Helsinki (24) and Good Clinical Research Practice and Good Laboratory Practice (25).

3.6 Research methodology

3.6.1 Study design

A prospective, contextual, comparative, descriptive study design was used.

A prospective study is an analytic study that establishes the relationship between a certain factor and its effect or outcome (87). The cohort, or group, of individuals or specimens is selected and the researcher follows the sample over a period of time (88). The outcome, such as the development of disease, is then related to the factors (87-90). This study was prospective as the samples were collected over a period of time until the sample size was realised.

Contextual studies are described as “micro” research or a “small-scale world”, which includes clinics, hospital wards or critical care units (91). This study was conducted contextually in the emergency theatres at HJH.

The comparative descriptive design compares and describes differences in two or more groups with one or more variables occurring naturally in the setting (90). The description is usually specific to the sample and may not be applicable to a larger population (90). The results of this study were compared to the historical control group.

3.6.2 Study population

The study population consisted of the blades utilised in the theatres of HJH.

3.6.3 Study sample

Sample size

In consultation with a biostatistician, it was anticipated that approximately 25% of the blades would be contaminated. A sample of 73 blades estimated the contaminated proportion to an accuracy of within 10% with 95% confidence.

Sample method

A convenience sampling method was followed in this study.

Alternative terms for convenience sampling include accidental or availability sampling. The subjects or objects for the study are easily accessible (89). The subject selection is in the right place at the right time (90). The risk with convenience sampling is that the sample may not be adequately representative of the whole population (89, 90, 92). The samples were collected on days convenient to the researcher.

Eligibility criteria

"Ready-to-use" size 4 blades from theatres 6 and 11 were included in this study.
Exclusion criteria:

- any infringement of the aseptic technique during sample collection
- any infringement of the accepted transport technique.

3.6.4 Data collection

Venter (16) showed that the decontamination technique utilised at HJH resulted in a 57.3% contamination rate in "ready-to-use" blades. Subsequently, beginning in

March 2013, a new decontamination protocol (Appendix A) was instituted. Data was collected over a two-month period from mid- August to mid-October 2014 to evaluate this new technique.

Five control samples were collected by the researcher. This involved the researcher taking the blade and following the decontamination process precisely and using an aseptic technique. This was done to attempt to evaluate the possible point of contamination once a blade was decontaminated.

3.6.4.1 Current decontamination technique for blades at HJH

A new decontamination protocol for laryngoscope blades was implemented at HJH. At the beginning of every case, a clean paper towel and clean “ready-to-use” airway equipment including laryngoscope blades and handle, artery forceps, Magill forceps, face masks and a syringe was placed on the anaesthesia machine tabletop. After successful intubation, the anaesthesia machine tabletop is kept as clean as possible by not placing any dirty/used items on it. The blade is placed in the packet of the endotracheal tube and the handle is given to the anaesthetic sister to clean with an alcohol-soaked swab. At the time of developing this protocol, SASA had not yet published their guidelines.

The decontamination process involves four steps: cleaning, disinfecting, rinsing and drying. The blade is placed in a container of enzymatic detergent solution and then rinsed thoroughly with water, ensuring all macroscopic soiling has been removed. Excess moisture is removed and the blade is then placed in a container with Cidex®OPA, a high-level disinfectant. The lid of the container needs to be securely fitted and the entire blade covered by the solution. The blade is immersed for five minutes, removed and thoroughly rinsed with water. A total of three rinses lasting one minute each are required to prevent toxicity. The blade is then dried with paper towel and placed on the anaesthesia tabletop for use.

3.6.4.2 Data collection process

As per the study conducted by Venter (16) at HJH, samples were collected in the same predetermined standardised manner. The size 4 blades in the two emergency theatres, theatre 6 and 11, at HJH were swabbed. There were days when theatre 10 was used for orthopaedic emergencies instead of theatre 11. This

was due to technical reasons, for example, dim operating lights and anaesthesia machine failure.

Area 2 (Figure 3.1) was the area swabbed on each blade. This area was chosen as the results from the study conducted by Venter (16), although not statistically significant, showed more bacterial growth in this area than in area 1, 55.5% versus 60% 9 ($p = 0.563$) (16). It was not specified whether the microorganisms cultured on the two separate areas differed. Area 1 was the area on the left lateral aspect of the blade which is used to push the tongue out the way on entering the oral cavity and area 2 was the flange of the blade, the part that lies on the tongue during intubation, as depicted in Figure 3.1. Each blade was entered as a separate sample, therefore, two samples were collected daily and labelled so as to identify it; with occasional days of two separate collections several hours apart.

On some days, two separate collections were performed, several hours apart. This was as a result of time constraints and the office hours held by the laboratory. No after hour samples were collected as the Infection Control Services Laboratory closed at 16:00 on weekdays and was not available over weekends. In order to ensure variety of the times that the samples were collected during the day, some samples were collected early in the morning around 6:30 and a second collection may have been done at around 14:30.

