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CURRENT PRACTICE IN DECONTAMINATION OF NEBULISERS IN VENTILATED PATIENTS, JOHANNESBURG, SOUTH AFRICA

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Masters of Science (Physiotherapy)

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ABSTRACT

Background:

Jet nebulisers are one of the primary devices used in the nebulisation of ventilated patients. It has been observed that due to cost restraints devices marked as “single use” are inadvertently being used as “single-patient-use” devices. This has both ethical and medico legal implications for the ICU. Ventilator-associated pneumonia (VAP) in limited-resource countries carries a large burden of increased mortality, morbidity and cost. Ineffective or absent nebuliser decontamination in ventilated patients can increase the risk of the development of VAP as well as the risk of antibiotic resistance.

Objectives:

The aim of this study was to examine the current practice of nebuliser decontamination and the incidence of contamination of nebulisers after use within a ventilator circuit, in ICUs in Johannesburg, South Africa. The secondary objectives of the study were to assess the presence of and adherence to a decontamination protocol in intensive care units (ICU) in Johannesburg and to identify which practices were associated with lower or no bacterial growth.

Methods:

A cross-sectional study design was used which included an interview with the unit manager and an audit of current nebuliser practice in the ICU. Nebulisers that were identified in the interview were then swabbed and streaked on blood agar plates (BAPs). Blood agar plates were then incubated and assessed for bacterial colonisation, number of colony forming units (CFUs) and number of different species of CFUs that were formed.

Results:

Single-use jet nebulisers represented 93% of nebulisers used within a ventilator circuit. All of the single-use jet nebulisers were being re-used (n=42). None of the hospitals studied had a nebuliser decontamination protocol. The contamination rate for jet nebulisers that had been re-used within the ventilator circuit was 52%. In the group of nebulisers that had bacterial colonisation, the nebulisers that were stored in a sterile drape had a significantly higher concentration of bacterial growth, than those that were not stored in a sterile drape ($p=0.03$). Nebulisers are often used in the administration of bronchodilators in ICUs in Johannesburg, South Africa. Colonised nebulisers can create bacterial aerosol when used within a ventilator circuit. A change to single-patient-use devices, such as vibrating mesh nebulisers, may assist in reducing the problem of colonisation of jet nebulisers.

Conclusion:

The rate of colonisation of jet nebulisers that have been re-used is unacceptably high. ICUs need to develop nebuliser decontamination protocols. Physiotherapists should assist with creating awareness and driving the creation of these protocols. ICUs should be encouraged to change single-use devices to single-patient-use devices. Nebulisers should not be stored in sterile drapes after use in a ventilator circuit.

DECLARATION

I, Amy Ellis, declare that this research report is my own work. It is being submitted for the degree of Masters of Science (Physiotherapy) in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.



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…28th…….day of …October……, 2010

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LIST OF ABBREVIATIONS

BAP	blood agar plates
CFU	colony-forming units
ETT	endotracheal tube
HAP	hospital-acquired pneumonia
HREC	Human Research Ethics Committee
ICU	intensive care unit
MDI	metered-dose inhaler
MRSA	methicillin-resistant *Staphylococcus aureus*
PEEP	positive end expiratory pressure
PML	Pharmaceutical Microbiology Lab
SD	Standard Deviation
VAP	ventilator-associated pneumonia
VMN	vibrating mesh nebuliser
vs	versus

CHAPTER 1

1. INTRODUCTION

1.1 BACKGROUND

Nebulisation is a widely accepted form of medication administration both inside and outside of the intensive care unit (ICU). Nebulisation is the aerosolisation of a liquid in order to allow deposition of particles into the lower respiratory tract. This form of medication delivery allows for directed administration of pharmacological agents directly to the lungs, resulting in decreased systemic side effects and improved local effect. Inhalational therapies will continue to be important to clinical practice within the ICU due to this local effect (Robinson, Athota & Branson, 2009). It is thus imperative that all aspects of the administration of these therapies be examined.

Ventilator-associated pneumonia (VAP) is a disease that develops in ventilated patients after greater than 48 hours of ventilation (Mayhall, 2001). A contaminated nebuliser within a ventilator circuit holds the potential to deliver pathogens deep into the lower respiratory tract. The type of device used during nebulisation will affect particle size, and thus depth of penetration. Jet nebulisers are commonly used in the hospital environment, followed by ultrasonic and more recently vibrating mesh nebulisers. Physiotherapists frequently use nebulisation during respiratory treatments in order to assist with sputum clearance and to reduce bronchoconstriction.

There is no current information on the incidence of contamination of jet nebulisers used within a ventilator circuit, and the efficacy of decontamination methods currently in use. Clinical experience indicates that there may be a high rate of contamination of jet nebulisers that have been used in a ventilator circuit and incompletely decontaminated. It has been observed that current practice seems to be the storage of the nebuliser, with residual medication still in the chamber, in either a glove or a sterile drape.

1.2 JUSTIFICATION FOR RESEARCH

Jet nebulisers are one of the primary devices used in the nebulisation of ventilated patients. It has been observed that due to cost restraints devices marked as “single use” are inadvertently being used as “single-patient-use” devices. This has both ethical and medico legal implications for the ICU. If a device is to be used in a manner other than is recommended by the manufacturer then there must be evidence to support this alternate use and clear guidelines must be established to ensure patient safety. It is this clinical dilemma that has highlighted the problem to be addressed in this research report.

1.3 STATEMENT OF PROBLEM

There is currently no information on the incidence of contamination of single-use jet nebulisers that are re-used within a ventilator circuit or documentation of which decontamination methods are currently in use.

1.4 RESEARCH QUESTION

What is the incidence of jet nebuliser contamination after use within a ventilator circuit? What is the current practice regarding decontamination of a jet nebuliser after use in a ventilator circuit?

1.5 RESEARCH AIM

The aim of this research project is to determine the current incidence of contamination of jet nebulisers that have been used within a ventilator circuit and to determine current practice regarding decontamination of such nebulisers in ICU.

1.6 RESEARCH OBJECTIVES

Primary objectives:

- To assess current practice with regard to the decontamination of jet nebulisers used within ventilator circuits in ICUs in Johannesburg, South Africa;
- To determine the incidence of contamination of jet nebulisers after use within a ventilator circuit.

Secondary objectives:

- To examine which types of nebulisers and which nebulised medications are being used in ICUs in Johannesburg;
- To determine if ICUs that are re-using single-use jet nebulisers have a formal nebuliser decontamination protocol;
- To do a sub-analysis of current practice to determine compliance to the protocols;
- To identify which practices were associated with bacterial growth, higher concentrations of bacteria and multiple species within nebulisers that were re-used.

1.7 SIGNIFICANCE OF STUDY

Physiotherapists and nursing sisters in ICU regularly use nebulisation to administer medication such as bronchodilators and/or mucolytic drugs to an intubated patient. The nebuliser is often stored under a sterile drape next to the patient's bed until the next dosage of medication needs to be administered. This project, a cross-sectional study of ICUs in Johannesburg, South Africa, aims to examine current practice in the use and decontamination of nebulisers that are used within a ventilator circuit. Examination of current practice and identification of practices associated with a higher risk of contamination will set a foundation for further research on the implementation of realistic, cost-effective and effective decontamination protocols for nebuliser use by various professionals in the ICU setting.

CHAPTER 2

2. LITERATURE REVIEW

2.1 INTRODUCTION

This chapter serves to highlight and discuss current literature that is relevant to the research problem presented in Chapter 1. This review will discuss the clinical significance of inhalation therapy in the ICU; the potential for nebulisers to create a bacterial aerosol; the significance of VAP in resource-limited countries; and current practice and guidelines for nebuliser decontamination. The terms “nebulis(/z)er”; “ICU”; “Physiotherapy”; “cleaning protocol” and “bacterial contamination” were searched in Pubmed and PEDro to source articles for this literature review.

2.2 INHALATIONAL THERAPY

2.2.1 Types of Devices in Use

The delivery of medications into the airways is one of the earliest methods of administration of medications. The inhalation of smoke and steam has been documented in many cultures throughout history (Shehata, 2009). Ancient documents dating back to 1550 BC have indicated that the Egyptians were using smoke and vapour of volatile oils for the relief of respiratory ailments (Shehata, 2009). Modern methods that are currently used in ventilated patients within the ICU are: direct instillation, metered-dose inhalers (MDIs) and nebulisation (Robinson, Athota & Branson, 2009). Inhalational therapies have an advantage over parenteral and enteral drug administration, because they have a direct effect on the lung tissues and have reduced systemic side effects. Risks however include increased local side effects such as bronchospasm and delayed systemic effects, such as tachycardia and tremors.

Nebulisers are devices that are designed to aerosolise a medication into particles that can be inhaled and delivered to various levels of the airways. Larger particles are deposited into the upper airways and smaller particles are able to move deeper into the peripheral airways (Fink, 2009). Several types of nebulisers are currently being produced. They can be divided into three categories: jet nebulisers, ultrasonic nebulisers and vibrating mesh nebulisers (VMNs). A jet nebuliser is a device that uses a flow of gas (oxygen or air) to generate an aerosol by passing through a reservoir of medication (Kendrick, Smith & Wilson, 2009; Fink, 2009). Ultrasonic nebulisers create the aerosol through the vibration of a piezoelectric crystal; a flow of gas is used to deliver the aerosol. Ultrasonic nebulisers create a smaller particle size than jet nebulisers (Wilkins et al., 2009). Ultrasonic nebulisers use the vibration of a piezoelectric crystal to break up the medication into particles small enough to be delivered into the lower airways (Fink, 2009). More recently VMNs have been developed

but are currently not widely used. These nebulisers consist of a dome-shaped aperture plate which vibrates at a high frequency. The medication moves through the apertures and is aerosolised during this process (Wilkins, 2009). There is no communication between the flow of gas and the medication reservoir.

2.2.2 The Context of Inhalational Therapy in Ventilated Patients

Within the ICU setting, inhaled medications are delivered to patients using a variety of devices, depending on the respiratory status of the patient. Medications that can be administered in this way are bronchodilators, corticosteroids, mucolytics, antibiotics, pulmonary vasodilators and inotropic drugs (Robinson, Athota & Branson, 2009).

There is debate surrounding the selection of devices to deliver aerosol medication to ventilated patients. Dhand (2008) found, in his review of devices used in aerosol delivery of bronchodilators for ventilated patients, that both MDIs and nebulisers were able to deliver aerosol effectively into the lungs. His review concludes that nebulisation is an efficient means of delivering bronchodilators to ventilated patients and that optimising ventilator settings and the positioning of the device can improve drug delivery. Nebulisers and MDIs should be placed in the inspiratory limb of the ventilator circuit, above the level of the y-connector (Dhand, 2008).

