What is the effect of suctioning and frequency on oxygenation and bradycardias in infants ≤30 weeks gestation requiring Bubble Continuous Positive Airway Pressure (CPAP)?

A thesis presented in partial fulfilment of the requirements for the degree of

Masters in Philosophy

In

Nursing

at Massey University, Albany,

New Zealand.

Susan Elizabeth Greensill

2014

Abstract

Background: Previous research around suctioning premature infants has focused on endotracheal suctioning. Continuous positive airway pressure (CPAP) has become a major mode of respiratory support. Consequently, there is a need for research that is relevant to this mode of respiratory support.

Aim: To determine the effect suctioning and suctioning frequency has on oxygen saturation levels and bradycardias in infants ≤30 weeks gestation on “bubble” CPAP.

Method: The research comprised of two parts:

- An observational study to determine the effect of suctioning on oxygen saturation, desaturations, and bradycardias.
- A randomised crossover study to determine the effect of frequency of suctioning on oxygen saturation, desaturations, and bradycardias.

Results: *Part One:* Analysis demonstrated that increased suctioning frequency significantly decreased oxygen saturation levels and resulted in more desaturations. However, one more desaturation per hour required 5.3 and 7 more suctioning episodes each day for desaturations of ≥10 seconds and ≥60 seconds respectively. Of note was the increased likelihood of desaturations when the suctioning interval was longer. An increase interval of 1 hour 40 minutes between suctioning times led to one more desaturation ≥10 seconds per hour, with one more desaturation ≥60 seconds with 3½ hours increase in interval. Bradycardias were also significantly increased by one per hour, when suctioning frequency increased by 15 intervals per day. Conversely, the odds of a bradycardia occurring if the suctioning interval increased one hour was 1.9. *Part Two:* Analysis demonstrated that overall there were less desaturations and bradycardias with 2 hourly suctioning compared to 4 hourly. However, numbers were too small to determine statistical significance. Data from the effect of suctioning, for both parts, demonstrated prolonged periods of recovery for infants, with minimal or no change in supplemental oxygen, which may have affected results.

Conclusion: Significance was demonstrated in relation to more desaturations and bradycardias with increased frequency of suctioning in Part One, though the prolonged recovery time may have influenced these outcomes. Of more significance were the findings that demonstrated increased desaturations and bradycardias with longer intervals between suctioning. Results from Part Two were inconclusive due to small numbers of participants. This study provides a baseline for evidence on suctioning premature infants on CPAP, guideline development and a foundation for future research.

Acknowledgements

I would like to thank the wonderful team of the study NNU, for their aid, support and guidance in helping me to complete this study. Especially I would like to thank Niccy Brougham, Mike Meyer, and Lindsay Mildenhall, for their on-going support in developing and managing my research. I would also like to thank my colleagues in my current position, for their support, encouragement, and aid in completing my thesis. In addition, I would like to acknowledge and thank the families whose infants were fundamental in developing this study. Thank you for allowing your precious little ones to participate in my research.

I extend my thanks to my supervisor, Dr Stephen Neville, for all his guidance, patience, and support in writing my thesis and reviewing my work. Also, Mary Lynch for her support in determining my thesis topic. No quantitative research study is complete without statistical analysis and I would like to acknowledge the guidance, patience, and support of Irene Zeng, who contributed to the process and development of the data analysis for the study and the analysis of the results. My thanks to the CCRep team for the research grant to support my research. Fisher & Paykel Healthcare and Promed Technologies supplied the monitors for data recording, and I appreciate their support for my research. I would like to acknowledge and thank Jess Donnelly and Chris Beaumont for all their support in setting up the recording and downloading programmes for the data loggers. Special thanks go to Jess for his role in combining the data from both monitors into one format to aid analysis. This was a huge task and I really appreciate the effort given to complete the task. Many thanks to Jan Smeath for providing support in managing data recording and the recorded data from the Masimo monitors.

Most of all I would like to thank and acknowledge the never-ending support and belief from my husband, David, and daughters, Eva and Diana. Without their constant understanding, patience, and encouragement, I would have not been able to complete my thesis. Thank you, normal life will now resume.

Lastly, I would like to dedicate my thesis to my mother, Nancy Strachan, who passed away as I started this study. Thank you for making me the person I am and encouraging me to strive to do better and be the best I can be. I am sorry that you are not here to see me complete the process.

Su Greensill

Table of Contents

Index of Tables

Index of Figures

Chapter One

Introduction to the Study

Introduction

Continuous Positive Airway Pressure (CPAP) is increasingly being utilised as the primary mode of respiratory support in premature infants (Sankar, Sankar, Agarwal, Paul, & Deorari, 2008). Studies have found that with the early application of CPAP there is a reduction in the need to intubate infants (Narendran et al., 2003), decreasing the need to mechanically ventilate, and subsequently fewer painful procedures being performed on these fragile premature infants (Axelin, Ojajärvi, Viitanen, & Lehtonen, 2009). With the rise in use of CPAP for respiratory support, there is a need to ensure that the evidence used in benchmarking care, procedures, and practice around CPAP are applicable to this mode of respiratory support. However, there is little understanding as to which aspects of CPAP application and care are vital for optimal respiratory support, or the role airway management, by way of suctioning, has on the outcomes (Polin & Sahni, 2002).

This thesis attempts to determine the effect that nasopharyngeal and oral suctioning may have on supplemental oxygen requirement, desaturations, and bradycardias in infants ≤30 weeks gestation requiring CPAP in a metropolitan level 3 neonatal unit (NNU) within New Zealand. This chapter will introduce the context of the study, the use of respiratory support in infants, discuss the background, history of the establishment, and benefits of CPAP within neonatal care. The use of oxygen and suctioning practices for premature infants will be reviewed and the context of the study, the research question, and the study aims presented. Many older references used within this thesis are seminal pieces of work and as such reflect the background and knowledge base within neonatal care.

Context of Study

An interest in the effect suctioning has on CPAP stemmed from observations within the study NNU. As a midwife and neonatal nurse with over 16 years of neonatal intensive care experience, spanning 25 years, changes in practice had been noted over time, with new treatments and research providing evidence to support and enhance our practice. In 1996 “bubble” CPAP was introduced within the study NNU. This led to a dramatic change in care for infants requiring respiratory support. The first-hand experience of the effects the change of practice and improved outcomes, with the new mode of CPAP delivery, had on the infants, lead to the challenge of determining whether nasopharyngeal and oral suctioning, which is an invasive procedure, benefited the infants on CPAP. The frequent suctioning, which is seen as part of the regime, appeared to make a difference for infants. The results were perceived as fewer desaturations and a reduction in the need for supplemental oxygen. However, there was no research to support this.