Sample taking

Samples were collected by a single researcher. If this researcher was unable to collect the sample, a second trained researcher was available to collect and transport the specimens. The second researcher was not utilised.

An aseptic technique was employed to swab the blades. This technique included wearing a surgical face mask, hand washing prior to taking the sample, donning sterile gloves and using a sterile swab to swab the blade.

The same sampling technique was utilised as in the study conducted by Venter (16). A sterile swab was used to swab along the area of the blade described above. The swab was moistened by dipping the tip into 10 ml of sterile $^1/_4$ Ringers Lactate solution, the transport medium. The wet swab was then coursed along the blade utilising a continuous rolling technique. The wet swab was rolled along area

2 from point D to point E which included the tip of the blade (Figure 3.1). A sterile blade was used to cut the tip of the swab off and thereafter placed in the remaining Ringers Lactate solution transport medium. The sample bottle was sealed and labelled. (16)

Five control samples were performed by the researcher. This entailed decontaminating the laryngoscope blade as per the protocol utilised at HJH (Appendix A). After cleaning the blade with enzymatic detergent, rinsing and drying with a sterile drape, it was placed in the Cidex®OPA solution for the appropriate immersion time (this was timed) and then removed by the researcher with sterile gloves, thoroughly rinsed and dried with a sterile drape and then swabbed. The researcher donned a double pair of gloves and removed the outer gloves after drying with a sterile towel and before swabbing to ensure sterility.

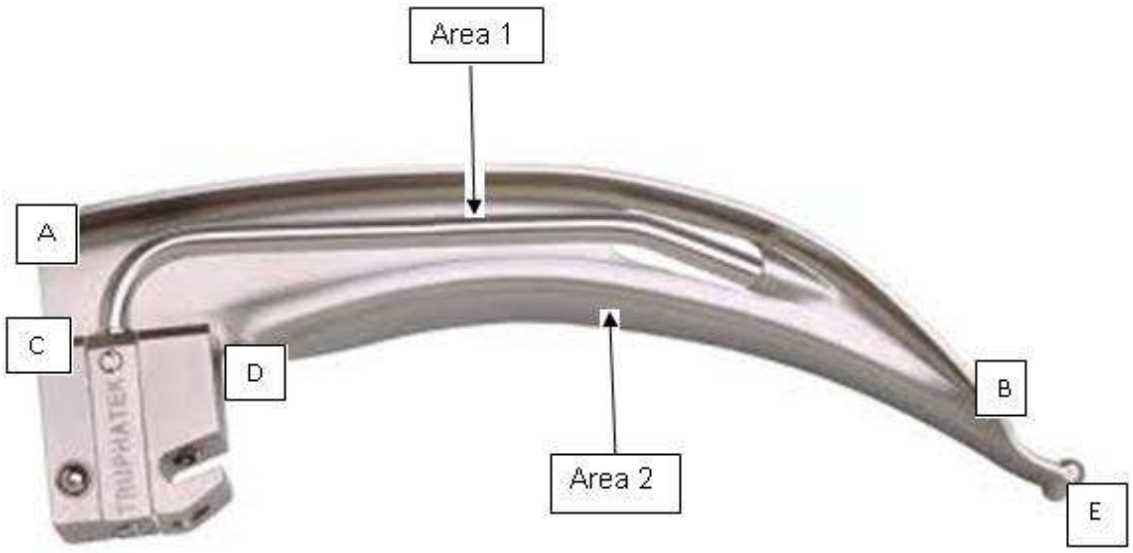

Figure 3.1: Area 1 and 2 for sample taking (22)

Sample Labelling

A standard NHLS request form was used to enter each sample's differentiating information. The following information was entered:

Patient surname: Research

Patient first name: Dr M Fourtounas

Patient hospital number: This was a unique study number for each sample collected e.g. 01/1-TH6-Tc

The first number, 01/1, referred to the date and the month that the sample was taken.

TH6 indicated the theatre number that the sample was collected from. Two theatres were utilised, theatre 6 and 11.

Tc indicated the time of day the sample was collected.

The following standard data was entered on the NHLS form:

- Hospital/Clinic: HJH
- Ward: Theatre
- Diagnosis/Reason for request: Research
- Date taken: dd/mm/yyyy
- Time: hh:mm
- Taken by: Dr M Fourtounas.

A count and culture investigation was requested on the NHLS form. Each NHLS form has a unique barcode. This barcode was correlated with the unique study number on the data collection sheet (Appendix E), enabling easy recovery of results and matching of specimens and results.

Sample storage and transport

Samples were collected at HJH mostly once during the course of the day and required delivery to the Infection Control Services Laboratory at the Department of Clinical Microbiology and Infectious Diseases of the Witwatersrand School of Pathology, University of the Wits Medical Campus. In the interim, samples collected were stored in the fridge at 4 °C and were transported to the laboratory at Wits Medical Campus at the earliest possible time thereafter. These samples were transported in a cooler box maintained at 4 °C using ice packs and were delivered by the researcher to the final destination.