Jet nebulisers are either run from wall oxygen, via a flow meter, or can be connected into a port on the ventilator which diverts flow through the nebuliser. When a jet nebuliser is used for ventilated patients, it is a separate devise that is introduced into the ventilator circuit. The design of the device indicates that the reservoir of the jet nebuliser lays dependant. This positioning indicates that the medication reservoir is at an increased risk of contamination from secretions from the endotracheal tube (ETT) as well as condensate from the circuit draining down into the medication reservoir. The jet nebuliser needs to be removed from the circuit after nebulisation. Due to the design of jet nebulisers, if the flow of the driving gas is stopped, the flow of gas from the ventilator will push the residual medication down into the oxygen tubing connected to the nebuliser. This could result in the residual fluid blocking the oxygen tubing over time. In patients with refractory bronchospasm who require frequent or continuous nebulisation, opening the ventilator circuit to refill the reservoir may result in loss of positive end expiratory pressure (PEEP) and thus worsen patient outcomes by resulting in de-recruitment of dependant and affected lung segments and increased work of breathing (Miro, Pinsky & Rogers, 2004). Jet nebulisers can either run continuously throughout inspiration and expiration or they can be synchronised with inspiration when connected directly to the ventilator (Dhand, 2008).

Vibrating mesh nebulisers are a recent development in nebuliser technology and are either a clip-on unit or a ventilator with the VMN built into its design (Dhand, 2008). The medication reservoir of the VMN lies independent of the flow of gas in the circuit (Dhand, 2008). The reservoir of the VMN can be re-filled without having to break the ventilator circuit. The medication reservoir of the VMN is separated from the ventilator circuit by the mesh plate. When the VMN is not running, the mesh plate lies closed; thus medication can be added to the reservoir through syringe connection ports without affecting ventilator circuit. A VMN that is integrated into the software of a ventilator can be set to generate aerosol during a specific portion of inspiration and thus optimise drug delivery (Dhand, 2008). The VMN units were originally only available in an autoclavable design but recently a single-patient-use device has been released onto the market (Aerogen, 2010).

Ultrasonic nebulisers can also be used within a ventilator circuit. The Siemens Servo ventilator circuit come with an ultrasonic nebuliser attachment (Fink, 2009), and controlling mechanisms built into the software, similar to the VMN. The use of ultrasonic nebulisers is also similar to the VMN as it does not introduce extra flow into the ventilator circuit, which assists in reducing the number of compensatory changes required to be made to the ventilator during nebulisation (Fink, 2009). This method of nebulisation is similar to the jet nebuliser in that the medication reservoir is still dependant to the flow of gas in the ventilator circuit, thus the risk of contamination is similar to that of the jet nebulisers. Ultrasonic nebulisers also heat up the nebulised solution, which can result in denaturing of the solution (Fink, 2009).

2.2.3 **Role of Physiotherapists and Nursing Staff in Nebulisation**

In an era of increasing rates of healthcare-related infections and antibiotic resistance (Dettenkofer & Spencer, 2007), infection control is an area of concern for all healthcare professionals. Physiotherapists working in the ICU have an important role to play in the development of evidence-based, cost-effective and practical infection control measures in their scope of practice. Most physiotherapists adhere to infection control regulations regarding hand washing and cleaning of stethoscopes between patients in ICU but there seems to be little knowledge about the role physiotherapists should play in the decontamination of jet nebulisers and which methods should be used. There are currently no studies available that examined physiotherapists' knowledge and compliance to nebuliser decontamination procedures and protocols for ventilated patients. The nebulisation of medications is a technique used by physiotherapists in South Africa (Department of Health, 2009). Physiotherapists also play an active role in the treatment and prevention of VAP (Jones, Ntoumenopoulos & Paratz, 2008). Nurses in the ICU will also administer medication through jet nebulisers as part of implementing their nursing-care plan

for ventilated patients (Ball, Cox, Englebretson, Hill & Thacker, 2005). Once the selected medication has been delivered through nebulisation, storage of the nebuliser will have a large impact on the efficacy of further nebulisation treatments (Standaert, Morlin, Williams-Warren, Joy, Pepe, Weber & Ramsey, 1998) and might re-introduce pathogens into the lower airways.

2.2.4 Summary

This section has shown that aerosol therapy is an important method of drug delivery for ventilated patients and will continue to be so in future. Jet nebulisers are used mostly to deliver aerosol therapy to ventilated patients. These nebulisers are at increased risk of environmental contamination and bacterial growth due to the design of most ventilator circuits and the fact that they are stored outside of the ventilator circuit in between use. Other options for aerosol delivery for ventilated patients include VMN, ultrasonic nebulisers and MDIs. Both physiotherapists and nurses are involved in the administration of aerosol therapy to ventilated patients.

2.3 SINGLE-USE AND SINGLE-PATIENT-USE DEVICES

2.3.1 Significance of Single-Use Devices in Healthcare

One of the main themes in the topic of jet nebuliser decontamination is the use of single-use versus (vs) single-patient-use devices (Kendrick, Smith & Wilson, 1997). Single-use devices are intended for one episode of use only (Therapeutic Goods Administration, 2006) and should be discarded after treatment. Single-patient-use devices are those that can be re-used safely for the same patient. Single-patient-use devices should not be used for more than one patient. The method of decontamination, storage instructions and an indication of the time frame in which the device can be safely used should be marked clearly (Therapeutic Goods Administration, 2006). It has been found internationally that devices intended for single-use have been re-used on the same patient with little or no decontamination or reprocessing between nebulisations (Allan, Cunniffe, Edwards, Kretzer, Legerton, Makintosh & Murray, 2004). The rationale behind the reprocessing of single-use nebulisers is the high cost involved in using a new device with each nebulisation. Due to cost constraints the type of nebulisers used in the ICU tend to be less expensive, disposable single-use devices; however the cost of healthcare-associated infections far outweighs this cost difference. Using a new device with every nebulisation also raises the issue of waste management and the environmental impact of medical waste disposal (Daschner & Dettenkofer, 1997). As the impact of waste on the environment is a global issue, healthcare professionals should be examining ways in which healthcare related waste can be reduced. Nebulisers are made from plastic which carries a high level of waste burden because it requires a longer time to degrade, and because of toxic by-products

created during manufacturing (Thompson, Moore, Vom Saal & Swan, 2009). Devices that have been used within a healthcare setting cannot be recycled, due to the biohazard risk of viral and bacterial contamination. For this reason discarded nebulisers are sent for incineration, which generates toxic by-products and has a cost implication for the hospital. There also is an increasing pressure from the public for hospitals and healthcare providers to become more environmentally aware and active.

2.3.2 Can Single-Use Devices Be Safely Re-Used?

Standaert et al. (1998) set out to study the effects of device performance after the re-use of single-use nebulisers. They conducted an in-vitro study which tested the performance of four disposable models against one durable model, after various methods of cleaning and repeated use. The findings of this well-conducted and well-controlled trial was that single-use nebulisers were able to perform up to 100 re-uses without a significant reduction in performance provided they were cleaned in between use and were not seen to be leaking or grossly malfunctioning. The control group consisted of a group of matched nebulisers that were run repetitively without cleaning in between use. There was a higher rate of failure of nebulisers and a marked reduction in aerosol output in the control group, compared with the experimental group. Their conclusion was that the build-up of and crystallisation of solutes within the chamber were the cause of the damage to the jet nebuliser, and thus the resultant increase in particle diameter and drop in performance. They did however consider the performance of the nebuliser separately from bacterial growth within the nebulisers. They indicated that following the manufacturer's recommendations would not necessarily ensure suppression of bacterial growth within the nebuliser. They concluded that there should be further research conducted into the effect of improper cleaning on bacterial growth within nebulisers. For a ventilated patient that was hypothetically receiving four-hourly nebulisation of a bronchodilator, 100 uses would equate to 17 days of use for a single nebuliser.

2.3.3 Manufacturer's Recommendations on the Re-Use of Single-Use Devices

The main focus of research into decontamination of nebulisers is the re-use of devices in the community (Standaert et al., 1998), and specifically in patients with cystic fibrosis. Standaert et al. (1998) also indicated that the manufacturer's guidelines for jet nebulisers are for cleaning only and do not give an indication of microbial contamination of the devices and the efficacy of cleaning guidelines in achieving decontamination. The manufacturers themselves have issued statements indicating that their cleaning guidelines do not sterilize the device and that microbial contamination of the device may persist after a cleaning procedure (Phillips, 2000). There is an impression that manufacturers have reverted to labelling their devices as single-use rather than single-patient-use in order to circumvent

the need for supplying an effective and reliable decontamination method for nebulisers, thus shifting the legal responsibility on to the healthcare provider who intentionally re-uses a single-use device (Phillips, 2000).

2.3.4 Medico-Legal Aspects of Re-Use of Single-Use Medical Devices

When staff re-use devices that have been labelled as single-use by the manufacturers they take the legal responsibility of this altered use on themselves. This means that should there be an adverse event for a patient resulting from this altered use, the healthcare provider will be held liable, and not the manufacturer (Allan et al., 2004). Nosocomial infections are such events that could be linked to re-use of single-use nebulisers. Ventilator-associated pneumonia occurs in 10 to 20% of patients who receive ventilation for longer than 48 hours (Safdar, Dezfulian, Collard & Saint, 2005) and represents 86% of hospital-acquired pneumonia (HAP) seen in the ICU (Rotstein, Evans, Born, Grossman, Light, Magder, McTaggert, Weiss & Zhanel, 2008). Thus physiotherapists and nurses are potentially putting themselves at risk for litigation every time they re-use a device that is marked as single use by the manufacturer. The one solution to this issue would be the introduction of evidence-based protocols for the re-use of these devices. The introduction of such protocols would reduce the risk to the patients, healthcare providers and the hospitals. If an institution is using a device in a way other than is recommended by the manufacturer there must be a specific protocol in place outlining the use of the device and the evidence to support this alternate use (Kendrick, Smith & Wilson, 1997; Phillips, 2000). In a statement issued by Hudson RCI, in response to the problem of the re-use of nebulisers, they argued that “cleaning, disinfecting and repeated re-use is at the sole discretion of the respective institution and its staff, and neither Hudson RCI nor the distributor warrant, guarantee or accept responsibility for the outcome” (Phillips, 2000).

