CONTAMINATION AND CURRENT PRACTICE IN DECONTAMINATION OF NEBULISERS IN VENTILATED PATIENTS

Lizl van Heerden

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 Masters of Science (Physiotherapy)

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ABSTRACT

Background

Aerosol therapy is an important and frequently used method of delivering drugs to the patient on mechanical ventilation (MV). Different types of aerosol devices are available to deliver drug therapy during MV. These devices need to be used according to the manufacturer's guidelines which include methods for decontamination and application. The methods used to store these nebulisers and the pathogens in the surrounding air may contribute to the contamination of these devices. Nebulisers have been identified as a possible source of ventilator-associated pneumonia (VAP). The incidence of contamination of nebulisers associated with current decontamination and storage protocols will lay the foundation for the development of evidence based practice of aerosol therapy in MV.

Objectives

The aim of this study was to determine the current incidence of contamination of nebulisers used within a ventilator circuit and surrounding air in the intensive care units (ICUs) of hospitals in Pretoria and to determine the current practice regarding decontamination and storage of these devices. Micro-organisms that colonise these contaminated nebulisers and the surrounding air were also identified.

Methods

A cross-sectional observational analytical study was done in seven ICUs in Pretoria whereby 61 nebulisers and the surrounding air were sampled and assessed. The unit manager of each ICU was asked questions to identify the current decontamination and storage protocols for nebulisers used within a ventilator circuit. Swabs were taken from the chambers of nebulisers used within a ventilator circuit and streaked on blood agar plates (BAPs). An air sampler was used to collect air samples from the surrounding environment. The BAPs of nebulisers and air were incubated for possible bacterial and fungal contamination. Species of the most recurrent colonies observed were identified in both air and nebuliser samples.

Results

A total of 61 nebulisers were sampled including 37 Micro Mist nebulisers and 24 Aeroneb nebulisers. The incidence of contamination found in the Micro Mist nebulisers were 51.4% (n=19) and the Aeroneb nebulisers were 50% (n=12). Most of the Aeroneb nebulisers in the ventilator circuit were wet which resulted in 50% bacterial contamination. All the ICUs in the hospitals in Pretoria had decontamination and storage protocols for the Micro Mist nebuliser. These protocols differed between ICUs and ICUs within the same hospital. Staff adherence to these protocols was low as the methods

observed for storage and decontamination differed from the protocols stated to be used in the ICUs. Contamination rate was the least when the Micro Mist nebuliser was rinsed with alcohol and left open to the environment. Micro Mist nebulisers that were taken apart and left to dry under a sterile cloth resulted in the most fungal and bacterial contamination. No contamination was found in Micro Mist nebulisers that were used for Bisolvon aerosolisation. Coagulase-negative *Staphylococcus* species (spp.) was mostly found in air and Aeroneb samples and *Enterococcus* spp. mostly in the Micro Mist nebuliser. Both of these micro-organisms are common causes of VAP.

Conclusion

Both types of nebulisers presented with similar rates of contamination. Although the ICUs in the hospitals had decontamination and storage protocols in place, the incidence of contamination in the Micro Mist nebulisers was high. The rate of contamination in the Micro Mist nebulisers can be associated with different decontamination and storage protocols. This is the first study to identify the rate of contamination in the Aeroneb nebuliser. Most of the Aeroneb nebulisers were wet during the time of MV which increased the possibility of contamination. The micro-organisms found in nebulisers and air samples harbour pathogens that can cause VAP.

DECLARATION

I, Lizl van Heerden, hereby declare that this research report is my original work. It is being submitted for partial fulfilment of the degree of Masters of Science (Physiotherapy) in the University of the Witwatersrand, Johannesburg. Neither the substance of any part of this work has been, or is being, or is to be submitted for another degree at this or any other university.

Signed: .....

Date: .....day of 2015

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BAP	- Blood Agar Plate
CF	- Cystic Fibrosis
CCF	- Cystic Fibrosis Foundation
COPD	- Chronic Obstructive Pulmonary Disease
CoNS	- Coagulase-negative *Staphylococcus aureus*
DNA	- Deoxyribonucleic acid
HAI	- Healthcare-Associated Infection
HAP	- Hospital-Acquired Pneumonia
HEPA	- High efficiency particulate air
ICU	- Intensive Care Unit
ICT	- Infection Control Team
INICC	- International Nosocomial Infection Control Consortium
MDI	- Meter-dose inhaler
pMDI	- pressurised Metered-Dose Inhaler
MDR	- Multi-drug resistant
MHRA	- Medicines and Healthcare Products Regulatory Agency
MRSA	- Methicillin-resistant *Staphylococcus aureus*
MSSA	- Methicillin-sensitive *Staphylococcus aureus*
MV	- Mechanical Ventilation
NHS	- National Health System
NICU	- Neonatal Intensive Care
NP	- Nosocomial Pneumonia
PML	- Pharmaceutical Microbiological Laboratory
SARS	- Severe Acute Respiratory Syndrome
SMLT	- Surgical Materials Testing Laboratory
TSA	- Tryptone Soya agar
UV	- Ultraviolet
VAP	- Ventilator-associated pneumonia
VMN	- Vibrating-mesh nebuliser
SPP.	- Species
SP.	- A species

CHAPTER 1

1. INTRODUCTION

1.1 BACKGROUND

Delivery of aerosolised pharmacologic agents is described as one of the most important adjunctive therapies related to patient care, during mechanical ventilation (MV) (Kallet, 2013). Nebulisation is the process whereby liquid medications are aerosolised in order to enhance their penetration into the lower respiratory tract of patients in need of symptom relief. A range of aerosol devices are used for administration of medication to patients during the period of MV. These devices include the jet pneumatic nebuliser, vibrating-mesh nebuliser, ultrasonic nebuliser and pressurised metered-dose inhaler (pMDI) with spacer (Ari, Areabi, & Fink, 2010). The jet nebuliser is mostly used in the ICU followed by the ultrasonic nebuliser and more recently vibrating mesh nebulisers (Dhand, 2008; Robinson, Athota, & Branson, 2009).

Inhaled drug therapy is routinely employed by physiotherapists and ICU nursing staff for the management of patients receiving MV. Bronchodilator agents are among the drugs most frequently administered in the ICU (Dhand, 2007; Ellis, Van Aswegen, Roos, & Becker, 2013). The main bronchodilator agents that are used in patients receiving MV are beta-adrenergic agonists (Dhand, 2008). Inhaled drug therapy is also implemented for patients who suffer from symptoms apart from bronchospasm and include corticosteroids, prostanoids, surfactant, mucolytics and antibiotics (Dhand, 2007). The nebulisation of medication during MV, results in rapid localised and systemic effects with little side-effects (Dolovich & Dhand, 2011).

Ellis et al. (2013) performed a study to determine the incidence of contamination and the practice of decontamination of nebulisers used within a ventilator circuit in ICUs in Johannesburg, South Africa. Results showed that nebulisation was mainly done through the re-use of single-use jet nebulisers. It has been noted that 93% of all nebulisers assessed were not being used in accordance with the manufacturer's guidelines as they were marked as single-use devices. Ultrasonic nebulisers were the only additional nebuliser devices used for nebulisation within a ventilator circuit (Ellis et al., 2013).

More than half of the re-used jet nebulisers (52%) used within a ventilator circuit presented with contamination. Protocols for decontamination and storage were absent in these ICUs and healthcare providers' lack of knowledge regarding the implications of re-using jet nebulisers was evident (Ellis et al., 2013).

Ellis et al. (2013) reported that physiotherapists and nursing staff in the ICUs stored these jet nebulisers after aerosolisation sessions without decontamination. Some nebulisers were stored with residual medication and visible secretions within the chambers of these devices. Secretions coughed up by patients can drain into the nebuliser chamber during aerosolisation or when left in the ventilator circuit after an aerosolisation session. These devices were disconnected from the ventilator circuit and stored next to the patient's bed in a variety of methods which included a) stored within a latex glove; b) covered with a sterile drape; c) stored within a paper bag and d) open to the environment (Ellis et al., 2013). These practices could potentially have contributed to the growth of bacteria in the nebuliser chambers. Eleven percent of nebulisers were stored without protective covering, thus open to the air in the ICU. It was suggested that this method of storage might also have contributed to contamination due to contaminated air and should be investigated (Ellis et al., 2013).

Ventilator-associated pneumonia (VAP) is an infection that occurs 48 hours after intubation and represents 86% of pneumonias acquired in ICUs in America (Rotstein et al., 2008). Research regarding VAP in South Africa is limited and only two papers relating to nosocomial infection in paediatric ICUs have been published in the last 10 years (Morrow et al., 2009). Several studies have shown that contaminated nebulisers have been linked to the incidence of VAP (Ball et al., 2005; Dhand, 2008). Contaminated nebulisers are able to deliver pathogens deep into the lower respiratory tract and the depth of penetration depends on the particle size generated by the aerosol device (Miller, Amin, Palmer, & al, 2003). Safdar, Crnich & Maki (2005) reported that the main sources of epidemic VAP were contaminated respiratory equipment and medical aerosols.

Contaminated hospital air and water are environmental reservoirs contributing to Nosocomial Pneumonia (Safdar, Crnich & Maki, 2005). Airborne transmission is well recognized for many human pathogens. Diseases in the air can be transmitted over small and large distances by direct/indirect contact or a combination of routes (Beggs, Noakes, Sleigh, Fletcher, & Siddiqi, 2003). The survival of infectious agents in the air depends on environmental factors such as temperature, humidity, ultraviolet (UV) light and other pollutants in the atmosphere (Eames et al., 2009).

Huang et al. (2013) collected samples of the surrounding air and various surfaces in two ICUs to investigate the extent of microbial contamination. It was noted that *Pseudomonas aeruginosa* was the most frequently detected and abundant bacterium in both surface and air

samples. Samples were taken around the bedsides of patients and the surrounding air. The ventilator represented the most heavily contaminated surface location in both total pathogenic bacteria colony counts, and frequency of positive detection. The study also indicated that bacterial counts after visitation periods were higher (Huang et al., 2013). Studies investigating the correlation between surface-bound microbial contamination and airborne contamination remain limited. There is no information regarding the correlation between micro-organisms cultured from contaminated nebulisers and air samples taken from around the patient's bedside.

1.2 PROBLEM STATEMENT

There is currently no information regarding the type of nebulisers used within ventilator circuits or the incidence of contamination of these devices in ICUs in Pretoria, South Africa. There is no documentation regarding the current practices of decontamination and storage of nebulisers in these ICUs. Research is limited regarding the possible correlation between organisms identified in contaminated nebulisers stored at a patient's bedside and organisms detected in the surrounding air.

1.3 JUSTIFICATION FOR RESEARCH

Investigation into the contamination and decontamination of nebulisers used within ventilator circuits in ICUs of hospitals is a novel area of research in South Africa. Ellis et al. (2013) were the first to report in this field. Ellis et al. (2013) studied the current practice in decontamination of nebulisers used with in a ventilator circuit in the ICUs of hospitals in Johannesburg. A limitation of the study by Ellis et al. (2013) is that they showed bacterial growth in contaminated nebulisers but did not identify the bacteria. They also didn't collect air samples around patients' bedsides to determine if bacteria in the air contributed to nebuliser contamination. This study sets out to determine if similar practice regarding nebuliser use and decontamination of nebulisers, as reported by Ellis et al. (2013), will be found in ICUs of hospitals in Pretoria. In addition air sampling was done to investigate its role in contamination of nebulisers. Bacterial colonies, cultured from the air and nebuliser samples at the same bedside were identified for possible correlation.

1.4 RESEARCH QUESTIONS

1.4.1 What is the incidence of nebuliser contamination within a ventilator circuit in the ICUs of hospitals in Pretoria, South Africa?

1.4.2 What is the current practice regarding decontamination and storage of nebulisers after use in ventilator circuits in ICUs of hospitals in Pretoria?

1.4.3 What is the extent of air borne contamination around the area where these nebulisers are being kept?

1.4.4 Is there any correlation between airborne contaminants and bacteria found in nebulisers?

1.5 HYPOTHESIS

There is a high rate of contamination of nebulisers used within a ventilator circuit in ICUs of hospitals in Pretoria, South Africa because nebulisers are not effectively decontaminated after being used within a ventilator circuit.

The micro-organisms identified in contaminated nebulisers are similar to the micro-organisms from air samples taken around the patient's bedside where nebulisers are kept.

1.6 RESEARCH AIM

The aim of this study is to determine the current incidence of contamination of nebulisers used within a ventilator circuit and surrounding air in ICUs in Pretoria and to determine the current practice regarding decontamination and storage of such devices.

1.7 RESEARCH OBJECTIVES

1.7.1 To examine which types of nebulisers and which nebulised medications are being used in ICUs in Pretoria.

1.7.2 To determine whether staff in ICUs are informed regarding the correct application of nebulisers used in MV circuits.

1.7.3 To determine whether a formal nebuliser decontamination protocol exists in these ICUs and of the protocol is part of daily practice in these ICUs.

1.7.4 To determine the incidence of contamination of jet nebulisers after use within a ventilator circuit in ICUs in Pretoria.

1.7.5 To identify which practices are associated with bacterial growth, higher concentrations of bacteria and multiple species within nebulisers that were used or re-used.

1.7.6 To identify the micro-organisms in contaminated nebulisers used within ventilator circuits.

1.7.7 To identify the micro-organisms in selected air samples where patient's nebulisers are kept.

1.7.8 To determine whether there is some correlation between micro-organisms cultured from contaminated nebulisers and the surrounding air.

1.8 SIGNIFICANCE OF THE STUDY

Determining the incidence of contamination of the different types of nebulisers used within ventilator circuits by physiotherapists and nursing staff will highlight current practice relating to nebuliser care in ICUs in Pretoria, South Africa.

Establishing current practice in nebuliser decontamination and storage protocols as well as identifying micro-organisms contaminating nebulisers and surrounding air, will provide a platform for development of evidence based protocols for in-line nebuliser usage, decontamination and storage. The implementation of evidence based decontamination and storage protocols may contribute significantly to the prevention of VAP in these ICUs as previous studies have highlighted the link between contaminated nebulisers and the incidence of VAP (Ball et al., 2005; Dhand, 2008).

CHAPTER 2

2. LITERATURE REVIEW

2.1 INTRODUCTION

The literature reviewed in this chapter is organised according to the following sections: inhalation therapy, types of nebuliser devices, pathogens leading to VAP, role of hospital air and infection control protocols to provide the background for this study. The main search engines used to identify the literature included: Google scholar, Science Direct, PubMed, Ebsco Host. Papers published between 2000 and 2013 were reviewed as well as references within these papers and cited on the basis of their relevance.

In this literature review information on this study topic was identified by using the following search terms: " VAP", "aerosol devices", "contamination of respiratory devices", " jet nebuliser", "single-patient-use-devices", "single-use-devices", "aerosol therapy", "decontamination of respiratory devices", "inhalation therapy", "aeroneb device", "inhalation drugs", "position of nebuliser in ventilator circuit", "aerosol particle size of aerosol devices", "prevention of VAP", "nebuliser re-use", "microbial colonization of respiratory devices", "airborne transmission of organisms", "microbial air contamination", "healthcare environment", "hospital air", "pathogens in hospital air", "pathogens causing VAP", "air-sampler", "hospital surface environment", "airborne and surface-bound contamination", "infection control", "management of VAP", "ventilator circuit", "aerosol therapy during mechanical ventilation", "bronchodilator therapy in mechanically ventilated patients".

2.2 INHALATION THERAPY

The inhalation of aerosolised medications, is an ancient method of drug therapy delivery, that was used for the treatment of respiratory tract diseases and dates back as far as 4 000 BC. Ayuravedic literature indicates that inhalation therapy was used for the relief of asthma symptoms (Rau, 2004).

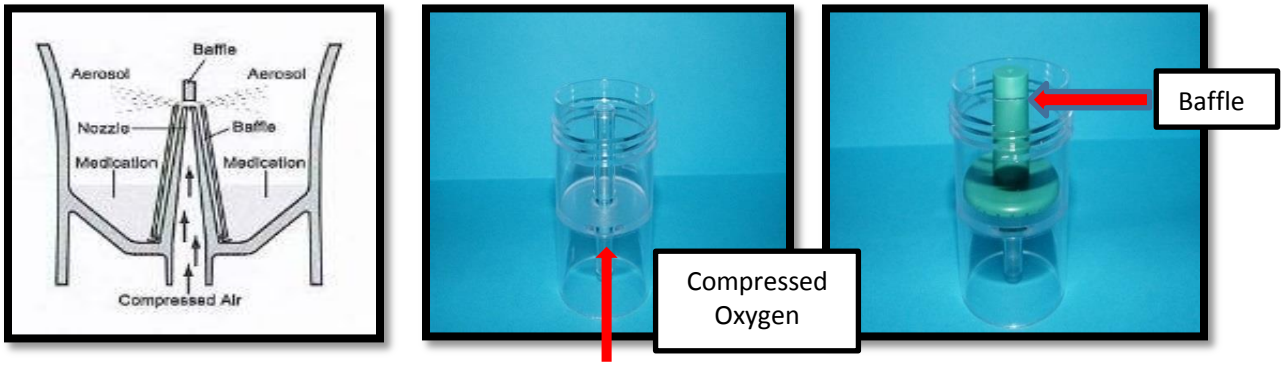
Since the 20th century, inhalation therapy has become a very important method of delivering drugs to the respiratory system (Rau, 2004). Extensive developments have been made regarding the type of devices as well as the spectrum of medications that can be aerolised, which includes respiratory and non-respiratory medications (Rau, 2004). The current methods of delivering aerosol therapy to ventilated patients in South African ICUs are metered-dose inhalers (MDIs) and nebulisation (Ellis et al., 2013).

The delivery of aerosolised medication is probably the most important adjunctive therapy for patients with respiratory disease on MV. The goal of aerosol therapy is to reverse the underlying pathology and/or to stabilize gas exchange (Kallet, 2013). A recent international survey indicated that 95% of intensivists in the ICU implement aerosol therapy for the pharmacological management of various pulmonary diseases during MV (Ehrmann et al., 2013).

The most important advantage of aerosol therapy is the delivery of low doses of aerosolised drugs to the airway surfaces for a localised effect that leads to a rapid clinical response (Dolovich & Dhand, 2011). The risks however, may include local side effects such as bronchospasm and delayed systemic effects, such as tachycardia and tremors depending on the type of medication administered (Ellis et al., 2013).

2.2.1 Types of Nebuliser Devices used during Mechanical Ventilation

Nebulisation of medication in liquid form and inhalation of medication as a pressurised gas, are the two primary methods of delivering aerosolised drugs to patients on MV. Three types of devices are used for nebulisation of liquid medication within a ventilator circuit namely jet, ultrasonic and vibrating-mesh nebuliser (VMN). The device adapted for inhalation of medication as a pressurised gas within a ventilator circuit is the pMDI (Michalopoulos, Metaxas, & Falagas, 2011). The jet nebuliser is the most frequently used device within a ventilator circuit in the ICU, followed by the ultrasonic and more recently the VMN (Ehrmann et al., 2013). These devices produce aerosols of different particle sizes and consequently result in different depths of penetration within the respiratory tract (Dhand, 2008; Robinson, Athota & Branson, 2009; Ari, Areabi & Fink, 2010). During the operation of a jet nebuliser, compressed gas (usually oxygen) is responsible for the atomisation of the liquid medication in the nebuliser chamber. The nebuliser is connected to a port on the ventilator, which diverts flow through the nebuliser (Ellis et al., 2013). This pressurised oxygen is delivered as a jet stream through the bottom of the nebuliser chamber, creating a region of negative pressure. The drug solution is routed by the gas stream, in the form of a liquid film, towards the baffle at the top of the nebuliser chamber. The unsteady film breaks into particles as it is projected against the baffle. Small particles form an aerosol which is injected into the oxygen stream and exits at the top of the nebuliser. The small aerosol particles are inhaled by the patient while the larger particles are diverted back to the liquid in the chamber, where it can be re-nebulised into smaller particles (Hess, 2000; Ari et al., 2010).



"Picture taken from Amazon webpage [http://www.amazon.in/Omron-NE-C28-Compressor-Nebulizer/dp/B0074I7AYA] [accessed on - 08.02.2015]"

Figure 2.1: Function of the Jet Nebuliser

The MICRO MIST® small volume nebuliser manufactured by Hudson RCI is a jet nebuliser and can be used for aerosol therapy in the ambulatory patient (hand-held) and during MV. The nebuliser consists of a nebuliser cap, nebuliser chamber where medication is instilled and the loose baffle in the basis of the chamber. The nebuliser is connected at the nebuliser air-inlet connector with tubing to the ventilator port from where the compressed oxygen is transported to the nebuliser. According to the Surgical Materials Testing Laboratory (SMLT), Hudson RCI and Henleys have performed validation studies and have demonstrated that the MICRO MIST® small volume nebulisers may be re-used on the same patient three times a day for 30 days. However, the medical and nursing staff clean the nebuliser according to instructions after every treatment. Hudson RCI however emphasised that the cleaning procedure does not sterilise the nebuliser and recommend that the nebuliser should be discarded and replaced by a new nebuliser with every treatment, if the patient has an infectious disease (SMLT, 2000).

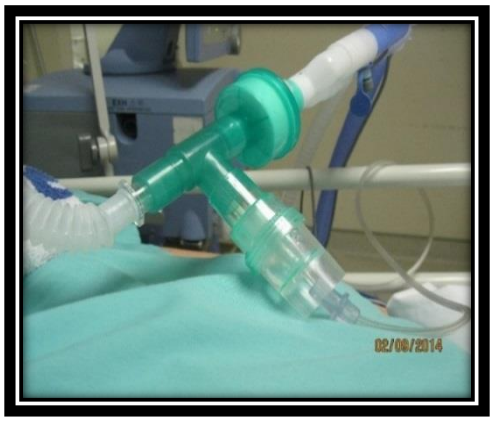


Figure 2.2: The MICRO MIST® Small Volume Nebuliser with Tee connector

The nebuliser is connected to the ventilator circuit with a Tee Connector illustrated in Figure 2.2. The Neb-Tee is a different Tee Connector which is a spring-loaded, self-opening and closing adaptor which allows the nebuliser to be connected without breaking the circuit or interrupting ventilation. The Neb-Tee is instilled into the ventilator circuit and left in place and therefore a single-patient-use device. The valve of the Neb-Tee adaptor opens/closes automatically upon insertion/removal of the nebuliser and thus helps to prevent the patient's aerosol from leaking into the ICU environment (Teleflex, 2014).

The ultrasonic nebuliser uses a piezoelectric transducer to produce ultrasonic waves through the use of electric current. This action results in the formation of standing waves. The crests of these waves are transmitted to the nebuliser chamber in which the liquid medication is housed and breaks the liquid into gas particles which are inhaled by the patient (Dolovich & Dhand, 2011). An advantage of the ultrasonic nebuliser is the higher rate of aerosol output and shorter duration of therapy compared to the jet nebuliser (Kallet, 2013).

