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To Suction or Not To Suction
That is the question

Studies of endotracheal suction in post-operative cardiac patients

Eileen Gilder

A thesis submitted in fulfilment of the requirements for the degree of Doctor of Philosophy,

The University of Auckland, 2020.

Abstract

Background

Globally, cardiovascular disease is the leading cause of death with an estimated 17.9 million deaths worldwide. Cardiac surgery is widely performed, with post-operative care often including admission to an intensive care unit and planned mechanical ventilation. Airway management includes endotracheal suction, which is known to have deleterious effects. This body of work investigates endotracheal suction in uncomplicated cardiac surgical patients.

Aim

The overarching aim of this thesis was to assess the safety of actively avoiding endotracheal suction in post-operative cardiac surgical patients ventilated for less than 12 hours. Additional aims included reviewing what evidence was available about avoidance of endotracheal suction in the adult intensive care unit patient population; describe local endotracheal suction practice, and elucidate the patient experience of the endotracheal tube and endotracheal suction.

Methods included:

- A systematic review investigating the evidence for the avoidance of endotracheal suction in the adult intensive care population.
- An observational audit describing endotracheal suction practice within the cardiac intensive care unit in Auckland City Hospital.
- A point prevalence observational study describing suction practice across intensive care units in New Zealand and Australia.
- A qualitative study to elucidate the patient experience of the endotracheal tube and endotracheal suction.
- A prospective, non-inferiority, randomised controlled trial investigating the safety of avoiding endotracheal suction.

Results

The systematic review showed an absence of evidence regarding the avoidance of endotracheal suction. Both the observational and studies identified discrepancies between clinical guideline recommendations and clinical practice.

The qualitative study found that half the participants recalled the endotracheal tube, although none recalled suction. Participants provided descriptions about emerging from the fog of sedation, hallucinations and early post-operative recovery.

The randomised controlled trial demonstrated that endotracheal suction could safely be avoided in a patient cohort having cardiac surgery with no increase in complications of extubation or escalation of oxygen therapy.

Conclusions

This body of work adds to the evidence about endotracheal suction; provides the first evidence about avoidance of endotracheal suction; describes the patient experience of the endotracheal tube and early post-operative recovery. These findings can be used to inform clinical practice and nurse education and training.

Dedication

The World Health Organization has designated this year (2020) as the International Year of the Nurse and Midwife, marking 200 years since the birth of Florence Nightingale. At the time of writing the world is in the grip of the COVID-19 pandemic, which has seen the closure of borders, countries put into lockdown, and cost over 700,000 lives to date, including many nurses and health care workers.

Nurses across all disciplines have been in the front line of care delivery, with intensive care nurses and staff being under particular pressure.

As an intensive care nurse in New Zealand, a country where the borders were shut early, protecting both the population and the health care system, so far New Zealand has been spared the worst case scenario many other health care systems are dealing with.

This work is dedicated to all the nurses and health care workers who have died of COVID-19, to those still on the front line of intensive care globally, and friends and colleagues who are currently working in intensive care in pandemic affected countries.

Acknowledgements

This project has occupied four years of my life and has only been made possible with the support of many hidden figures. I must acknowledge those, without whose support and encouragement, this work would not have come to fruition. First I would like to thank my supervisors, Associate Professor Rachael Parke, and Professor Andrew Jull who encouraged me to take the leap. Your interest in this body of work has sustained me, while your knowledge and expertise has got me to this point. I can recall Rachael's advice to "select supervisors who would make a strong team, and have complementary skill sets". I think I did just that, and have been so fortunate to have two such experienced academics and researchers who challenged and pushed me to develop and think differently, taking me out of my comfort zone. I have learned so much about research. Thank you for the support, challenge, and encouragement.

The pathway to a PhD is often compared to a journey, and there have been many people who I have been lucky enough to meet along the way, and who have willingly shared their expertise. A special thank you to Dr. Alana Cavadino, biostatistician extraordinaire and Dr. Julia Slark. Alana, you showed no end of patience with someone for whom statistics is not a natural fit. Your expertise was invaluable for both the systematic review and the statistical challenges associated with a non-inferiority study. Julia, your enthusiasm and expert advice for the qualitative study was wonderful. Your suggestions were enlightening and informative for a novice qualitative researcher. Thank you both.

Research is only possible with teamwork. I am lucky enough to be part of the cardiothoracic and vascular intensive care unit research team who have supported me through this project. You are one of the best teams I have had the pleasure of working with. During the course of this work some of you have moved into other roles, others have got married and had babies, but you were all interested in this work, asking great questions, never hesitating to make suggestions and share ideas. Thank you to Dr Rachael Parke, Keri-Anne Cowdrey, Magdalena Butler, Melissa Woollett, Karina O'Connor, Samantha Ryan, Jane Hallion, Philippa Neal, and Stephnie Long. Your professionalism, along with your sense of fun have made all the difference, not to mention team bonding dinners and drinks.

Thank you to my clinical supervisor, Dr Shay McGuinness, Intensivist, cardiothoracic and vascular intensive care unit. Your encouragement got the ball rolling, and your clinical and research expertise have been invaluable, in particular when selecting the primary outcome for the randomised controlled trial.

I would like to acknowledge and thank the dedicated staff, both nursing and medical, in the cardiothoracic and vascular intensive care unit, Auckland City Hospital. The support and interest in the study have helped me through the challenges of conducting research in a busy intensive care unit. Hopefully, the results of this work help to confirm the relevance of clinical research in an acute clinical setting, and can help us provide the best evidence-based care for our patients.

I have been the recipient of a Clinical Fellowship Training Award from the Health Research Council of New Zealand, and a PhD scholarship from the Green Lane Research and Education Fund. Both sources of funding have been so beneficial, allowing me to transition to full-time study, completing this body of work in a timely manner. I am truly grateful, thank you.

In particular, I would like to thank all the patients who so willingly gave their consent to participate in these research studies. Your willingness to even consider participating in a research study before having cardiac surgery is extraordinary while agreeing to participate is more than generous. Many of you said that you wanted to help future patients, possibly including family/whānau and friends. These results will help to inform and guide our nursing practice for future patients. I hope I have given you a voice that will help staff to deliver the best care. Thank you.

Last, but by no means least, I owe a debt of gratitude to my husband, Shaun. Your endless support, encouragement and belief that I could do this has got me over the finish line. You constantly make me laugh, seem to have an endless supply of appropriate memes, and have kept me supplied with the essentials including a work-life balance. I know that you have made many sacrifices of your own to make this possible, and that this has been a significant part of your life over the last four years. Thank you for picking up the pieces when needed and always believing I would get there in the end. Now it's time to get back out on the water.

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Publications and Presentations

Publications

Gilder E, Parke RL, Jull A. Endotracheal suction in intensive care: A point prevalence study of current practice in New Zealand and Australia. Aust Crit Care. 2019; *32*(2): 112–115. https://doi.org/10.1016/j.aucc.2018.03.001

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Gilder E, McGuinness SP, Cavadino A, Jull A, Parke RL. Avoidance of Routine Endotracheal Suction in Patients Mechanically Ventilated for ≤12 hours following elective Cardiac Surgery: A non-inferiority, randomised controlled trial. Respir Care. https://doi.10.4187/respcare.07821.

Gilder E, Slark J, Jull A, Parke RL. Patient's experiences of endotracheal tubes and suction following cardiac surgery. Nurs Crit Care. 2021; 1-8. https://doi.org/10.1111/nicc.12604

Presentations

Intensive Care Research Coordinators Interest Group Workshop, March 2016, Noosa, Australia – Point Prevalence Study background. Oral presentation.

Australia and New Zealand Intensive Care Society New Zealand regional meeting, April 2017, Wellington, New Zealand – Endotracheal suction of cardiothoracic surgical patients – what are we doing? A single-centre survey of current practice. Poster presentation.

Intensive Care Research Coordinators Interest Group Workshop, March 2017, Noosa, Australia – Point Prevalence Study results. Oral presentation.

Intensive Care Research Coordinators Interest Group Workshop, March 2018, Noosa, Australia – Avoidance of Routine Endotracheal Suction Study Protocol - Oral presentation.

World Congress of Intensive Care, October 2019, Melbourne, Australia – Avoidance of Routine Endotracheal Suction Study results. Oral presentation.

Green Lane Research and Education Fund/Cardiovascular Directorate Academic Grand Round, November 2019, Auckland, New Zealand - Avoidance of Routine Endotracheal Suction Study results. Oral presentation.

Intensive Care Research Coordinators Interest Group Workshop, March 2020, Noosa, Australia – Avoidance of Routine Endotracheal Suction Study results. Oral presentation.

University of Hong Kong School of Nursing, U21 Research Postgraduate Symposium, December 2020, virtual meeting – To Suction or Not to Suction. Oral presentation.

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Abbreviations

ABG	Arterial blood gas
ACH	Auckland City Hospital
ANZ	Australia and New Zealand
ANZCTR	Australia and New Zealand Clinical Trials Registry
ARETS	Avoidance of Routine EndoTracheal Suction study
BP	Blood Pressure
CABG	Coronary artery bypass graft
CMV	Continuous mandatory ventilation
CPAP	Continuous positive airway pressure
CPOT	Critical care pain observation tool
CVICU	Cardiothoracic and Vascular Intensive Care Unit
CVP	Central venous pressure
CXR	Chest X-Ray
ETS	Endotracheal suction
ETT	Endotracheal tube
FiO_2	Fraction of inspired oxygen
FRC	Functional Residual Capacity
HR	Heart Rate
ICU	Intensive Care Unit
ITT	Intention to treat
MAP	Mean arterial pressure
MV	Mechanical ventilation
NPS	Numerical pain score
NZ	New Zealand
$PaCO_2$	Partial pressure of carbon dioxide
PaO_2	Partial pressure of oxygen
PaO_2/FiO_2 ratio	Ratio of partial pressure of oxygen to fraction of inspired oxygen
PCI	Percutaneous coronary intervention,
PCV	Pressure control ventilation
PEEP	Positive end expiratory pressure
PETS	Patient Experience of endoTracheal Suction study
RoB	Risk of bias
PP	Per protocol
PPP	Point prevalence programme
RASS	Richmond agitation and sedation score
SpO_2	Peripheral capillary oxygen saturation
TA	Thematic analysis
TV	Tidal volume

Glossary

Atelectasis - A collapsed or airless state of part or all of the lung.

Barotrauma – can occur in the lungs or inner ear as a result of pressure differences between the internal and external surfaces.

Cardiopulmonary bypass - Bypass of the heart and lungs during cardiac surgery, providing a bloodless field for cardiac surgery.

Cardiovascular disease - A general term for a group of diseases affecting the heart and blood vessels.

Central venous pressure - The pressure within the thoracic vena cava near the right atrium.

Continuous mandatory ventilation - A mode of mechanical ventilation. Delivered breaths are mandatory, set at a pre-determined rate. Patient inspiratory effort during expiration will trigger the next breath.

Confidence interval - The range of upper and lower values that are estimated to contain the population value.

Congenital heart disease - A problem with the structure of the heart that is present at birth.

Coronary artery bypass graft - Surgery to improve blood supply to the myocardium, bypassing a narrowing within the coronary artery.

Dead space (anatomical) - The volume of air that fills the nose, trachea, and bronchi. Consists of approximately 30% of tidal volume, does not take part in gaseous exchange and ventilation.

Dependent variable - The outcome variable the investigator wishes to explain, is the outcome caused by, or dependent upon another (independent) variable.

Endotracheal suction - Mechanical aspiration of pulmonary secretions when an artificial airway is in situ.

Endotracheal tube - A flexible tube that passed into the trachea in a procedure called endotracheal intubation. The purpose of using an endotracheal tube is to maintain a patent airway.

EuroSCORE II – A tool used to predict mortality in patients.

Extubation - The process of removing an endotracheal tube.

FiO_2 - The fraction of oxygen in inspired air.

Functional residual capacity - The volume of air present in the lungs at the end of passive respiration.

Hypercapnia - An increase in the amount of carbon dioxide in the blood.

Hypothesis - A prediction of outcomes, prediction of a relationship between variables.

Hypoxia - A decrease in the amount of oxygen in the blood.

Independent variable - The manipulated or treatment variable hypothesised to influence the dependent variable.

Mean arterial pressure - Average arterial pressure throughout the arterial cycle.

Mechanical ventilation - A form of life support delivered by a mechanical ventilator that takes over the work of breathing.

Meta-analysis - A statistical analysis that combines the results of multiple studies.

Non-inferiority trial - A study that attempts to demonstrate a treatment is not unacceptably worse than the current standard of care.

Null hypothesis - A hypothesis that predicts no relationship between variables.

PaO_2 - A measure of oxygen pressure in the blood.

Positive end expiratory pressure - Airway pressure is maintained above atmospheric pressure at the end of exhalation, preventing alveoli collapse, improving oxygenation.

Pressure control ventilation - A ventilator mode that maintains a pre-set airway pressure for a given inspiratory time, setting a maximum peak pressure.

Percutaneous coronary intervention - A non-surgical intervention to revascularize the coronary arteries, placing a stent within a coronary artery.

pH - The acidity or alkalinity of a solution.

Pneumothorax - The presence of air or gas in the cavity between the lungs and the chest wall, causing collapse of the lung.

Statistical significance - The chances of a relationship between variables being the result of chance alone.

Systematic review - Secondary research that uses systematic methods to appraise the research studies and generate findings to answer a research question.

Transcatheter aortic valve replacement - A treatment for severe aortic stenosis, less invasive than cardiac surgery.

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Extent of contribution by PhD candidate (%)	90

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Dr. Alana Cavadino	Statistical advice and review.

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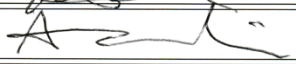
Alana Cavadino		01/07/2019

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Nature of contribution by PhD candidate	Preparing the protocol, data analysis and drafting the publication.
Extent of contribution by PhD candidate (%)	95

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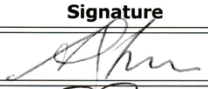
Andrew Jull		31/01/2018
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Nature of contribution by PhD candidate	Protocol preparation, conducting the interviews, data analysis and drafting the publication.
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A/Prof Rachael Parke	Protocol and manuscript guidance.

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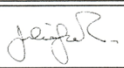
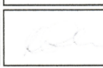
Julia Slark		24/06/2020
Rachael Parke		25/06/2020

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Extent of contribution by PhD candidate (%)	95

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Extent of contribution by PhD candidate (%)	90%

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Shay McGuinness	Clinical supervision, advice developing the protocol, review the manuscript.
A/Prof Rachael L Parke	advice with protocol development, manuscript review and guidance.

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Rachael L Parke		23/12/2019

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"If we can transform – by a few years of persistent effort the habits of centuries our progress will not have been slow but amazingly rapid!"

Florence Nightingale (1820-1910)

Chapter 1

Prologue

During my post-graduate cardiothoracic training, I was orientated to the intensive care unit (ICU). Training included how to safely perform endotracheal suction (ETS), a procedure to remove pulmonary secretions in patients who are intubated and unable to clear secretions naturally. My initial experience of witnessing suction was quite a shock. Depending upon the patient's level of sedation, suction causes the patient to cough, and while this can help with secretion removal, appears to be physically exhausting. Although taught to always explain the procedure to patients beforehand, and perform suction with care, I had a sense that although suction is undoubtedly necessary for many mechanically ventilated ICU patients, the procedure appeared to be very uncomfortable, and at times very distressing.

Although today suction is considered very much a nursing intervention, this has not always been the case. In 1951, Weyl wrote that "*endotracheal aspiration is often a lifesaving procedure. It should be done with skill and care. It should not be made a routine procedure and left to the intern or the nurse"* (p71) (1). Endotracheal suction (ETS) requires a suction catheter to be inserted into the endotracheal tube, often until resistance is met, followed by the application of negative pressure and withdrawal of the suction catheter, removing secretions in the process. Today evidence-based clinical practice guidelines are available (2–4) intended to inform endotracheal suction practice. Suction can be a lifesaving procedure, and will always be needed for long-term ICU patients. However, answering the question 'can suction be safely avoided?' for specific patient cohorts has the potential to reduce patient exposure to an invasive procedure.

For me, ETS has always appeared an uncomfortable procedure for patients, with some nurses' appearing to have a gentler touch than others. This thesis includes an exploration of the patient experience. Describing the patient experience adds the human dimension to the procedure, providing context about how it feels to be on the receiving end, giving patients a voice that can inform the training and education of ICU nurses.

The possibility of actively avoiding ETS is a novel concept and forms the background of this thesis. If the results demonstrated that ETS could be safely avoided in a defined patient cohort, there is the potential to change practice.

Introduction

ICU is defined as "*a specially staffed and equipped, separate and self-contained section of a hospital for the management of patients with life-threatening or potentially life-threatening conditions*" (p8) (5). The polio outbreak in Copenhagen in 1953 saw the birth of the modern Intensive Care Unit ICU (6). At the height of the outbreak over 300 patients a week were admitted to hospital, with 10% "*suffocating or drowning in their own secretions*", (p376) (7) as a result of respiratory failure caused by polio. The

mortality rate was between 85% and 90% (7). Insufficient 'tank respirators' ultimately led to the introduction of positive pressure ventilation. Medical staff in Copenhagen had four years' experience of performing tracheostomies and in collaboration with anaesthetic colleagues incorporated positive pressure ventilation, a recent introduction in anaesthesia, into the management of polio. Medical and dental students hand ventilated patients, delivering the first positive pressure ventilation, which saw a 45% to 50% reduction in mortality (7,8). Although ICU is considered a new discipline, (7,9) it is one of the fastest developing. The development of ICU coincided with developments in cardiac medicine and surgery, including the introduction of the cardiopulmonary bypass machine in 1955, (10) which allowed surgeons to access the heart and cardiac structures. The first cardiac surgery in New Zealand was performed in 1958, (11) and the Auckland cardiac ICU opened in 1963 (11). Today it remains common practice for patients to be admitted to an ICU for post-operative recovery following cardiac surgery, (12) with endotracheal suction performed as standard of care.

1.1 Cardiovascular disease

Globally, cardiovascular disease (CVD) is the leading cause of non-communicable disease deaths, with an estimated 17.9 million deaths worldwide, and 31.4% of global mortality (13–15).

Cardiovascular disease is a group of disorders that includes:

- Coronary heart disease – disease of the blood vessels that supply the heart.
- Cerebrovascular disease – disease of the blood vessels that supply the brain.
- Peripheral vascular disease – disease of the blood vessels that supply the peripheries.
- Rheumatic heart disease – damage to the heart valves resulting from rheumatic fever.
- Congenital heart disease –malformation of heart structures present at birth.

In 2012 coronary heart disease, also known as ischaemic heart disease (IHD) or coronary artery disease, accounted for approximately 13% (7.4 million) of deaths globally (15). The burden of CVD falls disproportionately upon the poorest and most socially disadvantaged. Globally three-quarters of CVD deaths occur in low and middle-income countries, (13) while those with lower socio-economic status and highest levels of deprivation are at the greatest risk of developing CVD (16,17). CVD is the second leading cause of death in New Zealand, after all forms of cancer, accounting for 17.6% of deaths (18). In 2016 there were 8,652 cardiac-related deaths in New Zealand (NZ), made up of ischaemic heart disease, cerebrovascular disease and other cardiac diseases, (18) with Māori and Pacifica disproportionately represented (19). In 2009-2010, adjusted case fatality for IHD was 27.6% for Māori and 26% for Pacifica, compared to 20.5% for NZ European (17). Rates of acute rheumatic fever in New Zealand are among the highest in the world, and similar to rates in developing countries, (20) with ethnic inequalities reflected in the figures. Between 1993-2009 infection rates increased by 79% for Māori and 73% for Pacifica children, while at the same time dropping by 71% in non-Māori/non-Pacifica children (20).

1.2 Cardiac surgery

Globally, cardiac surgery is one of the most widely performed surgeries, (21) although there are disparities between developed and developing countries (22). In 2002 80% of health care interventions

were delivered in the developed world, which represented 9% of the world population (21). Cardiac surgery has continued to grow since its inception in the 1960s (23) with developments in surgical technique, cardiopulmonary bypass machines and ICU leading to improved patient outcomes (23). Surgical interventions include uncomplicated coronary artery bypass graft (CABG) or valve repair/replacement through to complex multi-valve replacement, 're-do' surgery, and surgical intervention to correct congenital heart disease (23). The increased use of percutaneous coronary intervention (PCI), and the introduction of transcatheter aortic valve replacement, has resulted in a changing demographic of the cardiac surgical population with an increasing number of complex, higher risk surgical interventions being performed (23,24). The most frequently performed procedures are CABG and cardiac valve surgery (12).

Government initiatives over the last ten years have led to an increase in the volume of cardiac surgery delivered in New Zealand (25). In 2017 there were 2,727 cardiac surgical operations: 48.1% isolated CABG, 23.6% isolated valve surgery, and 20.9% valve plus other cardiac surgery (26). New Zealand has high levels of valve surgery (45%) when compared to other countries; for example, in the United States of America, 24% of cardiac surgery is isolated and combined valve surgery (27). The higher incidence of valve surgery in New Zealand reflects the incidence of rheumatic fever. The Cardiothoracic and Vascular Intensive Care Unit (CVICU) at Auckland City Hospital admits approximately 1200 patients per year following cardiac surgery and is the largest cardiac surgical unit in Australasia.

Following cardiac surgery, the majority of patients are admitted to ICU for post-operative recovery (12). Recovery includes a period of controlled warming, mechanical ventilation, and cardiovascular monitoring. On admission to ICU patients remain sedated and ventilated during re-warming, with the aim of extubating patients within 3 to 6 hours of ICU admission (12). Early extubation is associated with improved recovery, (12) and the successful introduction of nurse-led extubation has led to reductions in the duration of mechanical ventilation (MV) (28,29).

Airway management during mechanical ventilation includes ETS, known deleterious effects include hypoxia, cardiac arrhythmias, loss of positive end-expiratory pressure (PEEP), hypoxia and atelectasis (30,31). Some cardiac patients have been shown to have an ongoing reduction in functional residual capacity following ETS (32). The American Association for Respiratory Care (AARC) ETS clinical practice guidelines recognise that the evidence underpinning ETS is low to medium quality (33). Much of the evidence about ETS focuses upon patients who are mechanically ventilated for more than 24 hours (30,34–38). In addition, although there is a growing body of evidence that ETS is distressing and painful for patients, (36,39–42) there is less evidence about the experience of ETS in those exposed to short-term MV (43,44).

1.3 Research aims

This thesis presents the findings from five different studies that together can guide future practice and inform nurse education.

The overarching aim of this body of work was to assess the safety of active avoidance of ETS in patients who received equal to or less than 12 hours MV following planned cardiac surgery. There was the

additional opportunity to investigate and describe the patient experience of both the endotracheal tube and ETS.

The main objectives were:

1. Review what is the current evidence about avoidance of endotracheal suction in short-term mechanically ventilated patients (ventilated for equal to or more than 72 hours).
2. Describe current ETS practice in the CVICU, including what triggers nurses used to perform suction.
3. To document current ETS practice across New Zealand and Australia, in both cardiac and non-cardiac ICUs.
4. Explore and describe the patient experience of both the endotracheal tube (ETT) and ETS.
5. To assess the safety of avoiding endotracheal suction in patients mechanically ventilated for equal to or less than 12 hours following planned cardiac surgery.

1.4 Thesis overview

This thesis consists of the following chapters:

- Chapter 2 – describes airway management and endotracheal suction. This chapter describes the effects of endotracheal intubation, mechanical ventilation and endotracheal suction on respiratory physiology.
- Chapter 3 – describes the methodological concepts underpinning this body of work.
- Chapter 4 – presents a submitted manuscript of the systematic review. The chapter describes the review methods, and the challenges resulting from the inclusion of animal studies.
- Chapter 5 – describes a survey undertaken to determine current ETS practice in the Cardiothoracic and Vascular Intensive Care Unit, Auckland City Hospital.
- Chapter 6 – presents a point prevalence study undertaken to describe current ETS practice in ICUs across New Zealand and Australia.
- Chapter 7 – describes a qualitative study investigating the patient experience of the ETT and ETS.
- Chapter 8 – describes the published protocol for the proposed randomised controlled trial investigating the active avoidance of ETS in a cardiac surgical population.
- Chapter 9 – presents the results of the first randomised controlled trial to investigate the active avoidance of ETS in an a cardiac surgical population.
- Chapter 10 – summarises and discusses the key findings of this body of work, the implications for current practice and future research.

Chapters 4 and 6 – 9 present the published or submitted manuscripts, in the house style for each journal. The tables and figures within published manuscripts are not linked to the body of the thesis but presented as seen in the journal. It should be noted that the randomised controlled trial reported in chapter 9 is formatted as per the journal requirements, including the use of American spelling. Although the referencing styles for the publications were journal specific, for continuity Vancouver referencing is used throughout this thesis. All artwork used is under creative comms license or with permission. References

contained within the published articles are included within the body of the thesis. Appendices 1 – 5 includes the supporting documents for each study.

Endotracheal suction – "The closest I have come to hell on earth." *Neil Sawyer* (45)

Chapter 2 : Airway Management

The primary goal of airway management is to maintain a patent airway, thereby oxygenating patients who have reduced consciousness and are at risk of airway obstruction (46). In any medical emergency initial clinical assessment is A, B, C – airway, breathing, and circulation, highlighting the significance of airway management. This chapter provides an overview of the anatomy and physiology of the lungs and respiration, briefly describes the endotracheal tube (ETT), and importantly outlines the effect of suction on respiratory physiology and mechanical ventilation.

2.1 Anatomical airway and physiology

Anatomically, the airway consists of the upper airway: the nose, pharynx, and larynx, and the lower airways: trachea, right and left main bronchi through to the bronchioles.

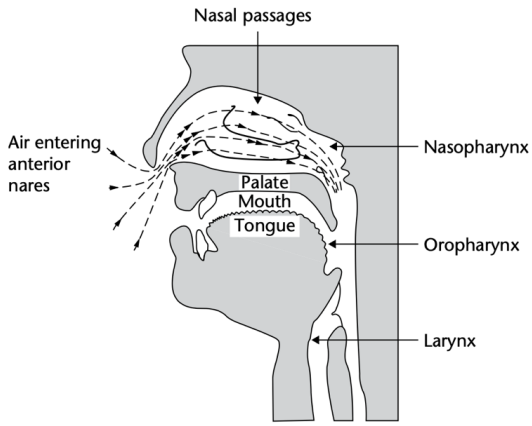

Figure 1: Upper airway anatomy

Ciliated columnar epithelial cells line the respiratory tract and are present in the nasal cavity, extending down to the 16th bronchial division (47) warming, moistening and filtering inspired air. The cilia function in conjunction with a naturally produced mucus, serving to trap inhaled particles, propelling particles upwards out of the lungs. This process of mucociliary clearance is known as the mucociliary escalator, (47) which together with the cough reflex maintains pulmonary hygiene (47).

The pharynx extends from the base of the skull to the level of the sixth cervical vertebra, and is made up of three regions as seen in Figure 1:

- Nasopharynx (upper).
- Oropharynx (middle).
- Laryngopharynx (lower).

The pharynx contributes to respiration, warming and filtering inspired air (48). The trachea forms the main airway, bifurcating to form the right and left main bronchi. The trachea and right and left main bronchi are the final opportunity for inspired air to be filtered (48).

2.1.1 Normal physiology

The purpose of respiration is to supply the body with oxygen and remove excess carbon dioxide (CO_2) produced as a result of cell metabolism (48). The lungs consist of lobes, three in the right lung, two in the left, with respiration controlled by the nervous system and chemical signals. Clinically, respiration refers to one inspired and one expired breath, with an average healthy adult breathing 12 – 15 breaths/minute (48). The lungs and thorax are elastic structures, exerting forces that pull against each other. Before inspiration, lung pressure equals atmospheric pressure (760mmHg/1bar), pressure changes during the respiratory cycle result in a -8mmHg pressure drop during inspiration and -2mmHg during expiration (48). Inspiration is an active process; contraction of the intercostal muscles and diaphragm generates negative pressure as the walls of the thorax move upward and outward expanding the lungs. The resultant negative pressure gradient causes air to flow into the lungs (48). Expiration is passive, elastic recoil of the lungs and chest wall follows the relaxation of the respiratory muscles (48).

2.1.2 Impaired respiratory function

There are multiple causes of impaired respiratory function; post-operative causes include anaesthesia, sternotomy, pain, and immobility (49). Impaired respiratory function can contribute to reduced lung volume, hypoxia and decreased lung compliance (the ease with which the thoracic wall and lungs expand) (12). Infection, trauma or MV contribute to atelectasis or consolidation, with post-operative cardiac surgical patients being at particular risk (48–50). Risk factors include general anaesthesia in combination with prolonged supine positioning during surgery, the systemic and pulmonary inflammatory response following exposure to cardiopulmonary bypass, the impact of a sternotomy wound and dissection of the internal mammary artery (12,49,51,52). The incidence of atelectasis is reportedly between 17% and 88% in post-operative cardiac surgical patients (51).

2.2 Mechanical ventilation

The goal of MV is to support the work of breathing and improve oxygenation (53). Mechanical ventilation is diametrically opposed to normal respiration, using positive pressure to ‘blow’ air into the lungs, with the normal negative intrathoracic pressures reversed (50). Positive pressure impedes blood flow back to the right side of the heart, compressing the heart and reducing cardiac output while increasing pulmonary artery pressures (53,54). Other sequelae and potential complications include hypotension, atelectasis, and ventilator-induced lung injury (53,55). Ventilator-induced lung injury results from repeated inflation and deflation of the alveoli, triggering an inflammatory cascade reaction leading to pulmonary fibrosis, and impaired O_2 and CO_2 exchange (53). Modern ventilators have the functionality to provide a variety of ventilation modes summarised as in Table 1.

Table 1: Summary of ventilation modes

Mode of Ventilation	Description
Continuous Mandatory Ventilation / Assist Control	Either ventilator-initiated (CMV) or patient-initiated breath (AC). Full ventilatory support is provided, each breath is the same volume. Used when patients are deeply sedated, making no spontaneous respiratory effort.
Volume Control	Each ventilator breath provides a set tidal and minute volume. This mode does not limit the peak inspiratory pressure.
Pressure Control	Each ventilator breath is delivered until a pre-set pressure is achieved. The respiratory rate is pre-set. PC results in variable tidal volume delivery. Peak inspiratory pressure is limited, reducing the risk of barotrauma.
Synchronous Intermittent Mandatory Ventilation	Ensures a programmed number of ventilator supported breaths. Mandatory breaths will be triggered by the ventilator if not initiated by the patient, and are synchronised with the patient's spontaneous breath. Can be used to assist patient weaning from mechanical ventilation, and can be used with volume and pressure control.
Pressure Support Ventilation	Set pressure is delivered during inspiration to support spontaneous breathing, no pre-set respiratory rate is set. PSV improves patient-ventilator synchrony and may reduce the work of breathing. The tidal volume achieved is dependent upon the patient's breathing effort. Pressure support can be added to overcome the resistance of the ventilator tubing, reducing the work of breathing.
Continuous Positive Airway Pressure (CPAP)	Spontaneous ventilation mode with no pre-set tidal or minute volume. CPAP maintains open alveoli improving oxygenation and is used when weaning patients from mechanical ventilation.

Ventilator development and the move towards using lighter levels of sedation has seen continuous mandatory ventilation (CMV) superseded by modes such as volume-controlled (VC) and pressure-controlled (PC) ventilation. Both VC and PC are more comfortable for the patient, improving patient synchrony with the ventilation (56).

2.3 Airway management

Airway management in ICU requires knowledge of available airway adjuncts, including the ETT, humidification and endotracheal suction in order to maintain a patent airway. All those exposed to an ETT are at risk of airway complications which include airway obstruction, ventilator-associated pneumonia, ETT or tracheostomy dislodgement, and tissue trauma (57,58). Complications can occur at the time of intubation, during anaesthesia, or as a result of MV (57).

2.3.1 Airway complications

Airway obstruction is the blockage of either the anatomical or artificial airway, resulting in the inability to ventilate and is a life-threatening condition (59). Critically ill ICU patients are at high risk of airway obstruction for a myriad of reasons including, the presence of an artificial airway, impaired cough, abdominal or thoracic surgery (59–62). The presence of the ETT results in the loss of the cough reflex, reduced function of the cilia and mucociliary escalator, (62) and can lead to the accumulation of

secretions, (63) and in combination with medical gases increases the risk of mucus plug formation and airway obstruction (64).

Ventilator-associated pneumonia (VAP) is an infection of the lower respiratory tract with microorganisms originating in either the oropharynx, subglottic region, or gastrointestinal tract (65), although globally, there is no agreed definition of VAP (65–67). The Centres for Disease Control and Prevention (CDC) has a three-tiered definition that comes under the umbrella term ventilator-associated event (68). Lack of an agreed definition causes problems for incidence reporting, (69,70) however there is agreement that VAP is the most common nosocomial infection in mechanically ventilated patients, with the incidence reported to be between 9% and 30%, (66,67,71) increasing to 43% when the pathogen is Pseudomonas aeruginosa or Acinetobacter (72). The presence of an ETT increases the risk of VAP due to impaired cough, biofilm accumulation within the ETT, and tissue trauma to the oropharynx and trachea leading to inflammation and swelling (73). An ETT allows opportunistic pathogens direct access to the lower respiratory tract through micro-aspiration of oropharyngeal and gastric secretions (72).

ETT related mucosal and vocal cord injury are well described in the literature, (47,57,74–76) with mechanisms of injury including vocal cord erythema, granuloma, mucosal abrasions and pressure necrosis (77). Injury can have both short and long term sequelae, including hoarse voice, mucosal ulceration, swallow dysfunction and vocal cord paralysis (75,76,78). Movement of the artificial airway or high cuff pressures can contribute to tissue trauma, including inflammation, swelling, granuloma, or ulceration (60).

2.3.2 Endotracheal tube

An ETT (Figure 2) maintains the airway during anaesthesia and mechanical ventilation. Adult ETT sizes range from 6.5mm to 9.0mm internal diameter, each with a predictable amount of resistance (79). The design includes a high volume, low-pressure cuff near the distal end of the ETT, which reduces the risk of micro-aspiration of secretions and prevents air leak from the lungs during mechanical ventilation.

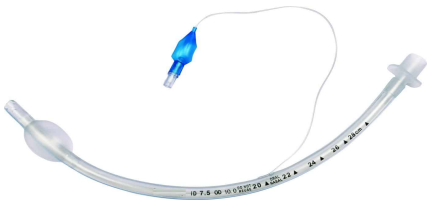

Figure 2: Endotracheal tube
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As seen in Figure 3, intubation using an ETT maintains an open airway, bypassing the pharynx, preventing the natural warming, filtering and moistening of inspired air. Airway management in ICU includes maintaining ETT patency and is achieved through humidification of medical gases, and endotracheal suction to remove secretions that the patient is unable to remove naturally (59,62).

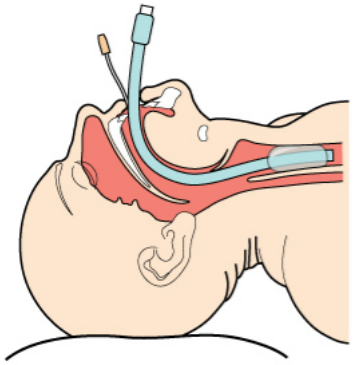

Figure 3:Tracheal intubation

2.3.3 Humidification

Humidification helps maintain the integrity of the ETT, preventing drying of secretions, maintaining the mucociliary function, and reducing the formation of mucous plugs (59). Effectiveness of humidification depends upon the temperature of the delivered gas and achieving a desired relative humidity. In health, the upper airways provide 75% of the heat and humidity delivered to the alveoli, (80) the body maintains the air temperature at 37ºC and 100% relative humidity (known as isothermal saturation). The presence of an artificial airway interrupts normal humidification, resulting in a heat and moisture deficit, causing impaired mucociliary function (80). To compensate for this deficit, it is recommended that humidification provides a gas temperature between 34ºC and 41ºC (81). Below this temperature, drying of secretions and subsequent risk of mucus plug formation can occur (81).

Two methods of humidification are commonly used; the heat and moisture exchanger (HME) system and direct heated humidification. HME is passive, designed to conserve heat and moisture during expiration, releasing heat back into the inspired gases during inspiration (59,81). Direct heated humidification is active, water is heated via a base heating unit and warmed air delivered to the lungs via ventilator tubing. HME humidification is the standard of care for the first 24-hours of MV in the CVICU where these studies were conducted, transitioning to direct heated humidification in those who require over 24 hours MV.

2.4 Endotracheal suction

Endotracheal suction is a component of airway management and pulmonary hygiene for mechanically ventilated patients, (2,59,62) and has been defined as "*the mechanical aspiration of pulmonary secretions from a patient with an artificial airway in place*" (p758) (2). Although ETS is used to remove secretions and reduce the risk of infection, ETS may inadvertently increase the risk of infection with potential contaminants introduced during the procedure, (30,82) or secretions within the ETT being propelled further forward into the lungs during catheter insertion (83).

2.4.1 Types of suction

Suction systems are either open, closed, or quasi-closed.

2.4.1.1 Open suction

Open suction requires patient disconnection from the ventilator, the introduction of a single-use suction catheter into the ETT, application of negative pressure during suction catheter withdrawal, finally reconnecting the patient to the ventilator. Although open suction results in reduced lung volume, the effects can be short lived, particularly in those with mild to moderate lung disease, with a lack of significant arterial desaturation, suggesting that open suction may be clinically safe (84). This is supported by a systematic review that found no clinically significant differences in heart rate, SpO_2 or mean arterial pressure between open and closed suction (85).

2.4.1.2 Closed suction

Closed suction utilises a multi-use suction catheter, enclosed within a plastic sleeve incorporated into the ventilator circuit (Figure 4). The system can be left in situ for 24 - 72 hours (30,82).

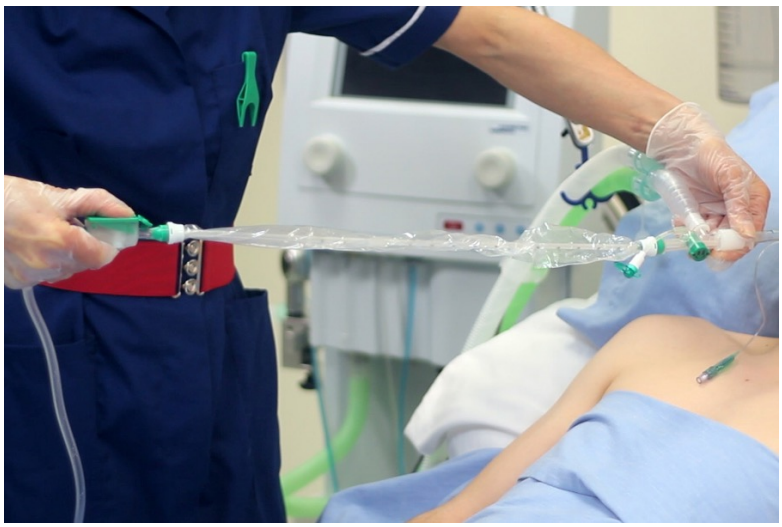

Figure 4: Closed suction system

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Advantages of a closed system include reducing the infection risk to healthcare staff, preserving lung volumes, preventing de-recruitment, allowing continued delivery of tidal volumes during suction, and limiting haemodynamic instability (86,87). Despite these perceived advantages, concerns have been raised about the potential to generate sub-atmospheric pressures in the alveoli, (87,88) which can occur if the suction flow in the catheter is higher than the ventilator airflow. Additionally, there is evidence that end-expiratory lung volume recovers more slowly than anticipated following closed suction (86), suggesting that closed suction may not be as benign as previously thought. Closed suction has been hypothesised to be superior to open suction for the prevention of VAP. However, this hypothesis has not been supported in the literature. Both systematic and rapid reviews, (82,85,89,90) and observational studies (71,91) have failed to report VAP reduction with closed suction.

2.4.1.3 Quasi-closed suction

Quasi-closed suction uses a catheter mount (connecting the ETT to the ventilator) that incorporates a one-way valve that the suction catheter is passed through (Figure 5). This avoids ventilator disconnection and has been shown to minimise lung derecruitment in those with acute lung injury (84,92).

Figure 5: Swivel quasi-closed suction catheter mount

Quasi-closed suction is standard of care in CVICU, Auckland City Hospital, where these studies were conducted.

2.4.2 Effect of negative pressure

Early work described the principles of airflow and pressure (93) and the physiological effect of negative pressure during ETS (94). The term 'negative pressure' refers to sub-atmospheric pressure, (93) when one end of a tube is open to the atmosphere, or immersed in a liquid at atmospheric pressure, while pressure at the other end is below atmospheric pressure. The resulting gradient causes air or liquid to flow into the tube (95). During ETS, air enters the ETT causing a pressure difference between the proximal and distal end of the ETT, leading to sub-atmospheric pressure at the tracheal tip of the ETT (93,96). Negative pressure in combination with the resistance within the suction tubing determines the rate of secretion removal (95). The single biggest influence upon the flow through a tube appears to be tube diameter, (93,96,97) leading to the recommendation that "*a suction catheter with an external diameter larger than half the internal diameter of the trachea is not used*" (p55) (94). This recommendation is supported by recent evidence using a bench top model (96). Five sizes of suction catheter were tested, with ETS using larger suction catheters in smaller ETTs producing higher tracheal pressures, while suction catheter to ETT ratio of 0.5 or less, as recommended by Rosen and Hillard, (94) resulted in minimal increases in negative tracheal pressures (96). Other laboratory studies have demonstrated increases in negative pressure and reductions in alveolar ventilation as the diameter of the ETT decreases and the diameter of the suction catheter increases (88,96–98). This effect was exaggerated with the addition of artificial secretions, the effects were noted to be erratic and unpredictable, (97) with a marked increase in PEEP during volume-controlled ventilation, and reduced tidal volume during pressure-controlled ventilation (88).

In contrast to laboratory studies, a recent ICU study compared the effect of three different negative suction pressures, 80, 150 and 250 mmHg (99). The cohort was a general ICU population, mechanically ventilated for at least 48 hours. The total volume of secretion removal increased as suction pressures were increased, but counter-intuitively, the erythrocyte and epithelial cell count reduced, implying that higher suction pressures did not contribute to lung injury. There was no evidence of tracheal bleeding in any group, and the authors concluded that increased pressures did not cause tissue trauma or hypoxia. The incidence of atelectasis was not reported. The relevance of these findings to ICU practice is unclear, but as increasing negative pressure may contribute to atelectasis and hypoxia (30,100) the use of negative pressures up to – 250 mmHg does not appear warranted.

Given the paucity of evidence in the human adult population, and despite the limitations of laboratory models, including that rigid lung models do not reflect human physiology, and that pressure changes

may differ considerably when compared to humans, (88,96,97) overall, the available evidence continues to support the recommendations of a maximum negative pressure no greater than 150 mmHg, and the suction catheter to be no greater than half the diameter of the ETT (94,95).

2.4.3 Effects of suction upon lung physiology

The application of negative pressure results in reduced lung volume, (84,87,101) due to differences between the diameter of the suction catheter compared to the internal diameter of the ETT, (88,96) and type of suction system, that is open, closed or quasi-closed (84). Although closed and quasi-closed suction have been shown to reduce lung volume loss, (84) lung volumes have been seen to recover more slowly than anticipated following closed suction (86). The reasons remain unclear, some evidence suggests that ventilator settings may play a part, with lower flow triggers in volume-controlled ventilation contributing to large negative pressures (86). The majority of post-operative cardiac surgical patients have reduced lung volume, (12,49) and ETS may exacerbate pre-existing atelectasis (32,102), however, importantly lung volume changes may be transient and clinically insignificant (84).

Hypoxia can occur as a result of patient disconnection from the ventilator which dilutes the fraction of inspired oxygen (FiO_2) with room air, (103) and may be exacerbated by the loss of PEEP and application of negative pressure (104,105). Pre-oxygenation with 100% oxygen before suction may be warranted in those patients requiring over 50% oxygen, (2) however, it should be used with caution as hyperoxia has been shown to contribute to the development of absorption atelectasis (106,107). Negative intra-airway pressure causes alveoli collapse and potential shunt, contributing to hypoxia and impaired lung function (108). Shunts occur when alveoli are perfused but not ventilated (104). Repeated alveoli collapse and re-inflation and the pressure changes associated with ETS can cause barotrauma, (109) which may be exacerbated by repeated derecruitment following ETS, and be particularly deleterious for those with acute lung injury (92). The suction catheter can also cause direct injury to epithelial cells leading to oedema and inflammation (74). The potential risks of suction have to be balanced against the risk of atelectasis that may result from retained secretions.

Seymour and colleagues (102) investigated the effect of closed suction in intubated, spontaneously breathing ICU patients, hypothesising that suction in the absence of sedation may affect respiratory function. The participants were a spontaneously breathing general ICU population, mechanically ventilated for a median of five days. At the time of the suction episode, patients had a Richmond Agitation and Sedation score (RASS) of -1, which is drowsy but can stay awake to verbal stimuli (110). During closed suction tidal volume decreased, respiratory rate increased and full recovery took up to seven minutes, compared to one minute in sedated patients, the authors concluded that these changes were clinically significant. Changes in SpO_2, MAP and heart rate, although statistically significant were not judged to be clinically significant. The authors suggested that suction at the time of extubation could cause tachypnea and reductions in tidal volume, and recommended that the timing of suction at extubation should be given due consideration. Although this study was not undertaken in a cardiac population, post-operative cardiac surgical patients are awake and spontaneously breathing when extubated, and the findings could apply to this patient cohort.

2.4.4 *Effects of suction upon haemodynamic function*

Cardiovascular effects of ETS are well documented in the literature, (102,111–114) and include cardiac arrhythmias and alterations in cardiac output. Although the mechanism is unclear, there is evidence from animal studies that insertion of the suction catheter, without the application of negative pressure, can cause cardiac arrhythmias (113,115). The hypothesis is that arrhythmias occur from stimulation of the trachea or vagus nerve (113). Suction related hypoxia is thought by some to contribute to cardiac irritability (104,105,113).

Walsh and colleagues (112) identified significant falls in mixed venous saturation (SvO_2) in mechanically ventilated patients with respiratory failure. SvO_2 is a marker of tissue hypoxia, reflecting the balance between oxygen delivery and oxygen consumption, (116) where a drop in SvO_2 indicates tissue hypoxia. However, suction was open suction including the instillation of saline before suction, a practice that is no longer recommended (2). Walsh et al. (112) also noted that a strong cough during ETS, agitation, or patients resistance to ETS exacerbated the fall in SvO_2. Similar changes in SvO_2 have been reported by others when comparing open to closed suction, (117) with reductions in SvO_2 following open suction, despite the use of hyperoxygenation before and after suction. Duration of suction was 10 seconds, and saline instillation was avoided, and 61% of the patient cohort were post-operative cardiac surgical patients. Open suction resulted in a 4% drop in SvO_2 from 66% to 62%, (range 44% to 88%) returning to baseline values within four minutes, while closed suction, using ventilator delivered pre and post oxygenation, resulted in an increase in SvO_2 following suction from 67.7% to 70.8% (range 50% to 91%) two minutes after suction. The authors concluded that some form of hyperoxygenation is recommended before and after suction (117). Maintaining adequate oxygenation following cardiac surgery is essential to preserve end-organ function and reduce the risk of post-operative heart failure which can be exacerbated following cardiac surgery (118). However, as normal SvO_2 is between 60% and 80% (119) it remains unclear whether all patients benefit from hyperoxygenation before and after suction, particularly uncomplicated cardiac surgical patients receiving short-term MV.

It has been hypothesised that interruption of oxygen delivery and loss of PEEP during open suction may increase sympathetic activity, in turn contributing to haemodynamic changes, while inhibition of parasympathetic efferent activity may contribute to bradycardia and cardiac arrhythmias. This was investigated by Bourgault and colleagues, (105) in a mixed ICU population that included those with coronary artery disease. Both open and closed suction were tested using the current AARC guidelines, (2) no significant differences were reported between suction methods. However, Baun and colleagues (120) described decreases in right atrial pressure during suction, while right ventricular afterload increased with both open and closed suction when PEEP was used in an animal model. The reasons were unclear, although the authors hypothesised that increases in intrathoracic pressure due to PEEP, in combination with hyperinflation, compress the great veins and heart, causing a reduction in left ventricular volume with an increase in left ventricular end-diastolic pressure. Stone et al. investigated the effect of hyperinflation upon mean arterial pressure, cardiac output, and pulmonary artery pressure in a post-operative cardiac surgical cohort (121). All participants were cardiovascularly stable at the time of the intervention and had been admitted to ICU for 3.5 hours. The purpose of the study was to elucidate the mechanism for reported increases in mean arterial pressure seen with hyperinflation. Although the results reported increases in mean arterial pressure, cardiac output, and pulmonary artery pressure with

hyperinflation prior to ETS, hyperinflation is not mentioned in the current AARC guidelines. Hyperinflation may compromise post-operative cardiac surgical patients due to underlying cardiovascular disease.

2.4.5 Interaction of endotracheal suction and mechanical ventilation

For the uncomplicated cardiac surgical population, post-operative management includes minimising the duration of MV (12). Interactions between MV and ETS become relevant for those who may have prolonged MV following complicated cardiac surgery. Closed suction has been shown to lead to dramatic increases in airway pressure when used with volume-controlled ventilation, (88,122,123) one laboratory study recorded an increase in PEEP from 11 to 23 cmH_2O, leading the authors to recommend avoidance of closed suction with volume-controlled ventilation (88). One human study found that volume-controlled ventilation resulted in a greater fall in sub-atmospheric airway pressure than pressure-controlled ventilation (123). To date, there is no evidence regarding which mode of MV and ETS is recommended in those having planned short-term MV.

2.4.6 Suction and the cardiac patient

Several studies have investigated the effects of suction on the cardiac surgical population (32,111,121,124,125). An early study evaluated the effect of suctioning upon arterial blood gases. (125) The method of suction used is not reported, however, as the study was conducted in 1978 it is assumed that open suction was used as closed suction was not in regular use until the 1980's (91). Although PaO_2 declined across all groups, all reported PaO_2 results were within the normal clinical range. A more recent study investigated the effect of open and closed suction on haemodynamic parameters in cardiac surgical patients and reported a statistically significant result in favour of closed suction. However none of the reported results, including oxygen saturation, PaO_2 and $PaCO_2$ appeared to be clinically significant (111).

Others have investigated the use of recruitment manoeuvres and hyperinflation (32,121). Stone and colleagues (114,121) investigated the effect of hyperinflation and repeated suction upon haemodynamic parameters. The studies demonstrated a rise in mean arterial pressure and cardiac output, with a corresponding fall in mean pulmonary artery pressure. Although these results demonstrated the effect of repeated suction, given that current practice is to extubate post-operative cardiac surgical patients within six hours of admission to ICU (12), it appears unlikely that this patient cohort would be exposed to frequent ETS, suggesting that this study is a proof of concept.

A more recent study compared open and closed suction in a post-operative cardiac population in Iran (126). Neither the duration of MV nor how ETS was delivered is reported, including duration of suction, or suction pressures used. Although the authors concluded that closed suction caused fewer haemodynamic changes compared to open suction, except for the effects of open suction three minutes following suction, all the reported outcomes, including SpO_2, PaO_2, or $PaCO_2$ were within clinically acceptable limits, including five minutes following suction.

These findings provide insufficient data to make a recommendation about which suction method is preferable in this patient cohort. It could be argued that minimising ETS in this patient cohort could be the most appropriate clinical management.

2.4.7 *Clinical practice guidelines*

There are numerous recommended best practice and clinical practice guidelines intended to inform evidence-based practice (2,4,127–129). The widely cited AARC guideline recommendations (2) include performing suction as required, use less than 150 mmHg negative pressure, avoid the instillation of saline before suction, and listening to coarse breath sounds over the trachea to assess the patient need for suction (2). Others make no recommendation about listening to tracheal breath sounds when assessing the need for ETS (4). Systematic reviews have concluded that included studies lack a strong evidence base (30,33,85,89,128). The lack of a robust evidence base may contribute to the known discrepancy between clinical practice recommendation and clinical practice (130–132). The evidence base for ETS is further complicated by the use of different suction strategies, suction pressure, and patient populations, (132) leading to challenges for clinicians when trying to interpret the data. Studies may present statistically significant results that may or may not have clinical significance (132).

2.5 Summary

Understanding airway management is a core requirement for all ICU nurses, yet presents numerous challenges. Airway management in ICU presents particular challenges due to the underlying pathology of the critically ill (61). Despite years of research, a robust evidence base remains elusive, in part due to the heterogeneity of research that includes animal and bench models, paediatric and adult research. As has been described, numerous factors can influence the effectiveness of ETS, including the size of the ETT and suction catheter, underlying pathophysiology, and the amount of negative pressure applied. All of these influences and lack of robust data may have contributed to discussions in the literature about the extent to which suction is an art or a science (133,134). Before embarking upon a programme of research, selecting appropriate research methods was paramount and is described in Chapter 3.

Chapter 3 : Methodology

"To maximise the benefit to society, you need to not just do research but do it well."

Professor Doug Altman.

3.0 Background

Research has been defined as "*the systematic and rigorous process of enquiry which aims to describe phenomena and develop explanatory concepts and theories"* (pg. 1) (135). Research in a healthcare setting is complex and involves numerous decisions; consideration needs to be given to whether the research is necessary, the vulnerability and views of patients, as well as the practicalities of conducting robust research in a dynamic environment. This chapter will describe aspects of philosophy, how it influences methodological choices, and the rationale underpinning my choices when designing the studies within this thesis.

3.1 Philosophical considerations

Philosophical concepts underpin decisions about research study design and methodology. Ontology and epistemology are closely linked and drive methodological choices (Figure 6). The Oxford English Dictionary defines ontology as "*the branch of metaphysics dealing with the nature of being"*, while metaphysics is defined as "*the theoretical philosophy of being and knowing, the philosophy of mind"* (Oxford English Dictionary). Ontology is frequently seen as the researchers' perception of reality and ontological positions range from realists to anti-realists (136). Realists believe that the world exists outside the influence of the researcher, (136,137) and is there to be discovered. Anti-realists, also known as relativists, reject this concept, believing the world is dependent upon the views and experiences of the individual and that reality is a cultural or social construct (136,137). Ontological beliefs about reality influence how researchers examine the world they inhabit (138) with epistemological choices based upon ontological beliefs.

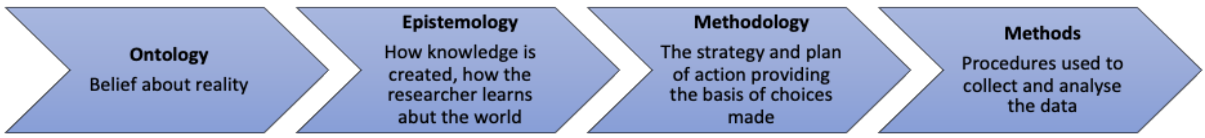

Figure 6: Philosophical concepts of acquisition of knowledge

Epistemology is defined as "*the theory of knowledge, especially with regard to its methods and validation"* (Oxford English Dictionary). Philosophically, epistemology relates to an individual's belief about how they know and understand their world and the process of obtaining that knowledge (136). Some consider epistemology as "*the theory of knowledge embedded in the theoretical perspective and thereby in the methodology*" (pg.3) (139). Knowledge generation is considered to be either positivist/post-positivist or constructivist (139).

Objectivism considers the possibility that there is a single version of reality, existing outside of consciousness. Knowledge and truth are derived from data collection, with no interference from the researcher. Deductive methods, experimental design and robust statistical analysis form the basis of enquiry and fit within the scientific model and positivism/postpositivism (137,139,140). Constructivism rejects this view and considers that knowledge and truth are derived from how individuals experience the world, accepting that there may be multiple meanings, (136,139) and that 'truth' is different for everyone. Constructivists investigate what is the experience or meaning of phenomena, (136) using inductive methods such as narrative enquiry, phenomenology and grounded theory.

The researcher's ontological and epistemological stance is influenced by their experience of the world, (141) and is influential in shaping the researcher's search for understanding and how the research question/s are addressed (142). For example, those exposed to prejudice as a result of colour, gender or religion may favour interpretivist research methods that provide a rich description of the phenomena under investigation. Addressing the question 'what is the nature of reality?', although on the surface may appear abstract, is considered the building block of science (143). Epistemology builds upon researcher's ontological position as a researcher reflects upon how they engage with inquiry to develop knowledge that is considered legitimate and valuable (143). Research methodology then addresses how researchers develop new knowledge. Methodology can be considered "*a set of guidelines and principles that put an epistemology and an ontology into action in a given research project"* (pg. 688) (143). The relationship between ontology, epistemology and methodology is summarised in Figure 6. Finally, the values and judgement that shape and influence the research approach, known as axiology, leads the researcher to consider how and why specific kinds of research become seen as valuable and worthwhile and can impact the methodological choice (143). The methods used in this thesis fit within the pragmatic paradigm, are postpositive dominant, utilising the constructivist paradigm to investigate and describe the patient experience of the ETT and ETS. These terms will be explored in the following sections.

3.2 Paradigms

Paradigms are considered to be the lens through which researchers view the world (141). The term was coined in 1962 by the physicist and philosopher of science Thomas Kuhn (142). Kuhn considered that paradigms were tools for researchers to summarise their beliefs (144). They were seen as "*a disciplinary matrix which contains values, rules, regulations, knowledge building methods, for the 'puzzle-solving' activities of the scientific community"* (pg. 672) (145), and consist of "*concepts, practices and language that define a particular approach to science"* (pg. 687) (143). Definitions include "*a set of basic beliefs or a frame of reference that explains how individuals perceive the nature of the world and their places in it*", (pg. 34) (146) and a "*general perspective on the complexities of the world*" (pg. 9) (147). Kuhn considered that paradigms can and do change (145). Each paradigm has underlying ontological, epistemological and methodological differences, (138) leading to different research methods as seen in Table 2. Over time paradigms have evolved, and now include positivism, postpositivism, constructivism, and pragmatism (138,141,148).

Paradigm choices are influenced by multiple factors, including the discipline conducting the research, the influence of those around the researcher, and the researcher's experience (141). With increasing multidisciplinary research collaboration, an understanding and awareness of the ontological and

epistemological beliefs of other researchers can help all those involved in research to engage in a meaningful way (143).

Table 2: Philosophical positions underpinning paradigms

Paradigms				
	Positivism	Postpositivism	Constructivism	Pragmatism
Ontology	Empiricism and objective. Truth is "external" and independent	Objective. Independent of the researcher. Accepts reality may potentially be imperfect	Relativist, Influenced by the lived experience and cultural influences. Subjective, no absolute truths.	Reality is created through interaction with the world. Draws on qualitative and quantitative assumptions.
Epistemology	Objectivity and hypothesis testing. The researcher is independent of the research.	Observable phenomena, credible facts. Researcher is detached from the research. Provides an estimation of the truth, not absolute truth.	Focus is upon 'how we know', and socially constructed. Knowledge generated from participants and researcher working together.	Focuses upon the practicalities of applied research. Truth is not based upon duality. The focus is on applied research, that integrate the data.
Method	Quantitative. Deductive reasoning.	Quantitative dominant.	Qualitative. Inductive, interpretative methods.	Quantitative and qualitative. Freedom of choice. Methods used are appropriate to the research question.
Axiology	Research is "value-free", i.e. free of the researchers values and beliefs	Accepts that research cannot be totally unbiased, researchers values will have an influence.	The researcher is part of the research. Researcher and participants are not independent.	Knowledge gained is influenced by the researchers values, politics and experience.