The NNU, where the study took place, is a 28-cot unit, providing neonatal intensive care services to a diverse population of around 490,000, encompassing a large proportion of Māori and Pasifika, with 700-900 admissions per year (Counties Manukau

Health, 2012). The study NNU predominately utilises CPAP as the main mode of respiratory support.

Background

The ability to provide respiratory support to infants, utilising distending pressure within the lungs, has only been fully developed over the past 50 years (Touch, Shaffer, & Greenspan, 2002). Prior to this, warmth, nutrition, and oxygen, were the only measures available to healthcare professionals caring for respiratory compromised infants (Dunn, 2007). The successful use of CPAP, to support respiratory function in premature infants with respiratory insufficiency, was first described in 1971 (Bonner & Mainous, 2008; Gregory, Kitterman, Roderic, Tooley, & Hamilton, 1971). However, historical records have demonstrated the use of positive pressure to inflate infants' lungs and provide respiratory support during resuscitation being utilised as early as 1914 (von Reuss, as cited in Dunn, 1990). The use of masks and tubes, for the removal of secretions and administration of oxygen under pressure to support the infant were also mentioned, with the aid of a column of water to provide an end pressure (Dunn, 1990). The method of providing end pressure with a column of water resembling the system set up used in bubble CPAP today (can be viewed *Figure B1*, Appendix B).

The bubble CPAP method, initiated in 1996 within the study NNU, adhered to the principles and regime of the Columbia Presbyterian Medical Center Neonatal Unit, in application, use of CPAP, and frequency of suctioning (De Klerk & De Klerk, 2001a). Columbia Presbyterian Medical Center first treated infants requiring respiratory support with CPAP in 1973, utilising a system that is similar to the current model operating within the study NNU (Wung, Driscoll, Epstein, & Hyman, 1975). Columbia Presbyterian Medical Center was identified in a landmark study of eight centres in North America, as having a remarkably low level of bronchopulmonary dysplasia (BPD) compared to the other centres (Avery et al., 1987; Bonner & Mainous, 2008). The outcome of this study identified that the application and use of CPAP at Columbia may have been a factor in these outcomes (Avery et al., 1987). BPD or chronic lung disease (CLD), is a side effect of respiratory support in premature infants, resulting in multiple sequelae (Avery et al., 1987; Bonner & Mainous, 2008). Within this thesis BPD will be used to describe the damage to premature infants' lungs due to respiratory support and oxidative damage, as a consequence of immature lungs.

CPAP has many benefits that can support premature infants' respiratory effort, due to their immature lungs, and reduce morbidity. Premature infants have poor lung compliance, reducing their ability to maintain a residual capacity (Bonner & Mainous, 2008). CPAP splints the airways and diaphragm allowing effective breathing (Aly, 2001). The distending pressure of CPAP reduces surface tension within the alveoli and promotes alveolar expansion, supporting spontaneous respirations (Touch et al., 2002). CPAP also enhances surfactant production within the lungs, through allowing lung expansion, splinting the airways and reducing the effort premature infants need to exert to breathe (Polin & Sahni, 2002). Surfactant is a phosopholipoprotein produced in the alveolar type II cells, which aids lung function by reducing the surface tension within the alveoli, making lung expansion easier and reducing the risk of lung collapse (Van Marter et al., 2000). This decreases the effort expended by the premature infant to inflate their lungs. The reduction in exertion required to maintain respiration, lessens the frequency of apnoea of prematurity due to respiratory insufficiency (Polin & Sahni, 2002).

CPAP has also been found to be beneficial in reducing the risk of BPD. Infants given CPAP are less likely to be exposed to barotrauma, more commonly a sequelae of ventilation (Bonner & Mainous, 2008; Clark et al., 2001; De Klerk & De Klerk, 2001a; Ho, Subramaniam, Henderson-Smart, & Davis, 2002; Meyer, Mildenhall, & Wong, 2004; Narendran et al., 2003). Infants given early CPAP require fewer days of ventilation, compared to those intubated and given surfactant, with no increase in the risk of BPD (Finer et al., 2010).

Consequently, CPAP has become an important tool in the respiratory management of the premature infant. The need for respiratory support in premature infants stems from their lungs being at the canalicullar stage of development, where there is minimal development of alveoli, leading to reduced surface area and ability for gas exchange (Meeks & Hallsworth, 2010). The prematurity of the lungs increases their susceptibility to respiratory complications, such as BPD, with instigation of respiratory support, and the potential for damage to occur due to oxidative stress, as a result of the requirement for supplemental oxygen (Belik, 2008; Saugstad, 2010). Lung compliance is poor, leading to increased risk of alveolar collapse and reduced surfactant production, resulting in a risk of higher morbidity and mortality (Bonner & Mainous, 2008; Ho et al., 2002).

At approximately 27 weeks gestation, the lung wall lining is thin enough to allow gas exchange, although the alveoli are not yet fully developed (Hislop, 2003). Surfactant production is also limited at this stage of development due to the prematurity of the lungs. Hislop (2003) discusses the presence of surfactant in the amniotic fluid after the canalicullar stage of lung development, thus indicating that surfactant may only be produced at around 24-27 weeks in the alveoli. Therefore, infants of 24-28 weeks gestation have poor lung expansion and lack surfactant, diminishing the ability for gas exchange, which can lead to an increased risk of oxidative damage, due to supplemental oxygen use.

Supplemental oxygen is effective in preventing hypoxia in infants (Sola, Saldeno, & Favareto, 2008). Ventilation-perfusion mismatch and hypoventilation, due to premature lungs, also responds well to oxygen therapy (Walsh, Brooks, & Greiner, 2009). Hence, supplemental oxygen can be beneficial in the care of premature infants. Oxygen was first isolated as a gas in 1772 (Robertson, 2003). For over 100 years, oxygen has been utilised in neonatal care, to support respiration (Walsh et al., 2009). However, over exposure to oxygen, hyperoxia, can result in retinopathy of prematurity (ROP) and blindness, which was not realised until the 1950's. Robertson (2003) found that increased levels of retinopathy in premature infants were higher when infants were exposed to unrestricted oxygen compared to those infants with restricted oxygen. Oxygen toxicity or oxidative stress, due to hyperoxia, is now recognised as a major cause of neonatal morbidity (Sola et al., 2008; Walsh et al., 2009).