Sample processing

The samples were delivered to the laboratory by the researcher. The culture and isolation of bacteria was performed by trained laboratory personnel using standard microbiological techniques. The sample was incubated for 48 hours aerobically and the colonies examined, tallied and detailed.

Data capturing

Data was captured on a data collection sheet (Appendix E). The following information was recorded:

- Sample information
    - study sample number
    - date collected
    - time collected
    - theatre (6 or 11)
    - NHLS barcode
- Microbiological information
    - bacterial contamination
    - organisms isolated
    - level of contamination/number of CFUs.

3.6.5 Data analysis

A Microsoft Excel 2007 spreadsheet was used to capture the data. This data was then analysed with descriptive statistics and a statistics programme, GraphPad InStat was used for statistical analysis. A Fisher's exact test was used to determine a two-tailed p-value. P-values <0.05 are considered statistically significant.

Where the contingency table was bigger than a standard 2 x 2 table, a Fisher's exact test with a 2 x 3 contingency table was used with the application of the Freeman-Hamilton extension of the Fisher's exact test. The proportion of contaminated samples was determined and expressed as a percentage along with its 95% confidence interval.

3.7 Validity and reliability of study

The word "valid" is derived from the Latin word *validus* meaning strong. Validity ascertains whether an instrument or study accurately measures what it is suppose to measure (89, 93). Validity measures the accuracy of a statement. Reliability is the consistency of the measures obtained and if the results can be used

repeatedly over time (90, 94). It indicates the extent of random error in the measurement method (90).

The validity and reliability of this study was maintained by:

- The sample size was determined in consultation with a biostatistician.
- All sample collections, labelling, storage and transportation was performed by a single researcher using a standardised method and sample collection was done using an aseptic technique. If the researcher was unable to obtain and transport the specimens, a trained assistant facilitated with sample collection and transportation. A second researcher was not utilised.
- A single service provider analysed the specimens: the Infection Control Services Laboratory, Department of Clinical Microbiology and Infectious Diseases, Witwatersrand School of Pathology, University of the Witwatersrand. Qualified laboratory personnel employed at the laboratory processed the samples using standard protocols and laboratory equipment.
- Good laboratory practice was adhered to when processing samples.
- An appropriate study design was used.
- Data analysis was done with the assistance of a biostatistician.

3.8 Summary

This chapter included the problem statement, aim and objectives, ethical considerations, research methodology, validity and reliability and a summary. The results of the study will be presented and discussed in the next chapter.

Chapter 4: Results and discussion

4.1 Introduction

This chapter contains the results of the study and the discussion thereof. The results are presented according to the research objectives. The objectives of this study were to:

- describe the identity and quantity of microorganisms isolated from five blades (control samples) immediately after high-level disinfection with a newly implemented decontamination protocol;
- describe the identity and quantity of the microorganisms isolated from blades on the anaesthesia tabletop after implementation of a new decontamination protocol;
- evaluate the effectiveness of the newly implemented decontamination protocol by comparing microbial growth on blades to those from a historical control group from HJH.

4.2 Sample realisation

A total of 78 samples were collected. Five were part of the control group of which two were misplaced by the laboratory and no results were recovered; these two samples were repeated. The remaining 73 samples were collected over a two month period with 4 samples misplaced by the laboratory and for which no results were recovered, with 69 samples available for analysis.

4.3 Results

The findings of the study are described using descriptive and inferential statistics. A Fisher's exact test was used and a two-tailed p-value of <0.05 is considered statistically significant.

4.3.1 Identity and quantity of microorganisms isolated from five blades (control samples) immediately after high-level disinfection with a newly implemented decontamination protocol

Five control samples were collected by the researcher. This involved following the decontamination protocol precisely and doing so in an aseptic manner so as to

eliminate any contamination. The results of all five blades showed a quantitative count of zero and no bacterial growth.

This control group provided a baseline for formulating possible points of contamination during the routine decontamination process.

4.3.2 Identity and quantity of the microorganisms isolated from blades on the anaesthesia tabletop after implementation of a new decontamination protocol

Only 2 of the 69 samples had microorganisms identified, *Chryseobacterium indologenes and Streptococcus salivarius*. A further 6 samples had a quantitative count without microorganism growth and identification. These samples all had a very low count of <10 CFUs.

The Infection Control Services laboratory clarified the discrepancy of the samples with a positive quantitative count and no bacterial growth. This occurs as the plate count (CFUs) are performed on a petri film plate and the culture on a blood Agar plate. A petri film plate at <10 CFUs cannot be considered as positive.

The quantitative count of the microorganisms was expressed as CFUs per 1 ml of ¼ Ringers Lactate solution. Three levels of contamination were adopted in consultation with the microbiologist involved in the study. These levels were classified in the same manner as the study by Venter (22). Low-level contamination was defined as a count of 1 to 99 microorganisms per sample, intermediate-level contamination as 100 to 300 microorganisms and high-level contamination as more than 300 microorganisms per sample (22).