The vibrating-mesh nebuliser is the latest nebuliser introduced to the aerosol therapy generation. The VMN uses electricity to vibrate plates with multiple micrometre-sized apertures through which liquid drugs are extruded to generate aerosols. Vibrating-mesh nebulisers do not heat the liquid during atomisation and are classified as passively or actively vibrating nebulisers (Elhissi et al., 2013). The Aeroneb Pro vibrating-mesh nebuliser is specifically recommended for delivery of drugs during MV (Fink, Schmidt & Power, 2001a; Pederson et al., 2006). The Aeroneb Pro vibrating-mesh nebuliser is an actively vibrating nebuliser and operates via a micro-pump system which employs a mesh plate with up to 1000 dome-shaped apertures. This perforated plate is surrounded by a ceramic vibrational element which contracts and expands upon application of electrical current. The result is upward and downward movements of the perforated plate by a few micrometres, which extrudes the liquid through the mesh pores, generating an aerosol which is inhaled by the patient (Ghazanfari et al., 2007; Elhissi et al., 2013; Najlah et al., 2013). The VMN was used less than the jet nebuliser and ultrasonic nebuliser in an international survey. Ehrmann et al. (2013) suggested that cost could be the reason why they are used less. In South Africa the cost of the Aeroneb nebuliser is almost ten times the price of the Micro Mist small volume nebuliser with Tee Connector. The price according to a private hospital group is ±R500 for the Aeroneb®Pro nebulisers and ±R50 for the Micro Mist® small volume nebuliser with Tee Connector.

The Aeroneb® Solo System is a VMN device manufactured by Aerogen that has a combination of re-use and single-patient-use components. The Aeroneb® Solo System, which consists of the Aeroneb® Solo nebuliser and the Aeroneb Pro-X controller, is a nebuliser system designed for use within mechanical ventilators. It is used for aerolising physician-prescribed medications for inhalation which are approved for use within general nebulisers. The Aeroneb® Solo nebuliser is for single-patient-use and the Aeroneb® Pro-X controller is for re-use. The Aeroneb® Solo nebuliser consists of a nebuliser unit (aerosol generator and plug) and the Tee Connector and should be replaced between patients (Aerogen, 2014).

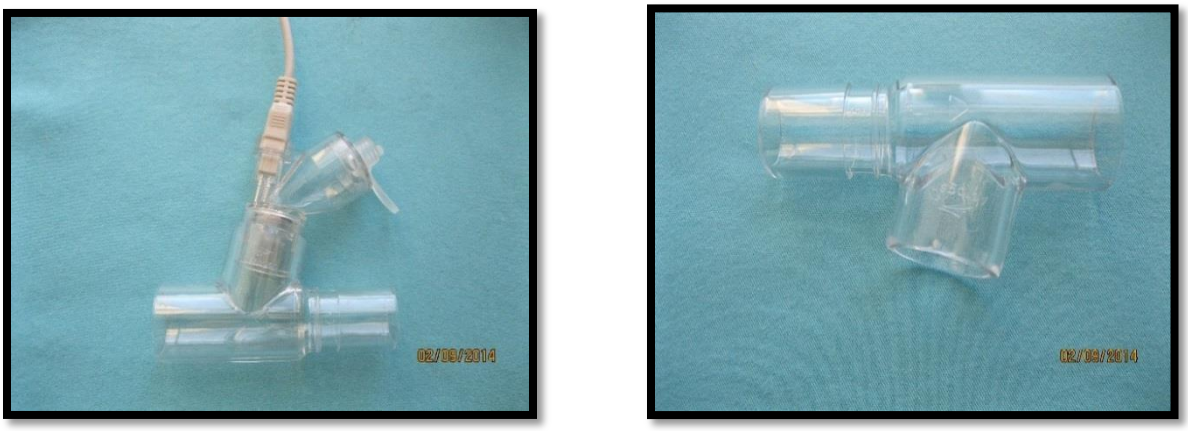


Figure 2.3: Aeroneb ®Solo Nebuliser and Tee Connector

Figure 2.4: Aeroneb®Pro-X controller

Pressurised metered-dose inhalers are convenient, portable and multi-dose devices that employ a propellant under pressure to generate aerosol through an atomisation nozzle. In a ventilator circuit the pMDIs are applied to the inspiratory limb of the ventilator, using a compatible spacer device (Dolovich & Dhand, 2011). These devices are less expensive,

provide a reliable dose, require a shorter time to administer and do not pose a risk to bacterial infection. Furthermore if a collapsible cylinder spacer is used within the ventilator circuit no disconnection is necessary which decreases the possible risk of infection and development of pneumonia (Dhand, 2007). In spite of the advantages of using MDIs in mechanically ventilated patients, this method of drug administration has not gained universal approval among intensive care unit physicians. It is believed that drug deposition in the ventilator circuit and endotracheal tube makes this device less effective (Georgopoulos et al., 2000). Georgopoulos et al. (2000) showed that with the correct technique of administration and the use of a spacer when applied during MV, MDIs are as effective as nebulisers, despite a significant lower output dose. Ehrmann et al. (2013) reported results of an international survey on ICU physicians' use of aerosol therapy during MV. The results showed that jet nebulisers (55%) were mostly used, followed by ultrasonic (44%) and less frequently vibrating mesh nebulisers (14%). Results indicated that 55% also used pMDIs and that only 2% used MDI exclusively.

2.2.2 **Single-Use versus Single-Patient-Use Devices**

Single-use nebulisers are intended for one treatment only and should be discarded after use while single-patient-use nebulisers are devices that can be safely re-used by the same patient (Therapeutic Goods Administration, 2006). Single-patient-use devices must never be reprocessed or be used on another patient (NHS, 2012). When using a single-patient-use nebuliser the manufacturer's guidelines regarding the method of cleaning and the extent by which the device can be used should be followed.

Reusable nebulisers can be used on different patients following the appropriate reprocessing between patients as indicated by the manufacturer (Kendrick, Johns & Leeming, 2003).

Reprocessing is the process by which a device is made available for safe re-use and includes any or a combination of the following methods; cleaning, disinfection, decontamination, sterilisation, refurbishment and repackaging (MHRA, 2013).

The Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom has published a document on single-use medical devices, which states that a device designated as "single-use" must not be re-used. The device should only be used on an individual patient during a single procedure and then discarded. The re-use of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to avoidable risks (MHRA, 2013).

The re-use of single-use devices has legal implications and medical staff will bear the full responsibility for the safety and effectiveness when re-using single-use devices. In the case where the re-use or altered use of these devices results in an adverse reaction, the healthcare provider will be liable (Allen et al., 2005). Therefore, the packaging of the device must be checked for the symbol which means do not re-use/use only once/single use (MHRA, 2013).

“Do not re-use”, “single use”, or “use only once”

Single-use devices can also be marked as non-sterile which needs processing before use following the appropriate manufacturer’s instructions (MHRA, 2013).

“Symbol indicating that the device has not been sterilized”

The “single-use only” label to nebulisers has caused a negative reaction from medical and nursing staff in hospitals and has resulted in manufacturers of disposable nebulisers changing their labelling from single-use only to single-patient-use only. The hospital staff’s current practice of re-using single-use nebulisers were found to be unacceptable according to manufacturers. With the change in labelling to single-patient-use, the nursing staff can continue following the same application procedures of the nebulisers but with additional cleaning instructions (SMTL, 2000).

According to the SMLT, nebulisers that are reusable are labelled as such, and come with reprocessing instructions according to the reprocessing validation done by the manufacturer. These devices can also be used for extended periods according to the instructions, making costs lower. However, there is a cost associated with the reprocessing and that reprocessing instructions might not be followed, which can lead to the users being liable for any adverse consequences. Therefore hospital staff must be aware of the manufacturer’s cleaning instructions for a single-patient-use nebuliser to ensure safe re-use on the same patient (SMLT, 2000).

The Infection Control Team (ICT) of the Wirral Hospital National Health System (NHS) Trust in the United Kingdom identified an increase in the number of methicillin-resistant *Staphylococcus aureus* (MRSA) isolates in the sputum of patients in the respiratory ward in February 2002. With investigation, it was found that a number of single-patient-use nebulisers were contaminated with MRSA. These nebulisers were used for as long as aerosol therapy was prescribed even up to four times a day and for several days to weeks. There was no storage protocol in place and these nebulisers were left hanging open to the environment at the patients' bedsides. The ICT suggested that the wet nebulisers could have become contaminated by MRSA from patients in the same room. The different types of nebulisers under investigation were marked as single-use devices but were used as single-patient-use devices. Staff was also unaware that labelling of some nebulisers from the same manufacturer changed as older packaging were labelled differently. It has been noted that manufacturers are not required to inform their users of any changes made to the labelling of devices (Allen et al., 2005). The manufacturer's recommendations of these various nebulisers included washing and drying after each aerosolisation and usage for up to 30 days. However nebulisers used on patients with respiratory infection as well as single-use nebulisers, should be discarded after each use. Following this investigation protocols for cleaning were developed at the Wirral Hospital NHS Trust and single-patient-use nebulisers were bought from one manufacturer and replaced after every 24h. The re-use of single-use nebulisers was also not permitted. Replacing the nebulisers every 24h were reported to be less expensive than the cost of cleaning them as well as assuming less than the cost implications from possible outbreaks of infection in the future (Allen et al., 2005).

It is important to educate healthcare workers in the appropriate usage and decontamination of nebulisers (Parker, 2004). It is also suggested by Lester et al. (2004) that nebuliser cleaning/ disinfection/replacement education should be included in the curriculum of physiotherapy institutions or persons who dispense medication for nebulisations.

2.2.3 **Medication Used for Nebuliser Therapy during Mechanical Ventilation**

Delivering drugs through aerosol therapy during MV is being complicated by the presence of the endotracheal tube. The endotracheal tube causes a decrease in the efficiency of drug delivery and drug losses also occur within the ventilator circuit. Nevertheless, optimal methods used during the implementation of nebulisers or MDIs during MV, will ensure that drug delivery is as efficient as that of the ambulant, non-intubated device, its configuration with the ventilator, the patient's position, synchronisation with the ventilator, ventilator circuit conditions and

ventilator settings (Dolovich & Dhand, 2011). Ehrmann et al. (2013) reported that evidence from various studies have provided data for developing practices that are associated with an increase in efficacy and/or safety of aerosol therapy during MV (Dhand, 2004; Dhand, 2008; Dolovich & Dhand, 2011).

A long list of drugs are administered as aerosols to patients receiving MV that includes bronchodilators, prostaglandins, corticosteroids, mucolytics, proteins, surfactant, antibiotics, antibacterials, antifungals and a number of diverse agents for e.g. aerosolised insulin (Dhand, 2007; Khilnani & Banga, 2008).

Bronchodilators are the most frequently used drugs in patients with asthma or chronic obstructive pulmonary disease (COPD) receiving MV (Dhand, 2007). The administration of bronchodilator therapy to patients with COPD during MV with either a nebuliser or pMDI has shown to improve respiratory mechanics (Dhand, 2007). Indications for the use of bronchodilator administration in MV include the following conditions; acute bronchospasm or wheezing, increased airway resistance, dynamic hyperinflation, weaning difficulties or ventilator dependence. The aims of bronchodilator therapy are to decrease the work of breathing, alleviate bronchoconstriction and dyspnoea.

An international survey representing 611 departments in 70 countries, which included South Africa, showed that bronchodilators were the most common delivered drugs followed by steroid therapy in MV (Ehrmann et al., 2013). Aerolised bronchodilators and steroids are recommended as supportive treatment for patients suffering from COPD. Aerolised antibiotics were used by 30% of respondents in more than five patients a year and in some departments this was a general practice specifically for colistin (Ehrmann et al., 2013). Ellis et al. (2013) found that bronchodilators (76%) followed by mucolytics (21%) were mostly administered to ventilated patients in ICUs in Johannesburg, South Africa. Combivent (bronchodilator) was the medication mostly used and Bisolvon (mucolytic) was the only drug that contained preservatives. It was reported in this study that a nebuliser that was stored wet due to residual Bisolvon did not present with bacterial growth (Ellis et al., 2013). These findings support the hypothesis put forward by Oie et al. (2006) that preservatives may assist in the inhibition of bacterial growth within a nebuliser if no decontamination has been done prior to nebulisation. However, Oie et al. (2006) noted that some aerosol drugs with preservatives may have less antibacterial activity if diluted and that microbial contamination of the nebuliser is still a possibility.

The use of aerosolised antimicrobial agents for the treatment of VAP has gained much attention. This is mainly due to nosocomial micro-organisms developing quick resistance to various systemic antimicrobials in ICUs. Aerosolised antimicrobials in MV can result in a direct deposit at the point of infection (Safdar, Crnich & Maki, 2005). Aerosolised antibiotics are increasingly prescribed for the treatment of VAP caused by multi-drug resistant (MDR) Gram-negative bacteria (Abu-Salah & Dhand, 2011).

Infections caused by a range of multi-resistant Gram-negative bacteria, such as *Acinetobacter spp.* or *Pseudomonas aeruginosa spp.* have been successfully treated with aerosolised colistin and polymyxin B. The addition of aerosolised tobramycin to systemic therapy in the treatment of respiratory-tract infections caused by Gram-negative bacilli has also shown more rapid results (Safdar, Crnich & Maki, 2005).

Several evidence-based consensus groups have, however, recommended against routine use of aerosolised antimicrobials for prevention of VAP due to the possible promotion of antimicrobial resistance (Joseph et al., 2010). Authors have also raised their concern regarding prophylactic aerosolised antimicrobials as early as 30 years ago (Safdar, Crnich & Maki, 2005). The regular implementation of prophylactic aerosolised colistin to patients in a centre for cystic fibrosis (CF) has led to an unusual resistance of a strain of *Pseudomonas aeruginosa* to colistin and subsequently was transmitted to other patients in the unit. The route of transmission was inconclusive and it was suggested that patient to patient transfer was a possibility (Safdar, Crnich & Maki, 2005).

Aerosolized antibiotics can successfully kill bacteria in the initial stages of an infection limited to the airway epithelium but evidence is lacking to indicate if this would be the same for VAP (Joseph et al., 2010). Aerosolised antibiotics used in addition to intravenous antimicrobials have shown positive results in the treatment of VAP as well as VAP caused by MDR pathogens whereby intravenous antibiotics alone were not effective (Abu-Salah & Dhand, 2011). The routine use of aerosolised antibiotics can only be recommended when intravenous antibiotics alone are unsuccessful (Abu-Salah & Dhand, 2011).

Disadvantages of aerosolised antibiotics include acute bronchoconstriction due to preservatives and antioxidants when intravenous preparation is used instead of antibiotics specially formulated for aerosol therapy (Michalopoulos, Metaxis & Falagas, 2011). Aerosol antibiotics are often more expensive than systemic antibiotics (Rubin, 2008). The

disadvantage of using a nebuliser is the quantity of antibiotic solution that gets wasted. During nebulisation a proportion is delivered to the lungs and the rest remains deposited in the nebuliser and tubing or escapes into the environment (Michalopoulus, Metaxis & Falagas, 2011). Antibiotic resistance can develop due to insufficient antibiotic concentration with the treatment of bacterial infections. The low concentration of antibiotics cannot successfully kill bacteria and can lead to the development of resistant pathogens (MacIntyre & Rubin, 2007). Bacteria are very capable of obtaining genetic information through various mechanisms to survive in an environment where antimicrobials are being used. These mechanisms provide a passage by which mobile deoxyribonucleic acid (DNA) elements can be transmitted to distant related bacterial species which results in the rapid development and spread of MDR bacterial pathogens (Mcdermott & Robert, White, 2003).

Nebulisers can become colonised with more than one species of bacteria or a strain of the same species when exposed to the environment (Ellis et al., 2013). Nebulisers stored wet and exposed to a warm environment can promote the transferral of plasmids between species in the chamber of the nebuliser and can promote the development and transmission of antibiotic resistance (Ellis et al., 2013). Additionally if the wet nebuliser was stored and contained an antibiotic with multiple bacterial species, antibacterial resistance can develop in a shorter period (Ellis et al., 2013). Contaminated nebulisers that were used to nebulise antibiotics can result in micro-organisms and antibiotics nebulised back to the patient (Prober et al., 2000).

Antibiotic aerosols can contaminate the ICU environment with prolonged administration of aerosolised antibiotics in non-intubated patients and potentially lead to a selection of MDR micro-organisms (Prober et al., 2000; Michalopoulos et al., 2011; Kallet, 2013). Antibiotic contamination of the environment through aerosolisation is a simple process and occurs frequently. The concentration of antimicrobials can also accumulate in the local environment if doses are increased, which explains the presence of tobramycin that has been observed on patients' skin (Prober et al., 2000). Antibiotics that escape to the environment through the use of nebulisers are, however, unable to eradicate bacteria due to low concentration, but can promote resistance to environmental strains which can be transferred to other patients (Rubin, 2008). The contamination of the environment with aminoglycosides in the presence of multiple resistant Gram-negative organisms can result in a significant increase in resistance to tobramycin. It has been suggested therefore, that nebulisers exhaust circuit filters and vent-

free nebulisers should be implemented to minimise environmental contamination (Prober et al., 2000).

2.2.4 Storage Methods of Nebulisers Used within a Ventilator Circuit

Ellis et al. (2013) found that most nebulisers in ICUs in Johannesburg, South Africa were stored either in a sterile drape or covered by a latex glove. The nebulisers stored in a sterile drape presented with higher concentrations of bacterial growth than nebulisers stored in a glove, paper bag or opened to the environment. Although storage of nebulisers under sterile drapes is common practice, no evidence could be found to support this storage method. Ellis et al. (2013) suggested that the increase in bacterial growth could be contributed to the dark environment under the drape and not the drape itself, as light inhibits the growth of some bacteria such as MRSA (Sheldon, Kokjohn & Martin, 2006).

Storage of nebulisers in latex gloves allows for more light penetration but prevents the nebuliser from drying and can potentially contribute to the growth of bacteria. This is important as most of the nebulisers in Ellis' study were stored wet in the ICUs. Only one nebuliser was stored with visible secretions and as expected presented with bacterial growth (Ellis et al., 2013).

Nebulisers that were stored still connected to running oxygen (1L/ml), presented with no bacterial growth. Ellis et al. (2013) suggested that the reason for this finding could be either that the oxygen assisted in drying the chamber of the nebuliser or that the running oxygen inhibited bacterial growth. The role of paper bags (obtained after a sterile pack had been opened) used to cover nebulisers in prevention of contamination could not be determined as those nebulisers were also connected to oxygen. It has been reported elsewhere that paper bags has a greater absorbency than latex gloves (Fisher et al., 1999). Ellis et al. (2013) suggested that paper bags could be more beneficial than gloves and sterile drapes due to their absorbency and increased exposure to light. Additionally, recordings can be made on the bag regarding the patient's name, date and time of aerosolisation sessions (Ellis et al., 2013).

As previously mentioned, nebulisers left open to the environment can become contaminated by pathogens in the surrounding air (Allen et al., 2005). Nebulisers stored wet and open can become contaminated with antibiotic aerosols which can result in the development of MDR pathogens. Additionally, contaminated nebulisers stored wet with antibiotics solution still left in the chambers after aerosolisation can have the same outcome (Ellis et al., 2013).

2.3 VENTILATOR-ASSOCIATED PNEUMONIA

Approximately one in seven patients admitted to hospitals in South Africa are at high risk of acquiring a healthcare-associated infection (HAI) (Brink et al., 2006). Nosocomial pneumonia is the most common infection in ICUs and the second most common nosocomial infection in the world (Jadhav, Sahasrabudhe, Kalley, & Gandham, 2013). This type of pneumonia, also referred to as hospital-acquired pneumonia (HAP), is defined as pneumonia that occurs ≥ 48 hours after admission to a hospital and that was neither present nor incubating at the time of admission (Brink et al., 2006). Ventilator-associated pneumonia (VAP) is the secondary result of intubation and MV and is preventable (Fields, 2008). Ventilator associated pneumonia is further defined as early-onset (occurring in less than five days after intubation) and late-onset (occurring five days or longer after intubation) (Gillepsie, 2009). The incidence of VAP differs between units, hospitals and countries. The incidence of VAP also varies in different units within the same hospital and is more prevalent in high density units (Klompas, 2007; Pieracci & Barie, 2007; Rea-Neto et al., 2008). Mortality rates due to VAP vary from 20% to 50% and may be as high as 70% in patients with multi-resistant invasive pathogens (Gillespie, 2009).

Endotracheal intubation inhibits the cough reflex, compromises mucociliary clearance, disturbs the tracheal epithelial surface and provides direct access for bacteria into the lower respiratory tract (Efrati et al., 2010). Micro-organisms gain access to the lower respiratory tracts in patients receiving MV through four mechanisms: a) most frequently by aspiration of micro-laden oropharyngeal, gastric or tracheal secretions around the cuffed endotracheal tube (Crnich, Safdar & Maki, 2005); b) adjacent contribution such as a pleural space infection (Efrati et al., 2010); c) inhalation of contaminated air or medication aerosols (Efrati et al., 2010); or d) by hematogenous transport of micro-organisms to the lung (Safdar, Crnich & Maki, 2005).

Other mechanisms that can potentially contribute to the high prevalence of VAP are unclean hands, apparel of healthcare workers, contaminated hospital surfaces and environment and respiratory equipment (e.g. nebulisers, resuscitation bags, ventilator circuits, tracheal tube), hospital water (*Legionella* spp. mostly implicated) and hospital air (e.g., *Aspergillus* spp. or the severe acute respiratory syndrome (SARS) virus.

The endotracheal-tube acts as a reservoir for micro-organisms which adheres to the tube to produce a biofilm. Biofilms are highly resistant to the effects of antibiotic therapy and play an important role in the late-onset of VAP due to the persistent colonisation of resistant organisms (Safdar, Crnich & Maki, 2005).

The architectural design of an ICU must ensure adequate space, easy to clean furniture and convenient locations for sinks to promote compliance with hand hygiene. Evidence that the current recommendation regarding ICU design can assist in decreasing of nosocomial infection is greatly needed (Crnich, Safdar & Maki, 2005).

Finally, studies have shown that ICUs that are inadequately staffed or staffed by temporary staff had increased rates of nosocomial pneumonia (NP). The increased rates are likely due to increased patient-to-staff ratios with noncompliance to hand hygiene and temporary staff being unfamiliar with the ICU's policies and procedures (Crnich, Safdar & Maki, 2005). According to the International Nosocomial Infection Control Consortium (INICC), (2010) report, a higher number of days spent on ventilator in the medical-surgical ICU were associated with the high percentage of VAP (Rosenthal et al., 2010). Ventilator-associated pneumonia is associated with increased mortality and morbidity, increased ventilator days, prolonged length of stay in ICUs and hospitals. Consequently this leads to high hospitalisation costs. In the public sector a stay per day in an ICU costs a minimum of R5000 in South Africa (Gillepsie, 2009).

2.3.1 **Pathogens that Lead to the Development of VAP**

The early-onset of bacterial NP develops within the first four days in patients with no risk factors for multidrug-resistant bacteria, and are usually caused by *Streptococcus pneumoniae, Haemophilus influenzae,* methicillin-sensitive *Staphylococcus aureus* and *Moraxella catarrhalis* (Brink et al., 2006). Antibiotic-sensitive enteric Gram-negative bacilli such as *Enterobacter* spp., *Escherichia coli, Klebsiella* spp., *Proteus* spp. and *Serratia marcescens* are also responsible for early-onset of bacterial NP. These pathogens can also occur in the late-onset of bacterial NP, but are usually due to methicillin-resistant *Staphylococcus aureus* (MRSA) and other multi-drug-resistant pathogens which include *Pseudomonas*, *Acinetobacter* and *Klebsiella* spp. (including isolates producing extended-spectrum beta-lactamase) (Brink et al., 2006). *Pseudomonas aeruginosa* and *Acinetobacter anitratus* occur slightly later in the patient's stay in ICU and are a serious cause of VAP. Specific risk factors are associated with these pathogens such as prolonged hospital stay, prior antibiotic therapy and severe underlying diseases. (Feldman, 2005). The frequency of MDR Gram-negative bacteria and MRSA in VAP are increasing in the ICUs (Abu-Salah & Dhand, 2011). Other common causes

of VAP include infection by Enterococci and Coagulase-negative Staphylococci (CoNS) (Joseph et al., 2010). *Enterococcus* spp. are generally seen as part of the normal flora of the gastrointestinal and genitourinary tract of the body, however, they have emerged as one of the leading causes of nosocomial infections and shows an increase in multi-drug resistance (Prakash, Rao & Parija, 2005). Other pathogens that may also cause VAP, even though to a lesser extent, include fungi e.g. *Candida* and *Aspergillus* spp. and pathogens such as *Legionella* spp. (Feldman, 2005). Uncommon pathogens causing VAP includes the Herpes simplex virus, *Mycoplasma pneumonia*, *Neisseria* spp.*, Pneumocystis jiroveci* etc. (Joseph et al., 2010). The approximate frequency with which these micro-organisms cause NP is; Gram-negative bacilli (40-75%), Gram-positive cocci (5-30%) anaerobes (1-5%), fungi (1-5%) and other pathogens which include *Legionella* spp. and *Moraxella catarrhalis* (0-5%) (Feldman, 2005). Other factors contributing to the development of nosocomial infections are patient susceptibility and bacterial resistance (WHO, 2002).