High levels of inspired oxygen have also been found to increase the risk of infants developing BPD, as it impairs surfactant production (Araujo et al., 1998; Clark et al., 2001; Saugstad, 2010; Van Marter et al., 2000; Vento et al., 2009). With exposure to high concentrations of oxygen, over a prolonged period, there is an increased risk of the development of BPD, due to oxidative stress damage to the lung tissue (Stocks & Godfrey, 1976). Oxygen and the resulting oxidative stress are associated with other detrimental effects; increased length of hospital stay as a result of increased risk of respiratory disease and infection, impaired brain development, and cancer, due to the effect oxygen has on the activation of enzymes and the synthesis of DNA, RNA and protein (Sola, Rogido, & Deulofeut, 2007; Sola et al., 2008). Therefore, ensuring premature infants are exposed to minimal amounts of supplemental oxygen is prudent. However, managing supplemental oxygen levels and saturations within the desired level, can be a challenge for nursing staff, due to the rapid onset of desaturation and frequency of desaturations in premature infants (Walsh et al., 2009).

Oxygen saturation, obtained by the use of pulse oximetry, allows an estimation of the oxygen circulating in the blood, as a percentage of haemoglobin saturated with oxygen (Craft, Gordon, & Tiziani, 2011). Haemoglobin carries oxygen around the body, releasing the oxygen when levels of oxygen in the plasma fall, allowing oxygen to diffuse into the tissues (Craft et al., 2011). The oxygen dissociation curve, sigmoidal in shape, demonstrates the relationship between oxygen saturation of the haemoglobin and the surrounding fluid (Craft et al., 2011). Therefore, small changes in saturations over 95% can lead to greater changes in the level of partial pressure of oxygen (PaO_2), due to this sigmoidal shape flattening above this point (Sola et al., 2008).

The ability of fetal haemoglobin to retain oxygen at lower PaO_2 compared to adult haemoglobin differs. Consequently, the oxygen dissociation curve shifts to the left, when compared to that of adult haemoglobin (Sola et al., 2008). Therefore, allowing oxygen saturations to be higher than 95% can lead to episodes of hyperoxia in premature infants. Castillo et al. (2008) found that the risk of hyperoxia was significantly reduced when premature infants' with supplemental oxygen, had oxygen saturation target levels maintained between 85-93%. Subsequently reducing the risk of over oxygenation and managing supplemental oxygen to maintain these saturations and prevent hyperoxia occurring. Within the study NNU oxygen saturation target levels for infants <32weeks are set at 88-92% in-line with the current evidence, with increased oxygen requirement being an indication for suctioning (Counties Manukau District Health Board [CMDHB], 2012).

The use of suctioning for the removal of secretions from airways of infants, has been described since the early 1900's (Dunn, 1990). Suctioning has long been established as part of routine nursing care of infants requiring respiratory support, during the neonatal period (Gardner & Shirland, 2009). The use of suctioning can improve oxygenation, reduce airway resistance, and reduce episodes of hypoxia: inadequate oxygenation (Dall'Alba & Burns, 1990; Prendville, Thomson, & Silverman, 1986; Zemlicka-Dunn, 2001). Poiseuilles Law can best describe the effect of secretions in the airway, where the resistance in the airway is inversely related to the power of four of the radius (Grinnan & Truwit, 2005). Therefore, small changes in the radius of the airway, as a result of secretions, leads to a dramatic increase in gas flow resistance within the lung, resulting in more effort required for breathing. Hence, effective removal of secretions with suctioning would support respiratory effort.

Research associated with suctioning of premature infants, to date, has focused on endotracheal suctioning, where infants are mechanically ventilated via an endotracheal tubes (ETT), and the suctioning of term infants at birth (Carrasco, Martell, & Estol, 1997; Cordero, Sananes, & Ayer, 2001; Estol, Piriz, Basalo, Simini, & Grela, 1992; Gungor et al., 2006; Gungor et al., 2005; Kattwinkel et al., 2010; New Zealand Resuscitation Council Guidelines, 2010; Wilson, Hughes, Rennie, & Morley, 1992). This has led to a reduction of routine suctioning of infants' airways in practice. Mechanical ventilation via an ETT impairs the body's ability to clear mucous from large airways naturally (Singh, Kissoon, Frewwen, & Tiffin, 1991). Suctioning removes the secretions from the main airways, with research supporting less frequent suctioning with this mode of respiratory support. However, there is little to show that this is the case with infants requiring CPAP.

Animal studies have demonstrated that the flow and pressure of CPAP, in the upper airways, can inhibit swallowing of oral secretions, due to increase gas flow on the pharynx (Samson, Duvareille, St-Hilaire, Clapperton, & Praud, 2008; Samson et al., 2005). Consequently, there would be a need to maintain a clear airway, to reduce airway resistance, and an understanding of whether the effect of reduced frequency for suctioning would be similar for infants CPAP, as those mechanically ventilated.

Aly (2001) discusses the need for frequent suctioning with nasopharyngeal CPAP and "meticulous attention to the airway", (p.760). However, adverse effects of suctioning have been described; trauma to the mucosa in the airway, laryngospasm, apnoea and bradycardia (Hayes, Czarnecki, & Kaucic, 1999). Studies have also identified the risk of increased intracranial pressure with the increased risk of intraventicular haemorrhage (IVH) (Durand, Sangha, Cabal, Hoppenbrouwers, & Hodgman, 1989; Kaiser, Gauss, & Williams, 2008; Singh et al., 1991). However, in all the studies that discuss these adverse effects, the infants have received mechanical ventilation. Knox (2011) discusses the benefits of oronasopharyngeal suctioning in children, including improvement in oxygen saturation levels, reduced respiratory effort, and stabilisation of heart rate leading to a reduction in metabolic demands. The smaller airways, tidal volumes and low expiratory pressures decreases the ability for younger children to effectively clear these airways and suctioning may be of benefit, although excessive suctioning of lower airways can lead to the adverse effects previously discussed (Knox, 2011).

Within the study NNU suctioning is only performed down to the nasal pharynx area, to reduce the risk of vagal stimulation (CMDHB, 2012). Suctioning practices also ensure that infants are swaddled. The practice of swaddling, by way of wrapping the infant, provides containment during the procedure, to reduce stress (Ward-Larson, Horn, & Gosnell, 2004). Oral suctioning is performed gently, by slowly inserting the catheter to the side of the mouth and care is taken in removing the catheter to reduce startling the infant or causing trauma or a vagal response (CMDHB, 2012). These practices are aimed at reducing the stress and trauma that could be elicited when a premature infant is suctioned.

The necessity for suctioning to maintain a patent airway requires balance against the needs of the infant for rest, with the advent of developmental care leading to a “hands off” approach to premature infants care. Minimising stress by monitoring and responding to infants’ behavioural responses to care, allowing them periods of rest to recover and less disruption of sleep, was found to be beneficial and led to clustering care procedures and reducing painful stimuli where possible (Als et al., 1986). Within the study NNU suctioning is performed semi routinely based on the infant’s needs. Care procedures are clustered, with suctioning being undertaken prior to feeding and therefore occur 2-4 hourly depending on the nurses’ observation of the infants’ condition and monitoring, such as when they may have apnoeas, bradycardias, and desaturations.