3.2.1 Positivism

Although now largely discredited, (149) positivism has been influential upon nursing (148). Efforts to develop a scientific basis for nursing that was recognised by medical and academic institutions drove positivism in nursing (148). Positivism has its origins in the work of the 19th century philosophers including Rene Descartes, John Locke, David Hume and Auguste Comte, (137,147) and is traditionally associated with the study of the natural world and hypothesis testing (148,150). The mind is considered separate from the body, with disease being investigated from a realist ontology, using objective enquiry. Positivist ontology considers the world 'real' and 'ordered' according to the laws of the 'natural world', (138,149) and that the truth can be known. Epistemologically, positivism strives to be objective and bias-free, focusing upon gathering empirical data, (151) and is referred to as the scientific paradigm (150).

3.2.2 Postpositivism

Postpositivism emerged in the late 1950s, (146) challenging the nature of absolute truth as viewed by positivists (147,152–154). Karl Popper, Jacob Bronnwaski, Thomas Kuhn and Charles Hanson promoted postpositivist philosophy, (151) rejecting arguments of neutrality and human detachment, accepting that researchers are not immune from social and societal influences (155). Ontologically postpositivism accepts that truth and reality can never be completely known and is more uncertain than positivism suggests (155). There is a recognition that psychological and social factors influence health and disease. Postpositivism challenged dualism, (136) developing a more person-centred approach to investigating disease, with the epistemological acceptance that value-free inquiry is impossible (155). Ontologically, postpositivism retains strong links with positivism, continuing the scientific method of objectivity,

neutrality, hypothesis testing, and a belief that good science requires precision and logic (153). Research methods include objective inquiry and systematic data gathering to produce evidence. However, there is an acceptance that unobservable factors will have an effect upon and influence outcomes (148,151). Methodologically, Popper proposed the hypothetical-deductive method (149). Although the aim remained hypothesis testing, the focus moved to deductive testing. Popper considered the natural laws to be "*partially decidable…falsifiable only*", (pg. 6) (149) leading to the concept of null hypothesis testing (138,149). Postpositivism recognises that scientific knowledge is always provisional, (149) and that pluralistic methods can be practised (151,155).

3.2.3 Constructivism

Constructivism grew out of a rejection of the rationalist view that understanding (intellect) was the only power, growing out of work by Berger and Luekmann in 1967 (141). Constructivist ontology is founded on the belief that "*all knowledge, and therefore meaningful reality as such, is contingent upon human practices, being constructed in and out of interaction between human beings and their world"* (p42) (139). Ontologically, constructivists believe that meaning comes from conscious application, is constructed not discovered, and recognise that nothing can be described in isolation from the person experiencing the 'event' (139). Individuals construct meaning that is influenced by the society they inhabit. Research methods include inductive enquiry generating a pattern of meaning or theory (141). Researchers recognise and acknowledge that their own experiences and perceptions influence the interpretation of the research as the researcher is a tool for data collection and analysis, aiming to capture and interpret the participant experience (146). Constructivism has the potential to investigate social context while applying individual meaning.

3.2.4 Pragmatism

Pragmatism developed from the works of the philosophers Charles Pearce, William James, and John Dewey in the 1870s (141,144,156). Pragmatism as a paradigm has emerged more recently; pragmatists worldview *"arises out of actions, situations and consequences rather than antecedent conditions"* (p10) (141). For pragmatists, the philosophical assumptions underpinning the research are less important than using the correct research methods (152). For some, although pragmatism does not discount ontology and epistemology, it rejects the *"top-down" privileging of ontological assumptions*" (pg. 68) (144). Ontologically, pragmatism accepts that reality can be both realist and relativist, accepting pluralism, (146) with the focus being upon the research problem (141). Pragmatism is less interested in a single method rather which is the most appropriate method to address the research question (138,144,146). The quest for knowledge is considered a practical activity, (157) judged by whether the knowledge is useful (157,158).

3.3 Methodology

Methodology is concerned with research design (139) and sits along a continuum from qualitative to quantitative methodology (Figure 7). All designs have strengths and weaknesses. The following discussion will describe different research designs and how they best contribute to knowledge acquisition.

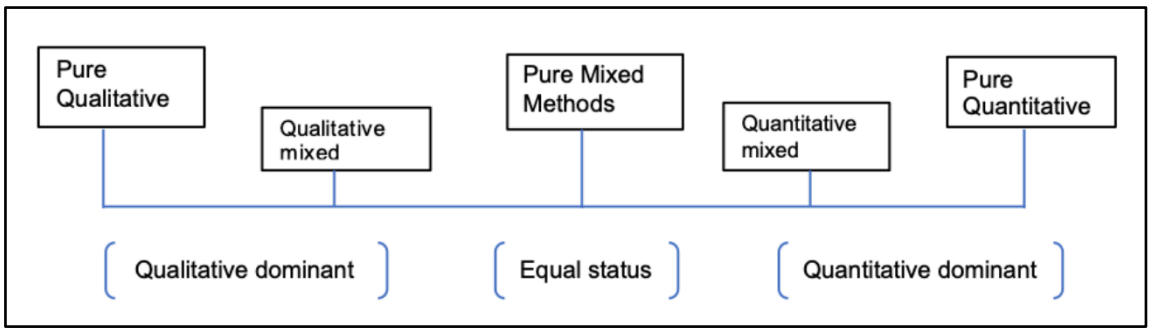

Figure 7: The research continuum

3.4 Experimental study design

A randomised controlled trial (RCT) has been defined as "*a full experimental test of an intervention, involving random assignment to treatment groups"* (pg. 742) (147). Experimental research design controls for extraneous factors (noise), that may influence or account for outcomes, (159) and investigates causal relationships. Researchers predict the effect of the independent variable upon the dependent variable while controlling for other factors (160). Three key principles are considered relevant to causality: the cause must precede the effect, the cause must be related to the effect, and there should be an absence of any other explanation of the effect (159). When estimating causal relationships, only the independent variable should account for the effect upon the dependent variable (159). RCTs are powered as if they are superiority trials, although, for some, an insignificant difference is nominated as the same as equivalence or similarity (non-inferiority). Non-inferiority study design has some special features that will be described separately.

RCT designs include:(161)

- Parallel group design – randomising participants to different groups and manipulating one independent variable (intervention).
- Factorial design – two or more independent variables can be manipulated, potentially testing interactions between interventions.
- Crossover study design – participants are exposed to both interventions being tested, acting as their own control. The difference is the order in which the interventions are delivered.
- Cluster study design – large groups rather than individuals are randomised to an intervention, for example, hospital wards.
- Non-inferiority and equivalence designs – a randomised controlled trial that seeks to determine whether a new treatment or intervention is no worse than or equal to the current standard treatment, as defined by a pre-specified margin.

Key features of experimental design include:

- Hypothesis and significance testing.
- Comparison of experimental (intervention) and control groups to test the effect of the independent variable on the dependent variable.
- Randomisation and allocation concealment.

- Blinding, which may include the intervention, research staff, participants, and outcome assessors.

3.4.1 Sources of error or bias in experimental research design

As behaviour is influenced by beliefs and expectation of outcomes, (162) research is prone to error and bias (163). Error has been described as "*any deviation from a true value*", (pg. 3) (164) can be random or systematic, (147,164) occurring at any stage during the research process, including design, conduct, and data analysis, ultimately affecting study reliability and validity (163).

Confounding is "*a difference between treatment groups in the characteristics that influence the association between treatments and outcomes. These include demographic characteristics, prognostic factors, and other characteristics that may influence someone to participate in or withdraw from a trial*" (p2) (165) and is managed by randomisation. Examples of confounders include differences in group demographics, prognostic factors or features influencing participation or withdrawal from studies either participant or investigator, protocol deviations and missing data, inadequate or non-random sequence generation (166,167). Confounding can introduce apparent effects between the dependent and independent variable, leading investigators to conclude an association when none exists (168).

Random error occurs by chance, is inconsistent distorting of results in either direction above or below the true value, (169) and is considered "*background noise*" (pg. 78) (170). Random error is minimised through appropriate sample size, (171) larger sample sizes reduce the effect of random error (assuming adequate control of systematic error), (170) with the sample more closely distributed around the true population value, (171) with smaller studies having a greater sampling variability (172). Increasing the sample size improves the likelihood of detecting a true effect. Participant dropout needs to be anticipated and accounted for in sample size calculations, with sample size adjusted accordingly (167). Sample size calculation can be managed through consultation with bio-statisticians and/or using recognised on-line tools such as G-Power (173).

Systematic error, "can lead to systematic deviations from the truth", (pg. 135) (135) and is known as bias (171). Distortion of results from bias can be above or below the true population value, and while some distortions are small, some are substantial, affecting all findings (174). Sources of systematic bias include selection bias, performance bias, detection bias, attrition bias, reporting and 'other' bias, for example, contamination between intervention and control groups (163,171,175).

Selection bias results in "*systematic differences between baseline characteristics of the groups that are being compared*", (pg. 195) (172) resulting in mismatched groups, and the sample population being systematically different to the population it is intended to represent (165). Contributors to selection bias include:

- Inadequate allocation concealment – selection bias can arise if investigators are aware of the allocation sequence in advance of randomisation (167).
- Response or volunteer bias, those who volunteer to participate systematically differ from those who do not.
- Participant dropout, while a loss of equal to or less than 5% is unlikely to introduce selection bias, a loss of over 20% is cause for concern (147).

Performance bias can occur when studies are unblinded, for example, one group may receive greater surveillance, or receive additional treatment or investigations (167). Both participants and investigators knowledge of the study intervention can contribute to performance bias, participants may have a more positive attitude to a study if aware of the study intervention, while investigators may treat participants differently if aware of the study allocation (167).

Detection (or ascertainment) bias (165) results from systematic differences in outcome assessment between groups (172). This is particularly relevant when outcome measures are subjective, (176) for example pain scores or wound assessment (177,178).

Attrition bias is a type of selection bias that results in systematic differences between groups in those who dropout or are lost to follow up during the study, (175) and can occur as a result of either protocol deviations or participant withdrawal (167). Participants who dropout may systematically differ from those who complete the study, resulting in an unrepresentative study population (167). Reasons for dropout can include the severity of illness, clinical deterioration, the burden of the intervention or follow-up procedures, or perceived lack of benefit (167). Duration of follow up can affect attrition, for example, studies with longer follow up are at risk of increased attrition (167,175). Attrition bias can contribute to confounding within a study (179).

Reporting bias - depending upon how the study outcomes are reported, investigators can introduce bias, for example only reporting outcomes that support the hypothesis (180).

3.5 Managing systematic error

Randomisation and blinding are powerful tools, which if successfully implemented, minimises systematic differences between study populations, either in baseline characteristics, intervention or treatment received (181). Effective randomisation reduces selection bias and confounding (182) while blinding protects against performance and detection bias (167).

3.5.1 Randomisation

Randomisation is the cornerstone of RCTs (170) and is used for two reasons, first to achieve treatment groups with similar characteristics, reducing selection bias and confounding (168,170,178,179,183). Second, statistical theory used for results analysis is based upon the concept of random sampling (170). Random allocation (184) is one of the "*fundamental principles of experimental design"* (pg. 81) (170). Effective randomisation achieves random treatment allocation, with all participants having an equal and known chance of being allocated to groups (183–185). Randomisation prevents both researchers and participants from influencing or predicting which group study participants are allocated to, and is considered a powerful tool to reduce selection bias (159,178). Methods of randomisation include simple, block and stratified randomisation (170). Simple randomisation is a single sequence random allocation, like tossing a coin (170). A weakness of simple randomisation is that each study group may have a different number of participants, reducing the statistical power to reject the null hypothesis (186). Block randomisation is used to randomise participants into equal groups, achieving balanced groups. Blocks are generally small, for example, blocks of four, six or eight (187). Stratified randomisation can be used when sample sizes are small, medical characteristics are rare, or when subgroups of participants are

expected to respond differently (170). Stratified randomisation achieves balanced groups within the strata while maintaining the benefits of randomisation. Separate block randomisation is used for each subgroup (stratum), following the identification of key prognostic characteristics (166,170,188) for example, stratifying by blood pressure, ward or hospital. Allocation sequence within the blocks is random, (166) reducing the potential for investigators to predict the allocation sequence and reducing allocation bias. Successful randomisation relies upon the generation of an unpredictable allocation sequence and allocation sequence concealment (178). Randomisation may not always result in balanced groups, however, any imbalance should have occurred by chance alone (170).

The allocation sequence should be randomly generated, preferably by an independent biostatistician (172) prior to recruitment commencing. Ideally, investigators should separate those performing sequence generation and those randomising participants (168). A predictable allocation sequence increases the opportunity for selection bias, (189) investigators have been known to have kept a record of study allocation in order to attempt allocation sequence predictions (189). Random allocation manages confound by minimising group differences, and consequently the risk of confounding relationships (171).

3.5.2 Allocation concealment

Allocation concealment safeguards the allocation sequence before randomisation, limiting selection and allocation bias (190). Allocation concealment "*is the prevention of knowledge of a given treatment allocation until after it is executed to avoid selective enrolment of patients into trials*", (pg. 39) (177) and means not disclosing the treatment allocation until the point of randomisation (191). Neither participants nor researchers have prior knowledge of treatment allocation, preventing investigators from selecting participants based upon beliefs about the intervention and which participants might benefit, and preventing participants from deciding upon participation based upon choosing their treatment allocation (167,168). Allocation concealment strategies vary depending upon study resources and include sequentially numbered, opaque, sealed envelopes containing the treatment allocation. The envelope is opened at the time of randomisation. Other strategies include centralised telephone or computer/web-based randomisation (177). Allocation concealment supplements randomisation and blinding, reducing the risk of systematic differences between treatment groups (191). Reporting of baseline characteristics helps readers evaluate the efficacy of the randomisation and allocation concealment.

3.5.3 Blinding

Blinding, or masking, "*refers to keeping study participants, those involved with their management, and those collecting and analysing clinical data unaware of the assigned treatment, so that they should not be influenced by that knowledge"* (pg. 504) (162). Benjamin Franklin is credited with identifying blinding as a powerful research method (178). Blinding can be applied to participants, researchers and/or outcome assessors, protecting against detection and ascertainment bias (192). Knowledge of treatment allocation can lead to unconscious changes in behaviour by all involved, investigators and participants may make decisions about continuing or stopping treatment as a result of knowing treatment allocation (178). Blinding can be 'double-blind', that is no one knows the treatment allocation, or 'single-blind', the participant is unaware of the treatment allocation (170). Although double-blind is considered the gold standard, in clinical research this is not always feasible. Pragmatic trial design considers single-blind acceptable in a clinical setting where it is impracticable to fully blind an intervention (193,194). Although

unblinded trials have been reported to demonstrate larger treatment effects that blinded trials, (162) using blinded outcome assessors may help mitigate observer bias. Observer bias may be less important when objective outcome measures, such as death, are used (162). Ascertainment bias related to researchers is known as *observer or assessment bias* and is "*a systematic discrepancy from the truth during the process of observing and recording information for a study"* (pg. 23) (176). Observer bias comes from variation within the observer or variation between observers (171). While within-observer variation is considered random, between-observer variation can contribute to systematic bias, observers can lose objectivity, affecting how participants are managed (167,176). Unlike observer bias, response bias happens as a result of participants knowing their treatment allocation, for example, in a nutrition study, those allocated to 'usual care' may have negative attitudes to the study, which in turn may influence their responses (167).

3.5.4 Other approaches to managing bias

Selective outcome reporting is another source of potential bias (195). Publishing trial protocols and prospective trial registration has been introduced with the aim of reducing reporting bias, (167,172) as reported outcomes can be compared against the planned outcomes described in the study protocol. Although this has led to more studies being registered, discrepancies remain between registered and published outcomes (172). Reporting bias affects what data is available to inform decision makers and the public. Reporting guidelines have been developed by the Consolidated Standards of Reporting Trials Group (CONSORT), to provide "*Transparent reporting of Trials*" (www.consort-statement.org). Clear reporting aids interpretation and critical appraisal of trial conduct and results.

Attrition bias that occurs as a result of missing data, can be managed through imputation (single or multiple imputation (175)) and intention to treat (ITT) analysis. Single imputation replaces missing data using the "*last observation carried forward*", (pg. 1) (196) where the last measurement collected is used for all subsequent missing data points (196). Although this method is considered attractive as a simple solution, it is thought by some to have "*little else to recommend it*" (pg. 1) (196). Replacing all missing data in this way can result in over-optimistic scores, (196) for example in studies of neurological disease, drop out due to clinical deterioration will carry forward overly-optimistic scores. This can be overcome by carrying forward the baseline value, which is also the approach used with categorical data when participants with missing outcome data are considered to be treatment failures. ITT analysis reduces the risk of selection bias (196) as all participants are analysed according to allocation, regardless of whether the allocation was received, (167) and has the effect of preserving the random allocation sequence. Given a large enough sample, differences in outcomes should be due to the intervention being tested and not as a result of systematic group differences (197). Pragmatic trials are potentially susceptible to missing data given their real-world setting. As ITT accounts for protocol deviations, or participants moving from one arm to another, ITT analysis will help inform readers about the external validity of a study's findings (198).

3.6 Non-inferiority RCT design

A non-inferiority trial "*seeks to determine whether a new treatment is not worse that a reference treatment by more than an acceptable amount*" (pg. 2594) (199). Unlike superiority trials, non-inferiority trials investigate whether one treatment/intervention (typically new) is no worse than another treatment by a

pre-specified margin. The non-inferiority margin is pre-specified, (200) and based upon the maximum or minimum margin considered to be clinically acceptable or "*clinically unimportant*" (pg. 436) (201). Sample size calculations are performed using both clinical expertise and available data (201). Although superiority and non-inferiority study design have much in common, including randomisation, allocation concealment, and appropriate blinding of participants, non-inferiority design has several specific considerations that are described below (200).

3.6.1 Methodological considerations for non-inferiority design

Key methodological differences with non-inferiority studies are directionality of hypothesis, pre-specified non-inferiority margins, statistical analysis, and use of one-sided confidence intervals when reporting results (200,202). Experimental research uses hypothesis testing to test interventions. Study hypotheses consist of the null and alternative hypothesis. In superiority study design, the null hypothesis (H_0) predicts the intervention being tested will have no effect, while the alternative (or experimental) hypothesis (H_1) predicts the effect of the intervention being tested (203,204). Hypotheses can be directional or non-directional, a directional hypothesis predicts the direction of the effect (a one-tailed test). A non-directional hypothesis states an effect will occur but does not predict the direction of the effect (a two-tailed test). Null hypothesis significance testing provides data that the researcher can use to retain or reject the null hypothesis (170). Non-inferiority study design tests whether comparable treatments are no worse, or 'non-inferior', to current standard practice (205). As seen in Table 3, the null hypothesis is 'reversed', starting at the position of inferiority (202).

Table 3: Superiority and non-inferiority null hypothesis

Superiority	**Non-inferiority**
H_0 – intervention has no effect	H_0 – intervention is inferior to usual care
H_1 – intervention is superior	H_1 – treatment is not inferior by a specified margin

As it is impossible to prove or disprove the null hypothesis, (204) significance testing uses the application of statistical tests to assess the probability that the observed results were obtained by chance alone (205). Test statistics provide a value that can be compared with a known distribution if the null hypothesis is true (205). This is represented in the tail area of the distribution curve (Figure 8).

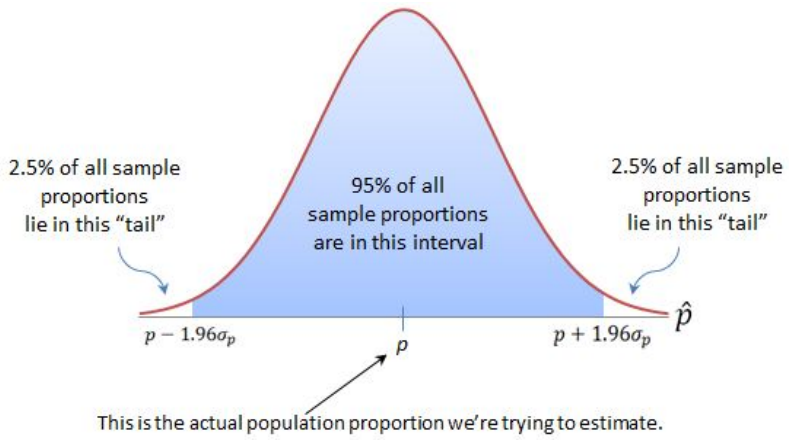

Figure 8: Distribution curve identifying the area that represents confidence intervals

Significance, reported as a P value, is an arbitrary cut off point frequently set at 0.05, (170,205) that is a true null hypothesis would be rejected five times out of 100 and is represented as p=<0.05, and is considered statistical significance. P values may be discipline specific, and can range from 0.01 to 0.05 (170). The use of P values can obscure uncertainty of results by forcing a choice between significance and non-significance (170). Some statisticians argue there is an over-emphasis on P values, and that confidence intervals are a better representation of effect (170). Non-inferiority design demands the use of confidence intervals for results analysis. Confidence intervals are a range of values that the researcher is confident contain the true value, and are a statistical value derived from the standard error of the sample, (135,170) and are often used to present the level of uncertainty about the estimated effect of the treatment or intervention (161). For example, if you repeat the same experiment 100 times with different populations, the point estimate is predicted to recur 95 times out of 100 when assuming a 95% confidence interval. This has been described as "*we expect that the 95% confidence interval will not include the true population value 5% of the time."* (pg. 163) (135). By convention, 95% and 99% confidence intervals are calculated (170). As seen in Figure 9, all but two of the samples contain the true value and cross the zero line. Where the confidence interval excludes zero the conclusion is the intervention had no effect (161). However, caution is required as differences may exist without being detected, for example, if the calculated sample size is too small (161).

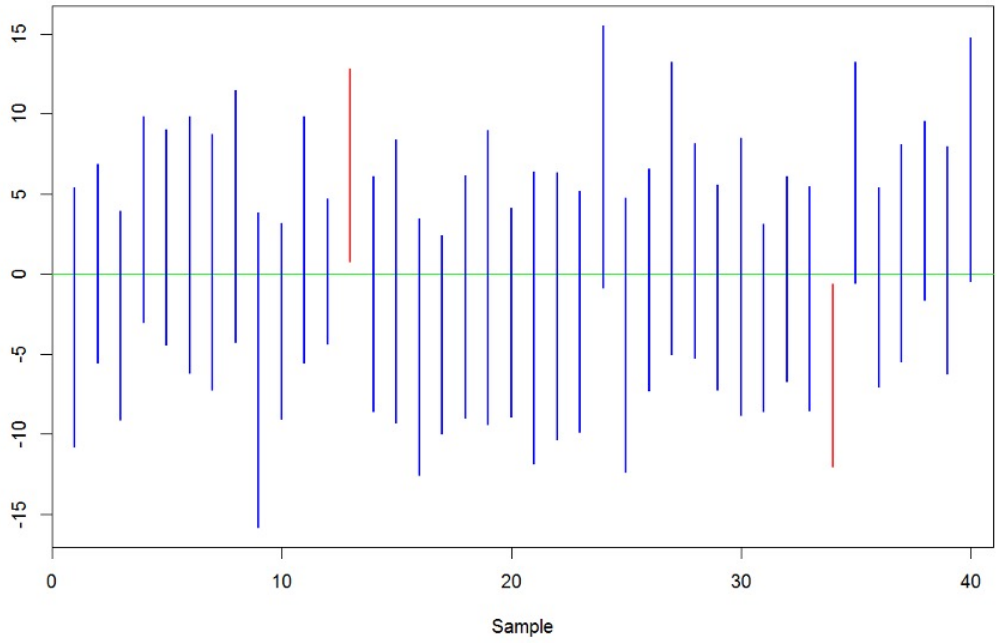

Figure 9: Confidence intervals
The samples that contain the true value in the population. Reproduced under CC-BY-SA

Non-inferiority margins are agreed in advance and if the lower bound of the confidence interval does not extend to beyond the agreed margin (Figure 10), non-inferiority can be claimed. There is no interest in the upper bound confidence interval (202). P-values and confidence intervals are linked, the P-value will be <0.05 when the confidence interval does not cross zero with a 95% confidence interval (202).

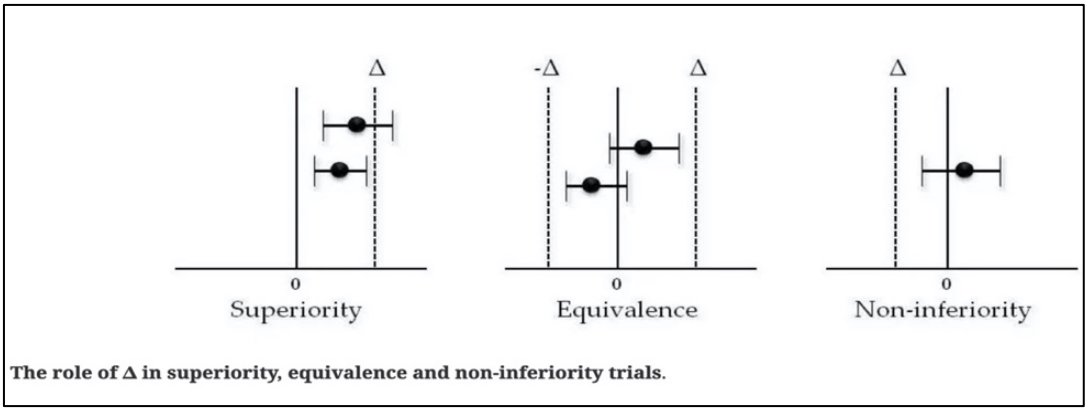

Figure 10: Non-inferiority margin

Reproduced with permission: Schumi and Wittes: Through the looking glass: understanding non-inferiority. Trials 2011 12:106.

Although experimental research uses significance testing to retain or reject the null hypotheses, error can occur, these are Type I and Type II error. In superiority trials Type I error referred to as a false positive, occurs when a true null hypothesis is rejected. That is, the investigator incorrectly concludes the intervention has an effect upon the population being investigated (170,206). Type II error, referred to as a false negative, (205) occurs when the investigator incorrectly concludes the intervention has no effect when an interaction exists (135). Non-inferiority design reverses Type I and Type II error as shown in Table 4.

Table 4: Classification of Type I and Type II error

	Superiority	**Non-inferiority**
Type I error	Incorrectly concludes an effect when there is none. (rejects the null)	Incorrectly concludes non-inferiority (no effect) (rejects the null)
Type II error	Incorrectly concludes there is no effect when an effect exists. (retain the null)	Incorrectly concludes inferiority (effect). (retain the null)

The choice of one or two-tailed tests will depend upon the predicted direction of any relationship between the dependent and independent variables (205). Superiority and equivalence tests use two-sided tests. Non-inferiority studies use a one-tailed test, where the intervention is predicted to be no worse than the control (135). These decisions are made before the start of the study (147). When using a two-tailed test, the critical region of the sampling curve includes 2.5% at either side of the curve, whereas a one-tailed test uses 5% at one side of the curve (Figure 11) (170).

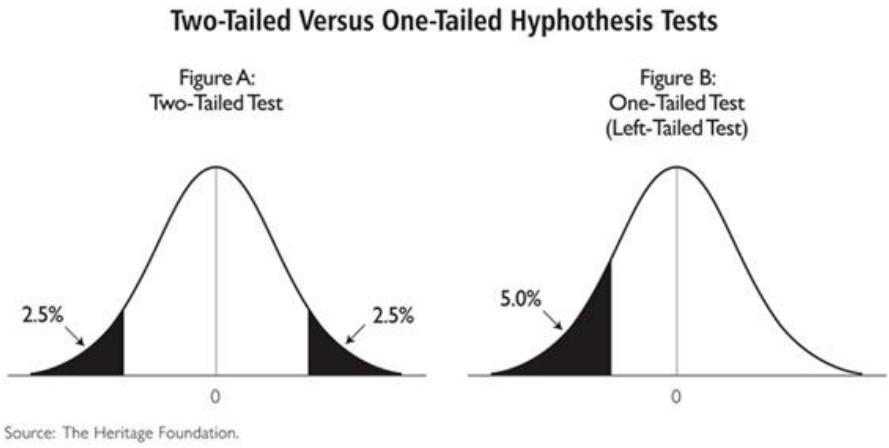

Figure 11: One-tailed and two-tailed tests

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The most appropriate statistical analysis for non-inferiority studies continues to be debated (147). Superiority trials by convention use ITT analysis, with all patients analysed according to allocation, regardless of whether the allocation was received. This approach produces a conservative result and is reflective of real-world practice where not all patients tolerate an intervention. As described previously ITT analysis retains the random allocation sequence. Per-protocol analysis includes only those who received the allocation intervention with no major protocol deviations (200,207). Per-protocol analysis can result in altering the random allocation sequence introducing bias (208). Unlike superiority trial design, ITT analysis is not considered conservative when applied to non-inferiority studies. Inclusion of those who cross over groups, those who drop out, or have poor protocol adherence may bias results towards non-inferiority or equivalence (209). The consensus for non-inferiority study analysis is that both per-protocol and ITT analysis are required, with per-protocol being the primary analysis (203,208). Non-inferiority is only conferred if both analyses go in the same direction (200).

Non-inferiority trials have a place in an increasingly complex health care setting. However, attention to selecting an appropriate non-inferiority margin, and design issues specific to non-inferiority design need to be given due consideration. Non-inferiority trials require robust design and reporting. The CONSORT statement has been extended to include reporting of non-inferiority design (200).

3.7 Systematic review design

Systematic reviews synthesise available evidence, making an objective judgement about "*to what degree that information can be trusted"* (pg. 17) (203) and are research in their own right (210). Systematic reviews are used to establish what is known and where are the evidence gaps. The Cochrane Collaboration (www.cochrane.org), is an international, not-for-profit organisation that focuses upon systematic reviews, with their methods recognised internationally as the 'Gold Standard' (211).

Although a definitive definition has yet to be agreed, (210) the Cochrane Collaboration suggests "*a systematic review attempts to collate all empirical evidence*" (pg. 6) (212) and includes the following characteristics:

- Clearly stated objectives with pre-defined eligibility criteria.

- Explicit and reproducible methods.
- An exhaustive and systematic search that attempts to include all available literature.
- Risk of bias (RoB) assessments.

Meta-analysis is a statistical method that summarises the results of independent studies (172). Not all reviews are suited to a meta-analysis due to the heterogeneity of studies. Advantages of systematic reviews include the use of explicit, reproducible methods, succinct presentation of a large amount of data, and provision of results that can be applied at the population level reducing the need for unnecessary further research (172). A meta-analysis, if conducted, adds a summary statistic to the review results (213). Although considered the top of the evidence hierarchy, (210) some caution needs to be applied when evaluating a systematic review (147,210). An inadequately conducted systematic review that includes poorly conducted RCTs will produce low quality evidence, in contrast to a robust, well-conducted RCT (213). A biased systematic review can lead to inaccurate conclusions (210) that can, in turn, lead to the adoption of ineffective or potentially harmful treatments, or dismissal of effective treatments (172).

Systematic reviews are used to address a wide range of questions, inform health care decisions and evidence-based practice (214). Review results are being increasingly used in the development of clinical practice guidelines (172,210,215). Summation of the effect of an intervention can provide clinicians and policymakers with the best level of evidence, (215) and if implemented may reduce the time-lag for the introduction of evidence-based treatments or therapies (210) helping translate research into practice (214).

The benefits of systematic reviews include:

- The full evidence base of a treatment is summarised.
- Results of all included studies can be combined using meta-analysis (210).
- Reviews can help to confirm or refute contradictory findings from individual studies (210).

However, as with all research, reviews themselves can be subject to error, and if not well conducted can magnify or replicate flaws in the included studies (210). To try and minimise flaws both the Cochrane Collaboration and the Institutes of Health in the United States have set out their methodological expectations (216,217).

3.7.1 Sources of bias in systematic reviews

A systematic review judges the overall RoB of the included primary studies (215). A well-conducted and reported systematic review can be considered high quality, even if the included studies are judged to be at high RoB (215). When judging bias within a systematic review, assessment is based upon how the review was conducted rather than the included studies (215). Bias can arise at any stage of a review as a result of "*flaws or limitations in the design, conduct, or analysis of a review"* (pg. 226) (215).

Unlike an RCT, systematic review eligibility criteria refers to the included studies, not the study participants. Several issues can lead to study selection bias, including an insensitive search strategy with a limited number of databases searched, limits by language, dates, or numbers of participants,

exclusion of grey literature, or use of a single person to screen and select studies (213). Exclusion of studies by language has been shown to increase bias as more studies with positive outcomes are published in English than non-English languages potentially exaggerating a positive effect (215). An exhaustive search needs to include citation databases, grey literature, searching reference lists, trial registries, and where necessary, contacting authors directly (218). Bias can arise from methods used for screening, determining study eligibility, and decisions about study inclusion. For example, it has been shown that reviews conducted by those considered experts in a particular field were less able to produce objective reviews (210). Reviewers may unconsciously select studies that support their personal hypothesis rather than select studies based upon the evidence, inappropriately excluding studies based upon subjective judgements rather than objective pre-defined inclusion criteria (210). This risk is increased when a sole reviewer screens and selects studies (210). Review teams can introduce unconscious selection bias through preconceived expectations about which studies to include or exclude, lack of expertise and training in systematic review methods, and prior knowledge of results of potentially eligible studies (215).

Flawed data collection or RoB assessment can lead to information bias (210). For example, there is evidence of exaggerated treatment effects in studies that lack allocation concealment (215). Transcription errors, failing to collect relevant data, missing data, or inappropriate statistical transformation can add to bias, (213) compounded by the use of inadequate data extraction tools, especially when a review is conducted by inadequately trained or single reviewers (213,215). Inadequate reporting of excluded studies, including the rationale for study exclusion, hinders readers assessing overall review bias (215).

Other weaknesses in systematic review can be introduced by failure to consider the following questions: (213)

- Is the analysis appropriate for the review?
- Has heterogeneity been taken into account?
- Has bias within the primary studies been addressed?
- Has missing data been correctly accounted for?

Failure to address these questions put the results of the systematic review at risk of bias (215).

3.8 Managing error in a systematic review

Study eligibility is managed using a review protocol, written and registered in advance (210,215,219). Protocols allow readers to compare reported results with planned search methods and study selection, as well as how data collection and analysis will be conducted. When pre-specified outcomes are available researchers can make an objective assessment of study eligibility, although this is only possible when a study protocol is available (215,220). Protocol registration is recommended, (213,215) and the International Prospective Register of Systematic Reviews (PROSPERO) (www.crd.your.ac.uk) is widely used. Registration of review protocols provides a public record that serves two purposes; avoidance of duplication of research and allowing comparison of the planned review methods with reported methods.

Prospective registration also reduces the potential for selection bias, with inclusion and exclusion criteria clearly defined in advance

Study selection bias is managed through an exhaustive and sensitive search retrieving as many eligible studies as possible (221). Accessing the skills of trained information specialists or specialist librarians has been shown to improve search results (215). A study protocol informs a comprehensive search strategy as previously described. The exclusion of grey literature can result in missing studies and increase bias. A sensitive search includes checking for duplicate studies which can be difficult to confirm but can lead to bias due to the effect multiple inclusion may have upon calculation of effect size (199). Decisions about study inclusion ideally should be made by two independent reviewers (213) using prespecified inclusion and exclusion criteria that inform the decision making process. Using two or more independent reviewers reduces the chance of excluding or rejecting relevant studies (215,219). Software, such as the Covidence platform (www.covidence.org), allows multiple reviewers to perform an independent assessment of potential studies.

Managing data collection and study appraisal. A multi-disciplinary review team reduces unconscious bias and biased RoB assessments (213). Ideally, a review team should include members with systematic review, clinical, and statistical expertise (172,210). Where possible training should be provided, and inexperienced team members should be supervised by experienced reviewers (172). Bias resulting from transcription errors or missing data is reduced when reviews are conducted using two or more independent reviewers, agreed data collection tools or software, and where possible, a third independent reviewer is available to adjudicate decisions if required (215). A thorough description of the included and excluded studies should be available to allow readers to make an informed decision about potential bias within the review, (213).

Managing data synthesis and findings. Statistical analysis and synthesis of findings should be appropriate to the review, planned *a priori* and described in the study protocol (219). Synthesis needs to account for how heterogeneity and missing data were managed (172). Heterogeneity of included studies may rule out a meta-analysis, with a consequent narrative analysis conducted and reported (215). Review findings may have unnoticed bias occurring from arbitrary decisions made during the review process, such as what weighting is given to a study (210). Sensitivity analysis helps answer the question "*are the findings robust to the decisions made in the process of obtaining them?"* (pg. 290) (210). Sensitivity analysis is a repeat of the primary analysis excluding studies with an unclear range of values (172). Any planned sensitivity analysis should be described in the study protocol. Statistical packages, such as the Cochrane collaborative RevMan software (www.training.cochrane.org) are available to help researchers perform a meta-analysis. The Covidence platform is designed to link with RevMan, allowing the transfer of data from Covidene to RevMan. Together the packages provide robust tools for data extraction and analysis that can help reduce bias.

Systematic reviews can be both affected by, and subject to, publication bias. As described above, the inclusion of duplicate studies can cause bias in the review due to the effect of double-counting results (172,215). Publication bias can lead to a positive bias in the available data as a result of studies not being published in full (172,213). Funding has the potential to introduce bias, for example, translation costs can be a barrier to the inclusion of non-English language studies. Declarations of financial support

or conflicts of interest should be made clear (199,218) so that readers can assess the independence of any review.

3.9 Observational research

Observational studies can provide timely data about current conditions that have societal implications. As an example, this thesis is being written during the COVID-19 pandemic (2020). COVID-19 has had worldwide societal implications, including jurisdiction lockdowns as governments attempt to halt virus transmission, protect the vulnerable, and protect health service infrastructures. A raft of observational data describing patient cohorts, disease pattern and outcomes, and public attitudes are being published (222–226). However, the race for publication has seen retraction of observational studies, including by two high impact journals, The Lancet and New England Journal of Medicine (227–229). This is a salient reminder of the importance of an appropriate research question, a well-written protocol, *a priori* statistical analysis plan, and the benefits of using guidelines and checklists to help achieve high-quality studies.

Observational studies dominate the literature, (210) can be descriptive or analytical (Figure 12), are non-experimental providing data about health, behaviour, and attitudes. Descriptive research is often the first step in enquiry, "*concerned with and designed only to describe the existing distribution of variables, without regard for causal or other hypotheses*" (pg. 145) (182). Unlike analytical observational research, descriptive studies have no comparison or control groups, and report on the frequency of an outcome, the natural history of a disease, observed usual practice, (230) or report disease characteristics (231).

Although considered to provide weak scientific evidence, descriptive studies have an important role. For instance, case reports brought the possibility of the thalidomide drug interaction with unborn babies to the attention of the medical world (231).

As seen in Figure 12, analytical observational research use comparison or control groups to describe possible associations, and are broadly classified into three categories; cohort (longitudinal and follow-up), case-control and cross-sectional (210,231). Analytical studies describe disease prevalence, risk factors, and investigate possible associations between risk factors and outcomes (232). Study design can be prospective, retrospective, or a prospective design using retrospective data (233). Data is said to address the five "W" questions, who, what, why, when, and where, (170) with findings used to inform future RCTs, (234) and complement experimental research (231). Observational research is frequently used in epidemiology and public health research to investigate the causes of disease. When used in clinical research, observational studies describe current practice often providing the foundation of a planned programme of research (235).

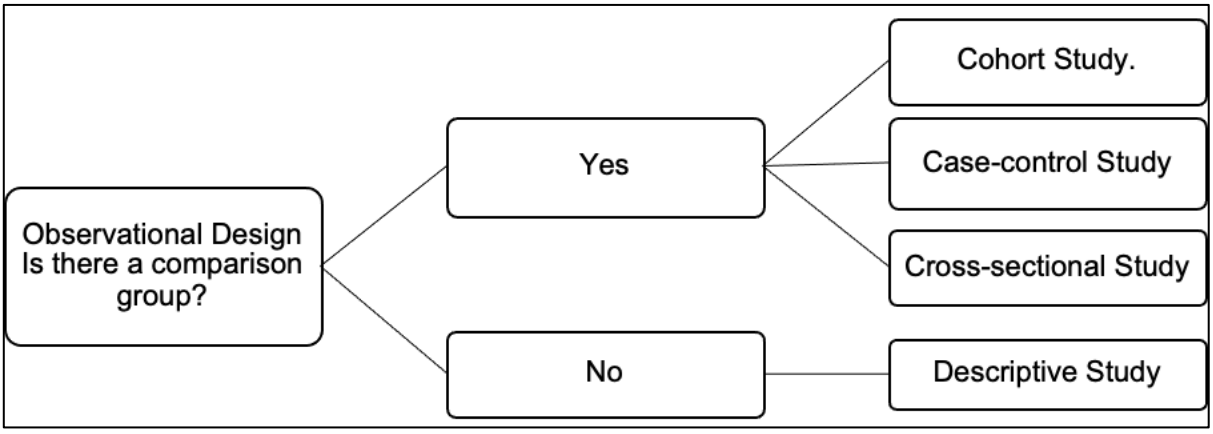

Figure 12: Observational study design classification

3.9.1 Observational research design

The following discussion will focus upon cohort, case-control and cross-sectional study design. *Cohort studies* are considered by some as the observational method of choice (236). Cohort studies follow a defined group (cohort) over time to assess outcomes of interest, with groups defined by exposure (237). Cohorts can either be two groups (exposed and unexposed) who are at risk of developing the outcome, (170) or a cohort of those who all have the disease of interest, an inception cohort (238). Participants are tracked forward in time from exposure to outcome (239). For example, a recent prospective cohort study investigated the possible association between cerebrovascular autoregulation and delirium following cardiac surgery. The patients were tracked from ICU admission (post-operative day 0) until post-operative day 1 (210). Cohort studies are seen as the best way to simultaneously gather data about incidence and the natural history of a disorder, (239) providing a temporal relationship between exposure and outcome (240). Cohort studies, if planned correctly, can investigate multiple outcomes, for example, the effect of smoking upon heart disease, cancer and lung disease. Longitudinal cohort studies, although resource intensive and expensive, can provide valuable data, adding to knowledge of diseases that take many years to develop such as the Framingham Heart Study (239).

Case-control studies investigate potential links between past exposure and present phenomena, (170) and in contrast to cohort studies groups are defined by outcome (241). Comparisons are made between participants with the disease or condition of interest (cases), compared to those without (controls) (210). Investigators start with an outcome for instance cancer and look back over time for an exposure that may have caused the outcome (238). The outcome of interest is compared between cases and controls, for example, lung cancer rates among smokers and non-smokers (170). A variety of methods of data collection are used including participant interviews, medical record and chart review (182). Controls should represent the population from which the cases are derived (170). Case-control studies are considered efficient in terms of time and effort, and are financially cost-effective (182). Diseases such as cancer, which have a long time-lag, are well suited to case-control study design (242).

Cross-sectional studies summarise attitudes, behaviour or conditions (238). The study design aims to select a representative population sample by taking a cross-section of the population (238). Cross-sectional studies provide an estimate of the prevalence of a condition over a particular period in time (230). Data is collected once but recruitment may take place over a longer time frame, (230) with the

data providing a snapshot of a behaviour or the prevalence of a condition. For example, a multi-centre study investigating the frequency of an intervention may be conducted once at each site but on different dates. Data about outcomes and exposure are collected at the same time, and consequently, temporal relationships may remain unclear. For example, does obesity cause arthritis, or does immobility resulting from arthritis lead to obesity? (243). Cross-sectional studies frequently use surveys and questionnaires for data collection (230). Cross-sectional design is practical in terms of cost and sample size, (170) and although random sampling is not always an option, a small population of interest, such as an ICU population, can be sampled in its entirety.

3.9.2 Sources of error in observational research design

Bias in observational research design broadly sits within three categories: confounding, selection bias (response and non-respondent bias), information bias (observation, detection, recall, classification or measurement bias) (232).

Confounding variables can be a greater risk in observational studies due to the lack of randomisation (244). Confounding arises when the exposure of interest is associated with another (unforeseen) exposure that impacts upon the outcome, (242,245) leading to an incorrect assessment of possible causal associations (236). Confounders are associated with both the exposure and outcome, but is not a causal link (236). Successfully managing confounding requires correctly identifying and measuring the confounder accurately (245).

Selection bias differs between studies. In cohort studies selection bias occurs from differences between the exposed and unexposed groups in some important aspect other than exposure, (232) while in case-control studies selection bias comes from inappropriate choice of controls, (245–247) particularly when random sampling is not used (246). Cross-sectional design using convenience sampling is at particular risk of selection bias, reducing generalisability of results (170). Unlike cross-sectional studies, cohort and case-control studies are both at risk of attrition bias (a type of selection bias), (170) that results in systematic differences between groups as a result of dropouts and loss to follow-up. Selection bias in cohort studies can be influenced by the healthy entrant effect, that is excluding those with the condition of interest at the start of the study (175). Response bias (a form of selection bias) can result from recruiting participants from inappropriate settings, for example, recruitment from special clinics may fail to achieve a representative sample population, (248) or from systematic differences in participants' response to questions (249). Non-response bias, another type of selection bias, stems from differences between those who accept an invitation to participate in a study, compared to those that decline (250). Non-response and response is a particular issue for cross-sectional studies (250). The evidence is that responders and non-responders differ demographically and socio-economically, (251) leading to unrepresentative population samples. Missing data exacerbates non-response bias, (250) with surveys and questionnaires at particular risk (170). Response rates are known to range from 50% to 80%, (242) with differences between responders and non-responders not easily accounted for (250).

Information bias results from missing data, incomplete datasets, differences in outcome measurement or surveillance differences between groups (239). Detection bias (a type of information bias), (231) also known as ascertainment bias, comes from the systematic distortion of outcome assessment measures, can be unconscious, and can come from researchers (observer bias), or participants (response bias)

(244). Observer bias occurs when outcome information is gathered in different ways, for example in case-control studies, collection of outcome data at the bedside for cases and by telephone for controls (230,242). Surveillance bias results from systematic differences between groups in clinical management or additional investigations requested. For example, in cohort studies high-risk participants may receive additional investigations, incidentally identifying other medical conditions (245,250). Subjective outcome measures, such as wound healing, are at particular risk of observer bias (246). Response bias occurs when participants provide inaccurate or untrue responses and may be exacerbated when investigating potentially sensitive topics such as drug or alcohol use (242,246). Additional sources of information bias include recall and interviewer bias. Recall bias is a particular issue for case-control studies and stems from differences in recall between cases and controls, cases may have a vivid recollection compared to controls due to the outcome being a significant life event (248). Recall bias can lead to inaccuracy increasing background 'noise', which may lead to an inaccurate estimation of associations between the exposure and outcome (249). Interviewer bias can occur when those conducting an interview know the study hypothesis, which can consciously or unconsciously affect data collection (242,245).

3.10 Managing bias in observational research

Validity and generalisability of findings depend upon recruiting a sample that is a representative population and is the biggest challenge for observational research (234).

Confounding is a particular challenge for observational research design, however, limited control can be applied through appropriate research design and *a priori* planning (237). Strategies include the use of exclusion criteria, pairwise matching, stratification and statistical tools (242). Exclusion criteria can effectively prevent recruitment of participants with confounding risk factors, for example excluding smokers if smoking is a suspected confounder. In case-controlled design, if smoking is a suspected confounding variable pairwise matching can be used, matching each case who smokes with a control who smokes. Disadvantages include that pairwise matching can result in cumbersome recruitment and that investigators are no longer able to examine the effect of the matched variable (246). Stratification and statistical analysis are post hoc strategies used to manage confounding (246). Post hoc stratification by smoking allows results to be calculated for smokers and non-smokers to estimate whether effects remain the same. Multivariate analysis can measure the effect of one variable, while controlling multiple others, for example measuring the effect of smoking while controlling for age, gender, and race. Multivariate analysis can add complexity to the interpretation of results (170,246).

Selection bias can in part be managed through study design and planning. Definition and diagnosis of 'cases' is the biggest challenge in case-control design (210,242). Achieving cases and controls that are comparable in all but exposure is fraught with difficulty (245). An agreed definition about when an individual becomes a 'case' is necessary as misclassification can lead to an overestimation of effect (210). Matching in case-control studies ensures that differences between cases and controls cannot be due to differences in the matching variables (170). Groups can be matched for age, gender, or occupation, reducing systematic differences, (210) with either 1:1 matching or matching more than one control per case (252). However, variables used for matching can no longer be investigated as possible risk factors for the outcome under investigation (170).

In a cross-sectional design maximising response rates reduces selection bias, strategies include covering letters explaining the study, the inclusion of stamped addressed envelopes in a postal survey, follow up email or text, using well-designed, concise questionnaires with clear instructions, or use of online survey tools (252). Several strategies are used to manage selection bias in prevalence studies and these include describing eligibility criteria of the target population, using appropriate sampling strategies and adequate sample size (170,252,253). Clearly defining the target population, study setting, participants, variables measured, and statistical methods used provide a clear explanation of the rationale behind the decisions made helping readers interpret the applicability of results (210,233).

Information bias in cohort and case-control studies is managed by ensuring that outcomes are obtained the same way for both groups, for example, collecting outcome data in a hospital clinic may elicit different responses to those collected in a community clinic (242,254). There is evidence that 'objective' markers, such as CXR, remain susceptible to different interpretations (242). Although blinding outcome assessors may reduce bias, in reality, there may be very little that can be done to manage information bias in case-control studies and this risk should be identified as a limitation (246). Response bias in cross-sectional studies can be minimised through efforts to maximise response rates as previously described. Use of validated questionnaires, that is instruments that have been assessed for reliability (consistency and reproducibility, freedom from random error) and validity (the instrument measures what it purports to measure) (244) can reduce information bias. As all retrospective studies are susceptible to recall bias, prospective study design helps mitigate against recall bias. (255). How missing data is managed can reduce information bias, strategies include reporting the number of, and reasons for missing values, how many participants were subsequently excluded, and appropriate statistical analysis including multiple imputation (135).

3.11 Qualitative research design

Qualitative methods are considered to originate from anthropology, sociology and psychology, (246) gaining momentum in the 1970s, as a move away from the domination of the positivist 'norm' (246). Put simply, qualitative research uses non-numerical data (interviews, audio-visual, observations and documents), (141,256) however, many consider this an oversimplification (257). Qualitative research refers to both the broad framework (paradigm) and the research method used to conduct the research study (256). Qualitative research has numerous different theoretical lenses, including feminism, Marxism, postmodernism, and social construction (256). Phenomenology, ethnography, grounded theory, narrative enquiry and case study methods remain popular and widely used in health sciences (141). While some consider that the various qualitative research methodologies are not amenable to 'shoehorning' into one paradigm, (258,259) others suggest that by using the paradigm definition described by Kuhn, that a research community has shared beliefs, values and assumptions, (256) the qualitative paradigm provides the overarching framework for the conduct and design the research study (256). Qualitative research methods help researchers explore "*the beliefs, values, and motives that explain why behaviours occur…to gain a better understanding of phenomenon through the experiences of those who have directly experienced the phenomenon."* (pg. 1877) (259)

Unlike the positivist paradigm, qualitative researchers acknowledge subjectivity within research; both the participants and researcher have their own history, values, politics and assumptions, (256) with the

researcher acknowledged as being part of the research rather than being invisible as in positivist/post-positivist research (141,256). Qualitative research, referred to by some as constructivist research, (148,256) generates meaning from the data collected, providing insight into participants experience, giving a voice for those who are otherwise marginalised, under-represented, or unheard, (260) such as minority groups or those who are socially disadvantaged, providing powerful and rich descriptions, including of the lived experience (261). Unlike quantitative research, there is no manipulation of variables or investigation of causal relationships. Qualitative research strives for rigour, trustworthiness, and credibility, rather than validity, reliability or generalisability (256). However, the imperative remains that qualitative research is conducted in a way that provides meaningful results, (262) using systematic observations and trustworthy interpretation (263). Data collection tools include structured, semi-structured or unstructured interviews and focus groups, embedded observation, diaries or videos, (264) and uses small sample sizes, frequently between 15 to 30 participants (261). Qualitative research values personal involvement can generate theory from the data (inductive rather than deductive) and can accommodate a shift in focus during the study (256).

Approaches include: (256)

- Grounded theory which seeks to describe and understand psychological processes that occur in social settings. Researchers aim to generate explanations of phenomena grounded in reality, building theories from the data.
- Ethnographic study which was developed from anthropology and investigates cultural patterns and experiences. Ethnographic research requires extensive fieldwork.
- Phenomenology which is concerned with the lived experience of human participants. The focus is upon how people make sense of their experience.
- Discourse analysis which identifies themes in the language connected to social reality.
- Thematic analysis which identifies themes and patterns of meaning across a dataset.

Qualitative methodology ranges from qualitative description, (258,265) as used in this thesis, through to interpreting participants experience, "*telling it like it is*", (pg. 21) (256) valuing and validating views, perspectives and experiences (141). Qualitative description is considered to use 'low inference' interpretation being less interpretative than other methods, however, all qualitative research requires interpretation as "*descriptions always depend on the perceptions, inclinations, sensitivities, and sensibilities of the describer.* (pg. 335) (265). Sandelowski argues that low-inference descriptions provide clearer descriptions of the situation being investigated, and as a result can lead to greater consensus among researchers about the conclusions of the study (265). Sandelowski argues that "*in the vast qualitative methods literature, there is no comprehensive description of qualitative description as a distinctive method…although it is one of the most frequently employed methodological approaches*" (pg. 335) (265).

Qualitative description methodology uses a variety of methods including, thematic analysis, descriptive phenomenology and content analysis (266). Thematic analysis (TA) was the method chosen for this thesis as it is considered a powerful method when seeking to understand participants experiences (267).

TA differs from other qualitative methodologies as it provides a method (tool or technique) for data analysis but does not prescribe data collection methods, theoretical positions, ontological or epistemological frameworks (256,267). TA is recommended as an introductory qualitative method, (147,256) advantages include flexibility of the research question, sample size and data collection (256,267). The flexibility of TA allows the research question to be expanded depending upon the themes identified (268). The flexibility is considered a potential weakness by some due to the potential for inconsistency, while others consider it a strength providing additional data and allowing participants the opportunity to expand upon their experience (256). Some argue that thematic analysis can bridge the gap between post-positive and constructivist paradigms, (267) and is considered by some to be a useful approach when doing "*applied"* research, allowing researchers to present findings in a way that is accessible to those outside of academia (269).

3.11.1 Rigour, trustworthiness and credibility in qualitative research

Quality within qualitative research remains vigorously debated, (256) with disagreement about how quality is measured (256). The consensus appears to be that quality can and should be assessed (257,270). As with observational and experimental research, checklists have been developed to aid critical appraisal (256,257). Studies are judged on clarity and relevance of the research question, appropriateness of methodological choices, recruitment strategy, data analysis, and clarity of findings (270,271).

Rigour is concerned with the thoroughness and appropriate choice of research method (272) and includes theoretical, procedural and interpretative rigour, all of which increase the quality of the research. Theoretical rigour relates to the choice of methods as applied to the research question, procedural or methodological rigour provides transparency about the research conduct, and interpretive rigour gives the reader information about data analysis, how many researchers were involved in data interpretation, and how consensus was reached (261,271).

Trustworthiness is considered a strength of qualitative research, (263) and is "*one way researchers can persuade themselves and readers that their findings are worthy of attention*" (p3) (264). The trustworthiness criteria chosen is considered by some to be a pragmatic choice based upon the usefulness of the research for various funders or stakeholders (264). Trustworthiness is considered to have four categories: *credibility* (corresponding to postpositivist internal validity), *dependability* (corresponding to reliability), *transferability* (a form of external validity or generalisability) and *confirmability* (257,264). Credibility relates to meaningful and clearly presented findings, (141) and allows researchers to check the reliability and consistency of findings including participant verification (257). Dependability attempts to increase the reliability of the research findings, (257,264) while transferability is concerned with the generalisability of findings and how well the findings can be applied to healthcare settings that differ from those where the study was conducted (264,273). Although there is disagreement between researchers about the relevance of transferability of qualitative research findings, (257,264) researchers have a responsibility to report findings in a way that helps readers and decision makers make informed decisions about the relevance of study findings to other populations, and is discussed below. Confirmability is concerned with accuracy and clarity of the researchers' interpretation and findings derived from the data (264).

3.12 Managing trustworthiness and quality

Validity and trustworthiness are intertwined and include an assessment of how much meaning the results convey to those reading the study findings (274). Managing validity and trustworthiness requires the use of appropriate research methods including data analysis and interpretation, member checking, triangulation, and reflexivity (263). Trustworthiness is achieved in part by checking the accuracy of findings from the position of the researcher and participants.

Triangulation refers to "*a process whereby two or more methods of data collection or sources of data are used to examine the same phenomenon…getting as close to the 'truth' of the object as possible*" (pg. 285) (256). Triangulation corroborates findings, (257) reducing potential bias created by the use of a single method, researcher or theory (256).

Triangulation can be achieved using: (261)

- Multiple data sources, for example, documents, and surveys.
- Multiple research methods, for example, interviews and focus groups.
- Using a team of researchers.

Investigator triangulation is when two or more researchers code, analyse and interpret the data, (147) building themes, adding validity to the study findings (256).

Member checking is the practice of checking findings or outcomes with study participants, (261) and is considered a measure of credibility, reassuring the researcher that participants are accurately represented (263). However, some argue that this absolves the researcher from interpreting the data, (256) adding complexity to data analysis as additional data requires further interpretation (256). While seen by some as reassuring, (147,275) those who consider that reality has 'multiple' aspects argue that researcher and participants interpretation will differ negating the need for member checking (141,263).

Credibility is achieved through transparency when writing up the study findings as studies are considered credible when others recognise the experience (141). Providing a rich description of the research setting can give readers the sense of a shared experience, (141) with the findings conveying greater realism and meaning (147,264). Other methods to increase credibility include the inclusion of negative findings as individuals views seldom align completely; (141) prolonged field time as used in ethnographic research, letting the community become accustomed to the presence of the researcher allowing the researcher to develop a detailed understanding of the phenomena being investigated; (141) and peer review and debriefing (147) with peer review questions clarifying interpretation and understanding, helping to ensure the research resonates with others(141).

Dependability relates to clarity of the research process and is judged through clear description and availability of audit trails, allowing others to examine the research process (141). Common methods include checking transcripts and documentation, ensuring coding is clear and consistent, the research team has a clear meaning for the coding and utilisation of cross-checking (141).

Transferability is achieved and managed through an in-depth description of the research context, participants, setting, and circumstances, allowing others to conclude whether the findings can be considered transferable to others (141,275).