2.3.5 Factors that Affect Decontamination Practices

Allan et al. (2004) in an editorial letter regarding jet nebuliser decontamination highlighted some of the issues associated with non-compliance to ward protocols. This letter described their experience in a hospital while they were reviewing the re-use of single-use nebulisers in the medical ward. They found in their initial assessment of current practice on their ward that single-use nebulisers were being re-used multiple times; that they were not being decontaminated in between use and that there was no protocol for storing the nebulisers in between use. The authors asserted that nebulisers that were stored open to the environment, visibly soiled and wet, were at high risk for the transmission of methicillin-resistant staphylococcus aureus (MRSA) and legionella bacteria. They concluded that it was impractical to follow the manufacturer’s recommendations at a ward level. This finding can be extrapolated into the ICU environment as the time and equipment required to clean

face mask jet nebulisers and T-piece nebulisers is the same. Anaissie, Penzak and Dignani (2002) reported that the time involved in washing and drying nebulisers increased the workload of the nursing staff. Thus indirectly, the cost of following the cleaning recommendations seemed to be more than the cost of simply replacing the nebulisers more frequently. The staff were also cleaning the nebulisers in hand basins or sluice sinks, which posed an infection risk for contamination of the basin and nebuliser. The conclusion of the investigation was that a simplified decontamination procedure combined with daily replacement of the nebulisers was best for their ward situation. The increase in cost was balanced by the reduction in risk to the patients and reduced workload of the staff (Anaissie, Penzak & Dignani, 2002)

The recommendation of using tap water to clean nebulisers may also result in an alternate source of colonisation of the nebulisers. Anaissie, Penzak & Dignani (2002) found that hospital water supply lines can be the source of outbreaks of nosocomial infections, with *Pseudomonas Aeruginosa* being one of the most virulent organisms found. The authors stated that cleaning a nebuliser in a sink with a water source that may be colonised, would increase the risk of passing that organism onto the patient. The problem of contamination of water sources is of concern in both resource-limited and developed countries (Angelbeck, Ortolano, Canonica & Cervia, 2006).

2.3.6 **Summary**

Currently jet nebulisers that are being marked as “single use” are being re-used, but to what extent this is happening in the ventilated patient population has not been determined. Studies based on nebulisers used in self-ventilated patients indicate that nebulisers marked as “single use” can be re-used up to 100 times without affecting flow rate and particle diameter. Incorrect cleaning of nebulisers that are re-used will result in device failure. Discarding a nebuliser after each use may result in a large waste and cost burden for hospitals, and is not in line with current social pressures to reduce waste and consumption. Using medical devices in a way other than the manufacturer has recommended may result in a risk of litigation, if an evidence-based protocol is not in place within an institution. Decontamination processes that take too long or are difficult to follow will result in a low adherence level and a high cost due to the time taken to follow the protocol. Current practice regarding decontamination of jet nebulisers that have been used within a ventilator circuit needs to be assessed. The effectiveness of decontamination techniques in reducing bacterial growth and maintaining device performance also needs to be assessed.

2.4 VENTILATOR-ASSOCIATED PNEUMONIA

2.4.1 The Role of Medical Devices in the Development of Ventilator-Associated Pneumonia

Ventilated patients are at risk of contracting colonies of bacteria from various devices that are used during the period of ventilation. As soon as medical devices such as endotracheal tubes, ventilator circuits and central venous catheters are introduced into a patient's environment, colonisation of these devices occurs with normal flora. Priority however is given to prevention of colonisation of these devices with pathogenic bacteria which would lead to the development of antibiotic resistance, re-introduction of bacterial colonies to the patient and transfer of these colonies between patients. Normal muco-cilliary function is reduced in ventilated patients due to the bypassing of the upper airway, low relative humidity levels in the artificial airway, the use of sedatives and suppression of the normal cough reflex (Branson, 2007). If bacteria are displaced from one of the colonies found in the patient's environment then the risk of developing pneumonia is greatly increased, due to the suppression of normal muco-cilliary function and mucus clearance (Rotstein et al., 2008). The mortality associated with the development of VAP is around 30% (Valencia & Torres, 2009).

Rotstein et al. (2008) in their clinical practice guidelines for HAP and VAP highlight certain medical devices associated with the development of VAP. Endotracheal tubes were found to be of importance due to bio-film formation, and the ability for colonies to be dislodged with suctioning, lavage and the accumulation of sub-glottic secretions. Ventilator circuits however have a lesser role to play in the development of VAP. It has been suggested that ventilator circuits should only be changed when gross failure is noted, or if there is visible contamination of the circuit (Rotstein et al., 2008). Regular changing of ventilator circuits was not associated with lower rates of VAP (Rotstein et al., 2008). This finding can be explained by looking at the risk of aspiration of bacteria that have formed within the ventilator circuit. The positioning of the circuit and the presence of heat moisture exchangers (HMEs) would both act to lower the risk of contaminated fluid being reintroduced into the airways.

When a nebuliser is used within the ventilator circuit the nebuliser is positioned in the circuit so as to ensure optimal deposition of the medication within the lung. The position would be before the HME and after the catheter mount, which acts as a spacer (Dhand 2008). Thus if there is bacterial colonisation of the medication reservoir of a nebuliser, then the bacteria will be aerosolised with the medication and deposited back into the patient's airways (Craven, Lichtenberg, Goularte, Make & McCabe, 1984; Dhand, 2008; Guerin, Fassier, Bayle, Lemasson & Richard, 2008). In an examination of ultrasonic nebulisers used in a hospital setting in non-ventilated patients, it was found that excess solution stored in the

device post nebulisation at an ambient temperature was contaminated with microbes such as *Pseudomonas Aeruginosa* (Oie, Makieda, Ishida, Okano & Kamiya, 2006). It was also found that the presence of a preservative in the solution tended to lower the microbial count. The reservoirs of jet nebulisers lay dependant in the ventilator circuit (Dhand, 2008; Guerin et al., 2008) and as a result can be directly contaminated by the secretions of patients who cough spontaneously or through the normal process of the colonisation of medical devices, as discussed previously. Once a nebuliser is removed from the ventilator circuit, environmental contamination of nebulisers may assist in the spreading of antibiotic-resistant pathogens (Dettenkoffer et al., 2007). If a nebuliser is incorrectly stored and basic infection control measures such as hand washing and regular cleaning after use are not adhered to, then a nebuliser may become colonised by bacteria from the environment and other patients (Craven et al., 1984). It is these factors, within the context of the bypassing of the upper airway and reduced muco-cilliary clearance, which indicate that nebulisers that are used within a ventilator circuit should be considered separately to those used in self-ventilating patients.

2.4.2 Factors Affecting the Development of Bacterial Resistance to Antibiotics

One of the factors that would increase the severity of VAP is resistance of the causative bacteria to antibiotics. Antibiotic resistance may develop through a DNA exchange. In this process genetic material can be swapped not only between organisms of the same species, but also between bacterial species (McDermott, Walker & White, 2003). Nebulisers that have become colonised with bacteria from within the respiratory tract, if not decontaminated appropriately after use, may play a role in the development of antibiotic resistance. Nebulisers which are stored wet and in a warm environment, such as the ambient temperature in an ICU, would promote the growth of bacteria within the solution (Trautmann, Lepper & Haller, 2005). Through environmental exposure this nebuliser could become colonised with more than one species of bacteria, or a strain of the same species which has developed resistance. In a warm, moist environment they would be likely to transfer extra chromosomal elements, known as plasmids (McDermott, Walker & White, 2003). Thus nebulisers that are colonised with more than one species of bacteria could play a role in the development and spread of antibiotic resistance.

As previously discussed, the presence of preservatives within residual solution would act to reduce bacterial growth if the nebuliser were to be stored without cleaning (Oie et al., 2006). This would assist in reducing the risk of re-contamination, however, if the solution that was nebulised contained an antibiotic, and was then stored in a wet, warm environment, with multiple bacterial species, this situation might induce antibacterial resistance at a faster pace (McDermott, Walker & White, 2003). The antibiotic would act as

a selective pressure within the bacterial population, and with random genetic mutation combined with the availability of plasmids, only bacteria that were resistant to the antibiotic would survive and grow to colonise the nebuliser.

2.4.3 Standardisation of Treatment

Valencia & Torres (2009) found in their systematic review of ventilator-associated pneumonia that the introduction of standardised group measures, otherwise known as “bundles”, could assist in the reduction of the rate of VAP. Standardized group measures also assist in reducing the cost of preventative measures introduced (Valencia & Torres, 2009). Standardized group measures are made up of protocols that have been shown to be best practice in the reduction of VAP. Protocols may assist in guiding staff action and reduce error in the treatment and handling of patients and their environment (Halpern, 2009).

2.4.4 Summary

Medical devices and specifically nebulisers play a role in the development of VAP. Incorrect cleaning, storage and re-use of jet nebulisers may increase the risk of developing an antibiotic-resistant VAP and the propagation of resistant strains of bacteria around the ICU. A standardized approach to cleaning of nebulisers could assist in reducing the rate of VAP and the costs associated with preventative measures. Ventilator-associated pneumonia increases mortality in the ventilated patient population, and has social and economic impacts for the patients and the hospital.

2.5 CONCLUSION

There exists controversy between manufacturers and ward ICU staff regarding the re-use of nebulisers that are marked for single use only. There is little evidence of recent studies that have examined the effects of re-using single-patient-use nebulisers within the ICU environment. The issue of re-use of single-use nebulisers is relevant to the ICU population, and specifically to ventilated patients. Nebulisers that are used within a ventilator circuit are at risk for creating bacterial aerosol. The manufacturer’s recommendation to discard the nebuliser after each use presents cost- and waste-management issues. It has been shown that with correct cleaning, single-use nebulisers can be re-used, if they are cleaned in between use. If staff in ICUs are re-using nebulisers they are shifting the medico-legal burden for any adverse events onto themselves unknowingly. Nebulisers that are incorrectly cleaned or stored wet may contribute to the development of VAP and the propagation of antibacterial resistance within the ICU. There is a significant cost and mortality burden related to VAP in ICUs in resource-limited countries.

There exists no data on what methods of nebuliser decontamination are currently in use in ICUs. There also exists no current data on the rates of nebuliser contamination after re-use of single-use nebulisers within a ventilator circuit.

CHAPTER 3

3. RESEARCH METHODS

3.1 INTRODUCTION

This chapter serves to describe the approach and methods used to collect the data for this research report. Details of the study design, planning of the project and data management will be discussed. The last section will cover the ethical considerations for this study.

3.2 STUDY DESIGN

This was a cross-sectional study of current practice regarding nebuliser use within ICUs in Johannesburg. No blinding of the assessor was necessary. The ICU staff was blinded as to the nature of the study until the time of interview, so as to assess current practice without influencing the staff's approach to nebuliser decontamination.

3.3 HYPOTHESES

The hypotheses tested in this research report are:

a) There is a high rate of re-use of single-use jet nebulisers that have been used within a ventilator circuit in ICUs, in Johannesburg, South Africa.

b) Single-use jet nebulisers are not effectively decontaminated after being used within a ventilator circuit.

3.4 SAMPLE SELECTION

3.4.1 Inclusion Criteria for Hospitals

All ICUs of government and private hospitals in Johannesburg, South Africa were conisdered for participation in this study. The hospitals that were approached were selected on the basis of geographical location and the size of the ICU. Within the private hospital group, representation of the three main hospital groups (Netcare, Life Healthcare and Medi-Clinic) was ensured. During selection geographical location was taken into account to assist in obtaining a representative sample.