Apnoeas are a common occurrence in premature infants and can result from a central or obstructive origin. Central apnoea occurs as a result of an immature respiratory drive (Bhatt-Mehta & Schumacher, 2003; Milner & Greenough, 2004). Obstructive apnoea is due to occlusion of the airway and can occur in conjunction with central apnoea, described as mixed apnoea (Milner & Greenough, 2004). The severity and incidence of obstructive and central apnoea can be lessened with the use of CPAP, which distends the airways (Di Blasi, 2009; Milner & Greenough, 2004). Suctioning can remove any obstruction that may occlude the airway, improving the effect of CPAP (De Paoli, Morley, & Davis, 2003). This in turn may lessen the occurrence of apnoeas. When infants are apnoeic they become bradycardic within 1-2 seconds (Milner & Greenough, 2004).

Transient periods of bradycardia, associated with periodic breathing, are a common occurrence among healthy premature infants (Hodgman, Gonzalez, Hoppenbrouwers, & Cabal, 1990). Apnoeas and bradycardia can also result from stress and handling in premature infants (Symington & Pinelli, 2006). Therefore, nurses need to be able to differentiate between these multi-factorial causes of apnoeas and bradycardias, balancing the need for suctioning judiciously and prudently: optimising the airway, reducing risk, preventing harm, as well as minimising respiratory support.

Ventilation, via an ETT, as a means of respiratory support, has been found to lead to a greater risk of BPD compared to the infant receiving CPAP or just oxygen (Stocks & Godfrey, 1976). There is a need to minimise the risk of BPD by optimising spontaneous breathing and limiting ventilation and oxygenation (Jobe, 2011). Therefore, utilising CPAP optimally may improve outcomes. To ensure effective CPAP is delivered, appropriate application of prongs and tubing, timely use of CPAP and frequency of suctioning, requires fastidious attention to detail (De Klerk & De Klerk, 2001b). The factors that affect the success of CPAP include poor application of prongs, inadequately secured tubing with a suitably sized hat, inappropriate sized prongs, and a build-up of secretions (Morley & Davis, 2004). Although there is minimal evidence available to support these claims.

Prong size is important in effective CPAP, reducing work of breathing and risk of air leak (Di Blasi, 2009). Short, wide-bore nasal prongs, such as the Hudson prongs used for CPAP within the study NNU (Hudson RCI, Temecula, CA, USA), reduce resistance, compared with other modes of delivering CPAP, leading to reduced work of breathing (Morley & Davis, 2004). The reduction in resistance relates to Poiseuilles Law, as previously discussed. Secretions in the airway can increase airway resistance and reduce the effectiveness of CPAP, obstructing the airway, leading to apnoeas and failure of

CPAP (De Paoli et al., 2003). Therefore, a major component of the CPAP regime is frequent suctioning of the nasal and oral pharynx to remove secretions and maintain a patent airway. Some of the indicators for suctioning are; increased apnoeas and bradycardias or increased oxygen requirement, which are based on anecdotal evidence (CMDHB, 2012).

Statement of Problem

Current practice within the study NNU are based on guidelines developed by the Columbia Presbyterian Hospital. On returning to the study NNU after a five year absence, the researcher observed a perceived increase in the length of time infants were on CPAP and receiving supplemental oxygen. There appeared to be an increase in the number of infants requiring low flow oxygen. Anecdotal evidence suggested that suctioning practises had moved away from two hourly suctioning, when indicated, to suctioning four hourly and in some instances six hourly (McHugh, 2009). Discussion within the study NNU nursing team highlighted developmental care research and research findings from endotracheal suctioning had contributed to this change in practice. A decision to investigate the topic further and determine, through research, what was beneficial for the infants on CPAP, was made. However, a review of the literature resulted in no evidence being identified relating to infants on CPAP, as all the research pertained to endotracheal suctioning only. Being a NNU that predominately utilised CPAP for respiratory support, it was vital that guidelines and procedures reflected best practice, underpinned by research relevant to this mode of respiratory support.

Study Aims

Research Question

What is the effect of suctioning and suctioning frequency on oxygenation and bradycardias in infants ≤30 weeks gestation requiring bubble Continuous Positive Airway Pressure (CPAP)?

Aim

To determine the effect nasopharyngeal and oral suctioning has on infants ≤30weeks gestation requiring CPAP and what effect frequency has in reducing supplemental oxygen requirement, desaturations and bradycardic events.

Preface of Chapters

Chapter one

Chapter 1 introduced the concept of CPAP and suctioning, the context of the study, and a background to the use of CPAP in infants. The effect that respiratory support and oxygen can have on premature infants and the research question and study aims were identified.

Chapter two

Chapter 2 provides justification for the study, with a review and critique of the literature relevant to the research study around suctioning, frequency and oxygen requirement in premature infants requiring CPAP. The lack of relevant literature supporting the need to perform the research is identified.

Chapter three

Chapter 3 presents the research question, study aim and outlines the theoretical framework, research methodologies and methods employed to answer the research question. The study population is outlined and justification given, with variables and all data collected presented. Data analysis is discussed and the relevance of the two separate parts of the study are explained. Statistical programmes utilised to analyse data are identified within this chapter. Ethical and cultural aspects within the research are acknowledged and the approval process, including informed consent are discussed.

Chapter four

Chapter 4 presents the findings of the data analysis for each part of the study. Demographics for each group are presented along with the variables that were investigated. Results are presented in headings according to the variable being discussed and tables and figures are utilised to support the findings. Other findings from the data are also included along with an overview of all infants admitted to the study NNU that were ≤30 weeks gestation, during the time of the study period.

Chapter five

Chapter 5 discusses the findings from the study and presents the outcomes, relating this to current literature and research. Limitations of the research and applicability to practice are discussed with the implication for care of infants on CPAP given. Recommendations for future research are also offered.

Conclusion

This chapter has introduced the background of respiratory support and CPAP use for premature infants and within neonatal care. The practice and use of suctioning and delivery of supplemental oxygen for premature infants were examined and concerns were highlighted. The context of the study was introduced, describing the setting and population base. A background in pathophysiology of the premature lung and fetal haemoglobin was explained to demonstrate the effect respiratory support and oxygen elicit on premature lungs. The issues relating to suctioning infants on CPAP in practice were identified and the need for research that underpins this mode of respiratory support discussed. The rationale for commencing the research and the study aim were conveyed and an outline of the forthcoming chapters presented.