Audit trails are considered a quality measure providing transparency about the conduct of the research, increasing confirmability, validity and trustworthiness, (256,257,275) audit tools include a study protocol, clear documentation of procedures, checking transcripts for errors and ensuring that coding is consistent throughout the duration of the study.(141).

Reflexivity is the acknowledgement of how the researcher's previous experience has influenced the current research question and methodological choices, acknowledging any background influences upon data interpretation and study findings (141). Reflexivity acknowledges that the role of the researcher is two-fold, both an investigator and an instrument for analysis (141). It is recommended that the researcher applies critical reflection in two ways; how the chosen research tools and processes influenced the research (functional reflexivity) and making the researcher visible within the research process (personal reflexivity) (141). The use of a diary or journal is recommended as a way of developing reflexivity (264). Reflexivity is considered an essential part of qualitative research (256).

3.13 Methodological approached used in this thesis

This thesis includes a pragmatic RCT (Chapter 9) and a qualitative study that investigated the patient experience of both the endotracheal tube and suction (Chapter 7). Both studies were conducted in a busy cardiothoracic surgical unit and were underpinned by a systematic review and two observational studies. Research that is undertaken in an acute clinical setting, relevant to the 'real world' clinical setting where the findings will be applied has seen an increase in pragmatic RCTs that aim to "*provide information on the relative merits of real-world clinical alternatives to routine care."* (pg. 1) (194). As mentioned earlier, researchers paradigms are influenced by personal experience, (141) as a nurse working in an acute clinical setting I consider myself a pragmatic researcher. I recognise the importance and value of both quantitative and qualitative research methods when answering clinical questions and informing staff about the patient experience, with both paradigms providing data that can inform clinical practice. Pragmatism is less concerned with which method is used, rather that the correct method is used to address the research question, (141) and I consider that this has been reflected in the methods chosen in this thesis (Figure 13).

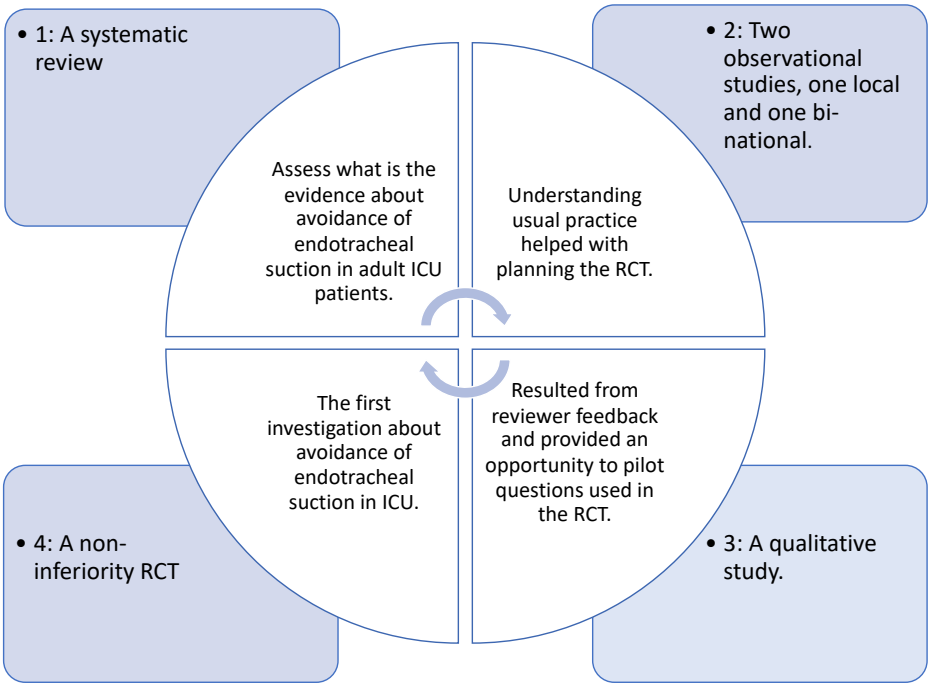

Figure 13: Methods used in this thesis

Before conducting a randomised controlled trial, it was necessary to evaluate what was already known about avoidance of ETS. This provided information about the relevance and need for the proposed RCT and is described in Chapter 4.

Awareness and understanding of current suction practice helped to inform the RCT design. The RCT planned to avoid suction, including at extubation, therefore understanding the triggers nurses used to provide suction, and whether nurses provided suction at extubation would help with the study design. Suction at extubation is common practice in the United Kingdom, (276) yet there was no local data describing how frequently nurses provided suction, and whether suction was indeed performed at extubation. The CVICU observational study addressed this question, and provided the first data about suction practice in CVICU and is described in Chapter 5. The second observational study (Chapter 6) provided the first data about current endotracheal suction practice across New Zealand and Australia, including data about the frequency of ETS, ETS at extubation and adherence to clinical guidelines. Both studies helped to inform the RCT design.

Part of the RCT included investigating the patient experience of both the ETT and ETS. Following reviewers comments, a qualitative study was included to explore the patient experience in more depth. This acted as a vanguard study to test the post-extubation questions planned as part of the RCT and is described in Chapter 7.

Finally, the pragmatic design of the RCT allowed the study to be successfully conducted in a busy cardiac ICU. The protocol and RCT are described in Chapters 8 and 9.

3.14 Summary

When considering the quantitative/qualitative research continuum (figure 7), this research sits within the post-positivist paradigm, and, although quantitative dominant, recognises that qualitative methods contribute to knowledge and understanding, adding context to the investigation (277). Recent years have

seen an acceptance of the value and place of both quantitative and qualitative research, (151) with a recognition that paradigms perhaps have more in common than some would care to admit (148). Historically, nursing has strived for the acquisition of knowledge, developing a professional education with a knowledge base able to respond to society's needs and increasing the scope of nursing practice (147,256). Nursing has adapted to societal changes, (278) and embraced the use of different methodologies dependent upon the research question, (142,146,148) and is reflected in this thesis.

Chapter 4 : Systematic Review

Preface

This chapter describes the systematic review undertaken before embarking upon the randomised controlled trial. The review explored what is the current available evidence about avoidance of endotracheal suction in short-term (less than 24-hours) mechanical ventilation. The initial search retrieved no human studies and it became clear that there was no agreed definition of “short-term” ventilation, therefore, a pragmatic decision was made following discussion with my academic and clinical supervisors to set the limit at less than three days. It is recognised that this may not be considered short-term by all, however, for the purposes of the review, it provided an opportunity for an inclusive search, with the best chance of retrieving any available evidence. Initially, this review did not plan to include animal studies, however, the initial search retrieved one animal study and no human studies. The decision was taken to broaden the search strategy and include animal studies in an effort to be as thorough as possible.

The inclusion of animal studies in systematic reviews is a recent development considered by some to lack the rigour of systematic reviews that include human studies (279,280). However reporting guidelines have been developed for use when systematic reviews include animal studies, including Animals in Research: Reporting In vivo Experiments guidelines (ARRIVE) (279) and Systematic Review Centre for Laboratory Animal Experimentation (SYRCLE) tool (281). SYRCLE is a risk of bias (RoB) tool designed for use in systematic reviews that include experimental animal studies and developed to align with the Cochrane RoB tool. SYRCLE includes factors specific to animal studies, such as blinding of the animal caregivers and random housing of the animals in the animal room.

See Appendix 1 for supporting documents, including the review protocol, search strategy and excluded studies.

Avoiding endotracheal suction in subjects receiving short-term mechanical ventilation (≤72 hours): A systematic review of human and animal model studies.

Eileen Gilder, Rachael L Parke, Alana Cavadino, Andrew Jull.

Abstract

Background

Mechanical ventilation requires an endotracheal tube. Airway management includes endotracheal suctioning (ETS); a frequent procedure for Intensive Care patients. Associated ETS risks include hypoxia, atelectasis, and infection. Given the ubiquity of ETS, this search focused upon evidence for avoiding endotracheal suction, with particular attention focused on adult patients exposed to short-term mechanical ventilation (< 72 hours).

Objective

To investigate the concept of avoiding ETS in subjects with an artificial airway in situ; evaluate the need for ETS with short-term ventilation.

Methods

A systematic review using Cochrane methods. Data sources were electronic databases including Medline, EMBASE, CINAHL, Cochrane Controlled Trials Register and clinical trial databases. Studies included those dated from 1960 to 2018, there were no language restrictions. Search terms included adults, animals, avoidance of endotracheal suction, mechanical ventilation, intensive care, endotracheal suction, operating theatre, post anaesthetic units, oxygenation, airway complications, hypoxia, and atelectasis.

Inclusion criteria

Randomised or controlled clinical trials of adult human or animal subjects exposed to an ETT with suctioning versus no suctioning.

Results

We screened 134 studies, of which eight trials met the inclusion criteria - two human and six animal model. Heterogeneity of the studies precluded a meta-analysis; a narrative analysis was performed. Two studies concluded tracheal stimulation alone, rather than the application of suction, contributed to oxygen desaturation. One adult study demonstrated the application of suction, in the presence of apnoea, did not worsen oxygenation when compared to apnoea alone, during anaesthesia. There was no evidence that avoidance of suction impeded oxygenation, or exacerbated complications of intubation, including in the presence of acute respiratory distress syndrome.

Conclusions

This review found no evidence to support either suctioning or avoidance of suction during short-term mechanical ventilation. None of the studies were conducted in an intensive care unit and further research is required to investigate the effect of no suction in those patients mechanically ventilated for <72 hours.

Key words: avoidance, endotracheal suction, intensive care, short-term ventilation, oxygenation, mechanical ventilation.

4.1 Introduction

Invasive mechanical ventilation (MV) necessitates the use of an artificial airway, either an endotracheal tube (ETT) or tracheostomy tube. An ETT prevents patients from clearing secretions naturally and interrupts the function of the mucociliary escalator, which may increase both the inflammatory response within the trachea, and the risk of infection (31,59,62,74). Airway management in intensive care units includes endotracheal suction (ETS) to maintain pulmonary hygiene, remove secretions, and prevent a build-up of biofilm on the internal surface of the ETT (282). Previous systematic reviews have reviewed ETS and infection risk, (82,89,283) insertion depth of the suction catheter, (284) open versus closed suction, (82) and the effect of ETS upon oxygenation, (285) none have investigated avoidance of ETS.

Clinical practice guidelines recommend suctioning patients “only when necessary,” following a patient assessment (2–4). The American Association of Respiratory Care guidelines (2) make recommendations about how to assess the need for, suction, these include saw-tooth pattern on the ventilator; the presence of coarse crackles over the trachea; increased peak inspiratory pressures during volume-controlled ventilation; deterioration in oxygenation and suspected aspiration (2). Other guidelines make no mention of tracheal beath sounds (4). None of the currently available guidelines mention avoidance of ETS, and whether it is safe or appropriate to do so. Providing suction ‘when necessary’ using clinical assessment to guide clinical need could potentially lead to avoidance of suction.

This systematic review aimed to investigate the avoidance of ETS. The initial search focused upon adult ICU patients exposed to short-term mechanical ventilation (≤12 hours), however, the search retrieved no human model evidence, and the review was broadened to include the concept of avoidance of ETS in those receiving mechanical ventilation (MV) for ≤72 hours, and included animal model evidence.

4.2 Methods

This review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines, (213,286) the protocol was prospectively registered on PROSPERO (CRD 42018081955). There were no language exclusions, and we included studies from 1960 to 2018. Inclusion criteria were, randomised controlled trials or controlled clinical trials involving adult (≥16 years) humans or animal models that evaluated the avoidance of ETS in subjects with an endotracheal tube in situ and received MV for ≤72 hours. Any ETS strategy was the comparator. Studies or protocols manipulating MV were excluded, as were studies of long-term or home ventilation and paediatric or neonatal studies. Outcome measures included physiological responses to suction such as changes in peripheral capillary saturation (SpO_2), arterial blood gases (ABGs), heart rate, and complications of ventilation including blocked ETT, re-intubation rates, respiratory infection rates, tissue trauma, and barotrauma.

Search strategy

We searched electronic databases in February 2018 and again in July 2018. Databases searched were Ovid MEDLINE 1960-present, Ovid MEDLINE daily, Ovid MEDLINE Epub Ahead of Print, In Process and other non-indexed citations, CINAHL plus (EBSCO) 1960- present, EMBASE classic 1947-1979, EMBASE 1980-present and the Cochrane Central Register of Controlled Trials (CENTRAL) (Supplementary file). We sought grey literature using OpenGrey, DART-Europe E-theses Portal, OAIster, citation databases SCOPUS, and Web of Science. We searched clinical trial registries (ClinicalTrials.gov, WHO ICTRP and the Australian New Zealand Clinical Trials Registry), as well as general search engines Google Scholar (https://scholar.google.com/) and the Turning Research into Practice (TRIP) database (www.tripdatabase.com). Reference lists were searched manually and where necessary authors contacted.

The search strategy used both keywords and MESH terms with seven search concepts. The concepts were adult (≥16 years) and animal, avoidance of ETS, ETS, artificial airway, artificial respiration, intensive care, and outcome complications. MESH terms included but were not limited to, adult, young adult, endotracheal suction, pulmonary hygiene, respiration artificial, airway management, airway obstruction, and pulmonary atelectasis. Keywords included but were not limited to, intensive care, endotracheal suction, tracheobronchial suction, tracheobronchial hygiene, no suction, re-intubation, and adolescent. The search concepts and a full search are included in the supplementary file.

Study selection and risk of bias assessment.

We used the Covidence software platform, (Covidence systematic review software. Available at (www.covidence.org)). Although it is common for two reviewers to conduct the initial screening, Cochrane methods at the time did not mandate two reviewers for this stage of the review (172). One reviewer (EG) screened the titles and abstracts for potential studies that met the pre-defined inclusion criteria, removed duplicates, and the selected studies uploaded onto Covidence. Two reviewers (EG and RLP) independently conducted a full-text review of all selected studies, with any disagreements resolved through discussion and if necessary adjudicated by a third reviewer (AJ).

Included human studies were independently assessed for risk of bias (RoB) as recommended by Cochrane (172). Selection bias was assessed using sequence generation and allocation concealment, performance bias through blinding of study personnel and outcome assessors, attrition bias by assessing incomplete outcome data, detection bias assessing blinding of study personnel and reporting bias assessed by reviewing selective outcome reporting. Systematic reviews that include animal studies are a recent development and have lacked the rigor of systematic reviews of human studies (279,280). Guidelines have been developed to address this issue, including the Systematic Review Centre for Laboratory Animal Experimentation (SYRCLE) tool (281). The SYRCLE tool is aligned with the Cochrane RoB tool, but includes factors specific to animal studies such as blinding of the trial animal caregivers, assessing the random housing of animals within the facility, were animals housed randomly during the experiment? Were animals selected at random for outcome assessments? RoB assessments were made independently by two reviewers (EG and RLP), with a third reviewer available for adjudication if required (AJ).

Data extraction and analysis

Two independent reviewers (EG and RLP) extracted directly into a RoB table using the Covidence platform. Given the heterogeneity of the included studies, a narrative synthesis was conducted. It has been estimated that narrative synthesis is reported in up to 50% of systematic reviews (287) and, as acknowledged by the Cochrane collaborative, these can be prone to bias due to the lack of robust data and statistical analysis to guide conclusions (172). Currently, there is a renewed focus upon the quality of reporting, and reporting guidelines have been developed (288). Guidance from the UK's Economic and Social Research Council (ESRC) (289) defines narrative synthesis as *"an approach to the systematic review and synthesis of findings from multiple studies that relies primarily on the use of words and text to summarise and explain the findings of the synthesis*" (pg.5). As recommended by Popay *et al* (289) this synthesis included an initial description of the included studies, followed by an assessment of any patterns across the included studies, an assessment of methodological robustness of the included studies that in turn underpin the quality and trustworthiness of the studies included in the synthesis. The included studies were judged by two independent reviewers (EG and RLP) to meet the review inclusion criteria and provided the best available evidence at the time of the review.

4.3 Results

One hundred and thirty-four references were imported into Covidence, of which 49 were duplicates. Forty-six of the remaining 85 studies were not relevant; 39 studies were fully screened with 31 excluded (Figure 14). The reasons for exclusion are described in the supplementary file. Eight trials met the inclusion criteria, two human and six animal studies.

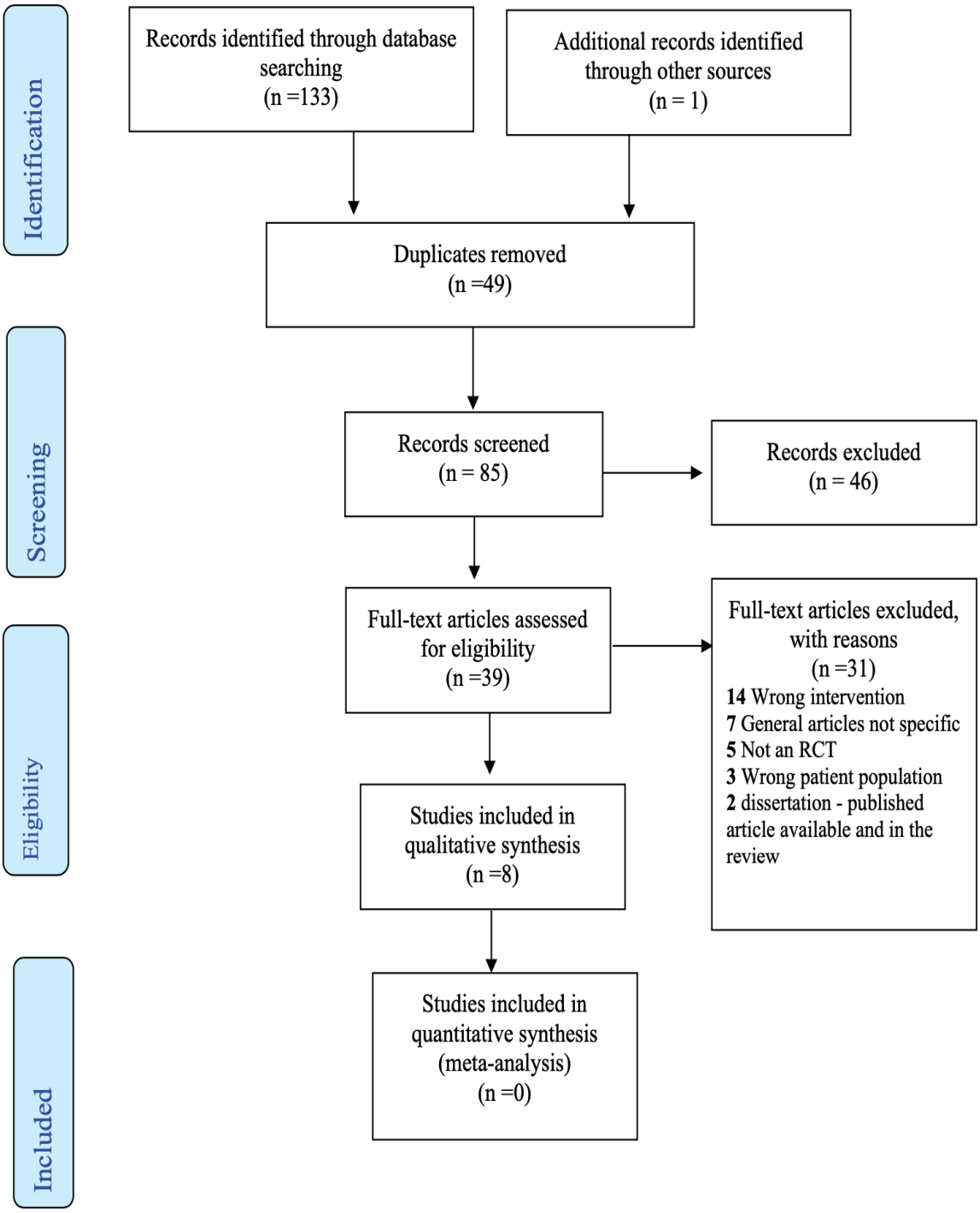

Figure 14: PRISMA flow chart

Overall, apart from one study, (290) all studies were judged at unclear or high risk of bias (RoB) (Figure 15).

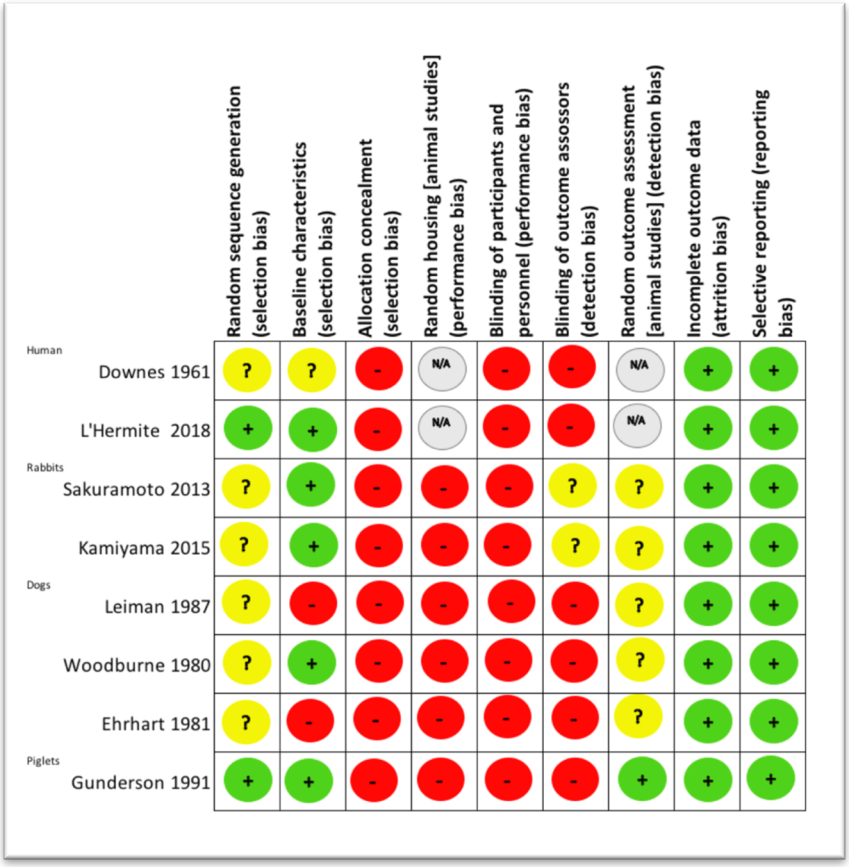

Figure 15: Risk of Bias assessment

Human studies: Using the 2017 Cochrane RoB criteria (172) as described above, we judged the human studies to be at unclear or high selection bias. One study (290) reported random sequence generation, and presented well-described baseline characteristics, whereas the second study was a within-participant trial that stated the sequence varied; allocation concealment was unclear in both. Both studies were judged to be at high risk of performance bias; although participants were blinded to the intervention, the type of intervention prevented the blinding of staff. Detection bias was judged to be high in both studies as neither study reported blinding of outcome assessors. Attrition bias: one study (290) presented a CONSORT diagram with one patient excluded from the final analysis, both studies appear to have no loss to follow up; both were conducted in the operating theatre environment, and all participants completed the protocol. Reporting bias was judged to be low in both studies; all planned outcomes appear to be reported. There is insufficient data to judge other RoB risk in Downes et al (291), although L'Hermite (290) appears to be at low RoB from other potential sources of bias, for example, deviation from the stated protocol.

Animal Studies: Overall, we judged the animal studies to be at unclear or high risk of selection bias. One animal study (113) reported randomisation using "computer-generated SAS software", two studies imply random sequence generation, (292,293) although this is not clearly reported, while three do not report

any type of sequence generation (115,294,295). Four studies reported baseline characteristics (113,292,293,296) with two studies reporting these in detail (292,293). None of the animal studies reported allocation concealment. All the animal studies were judged to be at high risk of performance and detection bias; none reported the housing of the animals within the laboratory or blinding of study personnel. While two studies (292,293) described blinded histology assessors, it is unclear whether the other outcome assessors were blinded. None of the other animal studies reported either blinded assessors or random outcome assessment of the animals. For the purposes of this systematic review, although blinding of histology assessors would provide a low RoB, blinding of the outcome assessors relevant to this review was not described and therefore the studies were judged as unclear RoB. Attrition and reporting bias was judged to be low across all animal studies. The planned outcomes were reported, and there appeared to be no missing data. The study protocols had a short duration; the interventions were performed in the animal laboratory; one study was conducted over several weeks (296) but did not report missing data. None of the studies reported sufficient data to judge other sources of potential bias and were judged as unclear.

4.4 Outcomes

Human studies.

The first study was conducted in the Department of Anaesthesiology, Tacoma General Hospital, Washington (291). The study included eleven adult and adolescent patients, ten of whom had pulmonary tuberculosis, all having either a wedge resection, segmental resection, or lobectomy under general anaesthetic (GA). Baseline characteristics were not reported. The study investigated and evaluated the effectiveness of hyperventilation with oxygen for a prespecified period before one or two minutes of apnoea. The aim was to determine the amount of oxygen desaturation in anaesthetised patients when exposed to apnoea, apnoea with suction, and apnoea with prior hyperinflation. Following anaesthesia induction, oxygenation (SaO_2) was monitored every ten minutes during the experimental period. Every patient had two series of tests performed; the first series was apnoea for one minute, both with and without suction. The second series included three tests; patients received hyperventilation with oxygen for 15 seconds, followed by one- and two-minute periods of apnoea; with an additional one-minute period of apnoea with suction following hyperventilation. Results were discarded if patients spontaneously breathed during the intervention. There was a four-minute rest period between interventions. In this study, endotracheal suction during apnoea did not result in any significant change in SaO_2 compared to apnoea alone (p >0.5), including in the presence of hyperventilation. Mean change and exact saturations were not reported.

The second study was conducted in the University Hospital of Nimes, France (290). This RCT tested whether a positive pressure breath at extubation increased time to oxygen desaturation following extubation. Outcomes included the time between extubation and oxygen desaturation <92%, airway and extubation complications, use of supplemental oxygen, reintubation and time taken for oxygenation (SpO_2) to be maintained >92%. Sixty-eight patients undergoing planned lower limb orthopaedic surgery requiring a GA were enrolled, 33 were allocated to the intervention (positive pressure breath at extubation, without suction) and 35 assigned to suction at extubation. Both groups had standardised anaesthesia and extubation procedures, with awake extubation in the supine position; the positive

pressure group received one or two positive pressure breaths administered via manual ventilation, then ETT cuff deflation and removal. The suction group had a suction catheter inserted into the ETT, ETT cuff deflation, and application of negative pressure during ETT removal (negative pressure and duration of suction were not reported). The authors did not report the usual practice at extubation, i.e. endotracheal suction or a positive pressure breath. Following extubation, oxygenation was monitored using a SpO_2 monitor. Supplemental oxygen was delivered at 3L/min when the SpO_2 dropped below 92%. Baseline characteristics described similar groups. There was no difference in time to desaturation - 214 seconds (SD 168) in the positive pressure group compared to 248 seconds (SD 148) suction group ($p = 0.44$), or in any of the secondary outcomes.

Animal studies

Two studies were conducted at the University of Tsukuba, Japan. The first included 36 male Japanese white rabbits, weighing 2.8 - 3.5 kg (292). This study investigated the long term and repetitive effects of open suction compared to closed suction in rabbits with saline lavage induced ARDS. The hypothesis stated that repeated suction over a longer duration could cause alveolar derecruitment and exacerbate lung injury. Outcome measures included PaO_2/FiO_2 (P/F) ratio, ventilation parameters, and histology markers. Following anaesthesia ARDS was induced using saline lavage, instilling warm saline directly into the ETT (15mL/kg), gently rotating the rabbits ensuring even distribution of the saline, and repeated until the P/F ratio was <100. Rabbits were divided into four groups, healthy controls (no ARDS or suction), ARDS with no suction, ARDS and open suction, ARDS and closed suction. The protocol duration was six hours, using a suction duration of 10 seconds, 140 mmHg negative pressure, and the intervention repeated every 30 minutes. Although the study focused upon repeated open suction and lung injury, one group allocation included avoidance of ETS in rabbits with induced ARDS. The baseline characteristics showed well-matched groups; with the exception of the open suction group, all groups maintained a P/F ratio >400. Open suction resulted in a decline in P/F ratio to <300, PF ratio was reported as “significantly lower” in the open suction group compared to the closed suction group ($p = 0.013$, $p = 0.005$ and $p = 0.000$ at four, five and six hours after induction of ARDS). A direct comparison of findings is not reported for the no suction group. Peak inspiratory pressure increased significantly across all ARDS rabbits compared to control ($p < 0.05$). There was no histological or inflammatory marker evidence of lung injury exacerbation resulting from open suction compared to closed suction over time.

A second study included 30 Japanese white rabbits, gender not reported, weighing 2.5 - 3.5 kg (293). The hypothesis was lung hyperinflation might cause ventilator-induced lung injury. Outcome measures included PaO_2, histology, and inflammatory markers. Following anaesthesia, ARDS was induced using saline lavage, instilling 18mL/kg of warmed saline directly into the ETT followed by gently rotating the rabbits from side to side and vigorous shaking to ensure even distribution of saline, and repeated until the PaO_2 was <100 mmHg. Rabbits were divided into four groups: healthy controls (no ARDS or suction), ARDS with no suction, ARDS with repeated open suction and ARDS with repeated open suction plus hyperinflation. The protocol duration was three hours, suction duration was 15 seconds, and 150 mmHg negative pressure. Baseline characteristics show well-matched groups. PaO_2 was maintained at >400 mmHg in both the control and ARDS (no suction) groups while PaO_2 declined in both the ARDS with open suction and ARDS with open suction and hyperinflation groups; the latter group reporting the most significant decline in PaO_2 (mean 226 $\pm$28.9 (SD) mmHg and mean 97.0 $\pm$ 30.7 (SD) mmHg respectively).

In this study, somewhat surprisingly, PaO_2 was significantly reduced in both ARDS open suction and open suction plus hyperinflation groups when compared to ARDS with no suction. Lung injury scores and inflammatory markers were increased in all the ARDS groups.

Three studies of dogs were conducted in the United States of America (294–296). The first study (294) enrolled five dogs, gender not reported, weighing 18-23 kg, with a total of 20 experiments conducted - four on each dog. The study investigated the efficacy of removing artificially produced tracheal secretions (Mucin 5ml) using a balloon catheter compared to endotracheal suction. Outcome measures included the volume of secretions retrieved, changes in PaO_2 and $PaCO_2$, alterations in heart rate, blood pressure, and pulmonary artery pressure. The dogs were anaesthetised and cannulated for monitoring and blood sampling; heart rate was monitored using an electrocardiogram (ECG). Mucin was injected directly into the ETT, followed by 30 seconds of positive pressure ventilation, either open suction or a balloon catheter was used for secretion removal, both requiring disconnection from the ventilator. Each dog received three interventions, secretion removal using a size 6 French (Fr) balloon catheter (performed twice in each animal) and endotracheal suction using a 12- or 18- Fr suction catheter (completed once in each animal). All interventions were 15 seconds in duration; suction used 250 mmHg negative pressure. There was a 15-minute rest period between interventions, and the ETT was cleaned. Baseline characteristics were not reported; there were no cardiac arrhythmias or significant changes in cardiovascular outcomes. PaO_2 was significantly lower in both suction groups compared to the balloon group (520 $\pm$ 33 mmHg (12 Fr), 451 $\pm$ 31 mmHg (18 Fr) and 564 $\pm$ 10 mmHg respectively) $p<0.05$.

The second study enrolled three female dogs, weight not reported (296). The study investigated the nature, duration, and potential mechanisms for falls in oxygenation following ETS and the response to different protocol challenges designed to reduce desaturation. The experiments were conducted at weekly intervals with each dog subjected to five tests. Dogs were intubated and cannulated to allow blood sampling. There were eight protocols tested, all suction catheters were 14 Fr, and 170mmHg negative pressure applied during suction. The investigators tested 10, 15, and 30 seconds duration of suction. Protocols I-III and IV–VIII tested various suction/no suction (catheter insertion only) protocols. PaO_2 was recorded at baseline (before intervention), immediately following intervention and 30, 60, 90, 180, and 300 seconds and seven, 10, 15, and 30 minutes post-intervention. Catheter insertion alone and catheter insertion with suction resulted in similar falls in PaO_2, only reaching significance in favour of catheter insertion alone 30 minutes after the intervention (71$\pm$ 3.8mmHg and 83$\pm$ 2.3mmHg respectively) $p<0.01$. This finding suggests that catheter insertion alone is a factor in PaO_2 reduction and that suction did not appear to exacerbate hypoxia. The reasons remain unclear, including how much, if any, effect the type of anaesthesia had upon the outcome. The study lacked a control group that received neither suction or catheter insertion, therefore it is unclear what effect avoidance of both ETS and suction catheter insertion would have on PaO_2.

The third dog study enrolled 12 dogs, weight, and gender not reported, (295) and assessed the effect of suction during apnoea versus apnoea alone in the presence of ARDS upon oxygenation and cardiovascular parameters. The study did not attempt to mimic apnoea related to ETS. The dogs were intubated and mechanically ventilated, and cannulated for monitoring, blood sampling, and drug administration; heart rate was monitored using an ECG. Haemorrhagic pulmonary oedema was induced in all dogs by infusing Oleic Acid (0.18ml/kg), the fraction of inspired oxygen (FiO_2) and ventilation were

titrated to maintain O_2 and CO_2 levels at 50-60 and 40-45 torr respectively. Mode of ventilation was dependent upon the FiO_2 requirement, dogs requiring FiO_2 >50% were allocated to continuous positive pressure ventilation (CPPV) (n=5) while the remaining dogs had intermittent positive pressure ventilation (IPPV). The interventions were commenced two hours after Oleic Acid administration; duration of suction or apnoea was 45 seconds, suction used 100mmHg negative pressure. Data were recorded at baseline, every 15 seconds during the intervention and 30 seconds following the intervention. Both suction and apnoea resulted in a significant difference in heart rate, blood pressure, and pulmonary artery pressure over time when compared to baseline, (*p* values not reported); no cardiac arrhythmias were reported. Overall there was no significant difference in oxygenation reported between the suction and apnoea groups in either IPPV or CPPV ventilation modes (PaO_2 46±2 torr (IPPV suction) and 45±1 torr (IPPV apnoea), PaO_2 49±6 torr (CPPV suction) and 50±7 torr (CPPV apnoea)), *p* values were not reported. Although the results reported no statistical difference between suction during apnoea and apnoea alone, the duration of ETS (45 seconds) was considerably longer than current recommendations (2). The findings provide some limited data to support the concept of avoidance of ETS, but cannot be extrapolated to the human population.

One study enrolled 11 newborn piglets, (113) seven female, and four males; mean weight 1247± 255g, mean length 36.0± 3.11cm, mean heart rate 130± 10 beats per minute and mean respiratory rate 32 ±10 breath per minute. The study investigated the bradycardic response to suction, hypothesising that bradycardia was due to vagally-mediated mechanical and/or neural stimulation. The protocol compared active suctioning to suction catheter insertion alone; administration of atropine followed the initial suction/no suction protocols. Once in the laboratory, all piglets were transferred to an incubator, warmed to 35.5^{o} C and baseline observations of resting heart rate, respiratory rate, and core temperature (rectal) recorded. Mechanical ventilation was adjusted to maintain oxygenation as close to normal as possible (PaO_2 >60 torr, $PaCO_2$ <50 torr and pH 7.35-7.45). Cannulation of the right carotid artery allowed fluid and medication administration and blood sampling access; maintenance fluid was administered every 30 minutes for the duration of the protocol. A stabilisation period of 15 minutes followed intubation and cannulation; suction duration was 10-seconds, using 80 mmHg negative pressure. The suction catheter insertion was via a side port, avoiding total disconnection from the ventilator; one full ventilator breath was delivered between interventions and a six-second recovery period. The no suction protocol (catheter insertion only) was the same without the application of negative pressure. A rest period of 10-15 minutes was provided between the suction/no suction intervention. The vagus nerve was checked for integrity by administering phenylephrine hydrochloride, and the protocol repeated. There was no significant difference in the pattern of decline in PaO_2 over time in either group (*p*=0.13). The suction group had a significant decrease from baseline at the 20 second time point, in both the pre and post atropine protocols, this had resolved by 60 seconds. Heart rate declined significantly in both the suction/no suction protocols prior to administration of atropine (110 bpm to 98 bpm in the suction group and 114 bpm to 108 bpm in the no suction group) *p* values not reported, administration of atropine obliterated the heart rate response. These results suggest that insertion of the suction catheter alone may have a negative effect upon both heart rate and oxygenation, potentially through stimulation of the vagus nerve and reduction of airflow due to the presence of the suction catheter. These results do not directly address the question of avoidance of ETS as the protocol included the introduction of the suction catheter without

the application of suction. As the results were similar for both suction and suction catheter insertion, the question remains about what the effect of avoidance of suction is.

The results of these studies provide conflicting data about the effect of suction upon oxygenation; some showed no effect of suction upon oxygenation, (113,290,291,295) others reported better oxygenation when suction was avoided (292–294). No studies reported blocked ETT or complications of ventilation. Tables 5 and 6 summarise the included studies and study results.

4.5 Discussion

Overall, the search failed to retrieve clinically relevant data about avoidance of ETS. None of the included studies were designed to directly compare active avoidance of suction to suction in the adult ICU population, and results were extrapolated from studies that included a group where suction was avoided.

The two human studies (290,291) showed neither benefit or harm to the patient when suction was compared to either a positive pressure breath or apnoea. Neither human study was designed as a direct comparison assessing avoidance of ETS.

In half the animal studies avoidance of ETS improved oxygenation, (292–294) including in the presence of ARDS, (292,293) Why avoidance of ETS resulted in higher PaO_2 remains unclear, but may reflect the effects of repeated inflation and deflation of the lungs and subsequent tissue trauma. Repeated inflation and deflation of the lungs has been reported to exacerbate shear stress injury, potentially contributing to barotrauma, hypoxia and ventilator-induced lung injury (292,297,298). Sakuramoto et al.(292) reported no difference in inflammatory markers as a result of repeated open suction, while Kamiyama et al. (293) reported a rise in inflammatory markers in the suction and hyperinflation group. Although low lung volume and low pressure ventilation strategies are used to minimise the risk of ventilator-induced lung injury and improve oxygenation, (55,297) this may be less relevant in an uncomplicated post-operative cardiac surgical population where post-operative management aims to minimise the duration of mechanical ventilation to less than six hours (12). When low volume ventilation was tested in a post-operative cardiac surgical cohort there was no reported clinical benefit, as judged by pulmonary inflammation markers (299). Although one study found that secretion removal using a balloon catheter resulted in better oxygenation when compared to secretion removal using suction, the investigators used 250mmHg negative pressure, higher than the current recommendation of 80-150mmHg (2). As balloon catheter secretion removal has not translated into usual suction practice in ICU, and the suction pressure used in the study was >150 mmHg, the relevance of this study remains questionable in the context of avoiding suction. One study reported that, although oxygenation declined with both suction and apnoea, overall there were no differences between groups in the presence of ARDS (295). Although the study protocol used 45 seconds of ETS or apnoea, compared to the current recommendation of 10 to 15 seconds, (2) potential reasons for the lack of difference between groups could be the use of a small size suction catheter, maximising free flow of air into the lungs via the ETT, and that 100mmHg negative suction pressure was used. The findings differ from the previous studies that compared suction strategies with no suction, with no break in the ventilator circuit, (292,293) suggesting disconnecting the ventilator circuit may have a greater effect upon oxygenation than suction. Other studies have reported that suction catheter insertion, with and without the application of negative pressure, resulted in similar falls in oxygenation (113,296). Both studies concluded that stimulation of the trachea with the suction catheter

was the potential cause. Neither study had a control group that avoided insertion of the suction catheter and none of the included studies reported complications of ventilation.

It is not possible to extrapolate these results into clinical practice for the following reasons; the results retrieved heterogeneous studies preventing a meta-analysis; generalisability of animal studies to humans has been called into question; (300,301) and the included studies had a maximum duration of six hours MV.

4.6 Limitations

This review has the following limitations. We extended the inclusion criteria to animal studies as a consequence of no human studies being found in our early searches; while this approach added complexity and is uncommon, (302) the entirety of the evidence base is summarised. None of the studies used a sufficient duration of MV to identify significant ventilation complications. All included studies were conducted in the operating theatre or laboratory environment and their duration was insufficient to identify significant ventilation complications. These features reveal the absence of evidence supporting a clinical practice common to intensive care units.

4.7 Conclusions

These results signal that avoidance of endotracheal suction may not be detrimental for those exposed to short-term MV, however, the findings are very limited given that none of the studies were designed to directly compare suction to no suction, and that six of the included studies are animal models studies. None of the available data could be extrapolated to the human population to reliably inform decisions about avoidance of ETS in the adult ICU population. There is a need for high-quality evidence to guide clinical practice about avoidance of ETS in those having short-term mechanical ventilation.

4.8 Chapter summary

The generalisability of animal research findings to human subjects is currently under scrutiny due to the inadequate translation of results from animal studies to the human population (300–302). These results confirm the complexity of combining animal and human studies, the challenges of extrapolating results from animals to humans, and confirms the role of animal studies being exploratory and hypothesis generating in nature (302). Although submitted to several journals, the review has not been accepted for publication. That none of the studies were designed to directly compare suction with avoidance of suction, and that these results have been extrapolated from the study design may have contributed to reviewers decision. However, review feedback included that the inclusion of animal studies meant that the review did not fall within journals remit. This systematic review verified the dearth of evidence about avoidance of ETS in patients exposed to short-term ventilation confirming the need for the randomised controlled trial.

Table 5: Included studies

Human Studies					
Reference	**Aim & Intervention**	**Participants**	**Outcomes measured**	**Quality**	**Results**
Downes. (1961) USA	Determine the amount of arterial oxygen desaturation of anesthetised patients subjected three interventions. Duration ETS was 20 seconds, with a negative flow of 13L/min.	11 subjects, adolescent and adult. 10 had TB, all undergoing pulmonary wedge resection. Setting: Operating theatre	SpO_2 (reported as SaO_2).	Sequence generation – "sequence varied" but no other description Selection bias – groups not reported in detail. Performance bias – study procedures well reported. Detection bias – participant's blinded but unable to blind staff. Attrition bias – no missing data. Outcome reporting – all data collected was reported. Blinding of outcome assessors not reported. Overall – high risk of bias.	There was no significant difference in PaO_2 between apnea alone and ETS during apnea. There was a significant difference between hyperventilation and non-hyperventilation.
L'Hermite (2018) France	Investigate the effect of two different extubation strategies.	69 adult patients having elective orthopaedic surgery. Both groups maintained on room air post-extubation until desaturation (S_{pO2} < 92%) Setting: PACU	Primary outcome was the onset time of desaturation (SpO_2 < 92%) after extubation.	Sequence generation – RCT, computer generated, allocation concealment not reported. Selection bias – groups well matched. Performance bias – study procedures well reported. It is unclear who performed the intervention. Detection bias – participant's blinded but unable to blind staff. Unblinded but independent observer and data collector in PACU. Attrition bias – 1 patient missing. Outcome reporting – all data collected was reported. Overall quality -Low risk of bias.	There was no significant difference between groups.

Table 5: Included studies cont.

Animal Studies					
Reference	**Aim & Intervention**	**Participants**	**Outcomes measured**	**Quality**	**Results**
Sakuramoto *et al* (2013) Japan	ETS duration was 10 seconds with -140mmHg suction pressure.	36 Japanese white rabbits. Aim to determine whether repeated OS exacerbates lung injury compared to closed suction. 6-hour study protocol duration. Setting: Laboratory	P/F ratio, $PaCO_2$, physiology and ventilation parameters.	Sequence generation – Unclear. Selection bias – groups well matched. Performance bias – study procedures well reported. Who performed the intervention is not reported. Animal husbandry not reported. Detection bias – participants blinded but unable to blind staff. Attrition bias – no missing data. Outcome reporting – all data collected was reported. Blinding of outcome assessors not reported. Overall – unclear risk of bias.	Repeated open endotracheal suctioning causes gradual desaturation but does not exacerbate lung injury compared to closed endotracheal suctioning in a rabbit model. Control, CS and healthy control all had P/F ratio >400 for the duration of the study. Repeated OS resulted in P/F ratio <300
Kamiyama *et al* (2015) Japan	4 groups ETS duration was 15 seconds with -150mmHg suction pressure.	30 Japanese white rabbits. Aim to investigate the effect of hyperinflation after repeated OS. 3-hour study protocol duration. Setting: Laboratory	PaO_2, $PaCO_2$, HR, lactate, BP, Respiratory rate, PIP	Sequence generation– random allocation to group reported by not described. Selection bias – groups well matched. Performance bias – animal husbandry not reported. Unclear who performed suction. Detection bias – blinding not reported of animal carers or outcome assessors for physiology data. Attrition bias – none reported. Outcome reporting – all data collected was reported, however no specific aims were reported. Overall – unclear risk of bias.	We analysed 2 groups (ARDS with no ETS and ARDS with OS). ARDS without ETS had a higher PaO_2 for the duration of the study period and no reported complications of ventilation.

Table 5: Included studies cont.

Animal Studies					
Reference	**Aim & Intervention**	**Participants**	**Outcomes measured**	**Quality**	**Results**
Ehrhart (1981) USA	To assess the effect of suction and apnea on hypoxemia and cardiac arrhythmias ETS duration of 45 seconds with a negative pressure of -100 torr	12 Dogs – anesthetised and paralysed and haemorrhagic pulmonary oedema generated with oleic acid. Dogs were divided into either IPPV (7) or CPPV (5) Setting: Laboratory	Mean arterial pressure, Pulmonary artery pressure, cardiac output, PaO_2, $PaCO_2$, and pH were all recorded.	Selection bias- dogs not described. Randomisation – order of intervention described as random but sequence generation not reported. Performance bias – animal husbandry not reported. Detection bias – blinding not reported, of animal carers or outcome assessors. Attrition bias – none reported. Outcome reporting – all data collected was reported, however no specific aims were reported. Overall – high risk of bias.	No significant difference reported between groups. Lack of differences between the groups may be due to small numbers. No cardiac arrhythmias noted related to suction.
Leiman (1987) USA	To assess secretion removal with a balloon catheter versus ETS. Balloon catheter and suction were both performed over 15 seconds and pressure was -250mmHg.	5 Mongrel dogs To compare the secretion removal of suction vs balloon catheters. Animal stabilised for 30 minutes following anaesthesia prior to intervention. Setting: Laboratory	PaO_2 and volume of secretions. HR, BP and PAP, MAP recorded and no significant differences between groups	Selection bias- dogs reported as mongrel and weight range reported. Co-morbidities not reported. Randomisation – not reported. Performance bias – animal husbandry not reported. Detection bias – blinding of animal carers or outcome assessors not reported. Attrition bias – none reported. Outcome reporting – all data collected was reported, however no specific aims were reported. Overall – high risk of bias.	No significant differences HR, $PaCO_2$, PAP, MAP or cardiac arrhythmias between groups. PaO_2 was significantly lower in the suction group.

Table 5: Included studies cont.

Animal Studies					
Reference	**Aim & Intervention**	**Participants**	**Outcomes measured**	**Quality**	**Results**
Woodburne (1980) USA	Investigation of the mechanisms responsible for the sustained fall in arterial oxygen tension after endotracheal suctioning in dogs. Suction pressure was 170mmHg.	3 Dogs – interventions performed at weekly intervals, each dog having 5 interventions performed. Hypothesis – a reflex mechanism, initiated by mechanical stimulation of the airways is responsible for the sustained fall in PaO_2. Setting: Laboratory	PaO_2	Selection bias- dogs reported as 3 female mongrel dogs. Co-morbidities not reported. Randomisation – not reported. Performance bias – animal husbandry not reported. Blinding of staff delivering the intervention was not possible. Detection bias – blinding of animal carers or outcome assessors not reported. Attrition bias – none reported. Outcome reporting – all data collected was reported, however no specific aims were reported. Overall– unclear/high risk of bias.	Protocol 1b and 2 – catheter insertion and suction vs catheter insertion and no suction produced similar falls in PaO_2. The authors suggest that mechanical stimulation of the airways by a suction catheter was a significant factor in causing a sustained fall in PaO_2 in anaesthetised dogs. Further research is required.
Gunderson (!991) USA	To assess HR response to ETS following administration of atropine. Suction catheter withdrawn over 10 seconds, with or without suction. Suction pressure set at -80 torr. .	11 newborn piglets. Hypothesis – that the heart rate alterations associated with suction are due to mechanical +/- neural stimulation that is vagally mediated. Both interventions were assessed before and after vagal blockade. Setting: Laboratory	PaO_2 and heart rate at baseline then 20, 60, 120 & 180 seconds after intervention.	Selection bias- piglets well described and rationale for use made clear. Randomisation – order of intervention/protocols generated by SAS Performance bias – animal husbandry not reported. Each suction episode performed by the same investigator. Detection bias – blinding not reported, of animal carers or outcome assessors Attrition bias – none reported. Outcome reporting – all data collected was reported, however no specific aims were reported. Overall – unclear risk of bias	To explore the mechanical and neurogenic factors associated with suction. Ventilator operant during suctioning. There was no significant difference in the mean PaO_2 between groups when compared over time, there was a significant decline in PaO_2 at 20 seconds post baseline both for the suction and no suction group. Heart rate declined significantly prior to administration of atropine in both groups. This was obliterated following administration of atropine.

Table 6: Results of included studies

Study (year) Sample size, population	ETS duration seconds	Negative pressure mmHg	No ETS seconds	ARDS	ETS				Intervention / avoidance of ETS				Test for significant differences between ETS and intervention groups (method used & P-value, where reported)
					Mean O_2 Before ETS	Mean O_2 After ETS	Change in mean O_2	P value for test of change in means	Mean O_2 Before ETS	Mean O_2 After ETS	Change Mean O_2	P value for test of change in means	
Humans													
Downes (1961) Adolescents & adults; N= 11	20	neg flow 13 l/min	60 [i]	TB patients	SpO_2 98	SpO_2 89 (SE 1.9)	-9	<0.01	SpO_2 98	SpO_2 90 (SE 1.3)	-8	<0.01	**p>0.05 comparing ETS and during apnea** Statistical methods - t tests. Exact p value not reported.
L'Hermite (2018) [j] Adults; N= 68	Not reported	Not reported	PP breath	No	Not reported	248 (SD 148)	n/a	Not reported	Not reported	214 (168)	n/a	0.44	ITT analysis T test and chi squared 2-sided test.
Rabbits													
Sakuramoto (2013) [h] N=36	10	140	No suction	Yes	*P/F ratio:* 450 [c]	*P/F ratio:* 297 (SD 124)	- 153	Not reported	*P/F ratio:* >400 [c,k]	*P/F ratio:* >400 [c,k]	Not reported	Not reported	**P = 0.013 Worse PF ratio following open ETS when compared to control** Open suction did not reach statistical significance until 3 hours after intervention. Repeated measures ANOVA plus Bonferroni adjustment for multiple testing.
Kamiyama (2015) [g] N=30	15	150	No suction	Yes	400 [c]	226 (SD 28.9)	-174	<0.05	400 [c,k]	400 [c,k]	Not reported	>0.05	**Reached statistical significance between ARDS with suction and ARDS without suction 3 hours post intervention.** One-way ANOVA and repeated measures ANOVA. Bonferroni adjustment
Dogs													
Leiman (1987) N=5 (4 repeated measures per dog)	15	250	15 [e]	No	599 (SEM 10)	451 (SEM 31)	-148	<0.05	589 (SEM 11)	564 (SEM 10)	-25	Not statistically significant	**P <0.05 between ETS and intervention in favour of Foley balloon** Exact value not reported. 2-way ANOVA
Woodburne (1979) [f] N=3 (5 repeated measures per dog)	15	170	15 [b]	No	76 (SD 2.7)	67 (SD 1.1)	-9	<0.001	76 (SD 1.1)	70 (SD 4.0)	-6	Not reported	**P <0.01 in favour of catheter insertion** This result was only related to 15 seconds duration of ETS and only present 30 minutes after ETS. Paired t tests
Ehrhart (1981) [a] N=7 (5 repeated measures per dog)	45	100	45	Yes	56 (SEM 3)	46 (SEM 2)	-10	<0.05	56 (SEM 2)	45 (SEM 1)	-11	<0.05	**Not statistically significant.** Student t tests between groups and repeated measures ANOVA
Piglets													
Gunderson (1991) N=11	10	80	10 [b]	No	159 [c]	118 [c]	-41	<0.05 [d]	150	138	-12	<0.05 [d]	**Not statistically significant** Statistical method not reported in the paper

Abbreviations: ARDS – acute respiratory distress syndrome, ETS – endotracheal suction, ITT – intention to treat, PaO_2 – partial pressure of oxygen, PP breath – positive pressure breath, SpO_2 – peripheral capillary oxygen saturation, P/F ratio – ratio of partial pressure arterial oxygen and fraction of inspired oxygen, SD – standard deviation, SE – standard error, SEM – standard error of the mean. [a] Apnea and Oleic Acid used to induce ARDS, [b] suction catheter insertion, no suction applied, [c] measure of variance (SD, SE, SEM) not reported, [d] change statistically significant (p<0.05) at 20 seconds only, [e] Foley balloon catheter used for secretion removal, [f] 8 protocols tested. Protocol 1 (b) and 2 used for this review, [g] ARDS (no ETS) and ARDS with open suction used for this review N=16, saline lavage induced ARDS, [h] ARDS control (no ETS) and ARDS open suction, 1 hour after injury used for this review *n= 21, saline lavage induced ARDS, [i] ETS during apnea, [j] Positive pressure breath at extubation, no ETS, used time taken for to SpO_2 to drop below 92%, compared ETS to positive pressure breath at extubation, [k] No suction.*

Chapter 5 : A survey of endotracheal suction practice in the Cardiothoracic and Vascular Intensive Care Unit (CVICU).

Preface

This chapter describes a survey undertaken to investigate endotracheal suction practice in CVICU. Knowing current practice would help plan what education and training were needed before starting recruitment for the planned RCT. The survey identified areas of clinical practice that failed to align with the CVICU endotracheal suction recommended best practice guidelines.

This chapter describes the survey design and management, and the recommendations resulting from the findings. The results were presented as a poster presentation

See Appendix 2 for the supporting documents.

5.1 Introduction

CVICU uses recommended best practice (RBP) guidelines to underpin clinical practice within the unit. RBPs are evidence-based and reviewed every three years. CVICU has a diverse workforce and RBPs help ensure a consistent standard of care. CVICU has two suction related RBPs, one addressed suctioning endotracheal and tracheostomy tubes, the second addressed managing extubation of routine, uncomplicated, post-operative cardiac surgical patients. The endotracheal suctioning RBP in use at the time of the survey (appendix 2) was written in 2013 and recommended a suction pressure of 200 mmHg, to pre-oxygenate patients with an oxygen requirement of greater than 50%, apply suction for 10 seconds during catheter withdrawal, and to suction patients at extubation. Current endotracheal suction practice in CVICU had not previously been described, the knowledge gained would help identify any gaps in practice, informing education and training within the unit, including any specific education required before the start of a planned RCT.

The research questions were:

- What is the current endotracheal suction practice in CVICU?
- Did practice align with the unit RBP?

Aims and Objectives.

- To investigate the current endotracheal suction practice in CVICU. Identifying what, if any, differences there were between nursing practice and the RBP.
- To investigate suction practice in patients mechanically ventilated for less than 12 hours.

5.2 Methods

Participants

All nursing staff working in CVICU at the time of the survey were invited to participate in the survey. CVICU has an international workforce that includes both local and overseas trained nurses from Australia, the Philippines, India, the United Kingdom, and Ireland. The skill mix ranges from new graduate nurses to those with over ten years ICU experience. At the time of the survey CVICU employed 120 nursing staff.

Setting

The Cardiothoracic and Vascular Intensive Care Unit, Auckland City Hospital is a level III ICU, that is defined as having the ability to provide multi-system life support for an indefinable period of time, commitment to academic education and research, and that patients are managed by an intensive care specialist (303). CVICU provides the national heart and lung transplant and extracorporeal membrane oxygenation services with approximately 1200 cardiac surgical patients admitted annually.

Survey design and administration

This investigation was a single centre, cross-sectional, observational study conducted in January 2015. Survey administration was via an on-line, self-administered questionnaire. An on-line survey tool (SurveyMonkey [SurveyMonkey Inc. San Mateo, California, USA]) was used to administer the questionnaire and provided a confidential, easily accessible and convenient survey method. The survey was designed in consultation with experienced CVICU clinical researchers, limited to 10 questions, taking no longer than 10 minutes to complete. The survey questions included knowledge about the recommended best practice and clinical practice guidelines, and suction practice when patients are mechanically ventilated for less than 12 hours. Additional items included what triggers nurses used to help inform decision making, what clinical assessment was performed before providing ETS, and how nurses prepared patients for suction. Each question provided a selection of multiple choice answers, with the option to select more than one item, consequently results in some categories could sum to more than 100%. Question nine did not have a multiple-choice option, answers were free-text only. The full questionnaire is available in appendix 2.

Survey administration

An email invitation was sent to all CVICU nursing staff, explaining the survey and including a link to the on-line survey. The email link allowed staff to complete the survey at a time of their convenience. Staff received a follow-up email one month later. To maximise response rates, there were verbal reminders about the survey at the twice daily shift handover. SurveyMonkey provides participant anonymity; participation implied consent. The anonymity of the responses allowed respondents to be truthful as no judgement could be attributed to the individual. No demographic data were collected.

5.3 Results

The response rate was 53% (*n*=64). The majority of respondents checked the suction pressure before performing endotracheal suction (*n*=47, 75%), and 41% of respondents (*n*=26) knew the recommended

suction pressure. However, 16% (*n*=10) were unaware of the recommended pressure. Most respondents reported providing suction as required (*n*=55, 86%), applied suction for less than 10 seconds (*n*=56, 88%), and during withdrawal of the suction catheter (*n*=63, 98%) (Table 7).

Table 7: General knowledge of clinical practice guideline recommendations

Suction Canister *n* (%)	
Pressure checked *n* (%)	47 (75)
What is the recommended pressure mmHg	
100-150	26 (41)
151-250	27 (42)
251-350	1 (2)
Don't know	10 (16)
How frequently do you perform ETS *n* (%)	
Routine	9 (14)
1-2 hourly	3 (5)
3-4 hourly	13 (20)
PRN *	55 (86)
Duration of ETS *n* (%)	
<10 seconds *	56 (88)
10-20 seconds	7(11)
21-30 seconds	0
>30 seconds	0
When do you apply endotracheal suction	
During withdrawal of the suction catheter *	63 (98)
During insertion of the suction catheter	1 (1)
Intermittently	1 (1)

**Supported by the CVICU RBP*

Table 8 describes the most frequently reported reasons for performing suction which were deteriorating oxygenation as detected by SpO_2 (*n*=63, 98%), following auscultation, or audible or visible secretions (*n*=60, 94%). Sixteen respondents (25%) used suction to assess the patient's sedation level. Efficacy of ETS was assessed by rechecking the SpO_2 (*n*=60, 94%), auscultation (*n*=42, 66%) and re-checking the ABG (*n*=19, 30%).