2.3.2 The Role of Contaminated Nebulisers in the Development of Ventilator-Associated Pneumonia

Various studies, as early as the 1960s, have identified aerosols produced by nebulisers as a possible source of VAP (Reinarz et al, 1965; Edmondson, Reinarz & Pierce, 1966; Craven et al., 1984). In addition, early systematic reviews and other reports indicated the relationship between nosocomial infection and bacterial contamination of nebulisers and other apparatus used for the treatment of respiratory infections in hospitals (Mertz, Scharer, & McClement, 1967; Phillips & Spencer, 1965; Ringrose et al., 1968).

Ellis et al. (2013) reported that 52% of nebulisers that were used within ventilator circuits in ICUs in Johannesburg presented with bacterial growth. Single-use jet nebulisers were mostly used and all were being re-used although they were marked as single-use devices.

Jadhav et al., (2013) studied the microbial contamination of respiratory equipment including nebulisers used in the ICUs, wards, casualty, and outpatient departments. Bacteria were isolated in 47.5% of the nebuliser swabs taken from their chambers. The total number of bacterial isolates collected from the various respiratory equipment indicated that 87.14% were Gram-negative and 31.14% were Gram-positive cocci. The micro-organisms identified in the chambers of nebulisers included: *Pseudomonas* spp., *Acinetobacter* spp., *Klebsiella pneumoniae*, *Escherichia coli* and *Stenotrophomonas maltophila*, MRSA, Methicillin sensitive *Staphylococcus aureus* (MSSA), CoNS (Jadhav et al., 2013).

Oie et al. (2006) found that 26.3% of nebuliser solutions showed microbial contamination due to the use of contaminated ultrasonic nebulisers. Microbial contamination was significantly lower when disinfection of the ultrasonic nebulisers was performed at 24-h intervals. Additionally the use of multi-dose medication vials and the rinsing of nebuliser chambers with tap water may contribute to contamination of nebulisers and result in the development of VAP (Tablan, 2003).

No research could be found regarding contamination rates of VMNs when used in ventilator circuits. These nebulisers have only recently been introduced to ICUs in South Africa and specifically to ventilator circuits. There also seems to be a lack of knowledge regarding the role that physiotherapists should play in the decontamination of jet nebulisers, the protocols they should use and their adherence to these protocols. This is of great importance as physiotherapists use nebulisation as a source of medication on a regular basis as a technique in patients receiving MV in ICUs in South Africa (Ellis et al., 2013).

2.4 HOSPITAL AIR

The indoor quality of air in hospitals has become an important part of hospital management protocols. Healthcare-associated infections caused by transmission of pathogens through the airborne route have gained much attention in the last two decades. Critically ill patients that are exposed to airborne pathogens may be more susceptible to cross-infection and this can result in a significant increase in morbidity and mortality (Huang et al., 2013). This is of great concern especially in the hospitals in South Africa where human immunodeficiency virus (HIV) and tuberculosis (TB) occurs in high numbers (Setlhare et al., 2014).

The main pathogenic micro-organisms resulting in healthcare-associated infections by airborne transmission includes fungi such as *Aspergillus flavus,* Gram-negative bacilli such as *Neisseria meningitidis, Serratia mascescens, Staphylococcus aureus, Streptococcus pyogenes, Streptococcus pneumoniae* and Tuberculosis bacilli (Kim, Kim & Kim, 2010).

Pathogens in the air can be transported on particles derived from skin or droplets generated from the upper or lower respiratory tract, mouth, nose or droplets generated through vomiting, and diarrhoea (Eames, Tang, Li, & Wilson, 2009). Creamer et al. (2014) identified MRSA from air samples mainly in ward bays where MRSA-positive patients were hospitalised. Samples taken from patients or environment which included mattresses, bedrails and locker detected MRSA in 50% cases which suggest dispersal from patient to the surrounding air. Mattresses

were the item from which MRSA was mostly isolated. Methicillin-resistant *Staphylococcus aureus* are also able to survive on hospital surfaces for long periods and may be transmitted to patients and/or environment. Patients appear to shed skin scales more during the night and early mornings and can be dispersed over great distances with lengthy activities such as bed making. Higher rates of MRSA were detected in both air and surface samples early in the morning (Creamer et al., 2014.). Huang et al. (2013) studied airborne and surface-bound microbial contamination in two ICUs. *Pseudomonas aeruginosa* was identified as the most frequently isolated bacterium on surface and in air samples and was the only pathogen indicating a positive correlation of mean counts between both samples. The ventilator presented with the most contamination in both total pathogenic bacteria colony counts and frequency of positive detection. The order of positive detection frequency for the four bacteria identified in the air samples corresponded with both bacteria isolated from surface samples and the percentage of patients infected by the same bacteria (42% for *Pseudomonas aeruginosa* and *Escherichia coli*, 35% for *Staphylococcus aureus*, and 33% for *Acinobacter baumannii*). Furthermore, mean airborne counts and detection frequencies of these bacteria were higher after patient visitation periods (Huang et al., 2013).

Gaudart et al. (2013) studied the environmental variability of micro-organisms in a medical ICU and surgical ICU by measuring the total viable count on surfaces and in the air. The total viable counts of air and surface samples were generally higher in the medical ICU. Colony counts in the air and surface samples varied between height, locations, bedside area and bed occupancy. Severity of illness was a constant predictor of contamination. Surface contamination is affected by aero-contamination as some pathogens will eventually settle on surfaces. Pathogens in the air can be distributed across a room at different distances due to air movement (Gaudart et al., 2013). Organisms that have settled on surfaces may be transferred to other surfaces by touch or air currents generated by human movement in the unit. The air and surfaces within bed spaces were found to be consistently highly contaminated (Gaudart el al., 2013). Larger respiratory droplets can fall on the ground and contribute towards dust particles which can be suspended and re-suspended by activities such as dressing, sweeping or bed-making (Hobday & Dancer, 2013).

Filamentous fungi and moulds are the main pathogens commonly found in ambient air, including hospital air (Safdar, Crnich & Maki, 2005). *Aspergillus fumigatus*, *Aspergillus flavus, Aspergillus terreus* are being recognized as common causes of nosocomial infections (Jadhav et al., 2013).

Nosocomial infections caused by filamentous fungi are mostly acquired through air transmission (Crnich, Safdar & Maki, 2005). Outbreaks through this route have been related to breakdowns in hospital air-handling systems (Lutz et al., 2003) and during periods of hospital construction (Panackal et al., 2003).

The survival of pathogens in the air depends on multiple factors such as residence time in the air, humidity, temperature, UV light and other atmospheric pollutants (Eames et al., 2009). Furthermore, airborne droplets can be distributed by the movement of people and their clothes, opening of doors, ventilation systems and electrical equipment producing thermal gradients (Eames et al., 2009). Most of the pathogens that cause airborne infection cannot tolerate sunlight. *Streptococci* can survive for only five minutes in direct sunlight and over an hour in diluted daylight whereas sunlight kill *Staphylococci* within 70 minutes of direct exposure (Hobday & Dancet, 2013). *Streptococci* and *Staphylococci* are both Gram-positive cocci and are causes of early onset of VAP (Feldman, 2005).

In the pre-antibiotic era the hospitals were designed to allow fresh air and sunlight to reduce the possible risk of infection. Today modern healthcare settings are sealed insulated structures with forced ventilation that may favour the persistence and transmission of pathogens (Eames, 2009; Hobday & Dancer, 2013). Further research is needed to evaluate the risks associated with airborne pathogens in the healthcare setting and the potential benefits of fresh air and sunlight on surface decontamination (Hobday & Dancer, 2013). The lack of reports regarding the distribution and extent of microbial contamination of hospital air in South Africa is a concern especially with the increase risk of acquiring hospital-acquired infection (HAI) through airborne route and the emergence of drug resistance to infectious diseases (Setlhare et., 2014).

Providing ventilation to buildings is the process whereby outdoor air are supplied and distributed through the building and at the same time diluting and removing pollutants emerging from within the building (Eames et al., 2009). The conservation of adequate air exchange rates which refers to rate by which outside air replaces indoor air in a building together with air filtering has become important methods used in ventilation systems to ensure air quality in hospitals (Huang, 2013). Most hospitals use negative pressure isolation for areas highly exposed to infection such as operating theatres and ICUs. This method of ventilation assists in controlling and preventing the transmission of exogenously-acquired healthcare-associated infections (Huang, 2013).

Air purifiers include filtration units and chemical oxidisers (e.g., ozone and ionised air) and have also been used in clinical settings to control microbial contamination (Huang, 2013). High-efficiency particulate air (HEPA) filters have been shown to reduce the airborne concentration of *Aspergillus* spp. and fungal levels (Mahieu et al., 2000; Araujo et al., 2008). Recently an automated air disinfection system has shown to reduce both airborne microbial counts and environmental contamination in the hospital environment. This system produces hydroxyl radicals which have shown disinfection characteristics. Ventilation systems can become contaminated due to inadequate maintenance and poor design and have been associated with outbreaks of tuberculosis and MRSA (Hobday & Dancer, 2013).

2.5 FUNGAL INFECTIONS IN THE HOSPITAL SETTING

Fungal infections are increasingly becoming common in hospitals today, and more prevalent in ill patients especially in the ICUs. The National Nosocomial Infections Surveillance system report indicated a constant increase in the rate of nosocomial infection from January 1992 to June 2004. It is believed that fungi take the lead in infecting the immune-compromised patient who is usually well covered with antibiotics (Jadhav et al., 2013).

Jadhav et al. (2013), indicated another potential risk of fungal cross-infection. In the study, swabs were obtained from the inner surfaces of the oxygen humidifiers and Hudson nebuliser chambers in the ICUs, general wards, casualty and outpatient departments. A total of 53/70 (75.71%) fungal isolates were identified of which the ICUs presented with the highest growth 23/33 (69.70%). The ICUs included the medical ICU, surgical ICU and neonatal ICU. *Aspergillus fumigatus* (33.96%) was predominantly isolated, followed by *Aspergillus niger* (18.86%). The following fungal isolates were identified in swabs taken from the chambers from nebulisers: *Aspergillus fumigatus*, *A. niger*, *Fusarium* spp., *Chaetomium* spp., *Streptomyces* spp. and *Candida* spp. There are several reports on the on-going prevalence of non-albicans *Candida* among hospitalized patients (Jadhav et al., 2013).

As previously mentioned certain *Aspergillus* spp. have become familiar causes of nosocomial infections. *Aspergillus* species are ever-present and it can also be found in unfiltered air, ventilation systems, oxygen humidifiers, nebuliser tubing as well as dust from construction, carpeting, floor and ornamental plants. Hyalohyphomycosis e.g. nondematiaceous moulds have also recently been recognised as pathogens causing nosocomial infections (Jadhav et al., 2013). Nebuliser chambers colonized by fungi can result in the direct delivery of fungal pathogens to the patients' airways (Jadhav et al., 2013).

2.6 INFECTION CONTROL AND DISINFECTION PRACTICES

Infection control in the ICU emerged from hospital-wide infection-control programs due to the Staphylococcal pandemic of the late 1950s and early 1960s (Warren & Kollef, 2005). The increasing rates of healthcare-related infections and antibiotic resistance today (Dettenkofer & Spencer, 2007) and the importance of infection control is a field of great concern for healthcare professionals (Ellis et al., 2013).

The implementation and quality of infection control programmes varies across healthcare institutions in South Africa and the costs associated with HAIs drain the already limited financial reserves assigned to healthcare (Brink et al., 2006). Health-care professionals in the ICU need an infection-control policy that is well explained, evidence-based, and eagerly accepted by all staff. Leadership in the ICU and hospital is responsible to set a culture of cooperation (Warren & Kollef, 2005).

The hands of health-care professionals are the most common vehicle for the transmission of healthcare-associated micro-organisms between patients and within the healthcare environment. Hand hygiene is the most important measure for preventing the spread of antimicrobial resistant micro-organisms and for reducing healthcare-associated infections (Allangranzi & Pittet, 2009). Washing hands is therefore an important infection control and safety measure. Hands need to be washed as meticulously and promptly between patients and after contact with respiratory care equipment that are contaminated by them such as nebulisers, ventilators and humidifiers (Jadhav et al., 2013). An investigation of an outbreak of *Candida tropicalis* fungaemia in a neonatal intensive care unit (NICU) was reported in neonates who received parenteral nutrition and antibiotic therapy. Hand washing is an important infection control measure as *Candida tropicalis* was isolated from two NICU workers and not from the NICU environment (Jadhav et al., 2013). Hand hygiene in the ICU is especially important when handling critically ill patients as they are vulnerable to nosocomial infection due to their immune-compromised state. Qushmaq et al. (2008) indicated that only 20% of health-care providers (clinicians, nurses, residents and physiotherapists) adhered to the hand hygiene recommendations. The highest adherence to the current recommendation was among the physiotherapists.

Studies have indicated the association between increased nursing workload and the development of nosocomial infections amoung ICU patients (Dang et al., 2002; Crnich, Safdar

& Maki, 2005; Warren & Kollef, 2005). Therefore it is highly important for ICUs to be adequately staffed to ensure compliance with fundamental infection control practices and the performing of essential care (Crnich, Safdar & Maki, 2005). Studies worldwide have not highlighted the role that the staffing levels of other healthcare-care professionals including physiotherapists play in the incidence of nosocomial infection (Warren & Kollef, 2005). Therefore, it is highly important for ICUs to be adequately staffed to ensure compliance with fundamental infection control practices and the performing of essential care (Crnich, Safdar & Maki, 2005).

Ramsey et al. (2001) indicated that physiotherapists sharing multidose albuterol vials among several patients in a community hospital were associated with the outbreak of *Burkholderia cepacia*. *Burkholderia cepacia* was grown from cultures taken from three previously opened multidose vials. Nebulisers were not dried between aerosolisation sessions and probably contributed to the outbreak. It was suggested that physiotherapy departments in the hospital must emphasize the adherence to infection-control protocols, particularly among temporary and new physiotherapy staff (Ramsey et al., 2001).

The four steps in nebuliser care according to the Cystic Fibrosis Foundation (CCF) includes; cleaning, disinfecting, rinsing and air drying if permitted by the manufacturer (O'Malley, 2009). There are several disinfection protocols, but the protocol followed must be permitted by the manufacturer's guidelines. Tap water can only be used for the cleaning process prior to disinfection and not be used for the final rinse. Furthermore the final rinse must be done with sterile water as distilled water is only regulated to prevent coliform bacteria (e.g. *Klebsiella, Enterobacter* and *E. coli*) (O'Malley, 2009). O'Malley found that the hospital nebuliser cleaning protocol used for patients with (CF) conflicted with the CCF recommendations. O'Malley, (2009) studied the nebuliser protocol followed in the Children's Memorial Hospital in Chicago and found it was safe. There was no contamination found in nebulisers with *Pseudomonas aeruginosa, Staphylococcus aureus, Haemophilus influenza or Burkholderia cepacia* after it has been re-used without cleaning for 24h and then replaced.

Jadhav et al. (2013) found that contamination levels dropped significantly after nebuliser chambers were washed with soap and distilled water prior to disinfection with 70% alcohol. After implementing this protocol the fungi colonisation rate dropped from 70% to 15% and the bacterial colonisation rate from 75% to 12%. This protocol was done with strict compliance to hand hygiene (Jadhav et al., 2013).

Delivering care to the critically ill patient is complex, therefore policies and procedures are needed to assist in the organisation of any ICU. These ICU policies should include evidence-based infection control practices which demonstrate prevention or reduction of nosocomial infections. Almost all international accreditation programs for private as well as state hospitals base their review of ICUs not only on policies by law, but also whether these policies are adhered to. To succeed in the implementation of ICU policies, the policies should be easy to follow, easy to understand and realistic (Warren & Kollef, 2005).

Ellis et al. (2013) found that none of the ICUs in Johannesburg, South Africa had nebuliser decontamination protocols in place and that ICUs differ in their methods of storing re-used jet nebulisers. Physiotherapists play a vital role in the respiratory management of patients receiving MV in the ICUs. It is recommended that nursing staff and especially physiotherapists should be informed regarding the possible contamination of nebulisers used in ventilator circuits as nebulisation is used to either assist in the clearance of secretions or relieve bronchospasm while patients receive MV.

CHAPTER 3

3. METHODOLOGY

3.1 INTRODUCTION

The methodology followed in this study was based on a previous study undertaken by Ellis et al, (2013) in ICUs in Johannesburg hospitals, South Africa.

In the current study, additional air samples were taken at the bed sides where nebulisers were kept and apart from the jet nebuliser, samples were also taken from VMNs that were recently introduced to ICUs in Pretoria, South Africa. This section describes the audit tools used to gather information regarding nebuliser decontamination protocols and storage methods of these nebulisers. Details of the study design, sample selection, instruments and apparatus used to collect samples from nebulisers and the surrounding air to evaluate possible contamination have been included. The process of identifying bacterial and fungal colonies, multiple species and higher concentrations of bacteria as well as the methods used for bacterial culture identifications have been described. Matters related to ethical clearance for the study have also been included in this chapter.

3.2 STUDY DESIGN

A cross-sectional observational analytical study design was used to study the practise surrounding the use of nebulisers within a ventilator circuit and contamination levels in ICUs in Pretoria.

3.3 SAMPLE SELECTION

3.3.1 Hospitals

3.3.1.1 Inclusion criteria for hospitals

The ICU's of private as well as government hospitals identified in Pretoria, South Africa were approached for participation in this study. Three main private hospital groups were represented in this sample selection which included, Netcare, Life Healthcare and Medi-Clinic. These hospitals were selected within a geographical location to obtain a representative sample. All the ICUs were randomly approached for participation within the hospitals that gave consent to conduct this study.

Hospitals that were approached for participation in this study:

Private Hospitals:

- Unitas Hospital (Netcare)
- Medforum Hospital (Mediclinic)
- The Wilgers Hospital (Life Healthcare)
- Pretoria East Hospital (Netcare)
- Eugene Marais Hospital (Life Healthcare)
- Kloof Hospital (Mediclinic)
- Zuid-Afrikaans Hospital (independent)
- Little Company of Mary Hospital (Life Healthcare)
- Meulmed Hospital (Mediclinic)
- Jacaranda Hospital (Netcare)
- Astrid Hospital
- Moot Hospital (Netcare)

Government Hospitals:

- Steve Biko Academic Hospital
- Kalafong Hospital
- One Military Hospital
- Dr George Mukhari Hospital

3.3.1.2 **Exclusion criteria for hospitals**

Hospitals situated outside of Pretoria, South Africa were excluded.

3.3.2 **Nebulisers**

3.3.2.1 **Inclusion criteria for nebulisers**

Nebulisers in the ICU at the time of audit were selected for assessment. These nebulisers were used within a ventilator circuit either for an endotracheal or a tracheostomy tube.

3.3.2.2 **Exclusion criteria for nebulisers**

Nebulisers that were kept at the patient's bedside but not used for inhalation therapy within a ventilator circuit.

3.3.3 Sample Size

Ellis et al (2013) conducted a similar survey in Johannesburg, South Africa and screened 269 ICU beds. The sample size in their study was calculated according to the estimated prevalence of ventilated patients in ICU set at 50%. This calculation was based on the number of ICU beds in Gauteng as reported by Bhagwanjee and Scribante (2007). They found that the average number of ventilated patients in ICUs in Johannesburg was 4.43 (SD ± 2.94) and that 16.7% of these patients received nebuliser therapy; a total of 45 nebulisers were identified and assessed. Based on these results and in concordance with a statistician the sample size for the current study was set a minimum of 270 ICU beds to be screened to identify nebulisers used within a ventilator circuit in Pretoria.

3.4 PROCESS OF OBTAINING INFORMED CONSENT

3.4.1 Ethical Clearance

Ethical clearance to perform this study was sought and obtained from the University of the Witwatersrand, Human Research Ethics Committee (HREC) prior to the study. Ethics clearance certificate number M120514 (Appendix 1). The names of the participating hospitals were coded and kept confidential. The data collected was only accessible by the researcher. Each hospital has been given the opportunity to access their results.

3.4.2 Hospital Manager/Chief Executive Manager/Infection Control Manager

The hospitals were approached and communication done via a letter addressed to the hospital manager/chief executive officer (CEO) and the infection control manager. This letter included an information sheet to explain the nature of the study as well as a consent form (Appendix 2, 3). Possible participation of the hospitals was established through phone calls and meetings with the hospital manager/CEO/infection control manager of each hospital and confirmed by them signing the consent form. The manager/CEO/infection control manager was allowed to decline participation of their hospital in this study.

3.4.3 Intensive Care Unit Manager

The unit manager of the selected ICUs was approached after consent was obtained from the hospital manager/CEO/infection control manager of that hospital.

The unit managers of each ICU were identified and approached regarding the study via letter (Appendix 4, 5). This letter included an information sheet to explain the nature of the study as well as a consent form. After consent was obtained from the unit manager an interview was

set up to discuss an appropriate time and date for audit. The unit manager was also given the opportunity to ask questions and to highlight any concerns regarding the procedures that were to be followed.

3.4.4 Patients

There was no direct contact with patients during this study and therefore no consent from the patient was needed. The patient's treatments and nebulisation schedules were not altered or affected. Nebulisers were returned to the patient's bedside, in its original position and condition to reduce the impact on the patient's treatment. The use of sterile swabs and sterile procedures ensured minimal risk of possible contamination.

3.5 PILOT STUDY

Nebuliser and air swabbing protocols were established through a pilot study done at one of the participating hospitals. Prior to the pilot study the researcher practiced methods for swabbing and air sampling under supervision at the University of the Witwatersrand PML laboratory to ensure consistency. The methods followed during the pilot study included the following:

3.5.1 Swabbing and Streaking Method

Swabbing of the blood agar plates (BAP) (Figure 3.1) with regards to the nebuliser was undertaken with a sterile swab by streaking on the surface from side to side in parallel lines across the plate without digging into the agar. The BAPs were pre-prepared at the University of the Witwatersrand Pharmaceutical Microbiological Laboratory (PML). Mueller Hinton powder (19g) was mixed with 500ml of distilled water and autoclaved. The solution was mixed with 22.5ml (5%) sheep blood after it cooled down. An automatic pipette was used to pour the blood mixture into the plates to set. Before storing the plates in the fridge each plate was checked for purity, covered and stored upside down in steel baskets.