Chapter Two

Literature Review

Introduction

A literature review presents an outline of other literature and research findings that relate to the subject being investigated; providing a benchmark and establishing the importance of the study (Creswell, 2009). The previous chapter set out the history of respiratory support and CPAP, outlining oxygen use and suctioning within the context of neonatal care. This chapter provide a critical review of the literature related to suctioning practices for infants requiring respiratory support.

Previous studies have found that after the implementation of bubble CPAP, the risk of BPD, with reduced requirement of supplemental oxygen at 28 days and length of stay in hospital were reduced in premature infants (De Klerk & De Klerk, 2001a; Meyer et al., 2004). Although, there is little research to demonstrate what aspects of this form of respiratory support affects the outcomes of these infants, application of CPAP with a firm fitting hat and secure tubing, ensuring the bubble is present within CPAP tube system, or suctioning the infant to maintain a clear airway is required. Maintaining a clear airway through suctioning is seen as a foundation for this mode of CPAP, as it reduces resistance and effort of breathing (Bonner & Mainous, 2008). Nonetheless, there is a paucity of empirical evidence for this or the effect this procedure has on the premature infant on CPAP. Changes in suctioning practice were noticed within the study NNU over time, with a move away from the more frequent suctioning practised when the bubble CPAP was initially implemented. Suctioning frequency in some instances had at times been extended to six hourly (McHugh, 2009). The rationale for this change in practice was said to result from research around ETT suctioning, that promoted less frequent suctioning and developmental care studies that were based on minimal handling, as previously discussed (Hayes et al., 1999).

Today there is the need to ensure safe practice, promoting patient safety and research based care, by utilising evidence based practice (Salmond, 2007). To establish an understanding of current practice a review of the literature was instigated to examine nasopharyngeal suctioning for infants while on CPAP.

Search Strategy

An electronic literature search was carried out to identify articles published between 2000 and 2011, using Medline, CINHAL, Academic Search Elite, Health Source: Nursing/Academic Edition, Web of Science, and Scopus. Search terms used were: *suction*, CPAP, neonat*, infant, oxygen, frequenc*, airway management, oropharyn** and *nasopharyn**. The search was limited to articles in English. However, with the small numbers of articles obtained, the search was extended to include references from journal articles, literature reviews, and neonatology books, to source research material. As little research could be found pertaining specifically to suctioning infants while on CPAP, the search was extended to include endotracheal suctioning, and studies pertaining to paediatrics. The years for searching were also extended to include articles after 1987, to improve the opportunity of obtaining relevant articles. Studies prior to 1987 were not included due to the work of Als et al. (1987) around developmental care, which resulted in changes in practices in relation to stressful procedures, such as suctioning. Developmental care has changed the way infants are handled, especially during suctioning procedures with the clustering of routine cares performed and swaddling to reduce the impact on the infant and improve outcomes (Kondoh, 2004; Ward-Larson et al., 2004).

Studies were excluded if they pertained to suctioning of infants at delivery or with meconium exposure at delivery, as this was felt to be irrelevant to the research question, as they related to the adaptation from intra uterine life to extra uterine life. The only studies reviewed were those that described the effect suctioning had on the patient, the effect of frequency of suctioning, and studies related to infants or paediatrics. However, two further articles were added as they discussed the rationale behind initiating suctioning procedure and had some bearing on frequency.

Search Results

In total fourteen articles were found pertaining to the criteria set. One article was not reviewed due to not meeting inclusion criteria, leaving thirteen articles to review (see Appendix A for a summary of all articles reviewed). Most of the articles pertained to ETT suctioning and the many complex areas of performing this procedure and management of the airway, which differs from non-intubated infants. Therefore, the aspect of the effect of suctioning, the responses of the infants/children, and frequency were the only areas reviewed and highlighted from the articles retrieved. Out of the thirteen articles, eleven studies investigate ETT suctioning, six of the studies pertained to infants and were performed in NNUs, the other seven with children in Paediatric Intensive Care Units or wards (see *Figure 1*). Five main themes were established:

Suctioning non-intubated infants, suctioning intubated infants, frequency of suctioning, intracranial pressure related to suctioning, reducing the effect of suctioning for premature infants.

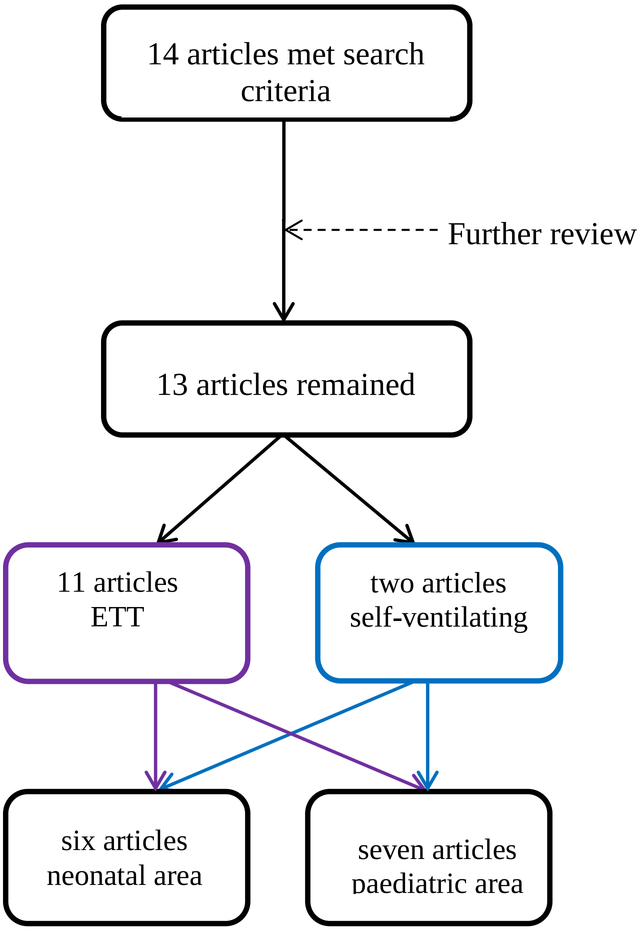

Figure 1. Search Results

Suctioning non-intubated infants

Only two studies focused solely on suctioning the non-intubated infant/child and one further discussed oral suctioning in conjunction with ETT suctioning. Hayes et al. (1999) performed a two-part study to determine the parameters nurses' used to identify the need to suction infants and what improvements there were in the infant after the procedure. The first part, a descriptive study, involved 46 registered nurses, from two different paediatric medical units, completing a questionnaire to rank order their assessment parameters prior to initiating suctioning. The results demonstrated that the most frequently used cues were audible secretions, visible secretions and a reduction in pulse oximetry readings, in order of preference. These parameters are verified by other research (Morrow & Argent, 2008).