The results in Table 4.1 reflect the microorganisms isolated with low-, intermediate- and high-level contamination. Of the 8 samples with positive quantitative counts, 6 (8.7%) samples had low-level contamination, 1 (1.4%) sample had intermediate-level contamination and 1 (1.4%) sample had high-level contamination. The samples with low-level contamination had no identification of microorganisms, with all samples having a count of <10 CFUs.

Table 4.1 Level of contamination of microorganisms isolated from blades

Organisms isolated	Low-level contamination (0-99 CFUs) n (%)	Intermediate-level contamination (100-300 CFUs) n (%)	High-level contamination (>300 CFUs) n (%)
Chryseobacterium indologenes			1 (1.4%)
Streptococcus salivarius		1 (1.4%)	
No identification	6 (8.7%)		

Although not part of the objectives, additional analysis could be made from the collected data regarding the time of day the swabs were collected and the two theatres used in the study.

Comparison of the quantity of microorganisms isolated on the blades during two separate time groups

Samples were collected at anytime between 06:00 and 15:00 on weekdays that was convenient for the researcher. Time 1 is indicative of the time period between 06:00 and 07:00. This period falls during the night shift. Time 2 is indicative of the time period between 07:00 and 15:00, the day shift.

Of the 69 samples collected and processed, 47 (68.1%) samples were collected during Time 1, indicating that the majority of the specimens were collected during the night shift. A further 22 (31.8%) samples were collected during Time 2. Three of the 5 samples with positive quantitative counts during Time 1 had low-level contamination, with one having intermediate-level and one having high-level contamination. Low-level contamination was found on the 3 samples with positive quantitative counts during Time 2. No microorganisms were isolated from the samples collected in Time 2.

A Fisher's exact test was used and a p-value of 0.057 was calculated. The groups were not statistically significantly different. This is shown in Table 4.2.

Table 4.2 Comparison of the quantity of microorganisms isolated on the blades during two separate time groups

Time period	Negative count n (%)	Positive count n (%)	Total
Time 1 (night shift)	42 (89.3%)	5 (10.6%)	47
Time 2 (day shift)	19 (86.4%)	3 (13.6%)	22
Total	61 (88.4%)	8 (11.6%)	69
			p = 0.057

Comparison of the positive samples in the two different theatres

The two emergency theatres at HJH were used to collect samples. Theatre 6 is used for surgical emergencies and septic cases and Theatre 11 is used for orthopaedic emergencies. During the course of sample collection, Theatre 10 was occasionally used as the orthopaedic emergency theatre due to technical problems in Theatre 11.

Of the 8 samples that had a positive count, 5 (7.2%) samples were from Theatre 6 and 3 (4.3%) samples were from Theatre 10/11. Both samples with microorganism growth and identification were from Theatre 6.

An initial comparison was made with the samples with a positive count, including the samples with <10 CFUs and without microorganism growth. A Fisher's exact test was used to calculate the p-value. The p-value of 0.710 showed that there was no statistical significance between the two theatres. This is shown in Table 4.3.

Table 4.3 Comparison of the quantity of samples with a positive count in the two separate theatres

Theatre	Negative count n (%)	Positive count n (%)	Total
Th6	30 (85.7%)	5 (14.2%)	35
Th10/11	31 (91.2%)	3 (8.8%)	34
Total	61 (88.4%)	8 (11.6%)	69
			p = 0.710

It was postulated that a difference may exist if only the samples with microorganism growth and identification were compared. A Fisher's exact test was used. A p-value of 0.493 showed no statistically significant difference in microorganism growth between the two theatres. This is shown in Table 4.4.

Table 4.4 Comparison of the samples with microorganisms isolated in the two separate theatres

Theatre	Negative growth	Positive growth	Total
Th6	33 (94.3%)	2 (5.7%)	35
Th10/11	34 (100%)	0 (0%)	34
Total	67 (97.1%)	2 (2.9%)	69
			p = 0.493

4.3.3 Evaluate the effectiveness of the newly implemented decontamination protocol by comparing microbial growth on blades to those from a historical control group from HJH

In the historical control group (16), size 4 blades were swabbed in two different areas at two separate but consistent times during the day over a two week period.

Microorganism growth was found on 63 (57.3%) samples compared to the 2 (2.9%) samples with positive growth in the current study. A Fisher's exact test was used and a p-value of <0.0001 was obtained, which is statistically significant. An

odds ratio of 44.904 (95%CI 10.463 – 192.71) was found, indicating that the blades in the current study were nearly 45 times more likely to not be contaminated.

Table 4.5 Comparison of the growth on the blades in the current study to the historical control group

Study	Negative growth n (%)	Positive growth n (%)	Total
Current study	67 (97.1%)	2 (2.9%)	69
Historical control (16)	47 (42.7%)	63 (57.3%)	110
			p < 0.0001

In the current study, only Area 2 was swabbed and this was compared with the results of Area 2 in the historical control group (16). The current study had microorganism growth on 2 of the 69 samples (2.9%) versus 33 of 55 samples (60%) in the historical control. A Fisher's exact test was performed with a p-value of <0.0001, which is statistically significant. An odds ratio of 50.250 (95%CI 11.137 – 226.72) was found, meaning that the blades in the current study were 50 times more likely to not be contaminated. This is shown in Table 4.6.