Hospitals approached to participate in the study included:

- ARWYP (pilot study)
- Charlotte Maxeke Johannesburg Academic Hospital (government)
- Chris Hani Baragwanath Hospital (government)
- Helen Joseph Hospital (government)
- Milpark Hospital (Netcare)
- Union Hospital (Netcare)
- Sunninghill Hospital (Netcare)

- Morningside Medi-Clinic (Medi-Clinic)
- Donald Gordon Medical Centre (Medi-Clinic)
- Sandton Medi-Clinic (Medi-Clinic)
- Fourways (Life Healthcare)
- Flora Clinic (Life Healthcare)
- Bedford Gardens (Life Healthcare)

3.4.2 Exclusion Criteria for Hospitals

Hospitals were excluded on the basis of location, i.e. outside of Johannesburg.

3.4.3 Inclusion Criteria for Nebulisers

The nebulisers that were in the unit at the time of audit were selected for assessment. Nebulisers had to have been used within a ventilator circuit or for a patient with an artificial airway. The airway could be either an endotracheal tube or a tracheostomy tube.

3.4.4 Exclusion Criteria for Nebulisers

Nebulisers that had not been used within a ventilator circuit, ie: face mask or mouth-piece nebulisers.

3.5 MEASUREMENT DEVICES

The attached audit tool (Appendix 1) consisted of two parts. The first related to collection of the demographic data of the unit on the day of audit (Section A), and the second (Section B) related to an individual assessment of each nebuliser that was used with a ventilated patient within the unit.

Sheep's blood agar was used to culture the swabs collected. Plate diameter was 6.5 cm. Plates were pre-prepared at the University of the Witwatersrand Pharmaceutical Microbiological Laboratory (PML), by Dr S van Vuuren and her staff. The swabs were cotton tipped and wooden handled. They were autoclaved in the PML before use.

3.6 DATA COLLECTION

The hospitals that were selected according to the inclusion and exclusion criteria were approached via a letter addressed to the hospital manager/ chief executive officer (CEO), as was appropriate to the hospital. This was followed up by phone calls and meetings with the appropriate administration and clinical staff of each hospital, until the participation of the hospital was confirmed. Staff approached included the nursing managers, the admin staff in the office of the hospital manager/CEO and the marketing manager. This differed between hospitals, and was dependant on their individual requirements.

Once consent was obtained from the hospital manager/CEO, the unit manager of the ICU was approached and an appropriate day for audit was agreed upon. The data collection period started in August 2009 and finished at the end of September 2009.

Sample size was calculated using a sample size calculation with alpha set at 0.05 and estimated prevalence of ventilated patients at 50%. It was calculated using the number of ICU beds in Gauteng (Bhagwanjee & Scribante, 2007). This gave the number of ICU beds required to be assessed in order to have a representative sample. The frequency of the use of nebulisers in a ventilated population in Johannesburg is an unknown variable, and thus could not be used for the power calculation. The number of ICU beds to be surveyed was set at 278.

3.6.1 **Unit Manager/Shift Leader Interview**

The researcher visited each of the hospitals once. On the day of assessment the first part of the audit tool (Section A) was completed by the researcher with the unit manager or shift leader (Appendix 1). The unit manager/shift leader then identified which beds in the unit had patients that were ventilated. Each bedside was then checked with the unit manager/shift leader to confirm the presence of a nebuliser. The beds with patients that were ventilated and nebulised were listed for the researcher to assess. All nebulisers that met the inclusion criteria were assessed in each ICU.

3.6.2 **Nebuliser Assessment**

In the second part of the audit (Section B) the researcher recorded observations of how nebulisers were stored and evidence of decontamination. The nurse caring for the patient was then approached. The study was explained to the nurse and she/he was given an information sheet and an opportunity to ask questions regarding the study. An individual assessment form for each nebuliser was completed by the researcher. The first section on data was collected from the chart of the patient. The second part of the assessment was done on visual inspection of the nebuliser.

3.6.3 **Nebuliser Swabbing Protocol**

Each nebuliser was then swabbed by the researcher to assess for contamination. The researcher was advised on the development of the swabbing protocol by Dr van Vuuren, from the PML. The protocol was followed in the pilot study that was done at Arwyp Medical Centre. No changes were made to the protocol after the pilot.

The researcher first did a hand wash using the appropriate technique, and then nitrile powder free gloves were applied. The nebuliser was first removed from the bedside and

taken to a clean and even surface close to the bedside, within the cubicle of the patient. If the oxygen tubing was attached it was removed to aid with the swabbing procedure. The outside of the nebuliser was first wiped with isopropyl alcohol, to ensure that there was no external contamination of the nebuliser. The nebuliser was then opened and placed on clean gauze swabs. The base plate was then removed from the nebuliser, ensuring that the sides of the chamber were not touched. Two sterile swabs were dipped into the residual solute within the reservoir of the nebuliser. If there was less than 2ml of liquid in the nebuliser, 2ml of sterile water was added to the reservoir. The swabs were then immediately streaked across a blood agar plate. The plates were then labelled and returned to the transport box. The area was cleaned and the nebuliser reassembled and returned to the patient's bedside, in its original position and condition. Nebulisers that were initially found dry were dried after the swabbing, due to the addition of sterile water into the medication reservoir.

3.6.4 **Laboratory and Transport Procedure**

The blood agar plates were premixed and stored at the PML at the University of the Witwatersrand. Plates were then transported in a cardboard box within a cooler box, in order to reduce the fluctuations in temperature during transport. Each nebuliser assessed resulted in two blood agar plates. One plate was incubated at 25 degrees Celsius ˚C for 7 days to monitor if any fungal contamination was apparent. The second plate was incubated at 37 degrees Celsius for 24 hours in order to incubate for possible bacterial contamination.

3.6.5 **Assessment of Plates**

On completion of the required incubation time the blood agar plates were then assessed. The plates were viewed on a white board and with a light box; a digital photograph of each plate was obtained at the time of assessment. Each plate was examined by the researcher. The researcher was trained by Dr S van Vuuren on assessment of BAPs. First the number of different colonies was identified. The number of colony-forming units (CFU) for each type of colony was then counted using visual inspection. The size, margin, shape, elevation, surface, density, pigments and the presence of haemolysis was then documented for each species that grew. The BAPs were double counted, and the verified result documented. Photographs of the BAPs were stored for archive in case the need for reassessment of a BAP arose.

The CFUs were categorised in the following way:

Table 3.1: **Categorisation of Colony Forming Units**

Concentration of CFUs		Number of different colonies	
0	No Growth	1	1 species
1	1 - 2 CFUs of 1 species	2	2 species
2	3 – 100 CFUs of 1 species	3	3 species
3	> 100 CFU of 1 species	4	4 species

For concentration of CFUs, if there were multiple species present, the species with the highest CFU count was considered for ranking.

CFUs were only differentiated by their visual characteristics when determining different species. No other testing was done so as to determine which species were present in the BAPs.

3.6.6 Pilot Study

The pilot study was conducted before the data collection period. The swabbing procedure was agreed upon and practiced by the researcher prior to the pilot study. Guidance for the development of the swabbing procedure was given by Dr S van Vuuren, PML. The entire procedure as set out for the main study was followed through at one single site, Arwyp Hospital to assess its feasibility. No procedural faults were identified and therefore no changes were made to the method of data collection for the main study. The data that was collected during the pilot study was thus included in the final results.

3.7 DATA MANAGEMENT

The descriptive statistics for the data collected were analysed using the programme Glantz SA. 2005. Statistical Software Program 6.0. *Primer of Biostatistics*. McGraw-Hill Publishing. The inferential statistical tests applied to this data set included Fisher's Exact test and t-test with equal variance. The statistical program used was: StataCorp. 2007. Stata Statistical Software: Release 10. College Station. TX: Statacorp. The statistical significance was set at 5% (p-value < 0.05) for all inferential statistical tests.

3.8 ETHICAL CONSIDERATIONS

Ethical clearance was applied for and granted by the University of the Witwatersrand, Human Research Ethics Committee (HREC) before the start of the study. Ethics clearance certificate number M090537 (see appendix 4).

3.8.1 **Hospital**

The names of the hospitals that were approached to participate will not be published outside of the submission of this report. This is in order to protect the hospitals that participated from any negative feedback that may result from the findings of this study. The hospital manager/CEO of the participating hospitals signed a consent form authorising access to the ICU and permission to approach the staff. The hospital managers/CEOs were able to decline participation.

3.8.2. **Intensive Care Unit Staff**

The staff of the ICU units that were assessed was given information sheets regarding the nature of the study and the information collected. No staff names or patient bed numbers were recorded. The ICU staff members were not directly observed, thus protecting the staff's identity and their professional reputation. As staff members were not being directly observed they did not have to give consent for the assessment of the nebulisers in the unit.

3.8.3 **Patients**

There was no direct contact with patients in this study. The patients' treatments and nebulisation schedules were not altered or affected. The patients whose nebulisers were assessed did not have to give consent as their treatment was not affected. No direct patient information as collected as part of this study. In order to reduce the impact on the patients the nebuliser was returned to the position and condition that it was found in. The use of sterile swabs and cleansing of the outside of the nebuliser before it was opened ensured that there was little risk of increased contamination of the nebuliser post swabbing and therefore reduced the impact of the procedure on the patient's outcome.

The results obtained through the abovementioned methodological process are described in Chapter 4.

CHAPTER 4

4. RESULTS

4.1 INTRODUCTION

This chapter will present and summarise the most relevant data that were collected. Results are presented in table form with relevant notes appending the tables. The structure of the chapter will follow the objectives as outlined in the Introduction chapter. A summary of statistical tests done to test hypothesis about decontamination processes is presented in Section 4.6. Section 4.7 serves to summarise other observations made during the data collection period, as noted on the nebuliser assessment forms.

A total of 12 hospitals were approached to participate in the study and one in the pilot study. The results from the pilot study were included in the results of the main study. Two hospitals refused to participate, and two failed to respond by the extended deadline. Of the hospitals that agreed to participate, all three private sector hospital groups were still represented, as well as the government hospitals. All of the government sector hospitals that were approached participated in the study, thus a total of 3 were included in the study. One of the hospitals had a government-private unit, which was included in the study. The four hospitals that did not participate were all from the private sector. A total of nine hospitals participated which represented 21 ICUs. A total of 13 private sector, seven government sector and one public/private collaboration ICU participated in the study. In total 269 ICU beds were surveyed, which resulted in data collection from 45 nebulisers that had been used within a ventilator circuit.