The second part of the research, a one-group pretest-posttest design, was to determine the effect of nasopharyngeal suctioning on respiratory assessment parameters. The study was performed on 33 infants, two weeks to 22 weeks of age, who required nasopharyngeal suctioning due to a respiratory infection. Hayes et al. (1999) found that the indicators nurses had ranked highest, audible secretions, visible secretions and a reduction in pulse oximetry readings, were also the same for most improvement in the infants post suctioning, with pulse oximetry showing the most significant improvement. Although pulse oximetery was only ranked third by the nurses in part one. Overall the findings of the second part of the study validated the cues identified by the nurses in the questionnaire. However, it was reported that half of the pulse oximetry data were lost and therefore not reported on. The lost data may have impacted on the overall outcome. The resulting effect of all the data, lost and available, being analysed could have led to there being no significant change in pulse oximetry readings and different conclusions reached.

Though nasopharyngeal suctioning was found to be beneficial, the findings are not clearly set out and a small sample size was used. The infants being studied were aged two weeks to 22 weeks old. The response of older infants to suctioning may be different from premature infants, and the infants in the study did not require any respiratory support. Difficulty may arise in trying to replicate the process as it was unclear if the questionnaires used were sent out prior to the assessment of the infants and whether some of the staff who completed the questionnaire worked in the same unit. This could have also introduced bias to the second part of the study. If the nurses, who completed the questionnaires, were working in the same unit as the infants studied in Part Two, had completed the questionnaire prior to the infants being observed, there is the risk that the questions posed may have led them to become more aware of their practice. This could then have elicited a change in practice. The findings also report that some staff were confused about their years of experience and so this was not included in the results. This aspect would have been interesting to follow considering that skill and expertise have a bearing on this multifaceted procedure (Thomas & Fothergill-Bourbonnais, 2005; Wallace, 1998).

The second study to look at nasopharyngeal suctioning was the only study that discussed oxygen requirements pre and post suctioning. Zemlicka-Dunn (2001) presented a paper describing the effect that suctioning had on weaning supplemental oxygen. In this retrospective observational study, 421 clinical notes, of infants ≤24 months, were reviewed to quantify the effect suctioning had on the ability to wean oxygen to a lower percentage. Data were collected on oxygen requirement, suctioning episodes and suctioning related morbidities. There were 1141 suctioning episodes recorded. Results showed that suctioning improved the ability to wean oxygen. However, this was only a conference paper and had not been published in a quality assured journal. Consequently, the details of the research were limited.

Retrospective studies pose issues around data which are limited to the accuracy of documentation at the time of care (Aschengrau & Seage, 2014). There was no breakdown of the population within the study by Zemlicka-Dunn (2001) to determine relevancy and ability to duplicate the trial. The assumption was made that, as these were older self-ventilating infants without need for respiratory support, the research may not be transferable to premature infants. Nonetheless, the results did show a reduction in inspired oxygen requirement post suctioning. As oxygen has been described as causing oxidative damage it would be wise to limit oxygen use with premature infants (Araujo et al., 1998; Clark et al., 2001; Saugstad, 2010; Van Marter et al., 2000). Therefore, nasopharyngeal suctioning has some benefits in self-ventilating infants, in that oxygen requirements post suctioning may be reduced. Due to the potential for oxidative damage when used in premature infants, this research study demonstrating a reduction in oxygen requirement after suctioning is significant to the research question.

Singh et al. (1991) explored the reactions to endotracheal and oral suctioning, using differing sizes of catheter and suction pressures in their prospective observational study of 17 infants with a mean age of 6.5 months. Parameters monitored comprised heart rate, respiratory rate, arterial blood pressure (BP), oxygen saturation (SaO_2), and intracranial pressure (ICP). These parameters were recorded prior to suctioning and at 30 second intervals after suctioning, until the infant recovered to baseline recordings of these parameters prior to suctioning. Though some infants were sedated or paralysed it was felt that this had no significance on the outcome, also there was no significant changes in BP. Significant changes were noted with ETT suctioning in other recorded parameters: increased heart rate, decreased SaO_2 and increased ICP. Oral suctioning was found to be comparable to ETT suctioning, though with less risk of desaturation.

However, there was no clear indication as to how soon after the ETT suctioning episode, the oral suctioning was performed. The timing of the oral suctioning, in relation to the ETT suctioning, could have impacted on the response of the infants as a result of a prior stressful procedure, leading to inaccurate results for oral suctioning.

When data were reviewed, the baseline recordings for oral suctioning differed from baseline recordings for ETT suctioning. Heart rate, respiratory rate and blood pressure were higher and SaO_2 was lower than the baseline for ETT suctioning. These results could be reflective of the infant already being stressed from ETT suctioning, as discussed previously. If the ETT suctioning had been performed directly prior to oral suctioning, the true effect of the procedure and responses of the infants being suctioned orally would be masked. There was also no indication of how long infants took to recover from the episode of suctioning. Cunningham, Baun, and Nelson (1984) found that the degree of severity of lung disease led to a different response to suctioning and that removal of peak end expiratory pressure (PEEP) led to lung collapse. There has been no indication in the any of the studies of the degree of lung disease the infants had. The severity of lung disease may affect the infants' response to suctioning, as already discussed; premature infants who are ventilated are at more risk of BPD and most of the premature infants studied would have a degree of lung disease due to requiring ventilation. Consequently, the recovery time after suctioning would vary accordingly.

Suctioning intubated infants

Morrow, Futter, and Argent's (2006) were the only study that mentioned any improvement post endotracheal suctioning, and this was only seen in infants and children with obstructive secretions. This observational study looked at lung compliance after suctioning. Participants consisted of 78 intubated infants 0.3-25 months old, of which 24 infants were removed due to air leakage around the ETT, leaving 54 infants, all of whom were sedated with morphine. Monitoring included ventilator setting, inspired oxygen, ETT size, age, weight, respiratory rate, PaO_2, oxygen index, and ventilation index, with carbon dioxide (CO_2) measured 5 minutes prior and post suctioning. Results demonstrated a significant decrease in lung compliance after suctioning, more so when larger bore suction catheters were used. In contrast, when secretions were present, there was improvement in compliance and participants with "stiff lungs" (poor compliant lungs) were found to have less reduction in compliance, than those with normal compliance.