Table 4.6 Comparison of the growth on the blades in the current study with the growth on Area 2 of the historical control group

Study	Negative growth n (%)	Positive growth n (%)	Total
Current study	67 (97.1%)	2 (2.9%)	69
Historical control (Area 2) (16)	22 (40%)	33 (60%)	55
			p < 0.0001

4.4 Discussion

After the results from the historical control group (16), a recommendation was made to alter the decontamination process to be in accordance with international regulations. This recommendation was implemented with a new decontamination technique developed using Cidex®OPA for high-level disinfection.

Cidex®OPA is used on a wide range of medical equipment and has been cleared as a high-level disinfectant by the FDA. Reports of effectiveness against *Staphylococcus aureus*, *Pseudomonas aerunginosa*, HIV-1 and even *Mycobacterium tuberculosis*, with longer immersion times, have been found. (20, 29, 39, 44)

Other Cidex® formulations may also be used for high-level disinfection of medical equipment, although care must be taken when using these solutions.

In this study, 61 (88.4%) samples had no microorganism growth and 8 (11.6%) samples had positive quantitative microorganism counts, with only 2 (2.9%) samples having positive growth and identification of microorganisms. Of the 2 microorganisms identified, the one was a Gram-negative rod and the other a Gram-positive coccus, *Chryseobacterium indologenes* and *Streptococcus salivarius*, respectively.

Both Gram-negative rods and Gram-positive cocci were reported in the international studies (2-4, 12, 13, 78) and by Venter (16), but the 2 microorganisms isolated in the current study were not specifically mentioned previously.

Chryseobacterium indologenes, formerly known as *Flavobacterium indologenes*, is a non-fermentative Gram-negative bacillus commonly found in soil and plants, as well as food and water sources, including those of hospitals (95). It was first described in 1983 (96), with minimal reported cases in the literature of *C. indologenes* bacteraemia. Although a rare human pathogen with unknown clinical significance, infection is associated with indwelling catheters and has been documented to cause bacteraemia in hospitalised patients, especially immunocompromised patients e.g. malignancies and diabetes mellitus (96-98).

This poses a concern as this microorganism is resistant to a wide variety of antimicrobial agents, especially those commonly used to treat other Gram-negative infections (96, 97).

The sample with *C. indologenes* was found to have high-level contamination, reported as innumerable by the laboratory. The possibility of cross infection with this microorganism exists and can result in morbidity and mortality, especially in immunocompromised patients.

Streptococcus salivarius, an α-haemolytic streptococci is a member of the group of viridans streptococci and normally inhabits the upper respiratory tract in humans (99, 100). These Gram-positive cocci are a common commensal in the oral cavity and usually enter the bloodstream accidently whilst brushing teeth or during dental work (99). Although infrequently pathogenic, this microorganism may result in septicaemia in patients with pre-existing neutropenia and is an important cause of infective endocarditis (99). The Public Health Agency of Canada describes reports of meningitis and bacteraemia (101). It has been directly linked to the development of halitosis. Patterns of antimicrobial sensitivity and resistance differ in the literature. Some studies have shown sensitivity to penicillin whilst others have shown this group of microorganisms to be resistant (99-102).

The reduction in positive cultures was expected as Cidex®OPA is a high-level disinfectant, as cleared by the FDA, with excellent antimicrobial activity (6, 20). The five control samples, all without microorganism growth, showed that high-level disinfection with OPA is sufficient to remove aerobic organisms from laryngoscope blades. The only possible point of contamination in the aseptic decontamination process was an unintentional dilution of the Cidex®OPA solution, if moist objects were placed in the container and therefore reducing the effectiveness of the solution.

The results from the routine sample collection showed that the new decontamination protocol is highly effective in reducing microorganism growth on blades. This is indicated by a statistically significant p-value <0.0001, with a reduction in microorganism growth from 57.3% (63 of the 110 samples) in the

Venter (16) study to 2.9% (2 of the 69 samples). This is important as it is a relatively simple technique to implement, with minimal additional equipment and consumables, in order to improve patient safety in hospitals, especially for immunocompromised patients.

The additional analysis made, that was not part of the objectives, including comparing the two separate time groups of sample collection and comparing the samples with a positive count and microorganism isolation in the two theatres, was not statistically significant. This is likely due to an under powered sample size as these comparisons were not part of the objectives and not considered during sample size calculation.

The possible reasons for obtaining positive growth on two samples include deviation from the new decontamination protocol or contamination acquired after decontamination from contaminated surfaces, contaminated objects on the anaesthesia machine tabletop or from theatre staff's hands or gloves. Contamination was unlikely during the sample collection process as a strict aseptic technique was used.