4.2 CURRENT PRACTICE IN NEBULISER RE-USE AND DECONTAMINATION

4.2.1 Descriptive Statistics of Intensive Care Unit Demographics

Table 4.1: **Intensive Care Unit Demographics**

	Mean	Standard Deviation (SD)	Standard Error (SE)	Median	Minimum	Maximum
Number of Beds	14.05	6.85	1.49	12	6	30
Ventilators	4.43	2.94	0.64	4	0	10
Ventilators with a nebuliser	2.19	2.29	0.50	1	0	7
Nurses: On Duty	11.62	5.52	1.20	10	4	28
Nurses: Permanent	7.48	4.85	1.06	7	1	20
Nurses: Agency	4.14	3.10	0.68	4	0	13
Physiotherapists: On Duty	3.04	1.67	0.36	3	0	6
Physiotherapists: Permanent	2.81	1.69	0.37	3	0	6
Physiotherapists: Agency	0.19	0.60	0.13	0	0	2

The average number of beds per unit was 14.05 (SD = 6.85) and the average ventilated patients per unit was 4.43 (SD = 2.94). Of the patients in ICU, 16.7% were ventilated and received nebulisation (95% CI 12.35%; 21.21%).

4.2.2 Rate of Re-Use of Nebulisers

Table 4.2: **Rate of Re-Use of Nebulisers**

	Single Use Jet Nebulisers n (%)	Single Patient Use Disposable Jet Nebulisers n (%)	Single Patient Use Autoclavable Ultrasonic nebuliser n (%)	Total
Government	5 (62.5%)	1 (12.5%)	2 (25 %)	8
Private	37 (100%)	0 (0%)	0 (0%)	37
Govt/Private collaboration	0 (0%)	0 (0%)	0 (0%)	0
Total	42 (93.3 %)	1 (2.2%)	2 (4.4%)	45

Key: n = number, Govt = Government

It was found that 100% (n=45) of nebulisers assessed were being re-used and 93% of all nebulisers assessed were not being used in accordance with the manufacturer's recommendations, as they were marked as single-use devices. Rate of re-use of single-use devices in the private sector was 100%. The percentage of nebulisers that were classified as single-use devices in the government sector was 62.5%. The private sector hospitals only used single-use jet nebulisers (n=37), where as the government sector used single-use jet nebulisers (n = 5), disposable single-patient-use jet nebulisers (n=1) and autoclavable ultrasonic nebulisers (n=2). There were no VMNs found in the ICUs surveyed.

4.2.3 Summary of Methods of Decontamination in Use

Table 4.3: **Current Methods of Decontamination**

	Yes		No	
	n	Percentage	n	Percentage
Nebuliser discarded after use	0	0.0%	45	100.0%
Nebuliser stored dry	8	17.8%	37	82.2%
If dry, solute visible in chamber	7	87.5%	1	12.5%
Stored in a glove	19	42.2%	26	57.8%
Stored with sterile drape	17	37.8%	28	62.2%
Stored open to the environment	5	11.1%	40	88.9%
Stored removed from O_2 tubing	3	6.7%	42	93.3%
Autoclaved	0	0.0%	45	100.0%

Most frequently (82.2%) nebulisers were stored wet. Of the nebulisers that were stored dry seven showed solute still in the chamber, indicating that cleaning had not occurred. The frequency of nebulisers being stored in a glove or sterile drape was 42.2% and 37.8% respectively. It was found that 93.3% (n = 42) nebulisers were stored connected via oxygen tubing to the flow meter or ventilator.

4.3 INCIDENCE OF CONTAMINATED NEBULISERS

Twenty-three of the nebulisers that were swabbed had growth of bacteria from the swabs collected; this represented 51.1% (n = 23) of nebulisers used within a ventilator circuit.

Isolation of the batch of single-use nebulisers that had been re-used (n = 42) as a separate group from the single-patient-use nebulisers, revealed a rate of contamination of 52.4% (n = 22).

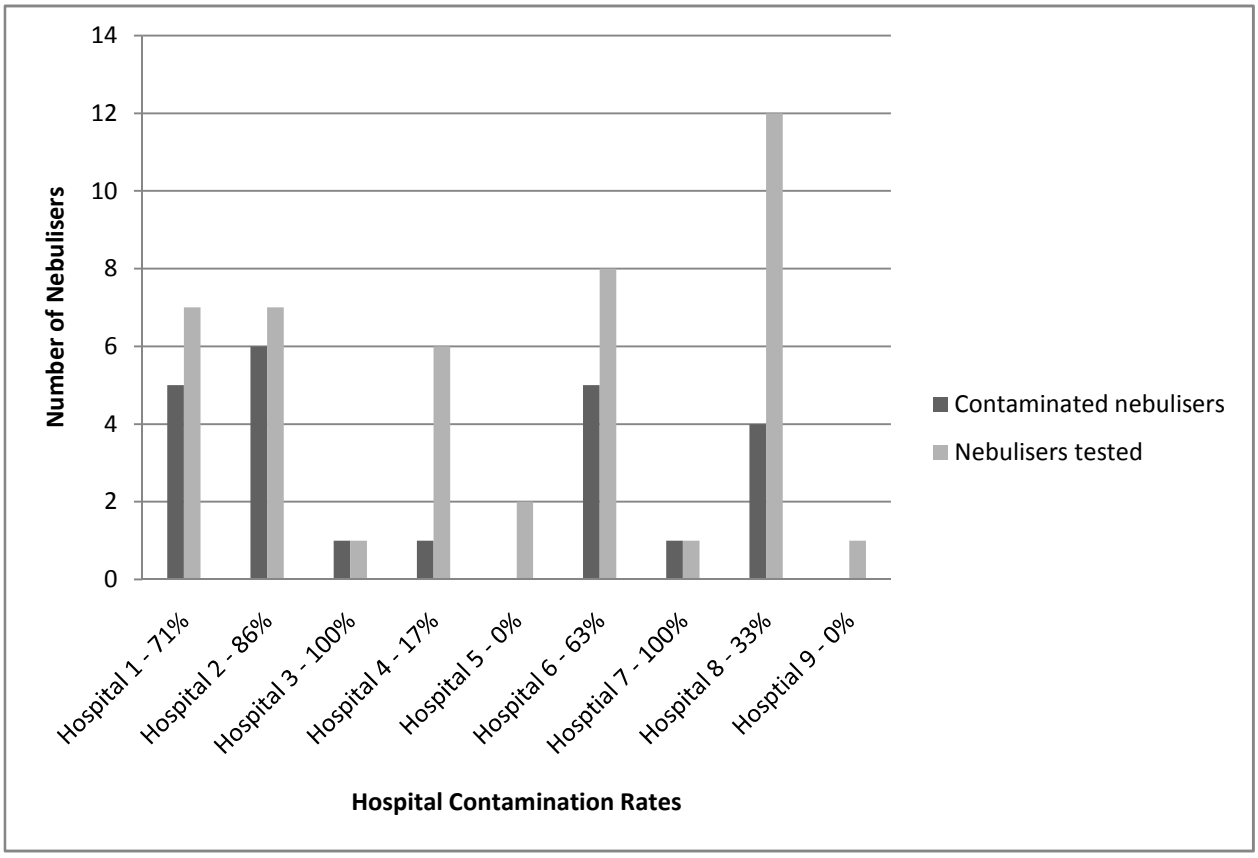


Figure 4.1: **Contamination Rates of Hospitals**

Two of the government sector hospitals had 100% contamination rates. One hospital had a contamination rate of 17%. Two private sector hospitals had a zero contamination rate. The rates of contamination for the other hospitals in the private sector were 71%, 86%, 63% and 33%.

4.3.1 Summary of Blood Agar Plate Assessments

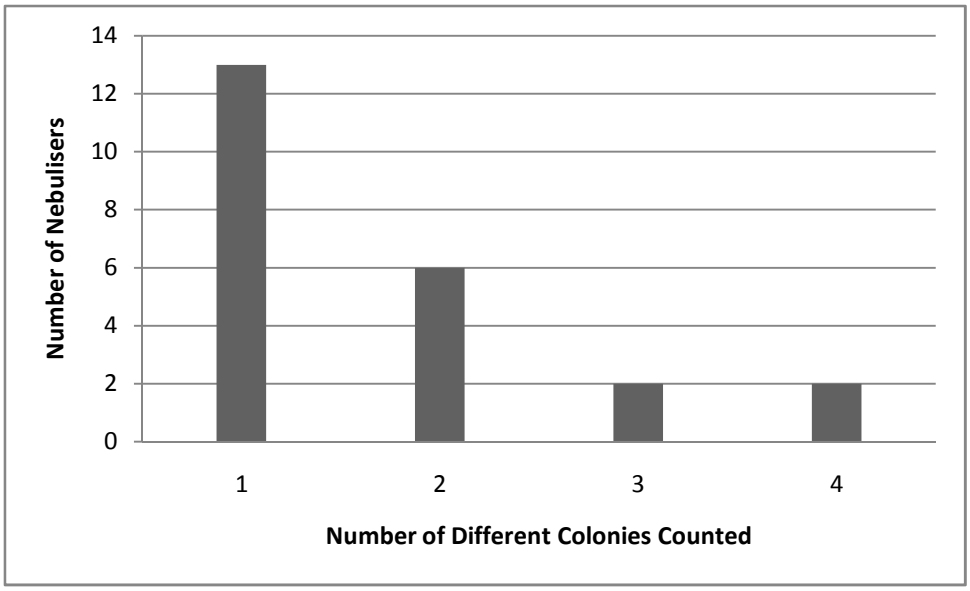


Figure 4.2: **Number of Different Colony Forming Units Identified**

Of the nebulisers assessed 13 had colonisation by only one species of bacteria. The highest number of species found on one plate was four. This shows that 10 out of the 23 nebulisers that had bacterial growth were colonised with more than one species of bacteria.

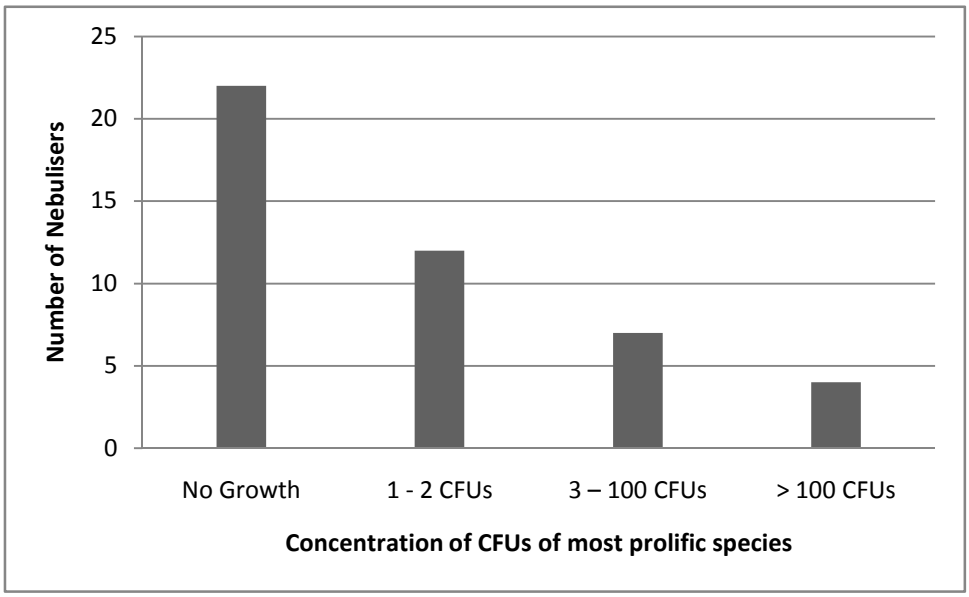


Figure 4.3: **Concentration of Colony Forming Units of Most Prolific Species**

No growth was found in 22 of the 45 nebulisers assessed. Twelve nebulisers showed growth showing a concentration of 1 to 2 CFUs per plate. Four nebulisers showed bacterial growth of greater than 100 CFUs per plate of the most prolific species. Seven nebulisers showed growth of between 3 and 100 CFUs per plate.