Morrow et al. (2006) concluded that lung compliance, represented as dynamic compliance, was reduced after suctioning, especially with smaller ETTs. One participant was removed from the study analysis, the rationale being that the results were far outside the other parameters and was thought to be due to measurement error. Morrow et al. (2006) felt that there would be no alteration of the findings because of this, though this would be difficult to verify as the participant was removed prior to analysis being performed. No indication of the effect suctioning had on the heart rate or SaO_2 were given within the results, nor the length of time to recovery post suctioning. SaO_2 was discussed within the study and used as a tool to support weaning of supplemental oxygen or fraction of inspired oxygen (FiO_2), though no data were seen in relation to this parameter.

Kerem, Yatsiv, and Goitein (1990) studied optimal methods to reduce hypoxia, seen as low SaO_2, and hypercarbia resulting from suctioning. They observed that parameters, such as SaO_2, PaO_2 and FiO_2, monitored in relation to ETT suctioning, returned to normal within five minutes after suctioning. This randomised case control study, with the participant acting as their own control, sought to determine the best method to reduce hypoxia associated with ETT suction. A total of 25 infants and children, from 1 day old to 10 years old, were studied. The control was defined as having no intervention, just the suctioning episode, the other methods included preoxygenation at 100%, or hyperinflation pre or post suctioning, with arterial blood gases taken prior, post and at 5 and 10 minutes post. All participants received each of the four methods. However, some may have been missed as only 97 episodes out of a possible 100 episodes, were performed, though no reason was given for this. Results demonstrated that preoxygenation was the best method to prevent hypoxia, and that hyperinflation post suctioning aided in recovery.

The sequence in which the participants received the four methods of hypoxia prevention being investigated was randomised. The suctioning was performed concurrently with only 30 minutes between each method to allow the participant to recover. Suctioning of this frequency could lead to increased stress in these participants, due to increased handling or anxiety and may have affected the results. However, the researchers felt that this would be reflected in the pre arterial blood gas results and any likely changes over the subsequent methods would be accounted for.

Preoxygenation with 100% oxygen, though done with these participants, would not be advised in premature infants due to the risk of oxidative damage (Sola et al., 2007; Sola et al., 2008). There is also the point that the rapid return to base line observations, of 5 minutes, may have been augmented as a result of the administration of 100% oxygen.

Although there was discussion of return to baseline observation levels, there was no mention of any improvement in condition post suctioning. Three other studies reviewed mention inspired oxygen, though none discussed any changes in oxygen requirement post suctioning (Durand et al., 1989; Kaiser et al., 2008; Morrow et al., 2006). Morrow et al. (2006) remarked on the time it took to return inspired oxygen to pre suction levels, without any reference to any reduction in requirement. Desaturations and thus the requirement of supplemental oxygen, has already been identified as a prerequisite for suctioning (Hayes et al., 1999).

Gilbert (1999) researched the assessment nurses undertook to determine the need to perform ETT suctioning. The study used mixed methods, observational and content analysis to determine the rationale for suctioning. The observational study involved 12 nurses, within four different paediatric intensive care units, performing suctioning on 12 children, till they were extubated. The findings demonstrated that clinical changes, such as coughing, secretions, behaviour of the child and changes in monitored signs, prompted nurses to suction. These results are similar to those of Hayes et al. (1999).

Not all children suctioned within the study were sedated and no indication was given as to how long the children were intubated for or their ages; all of which may have impacted on response, behaviour and secretion production. Staff were approached to participate within the study, which may lead to selection bias. There were no clear guidelines for staff selection and results will only reflect the practice of nurses who participated within the study. In addition, observer bias and information bias may have resulted, as the participants were aware that they were being observed during the procedure. The study was also limited to 4 days, with observation only occurring between 8am and 4pm. This would not be reflective of care and techniques over a 24 hour period and would have captured only a small window of the infants' and staff daily routine and practices. Again, there has been no mention of staff experience and frequency.

Kerr, Menzel, and Rudy (1991) commented in their study that suctioning practices were inconsistent. Kerr et al. (1991) looked at suctioning practices within a paediatric intensive care unit, on 24 ventilated children. Review of the study was limited, as only an abstract was available and gave a window into suction practices at that point in time. As with most of the articles retrieved, the study focus for Kerr et al. (1991) was ETT suctioning and the results for frequency of suctioning were inconclusive.

Frequency of suctioning

Wilson, Hughes, Rennie, and Morley (1991) and Cordero et al. (2001) both concluded that extended frequency of suctioning had no detrimental effect on the infants involved. In fact, Cordero et al. (2001) found in their sequential retrospective study, a protective effect, in that there was less colonisation of the lungs by bacteria. There is no mention of colonisation in Wilson et al.'s (1991) study, as the participants were only studied for the first 3 days of ventilation and infants with respiratory sequelae were excluded. There was also no mention of the experience of staff and results were not reflective of the population of premature infants, as only the more stable infants were studied. However, the results are now superseded by those of Cordero et al. (2001) as their research process appears more robust, with more detailed information given. All infants were included, regardless of respiratory sequelae, being more representative of the population, and the whole period of ventilation was analysed, not just the first three days.

Cordero et al. (2001) found that ETT suctioning could be extended to 8 hourly in premature infants with no significant difference in outcome. The study involved a convenience sample of 180 infants, 90 of which were admitted prior to a change in suctioning practice, from 4 hourly to 8 hourly suctioning, and 90 after the change. There was no significance difference found between the two groups. However, there was no mention of staff experience or skill mix over this time frame. There was also mention that another study, on open versus closed suctioning technique (Cordero, Sananes, & Ayers, 2000), being performed at the same time as the second group of participants were being studied and it is unclear if the second group participated in this study at the same time. Nevertheless, no significant difference was found to affect the primary research study. Although all these infants were ventilated there was no indication of any respiratory support post-extubation or of discharge on home oxygen therapy.

Throughout the study BPD was discussed, yet there was no data to determine differences between the two regimes, even though there was mention of no increase in severity of BPD between the two. Although SaO_2 was discussed with the management of FiO_2, there was no mention or recording of data around oxygen requirement or other parameters, such as heart rate or $SaO_{2,}$ as discussed within some of the other studies.