Deviation from the decontamination protocol could be due to staff shortages during the night shift as there is not always a dedicated anaesthetic nurse during this shift. The role of an anaesthetic nurse is then covered by the scrub sisters as they alternate between cases. Deviation may be a result of poor knowledge of the full decontamination technique or time constraints between cases with limited staff available to prepare theatres between cases.

There was concern that the theatre personnel responsible for the decontamination of the blades would became aware of the study and alter their normal technique in order to follow the protocol more accurately. This would cause an inaccurate reflection of the daily practice carried out. However, this did not seem to be an issue as very few samples had contamination and they occurred in the middle of the data collection period.

4.5 Summary

In this chapter the results of the study were reported and discussed. A statistically significant reduction in the number of contaminated specimens and the level of contamination was found. The following chapter contains a short summary of the study, the study conclusion and further recommendations.

Chapter 5: Summary, limitations, recommendations and conclusion

5.1 Introduction

This chapter contains a brief overview of the aim, objectives, study design and results of the study. The limitations will be addressed, recommendations for clinical practice and further research proposed and a conclusion of the study presented.

5.2 Study summary

Laryngoscopy is an invasive procedure commonly performed in all hospital settings, usually with a rigid laryngoscope. Several studies, both international and local, have shown that blades are contaminated with non-pathogenic and pathogenic microorganisms. The potential of cross infection via contaminated blades exists. These results have questioned decontamination protocols used in hospitals and their consistence with recommendations from authoritative bodies, such as the CDC, AANA and AAGBI.

5.2.1 Aim

The aim of the study was to determine the effectiveness of a newly implemented decontamination technique for blades at HJH.

5.2.2 Objectives

The objectives of this study were to:

- describe the identity and quantity of microorganisms isolated from five blades (control samples) immediately after high-level disinfection with a newly implemented decontamination protocol;
- describe the identity and quantity of the microorganisms isolated from blades on the anaesthesia tabletop after implementation of a new decontamination protocol;

- evaluate the effectiveness of the newly implemented decontamination protocol by comparing microbial growth on blades to those from a historical control group from HJH.

5.2.3 Summary of the methodology used in the study

The study design used was a prospective, contextual, comparative, descriptive study to assess a newly implemented decontamination protocol at HJH. A convenience sampling method was used and exclusion criteria were identified.

Five control samples were collected by the researcher. These samples were first decontaminated by following the decontamination protocol precisely and by doing so in an aseptic manner. Two of these samples were misplaced by the laboratory and the results were not recovered. These two samples were then repeated.

The size 4 blades used in the two emergency theatres at HJH were swabbed at various times of the day between 06:00 and 15:00. A single area on the blade was swabbed, the flange, using an aseptic technique. Sterile swabs were used and then placed in ¼ Ringers Lactate solution as the transport medium. The samples were transported to the laboratory where the count was performed on a petri film plate and the culture on a blood agar plate. These were incubated for 48 hours aerobically and then examined for colonies and identification of microorganisms.

The data was captured in a spreadsheet and then analysed with descriptive and inferential statistics using a statistics programme

5.2.4 Main findings

The previous decontamination technique at HJH used a low-level disinfectant to decontaminate to the blades. This was shown to be ineffective at eliminating microorganisms by Venter (22), raising the concern of cross infection especially in the immunocompromised population. A recommendation was made to alter the decontamination protocol used for the blades.

A new decontamination technique was implemented using Cidex®OPA. In 1993, Abramson and colleagues used 3.2% glutaraldehyde to disinfect laryngoscopes with an immersion time of 10 minutes (103).

The five control samples collected showed a quantitative count of zero and no bacterial growth. These results show that high-level disinfection, as per international recommendations, is sufficient to remove aerobic organisms from laryngoscope blades.

Of the 73 samples collected, four samples were misplaced by the laboratory with no results recovered. Positive quantitative counts were reported on eight (11.6%) samples, with only two (2.9%) samples having positive microorganism growth and identification and 67 (97.1%) samples reporting no microorganism growth. The two microorganisms isolated were *Chryseobacterium indologenes* and *Streptococcus salivarius*. This showed the effectiveness of the new decontamination technique, with a p-value < 0.0001, which is statistically significant.

5.3 Limitations

Results from this study should be examined in light of certain limitations. Contextual studies are described as “micro” research or a “small-scale world” (91). The study was contextual and therefore limits the generalisation of the results. Collecting data from a single hospital may not be fully representative of all hospitals. However, the effectiveness of the new decontamination technique needed to be evaluated.

Financial constraints limited the scope of the study to bacterial isolation and samples were only incubated aerobically. Other potential sources of infection such as viruses, blood or prion diseases were not tested for. This leaves a large gap regarding the potential of cross infection by these organisms after decontamination. Only a count (CFUs) and culture was conducted without sensitivity to antimicrobials also due to financial constraints. Therefore, the study was not able to determine if any of the microorganisms cultured were resistant to common antibiotics used in the hospital. This is of concern as *Chryseobacterium indologenes* has been reported to be resistant to a wide spectrum of antimicrobials, especially those used to treat Gram-negative infections.