Figure 3.1: Blood Agar Plate

A culture medium, such as blood agar, supports the growth and development of various micro-organisms. Sterile sheep blood is used to enrich microbiological culture media to demonstrate the typical growth features of these micro-organisms such as haemolysis. Most clinical microbiology laboratories use blood agar to identify the haemolytic reaction as well as colonial morphology of primary cultures. This establishes a platform whereby the selection of colonies from primary culture for further growth, can be made. Sheep blood is the most ideal used for blood enriched agar (Magbojos et al., 2011). The following procedures and protocols to collect nebuliser samples were established and followed during the pilot study:

The researcher followed a sterile procedure within the cubicle of the patient. A trolley was used as a working station. The trolley was wiped with 70% alcohol. Hands were washed using the appropriate technique and nitrile powder free latex gloves and plastic apron were applied before each procedure. Procedures were specifically followed according to the type of nebuliser sampled.

3.5.1.1 **Micro Mist small volume nebuliser**

The Micro Mist small volume nebuliser was removed from the oxygen tubing and/or covering and placed on sterile gauze on the trolley. The easy-seal threaded cap was removed and placed on sterile gauze. The base plate was then removed without touching the sides of the chamber and also placed on the sterile gauze. A sterile swab was dipped into the residual solute within the reservoir of the nebuliser without touching the sides of the chamber. The swab was immediately streaked across a BAP and covered. This procedure was repeated to collect two sets of BAPs. If the reservoir was dry or there was less than 2ml of liquid in the reservoir, 2ml of 9% sodium chloride was added to the reservoir. The BAP was marked according to date, time and hospital as well as type of organism to be cultured. Each nebuliser was reassembled and returned to the patient's bedside in its original position and condition.

3.5.1.2 **Aeroneb solo® nebuliser**

The same procedure was followed with the Aeroneb system. The Aeroneb system is manufactured to stay attached within the ventilator circuit and only its plug needed to be opened to do swabbing of the liquid within the reservoir. The sides of the chamber were not touched during the swabbing procedure. After two sets of streaked BAPs were collected the plug was closed.

3.5.2 **Method of Collecting Air Samples**

The air samples were collected with the use of an air sampler. The Surface Air System (SAS) sampler (SAS International PBI, Milan, Italy) was used to collect the air samples. The SAS (Figure 3.2) is considered the international standard for portable air microbiology samplers. The SAS sampler makes use of several models which use the same principle. Air is aspirated at a fixed speed for variable time through the aspirated head which consists of small holes of a special design. The laminar air flow is directed onto a contact plate. The plate is removed, covered and incubated after the chosen cycle has been completed. The organisms cultured after incubation are then visible to the naked eye and can be counted and assessed (SAS, 2014).

Figure 3.2: Air Sampler

For this study the SAS sampler has been programmed to sample a constant 200 L of air for each air sample taken which is in line with the procedures outlined by Perdelli et al. (2008). The objective for collecting air samples at the bed sides of patients where nebulisers were kept was to determine if colony counts were similar to that found in the nebulisers and to identifying similar micro-organisms cultured from contaminated nebulisers and air samples.

The handling and use of the air sampler were practiced at the PML to ensure the correct application. This included the cleaning of the body and the chamber of the air sampler. The cleaning was done by disinfecting the aspirating metal head and chamber with 70% alcohol. After allowing the air the SAS sampler to dry completely it was positioned upright on a stable surface and the BAP inserted. The sampler were programmed and set at 200L. At the end of the cycle, the agar plate was removed and the disinfecting procedure repeated. The following

procedures and protocol to collect air samples were established and followed during the pilot study:

Two air samples were taken at the selected bedsides where nebuliser samples were taken. The SAS sampler was positioned on the trolley no more than one meter away from the ventilator at the bedside. An aseptic procedure was followed at all times. The program was selected at 200 L. The procedure was repeated to collect two sets of air samples. Each BAP was coded and the time and date was documented. After collecting the nebulisers and air samples, each BAP was put in a zip lock bag and stored upside down in a cooler box for safe transportation to the PML at the Wits University and to prevent fluctuation of temperature. Cooler boxes were utilized during transportation to keep temperature constant. Microbial cultures remain dormant in cooler temperatures and thus kept in this manner until incubations were undertaken. The trolley was cleaned and the swabs, gloves, apron and gauze were discarded before the next assessment commenced.

Four BAPs were collected at each bed side, two air samples and two nebuliser samples. All samples were stored upside down in a cooler box and transported by car to the PML for incubation. One air BAP and one nebuliser BAP were incubated for 25°C for seven days for possible fungal contamination and the other BAPs incubated for 37°C for 24h for possible bacterial contamination. These BAP were placed upside down in the incubator and time and date were documented.

After incubation the plates were removed and the BAPs assessed with the assistance of an expert in microbiology for fungal and bacterial growth. The BAP (Figure 3.3) were assessed according to the number of colony forming units (CFU) and each colony was described according to elevation, colour, shape, size, surface, margins, density, pigments and the presence of haemolysis. The data collected during the pilot study were not included in the final results.

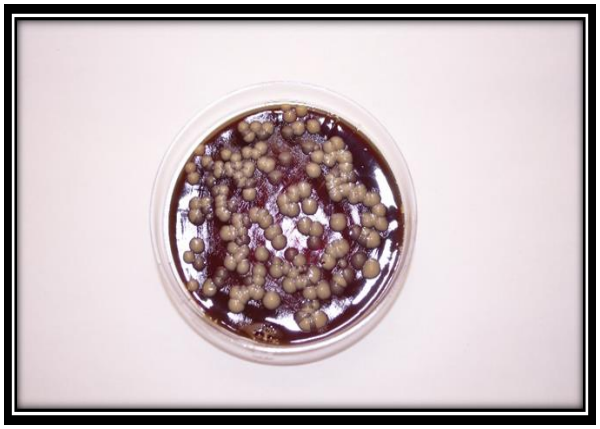


Figure 3.3: Blood Agar Plate with Colonies

3.5.3 Application of the Audit Tools

The audit tool used by Ellis et al (2013) was reviewed and adapted according to the objectives for this study. The content of the revised audit tool was reviewed by two senior researchers prior to its use in the study. Audit tools were completed during the pilot study to practice the collection of information from the environment and patients' charts.

The audit tool used to collect information consisted of two parts (Appendix 6). The first related to the collection of the demographic data (Section A) of the unit and the second related to the individual assessment (Section B) of each nebuliser selected according to the inclusion criteria. Section A included information regarding the type of ICU, number of beds in the unit, number of ventilated patients and those receiving nebulisation. The last part of Section A consisted of information regarding the protocol of decontamination of the unit and the method that was used to store the nebulisers. Any additional observations that were made during assessment were also documented.

Section B included information regarding the type of nebuliser, the manufacturer, single use/single patient use/autoclave, medication used for nebulisation, the days of nebuliser use and usage per day. The second part consisted of collecting information regarding the environment at the bed side and the method used to store the nebulisers. Visual inspection of each nebuliser was done to document the presence of contamination. Observations of the environment were also made and included the presence of windows, type of light, isolation cubicle and blinds. The methods used to store nebulisers were documented (e.g., open to environment, gloves, paper bag, sterile cloth and oxygen connection).

The time of assessment and additional observations of the environment were documented for e.g. if the patient was isolated and the various air filtering systems for each ICU. The additional information collected from the environment were not included in the final results. There were no discrepancies found regarding the methods of sample collection. During the pilot study the routine of the procedures were established and documented.

3.6 DATA COLLECTION

3.6.1 Completion of Section A of the audit tool with Unit Manager/Shift Leader

The unit manager or shift leader of the ICU was asked questions in order to complete Section A of the audit tool on the day of audit. Thereafter the unit manager/shift leader identified the beds in the unit of patients receiving MV. The unit manager/shift leader assisted in identifying nebulisers at the bedsides of patients in the ICU which was then listed for assessment.

3.6.2 Assessment of Nebuliser and Environment

The second part of the audit tool (Section B) was completed for nebulisers at the bed sides of patients that were identified by the unit manager for assessment. The nurse at the bedside was approached to discuss the nature of the study and to answer any questions arising from the discussion. The researcher ensured that the research procedure did not interfere in the patient's care at the time of audit. The first part of Section B was completed by gathering information from the ICU chart or with the assistance of the nurse. The second part consisted of observations made regarding the environment and the nebuliser at the bed.

3.6.3 Collection of Nebuliser and Air Samples

Nebuliser swabbing and air samples were done by following the protocols established and practiced through the pilot study mentioned above.

3.7 ASSESMENT AND IDENTIFICATION PROCEDURE

The BAPs were assessed for fungal and bacterial growth after the incubation time was completed as practiced at the PML. All information collected during the assessment of each BAPs was written up on a Microsoft Excel spreadsheet and filed. Similar colonies cultured from the air samples and nebulisers were grouped according to their visual description for each hospital. The most frequently observed colonies which were similar and identified in both nebuliser and air samples for each hospital were documented.

The five most frequently observed colonies cultured from the air as well as nebuliser for each hospital were identified and selected for identification. These colonies were streaked across Tryptone soya agar (TSA) for identification. These plates were pre-prepared at the PML at Wits University.

3.7.1 Streaking Method on TSA for Identification

Bacterial colonies grown on BAPs (Figure 3.4) were streaked on TSA for further identification under supervision at PML. A sterile petri dish with TSA was labelled at the bottom before streaking was done. The Bunsen burner was used to flame the inoculating loop to redness. After the loop was cooled down a loopful of colony was streaked on the petri dish from side to side in parallel lines similar to the method used for streaking the BAP. These plates were incubated for 37°C for 24 hours and stored upside down in steel baskets in the fridge. API strips were used to assist in identification of micro-organisms (higher concentration of bacteria as well as CFU). Figure 3.5 is a diagrammatic representation of the processed followed during the data collection period.

Bacterial colonies on BAPs of Micro Mist small volume Nebulisers

Fungal colonies on BAPs of Micro Mist small volume Nebulisers

Bacterial colonies on BAPs of Aeroneb Nebulisers

Fungal colonies on BAPS of Aeroneb Nebulisers

Bacterial colonies on BAPs of Air Samples

Fungal colonies on BAPs of Air Samples

Figure 3.4: Colonies on BAPs of Nebulisers and Air Samples

3.8 DATA ANALYSIS

Descriptive statistics was used to analyse data relating to ICU and nebuliser demographics. Demographic information described by categorical data such as nebuliser type, aerosol medication and nebuliser dose was summarized using numbers and percentages. Descriptive statistics relating to days and frequency of nebuliser use was summarized by using means and standard deviation. The Fischer exact test was used to ascertain the association of contamination of the Micro Mist small volume nebuliser to the following variables: stored wet, stored in a glove, stored under a glove and open to the

environment. Statistical significance was set at 5% (p-value < 0.05) for all inferential statistics. Percentages and numbers were used to describe the association of nebuliser contamination with different storage and decontamination practices. This information is included in the text and presented in graphs and tables. Data analysis was conducted using IBM SPSS 22 and Stata13.1. Data from the participating hospitals were pooled together in one data set and analysed as such to maintain hospital anonymity.

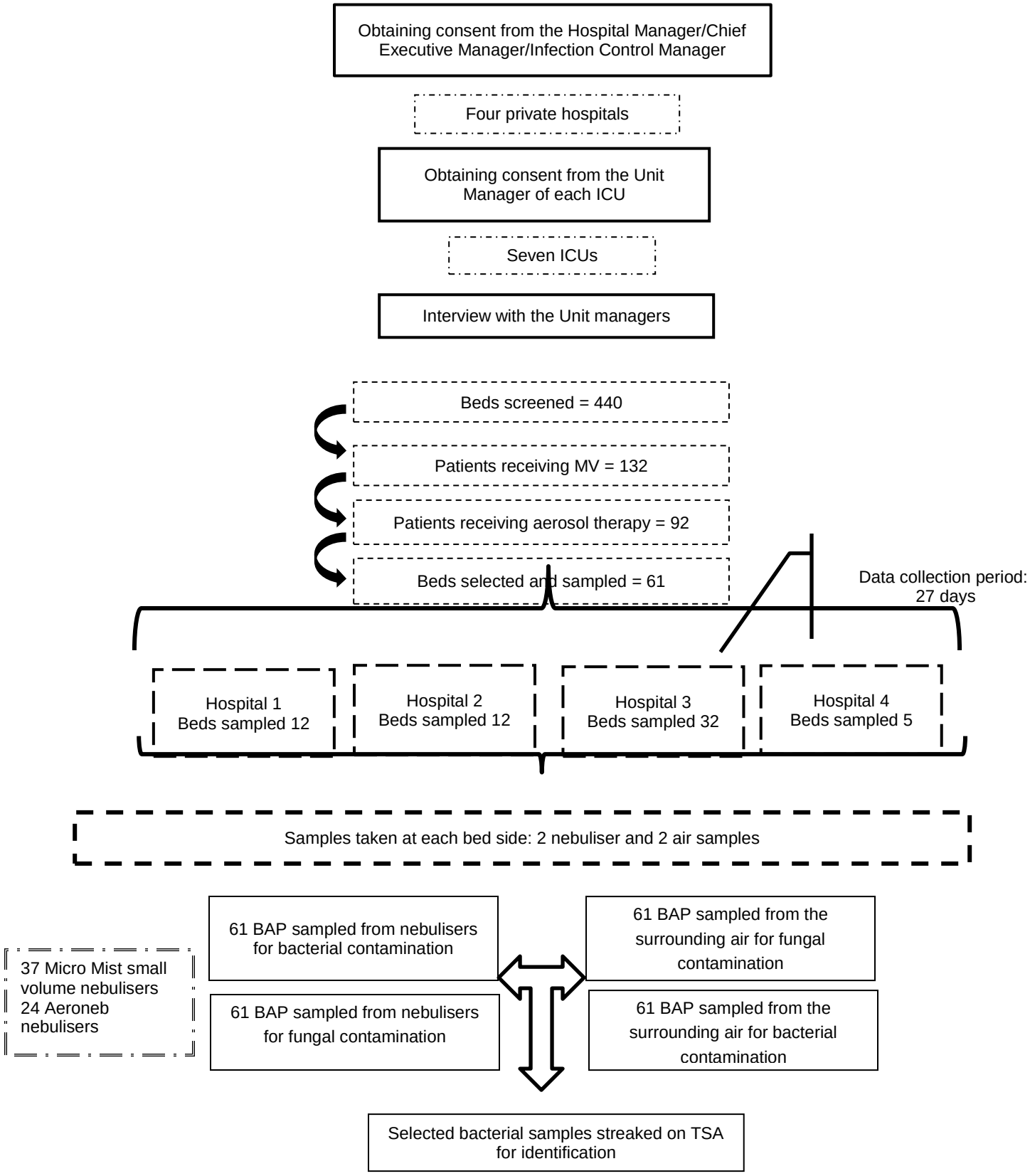


Figure 3.5: A Diagrammatic Representation of the Processes Followed During the Data Collection Period

CHAPTER 4

4. RESULTS

4.1 INTRODUCTION

This chapter presents the results obtained through data collected from both audit tools and samples taken. This includes information collected through visual inspection of the nebuliser, the storage method of the nebuliser and the surrounding ICU environment. Storage and decontamination protocols for each ICU were obtained by completing Section A of the audit tool with the unit manager. The type of aerosol medication and the frequency of application of this medication through the nebuliser was obtained from the patient's chart.

Consent was obtained from four private hospitals in Pretoria. Seven ICUs within these hospitals were selected for sampling. The types of ICUs included in the study were: cardiac care, medical, surgical, trauma, neurology and mixed units. A total of 440 beds were screened in the seven ICUs. Of these beds 132 (30.0%) patients received MV and 92 (69.7%) aerosol therapy. A total of 61 nebulisers and their surrounding air were sampled. The total nebuliser sample included 24 Aeroneb and 37 Micro Mist small volume nebulisers. The remaining nebulisers and their surrounding air were not sampled due to isolation of the patients and the risks of cross-infection or time constraints. Due to isolation of patients, the number of beds in the ICUs selected changed during the course of data collection.

The results obtained in this study will be discussed in line with the research objectives outlined in Chapter one.

4.2 THE TYPES OF NEBULISERS AND MEDICATION USED FOR AEROSOL THERAPY IN ICUs OF HOSPITALS IN PRETORIA

Two types of nebulisers were identified in the four hospitals during the study, namely the Aeroneb nebuliser, a new addition to the ventilator circuit and the Micro Mist small volume nebuliser. The Aerosol Tee connector that forms part of Micro Mist small nebuliser was the only type of Tee connector identified in the ICUs in Pretoria. Figure 4.1 provides information on the nebuliser types identified in the four hospitals.

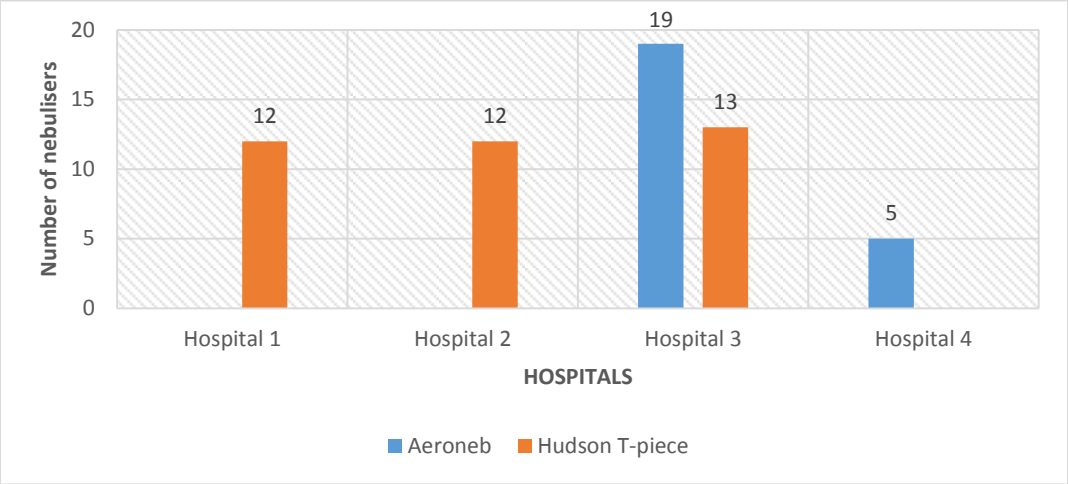


Figure 4.1: Nebuliser Types Identified in the Four Hospitals

In hospital one only the Micro Mist small volume nebuliser was used. In hospital two only the Micro Mist small volume nebuliser was sampled although both nebulisers were used. In hospital two the Aeroneb nebuliser was used to a lesser extent and only one was observed during the data collection period. In hospital three both devices were in use. In hospital four only Aeroneb nebulisers were sampled although both types of nebulisers were used to administer aerosol medication.

Figure 4.2 represents the different ICUs where the two types of nebulisers were sampled. The eight units represent different types of ICUs. Unit zero represents the cardiac ICU, unit one the medical ICU, unit two the surgical ICU, unit 3 the surgical and trauma ICU, unit four the trauma and neurology ICU, unit five the mixed ICU, unit six the surgical and medical ICU and unit seven the cardiac and surgical ICU. The mixed ICU [unit 5] used the most Aeroneb (n=11) and Micro Mist small volume nebulisers (n=17) when administering aerosol medication.

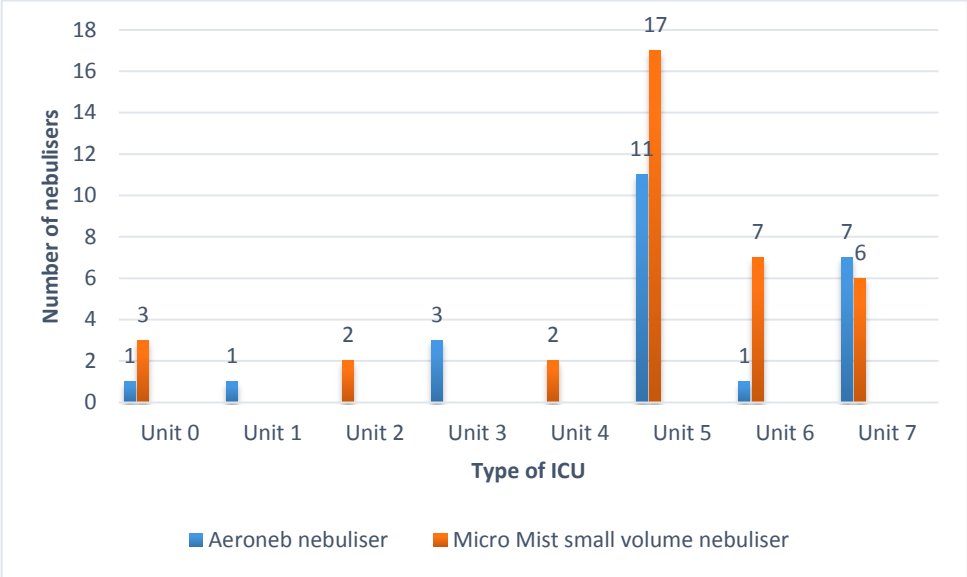


Figure 4.2: Type of Nebulisers in the Different ICUs

Four types of aerosol medication were identified namely, bronchodilators (e.g. Atrovent, Ventolin), corticosteroids (e.g. Pulmicort), saline (0.9%) and mucolytics (e.g. Bisolvon). Figure 4.3 provides information regarding aerosol medications used in the ICUs.

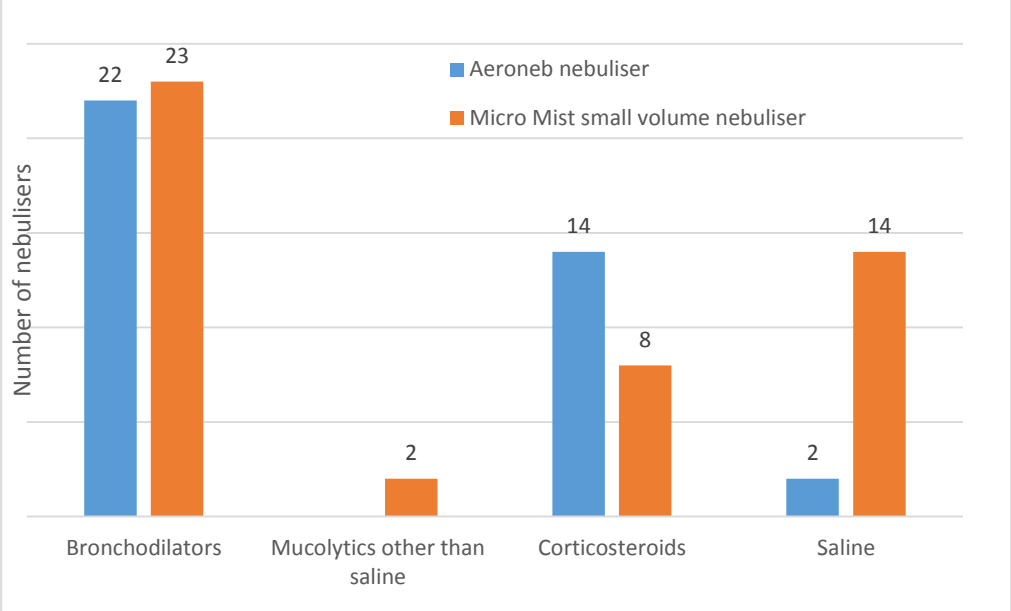


Figure 4.3: Types of Aerosol Medication

The aerosol medication mostly used in the ICUs was bronchodilators (n=45) and mode of application was similar (Aeroneb, n=22 and Micro Mist, n=23). The aerosol medication least used was mucolytics (n=2) other than saline. Saline aerosolisation was usually used with physiotherapy treatments (n=16) and the mode of application was mainly the Micro Mist small volume nebuliser.