Table 8: Triggers for suction and assessment of efficacy

Why do you perform ETS *n* (%)	
Deteriorating SpO_2 *	63 (98)
Auscultation/Audible/visible secretions	60 (94)
Patient coughing	45 (70)
Deteriorating ABG	44 (69)
Assess patient's sedation level	16 (25)
Assessing the effectiveness of ETS *n* (%)	
Recheck SpO_2	60 (94)
Auscultation	42 (66)
Recheck ABG	19 (30)
Do not reassess effectiveness	1 (1)
Suction procedures during extubation for patients ventilated for <12 hours *n* (%)	
Perform oral suction *	61 (95)
Suction prior to extubation *	56 (88)
Ask the patient to cough	49 (77)
Pre-oxygenate	24 (38)
Suction during extubation *	7 (11)
No ETS	4 (6)

*ABG- Arterial Blood Gas; ETS – endotracheal suction; SpO_2 – peripheral oxygen saturation; * support by the CVICU RBP*

Patient preparation for endotracheal suction included explaining the procedure to patients before performing suction (84%), explaining the procedure to families and visitors when present (6%). Other preparation included performing hand hygiene (36%), oral suction before ETS (6%), checking the patient's SpO_2 (10%), chest auscultation (4%) and administration of a sedation bolus (8%), and analgesia bolus (2%).

When patients were ventilated for less than 12 hours 88% (*n*= 56) of respondents performed suction before extubation, 38% (*n*=24) of respondents pre-oxygenated patients before suction (Table 8). Other procedures included performing oral suction before extubation (*n*=61, 95%) and asking the patient to cough at extubation (*n*=49, 77%).

5.4 Discussion

This survey identified areas of practice that both complied with, and differed from the unit RBP. The key findings included that most respondents applied suction pressure for less than 10 seconds, suction was applied during withdrawal of the suction catheter, and patients received suction as required. This survey identified the most frequent clinical indicators used to assess the patient need for suction were the assessment of oxygenation and/or the presence of audible or visible secretions, and is similar to paediatric ICU nurse practice (304,305). Two areas of practice failed to comply with the unit RBP the use of ETS to assess the patient's level of sedation, and the use of pre-oxygenation before extubating patients mechanically ventilated for less than 12 hours.

Conflicting guidelines

The survey identified a key difference between the unit RBP and internationally accepted clinical practice guidelines, in particular from the AARC about the recommended suction pressure to use (2). The unit RBP stated "*to set the pressure to 200mmHg*" and differs from the AARC recommendation which is to "*set as low as possible….less than 150mmHg"* (pg. 759) (2). Differences between international and local guidelines can create potential uncertainty for those delivering patient care, for example, which guideline should be followed. This result highlighted the need for CVICU to review the RBP and align with accepted international guidelines. Minimising differences between guidelines can reduce confusion for nursing staff about which guideline to follow, and is relevant when there is a multi-national workforce.

Non-adherent practice

The survey identified two areas of self-reported practice that did not align with the unit RBP. First, the use of ETS to assess sedation levels, ETS should not be used to determine patients' level of sedation. Validated tools are available for sedation assessment such as the Richmond Agitation and Sedation Score (RASS) tool (110) which is used in CVICU. It is not known how the use of ETS to assess sedation levels had become part of clinical practice. This finding was presented to the CVICU education team, unit Charge Nurses and unit staff. An agreed plan was to include additional information about sedation assessment in the unit orientation programme and was followed up by the education team. Further education about how to assess sedation level's using the RASS tool have been included in the orientation programme. Second, the results identified the inappropriate use of pre-oxygenation before extubation. The RBP guideline says to pre-oxygenate patients only when receiving greater than 50% oxygen.

Patients deemed ready for extubation will be receiving less than 50% oxygen, negating the need for pre-oxygenation. Although participant anonymity prevented clarification of respondents answers, this is a relevant finding. Awareness of this potential discrepancy between clinical practice and the RBP allows strategies to be put into place to improve staff knowledge about the appropriate use of pre-oxygenation.

These findings identified areas of practice that differed from the RBP, and are similar to others who have reported both poor knowledge about how to safely perform ETS, (306) and that practice differs from guideline recommendations (307,308). In jurisdictions where registered nurses and other staff groups perform ETS, practice differences have been reported between staff groups. For example in Brazil where suction is provided by registered nurses, nurse technicians, and nursing assistants, (309) although registered nurses reported greater knowledge about how to safely perform ETS, clinical practice differed from the recommendations, in particular the practice of installation of saline and duration of suction (309). In North America practice differences between nurses and respiratory therapists identified that nurses were less likely to instil saline before suction, (310,311) but that in Australia some paediatric nurses continue to use saline before suction (312) although the practice is no longer recommended (2).

The results from the CVICU survey identified differences between the unit RBP and clinical practice, and that the RBP differed to international clinical practice guidelines in the recommended suction pressure (2). When assessing the patient need for suction, respondents did not appear to utilise other evidence-based clinical indicators such as listening for coarse breath sounds over the trachea or use of ventilator waveforms (313). It is unclear whether staff are aware of these indicators, and it is recommended that this is incorporated in staff orientation and training to improve patient assessment and potentially reduce unnecessary suction episodes.

5.5 Strengths & limitations

SurveyMonkey is a free, easily accessible, on-line platform to conduct surveys; it was an effective and efficient tool to distribute the questionnaire. The ability to email all nursing staff added to the ease of use, limiting the survey to 10 questions helped keep the survey focused. The survey was conducted over two months and completed in a timely manner. Although the response rate was lower than hoped, the results provided a snapshot of current practice within CVICU. The on-line survey maintained respondents anonymity, thereby mitigating the potential conflict of interest resulting from the researcher working on the unit where the survey was conducted.

This study is subject to several limitations. Demographic data were not collected, for example, how long staff had worked in ICU/CVICU or whether respondents had post-graduate or specialist ICU training. Demographic data may have helped identify where education resources need to be focussed and should be collected in any future surveys. Questionnaires are subject to potential selection and responder bias (314). The use of voluntary sampling and an anonymous questionnaire was chosen to encourage participant response and as a result, it was not possible to assess differences in response or non-response bias. However, the response rate was over 50%, suggesting that staff engaged with the survey.

Following this survey, the recommendations were to align the unit RBP with AARC guidelines, on-going education and in-service training need to include the correct use of the RASS tool and pre-oxygenation.

Additional recommendations included the introduction of behavioural pain assessment tools, helping staff to assess pain in those patients unable to communicate.

5.6 Summary

Although the survey was small the findings provided preliminary data to inform the planned RCT, provided insight into current suction practice in CVICU, and identified the incorrect use of ETS to assess patients' sedation levels. Knowledge of unit suction practice, including suction at extubation, helped plan the education required before commencing the RCT investigating avoidance of ETS and develop the safety caveats for use in the RCT. The results from this survey helped to inform the questions for the point prevalence study investigating suction practice across New Zealand and Australia which would include the frequency of suction and what triggers nurses use to initiate suction.

Chapter 6 : Point Prevalence Study

Endotracheal suction in intensive care: A point prevalence study of current practice in New Zealand and Australia

Preface

The CVICU practice survey described in Chapter 5 identified current endotracheal suction practice in the unit. A literature search failed to identify any published data that described endotracheal suction practice in adult ICU patients across Australasia. One study reported paediatric practice, (315) and one single centre study in an Australian ICU reported ETS practice as part of a quality improvement programme (316).

The point prevalence programme (PPP) is an established programme of research and is a collaboration between the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG) and the Critical Care Division of The George Institute. The collaboration facilitates observational research across participating ICUs in Australasia, (317) the programme combines different observational research questions in a one day survey, allowing five or six observational studies to be conducted within one programme of research. Researchers submit study questions to the PPP management committee for review and if accepted are included in the PPP study day. The researcher provides the research questions and data dictionary definitions relevant to their research question; the PPP management provides all participating sites standardised case report forms and a data dictionary. Standardised definitions include diagnostic codes, illness severity scoring, and demographic data, which are standardised across the study. To facilitate data collection, there are two designated study dates, with sites selecting a date of their choice. Dates are one month apart, minimising differences between cohorts, for example, admissions with seasonal influenza. Trained research co-ordinators collect the data using direct data entry via the Research Electronic Data Capture (REDCap) platform (318). The principal investigator conducts the data analysis.

The point prevalence data provides a snapshot of current practice in over 50 participating ICUs on the study day. This PPP survey built upon the CVICU survey, investigating the frequency of ETS, what triggers nurses used to initiate suction, the suction pressure used, and suction practice before extubation. Understanding current endotracheal suction practice, both locally and across Australasia, would provide additional data to inform staff education and training before commencing the RCT, and provide context about the current use of ETS. This chapter presents the results of the PPP study, addressing the question “what is current endotracheal suction practice across New Zealand and Australia”. The data analysis and manuscript preparation is conducted by the principal investigator and provided the first description of ETS practice across Australasia.

The manuscript presented here was read and approved by all authors.

See Appendix 3 for the supporting documents.

Endotracheal suction in intensive care: A point prevalence study of current practice in New Zealand and Australia.

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Abstract

Background

Despite the evidence and available guidelines about endotracheal suction, a discrepancy between published guidelines and clinical practice persists. To date endotracheal suction (ETS) practice in the adult ICU population across New Zealand and Australia has not been described.

Objective

Describe ICU nurses' ETS practice in New Zealand and Australia including the triggers for performing endotracheal suction.

Methods

A single day, prospective observational, binational, multicentre point prevalence study in New Zealand and Australian ICUs. All adult patients admitted at 10:00 on the study day were included.

Main outcome measures

In addition to patient demographic data, we assessed triggers for ETS, suction canister pressures, use of pre-oxygenation, measures of oxygenation, and ETS at extubation.

Results

A total of 682 patients were included of which 230 were intubated. A total of 1891 ETS events were performed on 227 patients during the study day, a mean of 8 interventions per patient. The main triggers reported were audible (*n*=385, 63%) and visible (*n*=239, 39%) secretions. Less frequent triggers included following auscultation (*n*=142, 23%), reduced oxygen saturations (*n*=140, 22%) and ventilator waveforms (*n*=53, 9%). Mean suction canister pressure was -337 mmHg (SD 189), 67% of patients received pre-oxygenation (*n*=413) and ETS at extubation was performed by 84% of nurses.

Conclusion

Some practices were inconsistent with international guidelines, in particular concerning patient assessment for ETS and suction canister pressure.

Key words: airway management, endotracheal suction, intensive care, mechanical ventilation.

6.1 Introduction

Endotracheal suction (ETS) is performed to maintain patency of the airway and remove secretions in patients with an endotracheal tube (ETT) in situ. It is an important part of airway management in ventilated Intensive Care (ICU) patients. Patients with an ETT may be at increased risk of respiratory infections as they are unable to clear secretions by coughing. Recognised potential complications following ETS include hypoxia, tissue trauma, increased risk of infection, cardiovascular instability and atelectasis (31,85). Care and management of the patient and the ETT has been discussed in the literature since 1945 (319–321). To ameliorate the risks, the American Association for Respiratory Care (AARC) developed clinical practice guidelines (CPG) for ETS, ventilation and extubation (2,322,323). Current recommendations include; suction only when secretions are present, (2) consider pre-oxygenation if there is a clinically significant reduction in oxygen saturation with suctioning, using positive end-expiratory pressure (PEEP) or recruitment manoeuvres (applying a transient increase in pulmonary pressure to open collapsed alveoli) when required (324,325), and setting the suction pressure as low as possible to effectively clear secretions, less than -150mmHg is recommended (2,97). Patient assessment should include listening for coarse sounds over the trachea, assessing ventilator waveforms, (313) assessment of oxygenation or presence of pulmonary secretions (2).

Previous studies have shown that there is variability between clinical practice and adherence to practice guidelines (130,131,311). Less than 10% of nurses use the recommended suction catheter size with suction canister pressure monitored 55% of the time, (130) and differing practice about the use of 0.9% sodium chloride prior to ETS (130,311), although this is no longer a recommendation (2).

Recent work investigated ETS practice of Australian paediatric nurses, (305) and physiotherapists, (327) while an earlier paper investigated nurses' adherence to best practice in one Australian ICU (316). There is no published literature describing current nursing ETS practice in the adult ICU population across New Zealand and Australia (ANZ). This study aimed to describe current practice and triggers influencing nurses' decisions to perform suction in order to assess congruence with CPG recommendations.

6.2 Methods

This observational study was conducted as part of an existing Point Prevalence Program (PPP), using cross-sectional research methodology (317). The PPP is a prospective, bi-national, single day research initiative to facilitate researchers conducting observational research that will underpin future research. The George Institute for Global Health coordinates the PPP on behalf of the Australian and New Zealand Intensive Care Society Clinical Trials Group. Ethics approval was obtained in New Zealand (MEC/09/28/EXP) and for all Australian sites, a waiver of consent was granted.

To facilitate data collection, data were collected on either 15th September or 14th October 2015. Trained research staff at each site collected data on all adult (≥16 years) patients in their ICU at 10:00 hours on the chosen study day. Demographic data including age, gender, admission diagnosis, Acute Physiology and Chronic Health Evaluation (APACHE) II score on admission, admission source and 28-day mortality was collected. All patients intubated and ventilated by way of either an endotracheal or tracheostomy tube at 10:00 hours on the study day were included in this study.

The following data was collected:

- Number of ETS episodes during the 24-hour study period.
- For four consecutive ETS episodes:
    - Partial pressure of oxygen (PaO_2) and partial pressure of carbon dioxide ($PaCO_2$) in arterial blood prior to ETS,
    - Peripheral capillary oxygen saturation (SpO_2) pre and post ETS,
    - Suction canister pressure,
    - The triggers for performing ETS,
- Use of pre-oxygenation.
- Incidence of extubation or decannulation between 10:00 – 14:00 hours, and whether ETS was performed prior to extubation.

For this study, definitions of the triggers for a suction event were: hypoxia $PaO_2 \leq 60$mmHg/8.0kPa, hypercapnia $PaCO_2 \geq 50$mmHg/6.6kPa, decreased $SpO_2 \leq 88\%$, auscultation that identified reduced air entry, wheezes or crackles necessitating ETS, audible secretions (heard without the use of a stethoscope), visible secretions (secretions or sputum seen in the ET tube). Routine ETS included both "routine" and "routine as per unit policy". Pre-oxygenation was defined as the delivery of 100% FiO_2 for 3 - 6 breaths or 1 - 2 minutes before ETS was performed and suction at extubation was defined as during the removal of the ETT, or up to 5 minutes prior to extubation.

Data were entered into a single electronic database (Research Electronic Data Capture (REDcap) – Vanderbilt University, Tennessee) (318). Data were extracted into Excel (version 15.32 Microsoft Corporation, Santa Rosa, California) and analysed using SPSS (IBM SPSS Statistics for Macintosh, Version 24.0. Armonk, NY: IBM Corp.). Descriptive statistics were used to describe the cohort. Data were tested for normality and the mean and standard deviation (SD) are reported.

6.3 Results

In total 682 patients were enrolled at 51 ICUs across New Zealand and Australia, of whom 230 (34%) were intubated and ventilated on the study day. Baseline characteristics of the intubated patients are shown in Table 1. A total of 1891 ETS episodes were recorded on 227 intubated patients during the study day, data was not provided for 3 patients. A total of 614 (32.5%) were recorded as four consecutive ETS episodes and were analysed. There was an average of 8 interventions per patient (range 1-33) in the 24-hour study day period, and mean canister pressure was -337 mmHg (SD 189). Nineteen patients

were extubated in the first four hours of the study day (10:00 -14:00); of these, 16 (84%) received ETS at the time of extubation.

Table 1: Baseline characteristics of intubated patients (n=230)

Characteristic	
Age, years mean (SD)	55 (16)
Sex (male), *n* (%)	141 (61%)
Weight, * kg, mean (SD)	85 (26%)
APACHE II score, mean (SD)	20.0 (8.0)
ICU admission source, *n* (%)	
Emergency department	70 (30%)
Operating theatre, emergency	55 (24%)
Hospital ward	51 (22%)
Another ICU	23 (10%)
Operating theatre, elective	16 (7%)
Transfer from other hospital	15 (7%)
APACHE III diagnostic categories, *n* (%)	
Respiratory	55 (24%)
Cardiovascular	42 (18%)
Neurological	37 (16%)
Trauma	30 (13%)
Sepsis	24 (10%)
Gastrointestinal	21 (9%)
Other	21 (9%)
Discharged from ICU at day 28 (alive or dead), number (%)	194 (84%)
Alive at ICU discharge, number (%)	159 (69%)

*APACHE = Acute Physiology and Chronic Health Evaluation. ICU = intensive care unit. * Body weight is estimated or measured.*

Overall on the study day the most frequently cited reasons for ETS were audible secretions (*n*= 385, 63%), visible secretions (*n*=239, 39%), following auscultation (*n*=142, 23%) and reduced SpO_2 (*n*=140, 22%). Additional reasons for the patient receiving ETS can be seen in Table 2.

Table 2: Triggers for endotracheal suction

Triggers for endotracheal suction events (*n* = 614)		
	n	**%**
Audible secretions	385	63%
Visible secretions	239	39%
Auscultation	142	23%
Reduced SpO_2	140	22%
Routine	104	17%
Patient coughing	75	12%
Ventilator waveforms, e.g. saw tooth pattern	53	9%
Hypoxia – on ABG	33	5.3%
Patient or family request	27	4%
Physiotherapy	14	2%
Hypercapnia – on ABG	4	0.7%
CXR changes	2	0.3%

Although reduced SpO_2 was cited as the trigger for 22% of ETS interventions, it was frequently recorded as being within the normal physiological range (94-98%) (48). Over four consecutive suction episodes, the mean SpO_2 before and after ETS was 96% (SD 4.1) and 97% (SD 3.1) respectively. The lowest recorded SpO_2 prior to ETS was 68% increasing to 80% following ETS. As seen in Table 2, ventilator waveforms as an indicator for ETS were used infrequently as has been recommended in the literature (313).

The least frequent reasons for ETS were hypoxia (*n*=33, 5.3%) and hypercapnia (*n*=4, 0.7%) as measured on arterial blood gas (ABG) taken prior to ETS. The mean PaO_2 and $PaCO_2$ prior to ETS were 68.2 mmHg (SD 10.7) and 60.4 mmHg (SD 10.9) respectively. In contrast to the SpO_2, these were outside the normal physiological range.

Pre-oxygenation prior to ETS was provided prior to the majority of ETS episodes (*n*=413, 67%). The most frequent rationale for pre-oxygenation was documented as unit policy (*n*=309, 75%). Other reasons included patient condition (*n*= 45, 11%) and reduced SpO_2 (*n*=40, 10%).

6.4 Discussion

This is the first time that nursing practice regarding ETS across New Zealand and Australia has been described. We found that the most frequent triggers for performing ETS were audible or visible secretions; that ETS was performed at extubation for the majority of patients extubated during the study period; that pre-oxygenation prior to ETS was common; that suction canister pressure was higher than recommended in CPGs and that the rationale for performing ETS varied among nurses.

These results show that ANZ nursing practice deviates from CPG recommendations and that the discrepancies are similar to those found in other studies, (130,131,311) including non-adherence to recommended suction canister pressure. Although there are currently no guidelines about ETS best practice at extubation, the majority of patients in our study received ETS prior to extubation.

The most frequently cited reasons for performing ETS were audible and visible secretions and following auscultation as defined for this study. This is similar to other studies where, among the top 5 self-reported triggers for nurses and respiratory therapists were the patient coughing, chest auscultation and audible secretions (103,310). In our study, ventilator data, for example, waveforms such as saw-tooth patterns and raised inspiratory pressures, were seldom used as a trigger for ETS and nurses were not listening for coarse crackles over the trachea as recommended (2,313). It has been suggested that patients are assessed at least 4 hourly for indicators that ETS is needed, (313) and that coarse breath sounds over the trachea are a good indicator for the need for ETS (313). If this is incorporated into clinical practice, it would have the potential to improve patient care and maintain safe airway management in the ICU, while avoiding unnecessary ETS.

For patients extubated during the study period, the majority received ETS at the time of extubation. This is comparable to previously described practice, where suctioning the ETT and asking the patient to cough were among the most common nursing practices at extubation (276,328). However, ETS may increase atelectasis, (329) and consideration of a positive pressure breath (329), or the use of PEEP at extubation

(325,328–330) may reduce the risk of aspiration and atelectasis. Further research is required to determine best practice at extubation in the ICU setting.

In this cohort, pre-oxygenation prior to ETS was common, the unit policy being the biggest driver. Our results showed a higher number of nurses pre-oxygenating patients than previous self-reported results (331). However, nursing pre-oxygenation practice is consistent with described physiotherapist practice in ANZ (327).

Although hyperoxygenation is recommended in the CPG, (2) much of the evidence is based upon literature prior to the availability of closed or quasi-closed ETS apparatus (103). There remains a knowledge gap regarding the optimum FiO_2 delivery for pre-oxygenation, (106,107,332,333) and which patients may likely benefit. The current guidelines do not define hypoxia and there is recognition that the available evidence is weak (33). Given the known side effects of hyperoxygenation upon absorption atelectasis, (106,332,333) there is a need for more robust data to guide practice.

We found that the mean negative canister pressure on the study day was greater than that recommended in the CPG of “less than -150mmHg in adults” (2). This is a similar finding to other studies which have shown that suction canister pressure is frequently outside the recommended level (130,131). The consensus in the literature is that negative pressure should be set no higher than the minimum level required (2,97) thereby reducing the risk of trauma to the lung mucosa, atelectasis and pulmonary oedema. Nurse education and unit policies have been shown to influence practice, (334,335) therefore this gap in practice should be addressed by effective education and meaningful, evidence-based protocols (334,335).

Patients who survive ICU consistently describe ETS as one of the most painful procedures (336–339) and there is evidence that those who have experienced ventilation have poorer quality of life outcome measures up to 5 years following their ICU stay, continuing to recall pain and ETS (340). It has been reported that during their ICU admission 30% of ICU patients report pain at rest, with up to 50% of patients reporting pain during common ICU procedures including turning and ETS (339) and that there is frequently no analgesia provided either immediately prior to or within 2 hours of the patient receiving ETS (36). This may be due to reasons including staff being de-sensitised to the procedure and ETS being a brief intervention (338). However, given the evidence that ETS is painful and distressing anything that can be done to mitigate these effects for patients will be beneficial, potentially aiding physical and psychological recovery. This study highlights the need for ongoing nurse education in ICU, including how to assess the need and prepare the patient for ETS and increasing awareness about the experience and pain associated with ETS. Practitioner education is influential in changing practice, (334) and may help reduce the gap between CPG and clinical practice.

6.5 Strengths and limitations

Strengths of this study include the prospective design and a binational approach involving a large number of ICUs across a variety of settings. Data collection was undertaken by experienced research nurses/co-ordinators all working within the ICU speciality ensuring consistency across the data collection.

Although the study is a snapshot of nursing practice, describing practice only on the study day, this is the first-time ICU nursing practice of ETS has been documented across ANZ. This study will provide a platform for units to review their practice protocols and develop robust education programmes for ICU nursing staff, incorporating the best available evidence.

6.6 Conclusions

The lack of availability of high quality-evidence surrounding ETS continues to present challenges for clinicians. This study has identified key areas where improvements could be made to ICU nursing practice including education regarding patient assessment prior to performing ETS, guidance regarding pre-oxygenation and the need for further research to determine what is the best practice to prevent atelectasis at the time of extubation, including the effect of ETS at extubation, the use of recruitment manoeuvres, PEEP or asking the patient to cough. Improving practice will prevent patients being exposed to unsafe and potentially harmful clinical practice. The pain and distress caused by ETS and experienced by the patient may be reduced by improving nurses' knowledge and awareness of how and when to safely perform ETS.

6.7 Chapter summary

The results from this study confirmed the ubiquity of ETS as an ICU nursing procedure, with patients receiving an average of eight suction interventions in a 24-hour period, and that for patients extubated during the study period, most received ETS as part of the extubation procedure. Discrepancies between clinical practice guidelines and clinical practice were identified in both this study and the CVICU practice survey described in Chapter 5 reinforcing the ongoing need for staff training and education. Although ETS is a frequent intervention, the experience of ETS in the CVICU patient population had never been described, leading to the Patient Experience of Endotracheal Suction Study (Chapter 7).

Chapter 7 : The Patient Experience of Endotracheal Suction. A Qualitative Study.

"I want to sing again" – study participant

Preface

Often the focus in ICU is upon the technical aspects of care, including airway management that includes endotracheal suction, managing mechanical ventilation, maintaining normal physiological parameters, and invasive monitoring. The point prevalence study confirmed the ubiquity of endotracheal suction practice across Australasia, however, ICU patients often inhabit a place between unconsciousness and consciousness, that can be challenging and distressing. This impaired cogitative state has been described as "*emerging from the twilight zone*" (Sawyer 1997) (45). In this state, experiences and perception, good or bad, can be enhanced. What follows is the Patient Experience of Endotracheal Suction Study (PETS), which explores the patient experience in more detail. Participation in this study provided patients with an opportunity to share their post-operative experience of the ETT and recovery. This qualitative study was not only an opportunity to assess the planned questions that would be used in the RCT but would provide information about patients who otherwise rapidly transition through intensive care.

The manuscript presented here was read and approved by all authors and has been accepted by Nursing in Critical Care.

See Appendix 4 for all supporting documents.

Patient's experiences of endotracheal tubes and suction following cardiac surgery

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Abstract

Aims and Objectives

This study aimed to describe the patient experience of the endotracheal tube and suction, following mechanical ventilation in post-operative cardiac surgical patients.

Background

There is a growing body of evidence addressing the patient experience of intensive care, including patient reports that the presence of an endotracheal tube is bothersome and distressing, and that endotracheal suction is moderately to extremely painful. Yet there remains little information about the patient experience of the endotracheal tube and suction in those patients receiving planned short-term mechanical ventilation.

Design

This qualitative study used inductive thematic analysis. Participants having planned cardiac surgery, anticipated to receive less than 12-hours mechanical ventilation were approached pre-operatively and written consent provided.

Methods

Ten participants were recruited using purposive sampling. Semi-structured interviews were conducted between days four and six post-operatively. One researcher interviewed all participants; two researchers independently read, coded, and agreed themes.

Findings

None of the participants recalled endotracheal suction, while half had no recollection of the endotracheal tube. Three themes were identified; the experience of the endotracheal tube and extubation, the experience of emerging from sedation, and participants concerns about the future. The presence of the endotracheal tube was described as bothersome, whilst breathing through the tube and extubation were described as 'weird' and 'strange' but not painful.

Conclusions

Knowledge of the patient experience can help inform nursing practice by improving pre and post-operative care planning.

Relevance to clinical practice

This study adds to the body of knowledge about the patient experience of the endotracheal tube and extubation.

Trial registration

Prospective registration with the Australian New Zealand Clinical Trials Registry. www.anzctr.org.au (ACTRN12616001515482).

7.1 Introduction

Post-operative recovery after cardiac surgery requires admission to an intensive care unit (ICU), (12) for a period of haemodynamic monitoring, mechanical ventilation (MV) and organ support until the patient is assessed as ready for extubation (12). To facilitate MV an endotracheal tube (ETT) is in situ. Airway management strategies include endotracheal suction (ETS) as required, (2,3,127) and minimising the duration of MV (28). This study explored the patient experience of the endotracheal tube and endotracheal suction.

7.2 Background

Tracheal intubation, although essential to maintain a patent airway during mechanical ventilation, has potential side effects, including tissue trauma resulting from inflammatory reactions within the airway, (341) sore throat and vocal cord injury (342). Up to 50% of patients have reported ETT associated sore throat, (342) contributory factors include ETT size, female gender, and ETT cuff pressure (343). Not being able to talk has been reported as ‘horrid’, (344) with communication difficulties adding to feelings of loneliness and isolation (37,345) and loss of control (346).

The presence of the ETT contributes to pain and discomfort, and has been reported as one of the primary causes of ETT related distress (347). Cardiac surgical patients have reported the ETT as bothersome, with discomfort reported in the throat and chest, (43) while 88% of general ICU patients receiving over 24-hours mechanical ventilation reported the ETT as moderately to extremely stressful (44). Although evidence suggests that endotracheal suction is painful and distressing, (36,43,44,337) there continues to be infrequent use of prophylactic analgesia prior to nociceptive procedures, including ETS (336–338). In an effort to improve pain management in ICU, behavioural pain assessment tools have been developed to facilitate pain assessment in those unable to self-report pain, (39,348) and are included in the current pain, analgesia, and delirium guidelines (349). Despite a growing body of evidence about ETS associated pain (44,350,351) there is limited data describing the patient experience of the ETT, ETS and associated pain in those exposed to planned, short-term MV.

7.3 Methods

Study aims

This study aimed to describe the patient experience of the ETT and ETS in those receiving planned, short-term MV. The research question was; what did participants recall about the ETT and ETS? Objectives included: interviewing participants post-operatively to explore their experience of the ETT and ETS, identify and describing themes to inform nursing practice.

The primary researcher, (EG) is an experienced ICU nurse, novice qualitative researcher and PhD candidate, working in the cardiothoracic surgical unit where the study took place. JS is an experienced qualitative researcher and independently reviewed the study protocol, interview questions and transcripts. EG and JS agreed the final themes.

Study design

A qualitative study using inductive thematic analysis (TA). TA is considered a core qualitative method, accessible for novice qualitative researchers, suitable for most small projects (for example 6-10 interview participants), and all sampling approaches (256).

Ten participants were interviewed between post-operative days four and six, using a semi-structured interview. No previous qualitative research had been conducted in our unit, and the sample size was considered sufficient to provide insight into the experience of the patient population while being manageable for a novice qualitative researcher.

Setting and participants

This study was conducted in a cardiothoracic and vascular surgical unit in a metropolitan, tertiary, teaching hospital in New Zealand. The unit undertakes approximately 1200 planned cardiac surgical cases per year. Purposive sampling ensured participants reflected the population of interest with participants screened and recruited from operating theatre lists. We screened patients who were listed for planned cardiac surgery, and anticipated to receive less than 12-hours post-operative MV. Surgery included coronary artery bypass grafting and cardiac valve repair or replacement. The study inclusion criteria were: age ≥16 years, planned cardiac surgery with cardiopulmonary bypass, anticipated extubation within 12 hours of admission to ICU. Patients were excluded if they did not speak English, were ventilated for more than 24-hours or were documented as having chronic pain.

Data collection

Interviews took place in March 2017, and were conducted in a side room on the cardiothoracic ward, at a time convenient to the participant. The side room provided privacy, avoided interruptions, and allowed participants to talk freely. Before the interview participants were reminded about the reasons for the study, and verbal consent was obtained to continue in the study. Family/whānau members were invited at the participant's request; none took up the offer. The interviews took between 10 and 30 minutes. Any non-study concerns raised by the participants were escalated immediately to the ward Charge Nurse.

The interview was recorded onto a Dictaphone and transcribed within a week using a professional transcription service.

The semi-structured interview focused on the experience of the ETT and ETS. Participants were asked:

1. Can you tell me about your experience of the breathing tube?
2. Can you tell me about your experience of having suction through the breathing tube?
3. Can you describe how it feels to breathe through the breathing tube?

If necessary, clarification questions were used (Table 1). Although patients were able to share their broader intensive care experience, the study had not intended to describe the intensive care and post-operative recovery experience. There were no repeat interviews; transcripts were not returned to participants. Data were de-identified and stored on a secure, password-protected computer system. De-identified transcripts were uploaded onto NVivo software (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 12, 2018).

Table 1: Clarifying questions

Clarifying questions will be used as required and will include
1. Were you awake during suction and can you describe what happened?
2. Can you describe how much control you thought you had while in intensive care?
3. Tell me how comfortable you were while in intensive care?
4. How would you describe your experience of the breathing tube?
5. How would describe the feeling of the breathing tube?
6. How much information were you given about the breathing tube?
7. How would you describe your experience of having suction?
8. How much information were you given about being suctioned?
9. How would you describe the feeling of having suction?

Data analysis

Data analysis was conducted using inductive thematic analysis, a qualitative method that provides flexibility (268). Braun and Clarke argue that TA "*can be a method that works both to reflect reality and to unpick or unravel the surface of 'reality'*" (pg. 81) (268). Given the limited evidence about the patient experience of the ETT and ETS in this patient cohort, and as recommended by Braun and Clarke, (268) the analysis aimed to reflect the themes identified from the complete data set. Inductive analysis aims to identify the themes linked to the data, (256) and as themes are data driven "*the themes may bear little relation to the specific questions that were asked of the participants*" (pg. 83). The findings describe participants reality, focusing upon how participants experience and make sense of their world (256). Unanticipated themes may become apparent during data coding; consequently, the research question may evolve and expand as themes are identified (268).

7.4 Trustworthiness and credibility

To minimise bias, EG was not involved in the recruitment of participants or providing any direct patient care, and had not met the participants before the interview. Researcher independence can prevent a perceived conflict of interest, allowing participants to talk freely about their experience, both positive and negative (352). EG is an experienced ICU nurse, and has seen both the benefits and apparent distress

resulting from ETS. Seeking understanding and insight into the patient experience of the ETT and ETS, in those receiving short-term MV was the catalyst for this research study.

To check the accuracy of transcription EG listened to the audio recording while reading the transcripts. As recommended, the first step of data analysis is coding the data (256,353). To ensure study rigour and trustworthiness, two of the investigators, EG and JS, independently reviewed and coded the transcripts. Although potential themes can either be identified in advance or derived directly from the data, (256) it was agreed to identify themes from the data. Both investigators discussed the themes arising from the codes and agreed on the findings.

7.5 Ethics

Full ethics approval (16/STH/159), and local approval was in place before commencing the study. All participants provided written informed consent pre-operatively, consent was obtained by trained research nurses.

7.6 Findings

Findings are reported following the Consolidated Criteria for Reporting Qualitative Research.(352) In total 21 patients were screened, two consented participants received over 24-hours MV and were not interviewed. Ten participants were interviewed, eight male, two female, one New Zealand Māori, nine New Zealand European. The main reason for declining to participate in the study was pre-operative anxiety. Participant baseline demographics are described in Table 2, and reflect the local cardiac surgical population (26). The median duration of MV was 6.3 hours (range 4.1 - 17.4) and the median intensive care length of stay was 24.5 hours (range 17–72 hours). None of the participants recalled ETS, while half had no recollection of the ETT.

Table 2: Participant baseline characteristics

Baseline characteristics	
Age, mean (years, range)	64.1 (26-84)
Male sex, *n* (%)	8 (80)
Weight, (kg) mean (range)	84.4 (63-147)
Ethnicity, *n* (%)	
NZ European	9 (90)
NZ Maori	1 (10)
EuroSCORE II, median (range)	1.13 (0.50 – 3.29)
Co-Morbidities	
Recent MI, *n* (%)	3 (30%)
IHD, n (%)	5 (50%)
Current smoker, *n* (%)	2 (20%)
Type of surgery, *n* (%)	
CABG	6 (60)
Single valve	2 (20)
Valve and CABG	1 (10)
Multiple valve	1 (10)
Duration of mechanical ventilation (hours), median (range)	6.34 (4.1 – 17.4)
Length of ICU stay (hours), median (range)	24.5 (17-72)

ICU, Intensive Care Unit; CABG, Coronary Artery Bypass Graft; EuroSCORE, European System for Cardiac Operative Risk Evaluation; mg, milligram; mcg, microgram; MI, myocardial infarction; IHD, Ischaemic heart disease; kg, kilograms; ETS, endotracheal suction.

On average, participants received two suction episodes (range 0-5). We identified three main themes; experience of the ETT, emerging from the fog, and anxiety and concerns (Figure 1). Sub-themes included participants concerns about their family, lifestyle choices, the slow passage of time, the effect of drugs, and the challenges of recovery. Although two of the main themes are not related to the ETT, as previously described, TA allows the research question to expand during data analysis.

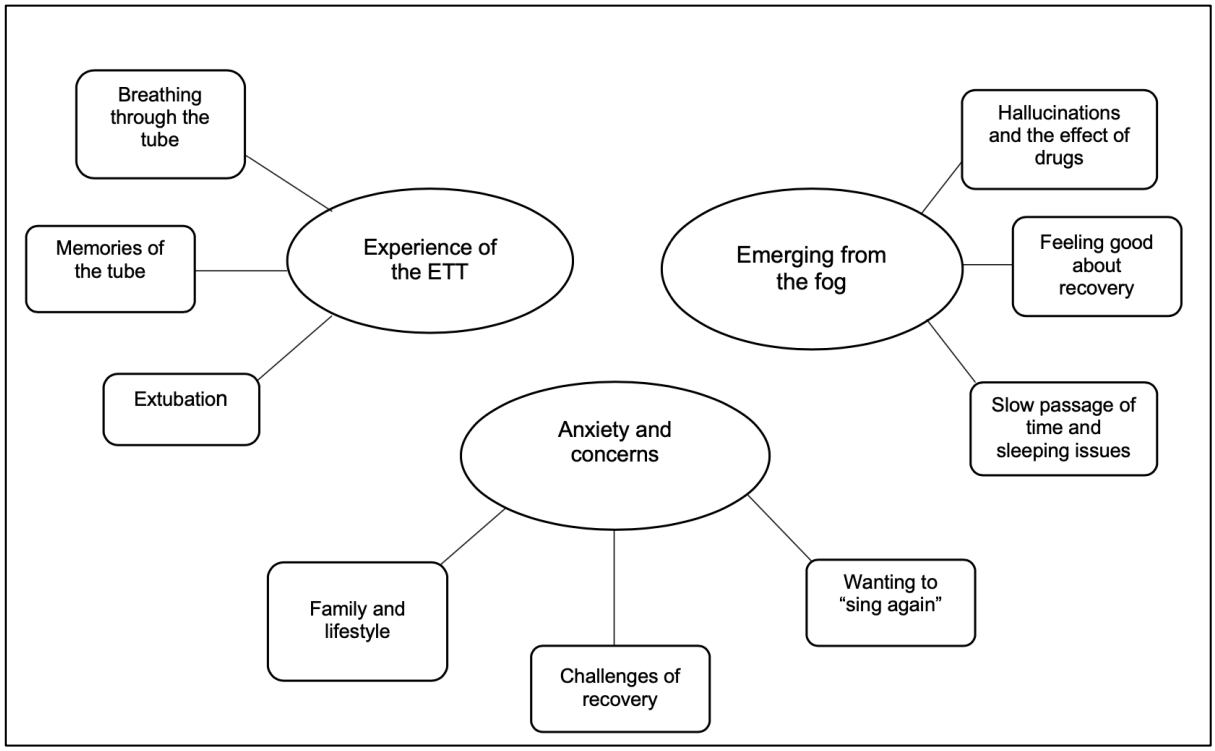

Figure 1: Themes and sub-themes.

7.6.1 Experience of the ETT.

Participants provided examples of their experience of the ETT, including memories of the ETT, breathing through the ETT and extubation.

Memories of the ETT

Five patients remembered the ETT; none reported it as painful. It was described as "*A little bit of pressure on the throat*" (P2) and causing a "*scratchy throat*" (P5) while one participant described it as "*a pretty weird experience"* (P4). Three participants described the effect of the ETT upon their throat and lips. Memories varied and ranged from vague personal recall, "*I think I noticed it on the lip; a bit numb on the lip"* (P8) to relying upon what they had been told by others, "*something about my big lip"* (P7). This participant went on to say he hadn't seen his lip and that he didn't know what they were talking about. One female participant described how she felt her tongue was thick, *"My tongue and my mouth was very bruised, and it was thick and I couldn't talk."* (P9). She did not report a sore throat and had no recollection of the ETT. Potentially, this memory could be related to tracheal intubation, although this is unclear. Unlike other studies, where movement of the ETT was described as adding to ETT discomfort (43), no participants in our study described movement of the ETT.

Breathing through the ETT

Three participants recalled breathing through the ETT. Two did not find it stressful, saying, "*I didn't have any particular problems breathing through the tube"* (P1) "*I seemed to be breathing easily*" (P5). The third participant recalled being panicky, biting the tube, trying to pull the tube out and being re-sedated, saying *"I couldn't breathe sort of thing…. I was like kicking the bed and; **** - pull this thing out."* He described breathing through the ETT "*like diving on 10 Barr when you know you shouldn't be diving*" and *"like sucking through a straw"* (P4).

Extubation

Five participants recalled extubation, two describing how the nurses talked them through the procedure, one participant recalled "*when I was waking up somebody was talking to me. It [the ETT] was there, they were going to remove it, and I felt it come out."* (P2). This participant described extubation as "*a bit of a weird sensation.*" None described extubation as painful or distressing, descriptions included "*it was a strange sensation*" (P1) but that "*they did it gently*" (P8).

Preparation for extubation was clearly described by participant number five saying,

> "*when I came round they said to me you've got a breathing tube in...that was the ICU nurse…then she told me this is what's going to happen...it went like clockwork."* (P5).

7.6.2 Emerging from the fog.

Memories of waking up included panic due to the presence of the ETT (P4), being aware of coming round (P5), and "*feeling damned happy that I woke up*" (P12). Six participants described the effects of the drugs, one saying, "*I asked them to stop giving me the thing through the IV line, because it was making me dopey as. Yeah I didn't like it*." (P4), others saying "*I was so doped up on drugs...it's all a blur to me"* (P1) and "*your brain sort of shuts things down*" (P7). Two participants described hallucinations; descriptions included "*they were giving me bad dreams and stuff*" (P11), and

> "*if I close my eyes, I look at a wall I see the architectural surface with patterns on it, maybe blue or pink…floating round over the wall…with curved corners rather than sharp corners…sometimes I have tried to keep my eyes open so that I don't have sleep and have those hallucinations*" (P1).

Recovery was associated with feeling good about being able to walk around, "*walking around is pretty sweet*" (P4), and *"I can walk around the ward, so I think I'm on the mend*" (P1). Feelings of progress were tempered by the tiredness of early recovery, one participant commenting that day one was "*not as complex or painful as day two and three…those were really heavy*" (P5), while another said, "*I've got more pain now that I'm more conscious*" (P1). One participant felt "*marvellous*", but also commented, "*you feel knackered for sure*" (P12).

7.6.3 Anxiety and concerns

Participants described anxieties and concerns about cardiac surgery, both pre-operative fears, and worries and concerns about their future. One participant said her main concern pre-operatively was about

the ETT and the possibility that she may not be able to sing again. She recalled, "*I remember asking the anaesthetist to be very careful….my throat's quite narrow*" (P9). The youngest participant said he became very frightened after reading the patient information literature. He had stopped smoking three weeks before surgery, then read the recommendation to stop six months before surgery. He said he did not know an ETT would be in place when he woke up. However, he recognised that the drugs he had received may have affected his recall,

> "*if they told me, oh you're going to have a tube in there, so when you wake up don't stress out - or something like that, but yeah because I was on drugs and shit, they might have – [I] might not have even remembered everything they said*" (P4).

Participants described their concerns about the future, including wanting to see their family grow up and making lifestyle changes that would have a positive impact upon their health in the future. At this stage, participants appeared keen to adopt and maintain healthy lifestyle changes.

7.7 Discussion

Although this study intended to focus upon the participant's experience of the ETT and ETS, inductive thematic analysis identified additional information that included participants pre-operative concerns, the experience of early post-operative recovery following cardiac surgery, and concerns about the future. An early study, conducted in 1979, investigated cardiac surgical patient's experience of intubation, and interviewed 100 patients on post-operative day five or six (354). At that time, usual post-operative management included benzodiazepines for both anaesthesia and sedation, while weaning from MV did not start until the following day. Five participants remembered the ETT, describing it as difficult to tolerate, while two mentioned ETS and sore throat. Benzodiazepines all result in some degree of amnesia, (349) these results suggest that sedation agents, sedation levels and duration of MV may influence patient recall. Post-operative management of cardiac surgical patients has changed over time; short-acting sedation is in common use, with the aim of extubating patients within six hours of admission to intensive care (12). In our study, the median duration of MV was 6.3 hours and all participants received short-acting sedation. That 50% of the participants in our study recalled the ETT may be reflective of changes in sedation practice, and suggests that while some studies have excluded those who were intubated for less than six hours, (43) more of this patient cohort may remember the ETT than previously anticipated. Our findings are similar to those reported by others in a similar patient population, (337) where 52% of patients remembered the ETT. Despite evidence that those exposed to a longer duration of MV have increased recall, (35) it remains unclear to what extent the duration of MV, and amount of sedation and analgesia, affected participants recall in our study.

Unlike others who have reported the presence of an ETT as a negative experience, (43) including that the ETT was moderately to extremely bothersome, (35,355,356) only one participant in our study described the ETT as causing feelings of panic, resulting in difficulty breathing. Our findings are similar to others who have reported that up to 80% of participants had no trouble breathing through the ETT, (44) and that the ETT was bothersome rather than painful (37). No participants in our study reported a sore throat or hoarse voice, although one described pressure in his throat. This is in contrast to findings in those who received over 24-hours MV, where 40% remembered ETT associated discomfort,

describing sore throat, hoarseness and communication difficulties contributing to ETT related discomfort. (44) The short duration of MV and small sample size may have influenced our findings.

It was surprising that none of the participants in our study recalled ETS as this has been reported as a painful nociceptive ICU intervention (36,337,338,357). Our findings differ from others (358) who reported that in a similar population, 6.5% of patients recalled receiving ETS, although participants had a longer mean duration of MV (9.5 hours) and the study had a larger sample size. In our study two participants did not receive ETS, the duration of MV was 6.3 hours, and standard care in our unit is suction 'as required', all potentially affecting participant recall.

Post-operative ICU management following cardiac surgery is complex (359) and remains a challenge due to the use of sedation and analgesia, and communication difficulties due to the presence of the ETT. Participants in our study described the effects of analgesia making them feel dopey, two participants described hallucinations. One tried to avoid going to sleep, and another asked to have intravenous analgesia stopped. Hallucinations have been well described by others, (347,355,360) and have been reported as the second most frequent source of ICU discomfort reported by patients, (347) and can be exacerbated by poor pain management, for example when the dose of analgesia is too high, in turn affecting the sleep cycle (355). Participants in our study had what was considered an uncomplicated post-operative recovery, and these findings confirm the complexity and challenges of post-operative management and recovery. Effective analgesia, mobilisation, and maintaining a day night routine reduce the incidence of hallucinations and delirium (349). Increasing nursing staff awareness about the effects of analgesia, the presence of hallucinations, benefits of mobilisation, and optimising the patient environment to support sleep and rest, if included in post-operative care planning, have the potential to enhance patients post-operative recovery.

Currently, there is very little literature about the patient experience of extubation, and our findings differ from others who have reported that 41% of participants remembered extubation as moderately to extremely bothersome (44). None of the participants in our study reported extubation as distressing, rather describing the procedure as weird and strange. Further research describing the experience of extubation would help address this gap in the literature. Some participants recalled being spoken to during extubation, with the nurse describing the procedure in advance. Given the evidence about patients' feelings of isolation and loneliness, (37) the descriptions of nursing staff talking to participants during extubation highlighted the positive effect nurses can have upon a patient's experience. Nurses being present and engaged increases patients feelings of being safe, respected and treated as a person. (360,361) However it should be acknowledged that nurses do not always deliver compassionate care, and that this can increase patients feelings of stress and anxiety (44,355,356,361). Nursing interventions and management in ICU is complex and varied, (362) however, nurses are well placed to improve patient's experience while in ICU. Understanding and awareness of the patient experience can help inform and improve nursing practice.

The effect of time upon recall and memory of the ICU experience remains unclear. Others have reported that memories of ICU include the presence of the ETT, hallucinations, and pain, (363) and can have an effect upon quality of life (364). ICU patients have been shown to have lower scores for factual recollection when compared to a reference group (347). In health, memories may not be recalled in

detail, details are reconstructed rather than remembered, with both pleasant and unpleasant emotions fading over time (365). Puntillo et al (363) interviewed participants between three and 16 months after ICU discharge, and found that those who were interviewed closer to ICU discharge recalled lower procedural pain intensity when compared to those interviewed later. Unlike our study, the participants had a median ICU length of stay of seven days. Others have interviewed participants between 24-hours and six months after ICU discharge (43,361,366,367). Although half the participants in our study had no recollection of the ETT, and none recalled ETS, these findings highlight the complexity of memory and recall in the ICU population. Follow-up interviews after hospital discharge could elucidate this further, and should be considered for future research.

These findings have implications for patient education as cardiac surgery is a stressful event for many patients. Anxiety may affect the patient's ability to focus upon the information they receive. As seen in this study, one participant reported being unaware that an ETT would be in place when waking up in ICU, although he had given pre-operative consent to participate in the study, and the information sheet described both the ETT and ETS. Checking the patient's understanding of pre-operative and post-operative information is essential, as is asking the patient about their main concerns, for example, the main concern for one participant was being able to sing again following intubation. Unexpectedly, the findings also revealed the participant's experience of intensive care and early recovery, and although not directly addressing the research question, have been included as these findings appear important to the participants, and relevant for nursing. As previously discussed, when using TA, the findings may digress from the research question (256,259). Raising awareness of these experiences can be useful for clinicians, knowledge of early post-operative recovery following cardiac surgery, including the patient's experience of the ETT, extubation, ICU, hallucinations and early days on the ward, can inform nursing practice. Understanding patients concerns can help staff provide patient-centred information, delivering appropriate support and education for patients whilst in hospital, and facilitate suitable discharge planning.

7.8 Limitations

This study has some limitations that need to be acknowledged. First, the small sample size may limit the applicability of the findings. That being said, the results are similar to other studies with larger sample sizes, and a similar patient population, that reported half the participants have no recollection of ICU (44,337). Second, the effect of recall bias is unknown, and it remains unclear when is the most appropriate time to interview patients post-operatively (363). Interviewing participants has to accommodate the stage of post-operative recovery and avoid tiring participants. Interviewing participants after hospital discharge may lead to recall being influenced by family descriptions of ICU and thus not reflect the participant's own experience. Advantages of pre-discharge interviews include minimising loss to follow up, and participants having recent recall about ICU.

The brevity of the interviews may be considered a limitation; however, the interview aimed to elicit the patient experience without exhausting participants during their early recovery. The findings provided additional insight into the experience of early recovery, and for trustworthiness, these themes have been included.

Implications for clinical practice

This patient cohort is underrepresented in the literature. Care planning should include assessing patients' understanding of pre-operative information, post-operative pain management, and how to support patients making healthy lifestyle changes. The findings reinforce the importance of good communication, and provide insight for all nurses working with cardiac surgical patients, both in ICU and on the ward.

7.9 Conclusions

At present there is limited data about the patient experience of the ETT and ETS in those receiving short-term MV, this study updates the evidence and provides new data about the experience of extubation. The findings report the challenges and anxieties faced by post-operative cardiac surgical patients, and the positive influence nurses can have upon the patient's recovery.

Chapter 8 : Study protocol: A randomised controlled trial assessing the avoidance of endotracheal suction in cardiac surgical patients ventilated for ≤ 12 hr.

Preface

The systematic review presented in Chapter 3 confirmed the absence of relevant evidence about avoiding ETS in the adult human population. The results signalled that minimising ETS might not be detrimental and provided the hypothesis for this randomised controlled trial, the Avoidance of Routine Endotracheal Suction Study (ARETS). This chapter presents the protocol for the planned RCT as published in the Journal of Advanced Nursing. As active avoidance of ETS has not previously been investigated the ARETS study was an opportunity to address this gap in the literature. The study was a non-inferiority randomised controlled trial. The population of interest were a low risk cardiac surgical population, expected to be extubated within 12-hours of admission to CVICU. The focus of the study was upon safety outcomes, including airway complications and oxygenation. If the study outcome confirmed non-inferiority in this patient cohort, there was the potential to change clinical practice.

The manuscript presented here was read and approved by all authors.

See Appendix 5 for all supporting documents.

Study protocol: A randomised controlled trial assessing the avoidance of endotracheal suction in cardiac surgical patients ventilated for ≤12 hours.

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Abstract

Aim

This study aims to assess the safety and efficacy of avoiding endotracheal suction in post-operative cardiac surgical patients mechanically ventilated for ≤12 hours.

Design

A prospective, single centre, single blind, non-inferiority, randomised controlled trial evaluating the safety and efficacy of avoiding suction in uncomplicated, post-operative, adult cardiac surgical patients mechanically ventilated for ≤12 hours.

Methods

Randomisation will be performed upon return to intensive care (ICU) with allocation to either usual post-operative care including suction or to usual care with no suction (intervention arm). The primary outcome is the ratio of partial pressure of oxygen (PaO_2) to fraction of inspired oxygen (FiO_2) (P/F) 6 hours after extubation. Pain assessments will be performed before, during and after endotracheal suction (ETS) and the patient experience will be investigated with a brief interview the following day. Ethics approval was received in October 2015.

Discussion

ETS is performed as part of airway management but has potential complications and there is little robust evidence to guide practice. This study will add to the evidence base about the need and benefit of endotracheal suction in this patient cohort.

Impact

As there is currently no published evidence about the safety of avoiding endotracheal suction. This study will provide the first evidence about avoidance of endotracheal suction in patients ventilated for less than 1 day. If non-inferior, the results have the capacity to change nursing practice by avoiding a potentially unnecessary procedure, it will build upon the body of knowledge about the patient experience.

Key Words: airway management; cardiac surgery; endotracheal suction; intensive care; safety; randomised controlled trial; nursing; patient experience.

8.1 Introduction

Cardiovascular disease continues to be a leading cause of death, both globally (15,368) and within New Zealand, (369) with cardiac surgery one of the most frequent major surgeries performed (23,27). Post-operative care in New Zealand requires admission to an Intensive Care Unit (ICU) for cardiovascular monitoring, haemodynamic management, analgesia and a period of sedation and mechanical ventilation (MV) until the patient is stable and ready to de-sedate. MV requires the use of an endotracheal tube (ETT) to maintain the patient's airway until the patient is deemed ready for extubation. Both cardiac surgery and MV can contribute to atelectasis (12,370,371). MV and the ETT may contribute to other complications such as inflammatory lung injury, infection, pneumothorax and an inflammatory response to the ETT (82,342). The aim following cardiac surgery is to extubate the patient as soon as possible once they are cardiovascularly stable, usually within 3 - 6 hours of admission to ICU (12).

8.2 Background

The presence of an ETT prevents the patient being able to cough and clear secretions normally therefore endotracheal suction (ETS) may be performed as part of airway management. ETS consists of a suction catheter being inserted into the ETT, application of negative pressure and removal of secretions. ETS may also help reduce biofilm accumulation within the ETT so maintaining patency of the ETT and pulmonary hygiene (372). ETS may require disconnection from the ventilator with subsequent loss of positive pressure, reduction in oxygenation and that affects ventilation thus potentially increasing the risk of hypoxia, atelectasis and risk of infection, while the application of suction potentially contributes to tissue trauma, hypertension and cardiovascular instability (3,30,31,373). ETS can cause pain and distress to the patient (36,374,375). A recent survey of current practice in the unit identified that the majority of nurses (84%) perform ETS at the time of extubation and that this is similar to previously described practice (276,328,376).

Although clinical practice guidelines (CPG) for endotracheal suctioning of mechanically ventilated patients have been developed by the American Association of Respiratory Care, (2) they are acknowledged to be based upon low grade evidence, (33) and are frequently not implemented in clinical practice (130,131). CPGs recommend that ETS should be provided "as required", (2) however, there is no specific recommendation to guide practice for patients who are ventilated for short periods of time, i.e. ≤24 hours. Although the most common practices at extubation are asking the patient to cough and suctioning the ETT at/during extubation, (328,329,376,377) ETS at extubation can increase the risk of atelectasis, in turn contributing to hypoxia (378,379). There is contradictory evidence about the benefit of a positive pressure breath or recruitment manoeuvres at the time of extubation (290,329,330).

Given the known potential complications associated with ETS, (30,109) the pain and distress experienced by patients, (380) and the lack of robust data to guide practice, the avoidance of ETS may be desirable in patient cohorts with a planned short duration of mechanical ventilation and this warrants investigation. If non-inferiority is demonstrated then this study has relevance for cardiothoracic nursing

practice internationally providing an opportunity to review current practice for this patient cohort and avoid a potentially unnecessary procedure.

8.3 The Study

Aim

This study aims to assess the safety and efficacy of avoiding ETS in post-operative cardiac surgical patients mechanically ventilated for ≤12 hours. We hypothesise that avoiding ETS in patients mechanically ventilated for ≤12 hours following cardiac surgery will result in a maximum difference of PaO_2/FiO_2 (P/F) ratio of 10% or less compared to usual post-operative care that includes ETS 6 hours after extubation.

Design

A single centre, prospective, single-blinded, parallel groups, non-inferiority randomised controlled trial (RCT).

Participants

The study will be conducted in a Cardiothoracic and Vascular intensive care unit (CVICU) in a metropolitan tertiary centre teaching hospital that performs approximately 1200 cardiac surgical cases per year.

Participants will be screened and seen pre-operatively by experienced research nurses and given the opportunity to participate in the study. Written informed consent will be obtained. Inclusion criteria: age ≥16 years; having cardiac surgery with cardiopulmonary bypass; expected to be ventilated for ≤12 hours. Exclusion criteria: previously documented difficult intubation; non-English speaking; clinician preference for the patient to receive ETS.

Participants will be re-screened on admission to ICU by either the research nurses or the clinical nurse coordinator on duty, and a decision made on the likely duration of MV. Participants who are anticipated to receive MV for ≤12 hours will be randomised and those anticipated receiving >12 hours of MV will be excluded. Participants who are randomised but subsequently have >12 hours MV will revert to usual care 12 hours after admission to ICU.

Intervention

Patients who are randomised to the study intervention will receive standard post-operative care as described below apart from ETS. Suction will be avoided including at the time of extubation unless specific conditions are met. The patient may have oral suction as part of usual care. For patient safety, ETS will be allowed only in the following circumstances.

- Oxygen desaturation (SpO2 <90%).
- Deteriorating arterial blood gases (PaO_2 8kPa/60mmHg or below).
- Reduced air entry on auscultation.
- On medical request.

Usual care

On admission to ICU, the patient will have an ETT in situ and receive MV. Airway management includes monitoring of arterial blood gases (ABGs), SpO_2 and end tidal CO_2, as well as providing ETS as required, including at extubation.

Background standard care for all participants.

Usual post-operative care includes warming the patient to 36.8°C, monitoring cardiovascular status, managing the patient's airway and ventilation, monitoring urine output, mediastinal and pleural drainage and providing analgesia. Patients are mechanically ventilated while warming and are sedated using a propofol infusion to achieve the prescribed sedation level. Oral suction is provided as part of oral hygiene whenever necessary. Once the patients are considered cardiovascularly stable, sedation is discontinued and the patient is allowed to wake. Once awake and assessed as suitable for extubation the patient is extubated onto standard oxygen therapy, either nasal prongs or simple face mask. Supplemental oxygen delivery is provided to achieve peripheral oxygen saturations (SpO_2) of 94-98%.