4.4 PATTERN OF USE OF NEBULISATION IN INTENSIVE CARE UNITS IN JOHANNESBURG

Table 4.4: **Medications Used in the Nebulisers Tested**

Medications	n	%
Combivent	12	26.7%
Saline	8	17.8%
Atrovent & Saline	5	11.1%
Atrovent	5	11.1%
Duolin	4	8.9%
Atrovent & Berotec	3	6.7%
Atrovent Beta	2	4.4%
Unkown Medication	2	4.4%
Atrovent & Pulmicort	1	2.2%
Bisolvin	1	2.2%
Duolin & Saline	1	2.2%
Lasix	1	2.2%
Total	45	100%

Medication administered to achieve bronchodilation constituted 76% of the use of nebulisers. The use of mucolytics and saline nebulisation ranked second for the type of medication used in the nebulisers (20.9%). One nebuliser was used for corticosteroid administration and one for Lasix nebulisation. The median time in which the nebulisers that were tested had been stored since nebulisation, was four hours.

4.5 NEBULISER DECONTAMINATION PROTOCOLS

None of the units assessed had a nebuliser decontamination protocol. Sub-analysis could thus not be done.

4.6 PRACTICES ASSOCIATED WITH BACTERIAL GROWTH

Fisher's exact test was used to examine the following hypotheses related to which practices affected bacterial growth within the nebulisers. Nebulisers that were stored in a sterile drape and had bacterial growth had higher CFU concentrations than those that were not stored in a drape and had bacterial growth ($p = 0.03$). For the subset of nebulisers that had bacterial growth, storing the nebuliser disconnected from oxygen tubing did not affect the concentration of growth observed ($p = 0.06$)

The type of nebuliser manufacturer did not affect the rate of contamination ($p = 0.66$). The medication used in the nebuliser did not affect the rate of contamination ($p = 0.39$). Storage of the nebuliser wet or dry did not have a statistically significant effect on bacterial growth ($p = 0.46$). For the sub-set of nebulisers that were stored dry, the presence of dried solute in

the chamber had no effect on bacterial growth (p = 1.0). Note that this result is based on a very small sample of one nebuliser. Storage of the nebuliser in a latex glove did not affect bacterial growth (p = 0.77). Storage of the nebuliser in a sterile drape did not affect bacterial growth (p = 1.0). Storage of the nebuliser open to the environment did not affect bacterial growth (p = 1.0). Storage of nebulisers connected to the oxygen tubing did not affect bacterial growth (p = 0.23). Note the groups were disproportionate as only three of the nebulisers were stored disconnected from oxygen tubing All three nebulisers had bacterial growth. For the sub-set of nebulisers that were stored wet, the appearance of the solution did not affect bacterial growth (p = 1.0). For the subset of nebulisers that had bacterial growth, storage of the nebuliser dry did not affect the concentration of growth observed (p = 0.75).

For the sub-set of nebulisers that had bacterial growth the following hypotheses were tested: Storage of the nebuliser in a latex glove did not affect the concentration of growth observed (p = 0.25). Storage of the nebuliser open to the environment did not affect the concentration of growth observed (p = 0.55).
The T-test was performed on the following two hypotheses. The amount of time the nebuliser was stored in between last use and sampling did not affect bacterial growth (t = 0.57). The number of days that a patient who was receiving nebulisation had been in ICU did not affect bacterial growth within the nebuliser (t = 0.57).

4.7 SUMMARY OF OTHER FINDINGS NOTED ON ASSESSMENT FORM

One nebuliser was visibly soiled with secretions. This nebuliser ranked two for concentration and four for number of different species of CFU noted. Two of the nebulisers in one specific ICU were left with 1ℓ/min of oxygen running through, i.e. they were incompletely turned off and the nebulisers were stored in paper autoclave bags. Both nebulisers were dry, but had residual solute in them. Neither of these two nebulisers had bacterial growth.

This chapter summarised the results obtained through the cross-sectional study that was performed on nebulisers used within a ventilator circuit in ICUs in Johannesburg. The next chapter offers an in-depth discussion of these results.

CHAPTER 5

5. DISCUSSION

The major findings of this research report were that a) of the nebulisers used within a ventilator circuit 93% of the nebulisers assessed were single-use devices that were being re-used; b) 52.4% of the single-use jet nebulisers that were re-used had bacterial growth on swabbing; and c) contaminated nebulisers that were stored in sterile drapes had higher bacterial concentrations than those that were not stored in a drape.

5.1 CURRENT PRACTICE REGARDING NEBULISER USAGE IN INTENSIVE CARE UNITS IN JOHANNESBURG

5.1.1 Rate of Re-Use of Nebulisers

In this study it was found that the majority of the nebulisers assessed were single-use jet nebulisers and that all of these jet nebulisers were being re-used. The re-use of these nebulisers was in direct contravention of the manufacturer's instruction for use, as they had been marked as single-use devices. In discussion with the staff members within the ICUs, many did not seem to be aware of the fact that the nebulisers they were using were single-use devices and not single-patient-use devices. This is the first time data of this nature has been collected in the ventilated ICU population in South Africa. Craven, Lichtenburg, Goularte, Make and McCabe (1984) studied contamination rates in jet nebulisers in ventilated patients in ICU but they did not indicate if the devices were single-use or single-patient-use devices. The authors reported a rate of bacterial contamination of 79% in nebulisers that had been used within a ventilator circuit. At the time of the study, 26 years ago, there may not have been such a clear distinction between the two types of devices. There is an urgent need to address the issue of re-use of nebulisers in ICU as the incorrect use of these devices may contribute to the development of VAP (Rotstein et al., 2008) and the progression of antibacterial resistance (McDermott, Walker & White, 2003).

5.1.2 Methods of Nebuliser Decontamination and Storage

None of the ICUs surveyed had nebuliser decontamination and storage protocols in place, despite all of them re-using single-use, single-patient-use and autoclavable devices. This was most likely due to a lack of evidence in the literature to show which method of decontamination would be most effective. Eighty-two percent of the nebulisers had been stored wet, thus indicating that either no cleaning or an incomplete cleaning process was done after use of the nebuliser. Of the nebulisers that were found dry, only one had no evidence of dried solute in the chamber. In other words the fact that they were found dry did not guarantee that the nebuliser had been effectively cleaned. However, results from this

study demonstrated that regardless of whether the nebuliser was stored wet or dry, bacterial contamination rate was not significantly affected.

The methods of storage after use observed in the current study included a) storage within a latex glove; b) under a sterile drape; c) open to the environment and d) within a paper bag. Storage of a nebuliser in a paper bag was an unusual finding. Another finding which seemed to affect the bacterial growth was whether the nebuliser was stored connected to the oxygen source or disconnected from oxygen. There was great variability in the methods of storage of nebulisers both between ICUs and within ICUs in the current study. Craven et al. (1984), in their study of nebulisers used within ventilator circuits, also recorded similar results of great variability in practice both within units and between units. Their results however cannot be directly compared to this research project as theirs was a telephonic interview rather than direct observation of the nebulisers, and they assessed the cleaning policy of the staff, rather than actual practice. It is interesting however that the authors had similar concerns regarding the risk of bacterial aerosol production as a result of incomplete decontamination of jet nebulisers after use within a ventilator circuit. In the past 26 years little research had been done to further clarify this issue.

5.1.3 **Contamination of Jet Nebulisers**

More than half of the single-use jet nebulisers that had been re-used had bacterial colonisation. This figure has to be viewed in the context of a 0% contamination rate if the nebulisers were discarded after use and a new nebuliser used for each nebulisation. This finding demonstrated that re-use of jet nebulisers without a specific decontamination protocol in place may put patients at significant risk of exposure to bacteria.

This rate of contamination is in line with the findings of Craven et al. (1984), who reported an initial contamination rate of 78.9%. They only sampled nebulisers from one unit and this may explain the higher rate of contamination. Practices of decontamination and storage were found to be more uniform within the unit studied. The rate of contamination for the current study was established by sampling 21 ICUs from nine different hospitals, which would give a greater indication of the expected rate of contamination within the whole population.

The use of MDIs to administer medication into a ventilator circuit may assist with overcoming some of the infection control issues presented by the moisture trapped within the jet nebulisers. This study demonstrated that the main class of medication used in nebulisers was bronchodilators. These drugs are readily available as MDIs. The MDIs could potentially replace nebulisers in some ventilated patients requiring bronchodilation.

A change to VMNs may also present another solution to the problem of re-using single-use jet nebulisers. The advantage of VMNs is that the reservoir of the nebuliser is separated from the ventilator circuit which potentially reduces the risk of contamination and colonisation. These types of nebulisers are available in two different models namely a) disposable single-patient-use devices and b) autoclavable devices. The control unit is either a separate device which can be attached to the ventilator or is incorporated into ventilator hardware and software. The VMN also has the added advantage of being electronically triggered at a specific phase of inspiration and does not introduce extra flow into the circuit, which may ultimately make this device more effective than jet nebulisers (Fink, 2009).

Ventilator associated pneumonia is associated with increased morbidity, mortality and cost in ICU populations (Valencia & Torres, 2009; Safdar et al., 2005; Hasan & Baber, 2002; Rello, Ollendorf, Orster, Vera-Llonch, Bellem, Redman & Kollef, 2002; Lode, Raffenberg, Erbes, Geerdes-Fenge & Mauch, 2000). Rates of device-associated nosocomial infections and bacterial resistance are three to five times higher in resource-limited countries (Rosenthal, 2008). Findings from the current study demonstrated that more than half of the nebulisers assessed were contaminated with bacteria. Microbial contamination of nebuliser solution does play a role in the development of VAP in developing countries (Hasan & Baber, 2002).

The development of evidence-based, cost-effective and practical infection control protocols is of specific importance in resource-limited countries so as to reduce the burden of VAP on society, government and the economy. Staff compliance is an important aspect of developing protocols for use in the ICU. Protocols that are too complicated or impractical may result in low staff compliance which would mean that the protocol is ineffective. Protocols for nebuliser decontamination need to be time- and cost-efficient in order to be beneficial to the ICU in which they are implemented.