Bronchodilators in order mostly used were; Combivent, Atrovent, Duolin and Ventolin. Pulmicort was the only corticosteroid used for aerosolisation and Bisolvon the only mucolytic other than saline. Pulmicort was also mainly used in conjunction with bronchodilators. The four types of aerosol medication used for aerosolisation are displayed according to their application in the eight types of units in Figure 4.4.

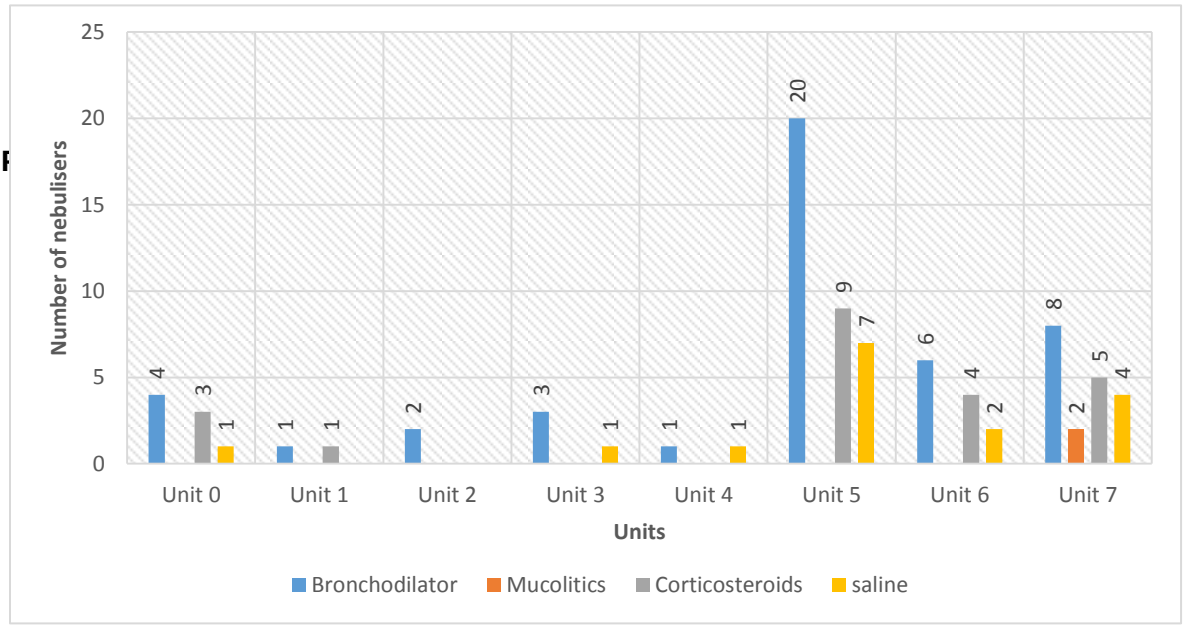


Figure 4.4: Aerosol Medication used in the Different ICUs

Bronchodilation therapy was used the most across all units and with higher frequencies noted in the mixed ICU (n=20) [unit 5], cardiac and surgical ICU (n=8) [unit 7] and lastly the surgical and medical ICU (n=6) [unit 6]. Corticosteroid therapy was the most used in the mixed ICU (n=9) [unit 5]. Saline administration as aerosol medication was the second most frequently used across ICUs as it was in use by six units. Mucolytic therapy (n=2) was only in use in the cardiac and surgical ICU [unit 7].

4.3 DAILY APPLICATION OF NEBULISERS IN THE ICU

The nebuliser dose describes the frequency of daily application and is illustrated in Figure 4.5. Eleven categories of nebuliser dose were identified. Categories that consisted of two time periods were due to two types of aerosol medications used within the nebuliser at different time intervals. The categories are as follows: zero: four hourly, one: as needed, two: six hourly, three: twice a day, four: eight hourly, five: twice a day and four hourly, six: six and eight hourly, seven: four and six hourly, eight: four and eight hourly, nine: two and three hourly, ten: eight and twelve hourly, eleven: six and twelve hourly.

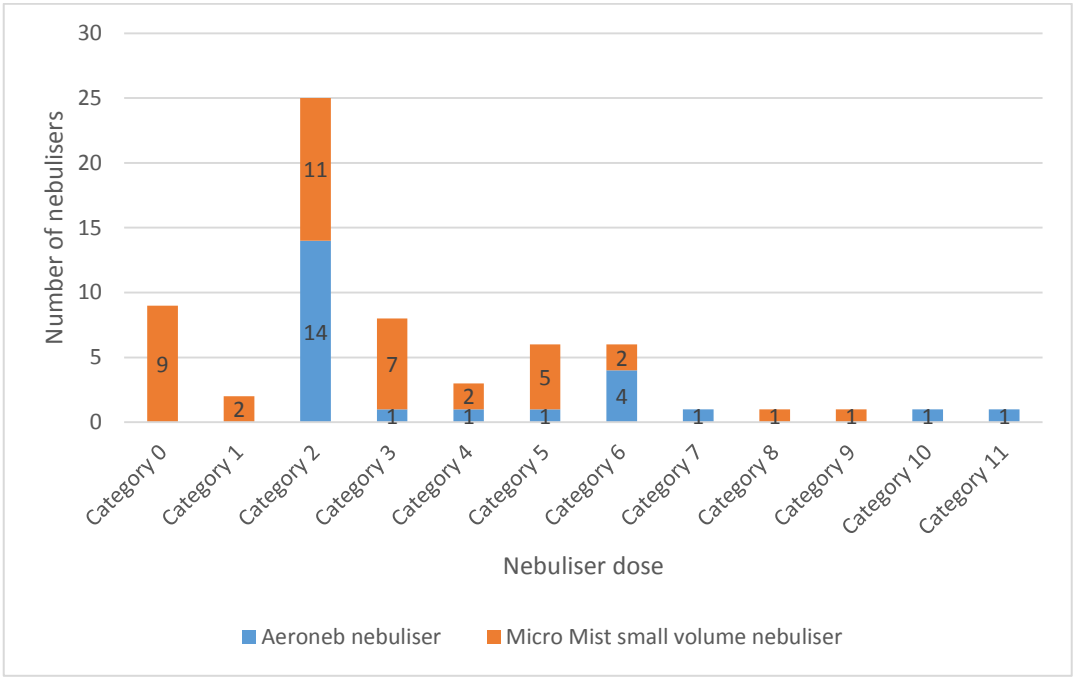


Figure 4.5: Aerosolisation Dosage for the Two Types of Nebulisers

The most frequently used dose to administer aerosol medication was a dose of six hourly (n=25) [category two] with the Aeroneb in use the most (n=14) and the Micro Mist less (n=11) in use in this dose category. The second most frequently prescribed dose was four hourly (n=9) as depicted by category zero.

Table 4.1 provides information regarding the mean number of days the different types of nebulisers were used as well as the mean number of aerosolisation sessions.

Table 4.1: Nebuliser Days and Aerosolisation Sessions

Type of Nebulisers	n	Minimum	Maximum	Mean	±SD
Aeroneb	24				
Nebuliser days	24	2.0	66.0	15.0	±14.6
Aerosolisation sessions	24	8.0	264.0	75	±74.9
Micro Mist	37				
Nebuliser days	37	1.0	62.0	11.6	±13.9
Aerosolisation sessions	37	2.0	496.0	56.2	±90.1

The mean number of days that the Aeroneb nebuliser was in use was 15.0 (±14.6) days and the mean number of aerosolisation sessions 75 (±74.9). The mean number of days the Micro Mist small volume nebuliser was in use was 11.6 (±13.9) and the mean number of aerosolisation sessions 56.2 (±90.1).

Six of the Micro Mist small volume nebulisers was used for more than 90 aerosolisation sessions and three Micro Mist small volume nebulisers was used for more than 30 days.

4.4 DECONTAMINATION PROTOCOLS AND STORAGE PRACTICES OF NEBULISERS IN THE ICUs

Six decontamination storage protocols were identified in the seven ICUs during the course of the study. A summary of the protocol is given in Table 4.2.

The ICU in hospital one had a decontamination storage protocol [protocol one], hospital two had two ICUs and both had the same protocol for decontamination and storage [protocol two]. Hospital three had two ICUs with different decontamination and storage protocols [protocol three and four] and hospital four had two ICUs with different decontamination protocols but the same storage protocol [protocol five and six].

None of the Micro Mist small volume nebulisers were discarded after use. All methods for decontamination differed in the type of rinsing solution used. Three types of rinsing solutions were identified namely, 70% alcohol, wash with bioscrub and sterile water. Most protocols stated that the Micro Mist small volume nebulisers be dried with a paper towel (n=4). Only one protocol had no method of decontamination however, nebulisers were being dried with a paper

towel after use. Decontamination protocols differed between ICUs, and between the two ICUs within Hospital three. There were no decontamination and storage protocols reported by the unit managers for the Aeroneb nebuliser. The Aeroneb nebuliser is developed to remain in the ventilator circuit during the period of MV and does not need to be decontaminated or stored separately from the MV circuit.

Storage protocol one was the only protocol whereby the Micro Mist small volume nebuliser was left open to the environment. However it was observed that the nebulisers were not stored on a hook at the bed side but left open in a petri dish. Storage protocols four to six stated that the Micro Mist small volume nebulisers be stored inside a latex glove while connected to the oxygen output of the ventilator. In protocol two, used in two ICUs, the Micro Mist small volume nebulisers were not dried before they were stored under a sterile cloth. According to the unit manager these sterile cloths are replaced every week. In protocol three the Micro Mist small volume nebulisers were stored inside an acceptor bag, however, no acceptor bag was observed during data collection in that ICU. Storage protocols differed between ICUs, and between the two ICUs within Hospital three.

Table 4.2: Type of Decontamination and Storage Protocols Reported by Unit Managers to be in Place for the Micro Mist small Volume Nebuliser

Protocol	Discarded	Rinsed	Method of Decontamination	Dried Nebuliser	Drying Method	Method of Storage
1	No	Yes	70 % alcohol	Yes	Paper towel	Connected to the oxygen output of the ventilator, stored on a hook at the bed side and open to the environment
2	No	Yes	Provac water	No	None	Connected to oxygen, taken apart and left to dry under a sterile cloth
3	No	Yes	Wash with bioscrub once a day	Yes	Paper towel	Stored in acceptor(sterile) bag
4	No	No	None	Yes	Paper towel	Stored in a glove connected to the oxygen output
5	No	Yes	Saline of Sterile water	No	None	Stored in a glove connected to the oxygen output
6	No	Yes	Wash with bioscrub after aerosolisation	Yes	Paper towel	Stored in a glove connected to the oxygen output

4.5 THE INCIDENCE OF CONTAMINATION OF NEBULISERS AFTER USE WITHIN A VENTILATOR CIRCUIT

A total of 61 nebuliser samples were collected and a total of 31 (50.8%) nebuliser swabs presented with contamination. The incidence of contamination of both types of nebulisers was similar: Micro Mist small volume (n=19; 51.4%) and Aeroneb (n=12; 50%). Figure 4.6 illustrates the incidence of contamination of the Micro Mist small volume nebulisers.

A total of 37 Micro Mist small volume nebulisers were included in this study. A combination of bacterial and fungal growth was seen the most in the Micro Mist small volume nebulisers (n=11; 29.7%). The total fungal growth (n=17) were more than the total bacterial growth (n=13) in the Micro Mist small volume nebulisers.

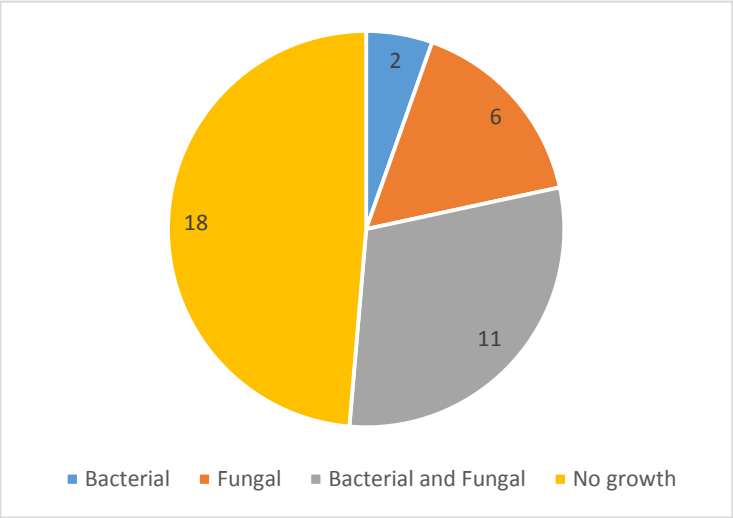


Figure 4.6: Incidence of Contamination of the Micro Mist small Volume Nebuliser

Figure 4.7 provides information regarding the incidence of contamination of the Aeroneb nebulisers. A total of 24 Aeroneb nebulisers were included in this study. A combination of bacterial and fungal growth (n=9; 37.5%) was mostly observed. The total bacterial growth (n=11) was almost similar to the total fungal growth (n=10) in the Aeroneb nebulisers.

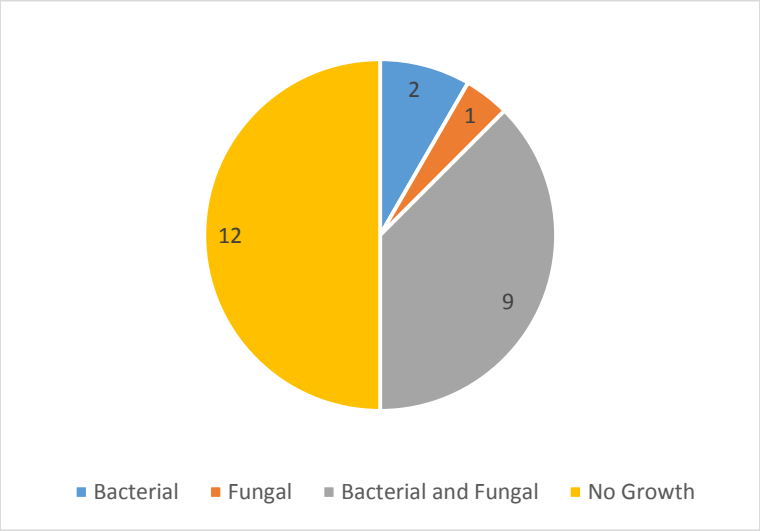


Figure 4.7: Incidence of contamination of the Aeroneb Nebuliser

The following figures present the incidence of contamination found in the different nebulisers in the four hospitals.

Hospital One

A total of 12 Micro Mist small volume nebuliser swabs were collected in Hospital one. The incidence of contamination in the Micro Mist small volume nebulisers in this hospital is shown in Figure 4.8. Only three Micro Mist small volume nebulisers (n=3; 25%) presented with contamination in Hospital one with an even distribution of bacterial (n=1), fungal (n=1) and bacterial and fungal (n=1) contamination.

Hospital Two

A total of 12 Micro Mist small volume nebuliser swabs were collected in hospital two. The incidence of contamination in the Micro Mist small volume nebuliser in this hospital is shown in Figure 4.9. In Hospital two, eight (66.7%) Micro Mist small volume nebulisers presented with bacterial and fungal growth (n=4; 33.3%).

Hospital Three

A total of 32 nebuliser swabs which includes, Aeronebs (n=19) and Micro Mist small volume nebulisers (n=13) were collected in Hospital three. The incidence of contamination of nebulisers in this hospital is shown in Figure 4.10 and 4.11. Eight (61.5%) Micro Mist small volume nebulisers in hospital three presented with contamination of which a combination of bacterial and fungal growth (n=6; 46.2%) was mostly observed. The total fungal growth (n=8) was more than the total bacterial growth (n=6) in the Micro Mist small volume nebulisers. Less

contamination was observed in the Aeroneb nebulisers in Hospital three, with nine (47.4%) nebulisers presenting growth where a combination of bacterial and fungal contaminants (n=6; 31.6%) were observed. The total bacterial growth (n=8) was more than the total fungal growth (n=7) in the Aeroneb nebulisers.

Hospital Four

A total of five Aeroneb nebuliser swabs were collected in Hospital four. The incidence of contamination of nebulisers in this hospital is shown in Figure 4.12. Three (60%) Aeroneb nebulisers presented with bacterial and fungal contamination (n=3).

Hospital two presented with the most contamination in the Micro Mist small volume nebulisers (66.7%) and Hospital four with the most Aeroneb contamination (60%).

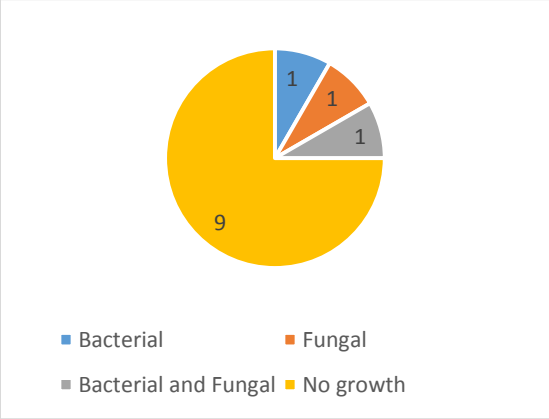


Figure 4.8: Incidence of contamination in Hospital One

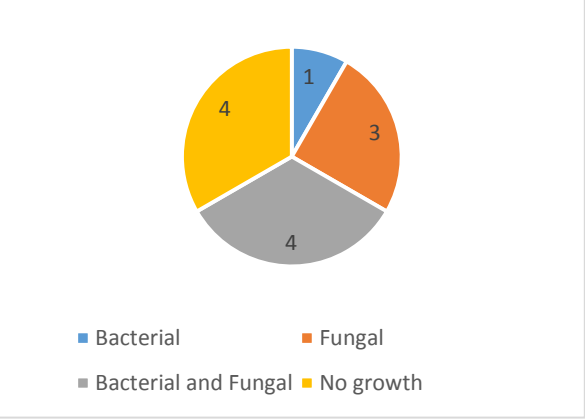


Figure 4.9: Incidence of contamination in Hospital Two

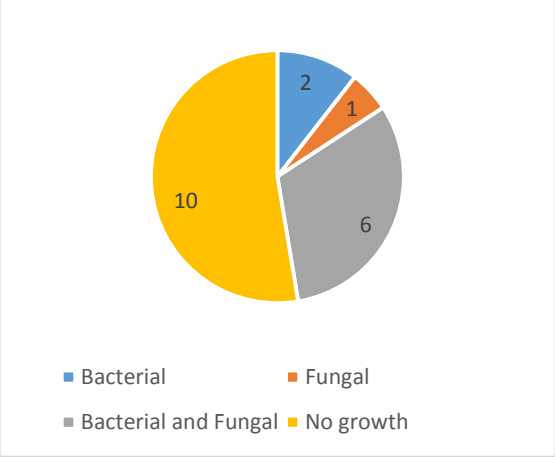


Figure 4.10: Incidence of contamination in Micro Mist small volume Nebulisers in Hospital Three

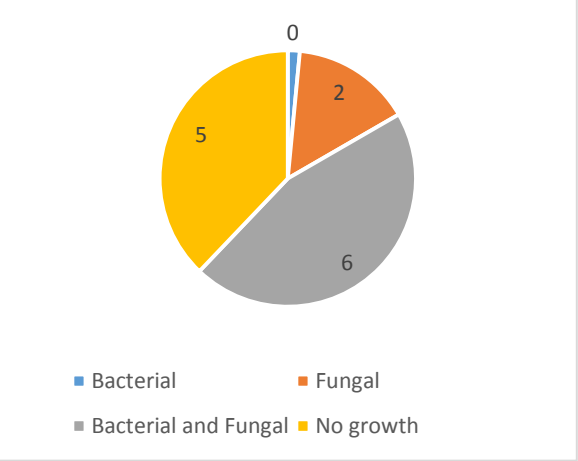


Figure 4.11: Incidence of contamination Aeroneb Nebulisers in in Hospital Three

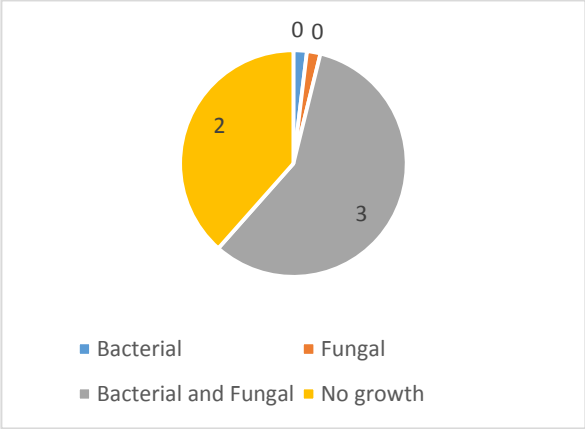


Figure 4.12: Incidence of Contamination in Hospital Four

A summary of the incidence of bacterial contamination in the different types of units found in both nebulisers is described in Figure 4.13. Unit zero represents the cardiac ICU, unit one the medical ICU, unit two the surgical ICU, unit 3 the surgical and trauma ICU, unit four the trauma and neurology ICU, unit five the mixed ICU, unit six the surgical and medical ICU and unit seven the cardiac and surgical ICU.

Bacterial contamination of nebulisers were mostly observed in the mixed ICU (n=10) [unit five] and secondly in the surgical and medical ICU (n=5) [unit six]. No bacterial contamination of nebulisers was observed in the surgical ICU [unit two] and the trauma and neurology ICU [unit four].

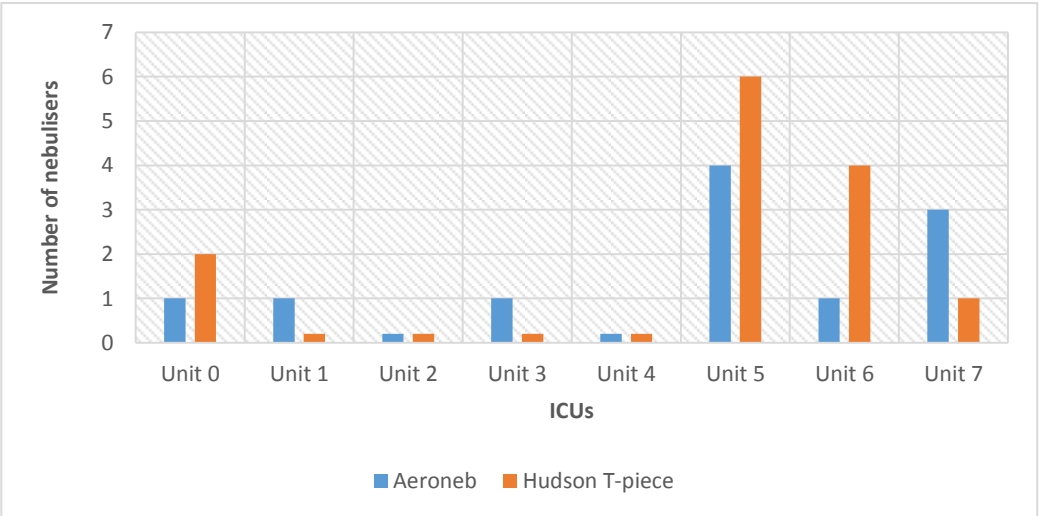


Figure 4.13: Bacterial Contamination According to Unit Type

A summary of the incidence of fungal contamination in the different types of units found in both nebulisers is described in Figure 4.14. The highest number of fungal contamination of nebulisers was observed in the mixed ICU (n=10) [unit 5] and secondly in the surgical and medical ICU (n=5) [unit 6]. No fungal contamination of nebulisers was observed in the surgical ICU [unit two].