Blinding

The participant will be blinded to the intervention as they will be unconscious; however, blinding the clinical staff is not possible, as bedside staff will need to know the participant allocation.

8.4 Outcomes

Primary outcome

The primary outcome is the PaO_2/FiO_2 (P/F) ratio 6 hours after extubation and the non-inferiority margin is a maximum of 10% worse P/F ratio in favour of usual care. The primary outcome was agreed following discussion with senior medical staff on the CVICU and based upon clinical experience and expertise. To the best of our knowledge, this is the first time a study avoiding ETS has been undertaken and there was no previous data to guide the decision-making. This cohort of patients are anticipated to have ventilation duration of <12 hours from admission to ICU, minimal co-morbidities and will be mobilised and transferred to the ward the following day. We anticipated that any respiratory complications following extubation would manifest within 6 hours of extubation.

Calculating an accurate P/F ratio in non-ventilated patients can be difficult due to challenges in measuring FiO_2, predominantly due to variable entrainment of room air in patients receiving supplemental oxygen via low-flow devices.

To mitigate this, we will do the following;

1. Participants receiving low flow supplemental oxygen (4 L/min or less) via nasal cannulae or simple facemask will be placed on room air for 5 minutes then an ABG taken. If the participants SpO_2 (measured with a pulse oximeter) drops below 90% during that 5 minutes they will be placed on high flow oxygen therapy (HFOT) at 50 L/min and the minimum FiO_2 required to achieve a $SpO_2 \geq 90\%$. An ABG will be taken after 5 minutes.

2. Participants receiving oxygen > 4 L/min and with a SpO_2 <90% will be commenced on HFOT at 50 L/min and the minimum FiO_2 required to achieve a SpO_2 ≥ 90%. An ABG will be taken after 5 minutes. The patient will then be recommenced on the supplemental oxygen being received prior to the HFOT, discussion with the medical staff is recommended for any patients in this group to review their oxygen therapy requirements.

3. Participants who are on HFOT or non-invasive ventilation 6 hours post-extubation will have an ABG taken on their existing device.

A flow chart (Figure 1) has been provided to guide the bedside nurse undertaking collection of the ABG to be used for assessment of the primary outcome.

Secondary outcomes

Pain assessments will be collected for all participants as described below and the remaining secondary outcomes are listed in Table 1.

Table 1: Secondary Outcomes

Secondary outcomes	
1	Requirement for escalation to HFOT for the six hours post-extubation
2	Complications of extubation; defined as laryngeal spasm, vomiting, aspiration, oxygen de-saturation (SpO_2 <90%), up to 30 minutes after extubation
3	Requirement for escalation of oxygen therapy in the first six hours after extubation
4	Oxygen saturation SpO_2 <90% in the first six hours after extubation
5	Tachycardiac (>100 bpm) in the first six hours after extubation
6	Increased mean arterial pressure (>85 mmHg) in the first six hours after extubation
7	Re-intubation rates

Pain assessment - all participants

Pain will be assessed for all participants receiving ETS, regardless of group assignment. Both the critical care pain observation tool (CPOT), (336,381,382) and a numerical rating scale will be used to assess pain prior to, during and 10 minutes following ETS. CPOT assessments will be performed when the participant has a Richmond Agitation and Sedation Score (RASS) (110) of -3 to +1 and again when the participant has a RASS of 0, but prior to extubation. As the gold standard for pain assessment remains the patient-reported pain score (383,384) a numerical rating scale will be used to assess pain when the participant is awake, but prior to extubation. A numerical rating scale will be estimated and recorded by the bedside nurse prior to the participant reporting his/her score and before, during and after a suction episode as described above. The nurse will document their estimated numerical rating scale prior to asking the participant their numerical rating scale as the evidence identifies a difference between the nurses and patients pain scores (385,386).

Sample size

Based upon previous work done in the same unit with a similar patient population (371) in a sample of 130 participants receiving supplemental oxygen four hours post-extubation, the mean P/F ratio was 301 (SD 83.9). As there is no available data for patients without supplemental oxygen, this data was used to

estimate the sample size and for power calculations. The G Power sample size calculator (173) was used for sample size calculation.

The International Council for Harmonisation (IHC) provides guidelines for the conduct of clinical trials, including selecting a non-inferiority margin. The guidelines state that "the determination of the margin in a non-inferiority trial is based on both statistical reasoning and clinical judgment, should reflect uncertainties in the evidence on which the choice is based, and should be suitably conservative" (387). Therefore, in consultation with the senior medical staff on ICU and an independent statistician, and using the available data and clinical expertise within the group, a non-inferiority margin of 10% was considered clinically acceptable for the P/F ratio agreed as the primary outcome. An estimated total sample size of 170 patients achieving the primary outcome will provide 80% power, with a confidence interval of 95% assuming an α of 0.05. Recruitment will continue until 170 participants have met the primary outcome. It is not anticipated that there will be any loss to follow up for the 170 participants achieving the primary outcome, as all the data will be collected prior to the participants leaving ICU.

Assignment of intervention

Sequence generation and randomisation

Computer-generated random numbers, generated by an independent statistician, will be used for group allocation with blocks of eight ensuring an equal number of participants in each arm. Allocation concealment will be maintained with the use of opaque, sealed, sequentially numbered envelopes. Non-study personnel will be used to prepare the study envelopes. Each envelope will contain a slip of paper, folded once, with the group allocation and the unique study number allocated to each participant. The research nurse or clinical nurse coordinator on duty will perform randomisation.

Data collection

Data will be collected by trained research nurses and entered into an electronic database (Research Electronic Data Capture (REDcap) – Vanderbilt University, Tennessee (388). Data will be collected on all randomised participants, those who receive >12 hours MV will have all demographic and physiology data, pain scores and ABG data collected for the first 12 hours following admission. Reasons for prolonged MV will be collected, as will reasons for exclusion for those not randomised at the secondary screening.

Post randomisation data collected will be, date and time of intubation and extubation; ICU admission and discharge date and time; all ABG's from time of ICU admission through to extubation and for the mandated post-extubation ABG's, at 2, 4- and 6-hours post-extubation. ABG data will be PaO_2; $PaCO_2$; SaO_2; base excess; lactate; in addition to SpO_2 and FiO_2. There will be two ABG's recorded 6 hours post-extubation, one while the participants are receiving supplemental oxygen and one when the participant is on room air (Figure 1). For patients who are receiving HFOT the 6-hour post-extubation ABG will be performed on HFOT, no room air ABG will be performed (Figure 1).

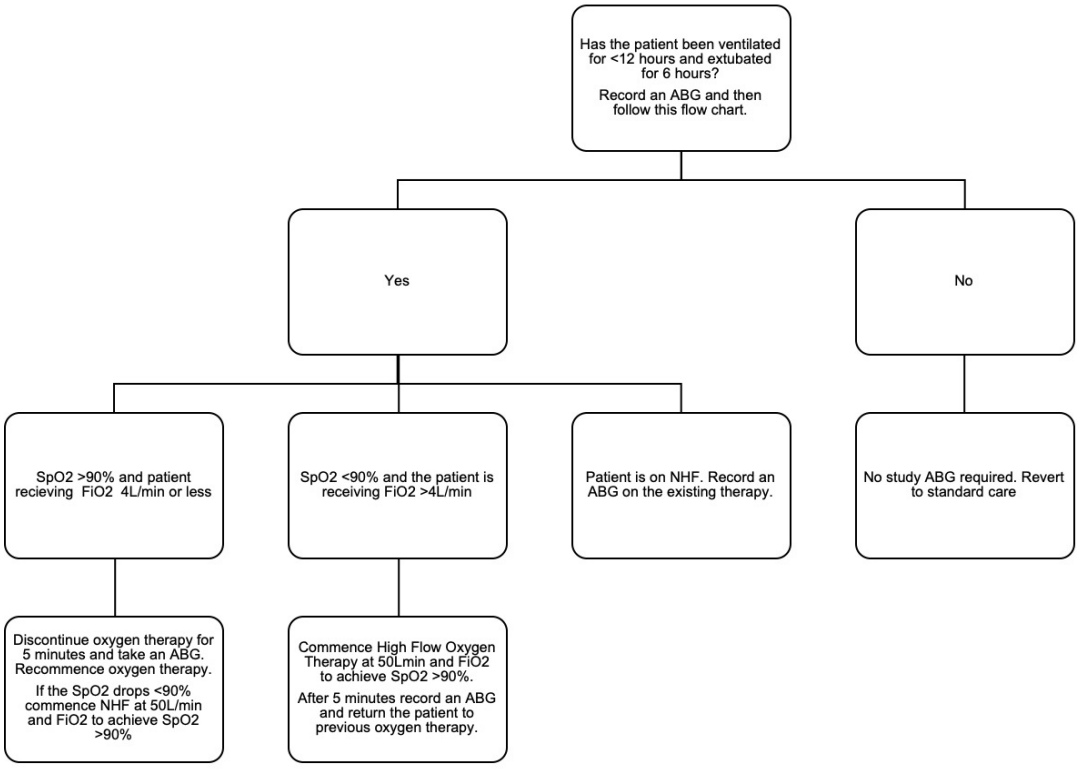

Figure 1: Flow chart for the primary outcome ABG 6 hours post-extubation

Physiology data (heart rate, respiratory rate and MAP) will be collected hourly from ICU admission through to 6 hours post-extubation. Secondary outcome data previously described will be collected.

Pain assessment data will be recorded by the bedside nurse on a paper case report form before, during and 10 minutes following ETS both when the patient is sedated with a RASS score of -3 to +1 and when awake with a RASS score of 0. All randomised participants will have a brief scripted interview about their experience of the ETT and ETS (for those who receive ETS); this will be conducted the day after surgery.

The numerical rating scale will be used for the interview and participants will be asked to rate pain from the ETT and ETS from 0 - 10, with 0 = no pain and 10 = the worst pain imaginable.

Participants will be asked:

1.Do you recall having the breathing tube in place while you were in Intensive Care?

2.If yes how painful was the tube?

Participants who received ETS will also be asked:

1.Do you recall having the breathing tube suctioned while in Intensive Care?

2.If yes how painful was suctioning?

This study provides an opportunity to explore the patient experience of both the ETT and ETS. The interview is designed to be brief, as it will be conducted the day after surgery. This may offer the best opportunity for the participants to recall their experience, but it is not appropriate to burden them with

multiple questions at this time. An unpublished qualitative study undertaken by the investigators prior to commencement of this RCT tested the study interview tool.

Data management

The REDCap platform will be used for data collection; the Medical Research Institute of New Zealand (MRINZ) will host this. Participants will have a unique identifier with all outcome data being de-identified; auto-validation will be used to help maintain data quality. All other data e.g. consent forms and source documents will be stored securely and source documents will be held on the secure hospital server. Data will be stored for 10 years before secure destruction.

Statistical analysis

Data will be extracted into IBM SPSS Statistics (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY:IBM Corp.) for analysis with demographic, safety and baseline data summarised by treatment groups. Descriptive statistics will be used for those participants who are ventilated for > 12 hours, and all data will be tested for normality. Analysis of non-inferiority trial data and conclusions drawn are sensitive to the method of analysis (389,390). Convention for superiority trials is an intention to treat analysis regardless of whether the participant received the intervention. For non-inferiority studies, this has the potential to bias towards non-inferiority, (390) in particular if there is significant cross-over between groups. It is recommended that per-protocol analysis is performed in addition to intention to treat analysis for non-inferiority studies, (389–391) as this analysis excludes those participants who have major protocol deviations, however, this may also contribute to bias as there may be differences in those who complete the protocol and those who do not (392). Given these challenges, the data will be analysed with both intention to treat and per-protocol analysis, with per-protocol being the primary analysis. The literature suggests conclusions of non-inferiority should only be drawn if both analyses lead to similar conclusions (389–391).

Data will be tested for normality and the primary outcome will be analysed using student t-tests with mean and standard deviation presented in treatment group tables, while categorical data will be analysed using Mann-Whitney test. To account for any ABGs being performed outside of the 6-hour time frame a sensitivity analysis will be performed excluding those who had ABG's performed outside of the study protocol. Baseline variables will be assessed and if imbalances are present an adjusted analysis will be performed using analysis of covariance (ANCOVA).

Data Safety & monitoring

For patient safety, a data safety monitoring committee (DSMC) has been formed consisting of a senior intensive care researcher not working in the study unit (Chair), a biostatistician, and an independent medical researcher. An unblinded interim safety analysis will be provided once 50 and 100 participants have been randomised. The principal investigator will notify the DSMC of any serious adverse events within 24 hours. A trained clinical trials monitor will independently monitor the study. There will be 100% monitoring of consent and primary outcome.

Ethics

Ethics approval has been obtained from the New Zealand Health and Disability Ethics Committee (15/NTB/138) in October 2015 with prospective registration on the Australian and New Zealand Clinical Trials Registry (ACTRN12615000897561) and the World Health Organisation International Clinical Trials Registry Platform (www.who.int/ictrp/en/). Any protocol amendments will be approved by ethics prior to implementation. Recruitment started in May 2017 and the study is anticipated to complete recruitment in December 2018.

Validity and reliability

The inclusion and exclusion criteria, together with random allocation and the use of a control group help to ensure internal validity. The non-inferiority margin has been discussed and agreed with the senior medical team in the ICU and is based upon clinical practice and expert knowledge as recommended by D'Agostino et al. (389) and has been agreed as appropriate for this cohort. The CPOT pain assessment tool is a validated tool, (393,394) and all the staff performing the pain assessments will have appropriate training.

8.5 Discussion

To ensure protocol adherence staff training will be provided prior to starting the study and will include education about the protocol and pain assessment tools. On-going one to one teaching will be provided while the study is running for new and returning staff with the aim of achieving adherence to the study protocol and intervention. This will ensure bedside nurses are familiar with the study, the rationale for the intervention and required bedside data collection. The study mandated post-extubation ABG's will be performed by bedside staff. To facilitate the primary outcome data collection study tools and aide-memoire will be left at participant's bedside. The research team will contact the bedside nurse to ensure that study handover has been received, in addition, the Clinical Nurse Coordinator on duty will be notified of any study patients. As the participant will have secondary screening on admission it CVICU, the research nurses will liaise closely with the shift coordinator to facilitate randomisation of participants if the research nurses are unavailable.

8.6 Limitations

This is a single study centre and although this may limit the generalisability of the findings for some patient populations, we consider that there will be generalisability among the cardiac population in a publicly funded health service, our practice may differ from privately funded health care. As this intervention has not been previously investigated, the non-inferiority margin selected has not been tested, however experts in the clinical field have been consulted. It is not possible to blind the staff providing the intervention; however, the participants will be blinded to their group allocation.

8.7 Conclusion

Based on a yet to be published systematic review, this trial is a first-in-world effort to evaluate the effects of minimising the otherwise routine and potentially unnecessary practice of endotracheal suctioning in uncomplicated cardiac surgery patients. The evidence base for ETS in the ICU patient population is

recognised to be of low quality, (33) with ETS having known effects upon ventilation, (86,109) and causing pain and distress for patients (36). There remains a divergence between CPGs and what happens in clinical practice (130,131,376,395). If the results of this study show that avoiding suction is non-inferior for this patient cohort then this has significant implications for clinical practice. There is the potential to avoid a painful procedure, aligning with the international Choosing Wisely initiative (http://www.choosingwisely.org/) that seeks to reduce the number of unnecessary medical treatments and interventions. Suction avoidance may potentially reduce workload for the nursing staff, in addition to improving the ICU experience for patients recovering from cardiac surgery. The study will provide an opportunity for patients to share their experience of the ETT and ETS, in turn, helping to inform future practice by adding to the body of knowledge about the patient experience of an ETT and ETS. A non-inferiority result has implications for future research, including further investigation about the avoidance of ETS with other patient groups, using the data to guide sample size calculations for future studies.

8.8 Chapter summary

This chapter presents the protocol for the planned RCT investigating avoidance of ETS. The systematic review (Chapter 4) verified the absence of evidence about avoidance of ETS, with the observational studies findings confirming discrepancies between CPGs and clinical practice, and the frequency of an invasive procedure. The planned RCT will be the first time active avoidance of ETS has been investigated. Chapter 9 presents the findings from the ARETS trial and the implications for practice.

Chapter 9 : Avoidance of Routine Endotracheal Suction. A single centre, non-inferiority randomised controlled trial.

Preface

This chapter describes the results of the Avoidance of Routine Endotracheal Suction study, an RCT comparing active avoidance of ETS to usual care in patients following planned cardiac surgery. Staff engagement was essential for trial success and was managed and maintained by working closely with the bedside staff, providing education before trial recruitment commenced, and on-going education and support for the duration of the study. Education included one to one bedside teaching, and presenting the study to new staff during their orientation programme. Given ETS is such a ubiquitous procedure, I had anticipated staff might be resistant to actively avoiding ETS for those patients allocated to the study intervention. However, this did not materialise; safety caveats allowed staff to provide ETS if required, potentially reassuring staff about patient safety. An unforeseen challenge during the study was protocol adherence when recording the primary outcome ABG. Several measures were put in place to try and address this challenge including flow charts and aide-memoire at the bedside, an evening telephone call to the bedside nurse caring for study patients, alert stickers on the ICU 24 hour observation chart, and informing the shift coordinator about randomised patients. Despite these efforts, several ABGs were either recorded too late for inclusion, or with the patient continuing to receive supplemental oxygen. This caused the duration of the study to be extended.

This was the first time actively avoiding ETS had been tested in an acute clinical setting. The findings are relevant to clinical practice and can help inform future practice.

The manuscript presented here has been read and agreed upon by all authors.

See Appendix 5 for supporting documents.

Avoidance of Routine Endotracheal Suction in Patients Mechanically Ventilated for ≤12 hours following elective Cardiac Surgery: A non-inferiority, randomised controlled trial.

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Abstract

Introduction: Mechanical ventilation requires an endotracheal tube. Airway management includes endotracheal suctioning (ETS); a frequent procedure for Intensive Care patients. Associated ETS risks include hypoxia, atelectasis, and infection. There is currently no evidence about the safety of avoiding endotracheal suction.

Objective: To assess the safety of avoiding endotracheal suction, including at extubation, in cardiac surgical patients, mechanically ventilated for ≤12 hours.

Methods: A single center, randomized, non-inferiority trial. The setting was a cardiac intensive care unit, in a metropolitan tertiary teaching hospital. Subjects were assigned to either avoidance of endotracheal suction or usual care including endotracheal suctioning, during mechanical ventilation. In total we screened 468 subjects and randomized 249 subjects (usual care, n=125; intervention, n=124). Subjects were elective cardiac surgical subjects anticipated to received ≤12 hours mechanical ventilation. The primary outcome was the ratio of partial pressure of oxygen/fraction of inspired oxygen (P_{aO2}/F_{IO2}) on room air six hours after extubation, with a non-inferiority margin of 10% (lower bound of one-sided 95% confidence interval to be less than 30).

Results: There were no differences in group characteristics at baseline. The primary analysis was a per-protocol analysis performed on 154 subjects. The median PaO2/FIO2 ratio was 323 for the intervention group, and 311 for the standard care group (median difference 12, one-sided 95% CI -14.3). The results were consistent when using an intention-to-treat analysis and a 97.5% CI. There were no differences between groups in complications or safety measures, including the escalation of oxygen therapy.

Conclusions: Endotracheal suctioning can be safely minimized or avoided in low-risk patients who have had cardiac surgery and are expected to be ventilated less than 12 hours after surgery.

Keywords: Intensive care; endotracheal suction; mechanical ventilation; airway management; nursing; patient experience.

9.1 Introduction

Worldwide, between 33% and 60% of patients admitted to an intensive care unit (ICU) will require a period of mechanical ventilation, which exposes 13,000 - 20,000 patients a day to the risks associated with mechanical ventilation (396,397). These include ventilator acquired lung injury and ventilator-associated pneumonia (59). Mechanically ventilated patients may receive endotracheal suction (ETS), which aims to maintain a patent airway and remove accumulated secretions (282). However, ETS can also contribute to hypoxia, atelectasis, tissue trauma, pain and distress for the patient (298,375,398). Initiatives have been implemented to minimize the duration of mechanical ventilation and reduce the frequency of ETS. These include early extubation, (28,29) and the development of clinical practice guidelines for the use of ETS (2,4,127). Yet the guidelines differ in their recommendations about how to determine the patient need for ETS (2,4). Suction at extubation is a common practice, (376) and aims to reduce the risk of aspiration and improve oxygenation (276,328). A survey of current ETS practice within our unit confirmed ETS at extubation is usual practice. Laboratory evidence demonstrated that a positive pressure breath at extubation may be more effective at reducing aspiration, (329) and a pediatric study showed an increased time to oxygen desaturation following the application of a positive pressure breath at extubation when compared to suction (399). The increased time to oxygen desaturation was not replicated in an adult population (290).

An initial literature review failed to find any trials assessing avoidance of ETS in adult patients mechanically ventilated for ≤24 hours, this was extended to ≤72 hours and broadened to include animals. There were no trials in the human population, while animal model studies showed that avoidance of ETS did not worsen oxygenation (113,115,292,293,295). Given the lack of evidence about the avoidance of ETS in the adult population, we hypothesized that avoiding ETS in subjects mechanically ventilated for ≤12 hours, including at extubation, would be non-inferior to usual care that included endotracheal suction (400).

9.2 Methods

The Avoidance of Routine Endotracheal Suction trial has been described previously (400). Briefly, it was a non-inferiority, randomized controlled trial, comparing avoidance of endotracheal suction to usual care in subjects admitted to intensive care following elective cardiac surgery. The trial was conducted in a tertiary teaching hospital that performs approximately 1200 cardiac surgical procedures per year. Ethics approval was obtained from the Northern B Health and Disability Ethics Committee (15/NTB/138). Written informed consent was provided before surgery. The trial was registered prospectively on the Australian and New Zealand Clinical Trials Registry (ANZCTR12615000897561) and a protocol outlining the trial in detail was published (400).

Participants

We screened elective cardiac surgical patients admitted between May 2017 and February 2019 for eligibility. Inclusion criteria: adults (≥16 years), requiring elective cardiac surgery using cardiopulmonary bypass, with an anticipated duration of ventilation ≤12 hours. Patients who had a documented previous difficult intubation, or were non-English speaking were excluded. All enrolled subjects were re-screened post-operatively on admission to the intensive care unit (ICU) and randomized if extubation was expected

to occur within 12 hours. As this was the first-time active avoidance of ETS had been investigated, we limited the duration of avoidance of ETS to ≤12 hours, minimizing patient risk when investigating a novel intervention.

Intervention

All subjects received usual post-operative care, which included warming the subjects to at least 36^0C, cardiovascular monitoring, appropriate pain and sedation management and extubation as soon as clinically stable. Assessment of readiness for extubation was guided by the unit protocol, and included that the patient is receiving ≤45% oxygen, was awake and obeying commands, and had no evidence of active bleeding. Airway management included ETS as required and at extubation. Suction as required is usual practice on our unit, suction was not mandated. The need for suction was assessed by the bedside nurse caring for the patient. Study safety indications for ETS included oxygen desaturation (S_{pO2} <90%), deterioration of P_{aO2} below 8kPa/60mmHg, reduced air entry upon auscultation, and on medical advice (400). Participants randomized to the intervention arm received all usual care with the exception of ETS as the intervention was active avoidance of ETS, including at extubation. We anticipated a low-risk population, however, the safety caveats described above allowed ETS to be provided if clinically indicated, or on medical request (400). Following extubation, arterial blood gas (ABG) analysis was mandated at two, four, and six hours post-extubation. Following randomization, and regardless of allocation, all subjects who required >12 hours ventilation reverted to routine post-operative management and were excluded from the study.

Quasi-closed ETS is usual practice in our unit. This uses a swivel connector catheter mount between the ventilator tubing and the ETT. This has a one-way value in situ, allowing the suction catheter to be passed through the valve. Suction negative pressure is applied during withdrawal of the suction catheter. Patients do not require disconnection from the ventilator during ETS, reducing lung volume loss during suction (84). The unit recommended best practice suction protocol mandated both the suction pressure (no greater than 200mmHg), and suction catheter size (ETT size – 2 x 2).

Outcomes

The primary outcome was the ratio of the partial pressure of oxygen/fraction of inspired oxygen (P_{aO2}/F_{IO2}) on room air six hours after extubation (400). Secondary outcomes included heart rate, respiratory rate, and mean arterial pressure, collected from ICU admission to six hours post-extubation. Safety data collected up to six hours post-extubation included P_{aO2}, P_{aCO2}, peripheral oxygen saturation (S_{pO2}) and complications of extubation including requirement for escalation of oxygen therapy or re-intubation, oxygen desaturation (S_{pO2} <90%), vomiting and aspiration. The Critical Care Pain Observation Tool (39) was used to collect pain scores before, during, and after suction episodes. Subjects completed a brief interview the day following extubation, describing their experience of the endotracheal tube and ETS if delivered. They also reported the amount of pain associated with the endotracheal tube and ETS. A numerical pain scale was used for the pain scores (401).

Sample size

A previous study, conducted in the same unit, with a similar population provided the inputs for the sample size calculation (371). In that study, the mean (SD) P_{aO2}/F_{IO2} ratio four hours post-extubation was 301 (83.9). Following consultation with senior medical staff, a non-inferiority margin of 10%, that is a P_{aO2}/F_{IO2} ratio no lower than 270, was agreed as clinically acceptable for subjects within the first 24 hours of cardiac surgery. We calculated that if there were no difference between usual care and the intervention, and using an anticipated SD of 80, 166 subjects in total would be needed to achieve 80% power with a lower limit of a one-sided 95% confidence interval (CI) above the 10% non-inferiority margin. G* Power was used for sample size calculation (173).

Randomization and blinding

Sequence generation was provided by an independent statistician, with 1:1 allocation in blocks of eight. Allocation concealment was achieved using sequentially numbered, sealed, opaque envelopes containing the patient allocation and unique study number on a slip of paper. Non-study personnel prepared the study envelopes. Randomization occurred on admission to ICU. It was not possible to blind bedside staff due to the nature of the intervention. Subjects were blinded to the allocation.

Data collection and monitoring

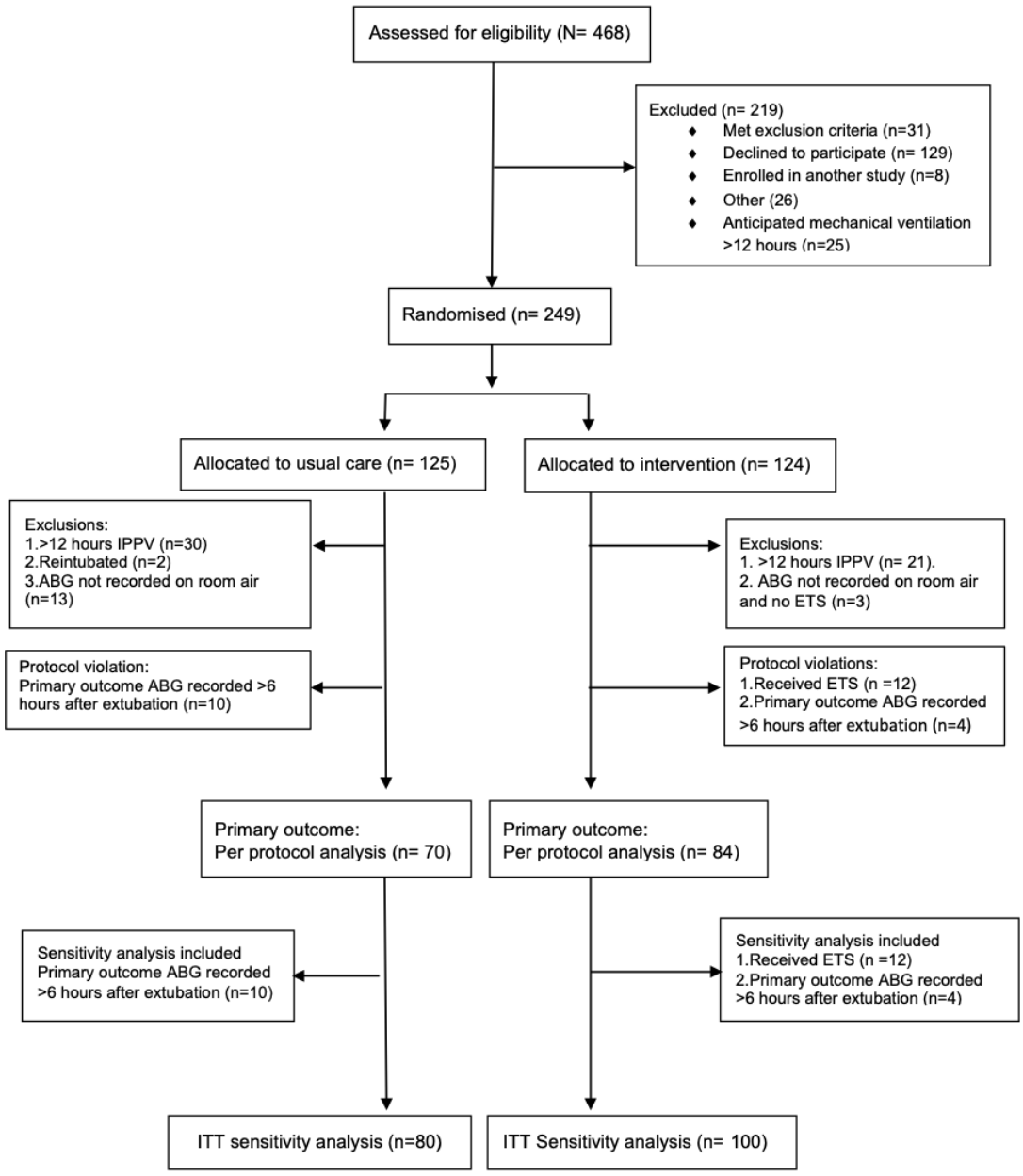
Unblinded research staff, not directly caring for the subjects, collected the data, and conducted the interviews. Data were entered directly into the Research Electronic Data Capture (REDCap) platform (318). REDCap included auto-validation. An independent monitor audited 100% of the consents and the primary outcome. A Data Safety Monitoring Board (DSMB) was established prior to the study commencing, and consisted of an independent ICU researcher (chair), a statistician, and an anesthetic researcher. The DSMB reviewed an unblinded report after the recruitment of 50 and 100 subjects.

Statistical analysis

Statistical analysis was specified *a priori,* with the statistical analysis plan available on the ANZCTR trial registry. As recommended for non-inferiority studies, (200,391) confidence intervals were to be reported. We anticipated any change in P_{aO2}/F_{IO2} ratio would be one directional, i.e. we did not anticipate that avoidance of ETS would improve oxygenation, therefore we used a one-sided 95% confidence interval. Continuous data were tested for normality, with the appropriate non-parametric tests used when required. The primary analysis was per-protocol (PP), followed by an intention to treat (ITT) analysis for sensitivity (402). The confidence interval was also tested for sensitivity using a one-sided 97.5% confidence interval. Non-inferiority was accepted if the lower limit of the one-sided 95% CI was above the pre-specified 10% non-inferiority margin for both analyses. Between-subjects' differences in the secondary outcomes (oxygenation, heart rate, respiratory rate and mean arterial blood pressure), were tested using a repeated measure multivariate analysis of variance (MANOVA). Categorical safety and complication outcomes were compared using a Chi-squared test. *P* values of < 0.05 were considered statistically significant. Data analyses were conducted using IBM SPSS Statistics (IBM Corp. released 2017. IBM SPSS Statistics for Macintosh, Version 25.0. Armonk, NY: IBM Corp.) and GraphPad Prism (www.graphpad.com).

9.3 Results

We screened 468 patients; 274 participants provided written consent and 249 were randomized with 154 participants included in the per-protocol primary analysis outcome (Figure 1). Inclusion in the PP analysis required that those allocated to the intervention group had not received ETS, and that the primary outcome was available. There were 180 subjects included in the ITT analysis.



Numbers recruited and analysed (Per Protocol and Intention to Treat).
PP = per protocol; ITT = intention to treat; ABG = arterial blood gas; IPPV – intermittent positive pressure ventilation

Figure 1: Consort Diagram

Table 1:Baseline Demographic and Clinical Characteristics

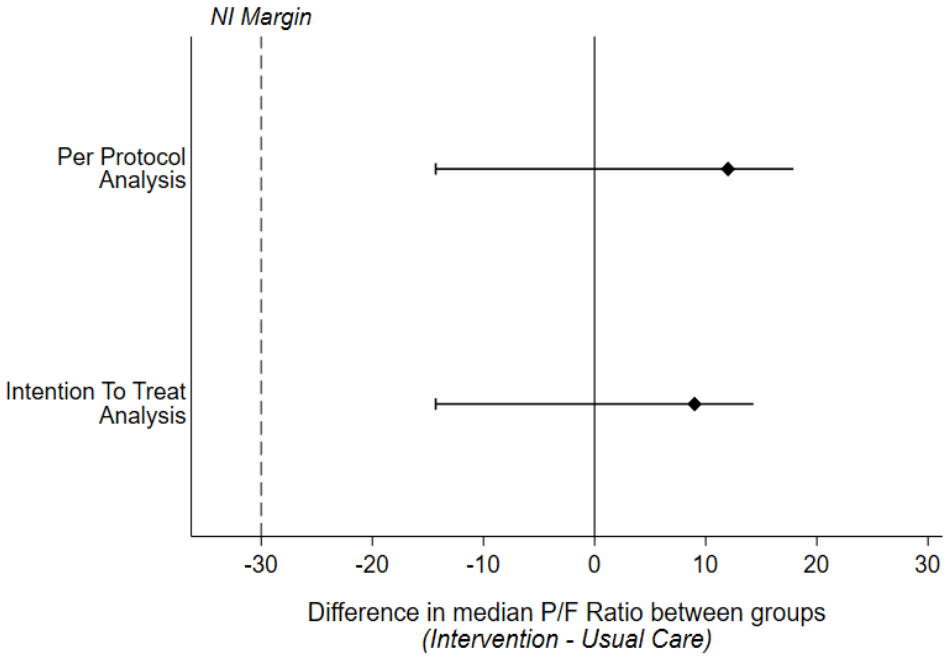
	Overall *N*= 249	Usual Care *n*=125	Intervention *n*=124
Age, years *Mean (SD)*	61.4 (11.8)	60.8 (11.6)	61.9 (12.0)
Gender, *N (%)*			
Female	51 (20.2)	23 (18.4)	28 (22.5)
Male	198 (79.5)	102(81.6)	96 (77.4)
Ethnicity *N (%)*			
NZ European	182 (73.1)	89 (71.2)	93 (75.0)
NZ Maori	20 (7.9)	11 (8.8)	9 (7.2)
Pacific peoples	25 (9.9)	15 (12.0)	10 (8.6)
Asian	16 (6.3)	9 (7.2)	7 (5.6)
Other	6 (2.4)	1 (0.08)	5 (4.0)
EuroSCORE II *Mean (SD)*	1.17 (0.72)	1.15 (0.76)	1.19 (0.68)
Smoking status *N (%)*			
No	143 (56.7)	72 (57.6)	71 (57.2)
Yes	25 (9.9)	17 (13.6)	8 (6.4)
Ex-smoker	81 (32.1)	36 (28.8)	45 (36.2)
Weight (kg) *Mean (SD*)	87.9 (17.3)	87.4 (17.8)	88.5 (17.1)
Co-morbidities *N (%)*			
Recent MI	54 (21.4)	26 (20.8)	28 (22.5)
Diabetes (on insulin)	11 (4.4)	6 (4.8)	5 (4.0)
Class 4 angina	9 (3.6)	4 (3.2)	5 (4.0)
COPD	11 (4.4)	5 (4.0)	6 (4.8)
Previous cardiac surgery	5 (2.0)	4 (3.2)	1 (0.8)
LV Function *N (%)*			
Good (>50%)	209 (83.9)	107(85.6)	102 (82.2)
Moderate (31-50%)	39 (15.6)	17(13.6)	22 (17.7)
Poor (21-30%)	1 (0.4)	1 (0.8)	-
NYHA *N (%)*			
I	139 (55.8)	68 (54.4)	71 (57.2)
II	94 (37.7)	48 (38.4)	46 (37.0)
III	14 (5.6)	7 (5.6)	7 (5.6)
IV	2 (0.8)	2 (1.6)	-
Surgery and ventilation data			
Type of surgery *N (%)*			
Isolated CABG	151 (60.6)	72 (57.6)	79 (63.7)
Single non-CABG	78 (31.3)	42 (33.6)	36 (29.0)
2 procedures	20 (8.0)	11 (8.8)	9 (7.2)
Surgery and ventilation *Median (IQR)*			
Duration of surgery (hours)	4.1 (3.4-4.6)	4.1 (3.4-4.5)	4.1 (3.3-5.0)
Duration of ventilation (hours)	6.5 (4.6-10.1)	6.6 (5.1-11.5)	6.4 (4.5-9.0)
ICU Length of stay (hours)	23.1 (20.4-43.3)	23.1 (20.5-44.0)	23.0 (22.3-42.4)

MI – Myocardial infarction; COPD - Chronic obstructive pulmonary disease (on inhalers); LV Function - Left ventricular function; NYHA- New York Heart Association Classification; CABG - coronary artery bypass graft; ICU - intensive care unit. SD – standard deviation; IQR – interquartile range. EuroSCORE - European System for Cardiac Operative Risk Evaluation

Participant groups were similar at baseline (Table 1). The majority were male (79.5%), New Zealand European, (73.1%) with good left ventricle function (83.9%). The mean (SD) EuroSCORE II was 1.17 (0.72) and most participants underwent isolated coronary artery bypass grafting (60.6%). The median duration of post-operative ventilation was 6.5 hours (IQR 4.6 - 10.1).

9.4 Primary outcome

Under per-protocol analysis, the median P_{aO2}/F_{IO2} ratio was 323 (IQR 286 - 349) for the intervention group and 311 (IQR 281 - 357) for the usual care group with a median difference of 12 (95% CI: -14.3, p = 0.354, Figure 2). When tested for sensitivity using an intention to treat analysis, the P_{aO2}/F_{IO2} ratio was 320 (IQR 282 - 353) for the intervention group and 311 (IQR 283 - 357) for the usual care group, with a median difference of 9 (95% CI: -14.3, p = 0.453, Figure 2). The margins in both groups for the PP and ITT analysis were within than the anticipated 10% non-inferiority margin and were robust when tested for sensitivity using the stricter 97.5% CI (PP analysis median difference 12, CI -14.3, p = 0.354, ITT analysis, median difference 9, CI -17.9, p = 0.453).

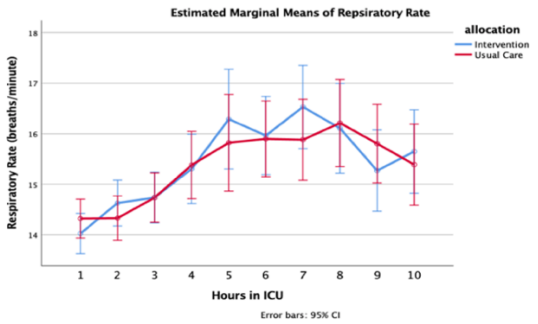


Per Protocol and Intention to Treat analyses of the median difference in P/F ratio between groups, with one-sided 95% CIs.

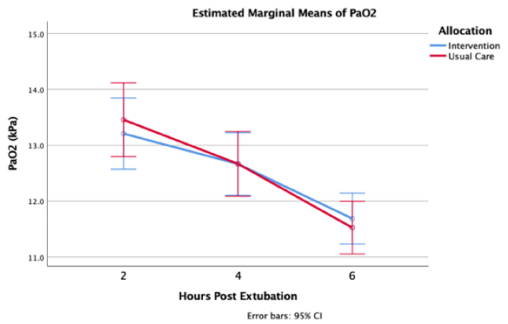
Figure 2: Primary outcome

Secondary outcomes

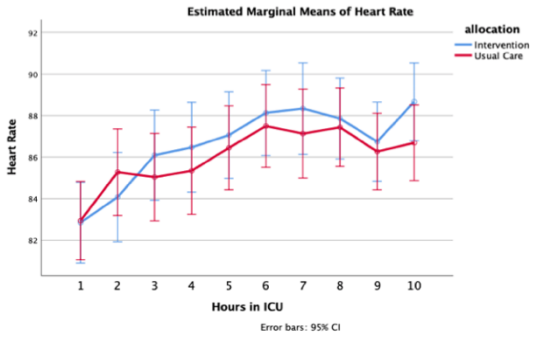
There was no difference between groups in physiological outcomes (V = 0.05, F(3, 225) = 0.344, p = 0.794, η_p^2 = 0.005), or for post-extubation oxygenation (V = 0.01, F(5, 170) = 0.327, p = 0.896, η_p^2 = 0.010, Figure 3). There were no significant differences between groups across safety outcomes, including complications of extubation (Table 2); with no incidence of re-intubation, aspiration or laryngeal spasm.



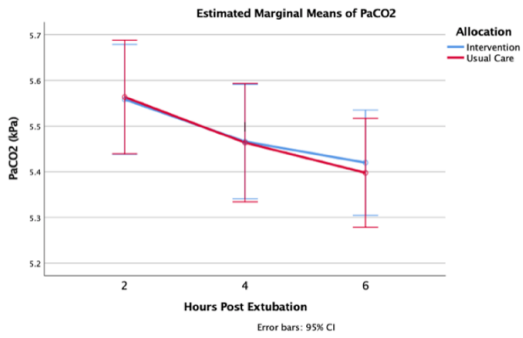
Between-subjects respiratory rate; ICU admission for ten hours. Standard Care, mean 15.3 (Std. Error .211) Intervention mean 15.5 (Std. Error .218)



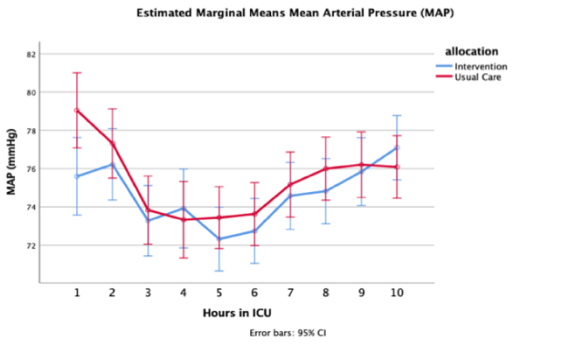
Between-subjects post-extubation PaO2. Standard Care, mean 12.55 (Std. Error .245) Intervention mean 12.52 (Std. Error .237)



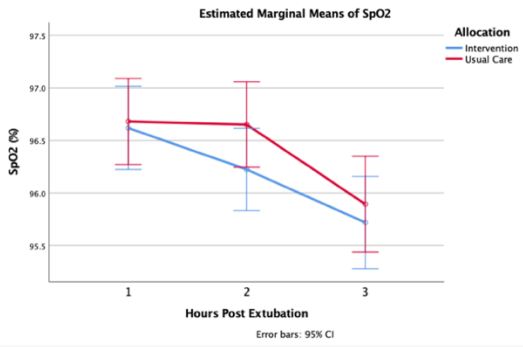
Between-subjects heart rate; ICU admission for ten hours. Standard Care, mean 86.0 (Std. Error .763) Intervention mean 86.6 (Std. Error .787)



Between-subjects post-extubation PaCO2. Standard Care, mean 5.47 (Std. Error .057) Intervention mean 5.48 (Std. Error .055)



Between-subjects MAP; ICU admission for ten hours. Standard Care, mean 75.4 (Std. Error .587) Intervention mean 74.6 (Std. Error .605)



Between-subjects Post-extubation SpO2 Standard Care, mean 96.4 (Std. Error .171) Intervention mean 96.1 (Std. Error .165)

Figure 3: Repeated measures of physiology and oxygenation outcomes

Table 2: Comparison of secondary and safety outcomes between groups

Characteristic	Standard care	Intervention	*P* value*	Risk Difference	95% Confidence Interval
Laryngeal spasm *N (%)*	0	0	NA	NA	NA
Aspiration *N (%)*	0	0	NA	NA	NA
Reintubation *N (%)*	0	0	NA	NA	NA
Escalation of oxygen therapy *N (%)*	11 (15.7)	8 (9.5)	0.25	-0.06	-0.17 to 0.04
Desaturation SpO_2 <90% *N (%)*	8 (11.4)	10 (11.9)	0.93	0.01	-0.10 to 0.10
Vomiting *N (%)*	7 (10.0)	5 (6.0)	0.35	0.04	-0.13 to 0.05
Episode of tachycardia >100 bpm[a] *N (%)*	15 (21.4)	23 (27.4)	0.39	0.06	-0.08 to 0.20
Episode of respiratory rate >25 bpm[b] *N (%)*	20 (28.6)	21 (25.0)	0.62	-0.03	-0.18 to 0.11
Episode of MAP >85 mmHg *N (%)*	27 (38.6)	41 (48.8)	0.20	0.10	-0.05 to 0.26

**Chi squared. MAP – mean arterial pressure; SpO_2 – peripheral oxygen saturation; [a] beats per minute; [b] breaths per minute.*

One hundred and sixty-seven (67%) out of 249 participants recalled the endotracheal tube and 40/249 (16%) participants recalled having ETS. The mean (SD) self-reported pain scores for the presence of the endotracheal tube and ETS respectively were 2.5 (2.8) and 2.9 (3.1). Of those who recalled the endotracheal tube and suction, most reported the endotracheal tube as bothersome rather than painful. Extubation was described by some as distressing; comments included, *"I felt like I was being strangled*" and "*I couldn't get my breath*".

Suction episodes

In total, 99 participants had documented suction episodes, 24 (19.2%) in the intervention group and 75 (60%) in the usual care group. Some participants had more than one suction episode, resulting in those allocated to usual care receiving a total of 108 suction episodes, while the intervention group received a total of 40 suction episodes. There were 43/70 (61.4%) of the usual care participants, who received a total of 61 suction episodes in the PP analysis. The mean (SD) suction pressure was -191 mmHg (SD 47).

9.5 Discussion

Avoiding endotracheal suction was not inferior to usual care with regards to oxygenation on room air six hours after extubation. There was also no increase in the requirement for escalation of oxygen therapy or the incidence of complications in the intervention group. These results suggest that avoiding ETS in a cohort likely to be ventilated for short durations is safe. In light of these findings, best practice guidelines should be reviewed and updated to incorporate this new evidence.

As far as we can determine this trial is the first to explore the avoidance of endotracheal suctioning in an adult intensive care population. Other studies have compared suction to a positive pressure breath, but only at extubation in post-operative pediatric and adult subjects (290,399). The primary outcome in both studies was time to oxygen desaturation S_{pO2} <92%. Although the pediatric study reported a more rapid oxygen desaturation to S_{pO2} <92% following suction, (399) this was not replicated in the adult study (290). Unlike our study, patients were extubated in the operating theatre or post anesthetic care unit and the

adults were extubated while in the supine position. In our study, subjects were extubated when awake and sitting up, F_{IO2} ≤45% and usual care included suction at extubation. Another study reported no benefit from the application of positive pressure at the end of anesthesia through to extubation (403). The extubation procedure was unclear, and the reasons for lack of efficacy remain uncertain. The participants in our study had a median EuroSCORE II of 1.17, confirming a low-risk cardiac population.

In our study, the primary outcome was P_{aO2}/F_{IO2} ratio on room air six hours after extubation. P_{aO2}/F_{IO2} ratio is an accepted marker of hypoxia (404). Post-operative cardiac surgical patients have reported P_{aO2}/F_{IO2} ratios >300 (405). A criticism of the P_{aO2}/F_{IO2} ratio is the influence of F_{IO2} (406). For example, the influence of F_{IO2} upon the P_{aO2}/F_{IO2} ratio can move patients from severe to moderate diagnosis when categorizing the severity of acute respiratory distress syndrome (406). To mitigate this concern, we discontinued supplemental oxygen for five minutes before the primary outcome ABG was obtained (400). There is increasing interest in the use of non-invasive assessments of hypoxia such as the S_{pO2}/F_{IO2} ratio. S_{pO2}/F_{IO2} and P_{aO2}/F_{IO2} ratios have been found to have good correlation (407,408). Future studies could consider using the S_{pO2}/ F_{IO2} ratio as the primary outcome, and incorporating validation of the P_{aO2}/F_{IO2} ratio. We recorded the primary outcome at six hours post-extubation because we anticipated that any acute complications of avoidance of ETS would be manifest within this period. Given the number of ABGs excluded from the primary analysis as a result of being recorded outside the six-hour window, future studies could consider the timing of any post-extubation ABG analysis required.

The provision of suctioning in the usual care group was lower than anticipated. A survey of ETS practice within the unit prior to the trial suggested that 100% of subjects in the usual care group would receive suction. However, the short duration of mechanical ventilation may have influenced the amount of suction delivered. That said, there was clear separation between the groups on receipt of ETS (60.0% in usual care group versus 19.3% in the intervention group) demonstrating ETS had been minimized in the intervention group. The median suction pressure was also higher than recommended in practice guidelines, but the unit protocol at the time of the study recommended that suction pressure be no greater than 200mmHg (and this recommendation is currently under review). Twelve of the 15 intervention participants who received ETS met the pre-specified safety caveats, (400) showing that the rescue protocol was used appropriately by the bedside staff.

Blocked endotracheal tubes, aspiration, or other complications of ventilation or extubation did not occur in our study. There were also no differences between groups in either the requirement for escalation of oxygen therapy or oxygen desaturation, S_{pO2} <90%. Although no previous human studies have compared suction with avoidance of suction, some animal studies have investigated suction versus no suction (113,292–295). None of the animal studies reported blocked endotracheal tubes or complications of ventilation, although all had a short duration of ventilation.

Our trial has three main limitations. First, the nature of the intervention meant it was not possible to blind the clinical staff to the patient allocation, but there was a clear difference between the groups in terms of suctioning and staff collecting the data were not involved in the participants' care. Second, due to the number of protocol violations regarding the collection of ABG for the primary outcome, the number of subjects in the PP analysis was lower than our sample size estimate (154 versus 166). However, the non-inferiority margins between the groups for the primary analyses were well within than the anticipated

10% lower bound of the confidence interval and posthoc recalculation of the power using the study data showed no loss of statistical power to detect a 10% non-inferiority margin (80% for n=154). Third, our study was conducted on a low risk, post-surgical cardiac population and thus may not be generalizable to higher-risk patient cohorts.

Further research incorporating multiple cardiac centers and other patient populations exposed to planned short-term mechanical ventilation of ≤12 hours would expand the generalizability of this trial. Future research could consider increasing the period of avoidance of ETS, in particular where routine use of humidification is in place. Future research could also investigate whether using the S_{pO2}/ F_{IO2} ratio is a better outcome measure than P_{aO2}/F_{IO2} ratio; S_{pO2}/ F_{IO2} ratio is non-invasive and therefore may have broader application, as not all ICU patients have an arterial line in situ.

9.6 Conclusions

Avoiding ETS, including at extubation, in post-operative cardiac surgical patients ventilated for ≤12 hours with appropriate use of rescue protocols was safe with no effect on complications.

9.7 Chapter summary

This chapter presented the final study in this thesis and is the first time active avoidance of ETS has been investigated and published. The research question stemmed from witnessing the discomfort patients can experience as a result of ETS, and wondering if this can be ameliorated. As confirmed in The point prevalence study (Chapter 6) ETS is a frequent intervention, these results do indeed provide an opportunity to facilitate practice change, reducing the frequency of ETS for this patient cohort. When compared to the PETS study (Chapter 7), participants in this study had greater recollection of both the ETT and ETS. How much this variation reflects differences in the timing of the interviews, post-operative day one compared to days four to six, is unclear. Extubation had not been previously been described and warrants further investigation in future research. The recommendations for clinical practice and future research are described in Chapter 10.

Chapter 10 : Discussion

Let us never consider ourselves finished nurses…..we must be learning all our lives."

Florence Nightingale

Introduction

This body of work has investigated endotracheal suction practice, an everyday and some might say mundane, procedure performed by ICU nurses. However, suction is far from every day and mundane for those on the receiving end. Health care delivery within ICU is complex (362,409), with multiple variables interacting and impacting on the implementation of evidence-based practice. Some variables such as attitudes (410) are measurable, while others such as personal beliefs, opinions and experience have less reliable metrics.

The over-arching aim of this work was to investigate the safety of active avoidance of ETS in patients who were mechanically ventilated for less than or equal to 12 hours after cardiac surgery. The most widely cited CPGs recommend that suction is performed 'as required' but make no comment about active avoidance of ETS (2) making the intention to actively avoid ETS a novel concept.

The research questions were:

1. What evidence is available about active avoidance of endotracheal suction?
2. What is the current endotracheal suction practice both within CVICU and across Australasia?
3. What is the patient experience of the ETT and ETS for those patients exposed to short-term mechanical ventilation?
4. Can ETS be safely avoided in uncomplicated, post-operative cardiac surgical patients ventilated for equal to or less than12 hours?

These research questions were addressed by undertaking a systematic review to investigate what evidence is available to support the avoidance of ETS, two observational studies that for the first time described endotracheal suction practice in CVICU and Australasia, a qualitative study that described the patient experience of the ETT and ETS, and a non-inferiority RCT investigating avoidance of ETS in those patients exposed to short-term mechanical ventilation following planned cardiac surgery. This chapter summarises the key findings and new information from this body of work and discusses the implications for current practice and future research.

10.1 Key findings

There are a number of key findings from the studies in this thesis that add to the body of evidence about endotracheal suction practice these are:

1. The absence of evidence about active avoidance of endotracheal suction in the adult ICU population.

2. Endotracheal suction practice, both in CVICU and across New Zealand and Australia, diverged from the recommended clinical practice guidelines.

3. None of the participants in the qualitative study remembered receiving endotracheal suction, and half had no recollection of the ETT, ETS or ICU

4. Avoidance of endotracheal suction is safe in an uncomplicated post-operative cardiac surgical population, receiving mechanical ventilation for ≤12 hours.

10.1.1 An absence of evidence

The results from the systematic review confirmed an absence of evidence about avoidance of ETS in the adult ICU population, and although the systematic review results signalled that avoidance of ETS may not be harmful it would be inappropriate to suggest that this finding could be translated into clinical practice for the following reasons. The use of Cochrane methods ensured that a robust, systematic review was conducted, and yet despite every effort to conduct the broadest review possible, including searching the grey literature, reference lists and citation databases, contacting study authors if required, and the inclusion of animal studies, the search failed to retrieve any literature directly comparing suction to active avoidance of suction. The included studies were not designed to test active avoidance of ETS, with the results extrapolated from studies where at least one intervention minimised or avoided suction. In addition, there are acknowledged limitations of animal studies, (300,302,411) however expanding the search to include animal studies provided the best opportunity to assess potential harm associated with avoidance of suction. Unlike other reviews that compared active treatments or interventions including, differences between open and closed suction, (82,283,412) the practice of installation of normal saline before ETS, (413) and the use of humidification, (414) this review sought to evaluate active avoidance of a frequent ICU intervention. It was perhaps not surprising that the search failed to retrieve any studies, given that avoidance of ETS is a novel concept. Although the review results cannot directly inform clinical practice, the findings confirmed an evidence gap about whether ETS could be safely avoided in ICU patients. The results provided a signal that avoidance of suction may not be harmful, underpinning the rationale for the ARETS trial.

10.1.2 Divergent practice

Since the introduction of CPGs in 1992, the number of guidelines has grown exponentially (415) with over 3,700 listed on the Guidelines International Network database (416). Clinical practice guidelines are now a key component of evidence-based healthcare, (417) and have been defined by The Institute of Medicine as "*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."* (pg. 9), (418) updated in 2011 to "*include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options*." (pg. 4) (419). The introduction of the Grading of Recommendations Assessment, Development and Evaluation system (GRADE), (420) was intended as a way of improving the quality of CPGs through grading the quality of the evidence. Introduction and use of CPGs remains a challenge with concerns about guideline trustworthiness, sub-optimal presentation, (417) and that guidelines produced about the same topic differ depending upon the organisation responsible for production (415). Guideline development also varies between jurisdictions.

The Best Practice Advocacy Centre New Zealand (421) has an agreement with the National Institute for Health and Care Excellence in the United Kingdom, which allows guidelines to be adapted for the New Zealand health sector. Given these challenges, it is perhaps unsurprising that the evidence consistently reports discrepancies between clinical practice, and implementation and uptake of clinical practice guidelines (130,131,422–424).

The results of the CVICU practice survey and point prevalence study, like others, identified incongruities between what happens in clinical practice and CPGs. It has been reported that healthcare staff use recommended guidelines to inform decision making 67% of the time, (422) with numerous examples of non-compliance with CPGs (130,131,308,310–312,424–427). For example, although no longer recommended, (2) installation of saline before suction continues (310–312). Reasons given include the patient's clinical condition, personal experience informing clinical practice, and unit culture and practice (311,312). Barriers to implementing guidelines include, staff disagreement with the evidence and guidelines, (312,424,425) staff reportedly being unaware of current guidelines, (131,310–312) that the volume of guidelines results in staff being unable to keep up to date, (410,415) inadequate resources and staff forgetfulness (425). Other reasons cited include difficulties applying evidence to practice because of ineffective continuing education, organisational barriers, for example, difficulty accessing CPGs at the point of care, and that guidelines are frequently based upon low-grade evidence (417). In addition there is minimal data about how to effectively implement guidelines. (428) Suggested strategies have included; pre-emptive identification of potential barriers, the use of appropriate language, guideline availability in multiple formats and supported by education, and pre-emptively identifying resource implications if guidelines are adopted (428). Education and training have led to the successful implementation of guidelines, (129,395,429) although it is less clear whether improvements are maintained in the long-term (129,395).

10.1.3 Lack of recall about endotracheal suction - the patient experience

The findings from the PETS study provided the first description of the CVICU patient experience of the ETT and early post-operative recovery. The key findings included that none of the participants remembered receiving endotracheal suction, and half had no recollection of the ETT, ETS or ICU, and are similar to others who have reported that many participants had little or no recall about ICU following cardiac surgery (38). Unlike the PETS study, interviews were conducted six-months after surgery and included those who had a complex recovery (38). Others have reported 42% - 54% of post-operative cardiac surgical patients not recalling the ETT (354,430). Grap et al. (430) interviewed cardiac surgical patients within 24-hours of extubation, reporting a mean level of ETT discomfort of 18.25/100, all descriptions of the ETT were reported as a negative experience(430). Unlike the PETS study, patients who received less than seven hours MV were excluded. Others interviewed a general ICU population five days after ICU discharge and again two months later, reporting that 41% of participants remembered the ETT as moderately to extremely bothersome (44). Key differences between these studies and the PETS study were the timing of the interviews and the duration of MV, which may account for some of the differences in the findings. Similar to Grap et al. (430) patients in the ARETS study were interviewed within 24-hours of extubation,16% recalled ETS. Unlike the PETS findings, 67% of patients recalled the ETT, some reported the ETT as painful and "*bloody awful",* saying that the ETT restricted their breathing,

made them gag, or made them feel that they couldn't get enough air. However, most participants in the PETS and ARETS studies recalled the ETT as bothersome rather than painful, which may be a reflection of the shorter duration of intubation and timing of the interview. Others have reported a reduction in ETT related sore throat two months post-surgery when compared to five days after surgery (44), although poor recall has been reported to last up to five months after cardiac surgery in patients receiving >24 hours of MV, (37) and it remains unclear when is the best time to interview patients post-operatively. During 2018, 2,625 patients received cardiac surgery across the five publicly funded hospitals in New Zealand (431). The vast majority of patients were a low-risk population, with observed mortality rates of 1.7% for CABG patients and 0.9% for isolated aortic valve repair/replacement, with a duration of MV between six and seven hours, and an ICU length of stay of 24 hours (431). Given the PETS study population reflects this patient cohort, the findings are relevant to a large number of patients in New Zealand.