Due to the office hours of the laboratory, collection times were limited to between 06:00 and 15:00 on weekdays. After collection of samples, they needed to be transported to the laboratory at the Wits Medical Campus at the earliest possible

time with processing of the sample initiated shortly thereafter. The majority of the samples were collected between 06:00 and 07:00, which is towards the end of the night shift. However, this is also the time that the theatres are prepared for the day shift to take over if no cases are in theatre. Therefore, this may not be a true reflection of the adherence to the decontamination throughout the night shift.

The concern that the theatre personnel would influence the study, by altering their adherence to the decontamination protocol, was abated by the results, which showed that the two positive samples were in the middle of the data collection period.

5.4 Recommendations

The new decontamination protocol was implemented in March 2013 after the theatre staff had been trained.

5.4.1 Recommendations for practice at the other hospitals on the Wits circuit

The effectiveness of the new decontamination technique was shown to be considered statistically significant, p-value < 0.0001. This should alert healthcare practitioners to the impact that can be made on improving patient safety in hospitals. The hospitals on the Wits circuit use Cidex® solutions for decontamination of endoscopic equipment. Therefore, this is readily available in the theatres and can be used for the decontamination of blades. These hospitals include Chris Hani Baragwanath Academic Hospital, Charlotte Maxeke Johannesburg Academic Hospital and Rahima Moosa Mother and Child Hospital. Currently, none of these hospitals have formal protocols regarding the decontamination of blades.

5.4.2 Recommendations for further research

Internationally, extensive research has been conducted regarding microorganisms on blades. In South Africa, a study from 1973 and one from 2012 both showed a wide variety of microorganism contamination on blades.

- Implement the decontamination protocol at the other hospitals on the Wits circuit and assess adherence by staff to the protocol on a regular basis.

- Evaluate staff knowledge on available decontamination techniques and guidelines and the decontamination method used at their hospital.

5.5 Conclusion

Laryngoscopy is performed daily in theatre complexes, commonly with a reusable laryngoscope blade. After determining the ineffectiveness of a low-level disinfectant for decontamination of blades, a new decontamination protocol was implemented with a high-level disinfectant which was shown to be effective in reducing aerobic microorganism growth on blades. Adherence to this protocol and its implementation at the other hospitals on the Wits circuit will improve patient safety and decrease the potential risk of cross infection.

5.6 Summary

This chapter contained a summary of the study, limitations, recommendations and conclusion of the study.

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Appendices

Appendix A: Decontamination protocol for laryngoscope blades

DECONTAMINATION PROTOCOL FOR LARYNGOSCOPE BLADES

A study conducted by Venter at Helen Joseph Hospital, showed that the contamination rate of laryngoscope blades was 57.3%. This new decontamination technique aims to reduce the rate of contamination and decrease the pathogens present on the blades.

ALWAYS adhere to universal precautions and wear personal protective equipment.

Contact with CIDEX® OPA Solution may discolour skin or stain clothing. If the solution contacts skin, wash with soap and water for a few minutes. The discoloration should disappear within 1 to 2 days.

At the beginning of every case:

1. Place clean paper towel on anaesthesia machine tabletop.
2. Place clean handle and 2 laryngoscope blades (blade) – one size 3 and one size 4 – on tabletop.
3. Place clean Magill forceps, artery forceps and introducer on tabletop.
4. Place clean facemasks, airways and syringe on tabletop.

NB: Used/Dirty equipment should NOT be placed on clean surfaces, including the anaesthesia machine tabletop.

After successful intubation:

1. Place used equipment on endotracheal tube (ETT) packet.
2. Secure airway and set ventilator.
3. Anaesthetist detaches blade from handle. Place blade in container with enzymatic detergent solution. Give handle to anaesthetic nurse to clean with alcohol-soaked swab.

DECONTAMINATION PROCESS

STEP 1: CLEAN

- Place blade in container with enzymatic detergent solution.
- Remove blade from enzymatic detergent solution and rinse with large amounts of fresh water to remove residual detergent.
- Remove excess moisture prior to disinfection.

This will help prevent excess water from diluting the CIDEX® OPA Solution below its Minimum Effective Concentration (MEC)

STEP 2: DISINFECT

- Immerse clean, dry instruments completely in Cidex®OPA solution.
- Cover the CIDEX® Solution tray with a secure lid.
- Soak instruments for 5 minutes at 20°C to achieve high-level disinfection.

Cidex® needs to be monitored carefully (see below). Ensure solution has not passed use by date on tray cover.

STEP 3: RINSE

- Rinse thoroughly with running water to prevent toxicity.
- Repeat twice – total of three rinses – 1 minute each rinse.
- Use a large volume of fresh water.

STEP 4: DRY

- Dry blade properly.
- Place on tabletop.
- Blade is now ready-to-use.