5.1.4 **Indications for use of Nebulisers in Intensive Care Units**

Nebulisers were primarily used for the administration of bronchodilators to ventilated patients in the current study. Mucolytics were also frequently administered. Bisolvon was the only medication used that contained preservatives. These preservatives may assist in inhibition of bacterial growth within a nebuliser if no cleaning was performed after use (Oie et al., 2006). It should also be noted that the nebuliser that contained Bisolvon was stored wet, but had no bacterial growth after swabbing. This finding may support Oie et al. (2006)'s hypothesis that the presence of preservative in the nebuliser solution could reduce the bacterial growth within the nebuliser after use. Further testing with larger sample sizes would be required to test this hypothesis.

It was also found that patients in ICU had been ventilated for an average of 12 days at the time of the study and had therefore received nebulisation during that time. This finding could indicate that the current patient population was already at an increased risk for the development of VAP, due to the prolonged period of stay in ICU (greater than five days) (Rotstein et al., 2008). Thus the development of protocols for decontamination and storage of nebulisers to reduce the risk of the development of VAP and antibiotic resistance are of significant importance to this group of patients.

5.2 PRACTICES ASSOCIATED WITH BACTERIAL GROWTH

5.2.1 Findings that Achieved Statistical Significance

5.2.1.1 Nebulisers Stored in a Sterile Drape

The only finding that achieved statistical significance was that nebulisers that had bacterial growth and were stored in a sterile drape had higher concentrations of bacterial growth. These devices had higher concentrations of bacterial growth than nebulisers that were stored either in a glove or open to the environment. This finding is of interest because the practice of placing nebulisers within a sterile drape after use was common practice but is one that is not based in evidence but rather in tradition. No articles were identified that supported the use of sterile drapes as a method of storage of nebulisers during the literature search. The drape itself may not have been the source of contamination, but it can be assumed that once a contaminated nebuliser was stored within a drape, the bacteria multiplied more prolifically than in nebulisers that were stored in other ways. The dark environment may have contributed to this growth of bacteria, as light inhibits the growth of some bacteria, such as MRSA (Sheldon, Kokjohn & Martin., 2006). The sterile drapes may stay with a patient for their entire period of ventilation, whereas latex gloves are more easily discarded and replaced.

5.2.2 Other Findings of Interest

5.2.2.1 Nebulisers Stored Connected to Oxygen Tubing

Results of the current study demonstrated that connection of a stored nebuliser to an oxygen source did not affect the concentration of bacterial growth. However, it should be noted that the groups were not evenly matched as the majority of nebulisers were stored disconnected from oxygen and a different level of significance may have been obtained had the groups been better matched.

Two of the nebulisers that were stored with a low flow rate of oxygen (1ℓ/min) running through them did not have any bacterial growth. The low flow oxygen could have acted in one of two ways to inhibit bacterial growth within the nebuliser. Firstly the flow of oxygen would have dried the nebuliser faster than if it had been stored with no oxygen running

through it. Although there is no statistical evidence in this study to prove that storing nebulisers wet or dry affects bacterial growth, it has been documented elsewhere that bacteria such as *Pseudomonas Aeruginosa* thrive in moist environments (Anaissie, Penzak & Dignani., 2002). Therefore it would be reasonable to accept that nebulisers that are stored dry would be less likely to encourage bacterial growth of certain strains. Secondly it had been reported that the high concentration of oxygen within the nebuliser chamber reduced bacterial growth, such as *Pseudomonas Aeruginosa* (Hassett et al., 2008; Schobert & Tielen, 2010). The concern that this argument raises is the safety and cost of having free flowing oxygen in the ICU as it could pose a fire hazard for the unit. There would also be a cost associated with the use of oxygen over long periods of time. These concerns in the context of an inferred benefit indicate that the application of oxygen for a short period through the nebuliser before storage may assist in the inhibition of bacterial growth within the nebuliser.

5.2.2.2 **Nebulisers Stored in a Paper Bag**

The two nebulisers that were stored in paper bags (obtained after a sterile pack had been opened) represent an interesting case. Although both of these nebulisers were also stored with the oxygen running through them, and that may have effected bacterial growth, the use of the paper bag may also have had an added benefit. It had been reported that paper has a greater absorbency than latex gloves (Fisher, Reddy, Williams, Lin, Thacker & Edlich, 1999) which are designed as a barrier to fluids and allows for more light than a sterile drape. However, latex gloves trap water and solute within the nebuliser and in so doing hamper the drying process. The use of paper covers for nebulisers could potentially offer the advantage of cost effectiveness over latex gloves and is more environmentally friendly. Another advantage of using a paper cover is that the patient's name, date the nebuliser was first used and a record of subsequent nebulisations could be recorded directly onto the cover itself.

5.2.2.3 **Visible Contamination of the Nebuliser**

There was only one nebuliser that was visibly contaminated. This nebuliser however was contaminated with bacteria and had a classification of two for colony concentration and four for number of different species observed. This finding is however based on a sample size of one. Bacteria are known to reside within sputum (Nicholas & Djukanovic, 2009) and in higher concentrations in purulent sputum (David-Ona, Dacuycuy & Alejandria, 2001). Purulent sputum would be more visible within the nebuliser than normal sputum, due to its darker colour (David-Ona, Dacuycuy & Alejandria, 2001). It would be reasonable to deduce that nebulisers that have visible contamination with sputum would be more likely to have bacterial growth within them.

5.2.2.4 Duration of Nebuliser Storage and Usage

It is difficult to determine from the results of this study what the optimum time would be for use of a nebuliser within a ventilator circuit before it is changed. This study found no link between the time the nebuliser had been stored and the presence of bacteria. Standaert et al. (1998) stated that single-use nebulisers could be used up to 100 times with adequate cleaning in between uses without having a significant effect on particle size and time required to complete nebulisation. This would equate to 17 days of use when calculated according to an average use of four-hourly nebulisation in ICU. This however, as discussed in the literature review, is related only to the efficacy of nebulisation and not to bacterial growth. The period of time that a nebuliser can be used in an ICU was not one of the objectives of this study.

5.3 LIMITATIONS OF THE STUDY

The researcher identified the following limitations while conducting this study:

- When testing for statistical significance it is preferable to use groups that have similar if not equal numbers of subjects in each group. This was a cross-sectional study and during analysis of decontamination practices that were associated with bacterial growth, several hypotheses had to be tested which resulted in data being distributed into unequal and small groups. This however was unavoidable due to the need to determine the prevalence of contamination of jet nebulisers used within a ventilator circuit, which required a cross-sectional design. The Fisher's exact test was used to accommodate the small sizes of the groups in this section of the results.

- The research project was designed as a cross sectional study and not as a longitudinal study. This Design was chosen as it was unknown what current practice within this population was; therefore a cross-sectional study is the most appropriate way to assess this objective. The limitation of this cross sectional study is that the number of nebulisers in each ICU could not be standardised. However the risk of assessing the same nebuliser multiple times made a longitudinal design with multiple site visits inappropriate to address the research question. With sequential visits to ICUs staff behaviour and approach to nebulisers may be affected by the presence of the researcher in the unit, thus negatively affecting the outcomes of the study.

- There was incomplete blinding of the assessor of the plates. At the time of assessment the plates were only identified by their assigned code. The information sheet regarding the observation of the nebulisers was kept separate from the assessor during examination of the plates. However, the assessor could deduce from the code which

plates came from the same hospital. This was also inevitable due to the nature of data collection which meant the samples from one hospital would be available for assessment at the same time. The assessment of plates is however unlikely to be largely affected by the assessor, as it is an objective rather than a subjective assessment. The same assessment structure was used for each plate. Each plate was counted twice to overcome the possibility of assessor error.

- During the process of applying for permission to include a hospital in the study it was possible for information to pass to clinical staff. This risk was reduced by contacting mainly administration staff prior to assessment; it was explained that it would be a blinded visit. Once permission was obtained an arrangement was made with clinical staff, without disclosing the nature of the study. Clinical staff information sheets were only distributed on the day of data collection. It would have been unethical to approach hospitals without getting consent for participation from hospital management, thus it is an acceptable risk.

- The researcher was unable to collect data on how long the nebuliser had been in use. None of the nebulisers had a documented date of first use. The time period the patient had been in ICU was documented and used for analysis as an approximation of the possible time period the nebuliser had been in use.

- It was found that two hospitals had a 0% contamination rate. These two hospitals had respectively only one and two nebulisers to be assessed, and thus the significance of the 0% contamination is reduced due to the small sample size.

5.4 IMPLICATIONS FOR CLINICAL PRACTICE

5.4.1 Suggested Guidelines for Decontamination and Storage of Jet Nebulisers in the Intensive Care Unit

- Both single use-and single-patient-use jet nebulisers, should be cleaned after use to ensure the consistency of the nebuliser's performance (Sandaert et al., 1998).
- Cleaning should not be done with tap water or in or around a basin, to avoid colonisation of water sources and taps by bacteria that may be inside the nebuliser (Trautmann, Lepper & Haller, 2005).
- Bacterial growth may be reduced if nebulisers are stored dry.
- Using oxygen to run through the nebuliser to complete the drying process may assist in reduction of bacterial growth.

- Nebulisers should not be stored in sterile drapes. A paper-based cover indicating the name of the patient, the date of first nebulisation and a record of the number of nebulisations for which the current nebuliser has been used may be more effective in reducing the risk of bacterial colonisation.
- Nebulisers that are visibly soiled by secretions that have a witnessed event of circuit condensate draining into them or visible malfunction may need to be immediately discarded and replaced.
- The number of nebulisations that a nebuliser is allowed to do may be determined by each ICU, depending on the manufacturer of the nebuliser they are using (Sandaert et al., 1998).

5.4.2 **Intensive Care Units**

Each ICU must examine its own method of nebulisation for ventilated patients. The staff should identify if the device that they are using is single use or single patient use. If they are using single-use devices the ICU staff must make a decision on whether to continue re-using the nebulisers, or to start discarding nebulisers after each use as per the manufacturer's recommendations. Those ICUs that continue to re-use single-use nebulisers must create a protocol for their unit highlighting such information as

- Number of nebulisations a nebulisers may complete before it should be discarded;
- Method of cleaning the nebuliser after use;
- Recommended storage procedure;
- Specific criteria that indicate the nebuliser should be discarded before the number of nebulisations has been completed;
- Method of recording usage of each nebuliser.

It is of importance that ICUs that are re-using single-use nebulisers as a matter of policy, institute evidence-based protocols to protect the patients and staff in the unit.

5.4.3 **Physiotherapists**

Physiotherapists should be aware of the practices and protocols of the ICU in which they work. They should approach the nursing and medical staff in the ICU to initiate discussion around current practice in the ICU and assist in developing a protocol for the ICU. Physiotherapists working with ventilated patients must also set an example to staff in the ICU, making sure to clean and store the nebuliser appropriately after use. The physiotherapist should also discuss with medical and nursing staff other options for the administration of aerosolised medications, such as MDIs and VMNs, and increase awareness of these other options.