The experience of extubation differed between the ARETS and PETS study participants. None of the participants in the PETS study recalled extubation as painful or distressing, and contrasts with some of the ARETS participants, one participant said he "*felt like he was being strangled".* It is unclear how much this finding was affected by the differences in the timing of the interview potentially influencing recall bias, that is participants selective recall of events/experience (135). Responses could also have been unintentionally influenced by interviewer bias, that is the interviewer asking leading questions, or participants feeling a social pressure to give a particular answer (135). To mitigate interviewer bias a script was used by all research staff for the ARETS study, and one researcher conducted all the PETS interviews. That said, the findings from the ARETS study support those of others who reported extubation as moderately stressful (44). There remains a gap in the literature about the experience of extubation in the ICU population.

Much of the current evidence about the post-operative cardiac patient's experience of the ETT and ETS has either excluded participants who have received less than six hours MV, (43) or focused upon those who have received over 24 hours MV (37,44,345,351). Neither the PETS or ARETS study inclusion criteria mandated a minimum duration of MV, hence the results represent patients who have previously been under-represented in this area of research, and are generalisable to similar cardiac populations within the NZ healthcare system. These findings add to the body of knowledge about the ICU experience of those who experience a potentially life changing event, but may be under-represented in the literature due to the perception that cardiac surgery is 'routine'.

10.1.4 Safety of avoidance of endotracheal suction

The findings from the ARETS trial provide the first evidence that avoidance of endotracheal suction in an uncomplicated, post-operative cardiac surgical population is safe, and presents the first empirical data about active avoidance of ETS in any adult ICU population. The findings add new knowledge to the existing evidence about endotracheal suction. No other studies have directly compared suction to no suction, with these results providing evidence to support a change in clinical practice and that the research question was worthy of investigation.

In an effort to improve oxygenation, reduce atelectasis and micro-aspiration, laboratory and clinical studies have investigated the effect of a positive pressure breath either following suction, in place of

suction, or at extubation (101,329,330,403). One study investigating post anaesthetic atelectasis compared the use of lung recruitment manoeuvres and PEEP to no recruitment manoeuvre and no PEEP 15 – 30 minutes before the end of anaesthesia, (403) while another study compared the time to oxygen desaturation following suction when compared to a positive pressure breath at the time of extubation (290). Both studies failed to show any improvement in oxygenation, and although neither study directly compared suction to no suction, the results lend weight to the hypothesis that suction might be safely avoided in specific circumstances or cohorts.

Trial design is arguably the most important component of a clinical study. The PRECIS-2 tool confirmed that the ARETS trial design was that of a pragmatic genre, that is "*designed to determine the effects of an intervention under the usual conditions in which it will be applied"* (pg. 464) (432). Unlike explanatory trials, which test an intervention in an 'ideal' setting, making every effort to standardise procedures, (194) pragmatic trials aim to maximise generalisability of results (433). The focus in pragmatic trials, as in the case of the ARETS trial, is upon maximising external validity while maintaining as much internal validity as possible (194). Although explanatory and pragmatic research sit along a continuum there is increasing concern that explanatory trials are poor predictors of real-world effectiveness of an intervention, (433) leading to an increasing interest in pragmatic trial design (194). The original PRECIS tool (432) has recently been updated (433) and has nine domains each scored 0 – 5 (Figure16).

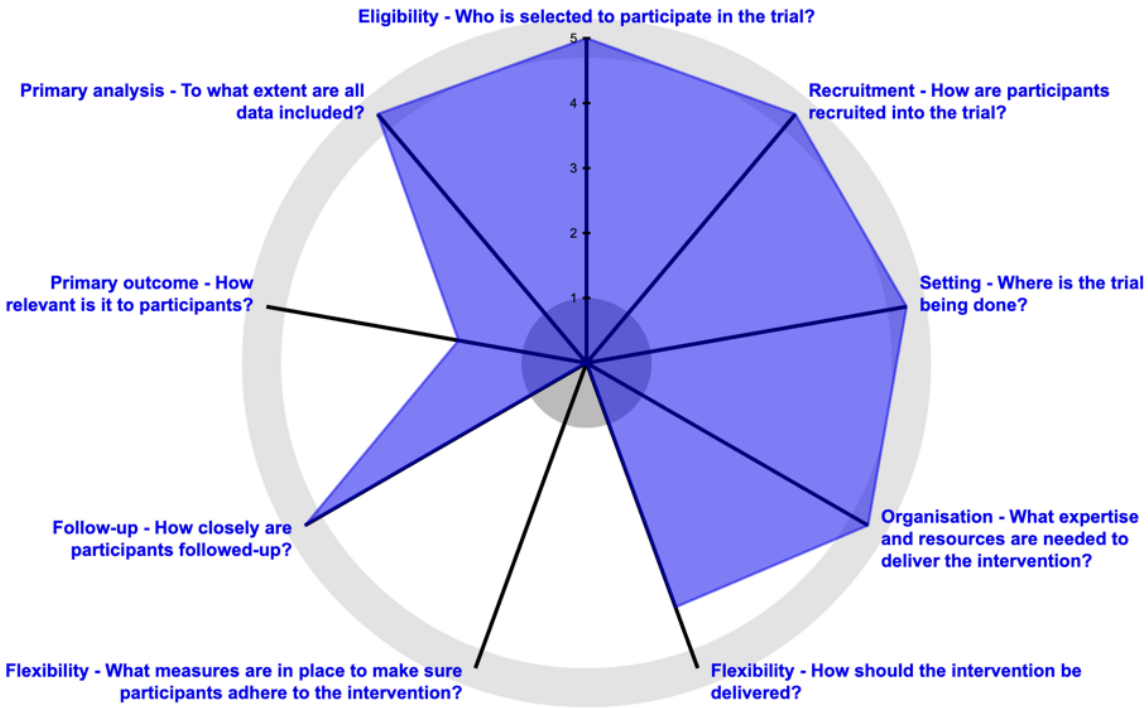


Figure 16: ARETS study as assessed using PRECIS-2

The domains are eligibility, recruitment, setting, organisation, the flexibility of delivery, the flexibility of adherence, follow-up, primary outcome and primary analysis. The closer the score to 5, the more pragmatic the trial (433). As seen in Figure 16, the PRECIS-2 tool confirmed the pragmatic design of the ARETS trial, with maximum scores in six of the nine domains, recruiting patients from within usual care, having broad inclusion and few exclusion criteria, the study population represented the population of interest, the intervention was delivered in the usual clinical setting with no additional resources required, and with the exception of the safety caveats, the intervention was delivered at the discretion of the nurse caring for the patient. Although the primary outcome was not of direct interest to the patients the results have shown that ETS can safely be avoided, reducing patient exposure to an invasive procedure.

10.2 Methodological limitations

10.2.1 Systematic review

Although systematic reviews are intended to provide information to support evidence-based practice, they can be subject to limitations, including an insensitive search strategy limited by the number of databases searched, language and date limitations, flawed data collection including transcription errors and missing data, and inappropriate conduct of the review, for example, a single person performing the review (213). To minimise bias in the systematic review in this thesis, and as recommended by the Cochrane Collaborative (172) the study protocol defined the research question and was registered in advance. The review was conducted by two reviewers, with a third reviewer available to provide expert advice and adjudication if required.

The inclusion of animal studies in the systematic review may be considered a limitation, there is a growing debate about the validity of animal studies being used to benefit humans, (434–436) with concerns about the applicability of results from animal studies to the human population (436). For example, only aspirin and tissue plasminogen activator have demonstrated efficacy in the treatment of head injury and stroke despite over 700 drugs being investigated using animal studies (300). Questions have been raised about how closely animal model studies predict performance in humans, as well as the moral and ethical considerations about the use of animals in research (434). It has been suggested that when used in animal research, models should have similar functional relationships, that is how "*the condition of interest in the model represents the condition of interest in the target",* (pg. 294) (434) leading to recommendations by some that animal studies are best used for hypothesis generation (300,436). The animals included in this systematic review were rabbits, piglets and dogs, (113,115,292–295) none of which could be considered to have similar functionality to adult ICU patients. Although some have conducted ETS experiments using adult pigs (437) and sheep (438) the results have not translated to clinical practice (437,438).

Currently, there is no agreed definition of either short or long-term MV, definitions of long-term MV range from 24-hours up to three months or longer (439). While most would probably agree 72-hours is not short term MV, this definition was used to achieve the broadest possible search results. The findings provided assurance that the concept of avoidance of suction was feasible.

10.2.2 Observational studies

Both the single-centre CVICU survey and point prevalence study were cross-sectional studies. Advantages of cross-sectional design include cost-effectiveness and that no follow up is required (440). However cross-sectional design is at risk of responder and non-responder bias as both may differ from the population of interest (230,440). Social desirability bias, that is when responders wish to portray themselves in the best light (135) may have influenced responses in the CVICU survey. Responders may have given the answer that they thought was most appropriate rather than describe their actual usual practice. Although there was no way to assess the effect of social desirability bias, that the results identified the inappropriate use of ETS to assess patients sedation levels, implies perhaps that social desirability bias may not have exerted a significant influence upon the findings. Non-responder bias may also have affected the findings of the CVICU survey which was dependent upon staff engagement, although a response rate of 50% suggests staff interest in the survey. No demographic data were collected, consequently, it was not possible to estimate any effect of non-responder bias and whether those who responded were representative of the unit staff at the time. That said, the findings identified a clinical practice that was non-adherent to the unit RBP at the time and provided data about suction practice at the time of the survey that helped inform the RCT design, for example confirming the use of suction at extubation led to the mandated avoidance of suction at extubation in the RCT protocol. In addition, awareness of current ETS practice helped to pre-emptively manage potential problems through staff education before the of the RCT. For example, the use of suction to assess patient sedation levels identified in the practice survey meant this was addressed before the start of the RCT.

The point prevalence study was a larger sample of ICU patients across ANZ and was conducted as part of an established research programme with urban, metropolitan and rural ICUs represented. Although the data collection occurred on two different days, one month apart, this would have minimal effect upon outcomes, for example, there was no seasonal difference between study days. The findings are limited to those units that are members of the ANZICS clinical trials group. ETS practice may differ between ANZICS member units where clinical research is embedded in unit practice. Although not possible to calculate, units not exposed to clinical research may have greater discrepancies between clinical practice and recommended guidelines. Cross-sectional design is not recommended for rare conditions as even a large sample may not include anyone with the disease (440). Endotracheal suction is a common and frequently performed ICU intervention, amenable to cross-sectional study design.

10.2.3 Qualitative study

Gaining pre-operative consent for the PETS study could be considered a methodological limitation. Informed consent is the cornerstone of clinical research and set out in both The Nuremberg Code (441) and The Declaration of Helsinki (442). Critically ill patients are considered a vulnerable population because they are "*a captive group and are dependent upon ICU staff for their care.*" (pg. 151) (443). When seeking consent to participate in clinical research pre-operative consent has advantages and limitations. Advantages include, that participants have time to consider participation unhindered by the effects of post-operative recovery such as pain, discomfort and the effect of analgesia and sedation (38,336,359,444,445). However, limitations include the risk of selection and response bias as a result of information contained in the information and consent form. There is evidence that up to 22% of cardiac

surgical participants consented pre-operatively have no recollection of agreeing to study participation, (446) although this differed from the findings of the HERO-2 consent sub-study (447) where 94% of participants recalled the consent process. A variety of methods have been suggested to increase participants ability to recall the consent process including, that the participant reads the consent form and someone checks understanding, (446,448) that information and consent forms are easy to read and understand, and that they are written for a lower reading age (447,449). Before the PETS interview, participants were asked about continuing in the study, all recalled providing consent to participate, even though half had no recollection of ICU. The available literature appears to focus upon processes that may improve patient recall of the consent process (443,447–450) rather than when is the optimal time to conduct research consent conversations. On balance, and drawing upon clinical experience, a decision was made to seek pre-operative consent.

Interviews for the PETS study were conducted on the ward, between post-operative days four and six, the timing was considered early enough in recovery for participants to recall their experience of the ETT and ETS while allowing time to recuperate from admission to ICU. Other studies have interviewed patients while still in ICU, (451,452) on the ward, (366,453) or between two and six months after hospital discharge (37,44). Limitations of interviewing patients before hospital discharge is the potential effect of post-operative cognitive decline affecting patient recall, while interviewing patients after hospital discharge may increase the risk of loss to follow up. Post-operative cognitive decline is a subtle but recognised neurological complication following any surgery, (454) with evidence that cardiac surgical patients experience a cognitive decline of up to 53% and 36% at hospital discharge and 6-weeks after surgery when compared to baseline (455). Older patients (over 60 years) undergoing major surgery can experience post-operative cognitive decline lasting up to three months (454). In-hospital interviews were conducted in the PETS study as a way of minimising loss to follow up, convenience for participants, and fitting within the budget constraints of the study.

The PETS study sample size was small (10 participants), however using purposive sampling ensured a participant population that reflected the population of interest as participants were recruited from operating lists and anticipated to require less than 12-hours MV post-operatively. It is incumbent upon researchers to only recruit as many participants as needed to elucidate the experience/phenomenon being investigated (456). The sample size in the PETS study met these criteria, improving the generalisability of the findings for this patient cohort across New Zealand public health providers.

10.2.4 Randomised controlled trial

Well conducted randomised controlled trials remain the gold standard within clinical research (170). The RCT in this thesis used random allocation, allocation concealment and blinding to reduce the risk of bias, (170) was a robust design with internal validity. However, as is common with pragmatic trials, and given the intervention, it was impossible to blind the bedside staff. Although this may be perceived as a limitation, the results demonstrated that suction was only used in the intervention (no suction) group as clinically indicated and using the safety caveats. Although the results may be limited to the cardiac surgical population, as the study was conducted in the largest cardiac surgical unit in NZ, the results have external validity within the NZ public health care system.

Where possible blinding of outcome assessors is preferred. However, research is frequently constrained by budget limitations, making blinded outcome assessment impossible. Although the ARETS study was unable to have blinded outcome assessment, the chosen primary outcome – PaO_2/FiO_2 ratio – is a clinical endpoint that is not subject to researcher manipulation.

10.3 Implications for nursing practice and education

Evidence-based nursing practice is only achieved if results from research are used and implemented in a systematic way (457). Translation of research into practice, although a goal of research, is complex and challenging (458,459). It is often quoted that translation of research has a 17-year time-lag, (459) although this is more nuanced than the claim implies, with time-lag affected by lack of agreed definitions, funding, how translation is measured, time points included, and the phase of the research (459). The results from this body of work include data from both quantitative and qualitative studies. The findings from both the single centre CVICU survey and the comprehensive point prevalence study found that like others, (130,131,460) there is a discrepancy between guidelines and clinical practice for the reasons previously described. Education has been reported as a key influence in the uptake and implementation of practice guidelines (410,425,461,462). Clinical educators, and those involved with nurse education and training, have an important role in increasing awareness of and encouraging the uptake and implementation of clinical practice guidelines.

This research has shown that ETS can be safely avoided in an uncomplicated post-operative cardiac surgical population. The safety caveats resulted in patients only receiving suction when required and align with current CPGs (2). Serendipitously, the ARETS results were reported as the participating CVICU moved from RBPs to standard operating procedures, with the results incorporated into the new CVICU endotracheal suction standard operating procedure. To evaluate whether the inclusion of these results in the standard operating procedure affects a change in practice, the CVICU survey conducted as part of this thesis will be repeated. This will act as a marker for the effectiveness of not only the standard operating procedure but about translation of research into practice.

Implementing avoidance of ETS in this patient cohort will reduce patient exposure to an invasive procedure, has no financial cost, and fits with the principles of the Choosing Wisely initiative (463). Choosing Wisely, a global initiative originating from the American Board of Internal Medicine which aims to, "*advance medical professionalism in the area of stewardship of healthcare resources"* (464) and has been the catalyst for discussions about avoidance of unnecessary low-value tests and investigations (465). The College of Intensive Care Medicine in Australia and New Zealand are signatories to Choosing Wisely, and have committed to the following: timely removal of invasive devices, judicious use of blood transfusion, lightening sedation, de-escalation of antibiotic therapy, and discussions with patients about 'goals of care' (463). The results from the ARETS trial align with the Choosing Wisely goals and will be made available to the NZ advisory group (466).

The findings from the qualitative study can be included in pre-operative patient education and have the potential to reassure those waiting for surgery. Sharing patients' stories and experiences can provide staff with insight into what it is like to experience cardiac surgery, helping staff to develop the skills and knowledge to support patients in their recovery. For example, raising nursing staff awareness about the experience of extubation can help nurses better prepare the patient about what to expect during

extubation. Although findings from qualitative research provide nurses with an evidence base to improve professional care, (457) questions remain about how findings from a few participants can be considered generalisable to larger groups of patients (457). Some consider that qualitative research findings can be used as a framework for interpretation, helping nurses support patients through an experience, (457) thus increasing the generalisability of findings. The results from this body of work have implications for both clinical practice and nurse education and training.

10.4 Limitations

The limitations of the individual studies within this thesis have been previously acknowledged. The limitation of this body of work is that, except for the point prevalence study, the studies were conducted in a single-centre. Advantages of a single-centre study include the relative ease of logistics, less heterogeneity of the study population, and cost-effectiveness (467). However, limitations include reduced generalisability of findings (467–469). The CVICU survey, while not generalisable to other ICUs, identified previously unknown discrepancies in CVICU suction practice. The ARETS study was conducted in the largest cardiac ICU in Australasia, with a patient demographic representative of the New Zealand cardiac patient population, and could arguably represent cardiac patients across New Zealand, with the pragmatic trial design increasing generalisability of findings within the New Zealand health care system.

10.5 Implications for future research

Following this work future research could include:

- Investigating the avoidance of ETS in other populations. Confirmation of results in other populations is recommended before the implementation of results in other patient groups.
- Studies have shown the influence of supplemental oxygen upon the PaO_2/FiO_2 ratio in those diagnosed with acute lung injury (407). How much influence supplemental oxygen has upon PaO_2/FiO_2 ratio in those without acute lung injury is unknown and warrants further investigation.
- Future research should consider extending the scope of the PETS study possibly using focus groups, interviewing participants before hospital discharge, and again six months later. A challenge when conducting qualitative research is the cost and location of conducting interviews. The utilisation of new technologies, such as video conferencing, have the potential to increase access to research for those participants who may otherwise have been excluded.

10.6 Summary of this body of work

The chief strength of this thesis is the comprehensive body of work that explored endotracheal suction in patients exposed to planned, short-term MV. The CVICU practice survey, point prevalence study, and RCT were conducted in the busiest cardiac ICU in Australasia. The pragmatic design of the RCT increases the generalisability of findings to cardiac surgical patients in New Zealand. The methods were sound, using clinically relevant outcomes, with a cohort enrolled that reflected the population of interest (470).

The systematic review confirmed a lack of evidence about avoidance of ETS in the adult ICU patient population, while the observational studies described the local suction practice in CVICU and across Australasia. The point prevalence study included 51 ICUs across Australasia, providing the first comprehensive description of ETS practice in New Zealand and Australia.

The PETS study has presented the first data about the post-operative experience of uncomplicated cardiac surgical patients in New Zealand, adding to the limited international data about the experience of this patient cohort. Although none of the participants recalled ETS, the findings described broader aspects of the ICU and post-operative experience, elucidating the human experience of cardiac surgery. The findings from the PETS study also reinforce the positive effect that nurses' can have upon the patient experience when nurses engage with patients about the delivery of care.

The RCT demonstrated that endotracheal suction can be safely avoided in a post-operative cardiac surgical population, that the ETT was well tolerated but bothersome, and that for some, extubation can be painful and distressing. The pragmatic study design confirmed that the intervention could be used in 'real-world' clinical practice. One of the biggest challenges for all clinical research is translating research findings into clinical practice. Barriers include nurses' lack of knowledge about how to appraise research, lack of managerial support, lack of authority to implement change, lack of time, and personal beliefs about research (458). The results of the ARETS study were available at the same time CVICU was preparing a new standard operating procedure for endotracheal suction, with the results included with immediate effect. The intervention has no financial or time cost, whilst at the same time reducing nursing workload, overcoming the barrier of lack of time to implement findings, which may help translation of findings in CVICU clinical practice. Crucially, the education team have been included in discussions about the standard operating procedure and the implication for staff orientation and training. It would be interesting to audit CVICU ETS practice following the implementation of the standard operating procedure, evaluating translation into clinical practice.

10.7 Conclusion

This body of work used a pragmatic approach, managing the challenges of conducting research in a busy ICU. Given the number of cardiac surgical procedures performed annually in New Zealand, (431) these findings have the potential to reduce patient exposure to an invasive and painful procedure while reducing workload for ICU nurses. The knowledge gained about the patient experience of the ETT and extubation in both the ARETS and PETS studies adds to the very limited evidence-base and will inform nursing practice. The findings confirm the benefit of a mixed-methods approach as a way of providing data to inform clinical practice that would otherwise be missed.

Questions have been asked about whether nursing and suction are art or science (134,145,278). I would suggest that the principles and practice of both are underpinned by science, but that effective and compassionate delivery of both is an art. This thesis adds to the science that underpins endotracheal suction, while increasing the understanding about the patient experience of the endotracheal tube and suction, enhancing compassionate nursing.

Appendices

Appendix 1: Systematic review documents

- Systematic review protocol
- Search strategy
- Excluded studies
- Review concepts

Systematic Review Protocol

Review title:

What is the effect of minimising endotracheal suction in intensive care patients ventilated for ≤3 days? A systematic review of safety and efficacy.

1 Background

There were 151,767 adult Intensive Care Unit (ICU) admissions in New Zealand (13,932) and Australia (137,835) in 2015-1016 (1). About a third of all ICU patients will require sedation and ventilation. Ventilation requires the use of an artificial airway endotracheal tube (ETT), resulting in patients losing the natural ability to cough and clear secretions and increasing the risk of infection, particularly ventilator-acquired pneumonia (VAP).

Part of ICU nurses' responsibilities include care and maintenance of the patients' airway and ETT, to maintain patency of the airway and reduce infection risk. VAP increases mortality and morbidity, adding to the overall cost of an ICU stay, both for the patient and for the economy (2).

Clinical practice guidelines (CPG) and care bundles that have been developed to reduce the risks associated with the ETT (3,4). CPG's include recommendations about endotracheal suction (ETS) for ventilated patients. The main aim being maintenance of pulmonary hygiene and patency of the ETT (3). ETS is not risk-free and can have a number of side effects including hypoxia, cardiovascular instability and arrhythmias, pain and distress, trauma to the trachea, atelectasis and infection (5,6).

CPG from the American Association of Respiratory Care (AARC) include recommendations about suction canister pressure, duration of each suction pass, pre-oxygenation, patient assessment for the need for ETS and the use of closed suction circuits (3). Although these guidelines are cited in the literature it is acknowledged that they are based upon low to medium grade evidence (7,4).

Much of the literature focuses upon patients with severe respiratory failure, VAP, Acute Lung Injury (ALI) and Adult Respiratory Distress Syndrome (ARDS) (4,8,9). These patients have specific ventilation requirements and the need for ETS will differ from patients who are ventilated for short periods of time e.g. post-operative patients or those without lung injury.

Methods of performing ETS

There are 2 methods of performing ETS, open suction (OS) and closed suction (CS). Some centres use a quasi-closed system. OS involves the patient being disconnected from the ventilator, manual breaths delivered via a manual resuscitator bag and ETS performed. This requires 2 staff and full personal protection for those involved. OS results in the loss of positive end-expiratory pressure (PEEP) provided by the ventilator, potential hypoxia and possibly increases the risk of infection. CS, which is an "in line" suction catheter, is part of the ventilator circuit, requires no disconnection from the ventilator, can prevent the loss of PEEP, prevent hypoxia and potentially reduced the risk of infection to both patients and staff. To date, there is no evidence about differing infection rates with either OS or CS (2,10,11). Although CS has been widely adopted (2) recent evidence has shown that contrary to expectations, there can be a

longer than expected recovery of ventilation following CS (12,13). It is unclear whether this is clinically significant.

Quasi-closed ETS involves the use of a one-way valve at the catheter mount and the suction catheter is passed through the value. This has the advantage of not breaking the ventilator circuit so allowing one person to perform ETS. It does create a leak in the ventilator circuit but reduces the loss of PEEP.

The CPGs recommend performing ETS when required, (3) however there is no consensus about how frequently ETS should be performed. The CPGs describe how to assess whether the patient needs ETS (3,14). Assessment should include an evaluation of the presence of audible secretions, coarse crackles over the trachea and a saw tooth pattern on the ventilator (3,14). Auscultation has been shown to be less effective yet the evidence suggests that this continues to be used by nurses (14).

Relevance

As previously discussed there are recognised side effects of ETS, yet there is little evidence about how frequently to suction patients. This systematic review will address this question.

Patients with ALI, ARDS and respiratory failure have specific ventilation and suction requirements and will not be included in the review. The focus will be patients ventilated for ≤3 days. Potentially patients in this cohort may be exposed to an unnecessary intervention, increasing the risk of side effects, pain and distress.

If there is evidence that it is safe and clinically acceptable to reduce the frequency of ETS, this will have implications for both the patient and nursing staff.

The current evidence and CPGs include evidence from small studies that lack homogeneity (4,6). In addition to this there is a disparity between CPGs and what occurs in clinical practice (15,16). Previous work has addressed the question of infection risk and control, (8) comparison of OS and CS (11) and the effectiveness of CS (9). No review to date has addressed the question of frequency of ETS, including the safety and efficacy of minimising/avoiding ETS in those patients ventilated for short periods, i.e. ≤3 days.

Justification

In a recent review updating the evidence, (4) 139 adult ETS studies were reviewed of which 12 assessed the effect of ETS in post-operative cardiac surgical patients who are frequently ventilated for <12 hours. The remaining studies reviewed patients who were critically ill or had respiratory disorders including VAP, ALI and ARDS. It is recognised that ETS in this patient population is necessary for the safe management of the patient's airway, to maintain the integrity of the ETT (10) and improve ventilation and oxygenation.

It is recommended that patients who are ventilated post operatively should have aggressive discontinuation from the ventilator and this is aided with good pain management (17). There is no specific guidance about the frequency of ETS in this patient population.

Specification

Safety outcomes will be assessed via airway complications, escalation of oxygen requirements or deteriorating ventilation, reported hypoxia, hypercapnia, blocked ETT, cardiovascular instability, re-intubation rates, infection rates, including ventilator acquired pneumonia. The PICO elements of this study are:

Elements	This question
Participants (P)	Adult (≥16 years) intensive care unit (ICU) patients, ventilated for ≤3 days via an endotracheal tube (ETT).
Intervention (I)	Avoiding or minimising endotracheal suction (ETS).
Comparator (C)	Routine use of ETS
Outcome (O)	Airway complications and deteriorating ventilation, e.g. blocked ETT, hypoxia, ventilation complications, cardiovascular instability, rate of infection, re-intubation rates, deteriorating arterial blood gases, hypercapnia.

2. Methods

Search strategy

The following databases will be used for this systematic review, MEDLINE (PubMed), EBSCO (CINHAL, PsychINFO), Cochrane library, Embase, Web of Science, Google Scholar and Scopus.

Key search terms

Key words: critically ill, intensive care, critical care, endotracheal suction, tracheal suction, suction*, tracheobronchial, bronchotracheal, complications, avoid*, artificial airway, ventilat*, mechanical ventilation, hyperinflation, pre-oxygenation, hypoxia, open suction, closed suction, quasi closed suction, ventilator acquired pneumonia, electrical impedance tomography (EIT), frequency, cardiovascular instability, infection, arrhythmia, pulse oximetry, atelectasis, adverse effects.

Safety outcomes will include assessment of hypoxia, respiratory and cardiac complications, infection, trauma, ventilation and ETT complications e.g. rates of re-intubation, occluded ETTs.

What other sources will you search?

To make the search as broad as possible we will include grey literature, thesis and dissertations. Reference lists from relevant studies will be searched and where necessary study authors will be contacted as appropriate.

Selection criteria

Inclusion criteria: randomised controlled trials; intensive care units; frequency of ETS; complications of ventilation and ETS; ventilation for ≤3 days; English language; dates from 1980 – 2017

Exclusion criteria: non-English language studies; studies prior to 1980, ventilation >3 days.

Initial selection will be based upon titles and abstracts. These will be assessed against the agreed inclusion and exclusion criteria.

Quality assessment & data extraction

An agreed risk of bias (RoB) tool will be used to assess for quality of the studies. Assessment will include methodology, randomisation and blinding. The Cochrane Collaborative have developed RoB and data extraction tools that have been updated in 2016. These will be used for this review. Data extraction tools include specific details about the interventions, populations, study methods, risk of bias including blinding, sequence generation and outcomes of significance to the review question and specific objectives.

Any disagreements that arise between the reviewers will be resolved through discussion and consensus. The clinical advisor who is a senior researcher and Intensivist will do final adjudication if required.

How will data extraction be performed, and how will extracted data be presented?

The relevant studies will be screened using the study abstract and for those selected studies the full article will be obtained and reviewed.

The primary reviewer will select the articles for review by the review team. The selected articles will be reviewed independently.

Data synthesis

Based upon the current available evidence it is anticipated that homogeneity of studies will be unavailable and therefore a narrative synthesis will be utilised. This will include a description of the types of studies, number and characteristics of the participants, description of the interventions and outcome measures, heterogeneity of the studies.

3. Timetable

Draft and final protocol	August 2017
Searching and study selection	September – December 2017
Data extraction	January – March 2018

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Search Strategy,

Ovid MEDLINE July 2018

Ovid MEDLINE(R) Epub Ahead of Print, In Process & Other Non-Indexed Citations, Ovid MEDLINE (R) Daily, and Ovid MEDLINE (R) 1946-Present

#	Searches	Results
1	Respiration, Artificial/	46163
2	Respiration, artificial.mp.	46219
3	mechanical ventilation.mp.	37642
4	Positive-Pressure Respiration/	16647
5	positive pressure ventilation.mp.	6745
6	Intermittent Positive-Pressure Ventilation/	2213
7	intermittent positive pressure ventilation.mp.	2942
8	IPPV.mp.	716
9	electrical impedance tomography.mp.	1454
10	EIT.mp.	1552
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	83829
12	Critical Care/	48811
13	intensive care.mp.	157748
14	Intensive Care Units/	49520
15	ICU.mp.	49656
16	critical care unit.mp.	1675
17	Recovery Room/	1248
18	PACU.mp.	2284
19	post anaesthetic recovery room.mp.	13
20	post an$esthetic recovery room.mp.	13
21	post anesthetic recovery unit.mp.	8
22	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21	197529
23	Airway Management/	2670
24	airway management.mp.	7608
25	Intubation, Intratracheal/	34378
26	endotracheal tube.mp.	7540
27	exp Intubation, Intratracheal/	37154
28	ETT.mp.	4607
29	nasopharyngeal tube.mp.	100
30	artificial airway.mp.	318
31	oropharyngeal airway.mp.	399
32	bronchotracheal tube.mp.	0
33	tracheal tube.mp.	2323
34	intratracheal tube.mp.	52
35	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34	49153
36	Airway Management/	2670
37	airway management.mp.	7608
38	endotracheal suction.mp.	195
39	SUCTION/	12140
40	suction.mp.	24304
41	ETS.mp.	12122

42	routine endotracheal suction.mp.	3
43	routine suction.mp.	7
44	Suction/	12140
45	tracheal suction.mp.	157
46	nasopharyngeal suction.mp.	20
47	bronchotracheal suction.mp.	0
48	tracheobroncheal suction.mp.	0
49	pulmonary hygiene.mp.	42
50	tracheobronchial hygiene.mp.	1
51	open suction.mp.	46
52	closed suction.mp.	569
53	minimally invasive suction.mp.	0
54	36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53	43881
55	hyperinflation.mp.	2857
56	preoxygenation.mp.	486
57	preoxygen*.mp.	569
58	pre-oxygen*.mp.	264
59	55 or 56 or 57 or 58	3668
60	minimal suction.mp.	8
61	avoid suction.mp.	5
62	no suction.mp.	78
63	avoid endotracheal suction.mp.	0
64	frequency of suction.mp.	13
65	frequency of endotracheal suction.mp.	1
66	reduce suction.mp.	1
67	60 or 61 or 62 or 63 or 64 or 65 or 66	105
68	airway complications.mp.	658
69	Airway Obstruction/	18366
70	airway obstruction.mp.	28159
71	blocked endotracheal tube.mp.	3
72	blocked tracheal tube.mp.	3
73	blocked ETT.mp.	0
74	HYPOXIA/	61779
75	hypoxia.mp.	147843
76	BAROTRAUMA/	1526
77	barotrauma.mp.	2868
78	Postoperative Complications/	346100
79	reintubation.mp.	1715
80	re-intubation.mp.	391
81	Airway Extubation/	1215
82	68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81	523737
83	Pneumonia, Ventilator-Associated/	3158
84	ventilator acquired pneumonia.mp.	75
85	VAP.mp.	4490
86	Pulmonary Atelectasis/	6347
87	pulmonary atelectasis.mp.	6535
88	atelectasis.mp.	10665
89	desaturation.mp.	10246
90	oxygen desaturation.mp.	3415
91	de-saturation.mp.	53

92	HYPOVENTILATION/	1965
93	hypoventilation.mp.	5860
94	HYPERCAPNIA/	8321
95	hypercapnia.mp.	13253
96	PNEUMOTHORAX/	16345
97	pneumothorax.mp.	25814
98	arterial blood gases.mp.	4392
99	Blood Gas Analysis/	21410
100	ABGs.mp.	291
101	ABG.mp.	1592
102	Oximetry/	12345
103	pulse oximetry.mp.	6229
104	SpO2.mp.	4343
105	peripheral oxygen saturations.mp.	23
106	peripheral oxygen saturation.mp.	654
107	83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106	108085
108	Arrhythmias, Cardiac/	59605
109	cardiac arrhythmia.mp.	5438
110	cardiovascular instability.mp.	530
111	HYPOTENSION/	21228
112	hypotension.mp.	64338
113	HYPERTENSION/	225636
114	hypertension.mp.	461009
115	BRADYCARDIA/	10599
116	bradycardia.mp.	25317
117	Oxygen Consumption/ or mixed venous oxygenation.mp.	101310
118	mixed venous oxygenation.mp.	60
119	SvO2.mp.	769
120	mean arterial blood pressure.mp.	10152
121	MAP.mp.	190103
122	Blood Pressure/	266908
123	blood pressure.mp.	427544
124	108 or 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123	1113815
125	ADULT/	4751191
126	ADULT/ or adult.mp.	5320335
127	Young Adult/	738235
128	ADOLESCENT/	1929410
129	adoles*.mp.	1997158
130	adolescent.mp.	1959473
131	Middle Aged/	4106666
132	middle aged.mp.	4119016
133	Aged/ or "Aged, 80 and over"/ or older person.mp.	2936418
134	125 or 126 or 127 or 128 or 129 or 130 or 131 or 132 or 133	7866361
135	Animals/	6397008
136	from 135 keep 1	1
137	11 and 35 and 54	1412
138	11 and 22 and 35 and 54 and 67 and 82 and 107 and 124 and 134	0
139	11 and 54 and 134	909
140	11 and 54 and 135	107

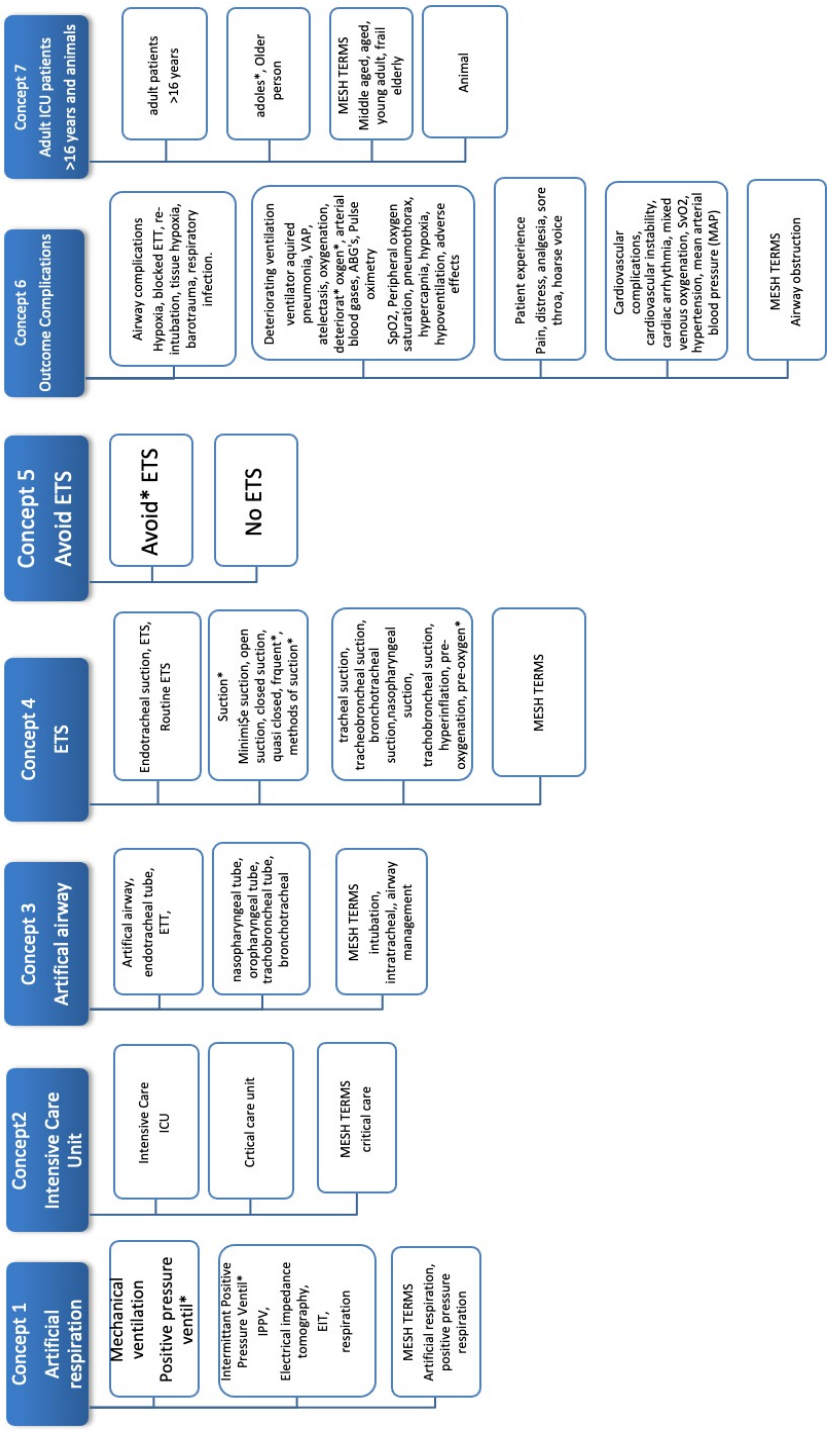
141 67 and 140	0
142 67 and 139	2
143 67 and 140	0
144 124 and 140	11
145 11 and 35 and 54 and 67 and 124 and 135	0
146 54 and 135	8174
147 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	83829
148 54 and 135 and 147	107
149 67 and 107 and 124 and 135	0
150 147 and 149	0
151 35 and 54 and 82 and 124 and 147	30
152 54 and 124 and 135	823
153 35 and 54 and 124 and 135	14
154 11 and 35 and 54 and 67 and 124 and 134	0
155 35 and 54 and 67 and 124 and 134 and 147	0
156 35 and 54 and 124 and 135 and 147	5
157 35 and 54 and 124 and 134 and 147	72
158 11 and 54 and 124	190
159 135 and 158	11

Systematic review - excluded articles

Author	Title	Publication	Reason for exclusion
Bourgault (2006)	Effects of Endotracheal Tube Suctioning on Arterial Oxygen Tension and Heart Rate Variability	Biological Research for Nursing, 2006; 7(4) 268-278	Wrong intervention
Boutros (1970)	Effects of Endotracheal Tube Suctioning on Arterial Oxygen Tension and Heart Rate Variability	Anesthesiology 1970; 32 (2) 114-118	Wrong intervention
Bruicia (1996)	The effect of suction catheter insertion and tracheal stimulation in adults with severe brain injury	Heart and Lung; 1996, 25(4), 295-303	Wrong intervention
Grap (1994)	Effect of level of lung injury on HR, MAP and SaO_2 changes during suctioning	Intensive and Critical Care Nursing, 1994, 10 (3), 171-178	Wrong intervention, does not compare avoidance of ETS.
Clark (1990)	Effects of endotracheal suctioning on mixed venous oxygen saturation and heart rate in critically ill patients.	Heart and Lung, 1990 19 (5), 552-557	Wrong intervention. Cardiac patients. Not comparing avoidance of suction
Hodgson (2000)	An investigation of the early effects of manual lung hyperinflation in critically ill patients	Anaesthesia Intensive Care 2000, 28 (3), 255-261	Wrong intervention.
Paulissian (1991)	Hemodynamic Responses to Endotracheal Extubation After Coronary Artery Bypass Grafting	Anesthesia & Analgesia 1991; 73(1), 10-15	Wrong intervention
Clark (1990)	Effects of endotracheal suctioning on mixed venous oxygen saturation and heart rate in critically ill adults.	Heart Lung 1990; 19)5), 552-7	Wrong intervention
Trawöger (1997)	Clearance of mucus from endotracheal tubes during intratracheal pulmonary ventilation	Anesthesiology 1997; 86(6), 1367-1374.	Wrong intervention
Miranda (2005)	Open lung ventilation improves functional residual capacity after extubation in cardiac surgery	Critical Care Medicine 2005; 33(10), 2253-2258	Wrong intervention, ventilation not suction
Minkovich (2007)	Effects of Alveolar Recruitment on Arterial Oxygenation in Patients After Cardiac Surgery: A Prospective, Randomized, Controlled Clinical Trial	Journal of Cardiothoracic and Vascular Anaesthesia 2007; 21(3), 375-378	Wrong intervention – ventilation not suction
Walsh (1987)	Controlled supplemental oxygenation during tracheobronchial hygiene.	Nursing Research 1987; 36(4), 211-215	Wrong intervention
Johnson (1994)	Closed versus open endotracheal suctioning: Costs and physiologic consequences.	Critical Care Medicine 1994; 22(4), 658-666	Wrong intervention
Cordero (2001)	A comparison of two airway suctioning frequencies in mechanically ventilated, very-low-birthweight infants	Respiratory Care 2001; 46(8), 783-8	Wrong population
Kobylianskii (2016)	Electrical impedance tomography in adult patients undergoing mechanical ventilation: A systematic review	Journal of Critical Care 2016; 35, 33-50	Systematic review
Dean (1997)	Evidence-based suction management in accident and emergency: A vital component of airway care	Accident and Emergency Nursing 1997; 5(2), 92-98	Not an RCT
Jelic (2008)	Clinical review: Airway hygiene in the intensive care unit.	Critical Care 2008; 12(2), 209.	Not an RCT
Laedwig (2009)	Central venous oxygen saturation monitoring	British Journal of Cardiac Nursing 2009; 4 (2) 75-79	Not an RCT
Favretto (2012)	Endotracheal Suction in Intubated Critically Ill Adult Patients Undergoing Mechanical Ventilation: a Systematic Review	Rev Lat Am Enfermagem 2012; 20 (5)	Not an RCT.
Ntoumenopoulos (2014)	Effects of manually-assisted cough combined with postural drainage, saline instillation and airway suctioning in critically-ill patients during high-frequency oscillatory	Physiotherapy Theory and Practice 2014; 30(5). 306-311	Not an RCT

	ventilation: a prospective observational single centre trial		
Branson (1993)	Endotracheal Suctioning Mechanically Ventilated Adults and Children with Artificial Airways.	Respiratory Care 1993; 38, 500-504	Not an RCT
Main (2004)	Respiratory physiotherapy vs. suction: The effects on respiratory function in ventilated infants and children	Intensive Care Medicine 2004; 30(6), 1144-1151	Wrong population
Fisher (1982)	Increase in Intracranial Pressure during Suctioning—Stimulation vs. Rise in $PaCO_2$	Anesthesiology 1982; 57(5), 416-417	Wrong population
Lewis (2002)	Airway clearance techniques for the patient with an artificial airway	Respiratory Care 2002; 47 (7) 808-817	A summary of current techniques and discussion about future research.
Annapooma (2005)	Effectiveness of standard endotracheal suctioning technique on patients with mechanical ventilators.	The Nursing Journal of India 2005; 96 (5) 109	Is described as an RCT but wrong intervention. There is very limited data in the article to facilitate decision making and no referencing is provided.
Branson (2007)	Secretion management in the mechanically ventilated patient.	Respiratory care 2007, 52(10) 1328-1342	Discussion article
Rosen (1960)	Aspects of Tracheal Suction	British Journal of Anaesthesia; 1960 32(10) 486-504	Describes the physiology of endotracheal suction.
Wood (1994)	Endotracheal suctioning: a literature review	Intensive and Critical Care Nursing 1994; 14 (3) 124-136	Review not RCT

Systematic review – search concepts



Appendix 2: CVICU survey documents

- Poster presentation. Presented at ANZICS New Zealand Regional Meeting. Wellington
- SurveyMonkey questionnaire
- CVICU Recommended Best Practice Guideline – Suctioning Endotracheal and Tracheostomy Tubes

ENDOTRACHEAL SUCTION OF CARDIOTHORACIC SURGICAL PATIENTS

A SINGLE CENTRE SURVEY OF CURRENT PRACTICE

Mrs Eileen Gilder – Cardiothoracic and Vascular Intensive Care Unit, Auckland City Hospital, New Zealand. PhD Student, School of Nursing, University of Auckland.
Dr Rachael Parke – Cardiothoracic and Vascular Intensive Care Unit, Auckland City Hospital, New Zealand. Senior lecturer, School of Nursing, The University of Auckland, New Zealand.
Dr Andrew Jull – Associate Professor, School of Nursing, The University of Auckland, New Zealand.

Abstract

Objective: To assess nurses' knowledge and current practice of endotracheal suction (ETS) in the Cardiothoracic and Vascular Intensive Care Unit (CVICU), Auckland City Hospital.
Methods: A 10-item self-administered questionnaire was emailed to all nursing staff.
Results: 120 nursing staff with varied skill level were included in the mail out. The total response rate was 53% (n=64). In order of frequency, deteriorating SpO2 (97%) audible or visible secretions (94%) and patient coughing (70%) were the most frequent reasons for performing suction. 87% of respondents perform ETS when required, 25% reported using ETS to assess the patient's sedation score. For patients ventilated for <12 hours, ETS is performed before extubation (86%), during extubation (10%), 6% of respondents do not perform ETS when extubating the patient.
Conclusions: The results of this survey may indicate a need for education addressing sedation assessment, alternative methods of assessing when patients need ETS, preparing the patient for ETS and the recommended suction pressure.

Background

Cardiac surgery utilising cardiopulmonary bypass is one of the most common forms of major surgery, with over 1 million patients having cardiac surgery worldwide each year (1). CVICU admitted 2379 patients in 2016, including 1200 planned cardiac surgical cases. Uncomplicated patients are ventilated for between 3-12 hours and woken up once cardiovascularly stable. Ventilation mandates the need for an endotracheal tube (ETT) to maintain the patient's airway while sedated and ventilated. To maintain patency and care of the ETT, nurses perform endotracheal tube suction (ETS). ETS is one of the commonest nursing interventions in intensive care (ICU). Clinical practice guidelines (CPG) have been produced (2). The rationale for ETS is to maintain pulmonary hygiene in patients who have lost the natural ability to cough and protect their airway as a result of the ETT being in place. One of the main complications of the ETT is the increased risk of infection, e.g. pneumonia (3). Current CPG are based upon low grade evidence (4) and there is little to guide practice about ETS in elective surgical patients ventilated for short periods of time.

A randomised controlled trial comparing no ETS to usual care is planned in CVICU at Auckland City Hospital. Current practice needed to be documented prior to the conduct of the trial.

Objectives and Methods

Objective:
To assess nurses' knowledge and current practice of ETS in CVICU.
Methods:
An email, including a Survey Monley link to a 10-item self-administered questionnaire was sent to all nursing staff. Questions addressed decision making, what are the triggers for performing ETS and patient assessment prior to and following ETS. There was the option to select more than one answer for some catagories, e.g. why do you perform suction? All answers were anonymous. The initial email was followed up with a reminder email. Data was analysed in Excel version 15.32.

Results

The response rate was 53% (64 nurses). Patient preparation prior to ETS included: informing the patient (84%), pre-oxygenation (52%), hand hygiene (36%), checking the SpO2 (10%), sedation bolus if required (8%), checking the position of the ETT (8%), suction the oral cavity (8%), explain the procedure to the family if present (6%), auscultation (4%). Analgesia was the least frequently mentioned when preparing the patient (2%).

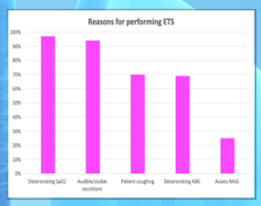


Figure 1: Reasons for performing endotracheal suction

The most frequently cited reason for performing ETS is deteriorating SpO2 (97%), followed by audible/visible secretions (94%). 25% of suction is performed to assess the patient's sedation level. (Figure 1).

Re-checking the SpO2 is the most common method of assessing the effectiveness of the suction episode (94%), followed by auscultation (75%) and rechecking the arterial blood gas (65%) (Figure 2).

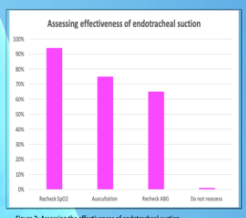


Figure 2: Assessing the effectiveness of endotracheal suction.

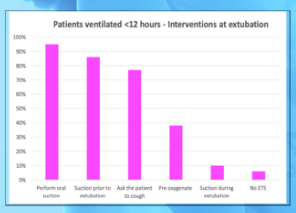


Figure 3: Interventions at extubation

In those patients ventilated for < 12hours, ETS prior to extubation is performed by the majority of nurses (86%), with 6% not performing ETS when extubating patients ventilate for <12 hours. (Figure 3).

Most suction episodes (88%) were < 10 seconds duration, 12% 11-20 seconds. 76% of respondents report checking the canister suction pressure prior to suction, but only 41% were aware of the recommended suction pressure (80 -150 mHg).

Discussion

This study provides information about current ETS practice in CVICU. It included all skill levels within the unit and although some practice appears to be in line with CPG, i.e. ETS when required, duration of suction and appropriate clinical indications for ETS (e.g. deteriorating SpO2), these results indicate a need for education that covers sedation assessment, additional methods for assessing when patients need ETS (5), how to prepare the patient for suction, including the use of anaglesia and the recommended suction pressure; this data can be used to inform education for both current and new staff.

This is a self-reporting study and may be a limited reflection of CVICU practice; however there was good response rate and all answers were anonymous. Self-reporting may account for the varied descriptions of patient preparation for ETS, e.g. hand hygine, it may be performed be not reported. We did not collect data about how much ICU experience individuals had, this may contribute to how much detail they report.

References

1. Ministry of Health. Cardiac Surgery Services in New Zealand - Cardiac Surgery Service Development Working Group Report. Wellington: Ministry of Health; 2008.
2. AARC. Endotracheal Suctioning of Mechanically Ventilated Patients with Artificial Airways 2010. Respiratory Care. 2010; 55(6);758-764.
3. Pedersen, C. M., Rosendahl-Nielsen, M., Hjermind, J., & Egerod, I. Endotracheal suctioning of the adult intubated patient--what is the evidence? Intensive & Critical Care Nursing. 2009; 25(1); 21-30. doi: 10.1016/j.iccn.2008.05.004
4. AARC. Clinical Practice Guidelines: From "Reference-Based" to "Evidence-Based". Respiratory Care. 2010; 55 (6); 787- 788.
5. 5. Sole ML, Bennett M, Ashworth S. Clinical indicators for endotracheal suctioning in adult patients receiving mechanical ventilation. American Journal of Critical Care. 2015; 24(4), pp.318-324.

Acknowledgements: Health Research Council of New Zealand: Clinical Training Fellowship and The Green Lane Research and Educational Fund PhD scholarship

SurveyMonkey questionnaire

Endotracheal Suction (ETS)- an investigation of current nursing practice in CVICU

This survey aims to assess current practice in our unit. It is anonymous and should take no longer than 5 minutes. The results will help identify any unmet training requirements. Thank you for your time.

Endotracheal Suction (ETS)- an investigation of current nursing practice in CVICU

1. Do you check the wall suction pressure prior to ETS?

- ◯ Yes
- ◯ No

2. What suction pressure is recommended?

	Yes	No
100-150 mmHg	◯	◯
151-250 mmHg	◯	◯
251-350 mmHg	◯	◯
>351 mmHg	◯	◯
Dont know	◯	◯

What suction pressure do you use?

Endotracheal Suction (ETS)- an investigation of current nursing practice in CVICU

3. When you are performing ET suction, when do you apply suction to the catheter?

- [ ] During insertion of the suction catheter
- [ ] During withdrawal of the suction catheter
- [ ] Intermittently
- [ ] All of the above

Other

Endotracheal Suction (ETS)- an investigation of current nursing practice in CVICU

4. Do you perform routine endotracheal suction, e.g every hour, 2 hours?

- ( ) Yes
- ( ) No

5. How frequently do you perform endotracheal suction?

- [ ] 1- 2 hourly
- [ ] 3-4 hourly
- [ ] PRN

Other (please specify)

6. Why do you perform endotracheal suction? (tick all that apply)

	Yes		No
Deteriorating SpO2	[ ]	[ ]	[ ]
Deteriorating ABG's	[ ]	[ ]	[ ]
Auscultation/audible/visible secretions	[ ]	[ ]	[ ]
Assess RASS	[ ]	[ ]	[ ]
Patient coughing	[ ]	[ ]	[ ]

other - please specify

Endotracheal Suction (ETS)- an investigation of current nursing practice in CVICU

7. Your patient is ventilated for <12 hours and is ready for extubation. Which of the following techniques do you use?(tick all that apply)

	Yes		No
Suction the ETT prior to extubation	☐	☐	☐
Suction the ETT during extubation	☐	☐	☐
Pre Oxygenate the patient	☐	☐	☐
Do not suction the ETT prior to extubation	☐	☐	☐
Ask the patient to cough	☐	☐	☐
Perform oral suction	☐	☐	☐

Other (please specify)

Endotracheal Suction (ETS)- an investigation of current nursing practice in CVICU

8. You are performing ET suction, how long is the duration of endotracheal suction, i.e. how long do you take to withdraw the suction catheter while suction is applied?

- ◯ Less than 10 seconds
- ◯ 10-20 seconds
- ◯ 21-30 seconds
- ◯ > 30 seconds

Endotracheal Suction (ETS)- an investigation of current nursing practice in CVICU

9. You are planning to perform ET suction on your patient. Describe how you routinely prepare your patient for endotracheal suction?

10. You have just performed ET suction. How do you assess the effectiveness of the suction episode? (tick all that apply)

	Yes	No
Recheck SpO2	☐	☐
Recheck the ABG	☐	☐
Auscultation of the patient	☐	☐
I do not assess the effectiveness following ET suction	☐	☐

Other (please specify)

Suctioning Endotracheal and Tracheostomy Tubes in CVICU and HDU

Document Type	Guideline
Function	Clinical Service Delivery
Healthcare Service Group (HSG)	Cardiovascular
Department(s) affected	Cardiovascular Intensive Care Unit (CVICU)
Patients affected (if applicable)	Adult patients in CVICU
Staff members affected	All clinicians in CVICU
Key words (not part of title)	Suction
Author – role only	Nurse Specialist, CVICU
Owner (see ownership structure)	Nurse Manager, CVICU, on behalf of the Nurse Advisor, CVICU
Edited by	Clinical Policy Advisor
Date first published	April 1997
Date this version published	May 2013
Date of next scheduled review	May 2016
Unique Identifier	PP2418/RBP/006

Contents

1. Purpose of guideline

The suctioning procedure is carried out by the nurse safely and efficiently in the Cardiovascular Intensive Care Unit (CVICU) within Auckland District Health Board (ADHB) as required and as indicated by the patient's condition.

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2. Pre procedure

Follow the steps below to gain the participation of the patient where possible and ensure the best outcome:

a) Explain the procedure to the patient;
b) Note baseline recordings i.e. cardiovascular status and oxygen saturations;
c) Ensure all equipment is at hand and wall suction preset.

As a guide only

The size of the suction catheter should be:

- Size of tube - 2 x 2
- e.g. ETT 9.0ch
- 9-2 x 2=14ch

The size of the suction catheter should occlude no more than half of the internal diameter of the artificial airway to avoid greater negative pressures in the airway and to potentially minimise fall in PaO_2.

- This procedure is undertaken using standard precautions
- Aim - keep the lungs clean
- Use one suction catheter per pass. i.e. may require 2 - 3 suction catheters per suction episode
- The suction equipment on the right ('clean') side of the bed (when facing the pendants) is used for suctioning ETT/trache only
- The suction equipment on the left ('dirty') side (when facing the pendants) is used for oral suctioning only

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3. Procedure

Follow the steps below to ensure safe suctioning of the patient:

a) Ensure high suction is set to 200mmHg/25Kpa measured when occluding the end of suction tubing;
b) Pre-oxygenate the patient with $Fi0_2$ 100% via ventilator for one minute prior to suctioning when oxygen requirement is greater than 50%;
c) Wash hands;
d) Attach suction catheter to tubing;
e) Don clean gloves and remove suction catheter from packaging ensuring neither is contaminated;
f) Insert suction catheter via valve opening in catheter mount and gently insert catheter with gloved hand;
g) Advance catheter to the carina (felt by resistance or stimulating a cough) and then withdraw catheter 1 cm;
h) Apply suction and withdraw using a smooth motion and taking no longer than 10 seconds (to prevent hypoxaemia);
i) Take care not to drag the used suction catheter across the patient's eyes as this can cause infection;
j) Observe oxygen saturation level after suctioning ensuring a return to normal range;
k) Repeat procedure as necessary;
l) Suction mouth and oropharynx at end of procedure using a clean catheter or Yankauer sucker;
m) If the patient has been pre-oxygenated, return FiO_2 to pre-suctioning values gradually/over one minute while maintaining saturations at pre-procedure levels.