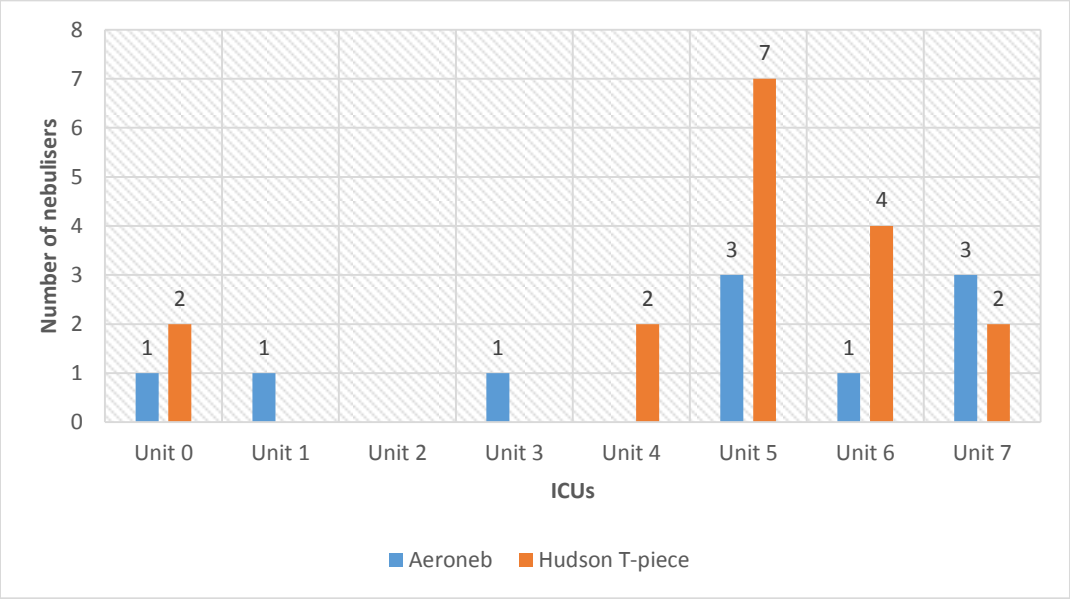


Figure 4.14: Fungal Contamination According to Unit Type

Ten of the 24 Aeronebs and 17 of the 37 Micro Mist small volume nebulisers presented with fungal contamination which can be divided into moulds and yeasts. These findings are presented in Figure 4.15. The nebulisers presented with yeast contamination were mostly observed in both Aeroneb (7/24; 29.2%) and Hudson Micro Mist small volume nebulisers (15/37; 40.5%). Less contamination with moulds and a combination of moulds and yeasts were observed in both Aeronebs and Micro Mist small volume nebulisers.

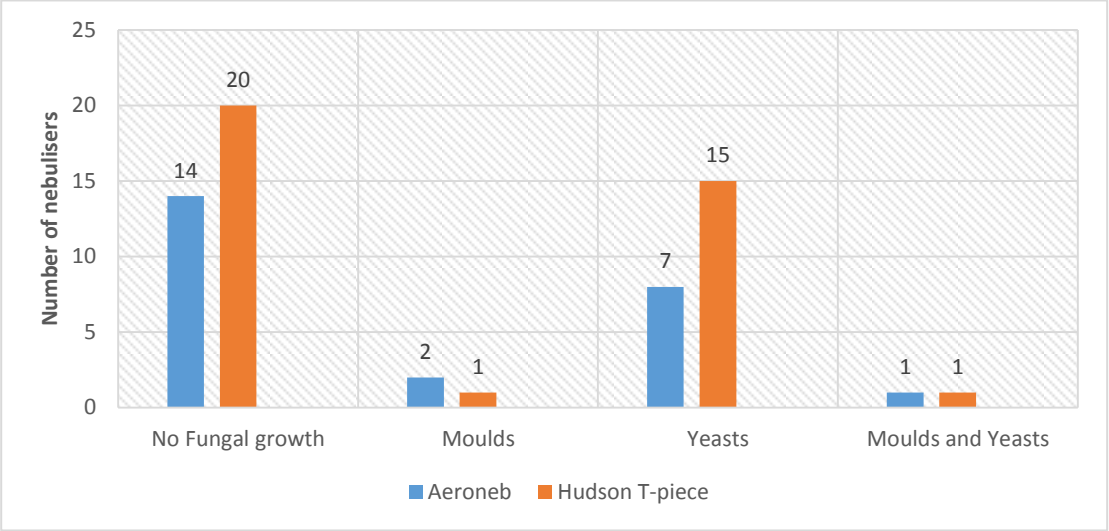


Figure 4.15: Incidence of Fungal Growth in Micro Mist small volume and Aeroneb Nebulisers

4.6 DECONTAMINATION AND STORAGE PROTOCOLS ASSOCIATED WITH BACTERIAL GROWTH

The type of decontamination and storage protocols for the Micro Mist small volume nebulisers associated with contamination, is illustrated in Figure 4.16. These protocols are outlined in section 4.3. Only protocol one to four is illustrated in Figure 4.16. Protocol five and six were not illustrated as no Micro Mist small nebulisers were swabbed in the ICUs where these protocols were implemented.

When Protocol one was followed the least amount of contamination was found (n=3; 25%). Protocol three resulted in the most contamination (n=4; 80%). Protocol two resulted in the most fungal contamination (n=3; 25%).

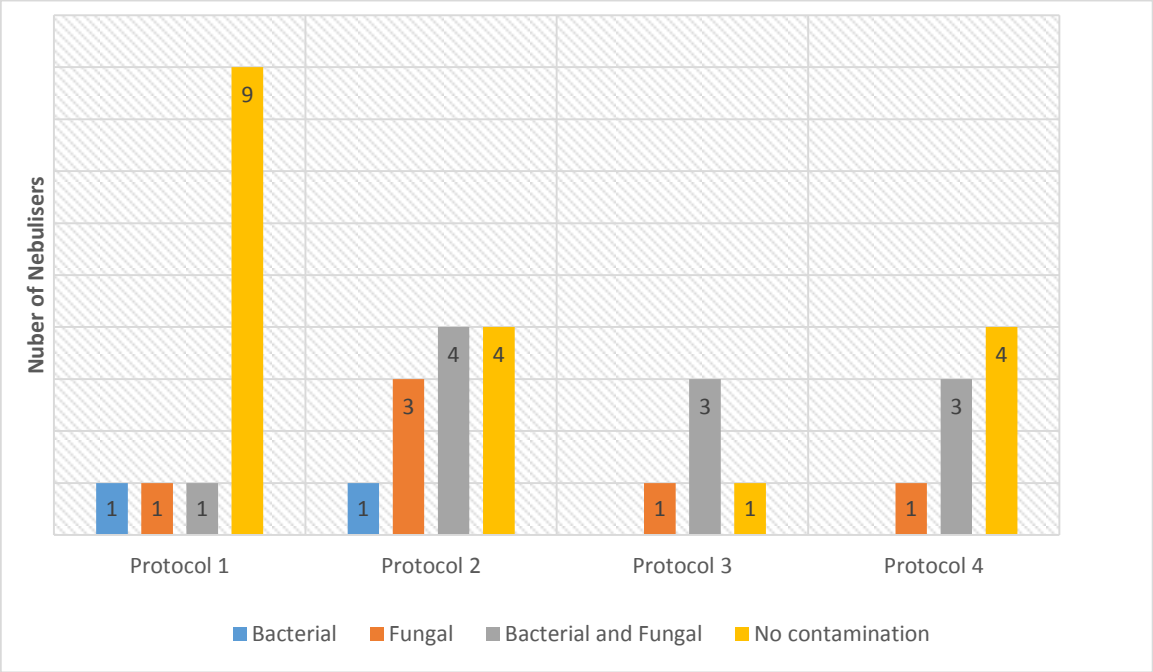


Figure 4.16: Bacterial and Fungal Contamination of Micro Mist small volume Nebulisers Associated with Decontamination and Storage Protocols

The following incidence of contamination was observed with different rinsing solutions and drying methods as part of the decontamination storage protocols reported by the unit managers.

4.6.1 Rinsing Solutions

Three types of rinsing solutions were identified in the decontamination protocols. Solution one: 70% alcohol; solution two: sterile water and solution three: washed with bioscrub. Solution one resulted in the least bacterial contamination of Micro Mist small volume nebuliser (n=2; 16.7%) and solution three resulted in the most bacterial contamination (n=3; 75%). Solution two resulted in bacterial contamination of (n=5; 41.7%) and using no rinsing solution, resulted in three out of the nine nebulisers presenting with bacterial contamination (33.3%). Solution one resulted in the least fungal contamination of the Micro Mist small volume nebulisers (n=2; 16.7%) and solution three resulted in the most fungal contamination (n=4; 100%). Solution two resulted in fungal contamination of (n=7; 58.3%) and using no rinsing solution, resulted in four out of the nine Micro Mist small volume nebulisers with fungal contamination (n=4; 44.4%).

4.6.2 Drying Methods

Two different methods were used to dry the Micro Mist small volume nebulisers as part of the decontamination protocols and are as follows, method one: dry the nebuliser with a paper towel; method two: take the nebuliser apart and leave to dry under a sterile cloth. Method two resulted in the most bacterial contamination (n=5; 41.6%) and fungal contamination (n=7; 58.3%). Method one resulted in the least bacterial contamination (n=8; 32%) and fungal contamination (n=10; 40.0%).

4.6.3 Storage Methods

Four types of storage methods were evaluated during visual inspection on the day of audit and are as follows: method one: stored in a glove; method two: stored under a sterile cloth; method three: stored open to the environment and method four: stored in a paper bag. Most Micro Mist small volume nebulisers were stored in a latex glove (n=20). More than a third of the Micro Mist small volume nebulisers, stored in a glove presented with bacterial growth (n=7; 35%) and half with fungal contamination (n=9; 47,4%). Since the p-value is 0.717 (>0.05), there is evidence of no relationship (association) between method one and bacterial growth.

Method two resulted in the most bacterial contamination (n=4; 44.4%) and the most fungal contamination (n=6; 66.7%). Since the p-value is 0.624 (>0.05), there is evidence of no relationship (association) between method two and bacterial growth.

Method three resulted in the least bacterial (n=2; 28.6%) and fungal contamination (n=2; 28.6%). No paper bags were observed during the sampling procedures. Since the p-value is 0.594 (>0.05), there is evidence of no relationship (association) between method three and bacterial growth.

One nebuliser was left in the ventilator circuit and presented with fungal contamination and no bacterial contamination. Five Micro Mist small volume nebulisers were stored connected to the oxygen port of the ventilator. Only one presented with bacterial and fungal contamination (n=1; 20%).

4.6.4 Aerosol Medication

Contamination associated with aerosol medication used in the Micro Mist small volume and Aeroneb nebulisers were observed. Bronchodilators were mostly used for aerosol nebulisation in Micro Mist small volume nebulisers followed by saline, corticosteroid and mucolytics (other

than saline). Bronchodilators were also mostly used in Aeroneb nebulisers followed by corticosteroid and saline. No mucolytics were used in Aeroneb nebulisers. The highest bacterial contamination was found in Micro Mist small volume (n=4; 50%) and Aeroneb nebulisers (n=8; 57.1%) associated with corticosteroids aerosolisation. Bronchodilator aerosolisation was associated with (n=9; 39.1%) contamination in the Micro Mist small volume nebuliser and (n=10; 45.5%) in the Aeroneb nebuliser. Saline inhalation was associated with (n=5; 35.7%) bacterial contamination. No contamination was found in Micro Mist small volume nebulisers used for mucolytics (n=2; 0%). No contamination was found in Aeroneb nebulisers used for saline aerosolisation.

4.6.5 **Wet and Dry Chambers**

Visual inspection of each nebuliser on the day of audit was performed to establish if the chambers were stored wet or dry. In this study a nebuliser was described as “wet” when fluid was observed in base of the chamber and the inner surface of the chamber. The results obtained through visual inspection of the Micro Mist small volume nebuliser is illustrated in Figure 4.17.

4.6.5.1 **Micro mist small volume nebuliser**

Most of the Micro Mist small volume nebulisers were stored wet (n=33; 89.2%). Only four nebulisers were stored dry (n=4; 10.8%). Bacterial contamination was found in 11 of the 33 wet Micro Mist small volume nebulisers (n=11; 33.3%) and fungal contamination found in 16 (n=16; 48.5%). One dry Micro Mist small volume nebuliser presented with (n=1; 25%) bacterial and (n=1; 25%) fungal contamination. Three out of the four dry Micro Mist small volume nebulisers presented with no contamination (n=3; 75%). One species was identified in seven wet Micro Mist small volume nebulisers (7/11) and in one dry Micro Mist small volume nebuliser (1/4). Two species were identified in three nebulisers (3/11) and three species in one nebuliser (1/11). Most of the wet Micro Mist small volume nebulisers presented with more than 50 colonies (6/11) as well as one dry nebuliser (1/4). Two Micro Mist small volume nebulisers presented with colonies between one and 10 (2/11) and two nebulisers with colonies between 21 and 30 (2/11). Although the odds ratio (0.67 and 95% Constant Interval = 0 – 5.42) shows a 33% reduced risk of bacterial growth in dried as compared to wet nebulisers, there is evidence of no association between dryness of the nebuliser chamber and bacterial growth (p-value=0.7367) because the p-value is not significant.

Three out of the six Micro Mist small volume nebulisers that was used for more than 90 aerosolisation sessions presented with both bacterial and fungal contamination (50%). Nine out of the 31 Micro Mist small volume nebulisers used for less than 90 sessions presented with bacterial contamination (29%) and eleven with fungal contamination (35.5%).

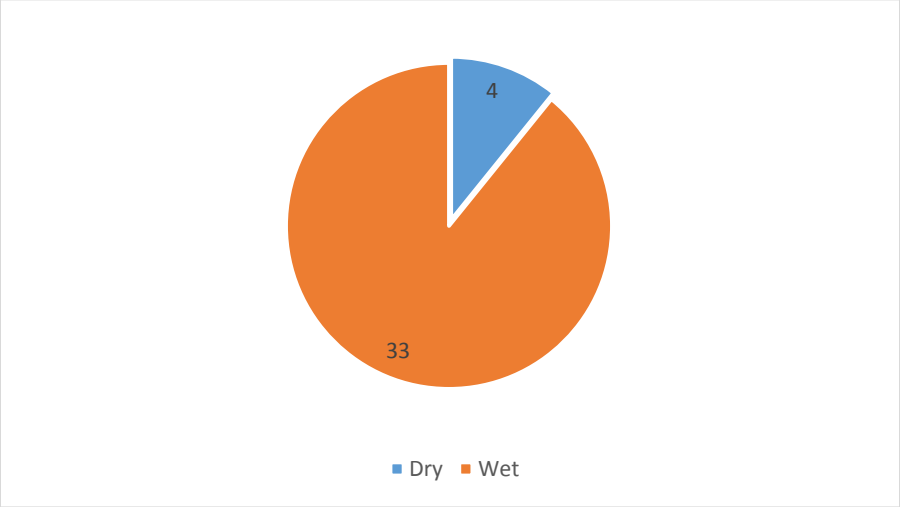


Figure 4.17: Visual Inspection of the Micro Mist small volume Nebuliser

4.6.5.2 **Aeroneb nebuliser**

The results obtained through visual inspection of the Aeroneb nebuliser are illustrated in Figure 4.18. Most of the Aeroneb nebulisers were found to be wet with visual inspection (n=20; 83.3%).

Only four were dry (n=4; 16.7%). Bacterial contamination was found in 10 of the 20 wet Aeroneb nebulisers (n=10; 50%) and in one dry nebuliser (n=1; 25%). Fungal contamination was found in 8 of the 20 wet Aeroneb nebulisers (n=8; 40%) and two dry nebulisers (n=2; 50%). One species was identified in all the wet Aeroneb nebulisers (10/10) and in one dry nebuliser (1/4). Colonies between one and 10 were identified in six wet Aeroneb nebulisers (6/10) and more than 50 colonies were identified in three wet Aeroneb nebulisers (3/10) and in one dry nebuliser (1/10).

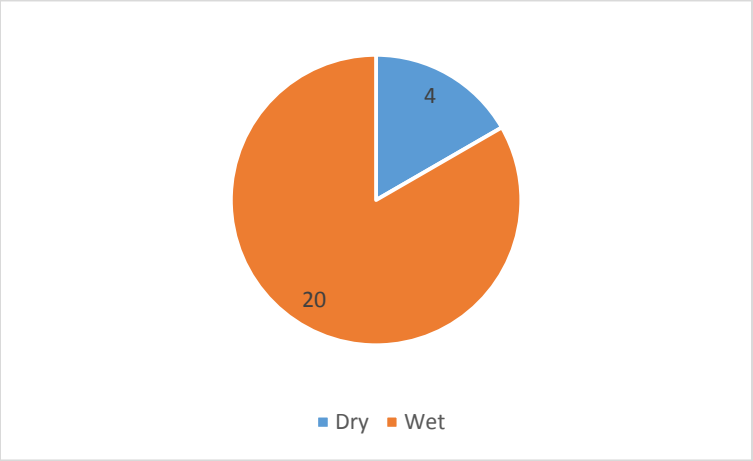


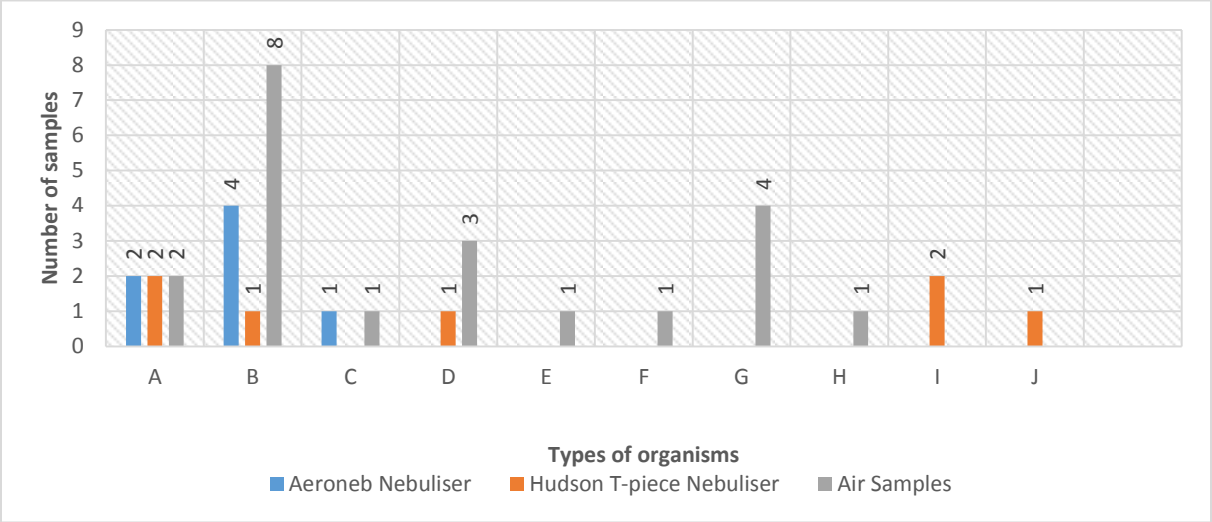
Figure 4.18: Visual Inspection of the Aeroneb Nebuliser

4.7 BACTERIAL MICRO-ORGANISMS IDENTIFIED IN CONTAMINATED NEBULISERS AND SURROUNDING AIR

Ten types of micro-organisms were identified in the nebulisers and surrounding air. This is shown in Figure 4.19. Micro-organisms were identified in 19 air samples, six Micro Mist small nebuliser and seven Aeroneb nebuliser samples. The different micro-organisms included; *Enterococcus* spp., Coagulase-negative *Staphylococcus* spp., *Staphylococcus aureus, Neisseria* spp.; *Bacillus* spp., *Micrococcus* and related species, *Pseudomonas stutzeri, Brevundimonas vesicularis*, *Empedobacter (F.) brevis* and *Stenotrophomonas* spp.

Coagulase-negative *Staphylococcus* was identified the most in air samples (n=8; 42.1%) followed by *Pseudomonas Stutzeri* (n=4; 21.1%) and *Neisseria spp.* (n=3; 15.8%). Coagulase-negative *Staphylococcus* (CoNS) was also the most identified in Aeroneb nebulisers (n=4; 57.1%). *Enterococcus* spp. was the most identified in Micro Mist small volume nebulisers (n=2; 33.3%) and also identified in all three types of samples.

The micro-organisms identified in the samples included seven contaminated nebulisers and their corresponding air samples. The same bacterial micro-organisms were identified in two nebulisers and their corresponding air samples (n=2; 28.6%). An *Enterococcus* sp. was identified in one Micro Mist small volume nebuliser and its corresponding air sample and a Coagulase-negative *Staphylococcus* sp. was identified in one Aeroneb nebuliser and its corresponding air sample.



A=Enterococcus spp.*, B*=Coagulase-negative *Staphylococcus* spp., C=*Staphylococcus aureus,* D=*Neisseria* spp.; E=*Bacillus* spp., F=*Micrococcus* and related *species*, G=*Pseudomonas stutzeri,* H=*Brevundimonas vesicularis*, I=*Empedobacter (F.) brevis, J=Stenotrophomonas* spp.

Figure 4.19: Bacterial Micro-organisms Identified in Contaminated Nebulisers and Air Samples

Figure 4.20 illustrates the bacterial and fungal contamination of the surrounding air where these nebulisers were kept. A high incidence of contamination was identified in air samples (n=60; 98.4%). Most of the air samples had bacterial and fungal contamination (n=43; 70.5%) followed by fungal contamination (n=12; 19.7%) and bacterial contamination (n=5; 8.2%). The total fungal contamination (n=55; 90.2%) in air samples was higher than the total bacterial contamination (n=48; 78.7%). The various ventilation systems were identified by questioning the unit manager in the hospitals and were as follows; Hospital one- HEPA filter; Hospital two- Chilled Water Fan Coil Unit and Direct Expansion System; Hospital three - Air Handling Unit; Hospital four- Chilled Water Fan Coil Unit.

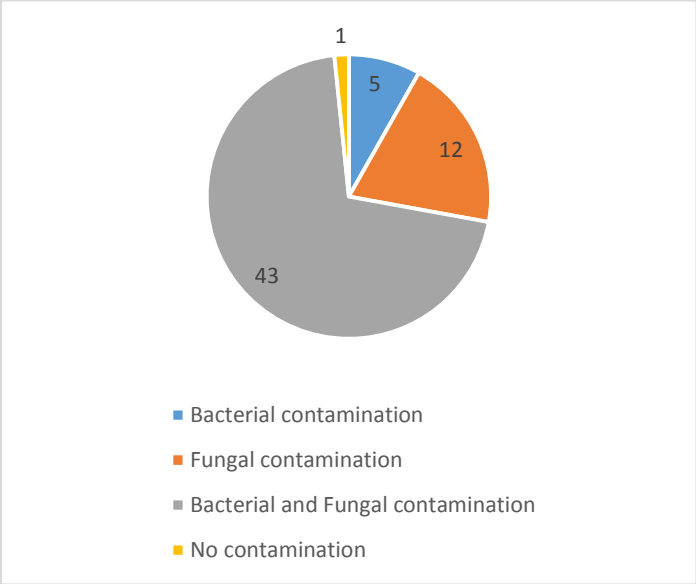


Figure 4.20: Bacterial and Fungal Contamination in Air Samples

More than two thirds of patients received aerosol therapy during MV. Bacterial and fungal contamination of nebulisers was mostly observed in the mixed ICUs. Although most of the protocols in the ICUs included drying of the Micro Mist small nebulisers, most of the Micro Mist small volume as well as Aeroneb nebulisers were found to be wet during visual inspection. The incidence of bacterial contamination was higher in the wet Aeroneb type nebulisers which are manufactured to be left in the ventilator circuit and continuously exposed to ventilator gasses. Most of the Micro Mist small volume nebulisers were stored in a latex glove. Storing Micro Mist small volume nebulisers under a sterile cloth resulted in a higher incidence of bacterial and fungal contamination. Rinsing the Micro Mist small volume nebuliser with 70% alcohol before storage resulted in the least amount of bacterial contamination. Incidence of contamination of the Aeroneb and Micro Mist small volume nebulisers was similar despite different application protocol, storage and cleaning methods.