MONITORING CIDEX®OPA SOLUTION

1. Using CIDEX® OPA Solution

- Always read the directions for use on the bottle label and package insert prior to using the solution.
- An unopened bottle of Cidex®OPA has a shelf life of two years.
- The solution requires no activation.
- Open the bottle and pour Cidex®OPA solution into Cidex® sterilising tray. If there is still solution in the bottle, it may be stored for 75 days.
- Record the date the solution is poured from the original container and the expiry date (not to exceed 14 days) on the tray cover.
- Monitor daily with Cidex®OPA Test Strips.
- Use Cidex®OPA solution in a well-ventilated area and in closed containers with tight fitting lids.
  NB: Without proper ventilation or engineering controls: Allergic reaction may result.
  NB: Without proper ventilation: May result in irritation to the respiratory tract and eyes, a stinging sensation in the nose and throat or difficulty breathing.

2. Test

- Cidex®OPA Test strips verify the concentration during its reuse life.
- Solution must be tested daily to ensure that the concentration of ortho-phthaladehyde is above minimum effective concentration (MEC) of 0.3%.
- Discard solution after 14 days – check date on tray cover.

- Cidex®OPA solution can be discarded down hospital drains in accordance with local regulations.
- Rinse container thoroughly and dry prior to pouring new solution.

Adapted from:

1. Rutala W, Weber D,Healthcare Infection Control Practices Advisory Committee. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Atlanta, GA: Centre for Disease Control, 2008.
2. Johnson and Johnson Advanced sterilisation products. Cidex®OPA.

Appendix B: Ethical waiver granted by the Human Research Ethics Committee of the University of the Witwatersrand

University
of the Witwatersrand,
Johannesburg

Human Research Ethics Committee (Medical)
(formerly Committee for Research on Human Subjects (Medical)

Secretariat: Reseearch Office, Room SH10005, 10th floor, Senate House • Telephone: +27 11 717-1234 • Fax: +27 11 339-5708
Private Bag 3, Wits 2050, South Africa

Ref: W-CJ-130301-1

01/03/2013

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: **Dr M Fourtounas (student no 742302).**

Project title: **Microorganisms cultured from laryngoscope blades in an academic hospital following implementation of a new decontamination technique.**

Reason: This is a laboratory study of organisms on clinical apparatus. No humans are involved.

UNIVERSITY OF THE WITWATERSRAND
PROF PE CLEATON-JONES
HREC (MEDICAL)
2013 -03- 01
JOHANNESBURG

Professor Peter Cleaton-Jones
Chair: Human Research Ethics Committee (Medical)

copy: Anisa Keshav, Research Office, Senate House, Wits

Appendix C: Permission from the Post Graduate Committee

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172040

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

07 January 2014
Person No: 742304
PAG

Dr M Fourtounas
PO Box 751552
Ruimsig Country Estate
Ruimsig
1746
South Africa

Dear Dr Fourtounas

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Microorganisms cultured from laryngoscope blades in an academic hospital following implementation of a new decontamination technique* 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

Appendix D: Permission from HJH

health and
social development
Department: Health and Social Development
GAUTENG PROVINCE

PERMISION FOR RESEARCH

DATE: 30/04/2014

NAME OF RESEARCH WORKER: DR MARIA FOURTOUNAS

CONTACT DETAILS OF RESEARCH (INCLUDE ALTERNATE RESEARCHER):
0827751345, maria.fourtounas@gmail.com
SUPERVISOR: JUAN SCRIBANTE

TITLE OF RESEARCH PROJECT MICROORGANISMS CULTURED FROM LARYNGOSCOPE BLADES IN AN ACADEMIC HOSPITAL FOLLOWING IMPLEMENTATION OF A NEW DECONTAMINATION TECHNIQUE

OBJECTIVES OF STUDY (Briefly or include a protocol):
PLEASE SEE PROTOCOL ATTACHED

METHODOLOGY (Briefly or include a protocol):
PLEASE SEE PROTOCOL ATTACHED

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

(i) CONFIDENTIALITY OF PATIENTS MAINTAINED: NO PATIENTS INVOLVED
(ii) NO COSTS TO THE HOSPITAL: NONE
(iii) APPROVAL OF HEAD OF DEPARTMENT: YES
(iv) APPROVAL BY ETHICS COMMITTEE OF UNIVERSITY: YES

SUPERINTENDENT PERMISION

Signature: [signature] Date: 5/5/2014

SUBJECT TO ANY RESTRICTIONS: FINANCIAL IMPACT ON THE HOSPITAL

Helen Joseph Hospital
Perth Road
Tel: 011 489 1011

Private Bag X47
Auckland Park
2006

Appendix E: Data collection sheet

Sample information	
Study sample number	
Date collected	
Time collected	
Theatre (6 or 11)	
NHLS barcode	
Microbiological information	
Bacterial contamination	YES / NO
Organisms isolated	
Level of contamination/Number of CFUs	

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