In-line suction catheters:

- Follow steps g) – m)
- Replace in-line suction catheters every 72 hours. Date and time catheter and record on CVICU/HDU Bypass Chart

Endotracheal or tracheostomy tubes with an above the cuff suction tube for removal of subglottic secretions:

- Aspirate 2/24 using a syringe with luer lock fitting and/or as per guidelines in Tracheostomy Management – Adult (see associated ADHB documents section)
- See Tracheostomy Management - Adult guidelines for further information re care

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4. Post procedure

Follow the steps below to ensure correct completion of procedure:

a) Discard used suction catheters and gloves ensuring no contamination of surroundings;
b) Clean suction tubing and Yankauer with sterile saline;
c) Ensure the patient is settled on ventilator and observations returned to normal range or the patient remains stable while self ventilating;
d) Document suctioning on Bypass Chart and comment on secretions in the patient's clinical record.

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5. Obtaining a sputum sample (tracheal aspirate)

A sample is obtained at the medical staff members request and when there are signs indicating possible infection.

Follow the steps below to ensure an uncontaminated sample is obtained:

a) Open sputum sample packet but do not remove from packet;
b) Wash hands;
c) Don gloves;
d) Remove sampling unit from packaging and tighten screw cap;
e) Connect suction catheter to flexible tube;
f) Attach suction tubing to connector (detachable);
g) Apply suction to collect specimen;
h) Remove suction tubing and detachable connector;
i) Detach catheter from flexible tube;
j) To seal specimen trap, bend flexible tube over to close suction port;
k) Attach label to specimen trap;
l) Complete request form;
m) Place specimen and form in biohazard bag and send to laboratory via Lamson tube.

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6. Supporting evidence

- Almgren B. Endotracheal Suction. A Reopened Problem. Uppsala University.2005
- Carsten M., Rosendahl-Nielsen M.,Hjermind J.,Egerod I. Endotracheal Suctioning of the adult intubated patient. Intensive and Critical Care Nursing.25 21-30.2009
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- Journal of Critical Care (2008) 23, 126–137 Comprehensive evidence-based clinical practice guidelines for ventilator-associated pneumonia: Prevention John Muscedere MDa, Peter Dodek MD, MHScb, Sean Keenan MD, MScb, Rob Fowler MD, MDCM, MSc, Deborah Cook MD, MScd, Daren Heyland, MD, MSca for the VAP Guidelines Committee and the Canadian Critical Care Trials Group1
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- Morrow B., Futter M., Argent A., Endotracheal suctioning: from principles to practice. Intensive Care Med. 2004.30: 1167-1174

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7. Associated ADHB documents

- Standard Precautions - Infection Control
- Tracheostomy Management - Adult
- Ventilation (Invasive) in CVICU

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8. Disclaimer

No guideline can cover all variations required for specific circumstances. It is the responsibility of the health care practitioners using this ADHB guideline to adapt it for safe use within their own institution, recognise the need for specialist help, and call for it without delay, when an individual patient falls outside of the boundaries of this guideline.

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9. Corrections and amendments

The next scheduled review of this document is as per the document classification table (page 1). However, if the reader notices any errors or believes that the document should be reviewed ***before*** the scheduled date, they should contact the owner or the Clinical Policy Advisor without delay.

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Appendix 3: Point prevalence study documents

- Health and Disability Ethics Committee – ethics approval
- Health and Disability Ethics Committee – annual approval
- Auckland District Health Board Local approval
- Point prevalence case report forms (baseline and endotracheal suction data documents)

Health and Disability Ethics Committees

Multi-region Ethics Committee
Ministry of Health
Level 2, 1-3 The Terrace
PO Box 5013
Wellington
Phone (04) 470 0655
(04) 470 0646
Fax (04) 496 2191
Email: multiregion_ethicscommittee@moh.govt.nz

4 May 2009
Amended 6 May 2009

Dr C McArthur
Dept of Critical Care
Auckland Hospital
Private Bag 92024
AUCKLAND

Dear Dr McArthur

Intensive Care Point Prevalence Programme
Lead Investigator: Dr C McArthur,
Co-Investigators: Ms Lynette Newby, Dr Ross Freebairn, Ms Rachael Parke, Ms Jan Mehrtens, Ms Judy Tai, Ms Diane Mackle, Ms Mary La Pine

MEC/09/28/EXP

The above study has been given ethical approval by the **Multi-region** Ethics Committee.

Approved Documents

- May 2009 Data Collection Form dated 28 March 2009

Accreditation
The Committee involved in the approval of this study is accredited by the Health Research Council and is constituted and operates in accordance with the Operational Standard for Ethics Committees, April 2006.

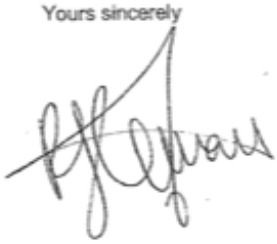
Progress Reports
The study is approved until **May 2012**. The Committee will review the approved application annually and notify the Principal Investigator if it withdraws approval. It is the Principal Investigator's responsibility to forward a progress report covering all sites prior to ethical review of the project in May 2010 . The report form is available at http://www.ethicscommittees.health.govt.nz. Please note that failure to provide a progress report may result in the withdrawal of ethical approval. A final report is also required at the conclusion of the study.

Amendments
It is also a condition of approval that the Committee is advised of any adverse events, if the study does not commence, or the study is altered in any way, including all documentation eg advertisements, letters to prospective participants.

Please quote the above ethics committee reference number in all correspondence.

It should be noted that Ethics Committee approval does not imply any resource commitment or administrative facilitation by any healthcare provider within whose facility the research is to be carried out. Where applicable, authority for this must be obtained separately from the appropriate manager within the organisation.

Yours sincerely



Rebecca Stewart
Multi-region Ethics Committee Administrator
Email: rebecca_stewart@moh.govt.nz

Health and Disability Ethics Committees
20 Aitken Street
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0800 4 ETHIC
hdecs@moh.govt.nz

29 October 2015

Dr Colin McArthur
Auckland City Hospital
Department of Critical Care Medicine
Park Road
Grafton
Auckland 1023

Dear Dr McArthur

Re:	**Ethics ref:**	**MEC/09/28/EXP/AM04**
	Study title:	Intensive Care Point Prevalence Programme

This letter is to confirm approval of the annual progress report for this study, reviewed by the Chairperson of the Northern B Health and Disability Ethics Committee on 27 October 2015. Existing approval remains valid.

Your **next progress report** is due by **7 November 2016.**

Please don't hesitate to contact us for further information.

Yours sincerely,

Raewyn Sporle
Chairperson
Northern B Health and Disability Ethics Committee

Encl: appendix A: documents submitted

Research Office
Level 14, Support Bldg
Auckland City Hospital
PB 92024
Grafton, Auckland
Phone: 64 9 307 4949 Extn. 23854
Email: SamanthaJ@adhb.govt.nz
Website: www.adhb.govt.nz/ResearchOffice

5 May 2009

Dr Colin McArthur
Dept DCCM
Auckland City Hospital

This is the ADHB Management Approval. Please keep in your Trial Master File.

Dear Colin

RE: Research project A+4397 (Ethics # MEC/09/28/EXP) Intensive Care Point Prevalence Programme

The Research Office under delegated authority from the Research Review Committee wishes to thank you for the opportunity to review your study and has given approval for your research project.

This approval is given based on the materials submitted for the ADHB-RRC via the Research Office. It is **essential** that you notify the Research Office immediately should there be changes or amendments to the study, and these changes must be highlighted on your documents, e.g. changes to the protocol, study finance, legal documents and/or change of study status. Continued Auckland DHB approval for research is dependant on the Research Office receiving all new documentation.

Please send a copy of your final report to the Research Office (Level 14, Support Bldg, Auckland City Hospital, PB 92024, Auckland) on completion of the project.

If you have any questions please do not hesitate to contact the Research Office.

Yours sincerely

On behalf of
the ADHB Research Review Committee
Dr Samantha Jones
Manager, Research Office
Auckland DHB

c.c Lynette Newby

POINT PREVALENCE PROGRAM

APPENDIX 6

BEDSIDE DATA COLLECTION SHEET
SUCTIONING EPISODES

Hospital ID: I__I__I__I

Patient ID: I__I__I

IMPORTANT INFORMATION

This data collection sheet applies to the first four suctioning epidoses that occur after 10am on the study day.

Suctioning includes any of the following:

- **Open suction:** suction performed with a Y suction catheter or similar where the ventilator circuit is disconnected from the endotracheal tube/tracheostomy tube.
- **Semi-closed:** suction performed through a self-sealing valve in the catheter mount with a Y suction catheter or similar where the patient ventilator circuit still remains connected to the mechanical ventilator.
- **Closed suction:** suction is performed using an inline suction system where the patient remains connected to the mechanical ventilator throughout the suctioning procedure.

A suction episode consists of the placement of a suction catheter through the artificial airway using one of the above methods into the trachea with the application of a negative pressure as the catheter is being withdrawn to remove airway secretions.

Within a suction episode, even though a clinician may undertake more than one suction pass, this is considered one suction episode.

What were the main indications/triggers for the first 4 suctioning episodes after 10am? (select all that apply)

	Episode 1	Episode 2	Episode 3	Episode 4
No further suction episode		Yes [Y] No need to complete further	Yes [Y] No need to complete further	Yes [Y] No need to complete further
Hypoxia indentified on arterial blood gas (ABG)	Yes [Y] **If Yes,** What is the PaO2 (mmHg)? I__I__I__I	Yes [Y] **If Yes,** What is the PaO2 (mmHg)? I__I__I__I	Yes [Y] **If Yes,** What is the PaO2 (mmHg)? I__I__I__I	Yes [Y] **If Yes,** What is the PaO2 (mmHg)? I__I__I__I
Saw tooth pattern on ventilator waveform	Yes [Y] No [N]	Yes [Y] No [N]	Yes [Y] No [N]	Yes [Y] No [N]
Hypercapnia identified on ABGs	Yes [Y] **If Yes,** What is the PaCO2 (mmHg)? I__I__I__I	Yes [Y] **If Yes,** What is the PaCO2 (mmHg)? I__I__I__I	Yes [Y] **If Yes,** What is the PaCO2 (mmHg)? I__I__I__I	Yes [Y] **If Yes,** What is the PaCO2 (mmHg)? I__I__I__I
Decreased SpO_2	Yes [Y] **If Yes,** What is the SpO2 (%)? I__I__I__I	Yes [Y] **If Yes,** What is the SpO2 (%)? I__I__I__I	Yes [Y] **If Yes,** What is the SpO2 (%)? I__I__I__I	Yes [Y] **If Yes,** What is the SpO2 (%)? I__I__I__I
Auscultation	Yes [Y] No [N]	Yes [Y] No [N]	Yes [Y] No [N]	Yes [Y] No [N]
Audible secretions	Yes [Y] No [N]	Yes [Y] No [N]	Yes [Y] No [N]	Yes [Y] No [N]

POINT PREVALENCE PROGRAM

APPENDIX 6

BEDSIDE DATA COLLECTION SHEET
SUCTIONING EPISODES

Hospital ID: I__I__I__I

Patient ID: I__I__I

	Episode 1	Episode 2	Episode 3	Episode 4
Visible secretions	Yes [Y] No [N]	Yes [Y] No [N]	Yes [Y] No [N]	Yes [Y] No [N]
Routine/as per unit policy	Yes [Y] No [N]	Yes [Y] No [N]	Yes [Y] No [N]	Yes [Y] No [N]
Other	Yes [Y] Please specify: _____ _____	Yes [Y] Please specify: _____ _____	Yes [Y] Please specify: _____ _____	Yes [Y] Please specify: _____ _____

For each suctioning episode, please record the following:

	Episode 1	Episode 2	Episode 3	Episode 4
Set suction pressure (mmHg)	I__I__I__I	I__I__I__I	I__I__I__I	I__I__I__I
SpO_2 pre suction (%)	I__I__I__I	I__I__I__I	I__I__I__I	I__I__I__I
SpO_2 post suction (%)	I__I__I__I	I__I__I__I	I__I__I__I	I__I__I__I
Patient was pre-oxygenated	Yes [Y] **If Yes,** please complete next question	Yes [Y] **If Yes,** please complete next question	Yes [Y] **If Yes,** please complete next question	Yes [Y] **If Yes,** please complete next question

Indicate the main reason for pre-oxygenation for each episode: (select all that apply for each episode)

	Episode 1	Episode 2	Episode 3	Episode 4
Unit policy	Yes [Y]	Yes [Y]	Yes [Y]	Yes [Y]
SpO_2 level	Yes [Y]	Yes [Y]	Yes [Y]	Yes [Y]
Patient condition	Yes [Y]	Yes [Y]	Yes [Y]	Yes [Y]
Other	Yes [Y] Please specify: _____ _____	Yes [Y] Please specify: _____ _____	Yes [Y] Please specify: _____ _____	Yes [Y] Please specify: _____ _____

POINT PREVALENCE PROGRAM

ICU ADMISSION DATA – ALL PATIENTS (Age 16 and above) FORM 1

Hospital ID: I__I__I__I

Patient ID: I__I__I

1.1 I__I__I/I__I__I/I__I__I__I__I Study Day Date

GENERAL PATIENT INFORMATION

1.2 M F Patient's gender

1.3 I__I__I__I Patient's age (years)

1.4 I__I__I/I__I__I/I__I__I__I__I Hospital admission date (dd/mm/yyyy)

1.5 I__I__I:I__I__I Hospital admission time (use 24 hour clock)

1.6 I__I__I/I__I__I/I__I__I__I__I ICU admission date (dd/mm/yyyy)

1.7 I__I__I:I__I__I ICU admission time (use 24 hour clock)

1.8 From where was the patient admitted to the ICU? *(select only one)*

- Y Emergency Department
- Y Hospital Floor (Ward)
- Y Transfer from another ICU
- Y Transfer from another hospital (except from another ICU)
- Y Admitted from Operating Theatre following **EMERGENCY** surgery
- Y Admitted from Operating Theatre following **ELECTIVE** surgery

1.9 Y N Has this patient previously been in ICU in **THIS** hospital during **THIS** hospital admission?

1.10 Y N Was this a **POST-OPERATIVE** admission to ICU? (Answer **yes** if patient admitted **DIRECTLY** from the operating theatre or the recovery room)

1.11 **APACHE III Code** [See list of codes in Data Dictionary, Appendix 1]

- I__I__I__I__I **If No,** What is the APACHE III **non-operative** diagnostic code?
- I__I__I__I__I **If Yes,** What is the APACHE III **postoperative** diagnostic code?

1.12 I__I__I__I Patient's weight (kg)

1.13 Was the above weight estimated or measured?

- Y Estimated
- Y Measured

Form continued on next page

POINT PREVALENCE PROGRAM

ICU ADMISSION DATA – ALL PATIENTS (Age 16 and above) FORM 1

Hospital ID: I__I__I__I

Patient ID: I__I__I

PATIENT SUB CATEGORY

TRAUMA

1.14 Y N Was trauma the patient's primary reason for hospital admission (include burns or any type of trauma including falls in the elderly)?

→ If **no**, go to question **1.22**

→ If **yes**, go to question **1.15**

Which of the following criteria for TRAUMA did the patient meet? (refer to Data Dictionary for definitions)

1.15 Y N An injury to the body produced by mechanical forces

1.16 Y N A primary admission diagnosis of burns

→ If **no**, go to question **1.18**

→ If **yes**, answer question **1.17**

1.17 I__I__I__I What was the percentage of body area of burns?

1.18 I__I__I What was the last GCS prior to sedation?

1.19 Was the GCS recorded in the patient record or estimated from a description of the patient's neurological state?

Y Recorded

Y Estimated

1.20 Y N Was a cranial CT scan performed prior to ICU admission?

→ If **no**, go to question **1.22**

→ If **yes**, answer question **1.21**

1.21 Y N Was there an abnormality on cranial CT consistent with acute traumatic brain injury?

SEPSIS ON STUDY DAY

1.22 Y N Does the patient meet BOTH of the following criteria for sepsis today (refer to Data Dictionary for definitions)

- a defined focus of infection (positive cultures not required)
- 2 or more of the **S**ystemic **I**nflammatory **R**esponse **S**yndrome criteria
  - Core temperature >38°C or <36°C.
  - WCC >12 x 10^9/L or < 4 x 10^9/L or > 10% immature neutrophils (Band forms)
  - Tachycardia - Heart rate >90 beats/minute
  - Tachypnoea - >20 breaths per minute or a $PaCO_2$ <32 mmHg or mechanical ventilation

ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS) ON STUDY DAY

1.23 Y N Did the patient meet ALL of the following criteria for **severe** ARDS? (refer to **Data Dictionary** for definition)

- Within 1 week of a known clinical insult or new or worsening respiratory symptoms
- Bilateral opacities not fully explained by effusions, lobar/lung collapse, or nodules
- Respiratory failure not fully explained by cardiac failure or fluid overload
- $PaO_2/FiO_2 \leq$ **100 mmHg** With PEEP ≥ 5cm H_2O

POINT PREVALENCE PROGRAM

ICU ADMISSION DATA – ALL PATIENTS (Age 16 and above) FORM 1

Hospital ID: I__I__I__I

Patient ID: I__I__I

APACHE & SOFA SCORE

APACHE II score

1.24 I__I__I What was the total APACHE II score **for the first 24 hours of the ICU admission**? (Record the APACHE II from your ICU database, or if necessary derive the score using an APACHE II worksheet. See Data Dictionary, Appendix 3)

1.25 I__I What was the chronic health points score (part C). If the patient had chronic health points, indicate all that apply below:

Y	Liver	Biopsy proven cirrhosis & documented portal hypertension (PH); episodes of upper GI bleeding due to PH; or prior episodes of hepatic failure/encephalopathy/coma
Y	Renal	Receiving chronic dialysis
Y	Cardiovascular	New York Heart Association Class IV – symptoms at rest
Y	Respiratory	Chronic restrictive, obstructive or vascular disease resulting in severe exercise restriction (i.e. unable to climb stairs, perform household duties); or documented chronic hypoxia, hypercapnia, 2º polycythemia, severe pulmonary hypertension (>40mmHg) or respiratory dependency
Y	Immunocompromised	Patient has received therapy that suppresses resistance to infection, e.g. immuno-suppression, chemotherapy, radiotherapy, long term or recent high dose steroids, or has a disease sufficiently advanced to suppress resistance to infection (e.g. leukaemia, lymphoma, AIDS)

SOFA Domains Please document each of the SOFA domains using data for **the most deranged score within the 24 hr study period** (see Data Dictionary, Appendix 4).

1.26 I__I SOFA Respiratory

1.27 I__I SOFA Coagulation

1.28 I__I SOFA Liver (Hepatic)

1.29 I__I SOFA Cardiovascular

1.30 I__I SOFA Renal

ICU RESEARCH CAPACITY

1.31 Y N Has this patient been enrolled in one or more interventional clinical trials during this ICU admission?

If **no**, go to question **1.32**

If yes, go to question **1.33**

1.32 Y N **If no**, was this patient eligible for an interventional clinical trial (fulfilled inclusion and no exclusion criteria) but not recruited, for any reason ("missed recruitment").

This form is finished. Go to Form 2.

1.33 If this patient is/was enrolled in an interventional clinical trial is it: (select all that apply)

Y A fully sponsored commercial trial?

Y A CTG endorsed multicentre trial?

Y Another investigator initiated trial?

This form is complete. Please go to Form 2.

POINT PREVALENCE PROGRAM

SECRETION CLEARANCE & SUCTIONING FORM 5

Hospital ID: I__I__I

Patient ID: I__I__I

IMPORTANT INFORMATION

Complete Form 5 for **INTUBATED** patients in the ICU at 10am on the study day.

A bedside form (study tool) is available to assist with bedside data collection for the first four suctioning episodes after 10am on the study day. Please provide bedside nurses with this form prior to 10am on the study day. Refer to the Data Dictionary for a copy of the bedside form and definitions.

Some questions in this form will require assistance from the bedside nurse and/or unit physiotherapist.

The final section of this form is only to be completed for patients who have been ventilated for 24 hours or more at 10am on the study day.

5.1 Y N Does the patient have an endotracheal tube (ETT) or tracheostomy tube?

→ If **No**, *(form is complete)*

→ If **Yes**, *(continue to question **5.2**)*

5.2 Indicate the type of intubation: *(select only one)*

Y Endotracheal tube (ETT)

Y Tracheostomy tube

SUCTIONING

5.3 Y N UKN Did the patient receive endotracheal or tracheostomy suctioning during the study day?

→ If **No** or **Unknown**, *(go to question. **5.34**)*

→ If **yes**, *(continue to question **5.4**)*

5.4 I__I__I__I UKN Please specify how many suctioning episodes occurred during the study day.

5.5 Y N Was the patient extubated or decannulated during the first 4 hours from 10am on the study day (10am - 2pm)?

→ If **No**, *(go to question **5.7**)*

→ If **Yes**, *(go to question **5.6**)*

5.6 Y N UKN Was the patient suctioned immediately prior to extubation?

Form continued on next page

POINT PREVALENCE PROGRAM

SECRETION CLEARANCE & SUCTIONING FORM 5

Hospital ID: I__I__I__I

Patient ID: I__I__I

SUCTIONING EPISODES

Questions **5.7** to **5.33** apply only to the next four suctioning episodes after 10am on the study day for this patient. Refer to the Data Dictionary for definitions.

These questions may be best answered by the bedside nurse. There is a bedside data collection tool as an appendix to the Data Dictionary.

Episode 1

5.7 What was the main indication or trigger for the suctioning episode? *(select all that apply)*

- [Y] Hypoxia identified on arterial blood gas (ABG)
  - → I__I__I__I mmHg **If Yes,** What is the PaO2?
- [Y] Hypercapnia identified on arterial blood gas (ABG)
  - → I__I__I__I mmHg **If Yes,** What is the PaCO2?
- [Y] Decreased SpO2
  - → I__I__I__I % **If Yes,** What is the Sp02?
- [Y] Saw-tooth pattern on ventilator waveform
- [Y] Auscultation
- [Y] Audible secretions
- [Y] Visible secretions
- [Y] Other, please specify: _____

5.8 I__I__I__I mmHg What was the set suction pressure?

5.9 I__I__I__I % What was the patients' SpO2 prior to suctioning?

5.10 I__I__I__I % What was the patients' SpO2 post suctioning?

5.11 [Y] [N] Was the patient pre-oxygenated prior to this suctioning episode?

- If **No**, *(go to questions for **Episode 2**, starting at **5.13**)*
- If **Yes**, *(continue to question **5.12**)*

5.12 What was the main reason for pre-oxygenation for the suctioning episode? *(select only one)*

- [Y] Unit policy
- [Y] SpO2 level
- [Y] Patient condition
- [Y] Other, please specify: _____

Episode 2

5.13 [Y] No further suction episodes for the study day, *(go to question **5.34**)*

5.14 What was the main indication or trigger for the suctioning episode? *(select all that apply)*

- [Y] Hypoxia identified on arterial blood gas (ABG)
  - → I__I__I__I mmHg **If Yes,** What is the PaO2?
- [Y] Hypercapnia identified on arterial blood gas (ABG)
  - → I__I__I__I mmHg **If Yes,** What is the PaCO2?
- [Y] Decreased SpO2
  - → I__I__I__I % **If Yes,** What is the Sp02?
- [Y] Saw-tooth pattern on ventilator
- [Y] Auscultation
- [Y] Audible secretions
- [Y] Secretions visible

Y Other, please specify: _____

5.15 I__I__I__I mmHg What was the set suction pressure?

5.16 I__I__I__I % What was the patients' SpO2 prior to suctioning?

5.17 I__I__I__I % What was the patients' SpO2 post suctioning?

5.18 Y N Was the patient pre-oxygenated prior to this suctioning episode?

If **No**, *(go to questions for **Episode 3**, starting at **5.20**)*

If **Yes**, *(continue to question **5.19**)*

5.19 What was the main reason for pre-oxygenation for the suctioning episode? *(select only one)*

Y Unit policy

Y SpO2 level

Y Patient condition

Y Other, please specify: _____

Episode 3

5.20 Y No further suction episodes for the study day, *(go to question **5.34**)*

5.21 What was the main indication or trigger for the suctioning episode? *(select all that apply)*

Y Hypoxia identified on arterial blood gas (ABG)

→ I__I__I__I mmHg **If Yes,** What is the PaO2?

Y Hypercapnia identified on arterial blood gas (ABG)

→ I__I__I__I mmHg **If Yes,** What is the PaCO2?

Y Decreased SpO2

→ I__I__I__I % **If Yes,** What is the Sp02?

Y Saw-tooth pattern on ventilator

Y Auscultation

Y Audible secretions

Y Secretions visible

Y Other, please specify: _____

5.22 I__I__I__I mmHg What was the set suction pressure?

5.23 I__I__I__I % What was the patients' SpO2 prior to suctioning?

5.24 I__I__I__I % What was the patients' SpO2 post suctioning?

5.25 Y N Was the patient pre-oxygenated prior to this suctioning episode?

If **No**, *(go to questions for **Episode 4**, starting at **5.27**)*

If **Yes**, *(continue to question **5.26**)*

5.26 What was the main reason for pre-oxygenation for the suctioning episode? *(select only one)*

Y Unit policy

Y SpO2 level

Y Patient condition

Y Other, please specify: _____

Episode 4

5.27 Y No further suction episodes for the study day, *(go to question **5.34**)*

5.28 What was the main indication or trigger for the suctioning episode? *(select all that apply)*

Y Hypoxia identified on arterial blood gas (ABG)

→ I__I__I__I mmHg **If Yes,** What is the PaO2?

Y Hypercapnia identified on arterial blood gas (ABG)

POINT PREVALENCE PROGRAM

SECRETION CLEARANCE & SUCTIONING FORM 5

Hospital ID: I__I__I__I

Patient ID: I__I__I

I__I__I__I mmHg **If Yes,** What is the PaCO2?

Y Decreased SpO2

→ I__I__I__I % **If Yes,** What is the Sp02?

Y Saw-tooth pattern on ventilator

Y Auscultation

Y Audible secretions

Y Secretions visible

Y Other, please specify: _____

5.29 I__I__I__I mmHg What was the set suction pressure?

5.30 I__I__I__I % What was the patients' SpO_2 prior to suctioning?

5.31 I__I__I__I % What was the patients' SpO_2 post suctioning?

5.32 Y N Was the patient pre-oxygenated prior to this suctioning episode?

If **No,** *(go to questions for **Episode 4**, starting at **5.34**)*

If **Yes,** *(continue to question **5.33**)*

5.33 What was the main reason for pre-oxygenation for the suctioning episode? *(select only one)*

Y Unit policy

Y SpO2 level

Y Patient condition

Y Other, please specify: _____

PATIENTS VENTILATED FOR 24 HOURS OR MORE AT 10AM ON STUDY DAY

5.34 Y N Has the patient been mechanically ventilated for 24 hours or greater at 10 am on the study day?

If **No,** *(this form is finished. Please go to **Form 6**.)*

If **Yes,** *(continue to question **5.35**)*

5.35 I__I__I . I__I cm What is the size of the endotracheal tube or tracheostomy?

5.36 What humidification system is in place? *(select only one)*

Y Heat and moisture exchanger

Y Water bath humidification

Y Neither

5.37 Does the patient have any of these devices or is the patient receiving any of the following therapies on the study day? *(select all that apply)*

Y High frequency oscillatory ventilation (HFOV)

Y Veno-venous extracorporeal membraneoxygenation (VV-ECMO)

Y Veno-arterial extracorporeal membraneoxygenation (VA-ECMO)

Y Ventricular assist device

Y Intraortic balloon counterpulsation device

Y Intracranial pressure monitoring (ICP)

Y Ventricular CSF drainage

Y None of the above

5.38 Y N Were any chest physiotherapy interventions documented during the study day?

If **no**, go to question. **5.40**

If **yes**, go to question **5.39**

Form continued on next page

PATIENT OUTCOME- ALL PATIENTS FORM 6

Hospital ID: I__ı__ı__I

Patient ID: I__ı__I

IMPORTANT INFORMATION

Please collect the following information from your hospital database on day 28 (counting the Point Prevalence Day as Day 1) so collect data on **Monday October 12th** or **Tuesday November 10th**, 2015, depending on the Point Prevalence Day chosen.

PATIENT OUTCOME

6.1 Y N At the end of day 28 has the patient been discharged (alive or dead) from your ICU?

If **No**, *(form is complete)*

If **Yes,** *(continue to question 6.2)*

6.2 I__I__I/I__I__I/I__I__I__I__I What was the date of ICU discharge? *(dd/mm/yyyy)*

6.3 Y N Was the patient alive at ICU discharge?

If **no,** form is **complete**

If **yes,** go to **6.4**

6.4 Y N At the end of day 28 has the patient been discharged (alive or dead) from your hospital? [This includes transfer to a different hospital]

If **no,** form is **complete**

If **yes,** go to **6.5**

6.5 I__I__I/I__I__I/I__I__I__I__I What was the date of hospital discharge? *(dd/mm/yyyy)*

6.6 Y N Was the patient alive at hospital discharge?

THANK YOU – Data Collection for this patient is complete.

Please fill out the Unit Level Questions (Form 7) once per ICU.

Appendix 4: Patient Experience of Endotracheal Suction documents

- PETS study proposal
- Health and Disability Ethics Committee approval
- Auckland District Health Board Local approvals
- A+ Charitable Trust funding letter
- Data dictionary
- Case report form
- Information and consent form

Research Proposal

The endotracheal tube and endotracheal suction

An exploration of

Adult Cardiac Surgical Intensive Care patients'

experience

Investigator

Eileen Gilder RN

Rachael Parke RN PhD

Andrew Jull RN PhD

Universal Trial Number - U1111-1186-9357

ACTRN12616001515482

Background

It has long been recognised that patients in the intensive care unit (ICU) experience pain and distress that can have a debilitating effect upon their recovery (1-3). Pain has been ranked in the top three stressors in the ICU setting (2) and is frequently underestimated as an issue for patients by the nurses caring for them (2,4).

The most common causes of pain in ICU are repositioning patients, endotracheal suction (ETS) and procedural pain (5). Endotracheal Suction (ETS) is a routine procedure in any ICU and is performed to maintain pulmonary hygiene when a patient has an endotracheal tube (ETT) (artificial airway) in place. Both the ETT and ETS are frequently described by patients as painful and uncomfortable, the skill of the nurse providing ETS affects the patient experience (1,6).

The Cardiothoracic and Vascular Intensive Care Unit (CVICU) has approximately 1200 planned cardiac surgical patients a year admitted following cardiac surgery. Each of these patients will be ventilated and experience both an ETT and ETS during their admission. A patient who has an uncomplicated, planned admission will be ventilated for 3-12 hours. There is currently minimal evidence about the need for ETS in this group of patients. A planned randomised controlled trial (RCT) of avoiding ETS in this group of patients is to be conducted in the CVICU. This single centre, non-inferiority, randomised controlled trial will assess the safety and efficacy of avoiding endotracheal suction in patients having planned cardiac surgery and who are ventilated for less than 12 hours.

The RCT will recruit 200 patients who are expected to have uncomplicated cardiac surgery. Participants will be randomised to receive standard care that includes ETS as routine, or standard care, without ETS. For safety reasons there is the option to provide ETS is the non-suction group, these are

- Oxygen saturation <90%.
- Deterioration of ABGs (PaO2 below 8Kpa).
- Reduced air entry on auscultation.
- On medical request/advice.

The study has the full support of the senior medical team in CVICU. Part of the RCT includes a brief, scripted interview with the patient, prior to discharge about their experience of both the ETT and ETS. This will be an opportunity for the patients to provide feedback to the nursing staff about the experience of ETS.

Prior to commencing the RCT, there is the opportunity to explore the patient experience of the ETT and ETS within the CVICU in greater detail. To ensure that this qualitative study aligns with the planned RCT inclusion and exclusion criteria will be broadly the same as the RCT and the patients will provide prior consent, however, this will be obtained following cardiac surgery to prevent the patients from having any preconceived ideas about the experience of the ETT and ETS. It will provide an opportunity to test the questions that will be used in the RCT for ease of use and appropriateness. This qualitative study will explore both the patient's perception of pain and the experience of the ETT and ETS.

Inclusion criteria

- ≥16 years old,
- Patients who have had cardiac surgery with cardiopulmonary bypass (CPB),
- Extubation ≤12 hours of admission to CVICU.

Exclusion criteria

- Ventilated for over 12 hours.
- Non-English speaking
- Documented chronic pain
- Pain Assessment

Patient's self-reported pain is the gold standard for pain assessment (7). However, frequently the ICU patient is sedated and unable to report their pain. The International Association for the Study of Pain states, "the inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment" (8). More recently, studies on ICU-discharged but still-hospitalized patients showed that 82% (n = 75) remembered pain or discomfort associated with the endotracheal tube and 77% (n = 93) remembered experiencing moderate to severe pain during their ICU stay. One week after discharge from the ICU, 82% (n = 120) of cardiac surgery patients reported pain as the most common traumatic memory of their ICU stay; 6 months later, 38% still recalled pain as their most traumatic ICU memory (9). Cardiac surgical patients frequently describe pain as a factor, this may be increased in this population due to the surgical incision (10).

There are a variety of pain assessment tools available, for use with the unconscious ventilated patient, conscious ventilated patient and the conscious non-ventilated patient. For the unconscious ventilated patient the most widely validated tools are the Behavioural Pain Score (BPS) and the Critical Care Pain Observation Tool (CPOT) (Appendix 1). The CPOT has been well validated in the cardiac surgical population (11-13) and includes the ability for use with the non-ventilated patient. The American Society of Pain Management Nursing recommends the use of behavioural pain assessment in critically ill unconscious patients, including the CPOT and the NRS. Other scales include visual analogue scales (VAS), numerical rating scales (NRS) and verbal rating scales (VRS). All of the scales are validated and the NRS consistently appears to be the most discriminative (14,15). The NRS has been adapted to a visually enlarged scale (NRS-V) (Appendix 2) and this has been shown to be a feasible tool that allows the conscious ventilated patients' to self-report pain by pointing to their pain score (14). These tools have been evaluated in both the ICU setting (13) and using cold presser trials to compare different pain scales for validity (12). The CPOT tool was evaluated by comparing the results of the CPOT reported pain and the patients self-reported pain at rest, following a nociceptive procedure (turning) and 20 minutes following the procedure (11). The study population were post-operative cardiac surgical patients and the CPOT was shown to have good specificity across all domains, it was less sensitivity when the patient was at rest and following the procedure. It demonstrated good sensitivity during the nociceptive procedure. It is recognised that the use of behavioural pain assessment scales needs further investigation and development, however, the CPOT appears to be a valid tool, has acceptable validity, sensitivity, and specify.

Current practice on CVICU is to assess patients pain when they are awake, however, there is no attempt to use a behavioural assessment tool to assess pain in the unconscious patient. This study will provide

such an opportunity as the nursing staff will assess the patients' pain prior to an ETS procedure. The CPOT and NRS-V will be used to assess patients pain when they are awake. A CPOT score of >2 indicates moderate pain, requiring intervention (11).

Aims and Objectives

The study aims to

- explore the patient's perception of pain and the experience of the ETT and ETS.
- The study will pilot the use of validated behavioural pain assessment tools not currently in use in CVICU.
- Compare the pain score results between patients and nurses. There is frequently a significant difference between these scores.
- To describe the patient experience of the ETT and the ETS.

There is a planned RCT to follow this study and this study provides an opportunity to test the questions for use in the RCT. This study will explore in detail the patient experience. The questions allow us to see if a brief interview is feasible and if the questions are appropriate to elicit the patient's perception of the ETT and the experience of ETS.

Study design and Methods

Consent.

This will be a prospective, descriptive study, using a semi-structured interview technique. Following ethics and institutional approvals, written informed consent will be obtained. The patients will be screened and approached by the CVICU research nurses pre-operatively. Current standard practice is to assess the patient's pain when they are awake, therefore the consent process will include permission to use the data collected as part of routine care. The consent process will also request permission to use the CPOT pain assessment data collected while the patient was unconscious. A member of the CVICU research team and not the principal investigator (P.I.) will seek consent, this will ensure that the patient has an opportunity to decline participation in the study without the P.I. influencing their decision. To provide consistency in the interviews, all interviews will be conducted by the P.I. The study will recruit 10 patients using convenience sampling.

Study procedures

Pain assessments

In addition to the standard care that includes ETS as required and a pain assessment when the patient is awake, the patients will have 2 study pain assessments performed during their ICU stay. These will be at the following times

1. While the patient is unconscious, ventilated and sedated, using the CPOT

    a. Time 1 = prior to ETS

    b. Time 2 = during after ETS

c. Time 3 = 10 minutes after ETS

2. When the patient is awake and intubated, using the CPOT and NRS-V

a. Time 1 = prior to ETS

b. Time 2 = immediately after ETS

c. Time 3 = 10 minutes after ETS

In addition to these 2 documented pain scores, the CVICU research nurse will conduct a pain assessment at the same time. This will allow an independent pain assessment and act as a comparison of the pain assessment by the bedside nurses and an independent observer. The CVICU nurses will be trained in the use of the CPOT to ensure continuity of data. CPOT evaluations will be conducted before the NRS-V to reduce the risk of the patients' self-reported score affecting the CPOT evaluation.

Interviews

In addition to these assessments, the patients will have an interview prior to discharge. This will be conducted in private, on the ward on day 4-6 after surgery. It is anticipated that the interview will last 10-30 minutes. The interview will be conducted in hospital, prior to discharge to try and maximise the patient recall of ETT and ETS. There is also the opportunity to address any clinical concerns that the patient may identify prior to the patient being discharged. The interview will be recorded and transcribed. This will be an opportunity to test the process for the RCT. The questions will be open-ended, non-leading questions. The interviewer will guide and prompt the interviewee but allow the patient to describe their experience.

The questions will be

1. Tell me about your experience of the breathing tube?
2. Tell me about your experience of having suction through the breathing tube?
3. Can you describe how it feels to breathe through the tube?

Clarifying questions will be used as required and will include

1. Were you awake during suction and can you describe what happened?
2. Can you describe how much control you thought you had while in intensive care?
3. Tell me how comfortable you were while in intensive care?
4. How would you describe your experience of the breathing tube?
5. How would describe the feeling of the breathing tube?
6. How much information were you given about the breathing tube?
7. How would you describe your experience of having suction?
8. How much information were you given about being suctioned?
9. How would you describe the feeling of having suction?
10. What could have been done differently?

These questions have been developed based upon work from previous studies that identified patients feeling isolated or lonely, not being able to communicate, receiving little information and have poor pain control (16).

The interviews will be conducted by the principal investigator (EG) to ensure consistency and continuity. They will be transcribed using a transcription service that has signed a confidentiality clause. The patients will be allocated a unique study number so there are no identifiers for the individuals.

Analysis

The data will be analysed following transcription, using thematic analysis. Thematic analysis aims to offer insights into the experience of individuals. Thematic analysis has been considered to be a foundational skill within qualitative research (17).

The data will be read and re-read by EG and emergent themes identified and coded. The analysis will be conducted using both the written transcripts and audio recordings. The initial findings will be reviewed by the co-investigators and discussion about emerging themes will be reviewed. Further refinement will be conducted by EG and once saturation has been achieved the findings will be written up for dissemination. Nvivo software will be used to aid data analysis. This is an established software programme that helps streamline the analysis of qualitative data.

Dissemination

The themes that emerge from the interviews will be written up and the findings will be presented back to the CVICU nursing and medical staff. This can underpin any change in practice, e.g. implementing the use of behavioural pain assessment in CVICU. There will be both local and international presentations and the results will be written up for publication in an appropriate peer-reviewed journal.

Discussion

This study will be the first time that a qualitative research study has been conducted within the CVICU research. It will allow patients an opportunity to provide feedback about the experience of ETT and ETS, one of the routine procedures performed by ICU nurses. It will add to the body of knowledge about the experience of the ETT and ETS in those patients who are ventilated for less than 12 hours. It has the potential to inform practice in this patient group both in CVICU and in other cardiac centres throughout New Zealand.

This study will form part of a programme of research that is evaluating the use and attitudes and planned avoidance of ETS in CVICU. It will be followed by an RCT that plans to avoid ETS in patients ventilated for 12 hours or less. If the RCT demonstrates that it is safe to avoid ETS in this patient group, and this study demonstrates that the experience is painful and distressing for patients this has the potential to support a change in practice, both within CVICU and for all uncomplicated post-operative cardiac patients with New Zealand and internationally. This will help to improve patient care for postoperative cardiac patients.

It is argued that pain should be considered to be the “fifth vital sign”, and be measured and documented as carefully and regularly as heart rate, blood pressure, respiratory rate and temperature. This study will

help us identify how we can improve our assessment and management of patients experience of the ETT and ETS.

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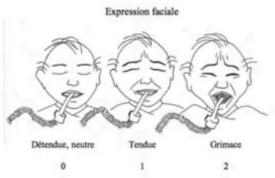
The Critical-Care Pain Observation Tool (CPOT)

(Gélinas et al., 2006)

Indicator	Score		Description
Facial expression  Caroline Arbour, RN, B.Sc., PhD(student) School of Nursing, McGill University	Relaxed, neutral	0	No muscle tension observed
	Tense	1	Presence of frowning, brow lowering, orbit tightening and levator contraction or any other change (e.g. opening eyes or tearing during nociceptive procedures)
	Grimacing	2	All previous facial movements plus eyelid tightly closed (the patient may present with mouth open or biting the endotracheal tube)
Body movements	Absence of movements or normal position	0	Does not move at all (doesn't necessarily mean absence of pain) or normal position (movements not aimed toward the pain site or not made for the purpose of protection)
	Protection	1	Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements
	Restlessness/Agitation	2	Pulling tube, attempting to sit up, moving limbs/thrashing, not following commands, striking at staff, trying to climb out of bed
Compliance with the ventilator (intubated patients)	Tolerating ventilator or movement	0	Alarms not activated, easy ventilation
	Coughing but tolerating	1	Coughing, alarms may be activated but stop spontaneously
	Fighting ventilator	2	Asynchrony: blocking ventilation, alarms frequently activated
OR **Vocalization (extubated patients)**	Talking in normal tone or no sound	0	Talking in normal tone or no sound
	Sighing, moaning	1	Sighing, moaning
	Crying out, sobbing	2	Crying out, sobbing
Muscle tension Evaluation by passive flexion and extension of upper limbs when patient is at rest or evaluation when patient is being turned	Relaxed	0	No resistance to passive movements
	Tense, rigid	1	Resistance to passive movements
	Very tense or rigid	2	Strong resistance to passive movements or incapacity to complete them
TOTAL	**___ / 8**		

Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

04 816 3985
hdecs@moh.govt.nz

17 October 2016

Mrs Eileen Gilder
CVICU - Ward 48
Auckland City Hospital
Private Bag 92024
Auckland 1142

Dear Mrs Gilder

Re:	**Ethics ref:**	**16/STH/159**
	Study title:	An exploration of Adult Cardiac Surgical Intensive Care patients' experience

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions (if applicable):

- The Committee requests that the interpreter box is removed from the Consent Form and replaced with a clear statement such as 'If you need an INTERPRETER, please tell us.'
- Please revise the formatting of the Participant Information Sheet to increase font size and white space to improve readability of the document. The Committee noted that this may cause the document to be 3 pages long but that this is their preference.

Non-standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to or reviewed by HDEC before commencing your study.

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the Standard Operating Procedures at http://ethics.health.govt.nz/home.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

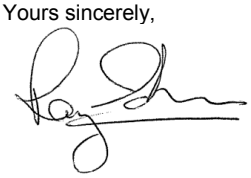
Your next progress report is due by 17 October 2017.

Participant access to ACC

The Southern Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Ms Raewyn Idoine
Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix B
Statement of compliance and list of members

Statement of compliance

The Southern Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Devonie Eglinton	Non-lay (intervention studies)	13/05/2016	13/05/2019
Mrs Angelika Frank-Alexander	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Fiona McCrimmon	Lay (the law)	27/10/2015	27/10/2018
Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz

Appendix A

AUCKLAND
DISTRICT HEALTH BOARD
Te Toka Tumai

Auckland DHB
Research Office
Level 14, Support Bldg
Auckland City Hospital
PB 92024, Grafton, Auckland
Phone: 64 9 307 4949 Extn. 23854
Fax: 64 9 307 8913
Email: mwoodnorth@adhb.govt.nz
Website:
www.adhb.govt.nz/ResearchOffice

Institutional Approval

15th December 2016

Mrs Eileen Gilder
Ward 48, Level 4 Building 32
Department of CVICU
Auckland City Hospital
Park Rd, Grafton
Private Bag 92024
Auckland Mail Centre
Auckland 1142

Dear Eileen,

Re: Research project A+7323 (Ethics: 16/STH/159) The endotracheal tube and endotracheal suction: an exploration of Adult Cardiac Surgical Intensive Care patient's experience.

The Auckland DHB Research Review Committee (ADHB-RRC) would like to thank you for the opportunity to review your study and has given approval for your research project.

Your Institutional approval is dependent on the Research Office having up-to-date information and documentation relating to your research and being kept informed of any changes to your study. It is your responsibility to ensure you have kept Ethics and the Research Office up to date and have the appropriate approvals. ADHB approval may be withdrawn for your study if you do not keep the Research Office informed of the following:

- Any communication from Ethics Committees, including confirmation of annual ethics renewal
- Any amendment to study documentation
- Study completion, suspension or cancellation

More detailed information is included on the following page. If you have any questions please do not hesitate to contact the Research Office.

Yours sincerely

On behalf of the ADHB Research Review Committee Dr Mary-Anne Woodnorth
Manager, Research Office, ADHB.

c.c. Andrew McKee, Shailendra Deo

..../continued next page

He Kamaka Waiora
Waitematā and Auckland DHB
Level 2, 15 Shea Terrace,
Auckland 0740,
New Zealand
Private Bag: 93-503

22/11/2016

Eileen Gilder
CVICU Research
Auckland City Hospital

Re: The endotracheal tube and endotracheal suction: an exploration of patient experience in Adult Cardiac Surgical Intensive Care.

Thank you for providing the following documents the:

- RRC application
- Study protocol
- PIS/CF
- HDEC application

The study is a qualitative exploration of patient experiences in Adult Cardiac Surgical Intensive Care patients in relation to endotracheal tube and endotracheal suction. The researcher aims to recruit up to 10 participants estimates that there may be 1 Māori participant based on Māori patient data (approx. 10 percent of total patient population in CVICU).

Māori responsiveness:
The research demonstrates Māori responsiveness in the following ways:

- Providing an explanation of Māori health disparity related to the studies specific area of focus,
- engaging in ethnicity data collection,
- including contact details for He Kamaka Waiora (Māori Health Team, Auckland and Waitematā District Health Boards) in the participation information sheet.

On behalf of the Waitematā and Auckland District Health Boards Māori Research Committee the study has been approved.

Heoi ano

Kim Southey
Kaupapa Māori Analyst
Waitematā and Auckland DHB

Level 2, 15 Shea Terrace, Auckland 0740, New Zealand, Private Bag: 93-503, p: +64 9 486 8920, email kim.southey@waitemata.govt.nz

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Phone: 09 630 9943
Ext: 23854
Website: www.adhb.govt.nz/ResearchOffice/

Mrs Eileen Gilder
Ward 48, Level 4 Building 32
Department of CVICU
Auckland City Hospital
Park Rd, Grafton
Private Bag 92024
Auckland Mail Centre
Auckland 1142

19th December 2016

Dear Eileen,

RE: 7323 - SPG-1609-005 The endotracheal tube and endotracheal suction. An exploration of the patient experience in Adult Cardiac Surgical Intensive Care patients: Is it really like breathing through a straw?

Thank you for submitting an application for a small project grant through the A+ Trust Research Grant.

Following consideration of your application, the A+ Trust Research Grant Review Board is pleased to inform you that your application for funding has been successful. The amount awarded is $4,090.

Approvals: The commencement of your funding is dependent upon the project being granted other relevant approvals (e.g. Ethics, Safety and Maori Research Review Committee approvals etc). Please forward an electronic copy of your ethics application and approval to Genevieve.Morris@adhb.govt.nz. If you have not already obtained such approvals and are unclear of the process please contact Genevieve for further advice. If the appropriate approvals are not received by the Research Office (RO) within **three months** of award the grant will be forfeited, unless previously negotiated and agreed.

Because the Committee who reviewed your application also sit as the Research Review Committee (RRC), it will not be necessary for you to submit your proposed research to the RRC for review unless you make amendments to your proposed research. Please discuss any amendments to your research with Mary-Anne Woodnorth, MWoodnorth@adhb.govt.nz, who can advise you on how to proceed.

Account Activation: Funds from this grant will be released based on invoicing via your service accountant, the Grant is considered activated from the day the first invoice is received. The Grant will be considered to have been withdrawn if there is no financial activity or email correspondence in the first **six months**.

An annual report: on study progress will be required each year and at completion of this project. If such reports are outstanding, further invoicing will not be processed. A template for reporting will be provided.

If you have any questions please do not hesitate to contact the Research Office.

Yours sincerely

Dr Richard Frith
Chair Auckland DHB Charitable Trust

Colin McArthur
Chair A+ Trust Research Grant Review Board

FORM 1- RANDOMISATION DETAILS

PETS

PRE-OPERATIVELY

	Patient Details		
1.01	Patient Initials	|___|___|___|	
1.02	Date of Birth	|__ |__|/|__ |__|/|__|__|__|__|	
1.03	Gender	Male |__|	Female |__|
	Inclusion Criteria (Must answer Yes to all to be eligible)		
1.04	≥ 16 years		Yes |__| No |__|
1.05	Scheduled to have cardiac surgery using cardiopulmonary bypass		Yes |__| No |__|
1.06	Not expected to have ICU stay >24 hours		Yes |__| No |__|
	Exclusion criteria (Must answer No to all to be eligible)		
1.07	Emergency cardiac surgery		Yes |__| No |__|
1.08	Non-English speaking		Yes |__| No |__|
1.09	Deaf		Yes |__| No |__|
1.10	Documented history of chronic pain		Yes |__| No |__|

Consent obtained
Date |__ |__|/|__ |__|/|__|__|__|__| **Time** |__|__|: |__| |__|

Randomisation date |__ |__|/|__ |__|/|__|__|__|__| **Time** |__|__|: |__| |__|

Patient Study Number: |___|___|___|

	FORM 2 OPERATIVE DATA	Pt Study Number: |___|___|___|___| Initials: |___|___|___|	PETS CVICU Research

2	CVICU Data	
2.01	Date of Surgery	|__|__|/ |__| |__|/ |__|__|__|__|
2.02	Date & Time of Intubation	|__|__|/ |__| |__|/ |__|__|__|__| |__|__|: |__| |__|
2.03	Operation performed	|__| Isolated CABG |__| Single Valve |__| Multi-Valve surgery |__| CABG + Valve |__| Re-do surgery |__| Other cardiac surgery
2.04	Duration of ventilation (ICU)	|__|__|__| (mins)
2.05	Number of suction episodes performed	|__|__|__|
2.06	Inotropes given in ICU	Yes |__| No|__|
2.07	If Yes what Dopamine Noradrenaline Adrenaline Other	 Yes |__| No|__| Yes |__| No|__| Yes |__| No|__|
2.08	Total amount of sedation given	|__|__|__| __| (mg)
2.09	Analgesia given prior to extubation	Yes |__| No|__|
2.10	If yes what analgesia and total amount	
2.11	Analgesia given post extubation	Yes |__| No|__|
2.12	If yes what analgesia and total amount	
2.13	Returned to theatre	Yes |__| No|__|
2.14	Discharged within 24 hours	Yes |__| No|__|
2.15	Date and time of discharge	|__|__|/ |__| |__|/ |__|__|__|__| |__|__|: |__| |__|

	FORM 3- Pain Assessment	PETS CVICU Research

Pain Assessments

	Patient Details	
3.01	Patient Initials	|___|___|___|
3.02	Study Number	|__ |__|/|__ |__|/|__|__|__|__|
	CPOT Pain Assessment – while the patient is sedated	
3.03	CPOT score prior to ETS	
3.04	CPOT score during ETS	
3.05	CPOT score 10 minutes following ETS	
	CPOT Pain Assessment – when the patient is awake and intubated	
3.06	CPOT score prior to ETS	
3.07	CPOT score during ETS	
3.08	CPOT score 10 minutes following ETS	
	Numerical Pain Scale (NRS- V) Assessment – when the patient is awake and intubated. Patient	
3.09	NRS-V score prior to ETS	
3.10	NRS-V score during ETS	
3.11	NRS-V score 10 minutes following ETS	
Numerical Pain Scale (NRS) Assessment – when the patient is awake. Bedside Nurse		
3.12	NRS score prior to ETS	
3.13	NRS score during ETS	
3.14	NRS score 10 minutes following ETS	
CPOT Pain Assessment – when the patient is awake and intubated. Research Nurse		
3.15	CPOT score prior to ETS	
3.16	CPOT score during ETS	
3.17	CPOT score 10 minutes following ETS	

Date	
Date |__ |__|/|__ |__|/|__|__|__|__|	**Time** |__|__|: |__| |__|

	FORM 4- Interview	**PETS**

Interview

	Patient Details	
4.01	Patient Initials	|___|___|___|
4.02	Study Number	|__ |__|/|__ |__|/|__|__|__|__|
	Initial Questions	
4.03	1. Tell me about your experience of the breathing tube? 2. Tell me about your experience of having suction through the breathing tube? 3. Can you describe how it feels to breathe through the tube?	
	Clarifying Questions	
4.04	1. CPOT score prior to ETS Were you awake during suction and can you describe what happened? 2. Can you describe how much control you thought you had while in intensive care? 3. Tell me how comfortable you were while in intensive care? 4. How would you describe your experience of the breathing tube? 5. How would describe the feeling of the breathing tube? 6. How much information were you given about the breathing tube? 7. How would you describe your experience of having suction? 8. How much information were you given about being suctioned? 9. How would you describe the feeling of having suction? 10. What could have been done differently?	

Date	
Date |__ |__|/|__ |__|/|__|__|__|__|	**Time** |__|__|: |__| |__|

Cardiothoracic & Vascular Intensive Care Unit

Service:	CTSU
Phone:	(09) 3074949
Phone Internal:	24470, 24471 and 24472
Fax:	(09) 3074906
Fax Internal:	24473
Address:	4th Floor, Building 32 Auckland City Hospital
Postal Address:	Private Bag 92-024 Auckland

PARTICIPANT INFORMATION SHEET

Study Title: The endotracheal tube and endotracheal suction

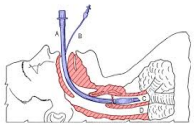
An exploration of Adult Cardiac Surgical Intensive Care patients' experience

Local Investigator Name:	Eileen Gilder
Site:	Cardiothoracic & Vascular Intensive Care
Contact No:	(09) 3074949 ext 24489

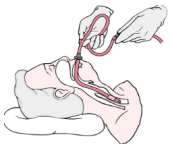
Invitation

You are invited to participate in a research study looking at the use of endotracheal suction following cardiac surgery in the intensive care unit (ICU). Your participation is entirely voluntary (your choice). You do not have to take part in this study. Whether or not you choose to take part you will continue to receive all usual treatment.
We would like to include you in this study because you are scheduled to have cardiac (heart) surgery. This study will involve 10 patients undergoing cardiac surgery at this hospital. Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

The Study



Cardiac surgery is complex and requires the admission to Intensive Care (ICU) following surgery. On return from theatre to the ICU patients are kept sedated and asleep for 3-12 hours after surgery and breathing is maintained using an artificial airway (endotracheal tube, ETT) attached to a breathing machine (ventilator).
The artificial airway means that patients lose the ability to clear secretions by coughing and so this is done by the nursing staff that perform ETT suction.



Endotracheal suctioning is the insertion of a catheter and the removal of secretions from an artificial airway, using a suction device attached to a negative pressure vacuum. The purpose is to clear secretions from the airway, to maintain a clear airway and to optimise ventilation and oxygenation.

We would like to explore the patient experience of ETT suction. To do this we would like to perform a brief interview with you before hospital discharge to ask about your experience of the breathing tube and suction (if used). The interview will take approximately 30 minutes and will provide information to feed back to the nursing staff. The interview will be recorded onto a Dictaphone. The

interview will be transcribed through an official transcription service. The transcription service will be required to maintain confidentially of all interviews transcribed. The interview will be on day 4-6 following surgery and a private room will be used for the interview. You are welcome to have a family/whanau member with you during the interview.

If you agree to participate in this study, you will receive all the usual care following your admission to the ICU. We will record information from your medical notes relevant to the study. We assess patients discomfort once they are awake. For this study we plan to pilot 2 pain assessment scales that are frequently used in other Intensive Care Units when patients are sedated. This data will be confidential. No material that could personally identify you will be used in any reports on this study. All the information is kept by the research nurses in a form that will not allow you to be identified. Information will be held for 10 years and will be destroyed confidentially.

Benefits of Being in the Study

This study aims to further medical knowledge and may improve future treatment of patients following cardiac surgery however it may not directly benefit you.

Risks of Being in the Study

Being in the study does not pose any extra known risk to you above the risks associated with usual care in the ICU. You will be closely monitored whilst in the ICU.

Is the Study Voluntary?

Participation in this study is entirely voluntary (your choice). It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. If you are too tired to participate in an interview you may withdraw from the study or it can be re-arranged for the following day.

Statement of Approval

This study has received ethical approval from the Southern Health and Disability Ethics Committee 16/STH/159

Questions

If you have queries or concerns regarding your rights as a participant in this study you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050 Free fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by telephoning 09 4868920 ext. 3204

Cardiothoracic & Vascular Intensive Care Unit

Service: CTSU
Phone: (09) 3074949
Phone Internal: 24470, 24471 and 24472
Fax: (09) 3074906
Fax Internal: 24473
Address: 4th Floor, Building 32 Auckland City Hospital
Postal Address: Private Bag 92-024 Auckland

Thank you for taking the time to consider this study.

If you wish to take part in the study, please sign the attached consent form. This information sheet is for you to keep

CONSENT FORM - Participants
The endotracheal tube and endotracheal suction

	Yes	No
Interpreter required		

I have read and I understand the information sheet dated **30th October 2016** for patients taking part in the suction study.
I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I have had the opportunity to use whānau support or a friend to help me ask questions and understand the study.

I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time if I wish. This will in no way affect my continuing future health care.

I have had this project explained to me by

_____

I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.

I have had time to consider whether I would want to take part in the study.

I know whom to contact if I consider a reason to withdraw from the study.

I know whom to contact if I have any questions about the study or about the study in general.

	Yes	No
I wish to receive a copy of the published results of the study when it is finished.		

Participant

I,_____ **(full name**)
hereby consent to my participation in this study

_____(signature)

__ __/__ __/__ __ **(date)** _ __: ___**(time 24 hour**)

Person explaining the study

_____ (full name)

_____ (signature)

_____(study role)

__ __/__ __/__ __ **(date**)

Local Investigator (Research Nurse) Name:	Eileen Gilder
Site:	Cardiothoracic & Vascular Intensive Care
Contact No:	(09) 3074949 ext 24489

Copies: Original in study file, 1 copy in clinical records, 1 copy to patient

Please feel free to contact any of the Cardiovascular Intensive Care Research team or the local investigator (Eileen Gilder; tel. (09) 307 4949 ext. 24489) if you have any questions about this study.