CHAPTER 5

5. DISCUSSION

5.1 INTRODUCTION

The incidence of contamination as well as the current practice of decontamination and storage of nebulisers used within a ventilator circuit in ICUs in Pretoria is unknown. A similar study was done in the ICUs in Johannesburg and the results of that study will be compared with the current study to assist in gaining an overall perspective of contamination and nebuliser practice in ICUs in Gauteng.

The main finding from the current study was the incidence of bacterial and fungal contamination of the Micro Mist small volume nebuliser and the Aeroneb nebuliser when used in a ventilator circuit. The incidence of contamination of the Micro Mist small volume nebuliser in this study corresponds with the incidence of contamination found in the same aerosol device in ICUs in Johannesburg (Ellis et al., 2013). The Aeroneb nebuliser is a new device that was recently introduced to clinical practice as a means of administration medication to a mechanically ventilated patient. No previous research regarding the incidence of contamination in the Aeroneb nebuliser could be sourced in the literature. The incidence of contamination found in the Aeroneb nebuliser was similar to the incidence of contamination in the Micro Mist small volume nebuliser. In the current study both of these nebulisers were used as single-patient use devices which is in contrast to the information reported by Ellis et al. (2013) as the Micro Mist small volume nebuliser was reclassified by the manufacturer from single-use to single-patient use device. Secondly, all the ICUs had decontamination and storage protocols in place for the Micro Mist small volume nebuliser, however, all of these protocols differed between hospitals and different ICUs within the same hospital. Thirdly, more Micro Mist small volume nebulisers that were stored under a sterile drape presented with bacterial contamination which corresponds with Ellis et al. (2013) study. Lastly, almost 90% of Micro Mist small volume nebulisers were stored wet. More than two thirds of ventilated patients, received aerosol therapy in the ICUs in Pretoria, which indicated that aerosol therapy was an important treatment during MV. This finding is supported by an international survey which found that 95% of intensivists prescribe aerosol therapy to patients receiving MV (Ehrmann et al., 2013).

5.2 THE TYPES OF NEBULISERS AND MEDICATION USED FOR AEROSOL THERAPY IN ICUs IN PRETORIA

The Micro Mist small volume nebuliser is a jet nebuliser which connects to a port on the ventilator and the Aeroneb nebuliser is a VMN which operates electronically within the ventilator circuit. The Aeroneb nebuliser was not identified as one of the nebulisers used in the ICUs in Johannesburg at the time of the study done by Ellis et al. (2013). The Micro Mist small volume nebuliser was mostly used in the ICUs in Pretoria. This corresponds with Ellis et al. (2013) study in ICUs in Johannesburg and an international survey conducted by Erhmann et al. (2013). The Aeroneb nebuliser was used less frequently in the ICUs of hospitals in Pretoria. A factor that could influence its usage might be the cost of this new device as the cost is markedly higher than the Micro Mist small volume nebuliser. The Aeroneb device is almost 10 times the cost of the Micro Mist small volume nebuliser. An international survey by Ehrmann et al. (2013) supports this assumption and showed that only 14% of respondents used VMN in MV whereby cost was suggested as a limiting factor.

According to the Unit managers in the ICUs that were surveyed, the Aeroneb nebuliser is used when a patient requires continuous positive end-expiratory pressure or if a patient is on long term ventilation. This is in contrast to the Micro Mist small volume nebuliser which is used more frequently in patients requiring ventilation following surgical procedures who are anticipated to be extubated from the ventilator soon.

Most Aeroneb samples were collected in the mixed ICUs. It could be hypothesized that there were more long-term ventilated patients in the mixed ICUs who required aerosol therapy. A report done by the International Nosocomial Infection Control Consortium (INICC) between 2003 and 2008 supports this hypothesis whereby the average length of stay (LOS) for patients in an ICU consisting of mixed conditions e.g. medical and surgical cases was found to be much higher than other types of ICUs (INICC, 2010).

Four types of aerosol medication were identified during the course of this study namely, bronchodilators, corticosteroids, saline and mucolytics. Bronchodilators were the most frequent aerosol medication used for nebulisation in the seven ICUs followed by corticosteroids, saline and mucolytics. This corresponds with the study done by Ellis et al. (2013) whereby bronchodilators were ranked the highest. Mucolytics however were the second highest ranked medication administered in ICUs in Johannesburg while in Pretoria ICUs these ranked last in

the group of aerosol medications. Mucolytics and saline were grouped together in the study done by Ellis et al., (2013) and therefore the higher rank of mucolytics. The mucolytics used in the ICUs in Johannesburg were Bisolvon, which was only used in one nebuliser, and saline, which was used in eight nebulisers. In the current study administration of bronchodilators were high in both the Micro Mist small volume and Aeroneb nebuliser. An international survey showed similar results whereby bronchodilators were administered the most frequent followed by steroids (Erhmann et al., 2013). No antibiotics were used for nebulisation during this study while in an international survey antibiotics and especially Colistin were regularly aerolised (Ehrmann et al., 2013). Most of respondents in this survey done by Ehrmann et al. (2013) worked in an adult mixed ICU setting and reported a positive viewpoint towards inhaled antibiotics as an adjunctive or primary treatment method for pulmonary infections.

5.3 DAILY APPLICATION OF NEBULISERS IN THE ICU

The Micro Mist small volume nebuliser and the Aeroneb nebuliser are single-patient use devices which indicate that they should be used on the same patient for a period of time according to the manufacturer's recommendations. The six hourly (four times a day) aerosolisation of medication were used the most in both Aeroneb and Micro Mist small volume nebulisers. Information regarding nebuliser dose and the date when aerosolisation commenced were collected from the patient's prescription chart or physiotherapy notes to calculate the number of aerosolisation sessions over a period of time. The mean number of days as well as the number of aerosolisation sessions that the Micro Mist small volume nebuliser was used, was less than that of the Aeroneb nebuliser. The Micro Mist small volume nebuliser can be used three times a day for 30 days which calculates to 90 aerosolisation sessions (SMLT, 2000). Allen et al. (2005) also recommended that the Micro Mist small volume nebuliser should be replaced every 24h if the patient had a respiratory infection. In the current study, the mean number of aerosolisation sessions 56.2 (±90.1) and days 11.6 (±13.9) in which the Micro Mist small volume nebuliser was used, was in accordance with what is recommended by the SMLT (SMLT, 2000). Only six of the Micro Mist small volume nebulisers were used for more than 90 aerosolisation sessions and three for more than 30 days. No recent literature could be sourced regarding the frequency in which the Micro Mist small volume nebuliser is used in South Africa or internationally. Replacing the Micro Mist small volume nebuliser could be costly and time consuming. The Valved Neb Tee, is a different type of Tee connector manufactured by Hudson RCI that is a single-patient use device and can be left in the ventilator circuit when the nebuliser is removed. A valve in the Neb Tee connector opens/closes upon insertion/removal of the nebuliser. The valve prevents loss of ventilation

pressure and the release of patient's aerosols in the surrounding environment (Teleflex, 2014). This could result in lower costs and less time spend to remove the Micro Mist small volume nebuliser from the circuit. The Aeroneb nebuliser in contrast is left in the ventilator circuit and can be set on an intermittent or continuous cycle. There is no specified limit to the frequency with which the Aeroneb nebuliser may be used (Aerogen, 2014).

During this study no documentation could be found on the ICU cardex or in the patient files to indicate how long the Micro Mist small volume nebuliser were in use or if it was replaced. The study design didn't allow interviews with nursing staff at the bed side and therefore the researcher speculates that the ICU personnel were not informed regarding the preferred application of the Micro Mist small volume nebuliser and/or Tee connector.

5.4 DECONTAMINATION PROTOCOLS AND STORAGE PRACTICES IN THE ICUS

Six different decontamination and storage protocols for the Micro Mist small volume nebuliser were identified in the seven ICUs assessed in Pretoria. In contrast, none of the ICUs assessed in Johannesburg had nebuliser decontamination and storage protocols in place, however, different methods of storage were observed by Ellis et al. (2013). In the current study the decontamination and storage protocols for the Micro Mist small volume nebulisers differed between hospitals and between ICUs within the same hospitals in Pretoria. The researcher speculated that the ICU staff were not aware of the manufacturer's recommendations regarding decontamination and storage of the Micro Mist small volume nebuliser. There were no decontamination and storage protocols found for the Aeroneb nebuliser in the ICUs of hospitals in Pretoria. The Aeroneb nebuliser is manufactured to be left in the ventilator circuit during the period of MV. The Aeroneb Pro-X controller is for re-use and should be cleaned between patients according to the manufacturer's recommendations (Aerogen, 2014)

Staff nurses at the patient's bed side where nebuliser sampling was done were not asked specifically if they were aware of these protocols and if they applied the protocols. No clinical documentation was found at the bed side regarding the application of a decontamination protocol of the Micro Mist small volume nebuliser after each aerosolisation in the ICUs in Pretoria. Different manufacturers have slightly different approaches in cleaning methods but all state that washing and drying should be done after each use (Allen et al., 2005).

Three types of rinsing solutions were identified in the six decontamination protocols namely, 70% alcohol, sterile water and bioscrub. A cleaning protocol for nebulisers developed by

Jadhav et al. (2013) included hand hygiene, washing the nebuliser with soap and distilled water and lastly cleaning it with 70% alcohol. This protocol was followed after high rates of bacterial and fungal contamination was found in the chambers of their nebulisers (Jadhav et al., 2013). Only one protocol in the current study used 70% alcohol for cleaning the Micro Mist small volume nebulisers. Hand hygiene was not evaluated or identified as part of the decontamination and storage protocols in the ICUs in Pretoria. The CFF's cleaning and disinfecting protocol for home nebulisers recommend that sterile water should be used for final rinsing after cleaning and that it should be air dried completely (O'Malley, 2009). Two protocols used sterile water for rinsing after remaining fluid were thrown out without prior washing of the Micro Mist small volume nebulisers. No literature could be found regarding the use of bioscrub for washing nebulisers which were included in two of the protocols identified in this study. Bioscrub is a disinfectant scrub specifically formulated for hands and the body to help kill micro-organisms and prevent skin infections. The use of bioscrub for the decontamination of Micro Mist small volume nebulisers has not been documented in international studies and could be totally ineffective as it's made of skin sanitation (GHSdirect, 2011).

During an outbreak of *Staphylococcus aureus* the ICT at the Wirral Hospital NHS Trust developed a protocol whereby the nebulisers were only drained after each use and stored covered with a paper towel, following the manufacturer's guidelines were impractical (Allen et al., 2005). The ICT also decided to replace nebulisers after 24h (Allen et al., 2005). O'Malley (2009) found that in-hospital nebulisers used for cystic fibrosis patients can be safely used for 24-hours and replaced without cleaning. No Micro Mist small volume nebulisers were replaced according to the cardex and files at the bedsides of patients in the ICUs in Pretoria.

In two of the protocols, drying was not done before storage which is in contrast with manufacturer's guidelines, specifically for Hudson RCI (SMTL, 2000). They recommend that the Micro Mist small volume nebuliser must be re-assembled after cleaning and run as empty to remove any remaining water and store in a dry clean place. Only in protocol one were the nebulisers dried and left open to the environment. The remaining storage protocols used methods to cover the Micro Mist small volume nebuliser which is in contrast with the manufacturer's guidelines (SMTL, 2000). It can be assumed that the nebulisers covered and not dried or dried thoroughly can remain wet. Nebulisers stored open to the environment have a better chance to dry completely. Storing nebulisers by using a glove was the method most included in the protocols (n=3) which corresponds with the method mostly used to store Micro

Mist small volume nebulisers in ICUs in Johannesburg (Ellis et al., 2013). The methods of storage used for the Micro Mist small volume nebulisers in the ICUs in Johannesburg corresponded with the storage methods stated in the storage protocols of ICUs in Pretoria.

5.5 THE INCIDENCE OF CONTAMINATION OF NEBULISERS AFTER USE WITHIN A VENTILATOR CIRCUIT

In this study the incidence of contamination found in the Micro Mist small volume nebulisers in the ICUs in Pretoria (51.3%) corresponds with the incidence of contamination found in the Micro Mist small volume nebulisers in the ICUs in Johannesburg (52%) (Ellis et al., 2013). Half of the Aeroneb nebulisers presented with contamination. No previous studies could be found regarding the contamination of Aeroneb nebulisers. The total level of contamination in both types of nebulisers in this study (50.8%) also corresponded with the contamination levels found in the nebulisers used in the ICUs in Johannesburg (Ellis et al., 2013). The results showed that the Aeroneb nebuliser can become contaminated and therefore is not the ultimate solution as previously assumed by Ellis et al. (2013). A study done by Jadhav et al. (2013) found that Micro Mist small volume nebulisers used in the ICU, wards and outpatient department presented with 47.5% bacterial contamination. This rate is close to what was found in the ICUs in Pretoria and Johannesburg. Furthermore, 75.1% of swabs taken from various sites presented with fungal growth which included swabs from Micro Mist small volume nebulisers (Jadhav et al., 2013). Our study showed similar results whereby swabs taken from the Micro Mist small volume nebulisers presented with both bacterial and fungal contamination. Fungal (45.9%) contamination was also higher than bacterial (35.1%) contamination in the Micro Mist small volume nebulisers, however, in the Aeroneb nebuliser bacterial contamination was slightly higher than fungal contamination. Hospital one had the least contamination and hospital two the most contamination. Three out of the four hospitals showed that bacterial together with fungal contamination were more prevalent in both nebulisers and corresponds with the study done by Jadhav et al. (2013).

In the mixed ICU [unit five] bacterial and fungal contamination was observed the most in both Micro Mist small volume and Aeroneb nebulisers, followed by the medical-surgical ICU. According to the INICC, the average LOS for patients in an ICU consisting of mixed conditions was found to be much higher than other types of ICUs. The increased LOS in the ICU with mixed conditions places the patient at higher risk to develop nosocomial infections and possible increase in ventilator time and risk for VAP (INICC, 2010). Both bacterial pathogens

and fungal pathogens (to a lesser extent) play a role in the incidence of VAP (Brink et al, 2006). These micro-organisms gain access to the lower respiratory tract of patients through various mechanisms and mainly due to the endotracheal tube which provides direct access for bacteria into the lower respiratory tract (Crnich, Safdar & Maki, 2005; Efrati et al., 2010)

In this study six Micro Mist small volume nebulisers (n=6) were used for more than 90 aerosolisation sessions, which is higher than the manufacturer's recommendations (SMLT, 2000). Half of those nebulisers presented with bacterial as well as fungal contamination. The 31 nebulisers used for less than 90 aerosolisation sessions presented with less bacterial contamination and higher fungal contamination. As previously stated the fungal contamination found in various sites which included Hudson nebulisers in the ICU were high and could contribute to the increase of fungal infections in the critically ill patient (Jadhav et al., 2013). However, it was outside the scope of the current study to test this assumption.

Bronchodilator medication was associated with the most bacterial contamination in both the Micro Mist small volume nebuliser and the Aeroneb nebulisers in this study. Furthermore mucolytics and specifically Bisolvon were used in two Micro Mist small volume nebulisers and presented with zero contamination. This corresponds with results obtained from the ICUs in Johannesburg and further supports Oie et al. (2013) hypothesis that preservatives in residual aerosol medication after usage could assist in reducing bacterial growth.

In this study there was more yeast than mould contamination in both types of nebulisers. Certain moulds have recently been recognised as emerging nosocomial pathogens and *Candida* spp. (yeast) causes a majority of nosocomial infections (Jadhav et al., 2013). In the study done by Jadhav et al., (2013) more moulds (*Aspergillus fumigatus* & *Aspergillus niger*) were isolated in the chambers of Micro Mist small volume nebulisers which included nebulisers from the ICU.

The decontamination and storage protocol that resulted in the least fungal and bacterial contamination was protocol one. This protocol consisted of rinsing nebulisers with 70% alcohol, drying with a paper towel and leaving them open to the environment. Jadhav et al. (2013) found that the fungal and bacterial contamination rate of Micro Mist small volume nebulisers decreased significantly after disinfecting with 70% ethanol which could explain the low rate of contamination found in the current study with protocol one. As previously stated, nebulisers stored open to the environment have a better chance to dry completely. Drying is a

very important part of a decontamination protocol as devices left wet can result in multiplication of bacteria (O' Malley, 2009). Ellis et al. (2013) found that two dry Micro Mist small volume nebulisers with residual solute observed during assessment presented with no bacterial growth. These two nebulisers were left connected to oxygen running at 1l/min and were completely dry. The flow of oxygen could have assisted in drying the nebulisers in a shorter period of time (Ellis et al., 2013). High concentrations of oxygen have also been shown to reduce the growth of certain bacteria (Schobert and Tielen, 2010). Certain bacteria grow more prolifically in moist environments and therefore it can be assumed that nebulisers stored dry have a lesser chance of presenting with bacterial growth (Ellis et al., 2013). In this study the oxygen flow stopped after the ventilator's aerosolisation cycle was completed and therefore could not assist in drying the chambers of the Micro Mist small volume nebulisers even though it was still connected to the ventilator.

In this study decontamination and storage protocol two resulted in a high incidence of contamination (n=8; 66.7%) especially fungal contamination. In this protocol, no drying of the Micro Mist small volume nebuliser was done as the nebulisers were rinsed with Provac water and left to dry under a sterile cloth. According to the unit manager these sterile cloths are replaced every week. Similar results were found by Ellis et al. (2013) whereby Micro Mist small volume nebulisers that were stored under a sterile drape presented with higher concentrations of bacterial growth than nebulisers stored in a latex/non-sterile glove or open to the environment. The dark environment created by the sterile drape could enhance the growth of certain bacteria as light inhibits the growth of these bacteria (Sagripanti et al., 2013). Protocol three resulted in the highest rate of bacterial (n=3; 60%) and fungal (n=5; 80%) contamination respectively. These Micro Mist small volume nebulisers were reported to be stored in an acceptor/sterile bag after being washed with bioscrub and dried. During data collection no paper bags were identified during assessment of the twelve Micro Mist small volume nebulisers where protocol three was in place. Nine of the 12 Micro Mist small volume nebulisers were stored in a glove, two open to the environment and one left in the ventilator circuit. Therefore it can be assumed that the storage protocol for that ICU was not followed. Ellis et al. (2013) found that two nebulisers stored in paper bags retrieved from sterile packs resulted in zero contamination. However these two nebulisers were left with 1l/min oxygen running through them while they were stored in these paper bags. Although paper has a greater absorbency than non-sterile/latex gloves the reason for the absence of contamination in the light of the results found in this study could be contributed to the continuous flow of oxygen. Therefore the results from the study done by Ellis et al., (2013) and from the current

study regarding the association of contamination with paper bags as storage method were inconclusive. No evidence regarding this type on storage method could be sourced from the literature.

As previously stated, drying the nebuliser after decontamination is an important step in the cleaning protocol. When nebulisers were dried with a paper towel the least contamination was found. Nebulisers taken apart and left to dry under a sterile cloth with no prior drying resulted in the most fungal and bacterial contamination. The high rate of contamination that resulted from method two could be due to the moist and dark environment created by the covering with the sterile drape as highlighted by Ellis et al. (2013).

The contamination associated with decontamination and storage protocols of each unit corresponded with the contamination resulted from methods of storage observed at the bed side. Most Micro Mist small volume nebulisers that were assessed were stored in a non-sterile/latex glove. As previously stated this also corresponded with the method used mainly to store Micro Mist small volume nebulisers in the ICUs in Johannesburg (Ellis et al., 2013). However the most bacterial and fungal contamination were found in the Micro Mist small volume nebulisers left to dry under a sterile cloth.

Most of the Micro Mist small volume nebulisers were stored wet and most of the Aeroneb nebulisers left in the ventilator circuit were also wet with assessment. More bacterial and fungal contamination was found in wet Micro Mist small volume and Aeroneb nebulisers. One dry Micro Mist small volume nebuliser presented with fungal and bacterial contamination and one dry Aeroneb with bacterial and two with fungal contamination. In this study there was a profound difference in the contamination levels between nebulisers stored wet and nebulisers stored dry. The assumption made by Ellis et al. (2013) that nebulisers that are stored dry can reduce the bacterial growth of certain strains is supported by the results of this study. The current practice of decontamination contributed to the high rate of contamination found in Micro Mist small nebulisers and supports the hypothesis stated in this study. Aeroneb nebulisers were left in the ventilator circuit and no decontamination protocol was applied. Therefore the hypothesis is rejected for this type of nebuliser.

Most of the BAPs of the Micro Mist small volume nebulisers (n=7) as well as Aeroneb (n=10) nebulisers presented with one bacterial species during visual assessment. More colonies (CFU) were found on the BAPs sampled from wet Micro Mist small volume nebulisers than

from wet Aeroneb nebulisers. Interestingly, one BAP of a dry Micro Mist small volume nebuliser and one BAP of a dry Aeroneb nebuliser presented with one species but with more than 50 colonies. Most BAPs of Micro Mist small volume nebulisers in the ICUs in Johannesburg presented with colonies (CFU) between one and two (Ellis et al. (2013) which stands in contrast with the findings found in Pretoria whereby most BAPs presented with more than 50 colonies.

5.6 BACTERIAL MICRO-ORGANISMS IDENTIFIED IN CONTAMINATED NEBULISERS AND SURROUNDING AIR

Ten types of organisms were identified in the samples taken from both types of nebulisers and their surrounding air. The predominant organism identified in air samples and Aeroneb nebuliser were CoNS. Only one Micro Mist small volume nebuliser presented with CONS (n=1; 16.7%). *Staphylococcus aureus* was identified in one Aeroneb nebuliser (n=1; 14.3%) and one air sample (n=1; 5.2%). Jadhav et al. (2013) identified MRSA, Methicillin-sensitive *Staphylococcus aureus* (MSSA) and CoNS in the chambers of Micro Mist small volume nebulisers, this included nebulisers used in the ICUs. *Staphylococcus aureus* and CoNS are pathogens known to lead to the development of VAP (Joseph et al., 2010). *Enterococcus* spp. were identified in two Micro Mist small volume nebulisers (n=2; 33.3%) and were also identified in Aeroneb nebulisers and air samples. *Enterococcus* species are also a common cause of VAP (Joseph et al., 2010). Other species identified by Jadhav et al. (2013) included *Pseudomonas* spp., *Acinetobacter* spp., *E. coli* and *Klebsiella* spp. which were not identified in the nebulisers in this study. Gram negative bacteria presented 68.9% of the total bacterial isolates and gram positive cocci 31.1% (Jadhav et al., 2013). In the current study, gram positive and negative cocci were equally prevalent. Furthermore, *Stenotrophomonas* spp. and *Neisseria* spp. were identified in one Micro Mist small volume nebuliser and *Neisseria* spp. in three air samples. These micro-organisms are an unusual cause of VAP (Joseph et al., 2010).