5.4.4 Hospital Management

Both nursing managers and financial managers need to examine the impact of the development of a protocol for their ICUs. The decision to start discarding nebulisers will have a financial impact on a unit. If this is not planned for, the strain may affect staff behaviour and result in decreased compliance to the protocol. Management also needs to address these issues with healthcare funders such as medical aids and health insurance companies. Medical aids and healthcare insurance companies have been known to try and influence and dictate the terms of use for certain consumables. The management of the ICU must be able to defend their decisions and protocols to the respective healthcare funder and the patient.

5.5 RECOMMENDATIONS FOR FUTURE RESEARCH

- The information that was obtained from this study supports the development of a protocol to assess and directly compare methods of decontamination and storage of nebulisers. This study assisted in a way to guide the development of such a protocol. The current study should act as a guide to the choice of medications to be tested, which are the most frequently used nebulisers and also to focus on which decontamination and storage procedure would be most likely to reduce bacterial growth within the nebuliser.

- The current study highlighted many concerns and problems with the use and re-use of jet nebulisers. As nebulisation is bound to continue to be performed in ICU it would be reasonable to recommend that the efficacy and efficiency of medication administration through jet nebulisers be compared to that of MDIs and VMNs in ventilated patients.

- This study focused on current practice regarding nebuliser decontamination and storage in ICUs in Johannesburg, South Africa. A continuation of this study in other cities in South Africa and potentially other countries around the world is recommended. A comparison of national practice with global practice may present alternative options regarding nebuliser decontamination and storage to what was presented in the current study.

- The current study highlighted a new and potentially useful method of nebuliser storage namely in a paper cover. An investigation into the effectiveness of this storage technique is recommended.

CHAPTER 6

6. CONCLUSIONS

The aim of this research report was to determine the current incidence of contamination and practice regarding decontamination of jet nebulisers that had been used within ventilator circuits in ICUs in Johannesburg, South Africa. Results from this study demonstrated that 93% of nebulisers used within a ventilator circuit were single-use jet nebulisers. It was found that 100% of the single-use jet nebulisers were re-used, in contravention of the manufacturer's recommendations for use. The rate of contamination of single-use jet nebulisers was 52.4%, which is high considering the rate would be zero if nebulisers were discarded after use and a new nebuliser used for each nebulisation. None of the ICUs assessed had formal protocols for the decontamination and storage of nebulisers. Furthermore, results suggested that nebulisers not be stored in a sterile drape after use as nebulisers that had bacterial contamination were more likely to grow higher concentrations of bacteria when stored like this ($p=0.034$).

The hypotheses that were tested with this study were a) that there is a high rate of re-use of single-use jet nebulisers for ventilated patients in ICUs in Johannesburg, South Africa, and b) that these nebulisers are not being effectively or consistently decontaminated. The results of this study support both hypotheses.

ICUs urgently need to address the problem of re-use of single-use nebulisers in a ventilator circuit. Issues to consider could include change of single-use devices after each nebulisation; change to single-patient-use devices; creation of a protocol for the cleaning and storage of nebulisers and lastly consideration of the implementation of devices such as MDIs and VMNs.

Physiotherapists play a vital role in the multidisciplinary team involved in the management of ventilated patients in ICU. One of the aims of physiotherapy management of ventilated patients is the clearance and management of secretion retention. This is achieved through the administration of bronchodilator and/or mucolytic drugs via a nebuliser attached/introduced to the ventilator circuit. Physiotherapists need to be aware of the potential danger of the re-use and incorrect cleaning of jet nebulisers in ventilated patients, and the potential role that contaminated nebulisers may pose in the development of antibiotic resistant VAP. Therefore it is recommended that physiotherapists, as members of the multidisciplinary team in ICU, should be actively involved in the drafting of and implementation of protocols for the decontamination and storage of nebulisers in ICU.

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APPENDIX 1: SECTION A

UNIT AUDIT TOOL: CURRENT PRACTICE IN DECONTAMINATION OF NEBULISERS IN VENTILATED PATIENTS, JOHANNESBURG, SOUTH AFRICA

Hospital code: _____

Type of institution: _____

Number of beds in unit: _____

Number of patients on a ventilator: _____

Number of ventilated patients receiving nebulisation: _____

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 the unit?_____

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
With residual solute	Yes	No
Attached to oxygen tubing	Yes	No
Nebuliser autoclaved	Yes	No
If yes, method used:		

Other observations made:

APPENDIX 1: SECTION B

NEBULISER ASSESSMENT FORM

Nebuliser number: _____

Hospital number: _____

Manufacturer: _____

Single use ☐ Single patient use ☐ Autoclave ☐

Prescribed medication: _____

Time of last nebulisation: _____

Time of assessment: _____

Number on Ventilation: _____

CRP: _____

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
Removed from oxygen tubing	Yes	No
Nebuliser sent to be autoclaved	Yes	No

Other observations made:

_____

_____

_____

_____

_____

_____

_____

APPENDIX 2

INFORMATION LEAFLET AND INFORMED CONSENT

Study Title : Current practice in decontamination of nebulisers in ventilated patients, Johannesburg, South Africa.

Sponsor : None/Privately funded

Investigator : Mrs Amy Jean Ellis

Institution : University of the Witwatersrand

Daytime and After Hours Telephone Number(s): 082 518 8877

Dear Participant

We, Mrs A Ellis and Dr H van Aswegen, are currently doing a study on jet nebuliser decontamination in ventilated patients. This study will help us to guide further research into evidence-based, cost-effective and practical nebuliser decontamination protocols and assisting to bring these findings into practice. Incorrect nebuliser cleaning, storage and usage may increase risk of patients developing a ventilator-associated pneumonia.

1. **INTRODUCTION**

You are invited to consider participating in a research study. Your participation in this survey 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 from the survey at any time. This information leaflet is to help you to decide if you would like to participate. You should fully understand what is involved before you agree to take part in this survey.
- If you have any questions, do not hesitate to ask me.
- You should not agree to take part unless you are satisfied about all the procedures involved.
- If you decide to 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.

2. **PURPOSE OF THE STUDY**

- The purpose of this survey is to determine the current practice in jet nebuliser decontamination in Johannesburg Intensive Care Units (ICUs).

3. **LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS:**

- Twelve hospitals in Johannesburg have been selected to participate in this survey.
- Data collection will occur in August 2009.
- There will only be one site visit.

4. **PROCEDURES:**

- If you agree to take part in this survey, you will first be asked questions regarding the demographics of your ICU and your nebuliser decontamination protocol. This will be followed by an audit of the unit. The nebulisers will be examined as they have been stored. Staff activity in the unit will not be observed.
- There will be no record 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 involved in the survey, the names will be published in the final research report that will be submitted to the university. However, there will be no link between the names of the hospitals and the results of the audit of the unit.

6. **BENEFITS**

- The potential benefit from your participation in this survey may be a better understanding of nebuliser decontamination and its potential effect on ventilator-associated pneumonia and the propagation of antibiotic-resistant pathogens.
- This survey aims to provide a basis for further research into a decontamination protocol that is evidence-based, cost-effective and practical within the South African context.

7. **RIGHTS AS A PARTICIPANT IN THIS STUDY**

- Your participation in this survey is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason.

8. **NEW FINDINGS*:***

- I will provide you with any additional information that becomes available during the survey, which may affect your willingness to continue with the survey.

9. **WITHDRAWAL*:***

- I retain the right to withdraw you from the survey if it is considered to be in your best interests.

10. **FINANCIAL ARRANGEMENTS:**

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

11. **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.
- 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.

- 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.

12. **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, Human Research Ethics Committee (HREC) or the South African Medicines Control Council (MCC).
- These records will be utilised by them only in connection with carrying out their obligations relating to this survey.

INFORMED CONSENT

I hereby confirm that I have been informed by the Researcher, Amy Ellis, about the nature, conduct, benefits and risks of the survey titled: Current practice in decontamination of nebulisers in ventilated patients, Johannesburg, South Africa.

- I have also received, read and understood the above-written information (Participant Information Leaflet and Informed Consent) regarding the clinical study.
- 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 and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself, in the capacity of Unit manager/Shift leader, prepared to participate in the study.

PARTICIPANT:

Printed Name Signature Date and Time

I, Amy Ellis, 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

TRANSLATOR / OTHER PERSON EXPLAINING INFORMED CONSENT……(DESIGNATION):

Printed Name Signature Date and Time

WITNESS (If applicable):

Printed Name *Signature* *Date and Time*

APPENDIX 3

ICU STAFF INFORMATION LEAFLET

Dear ICU staff member,

Your ICU has been selected to participate in the study described below. Consent for the study has been obtained from the unit manager and hospital manager/CEO of the hospital.

Study Title : Current practice in decontamination of nebulisers in ventilated patients, Johannesburg, South Africa.

Investigators : Mrs Amy Jean Ellis; Dr Heleen van Aswegen

Institution : University of the Witwatersrand

1. **PURPOSE OF THE STUDY:**
   - The purpose of this survey is to determine the current practice in jet nebuliser decontamination in Johannesburg Intensive Care Units (ICUs).

2. **LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS:**
   - Twelve hospitals in Johannesburg have been selected to participate in this survey.
   - Data collection will occur in August 2009.
   - There will only be one site visit.

3. **PROCEDURES:**
   - The unit manager and CEO/Hospital manager have given consent for this survey. You will not be asked any personal information. The questions regarding the demographics of your ICU and your nebuliser decontamination protocol will be answered by the unit manager. This will be followed by an audit of the unit. The nebulisers will be examined as they have been stored. Staff activity in the unit will not be observed.
   - There will be no record of which staff member is responsible for which nebuliser.

4. **RISKS**

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

5. **BENEFITS**

- The potential benefit from participation in this survey may be a better understanding of nebuliser decontamination and its potential effect on ventilator-associated pneumonia and the propagation of antibiotic-resistant pathogens.
- This survey aims to provide a basis for further research into a decontamination protocol that is evidence-based, cost-effective and practical within the South African 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.
- 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) or the South African Medicines Control Council (MCC)
- These records will be utilised by them only in connection with carrying out their obligations relating to this survey.

APPENDIX 4

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mrs Amy Jean Ellis

CLEARANCE CERTIFICATE	**M090537**
PROJECT	Current Practice in Jet Nebuliser Decontamination in Ventilated Patients
INVESTIGATORS	Mrs Amy Jean Ellis.
DEPARTMENT	Department of Physiotherapy
DATE CONSIDERED	09.05.29
DECISION OF THE COMMITTEE*	Approved unconditionally

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

DATE 09.07.07 **CHAIRPERSON** .....
(Professor P E 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...
.....