Appendix 5: The Avoidance of Routine Endotracheal Suction Study documents

- Health and Disability Ethics committee approval
- Auckland District Health Board Local approvals
- A+ Trust funding letter
- Case report form
- Data dictionary
- Information and consent form
- ARETS statistical analysis plan
- Data safety management board charter

Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

08 October 2015

Mrs Eileen Gilder
CVICU - Ward 48
Auckland City Hospital
Private Bag 92024
Auckland 1142

Dear Mrs Gilder

Re:	**Ethics ref:**	**15/NTB/138**
	Study title:	Avoidance of endotracheal suction in post-operative cardiac patients

I am pleased to advise that this application has been *approved* by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern B Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 07 October 2016.

AUCKLAND DISTRICT HEALTH BOARD
Te Toka Tumai

Research Office
Level 14, Support Bldg
Auckland City Hospital
PB 92024, Grafton, Auckland
Phone: 64 9 307 4949 Extn. 23854
Fax: 64 9 307 8913
Email: mwoodnorth@adhb.govt.nz
Website: www.adhb.govt.nz/ResearchOffice

28th October 2015

Institutional Approval

Mrs Eileen Gilder
Department of CVICU
Ward 48, Level 4,
Auckland City Hospital
2 Park Road, Grafton,
Private Bag 92024
Auckland 1142

Dear Eileen

Re: Research project A+6690 (Ethics: 5/NTB/138) Avoidance of Endotracheal Suction in the Post-Operative Cardiac Patient – A randomised clinical trial.

The Auckland DHB Research Review Committee (ADHB-RRC) would like to thank you for the opportunity to review your study and has given approval for your research project.

Your Institutional approval is dependant on the Research Office having up-to-date information and documentation relating to your research and being kept informed of any changes to your study. It is your responsibility to ensure you have kept Ethics and the Research Office up to date and have the appropriate approvals. ADHB approval may be withdrawn for your study if you do not keep the Research Office informed of the following:

- Any communication from Ethics Committees, including confirmation of annual ethics renewal
- Any amendment to study documentation
- Study completion, suspension or cancellation

More detailed information is included on the following page. If you have any questions please do not hesitate to contact the Research Office.

Yours sincerely

On behalf of the ADHB Research Review Committee
Dr Mary-Anne Woodnorth
Manager, Research Office
ADHB

c.c. Andrew McKee, Sam Titchener, Joy Farley, Shailendra Deo.

..../continued next page

He Kamaka Waiora
Waitematā and Auckland DHB
Level 2, 15 Shea Terrace,
Auckland 0740,
New Zealand
Private Bag: 93-503

16/08/2015

Eileen Gilder
CVICU Ward 48
Level 4
Auckland City Hospital

Re: Avoidance of Endotracheal Suction in the Post- Operative Cardiac Patient – A randomised clinical trial.

Thank you for providing the following documents the:

- RRC application
- Study protocol
- Questionnaire
- PIS/CF
- HDEC application

The study is part of an academic project and is looking at the use of endotracheal suction following cardiac surgery in the intensive care unit. The investigator will endeavour to recruit 120 participants, 12 of whom will be Māori.

In regard to Māori responsiveness the investigator is part of a team that has a history of working with and for Māori and report having a successful Māori recruitment processes in the past. The investigator will be gathering ethnicity data but no sub-analysis will be conducted because of the numbers. Finally the contact details for the Research Advisor Māori are given.

Comments:

- Please add Māori cultural contact details.
- Could you provide evidence of successful Māori recruitment in other studies
- While the numbers of Māori participants may be quite small, it will be worth noting whether there are any difference for them given all the other barriers to access that exist.

On behalf of the Waitematā and Auckland DHB Māori Research Committee the study is approved.

Eileen Gilder
CVICU/Ward 48,
Level 4,
Auckland City Hospital
Private Bag 92024
Auckland 1142

Service: ADHB Research Office
Level 14, Support Building
Auckland City Hospital
Grafton
Phone: 09 630 9943
Ext: 23854
Fax: 09 630 9978
Website: www.adhb.govt.nz/ResearchOffice/

24th June 2015

Dear Eileen,

RE: 6690 - PG-1504-009 - Avoidance of Endotracheal Suction in the Post- Operative Cardiac Patient – A randomised clinical trial.

Thank you for submitting an application for a project grant through the A+ Trust Research Grant.

Following consideration of your application, the A+ Trust Research Grant Review Board is pleased to inform you that your application for funding has been successful. The amount awarded is $28,450.

Please find attached the external reviewers' comments for your consideration.

The commencement of your funding is dependent upon the project being granted other relevant approvals (e.g. Ethics, Safety and Maori Research Review Committee approvals etc). Please forward an electronic copy of your ethics application and approval to Genevieve.Morris@adhb.govt.nz. If you have not already obtained such approvals and are unclear of the process please contact Genevieve for further advice. If the appropriate approvals are not received by the Research Office (RO) within **three months** of award the grant will be forfeited, unless previously negotiated and agreed.

Because the Committee who reviewed your application also sit as the Research Review Committee (RRC), it will not be necessary for you to submit your proposed research to the RRC for review unless you make amendments to your proposed research. Please discuss any amendments to your research with Mary-Anne Woodnorth, who can advise you on how to proceed.

Funds from this grant will be released based on invoicing via your service accountant.

An annual report on study progress will be required each year and at completion of this project. If such reports are outstanding, further invoicing will not be processed. A template for reporting will be provided.

If you have any questions please do not hesitate to contact the Research Office.

Yours sincerely

Dr Richard Frith
Chair Auckland DHB Charitable Trust

Kim Brackley
Acting Chair A+ Trust Research Grant Review Board

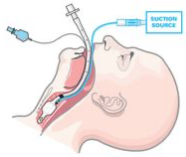
Avoidance of routine endotracheal suction in, Post-operative cardiac patients (ARETS Study)

A single centre, non-inferiority, randomised controlled trial assessing the safety and efficacy of avoiding endotrachael suction on patients having planned cardiac surgery who are ventilated for less than 12 hours.

Data Dictionary

Principal Investigator: Eileen Gilder

Co-Investigators: Dr Shay McGuinness, Dr. Rachael Parke



	Data Dictionary ARET Study	ARETS

Abbreviations

ABG	Arterial Blood Gas
BP	Blood Pressure
CRF	Case report forms
CVICU	Cardiovascular and Thoracic Intensive Care Unit
CXR	Chest X-Ray
CVP	Central Venous Pressure
ETT	Endotracheal Tube
ETS	Endotracheal Suction
FiO_2	Fraction of inspired oxygen
HR	Heart Rate
Kpa	Kilopascal
$PaCO_2$	Partial pressure of carbon dioxide in the arterial blood
PaO_2	Partial pressure of oxygen in arterial blood
PEEP	Positive End Expiratory Pressure
SpO_2	Saturation level of oxygen in haemoglobin; can be determined by noninvasive method of pulse oximetry.

The research nurses will screen patients; participants must answer YES to ALL the inclusion and NO to ALL the exclusion criteria.

Inclusion criteria	Yes	No
• ≥16 years old,		
• Patients having cardiac surgery with cardiopulmonary bypass (CPB),		
• Extubation expected within 12 hours of admission to CVICU		
Exclusion criteria		
• Documented difficult intubation		
• Expected ventilation >12 hours		
• Clinician preference for the patient to receive ETT suction.		
• Non- English speaking		

Number	Question	Definition/Explanation of question
	Patient Details	
	Record ID	Please enter the patient study number obtained from the randomisation form
1.01	Patient Initials	Please enter the patient initials in the format First Middle Last e.g. Harry James Potter = HJP, e.g. Harry Potter = HP
1.02	Date of birth	Date format is dd/mm/yyyy e.g. 02/06/1967 If the exact date is unknown, please enter as much information as possible.
1.03	Gender	Please select male or female

Inclusion Criteria - *all inclusion criteria must be answered **YES** for the patient to be eligible for inclusion in the study*		
1.04	Age ≥ 16 years	Cross | X | the YES or NO box
1.05	Scheduled to have cardiac surgery using cardiopulmonary bypass	Cross | X | the YES or NO box Patients who are planned to be operated on *off pump/off bypass* are excluded from this study. If a patient who is planned to undergo surgery on-pump subsequently is operated off-pump then they will still be included.

Exclusion criteria - *all exclusion criteria must be answered **NO** to all to be eligible*		
1.07	Emergency cardiac surgery	Cross | X | the YES or NO box Patient requires surgery be undertaken **before** beginning of next working day.
1.08	Non-English speaking	Cross | X | the YES or NO box
1.09	Documented difficult intubation, either previously or expected	Cross | X | the YES or NO box
1.10	Clinical preference for the patient to receive ETT suction	Cross | X | the YES or NO box
	Consent obtained	Please record the date and time that informed consent was obtained from the patient in the following format: dd/mm/yyyy 00:00 e.g. 13/06/2016 08:20
	Randomisation date and time	Please record the date and time that the patient was randomised and study allocation revealed in the following format: dd/mm/yyyy 00:00 e.g. 13/06/2016 08:20

	Data Dictionary ARET Study	ARETS

2.00	Demographics	
2.01	Date of birth	Date format is dd/mm/yyyy e.g. 02/06/1967 If the exact date is unknown, please enter as much information as possible.
2.02	Gender	Please select male or female
2.03	Patient weight (kg)	Enter the patients most recent weight in kilograms Weight should preferably have been measured and be documented in the patients' medical records prior to surgery.
2.04	Patient height (cms)	Enter the patients most recent height in centimetres Weight should preferably have been measured and be documented in the patients' medical records prior to surgery.
2.05	Ethnicity	Indicate which ethnicity the patient most strongly identifies with by selecting one of the following: European; Maori; Pacific Peoples; Asian; Middle Eastern/Latin American/African; or other ethnicity not listed.

	General/Baseline	
2.06	Age	
2.07	Chronic Pulmonary Disease	Cross | X_| the YES or NO box Select Yes if either confirmed with spirometry test and documented in the clinical record +/- the patient is on long term inhalers.
2.08	Smoker	Cross | X_| the YES, NO or EX box
2.09	Diabetic	Cross | X_| the YES or NO box
2.10	Previous Cardiac Surgery	Select Yes if patient has had previous cardiac surgery.
2.11	Intervention	Include major interventions on the heart such as: • CABG • valve repair or replacement • replacement of part of the aorta • repair of a structural defect

		• maze procedure • resection of a cardiac tumour
2.12	CCS class 4 angina	Select Yes if the patient has angina at rest
2.13	NYHA	Indicate the appropriate NYHA classification for this patient I = No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnoea (shortness of breath) II = Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnoea (shortness of breath) III = Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnoea IV = Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.
2.14	LV Function	Indicate the appropriate LV function for the patient: Good = LVEF > 50% Moderate = LVEF 31 - 50% Poor = LVEF 21 - 30% Very poor = LVEF 20% or less
2.15	Recent MI	Cross | X_| the YES or NO box
2.16	Preoperative EUROSCORE II	Please calculate the EUROSCORE II using the following link: http://www.euroscore.org/calc.html

ETT Data		
2.17	Date of intubation	Record DD/MM/YEAR. Taken from the anaesthetic record.
2.18	Time of intubation	Record using the 24 hour clock. Taken from the anaesthetic record
2.19	Date of admission to ICU	Record DD/MM/YEAR. Taken from CHIPS
2.20	Time of admission to ICU	Record using the 24-hour clock. Taken from CHIPS
2.21	Was the patient extubated by 12 hours	Cross | X | the YES or NO box If NO select from drop down menu for reasons - High inotrope requirements - Return to theatre - Tamponade - Bleeding - SMO decision - Poor oxygenation - Unknown - Other (free text) If extubated record date and time in next field.
2.22	Date of extubation	Record DD/MM/YEAR. Taken from ICU 24-hour chart.
2.23	Time of extubation	Record using the 24-hour clock. Taken ICU 24-hour chart
2.24	Date of ICU discharge	Record DD/MM/YEAR. Taken from ICU 24-hour chart.
2.25	Time of ICU discharge	Record using the 24-hour clock. Taken ICU 24-hour chart

Ventilation Data		
	Date & time completed	Taken from ABG & ICU chart data. Document using the 24-hour clock 00:00 Record the data for the first 12 hours after ICU admission. If not extubated by 12 hours **DO NOT RECORD ANY FURTHER DATA**

3.0	Arterial Blood Gases (ABG's)	
3.01	PaO_2	Partial pressure of oxygen in arterial blood (Kpa). Taken from arterial blood gas.
3.02	$PaCO_2$	Partial pressure of carbon dioxide in the arterial blood (Kpa). Taken from arterial blood gas.
3.03	SaO_2	Arterial oxygen saturation. Taken from the arterial blood gas
3.04	Base excess	From ABG data
3.05	Lactate	From ABG data
3.06	SpO_2	Saturation level of oxygen in haemoglobin; can be determined by non-invasive method of pulse oximetry (ICU chart).
3.07	FiO_2	Fraction of inspired oxygen. Recorded from ICU 24 hour chart.

4.00	Physiology	
		Record data for period prior to extubation and for the 6 hours post extubation. If not extubated by 12 hours **DO NOT RECORD ANY FURTHER DATA** (only record data up to 12 hours after ICU admission)
4.01	Heart Rate (HR)	Record the patient's heart rate in beats per minute as documented on the ICU bypass chart. Recorded from ICU 24-hour chart.
4.02	Respiratory Rate.	Respiratory rate (breaths per minute) Record the patient's respiratory rate in breaths per minute as documented on the ICU bypass chart. Recorded from ICU 24 hour chart.
4.03	Mean Blood Pressure. (MAP)	Record the patient's mean arterial pressure (MAP) in mmHg as documented on the ICU bypass chart. If there is no documented MAP please use the following formula to calculate MAP: MAP = 2/3 DBP + 1/3 SBP. Recorded from ICU 24-hour chart.

Allocation and suction data		
5.01	Suction performed	Cross | X_| the YES or NO box If not recorded ask the bedside nurse if available and bedside CRF (Appendix 1).
5.02	Number of suction episodes	Record how many suction episodes were performed. Include the intervention (non-suction group). Recorded on the ICU chart.
5.03	Suction canister pressure	Measured in mmHg. Taken from bedside CRF
5.04	Reason for ETS	Ask the bedside nurse (if available) for the rationale requiring the ETS. Otherwise use the ICU chart if documented. If not available document "not recorded"

Complications - recorded		
6.01	Laryngeal Spasm	Cross | X_| the YES or NO box Take documentation from medical clinical notes
6.02	Vomiting	Cross | X_| the YES or NO box As seen on ICU chart/medical/nursing notes
6.03	Aspiration	Cross | X_| the YES or NO box Take documentation from medical clinical notes
6.04	Escalation of oxygen therapy	Cross | X_| the YES or NO box As seen on ICU chart/medical/nursing notes
6.05	Oxygen desaturation (SpO_2) <90%	Cross | X_| the YES or NO box As seen on ICU chart/medical/nursing notes
6.06	Respiratory Rate >25bpm	Cross | X_| the YES or NO box As seen on ICU chart/medical/nursing notes
6.07	Tachycardia >100bpm	Cross | X_| the YES or NO box As seen on ICU chart/medical/nursing notes
6.08	Increased MAP >85mmHg	Cross | X_| the YES or NO box As seen on ICU chart/medical/nursing notes
6.09	Did the patient require re-intubating during their first ICU stay?	Cross | X_| the YES or NO box as appropriate to record whether or not the patient
6.10	Did the patient require a return to theatre for bleeding?	Cross | X | the YES or NO box as appropriate

CPOT and Pain assessments		
7.01	CPOT	Critical Care Pain Assessment Tool. (Appendix 2) Used while the patient is intubated. Validated behavioural pain scale developed with cardiac patients. There's an app https://www.mdcalc.com/critical-care-pain-observation-tool-cpot There's brief video http://www.iculiberation.org/Bundles/Pages/Pain.aspx
7.02	CPOT score - sedated	Record CPOT score while patient is sedated (RASS -3 - +1). Recorded on bedside CRF If not recorded enter 999 into the database
7.03	CPOT score – awake but intubated	Record CPOT score while patient is awake but intubated (RASS 0). Recorded on bedside CRF If not recorded enter 999 into the database
7.04	Numerical Pain Scale (NRS)	Validated pain assessment tool (Appendix 3). Allows the patient to score his or her own pain (gold standard).
7.05	Patient NRS score	Record from the bedside CRF and ICU chart. If unavailable record 999.
7.06	Nurse NRS score	Recorded from the bedside CRF. If unavailable check with the bedside nurse if possible or record 999.

Patient interview – brief scripted interview		
8.01	Patient interview	All patients will be approached prior to discharge Patients in the intervention group will be asked if they recall the ETT Patients in standard care will be asked if they recall the ETT and ETS
8.02	ETT All Patients	Ask the patient do they recall the ETT Cross | X_| the YES or NO box
8.03	If yes to the above	Ask the patient how painful was the ETT Cross | X_| the YES or NO box
8.04	ETS Standard care and those who had ETS	Ask the patient do they recall the ETS Cross | X_| the YES or NO box
8.05	If yes to the above	Ask the patient how painful was the ETS Cross | X_| the YES or NO box
8.05	Other comments	Ask the patient if they have any other comments they would like to add.

FORM 1- RANDOMISATION DETAILS

ARETS

PRE-OPERATIVELY

	Patient Details	
1.01	Patient Initials	___I___I___
1.02	Date of Birth	___ ___/___ ___/___ ___ ___ ___
1.03	Gender	Male |__| Female |__|
	Inclusion Criteria (Must answer Yes to all to be eligible)	
1.04	≥ 16 years	Yes |__| No |__|
1.05	Scheduled to have cardiac surgery using cardiopulmonary bypass	Yes |__| No |__|
1.06	Extubation expected within 12 hours of admission	Yes |__| No |__|
	Exclusion criteria (Must answer No to all to be eligible)	
1.07	Emergency cardiac surgery	Yes |__| No |__|
1.08	Non-English speaking	Yes |__| No |__|
1.09	Documented difficult intubation, either previously or expected.	Yes |__| No |__|
1.10	Clinician preference for the patient to receive ETT suction.	Yes |__| No |__|

Consent obtained
Date ___ ___/___ ___/___ ___ ___ ____ Time ___ ___:___ ___
Allocation :

Randomisation___ ___/___ ___/___ ___ ___ ____ **Time** ___ ___:___ ___

Patient Study Number: ___I___I___

	FORM 2 **BASELINE & POST OP DATA**	**Pt Study Number:** |___|___|___|___| **Initials:** |___|___|___|	**ARETS STUDY**

1 : DEMOGRAPHICS			
2.01	Date of Birth	___ ___/___ ___/___ ___ ___ ___	
2.02	Gender	Male |__| Female|__|	
2.03	Patient weight (kg)	___ ___ ___ kg	
2.04	Patient height (cms)	___ ___ ___	
2.05	Ethnicity (Select one)	|__| European |__| Maori |__| Pacific peoples	|__|Asian |__| Middle Eastern/Latin American/African |__| Other

2: General					
2.06	Age (years)	___ ___	2.12	CCS class 4 angina	Yes |__| No|__|
2.07	COPD	Yes |__| No|__|	2.13	NYHA	I II III IV
2.08	Smoker	Yes |__| No|__|Ex |__|	2.14	LV function	Good (>50%) Moderate (31-50%) Poor (21-30%) Very poor (<21%)
2.09	Diabetes on insulin	Yes |__| No|__|	2.15	Recent MI	Yes |__| No|__|
2.10	Previous cardiac surgery	Yes |__| No|__|	2.16	Euroscore II	|__|__||__|%
2.11	Intervention	Isolated CABG Single non CABG 2 procedures 3 procedures			

ETT TUBE DATA		
2.18	Date of Intubation	___ ___/___ ___/___ ___ ___ ___
2.19	Time of Intubation	___ ___: ___ ___
2.20	Date of admission to ICU	|___ ___/___ ___/___ ___ ___ _____
2.21	Time of admission to ICU	___ ___: ___ ___

FORM 3- Bedside Pain Assessment & suction canister record

ARETS

CVICU Research

Pain Assessments – during Endotracheal Suction (ETS)

Patient Details	
Patient study number	___ I___ I___

Pain assessment – record for ONE suction episode when sedated and ONE when awake

CPOT Pain Assessment – while the patient is sedated, intubated and ventilated (RASS -3-+1)	
CPOT score prior to ETS	
CPOT score during ETS	
CPOT score 10 minutes following ETS	
CPOT Pain Assessment – when the patient is awake & intubated	
CPOT score prior to ETS	
CPOT score during ETS	
CPOT score 10 minutes following ETS	
Numerical Rating Scale (NRS- V) Assessment – when the patient is awake & intubated. Nurse	
NRS-V score prior to ETS	
NRS-V score during ETS	
NRS-V score 10 minutes following ETS	
Numerical Rating Scale (NRS- V) Assessment – when the patient is awake & intubated. Patient	
NRS score prior to ETS	
NRS score during ETS	
NRS score 10 minutes following ETS	

Study ABGs

If extubated by 12 hours	**Time**
2 hours post extubation – on current FiO_2	
4 hours post extubation – on current FiO_2	
6 hours post extubation - on current FiO_2	
6 hours post extubation - on room air/Hi Flow (see flow chart)	

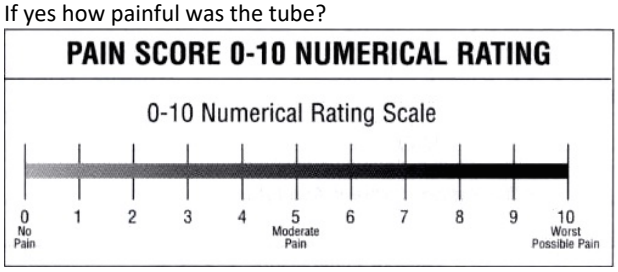
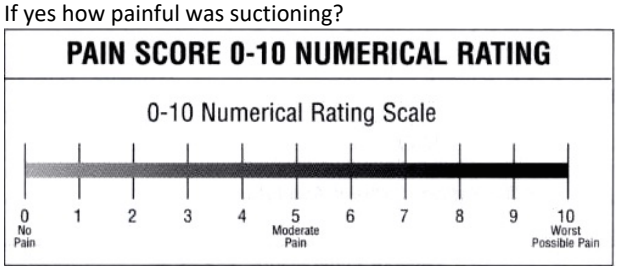
Suction record

Pressure (mmHg)	Patients RASS at time of suction	Reason for suction

	FORM 4- Interview	ARETS CVICU Research

Interview

	Patient Details	
4.01	Patient Initials	___I___I___
4.02	Study Number	___I___I___

	Questions
4.03	**Part A : All patients** 1. Do you recall having the breathing tube in place while you were in Intensive Care? Yes/No 2. If yes how painful was the tube? 3.  **Part B: Patients in the standard care group (i.e. had ET suction)** 4. 1. Do you recall having the breathing tube suctioned while you were in Intensive Care? Yes/No 5. If yes how painful was suctioning? 6. 

Date ___ ___/___ ___/___ ___ ___ ____ **Time** ___ ___:___ ___

FORM 5 – Adverse Events/Complications

ARETS CVICU Research

Adverse events/complications

Patient Details	
Patient Initials	___ I___ I___
Study Number	___ I___ I___

Adverse event/complications		
6.01	Laryngeal Spasm	Date and time|__|__|/ |__| |__|/ |__|__|__|__| |__|__|: |__||__| Resolved |__| Ongoing |__| Died |__| Source documents|__|
6.02	Vomiting	Date and time|__|__|/ |__| |__|/ |__|__|__|__| |__|__|: |__||__| Resolved |__| Ongoing |__| Died |__| Source documents|__|
6.03	Aspiration	Date and time|__|__|/ |__| |__|/ |__|__|__|__| |__|__|: |__||__| Resolved |__| Ongoing |__| Died |__| Source documents|__|
6.04	Escalation of oxygen therapy	Date and time|__|__|/ |__| |__|/ |__|__|__|__| |__|__|: |__||__| Resolved |__| Ongoing |__| Died |__| Source documents|__|
6.05	Oxygen desaturation SpO_2 <90%	Date and time|__|__|/ |__| |__|/ |__|__|__|__| |__|__|: |__||__| Resolved |__| Ongoing |__| Died |__| Source documents|__|
6.06	Respiratory rate >25	Date and time|__|__|/ |__| |__|/ |__|__|__|__| |__|__|: |__||__| Resolved |__| Ongoing |__| Died |__| Source documents|__|
6.07	Tachycardia >100 bpm	Date and time|__|__|/ |__| |__|/ |__|__|__|__| |__|__|: |__||__| Resolved |__| Ongoing |__| Died |__| Source documents|__|

FORM 6 – Protocol Deviation

ARETS

Protocol Deviation details

Patient Details	
Patient Initials	___ I___ I___
Study Number	___ I___ I___
Date and Time	|__|__|/ |__| |__|/ |__|__|__|__| |__|__|: |__||__|

Please specify the protocol deviation		
7.01	**Intervention Arm –** Protocol not followed (received ETS).	ETS received |__| Reason Action taken
7.02	**All Groups** Post extubation ABG not recorded as per protocol	Time ABG's performed Reason Action taken
7.03	**All Groups**	Randomised but not eligible|__| Reason Action taken

Cardiothoracic & Vascular Intensive Care Unit

Service:	CTSU
Phone:	(09) 3074949
Phone Internal:	24470, 24471 and 24472
Fax:	(09) 3074906
Fax Internal:	24473
Address:	4th Floor, Building 32 Auckland City Hospital
Postal Address:	Private Bag 92-024 Auckland

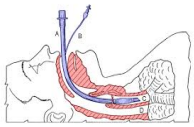
PARTICIPANT INFORMATION SHEET

Study Title: Avoidance of Endotracheal Suction in post-operative cardiac surgery patients
The Suction Study

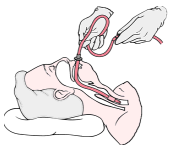
Local Investigator Name:	Eileen Gilder
Site:	Cardiothoracic & Vascular Intensive Care
Contact No:	(09) 3074949 ext 24489

Invitation
You are invited to participate in a research study looking at the use of endotrachael suction following cardiac surgery in the intensive care unit (ICU).
Your participation is entirely voluntary (your choice). You do not have to take part in this study. Whether or not you choose to take part you will continue to receive all usual treatment.
We would like to include you in this study because you are scheduled to have cardiac (heart) surgery. This study will involve 96 patients undergoing cardiac surgery at this hospital. Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

The Study



Cardiac surgery is complex and requires the admission to Intensive Care (ICU) following surgery. On return from theatre to the ICU patients are kept sedated and asleep for 3-12 hours after surgery and breathing is maintained using an artificial airway (endotracheal tube, ETT) attached to a breathing machine (ventilator).
The artificial airway means that patients lose the ability to clear secretions by coughing and so this is done by the nursing staff that perform ETT suction.



Endotracheal suctioning is the insertion of a catheter and the removal of secretions from an artificial airway, using a suction device attached to a negative pressure vacuum. The purpose is to clear secretions from the airway, to maintain a clear airway and to optimise ventilation and oxygenation.

However there is minimal evidence about the benefit of performing ETT in those patients who are ventilated for 12 hours or less. Some recent evidence suggests that the lungs take longer to recover from suction than had been previously thought and may contribute to increased risk of reduced oxygenation for a longer period. Due to the negative pressure used for suction, there may be some lower lung collapse that can take up to 30 minutes to resolve.

ETT suction can be painful and distressing for patients and we would like to perform a brief interview with you before hospital discharge to ask about your experience of the breathing tube and suction (if used). The interview will take approximately 5 minutes and will provide information to feed back to the nursing staff.

If you agree to participate in this study, you will receive all the usual care following your admission to the ICU, however you will be randomly allocated to receive ETT suction as per normal practice or to receive no ETT suction. The group you are in is decided randomly. This is like tossing a coin and you would have an equal (50:50) chance of being in either group. To ensure participant safety the non suction group can have suction performed if the doctor caring for you deems it necessary, or if your oxygen levels suggest it is needed. All other treatment and care in the ICU will be unaffected by being in this study.

We would also record information from your medical notes relevant to the study. No material that could personally identify you will be used in any reports on this study. All the information is kept by the research nurses in a form that will not allow you to be identified. Information will be held for 10 years and will be destroyed confidentially.

Benefits of Being in the Study

This study aims to further medical knowledge and may improve future treatment of patients following cardiac surgery however it may not directly benefit you.

Risks of Being in the Study

Being in the study does not pose any extra known risk to you above the risks associated with usual care in the ICU. You will be closely monitored whilst in the ICU. Participation in this study will be stopped should any harmful effects appear or if the doctor feels it is not in your best interests to continue.

Is the Study Voluntary?

Participation in this study is entirely voluntary (your choice). It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future.
New information may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

Compensation.

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2001 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.
If you have any questions about ACC, contact your nearest ACC office or the investigator.

Statement of Approval

This study has received ethical approval from the

Questions

If you have queries or concerns regarding your rights as a participant in this study you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050 Free fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by telephoning 09 4868920 ext 3204

Please feel free to contact any of the Cardiovascular Intensive Care Research team or the local investigator (Eileen Gilder; tel. (09) 307 4949 ext. 24489) if you have any questions about this study.

Thank you for taking the time to consider this study.

If you wish to take part in the study, please sign the attached consent form. This information sheet is for you to keep.

Statistical Analysis Plan

Cardiothoracic & Vascular Intensive Care Unit

Service: CTSU
Phone: (09) 3074949
Phone Internal: 24470, 24471 and 24472
Fax: (09) 3074906
Fax Internal: 24473
Address: 4th Floor, Building 32 Auckland City Hospital
Postal Address: Private Bag 92-024 Auckland

CONSENT FORM - Participants
The Suction Study

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

I have read and I understand the information sheet dated **21st June 2015** for patient's taking part in the suction study.
I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I have had the opportunity to use whānau support or a friend to help me ask questions and understand the study.

I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time if I wish. This will in no way affect my continuing future health care.

I have had this project explained to me by _____.

I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.

I understand that the treatment, will be stopped if it should appear harmful.

I understand the compensation provisions for this study.

I have had time to consider whether I would want to take part in the study.
I know who to contact if I have any side effects from the study or if anything occurs which I would consider a reason to withdraw from the study.

I know who to contact if I have any questions about the study or about the study in general.

	Yes	No
I wish to receive a copy of the published results of the study when it is finished.		

Participant

I,_____ **(full name**) **hereby consent to my participation in this study**

_____(signature)

__ __/ __ __/ __ __ **(date)** _ _: _ _**(time, 24hours**)

Investigator

_____ (full name)

_____ (signature)

_____(study role)

__ __/ __ __/ __ __ **(date**)

Local Investigator (Research Nurse) Name:	Eileen Gilder
Site:	Cardiothoracic & Vascular Intensive Care
Contact No:	(09) 3074949 ext 24489

Copies: Original in study file, 1 copy in clinical records, 1 copy to patient

Avoidance of endotracheal suction in routine, post-operative cardiac patients.

Version 1.1

SAP version date: 12/04/2019

A single centre, non-inferiority, randomised controlled trial assessing the safety and efficacy of avoiding endotracheal suction in patients having planned cardiac surgery who are ventilated for ≤12 hours.

SAP authors:

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Signatures		
Name	Signature	Date
Eileen Gilder		29/04/2019
Alana Cavadino		26/04/19
Shay McGuinness		29/04/2019
Rachael Parke		29/04/2019
Andrew Jull		29 April 2019

Abbreviations and Definitions

AE	Adverse Event
ABG	Arterial Blood Gas
BMI	Body Mass Index - a person's weight in kilograms (kg) divided by height in meters^2.
CABG	Coronary Artery Bypass Graft
CPOT	Critical Care Pain Observation Tool
eCRF	Electronic Case Report Form
ETS	Endotracheal Suction
ETT	Endotracheal Tube
FiO_2	Fraction of Inspired Oxygen
HFOT	High Flow Oxygen Therapy
HR	Heart Rate
ICU	Intensive Care Unit
ITT	Intention to Treat
MAP	Mean Arterial Pressure
MV	Mechanical Ventilation
NYHA	New York Heart Association classification. Measure of heart failure symptoms graded I-IV
PaO_2	Partial Pressure Oxygen in Arterial Blood
P/F Ratio	Ratio of partial pressure of oxygen (PaO_2) in arterial blood to the fraction of inspired oxygen (FiO_2) being delivered (PaO_2/FiO_2 Ratio)
PP	Per Protocol
RASS	Richmond Agitation and Sedation Scale
SpO_2	Peripheral Capillary Oxygen Saturation

Introduction

Non-communicable diseases (NCD's) now account for more global deaths in both developed and developing countries (1) with NCDs now the leading cause of death in all developing economies with the exception of sub-Saharan Africa (2). Ischaemic heart disease is the leading cause of NCD deaths (1,2) with cardiac surgery one of the most commonly performed surgeries both worldwide (3) and in New Zealand (NZ) (4). Although common, cardiac surgery is major surgery, not without risk, and requires postoperative admission to an Intensive Care Unit (ICU) with at least an overnight stay. During the ICU admission, the patient remains sedated and mechanically ventilated until cardiovascularly stable and assessed as ready for extubation. It is anticipated that patients will be ready to extubate within 3-6 hours of admission to ICU with transfer to the ward the following day.

Mechanical ventilation (MV) mandates the use of an artificial airway (endotracheal tube, ETT), this maintains the patient's airway allowing MV while the patient is sedated. Although MV is a frequent intervention in ICU (5), both the ETT and MV carry risks with potential complications including an increased risk of infection (6), inflammatory injury to the airways (7,8), ventilator lung injury as a result of repeated over-distension of the lungs (9,10) and pain and distress for the patient (11–13). Part of airway management includes providing endotracheal suction (ETS). ETS removes secretions from the lungs that the patient is unable to clear by coughing, prevents build-up of biofilm within the ETT and maintains the integrity of the ETT (14–16). However, ETS can contribute to potential complications including trauma to the lungs and airways, hypoxia, cardiac arrhythmias and atelectasis (6,17,18), it is also known to be a painful procedure for the patient (12). ETS is one of the most frequent nursing procedures performed in ICU (5) and is an important part of airway management for patients who have extended periods of MV, however, the evidence that underpins clinical practice is acknowledged to be of low quality (19). There is no published evidence about the avoidance of ETS in patients who have planned short term MV in ICU.

Previous research has identified that the majority of nurses perform ETS at the point of extubation (5,20). The rationale is that this will prevent aspiration of any secretions sitting above the ETT cuff when the balloon is deflated at extubation, however, there is laboratory evidence that a positive pressure breath at extubation may prevent aspiration (21,22).

Given the known risks associated with ETS we consider that further investigation into the safety and efficacy of avoidance of ETS in the uncomplicated post-operative cardiac surgical patient is warranted. We plan a randomised controlled trial (RCT) assessing the safety and efficacy of avoidance of ETS in patients having planned cardiac surgery and who are ventilated for ≤ 12 hours.

Study hypothesis

Avoiding ETT suction in patients ventilated for ≤12 hours following cardiac surgery is not inferior to usual care suction, including prior to extubation.

H_0: The P/F ratio in the intervention group will be inferior to the P/F ratio in the usual care group by greater than a 10% non-inferiority margin in favour of the usual care group.

H_1: The P/F ratio in the intervention group will be non-inferior to the P/F ratio in the usual care group allowing a 10% non-inferiority margin.

Study Aims and Objectives

The aims of the study are:

- Assess the safety and efficacy of avoidance of endotracheal suction in patients receiving mechanical ventilation for ≤12 hours.
- To investigate and describe the patient experience of both the endotracheal tube and endotracheal suction and to provide education and feedback to the nursing staff.

The objectives are

- Analyse the difference in P/F ratio between groups evaluating any difference in variances assessed for non-inferiority. If the intervention group is non-inferior to the usual care group this will to provide the first data about the efficacy of avoiding ETS in this patient cohort.
- To compare safety outcomes between groups by evaluating cardiovascular complications, ventilation complications and rates of escalation of oxygen therapy. If the intervention group has no greater incidence of complications this will provide data about the safety of avoiding ETS in this patient cohort.
- To record behavioural pain score of patients before, during and following ETS (for those receiving ETS).
- Describe the patient experience of both the ETT and ETS and report patients pain scores as recalled by the patient the following day. This data will inform education and training for nursing staff and will add to the body of knowledge about patients experience of the ETT and ETS while in ICU following cardiac surgery.

Study Design

The ARETS (Avoidance of Endotracheal Suction in Routine post-operative Cardiac Patients) study is a single centre, non-inferiority, randomised controlled trial assessing the safety and efficacy of avoiding endotracheal suction in patients having planned cardiac surgery who are ventilated for ≤12 hours. Non-inferiority design requires that the non-inferiority margin is pre-specified and the International Council for Harmonisation provides guidelines for the conduct of clinical trials, including selecting a non-inferiority margin. The guidelines state that “the determination of the margin in a non-inferiority trial is based on both statistical reasoning and clinical judgment, should reflect uncertainties in the evidence on which the choice is based, and should be suitably conservative” (23). Therefore, in consultation with senior medical staff on the ICU and an independent statistician, and using available data and clinical expertise within the group, a non-inferiority margin of 10% was considered clinically acceptable for the primary outcome - PaO2/FiO2 (P/F) ratio.

Study population and eligibility criteria

Participants will be patients scheduled for cardiac surgery with cardiopulmonary bypass, who are anticipated to receive mechanical ventilation for 12 hours or less.

Inclusion criteria

- ≥16 years old,
- Patients having cardiac surgery with cardiopulmonary bypass (CPB),
- Extubation expected within 12 hours of admission to CVICU

Exclusion criteria

- Documented difficult intubation
- Expected ventilation >12 hours
- Clinician preference for the patient to receive ETT suction.

Randomisation

Patients will be randomised 1:1 to either usual care including ETT suction or usual care with no ETT suction, including at the time of extubation, that is either immediately before or simultaneously with ETT removal. Research nurses or the clinical nurse coordinator will screen the patients on admission to ICU and if it is anticipated that the patient will be extubated within 12 hours of admission to ICU randomisation will occur. Allocation concealment will be achieved by the use of sequentially numbered, opaque, sealed envelopes containing the allocation on a slip of paper folded once. Non-study personnel will prepare the allocation envelopes and an independent statistician will generate the random sequence generation.

Variables Collected

	Pre-operative	Pre-extubation	Post-extubation (through to 6 hours post extubation)	Day 1
Baseline Demographics	x			
Comorbidities	x			
Smoking status	x			
EuroSCORE	x			
Arterial blood gases (ABGs)		x	x	
Physiology – HR, MAP, respiratory rate		x	x	
Complications			x	x
Pain scores		x		
Patient interview				x
Adverse event monitoring		x	x	x

Sample Size

Based upon previous work done in the same unit with a similar patient population (24) in a sample of 130 participants receiving supplemental oxygen four hours post-extubation, the mean P/F ratio was 301 (SD 83.9). We hypothesised that there would be less variability in the mean P/F ratio for patients not receiving supplemental oxygen (no data is available for this group), and therefore used a SD of 80 for the sample size calculations. We estimated that if there is truly no difference between the standard treatment and the intervention, then 166 patients would be required to be 80% sure that the lower limit of a one-sided 95% confidence interval will be above the 10% non-inferiority limit (P/F ratio no worse than 270). Recruitment will continue until 166 patients achieve the primary outcome. It is not anticipated that there will be any loss to follow up, as all the data will be collected prior to the patients leaving hospital. The G Power sample size calculator was used for sample size calculation (25).

Study Outcomes

Primary Outcome

The primary outcome of this study is the PaO2/FiO2 (P/F) ratio 6 hours after extubation (+/- one hour). P/F ratio is defined as the ratio of the partial pressure of oxygen (PaO2) in arterial blood to the fraction of inspired oxygen (FiO2) being delivered. It is used to quantify the degree of respiratory dysfunction and reduction in gaseous exchange. A lower P/F ratio is linked with a worse gaseous exchange with P/F ratio calculations influenced by the percentage FiO2 being delivered, therefore spontaneously breathing extubated patients receiving supplemental oxygen that is mixed with entrained room air will be unable to have an accurate P/F ratio calculated. For this reason, the 6-hour post-extubation ABG collected to derive the primary outcome will be taken with the participant breathing room air and not receiving supplemental oxygen. Where this is not clinically appropriate, for example, those patients receiving high flow oxygen therapy (HFOT), this ABG will be taken with the patient receiving HFOT. HFOT overcomes entrained room air thus providing an accurate FiO2 to calculate the P/F ratio. Both the PaO2 and the FiO2 will be recorded as part of the ABG data collection, and the P/F ratio will be calculated using these measurements.

Secondary Outcomes

- Frequency of escalation of oxygen therapy defined as oxygen therapy increased from nasal prongs/simple face mask to any non-invasive ventilation within 6 hours of extubation. This does not include participants who are extubated onto HFOT or who require HFOT for the 6-hour post-extubation ABG collected to calculate the P/F ratio as described in the protocol.
- Tachycardia (>100bpm) defined as one recorded heart rate >100 bpm anytime from admission to ICU to 6 hours post-extubation.
- Increased mean arterial pressure (MAP) (>85mmHg) defined as one recorded MAP > 85mmHg anytime from admission to ICU to 6 hours post-extubation.
- Increased respiratory rate (>25bpm) defined as one recorded increased respiratory rate >25 bpm anytime from admission to ICU to 6 hours post-extubation.

- Complications of extubation including laryngeal spasm, vomiting, aspiration, and oxygen desaturation as measured by SpO2 <90% 30 minutes after extubation. These complications are defined as occurring at least once 30 minutes following extubation.
- Oxygen desaturation as measured by SpO2 <90%, defined as one recorded SpO2 <90% anytime from admission to ICU to 6 hours post-extubation, with or without the requirement for escalation of oxygen therapy.
- Re-intubation rates any time from extubation through to 6 hours post-extubation.
- Pain scores before, during and after ETS. These will be recorded 10 minutes prior to ETS, during ETS and 10 minutes after ETS for those patients who have ETS performed.
- Patient experience as reported by the patient at a brief interview the following day. This will be recorded using a numerical pain scale to report pain from the ETT and ETS, 0 = no pain and 10 = the worst pain imaginable. These interviews will be conducted by experienced research nurses who are unblinded to the intervention and did not provide nursing care for study patients.

With the exception of the pain scores and patient experience, all of the secondary outcome measures will be recorded if the participant has one event within the study period, i.e. through to 6 hours post-extubation. This is to facilitate comprehensive safety data collection as to the best of our knowledge this intervention has not previously been performed. Pain scores will be collected at two time points, once with the patient lightly sedated (RASS -3 to +1), using the Richmond Agitation and Sedation Scale (RASS), this is a validated tool to measure agitation sedation levels in ICU (26) and once with the patient awake (RASS 0) and prior to extubation. The critical care pain observation tool (CPOT) (27) is a validated behavioural pain scoring tool and will be used for this study.

Data Sources

All data will be collected by trained research nurses and entered directly onto a password protected electronic case report form (eCRF). The REDCap platform will be used (28,29) and is hosted by the Medical Research Institute of New Zealand (MRINZ). MRINZ has the required security certificates and firewalls in place to protect patient data.

CONSORT Statement

All study participants will be accounted for using the methods recommended by the Consolidated Standards of Reporting Trials (CONSORT) Statement (30). The screening log will be used to provide data about the number of participants screened, numbers who declined and why, numbers consented and randomised and numbers not randomised on admission to ICU. These data will be presented in a flow chart (Figure 1). Data will be provided that describes the numbers allocated to the intervention and usual care group and numbers who did not receive the allocated intervention.

Statistical Analysis

There is currently a debate in the literature about which is the best statistical analysis model to use for non-inferiority studies (31–33), with recommendations that both Per Protocol (PP) and Intention to Treat (ITT) should be the lead analysis. The CONSORT group issued a statement extension in 2010 with

guidelines for reporting non-inferiority studies (34), recommending that the primary analysis is performed as a PP population analysis, with analysis repeated for sensitivity reasons using an ITT analysis. Data analysis for non-inferiority studies also requires that a confidence interval (CI) approach be used, and we follow these 2010 CONSORT recommendations in this statistical analysis plan. Data will be extracted into IBM SPSS Statistics (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY:IBM Corp.), which will be used for all analyses. Figure and Table shells for displaying results are displayed at the end of this document.

Baseline characteristics and co-morbidities

The baseline and demographic data will include gender, age, surgery, EuroSCORE II, smoking status, co-morbidities such as diabetes, chronic obstructive pulmonary disease, left ventricular function. Baseline data for all participants achieving the primary outcome will be presented according to treatment group. All continuous variables will be tested for normality; data will be presented as means and standard deviations where normally distributed and otherwise as medians and inter-quartile ranges. Binary and categorical variables will be presented as N (%) in each treatment group. Potential differences in treatment groups according to categorical variables will be assessed using a Chi-square test, or Fisher's exact test where there are low cell counts ($n<5$).

Primary Outcome analysis

The primary outcome analysis will test for differences in P/F ratio between the two treatment groups, which will be analysed for the PP population including only those participants who received their allocated intervention with no major protocol deviations and who had a 6-hour (+/- 1 hour) post-extubation ABG recorded. As described above, a sensitivity analysis of the primary analysis will also be assessed for the ITT population. If the PP analysis supports non-inferiority but the ITT sensitivity analysis does not, the reasons for this will be investigated and discussed. The analysis will be conducted using a one-tailed Student's t-test, or a Mann-Whitney U test if the outcome does not follow a normal distribution. A confidence interval (CI) approach will be used with a one-tailed 5% level of significance to assess and report non-inferiority, whereby non-inferiority will only be claimed if the lower limit of the CI does not exceed the 10% non-inferiority margin.

As this is an individualised randomised control trial, we expect baseline data and comorbidities to be similar in both groups. Baseline data will be checked, and if factors are strongly imbalanced adjustments will be made for these in the primary analysis using analysis of covariance.

Secondary outcomes analysis

A Students t-test (for normally distributed variables) or a Mann-Whitney U test (for non-normal distributions) will be used to assess differences in treatment groups for continuous secondary outcomes as described above. Additional data presented by treatment group will include the number of protocol deviations, ABGs performed out of range, numbers of patients excluded on admission to ICU and numbers of patients ventilated for over 12 hours.

A safety analysis will also be conducted using a modified PP analysis. The modification will be to include all patients who were excluded from the primary analysis because the collection of the ABG used to

calculate the primary outcome was outside the prescribed time i.e. later than 6 hours (+/- one hour) post-extubation. This analysis will include all the safety related secondary outcomes. This will maximise the power to detect any adverse safety signals.

Excluded patients

Those participants who are ventilated for over 12 hours will not have a 6-hour post-extubation ABG collected so the primary outcome cannot be calculated. For this reason, they will be excluded from the primary outcome analysis. Data about this group will be presented using descriptive statistics, including their baseline data and reasons for prolonged ventilation. This will help to assess whether this group of participants were different at baseline and the reasons for prolonged ventilation.

Data Safety Monitoring Board (DSMB) & Data Monitoring

There will be 100% monitoring of the primary outcome and consents and the first 10 patients will have 100% monitoring to ensure data quality. There will be monitoring of a further 10 patients meeting the primary outcome. Independent monitoring will be provided by MRINZ. For patient safety a data safety monitoring committee (DSMC) has been assembled, they will review the first 50 and 100 patients. The DSMC will consist of an independent statistician and two experienced researchers who are independent of the study. They will receive unblinded reports of the primary and secondary outcome measures in addition to adverse events.

Ethics

The study has been given both full ethical approval (15/NTB/138) and institutional approval.

Dissemination

Results will be published in appropriate peer-reviewed journals and presented at both local and international meetings. The results will also be presented to the staff in ICU and be used for teaching both current and new staff.

Conclusion

The findings will add to the body of knowledge about both ETS and the patient experience and can be used to develop nursing practice and improve patient care.

Tables & Figures

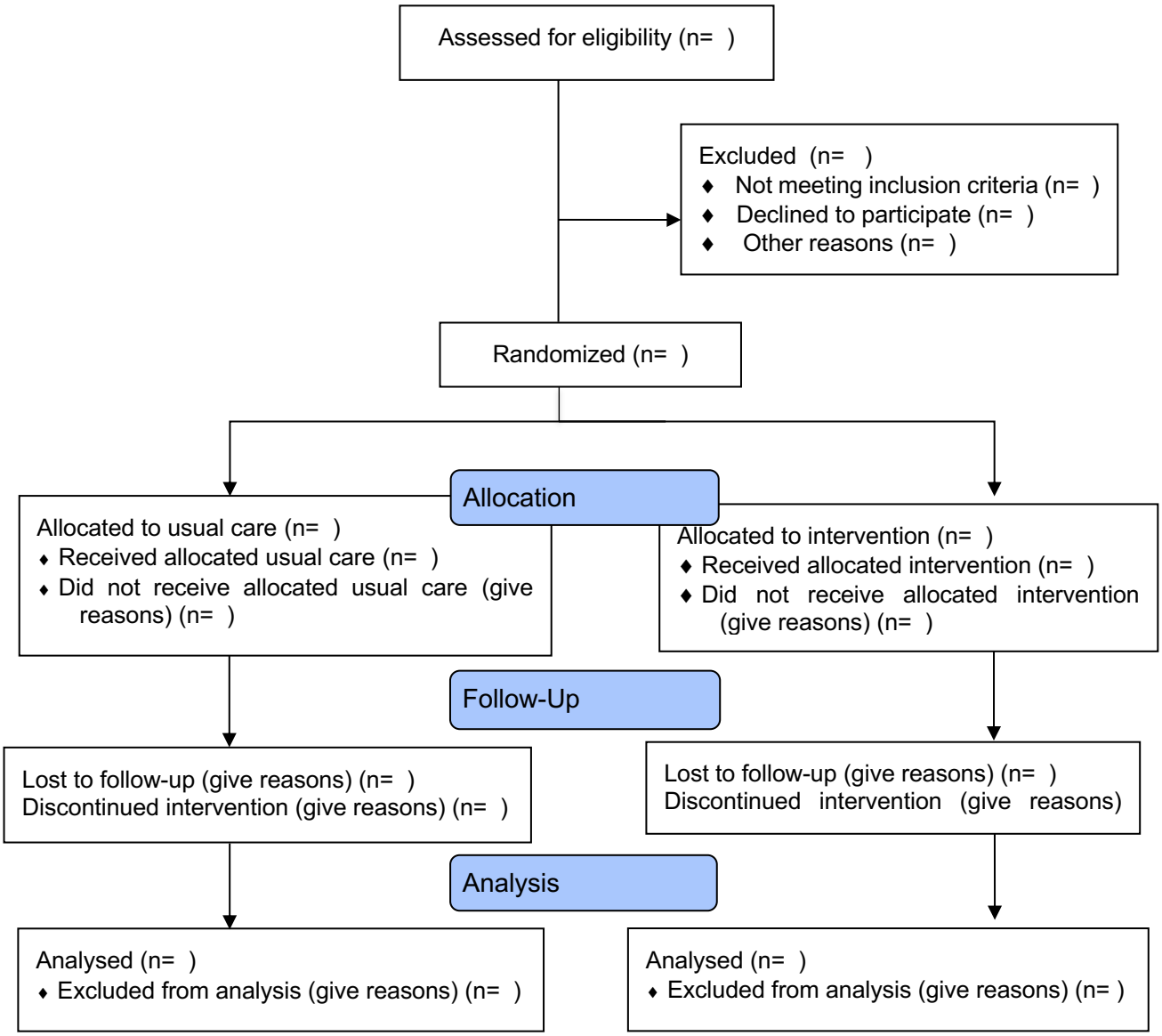

Figure 1: consort diagram

Table 1:-Baseline characteristic and co-morbidities.

	Usual Care *N (%) or mean ± SD*	Intervention *N (%) or mean ± SD*
Age, years		
Gender, Female Male		
Ethnicity NZ European NZ Maori Asian Other		
EuroSCORE		
Smoking status Yes No Ex-smoker		
BMI, kg/m^2		
Diabetes		
Chronic pulmonary disease		
Previous cardiac surgery		
Recent MI		
NYHA New York Heart Association functional classification I II III IV		
Class 4 angina		

Table 2: Surgery and ventilation

	Usual Care *N (%) or mean ± SD*	Intervention *N (%) or mean ± SD*
Type of Surgery - isolated CABG - single non-CABG - 2 procedures - 3 procedures		
Duration of surgery (hours)		
Duration of ventilation (hours)		
Length of ICU stay (hours)		
Patients ventilated >12 hours		

Table 3: Primary and secondary outcomes

	Usual Care	Intervention	Confidence interval	P value
Primary outcome	n (%)	n (%)		
P/F ratio: PP analysis				
P/F ratio: ITT analysis				
P/F ratio: modified PP analysis				
Secondary outcomes	mean ± SD	mean ± SD		
Heart Rate (per minute)				
Respiratory Rate (per minute)				

MAP, (mmHg)				

Table 4: Suction data

	N (%) or mean ± SD
Suction cannister pressure (mmHg)	
Number of suction episodes performed per patient in usual care	
Off protocol suction	

Table 5: Safety and complication outcomes

	Usual Care n (%)	Intervention n (%)	P value
Laryngeal spasm			
Vomiting			
Aspiration			
Escalation of oxygen therapy			
Desaturation (<90% SpO2)			
Re-intubation			
Respiratory rate >25			
Tachycardia >100bpm			
Increased MAP >85mmHg			
Return to theatre			

Table 6: Pain scores and patient experience

	Usual Care *N (%) or mean ± SD*	Intervention *N (%) or mean ± SD*	P value
Pain scores during ETS while the patient remains intubated			
CPOT Before During 10 minutes after			
Numerical pain score Before During 10 minutes after			
Patient recall			
Memory of the ETT			
Numerical pain score as described by the patient the following day			
Memory of ETS			
Numerical pain score as described by the patient the following day			

Table 7: Group characteristics and co-morbidities for those ventilated >12 hours

	Usual Care *N (%) or mean ± SD*	Intervention *N (%) or mean ± SD*
Patients ventilated >12 hours		
Age (years)		
Gender Female Male		
Ethnicity NZ European NZ Maori Asian Other		
EuroSCORE		
Smoking status Yes No Ex-smoker		
BMI, kg/m^2		
Diabetes		
Chronic pulmonary disease		
Previous cardiac surgery		
Recent MI		
NYHA New York Heart Association functional classification I II III IV		
Class 4 angina		

Table 8: Surgery and ventilation data for those ventilated >12 hours

	Usual Care *N (%) or mean ± SD*	Intervention *N (%) or mean ± SD*
Type of Surgery - isolated CABG - single non-CABG - 2 procedures - 3 procedures		
Duration of surgery (hours)		
Duration of ventilation (hours)		
Length of ICU stay (hours)		

Table 9: Exclusions

	Totals N(%)
Patients excluded on admission to ICU N (%) List reasons when available	
Final ABG outside the protocol timeframe N (%)	

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DATA AND SAFETY MONITORING BOARD CHARTER

Study Title	Avoidance of endotracheal suction in routine, post-operative cardiac patients.
Principal Investigator	Eileen Gilder
Registration number	ACTRN1261500089756
Protocol Number	1

DSMB Responsibilities and Data to Be Reviewed

Review the research protocol, informed consent documents and monitoring the overall conduct of the trial.
The DSMB will be responsible for safeguarding the interest of the trial participants.
The DSMB will provide recommendations about stopping or continuing the trial.
Evaluate the progress of the trial, including assessment of data quality and timeliness, participant recruitment, accrual and retention
Report on the safety of the trial; there will be an interim analysis once 100 patients have been recruited.

Membership

The DSMB will consist of 3 members including:
1. Dr. Colin McArthur–Chair
2. Dr. Douglas Campbell
3. Professor Thomas Lumley

Membership consists of persons completely independent of the investigators who have no financial, scientific, or other conflict of interest with the trial.

Board Process and Meeting Frequency

The first meeting will take place before initiation of the trial to discuss the protocol, approve the commencement of the trial, and to establish guidelines to monitor the study.
The DSMB will meet once 100 participants have been recruited and the data set is complete. Meetings may be convened as conference calls or face-to-face as required. An emergency meeting of the DSMB may be called at any time should questions of patient safety arise.

Meeting Reports

Scheduled Reports: The Principal Investigator (PI) will provide reports at least a week prior to the date of the meeting. The study team must submit reports after 100 patients have been enrolled and have completed the study intervention
The study team will prepare and submit a report that includes:
Accrual/Recruitment Information – including number of patients screened, enrolled, completed, withdrawn and reasons for withdrawals if any.
Adverse events – include description, grade, expectedness, relatedness.
Compliance with protocol – include protocol deviations.
Any other information.

Closed reports: Closed reports are available only to those attending the Closed Sessions of the DSMB meeting, should be provided by the study statistician, and should include:
Analyses of primary and secondary efficacy endpoints. The data provided to the DSMB will be unblinded.
Adverse events analyses.
Safety Reports:
1. Serious Adverse Events (SAE) that are determined by the PI and clinical advisor to be unexpected + related to the study intervention will be submitted to the DSMB by email within 7 calendar days of the determination. Submit written report no later than 15 calendar days of the determination.
2. All other SAEs will be collected and submitted with the report to the DSMB.

Meetings: The first meeting will be held before trial initiation and an interim analysis will be conducted once 100 patients have been recruited. Frequency of the meetings may be changed by the Chair based on need. Meetings may be in person or via teleconference, depending upon the schedule of the members.
The Principal Investigator will be notified of planned meetings no less than three weeks prior to the meeting date. The Principal Investigator will be expected to submit the required reports at least two weeks before to the scheduled meeting.
Open Sessions: The DSMB may request the attendance of the Principal Investigator and/or study team members to provide specific clarification or respond to issues. The DSMB may invite guests to meetings for their expertise or for needed information. Open session discussion will focus on the conduct and progress of the study with special attention to the pooled safety and efficacy data. The Principal Investigator may be asked to respond to Board questions.

Closed Sessions**:** Only DSMB members and DSMB coordinator(s) should be present at the closed session. In this session, the DSMB will review the efficacy and safety data. The DSMB should consider the data in relation to the conduct and progress of the study, and the study protocol. The DSMB should also decide, in closed session, on the written recommendation it will present to the Principal Investigator. The DSMB will evaluate study conduct (accrual), safety (adverse events), data integrity (subject eligibility, protocol deviations) and the risk benefit ratio for trial subjects.

Recommendations: Following a DSMB review, the board must submit a written report to the PI. The options available for the outcome of the review are:
Recommend continuation with no modification,
Recommend continuation with modification(s) to protocol,
Recommend suspension of enrolment pending additional information,
Recommend suspension of all trial activities pending additional information,
Recommend termination of trial.

Recommendations to the Principal Investigator must have majority approval by the Board members. Prior to dissemination, the Chair will review summary statements and recommendations from DSMB members.
Distribution of DSMB Report: The DSMB Chair will formalize the recommendations in a formal letter and forward to the PI. The PI is responsible for dissemination to the study team, HDEC and ADHB RRC and A+ Charitable Trust as required.

Confidentiality

All materials, discussions and proceedings of the DSMB are completely confidential. Members and other participants in DSMB meetings are expected to maintain confidentiality.

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