5.7 SIMILAR BACTERIAL MICRO-ORGANISMS CULTURED FROM CONTAMINATED NEBULISERS AND AIR SAMPLES

High contamination levels were identified in air samples (n=60; 98.4%). Fungal contamination was more prevalent than bacterial contamination in the surrounding air of the ICUs in Pretoria. In this study CoNS was the micro-organism most detected in air samples (n=8). These findings correlate with the study done by Qudiesat et al. (2009) whereby CoNS was one of the

micro-organisms most detected in the air in a private and governmental hospital. The other two micro-organisms detected in the air were *Staphylococcus aureus* and *Micrococcus* (Qudiesat et al., 2009). In this study *Staphylococcus* aureus and *Micrococcus* were only detected in one air sample respectively. In contrast with our study Huang et al. (2013) found that *Pseudomona aeruginosa* was the most frequent and abundant micro-organism found in air samples in two ICUs and showed a positive correlation of mean counts between samples taken from the air and surface.

The micro-organism identified in the chamber of a nebuliser and its surrounding air was identical in two instances in the current study. *Enterococcus* spp. was identified in a Micro Mist small volume nebuliser and its surrounding air and CoNS was identified in an Aeroneb nebuliser and its surrounding air. Although identical micro-organisms were identified in both nebulisers and its surrounding air, it cannot be assumed that the surrounding air was the only contributor as results showed that different decontamination and storage methods play an important role in the possible contamination of Micro Mist small volume nebulisers.

The findings do not support the second hypothesis stated for the study. Although the Aeroneb nebulisers were less exposed to handling and surrounding air, they still had contamination rates similar to the contamination rates found in the Micro Mist small volume nebulisers. It can be assumed that contamination found in the Aeroneb resulted from possible contamination of the ventilator circuit and that the moist environment encouraged the growth of micro-organisms. Therefore the hypothesis was rejected as the micro-organisms found in the nebulisers and the surrounding air were only identical in two instances.

CHAPTER 6

6. CONCLUSIONS

Two types of nebulisers used within a ventilator circuit in the ICUs in Pretoria were the Micro Mist small volume nebuliser and a fairly new device the Aeroneb nebuliser. The majority of nebulisers used within the ICUs were Micro Mist small volume nebulisers. All four private hospitals reported to have decontamination and storage protocols in place for the Micro Mist small volume nebuliser. The Aeroneb nebuliser is manufactured to stay in the ventilator circuit and therefore decontamination and storage is not applicable.

This study found that both types of nebulisers presented with fungal and bacterial contamination. The contamination rates found in the Micro Mist small volume and Aeroneb nebulisers were similar when compared to the contamination rate reported for the Micro Mist small volume nebulisers in the ICUs of hospitals in Johannesburg. Although the ICUs in Pretoria had decontamination and storage protocols the incidence of contamination were the same in the ICUs of hospitals in Johannesburg where no decontamination and storage protocols were implemented. Evaluation of staff adherence to the different protocols was not a specific aim of the current study as staff adherence to reported protocols may have played a role in contamination of nebulisers.

Most of the Micro Mist small volume nebulisers were stored wet and therefore it could be assumed that decontamination protocols were not followed. To further bring weight to this assumption is that the method used to store the nebulisers as observed during assessment did not correspond with the storage protocol reported by the ICU on the day of audit. Of these wet Micro Mist small volume nebulisers almost a third presented with bacterial contamination and almost half with fungal contamination. Most of the wet nebulisers presented with higher concentration of bacteria but only one type of species. Micro Mist small volume nebulisers that were stored under a sterile cloth presented with a higher percentage of fungal and bacterial contamination which corresponded with the results found in the Micro Mist small volume nebulisers the ICUs of hospitals in Johannesburg. The nebulisers that were stored open to the environment and rinsed with 70% alcohol had the least bacterial growth.

Air samples in this study revealed very high rates of contamination in the ICUs in Pretoria. Fungal contamination was more prevalent than bacterial contamination. Bacterial and fungal pathogens in the air can be distributed across distances in the hospital units and come to settle

on surfaces or transferred to other surfaces. Clearly nebulisers left open to the environment can become contaminated with pathogens in the air. This risk increases, when nebulisers are not properly dried. In this study two micro-organisms identified in the nebulisers were similar to the micro-organisms found in the air sample taken at the bed side where the nebuliser was kept. A coagulase-negative *Staphylococcus* sp. was identified in one Aeroneb nebuliser and its corresponded air sample and an *Enterococcus* sp. was observed in one Micro Mist small volume nebuliser and its corresponding air sample. Coagulase-negative *Staphylococcus* sp. was also mostly identified in air and Aeroneb nebulisers samples.

This study found support that aerosolisation of medication is an important and frequent therapy in the treatment of patients receiving MV. The development of more aerosol medication due to absorption benefits makes it necessary to develop protocols that will ensure the safety of aerosol therapy delivery to the critically ill patient.

6.1 LIMITATIONS OF THIS STUDY

- No government sector hospitals were included in the study as none gave consent in the time period set aside for acquiring consent and data collection.
- The ICU staff were not evaluated regarding their adherence to implementation of the decontamination and storage protocols in their ICUs as this was not the particular aim of the current study. The rate of contamination associated with the adherence to decontamination and storage protocols could have indicated the difference in the incidence of contamination of application and number of applications of these protocols.

- Pathogens identified within the respiratory system of patients where sampling were done, were not always documented on the cardex. Correlation of pathogens in the nebuliser and the patients' respiratory system could be done. This type of correlation could assist further in identifying the method by which the nebulisers could have become contaminated.

- Identification of the bacterial cultures grown on the BAPs, was costly and therefore BAPs of air and nebuliser samples were chosen through visual inspection of the most recurrent colonies for identification. Similar micro-organisms could have been found between air and nebuliser with the identification of more samples and could assist in identifying the role that environmental contamination can play in the contamination of Micro Mist small volume nebulisers and their method of storage.

6.2 RECOMMENDATIONS FOR FUTURE RESEARCH

- The incidence of contamination of nebulisers used within a ventilator circuit and decontamination protocols used in the ICUs in the government sector hospitals in Pretoria should be investigated and the findings compared with the results found in this study and the study done in Johannesburg, South Africa. This can further assist in the development of a national decontamination and storage protocol for nebulisers that is cost effective, practical and evidence based.

- This study and previous studies regarding contamination of nebulisers should form the platform for the development of evidence based decontamination and storage protocols. Nursing staff and physiotherapists in the ICU are the health professionals that give aerosol therapy on a regular basis to patients receiving MV and therefore must take the lead in the development of these protocols. The role that the surrounding air plays in the contamination of the ICU environment must be taken into account when developing these protocols.

- Unit managers should take the responsibility to inform ICU nursing staff and physiotherapists regarding the decontamination and storage protocols in their units and the importance of adherence to these protocols. Individual ICU staff and physiotherapists must aim to give aerosol therapy safely and effectively and therefore normal infection control activities like hand washing and gloving should be done. Furthermore nursing staff and physiotherapists in the ICU must be informed regarding the potential danger of contaminated nebulisers and the role they can play in the development of antibiotic resistant VAP.

- The results from this study support the development of an evidence based decontamination and storage protocol for jet nebulisers. Staff adherence to such an evidence based decontamination and storage protocol should be evaluated to assess the feasibility of such protocols.

- The future incidence of contamination after implementation of evidence based decontamination and storage protocol for jet nebulisers used within a ventilator circuit should be investigated.

- The incidence of contamination of Micro Mist small volume nebulisers in the High Care Units and general wards, in a South African context, is unknown. The existence of decontamination and storage protocols in these wards is also unknown. Patients who are discharged from the ICU to other units continue to use the same nebulisers and therefore investigation into the level of contamination of such nebulisers should be done.

- The rate of contamination of Micro Mist small volume nebuliser with the use of the Valved Neb Tee (tee connector) is unknown. The Valved Neb Tee that connects the Micro Mist small volume nebuliser to the ventilator circuit is manufactured to be left in the ventilator circuit. When the Micro Mist small volume nebuliser is removed from the Valved Neb Tee, the valve seals the opening, preventing the circuit from being exposed to the surrounding air. Less handling of the circuit is required which will promote the time to spend applying decontamination protocols.

- The application of other single-patient use respiratory devices with regards to contamination and storage e.g. Intermitted Positive Pressure Breath (IPPB) circuits used in IPPB machines could be investigated.

- The indoor quality of air must be investigated to identify the possible risks associated with airborne pathogens in the healthcare setting and especially in the ICUs where a critically ill patient is more susceptible to infections.

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APPENDIX 1

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ms Lizl van Heerden

CLEARANCE CERTIFICATE	**M120514**
PROJECT	Contamination and Current Practice in Decontamination of Nebulisers in Ventilated Patients
INVESTIGATORS	Ms Lizl van Heerden.
DEPARTMENT	Physiotherapy Department
DATE CONSIDERED	25/05/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 13/07/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr H van Aswegen

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

APPENDIX 2

- **INFORMATION LEAFLET: HOSPITAL MANAGER/CEO/INFECTION CONTROL MANAGER**

CONTAMINATION AND CURRENT PRACTICE IN DECONTAMINATION OF NEBULISERS IN VENTILATED PATIENTS

I, Mrs L van Heerden, am a registered postgraduate student in the physiotherapy department of the University of the Witwatersrand and am currently doing a study on jet nebuliser decontamination practices in ventilated patients. This study will assist further research into evidence-based, cost-effective and practical nebuliser decontamination protocols. Incorrect nebuliser cleaning, storage and usage may increase the risk of patients on mechanical ventilation developing ventilator-associated pneumonia.

1. **Introduction**

   Your institution is invited to consider participating in this research study, which is entirely voluntary. Before agreeing to participate, it is important that you read and understand the following explanation of the purpose of the survey, the survey procedures, benefits and risks, as well as your right to withdraw your institution from the survey at any time. If you have any questions, do not hesitate to ask me.

   You should not agree for your institution to take part unless you are satisfied about all the procedures involved. If you decide that your institution can take part in this survey, you will be asked to sign this document to confirm that you understand the survey. You will be given a copy to keep for your own records.

2. **Purpose of the Study**

   - The purpose of this survey is to determine nebuliser contamination rate and the current practice in decontamination of jet nebulisers in intensive care units (ICUs) in Pretoria. Secondly to identify the micro-organisms that contaminate nebulisers used and the air around the beds of patients who received nebulisation in the ICU.

3. **Length of the Study and Number of Participants**

   - Sixteen hospitals in Pretoria have been selected to participate in this survey.
   - Data collection will occur in the period July - September 2012.
   - There will only be one site visit at your institution.

4. **Procedures**

- If you agree that your institution may take part in this survey, the unit manager of the ICU will be asked questions regarding the demographics of the ICU and the nebuliser decontamination protocol that is currently in place. This will be followed by an audit of the unit to identify nebulisers currently used in ventilator circuits. The nebulisers will be examined by me as they have been stored. Each nebuliser will be swabbed according to the protocol for the study. Staff activity in the unit will not be disturbed.
- Air samples at the bedside of patients who had received nebuliser therapy will be taken thereafter
- There will be no record kept of which staff member is responsible for which nebuliser.

5. **Risks**

- While every effort has been made to ensure limitation of the publication of the names of the hospitals who participated in the survey, the names will only be published in the final research report that will be submitted for examination to the University of the Witwatersrand. However, there will be no link made between the names of the hospitals and the results obtained from the unit.

6. **Benefits**

- The potential benefit derived from your institution's participation in this survey is that knowledge will be obtained regarding possible current nebuliser contamination and air contamination around the patient's bedside. The absence or presence of current nebuliser decontamination protocols will also be identified.
- Based on this information the survey will provide a basis for future research into the implementation of evidence based decontamination protocols that are cost effective and practical within the SA ICU context.

7. **Financial Arrangements**

- There will be no financial re-imbursement for participation in this survey.

8. **Ethics Approval**

- This research protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC) and written approval has been granted by that committee to proceed with the study.

- If you want any information regarding your rights as a research participant, or have any complaints regarding this research study, you may contact Prof. Cleaton-Jones, Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent committee, established to help protect the rights of research participants at (011) 717 2229.
- The survey has been structured in accordance with the **Declaration of Helsinki** (last updated: October 2000), which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.

9. **Confidentiality**

- All information obtained during the course of this survey, including hospital names, personnel data and research data will be kept strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you or your hospital as a participant in this survey. The names of hospitals that have participated in the study will be stored in a general list, and there will be no link with the data collected.
- The information might also be inspected by the University of the Witwatersrand, HREC).
- These records will be utilised by them only in connection with carrying out their obligations relating to this survey.

APPENDIX 3

- **INFORMED CONSENT: HOSPITAL MANAGER/CEO/INFECTION CONTROL MANAGER**

CONTAMINATION AND CURRENT PRACTICE IN DECONTAMINATION OF NEBULISERS IN VENTILATED PATIENTS

I hereby confirm that I have been informed by the researcher, Lizl van Heerden, about the nature, conduct, benefits and risks of the survey titled: Nebuliser contamination and current practice in decontamination of nebulisers in ventilated patients, Pretoria, South Africa.

- I have also received, read and understood the above-written information regarding the survey.
- I am aware that the results of the study, including personal and professional details will be anonymously processed into a study report.
- I may, at any stage, without prejudice, withdraw my consent for my institution's participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself, in the capacity of Hospital Manager/CEO/Infection Control Manager to allow my institution to participate in the study.

HOSPITAL MANAGER/CEO/INFECTION CONTROL MANAGER

_____

Printed Name Signature Date and Time

I, Lizl van Heerden, herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

RESEARCHER:

_____

Printed Name Signature Date and Time

APPENDIX 4

- **INFORMATION LEAFLET: UNIT MANAGER**

Dear ICU Unit Manager

Your ICU has been selected to participate in the study described below. Consent for the study has been obtained from the Hospital Manager/CEO/Infection Control Manager of the hospital.

Study Title: Contamination and current practice in decontamination of nebulisers in ventilated patients.

Investigators: Mrs Lizl van Heerden

Institution: University of the Witwatersrand

1. **Purpose of the study:**

   The purpose of this survey is to determine nebuliser contamination rate and the current practice in decontamination of jet nebulisers in intensive care units (ICUs) in Pretoria. Secondly to identify the micro-organisms that contaminates nebulisers used and air around the beds of patients who received nebulisation in the ICU.

2. **Length of the study and number of participants:**
   - Sixteen hospitals in Pretoria have been selected to participate in this survey.
   - Data collection will occur in July 2012 – September 2012.
   - There will only be one site visit to your ICU.

3. **Procedures:**
   - The unit manager, CEO/Hospital manager and infection control manager have given consent for this survey. You will not be asked any personal information. You will be asked questions regarding the demographics of your ICU and your nebuliser decontamination protocol in your capacity as unit manager. This will be followed by an audit of the unit. The nebulisers will be examined as they have been stored. Each nebuliser will be swabbed according to the protocol for the study. Staff activity in the unit will not be disturbed.
   - Air samples at the bedside of patients who had received nebuliser therapy will be taken thereafter

- There will be no record kept of which staff member is responsible for which nebuliser.
- The only information that will be obtained from the patient's ICU nursing chart is that relating to nebuliser use as stipulated in Appendix 1 section B. No additional information will be obtained from patient records.

4. **Risks:**

- While every effort has been made to ensure limitation of the publication of the names of the hospitals who participated in the survey, the names will only be published in the final research report that will be submitted for examination to the university. However, there will be no link made between the names of the hospitals and the results obtained from the audit of the unit.

5. **Benefits:**

- The potential benefit derived from your ICU's participation in this survey is that knowledge will be obtained regarding possible current nebuliser contamination and air contamination around the patient's bedside. The absence or presence of current nebuliser decontamination protocols will also be identified.
- Based on this information the survey will provide a basis for future research into the implementation of evidence based decontamination protocols that are cost effective and practical within the SA ICU context.

6. **Financial arrangements:**

- There will be no financial re-imbursement for participation in this survey.

7. **Ethical approval:**

- This survey protocol has been submitted to the University of the Witwatersrand, **Human Research Ethics Committee (HREC)** and written approval has been granted by that committee.
- If you want any information regarding your rights as a research participant, or have any complaints regarding this research study, you may contact Prof. Cleaton-Jones, Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent committee, established to help protect the rights of research participants at (011) 717 2229.

- The survey has been structured in accordance with the **Declaration of Helsinki** (last updated: October 2000), which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.

8. **Confidentiality**

- All information obtained during the course of this survey, including hospital names, personnel data and research data will be kept strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you or your hospital as a participant in this survey.
- The information might also be inspected by the University of the Witwatersrand, Human Research Ethics Committee HREC.
- These records will be utilised by them only in connection with carrying out their obligations relating to this survey.

APPENDIX 5

- **INFORMED CONSENT: UNIT MANAGER**

CONTAMINATION AND CURRENT PRACTICE IN DECONTAMINATION OF NEBULISERS IN VENTILATED PATIENTS

I hereby confirm that I have been informed by the researcher, Lizl van Heerden, about the nature, conduct, benefits and risks of the survey titled: Nebuliser contamination and current practice in decontamination of nebulisers in ventilated patients, Pretoria, South Africa.

- I have also received, read and understood the above-written information regarding the survey.
- I understand that only information pertaining to nebuliser use will be obtained from the ICU charts.
- I am aware that the results of the study, including personal and professional details will be anonymously processed into a study report.
- I may, at any stage, without prejudice, withdraw my consent for my ICU's participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself, in the capacity of the unit manager to allow my ICU to participate in the study.

UNIT MANAGER

_____

Printed Name Signature Date and Time

I, Lizl van Heerden, herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

RESEARCHER:

_____

Printed Name Signature Date and Time

APPENDIX 6

SECTION A

- **UNIT AUDIT TOOL: CURRENT PRACTICE IN DECONTAMINATION OF NEBULISERS IN VENTILATED PATIENTS, PRETORIA, SOUTH AFRICA**

Hospital code: _____

Number of beds in unit: _____

Number of patients on a ventilator: _____

Number of ventilated patients receiving nebulisation: _____

What kind of ICU: Cardio____, Medical____, Surgical____. Trauma____, Neuro____, Mixed_____

Nurses:

Number of staff on duty: _____

Number of permanent staff: _____

Number of agency staff: _____

Physiotherapists:

Number of staff on duty: _____

Number of permanent staff: _____

Number of locum staff: _____

Is there a ventilator nebuliser decontamination protocol for this unit?	YES	NO
Nebuliser discarded after each use?	YES	NO
Nebuliser rinsed with a solution?	YES	NO

Solution?.....……..…

.

Nebuliser dried?	YES	NO

Material used to dry nebuliser?…….…….

Nebuliser stored:

Glove	YES	NO
Sterile cloth	YES	NO
Open to the environment	YES	NO

Paper bag	YES	NO
With residual solute	YES	NO
Attached to oxygen tubing	YES	NO
Nebuliser autoclaved	YES	NO

If yes, method used: ……

Other observations made:

……

……

……

……

……

APPENDIX 6

SECTION B

- **NEBULISER ASSESSMENT FORM**

Nebuliser number:_____

Hospital number:_____

Manufacturer:_____

Single use:_____Single patient use:_____ Autoclave:_____

Prescribed medication:_____

Date when nebulisation started_____ /____hourly_____

Time of last nebulisation:_____

Time of assessment:_____

Days on Ventilation:_____

Environment at bedside

Windows	YES	NO
Natural light	YES	NO
Artificial light	YES	NO
Cubicle isolated	YES	NO
Blinds	YES	NO
Nebuliser discarded after use	YES	NO
Nebuliser dry	YES	NO
If yes, is there dry solute in the chamber?	YES	NO
If no, appearance of solution	Clear	Opaque

Nebuliser stored:

Glove	YES	NO
Sterile cloth	YES	NO
Open to the environment	YES	NO
Paper bag	YES	NO
Removed from oxygen tubing	YES	NO
Nebuliser sent to be autoclaved	YES	NO

Other observations made

……

……

……

Air sample at bedside

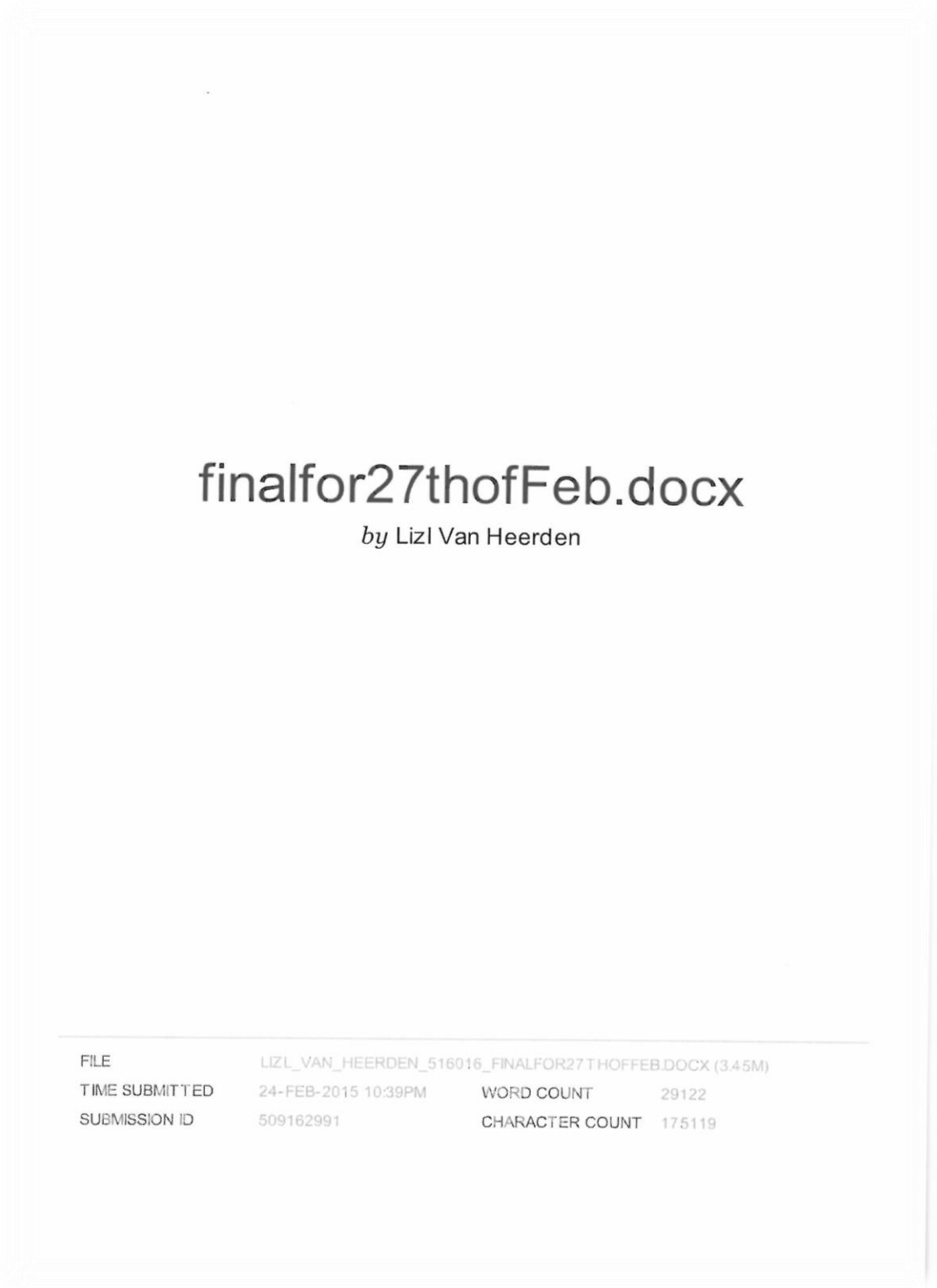
Persons at bedside:.....

Sample one: Time.....

Sample two: Time.....

APPENDIX 7

- **Turn-it-In Plagiarism Scan**



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by Lizl Van Heerden

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