Intracranial pressure related to suctioning

The majority of the research examined focused on intracranial pressure and risk of intraventricular haemorrhage (IVH). Durand et al. (1989), Fanconi and Duc (1987), Kaiser et al. (2008) and Singh et al. (1991) all studied the effect suctioning had on intracranial pressure (ICP). The studies were on intubated patients with three involving extremely low birth weight infants and one with older infants with a mean age of 6.5 months. All four studies identified an increase in intracranial pressure, which they identified led to an increase in incidence of IVH; although, none of the studies demonstrated this in the population being observed. Linder et al. (2003) in a retrospective study examining the risk factors for IVH, found that there was a reduced risk of IVH in the first 24 hours, in infants who had received more frequent suctioning, when compared to less frequent suctioning. These findings contradicted the belief that suctioning increases the risk of IVH. The first 24 hours are seen as the time when extremely low birth weight infants are at risk of IVH, with more than half of IVH occurring during this period (Linder et al., 2003). Despite this fact, suctioning was not identified as a risk factor in the study by Linder et al. (2003) and therefore should not be touted as a risk factor for IVH. However, other factors were seen as the main contributors to IVH: high FiO_2, pneumothorax, in vitro fertilisation and sepsis.

Durand et al. (1989) focussed on intracranial pressure and cardiopulmonary changes on 15 ventilated infants ≤1500grm and ≤30days old. Closed suction circuits were used for suctioning. Monitoring of heart rate, arterial BP, transcutaneous oxygen and carbon dioxide levels ($TcPO_2$ and $TcPCO_2$), ICP, and cerebral perfusion pressure (calculated by taking the ICP away from the mean arterial pressure) were recorded prior, during and at one minute intervals post suctioning for five minutes. Varying suction pressures were employed for suctioning with no mention of suction catheter to ETT size ratio. Results showed a lowering of heart rate with an increase in BP and ICP, which led to an increase in cerebral perfusion pressure (CPP), and a possibility of IVH.

Numbers in this study were low and there was no breakdown of the infants' gestation or age at enrolment to the study, all of which could have had an effect on their response to the procedure. Durand et al. (1989) discussed the possibility of increased ICP due to tracheal stimulation and the increased intrathoracic pressure impeding venous return. If this were the case, it would be interesting to note if the risk of increased ICP was the same for infants on CPAP with the suction catheter only being placed into the nasalpharynx or just into the mouth.

Fanconi and Duc (1987) undertook a prospective crossover study observing CPP with 28 intubated infants 28-36 weeks gestation, and found the converse to Durand et al.'s (1989) work. Infants' ETTs were suctioned three times without muscle paralysis and three times with muscle paralysis, with suctioning being performed hourly. Each infant received regular sedation during the study. Parameters measured were heart rate, BP, $TcPO_2$ and $TcPCO_2$, ICP and CPP, at least once to three times each day till extubated. The results showed an increase in ICP and reduction in cerebral perfusion pressure, though with paralysis the increase in ICP was lessened with a flow on effect to the cerebral perfusion pressure. No significant change was noted in heart rate or BP. However, there was a significant drop in $TcPO_2$, which was adjusted for by increasing the inspired oxygen, with no significant change in $TcPCO_2$. Some infants did not have ICP measured due to the smaller size of their fontanel. No numbers have been given to account for these infants, with no identification of the gestation either. If the infants who received no ICP measurements were the more premature infants, who are more prone to IVH due to their fragile vasculature, the results may not be reflective for the population and may have skewed the results.

Fanconi and Duc (1987) suctioned infants in their trial hourly. Not many NNUs practice suctioning this frequently now, with the tendency to only suction as required (Kaiser et al., 2008). Although the practices in Fanconi and Duc's (1987) study may not be reflective of current evidence for ETT suctioning, the results may have relevance to practices within the study NNU, because of the greater frequency of suctioning performed.

Kaiser et al. (2008) presented the results of an observational study, examining the effects of clinically indicated suctioning on cerebral haemodynamics on 73 ventilated infants from 25-29 weeks gestation, with normal head ultrasound scans. Parameters monitored were: BP, partial pressure of oxygen and carbon dioxide in arterial blood (PaO_2 and $PaCO_2$), and cerebral blood flow. These parameters were monitored 15 minutes prior to and 45 minutes post suctioning, for the first week of life. Results indicated an increase in cerebral blood flow of 31% and that the flow remained elevated for 25 minutes post suctioning. The number of participants recruited for the study was more than some of the other studies, though only 202 episodes of suctioning were recorded, due to the unit policy of suctioning only when clinically indicated.

More frequent suctioning was felt to increase the risk of IVH, though this was not demonstrated within their findings. No reference to the number of times the suction catheter was passed and quantity of secretions is mentioned. If infants were left there could have been the risk that the infants' airway would occlude due to the build-up of secretions and that this could have had an effect on the results; although pre and post suctioning monitoring should account for this. No comment was made in this study about any significance of changes in BP, yet a statement was made that increases in BP may increase cerebral blood flow in infants with reduced ability to cerebrally autoregulate. Kaiser et al. (2008) felt that all the infants within the study could autoregulate and that was reflected in the reduced risk of IVH. This was identified in the discussion as being no relationship between cerebral blood flow and mean BP, though not distinguished for the group studied within the results.

Reducing the effect of suctioning for premature infants

Throughout the studies reviewed so far there has been no mention of the nursing support for the participants involved. As previously mentioned premature infants are fragile, and handling and procedures can result in deterioration due to stress. Suctioning has been found to be a complex procedure (Clifton-Koeppel, 2006), that can cause pain and stress to premature infants (Kondoh, 2004; Ward-Larson et al., 2004). Nonetheless, suctioning is a vital procedure to ensure optimal ventilation when the infant demonstrates the need for suctioning with audible sounds, visible secretions, and changes in oxygen saturations seen as indications. Ward-Larson et al. (2004) looked at reducing the stress effect that suctioning can elicit by using facilitated tucking (wrapping the infant) to calm the infant. A total of 40 intubated infants, 23-32 weeks gestation, were studied in this randomised crossover study, each infant was suctioned with and without facilitated tucking, within a 12 hour period, with 2-4 hours between episodes. The results confirmed that facilitated tucking was effective in significantly reducing the pain and stress associated with endotracheal suctioning.

Three tools were described to measure stress and pain, yet only one was presented in the study, no other was discussed and no explanation given. Although heart rate and SaO_2 were monitored, these results were not discussed either. The infants' responses within these parameters would have been interesting to compare with other studies. The infants were only observed for 30 seconds post suction, which appears short, compared to results from other studies (Fanconi & Duc, 1987; Kerem et al., 1990; Singh et al., 1991).

Overall, there was no breakdown in the studies involving premature infants, of the gestation or outcomes for these infants. Information was only presented that reflected the main outcome of each particular study and it was difficult to compare the findings with other comparative studies, due to lack of gestational age breakdown. The majority of studies were performed on infants with ETT. Suctioning in a large main airway, as with ETT suctioning, may have more sequelae than oro or nasopharyngeal suctioning.

In all, it has proved difficult to find research pertaining to the effect suctioning and frequency of suctioning has on premature infants requiring CPAP and non-intubated premature infants. The literature to date tends to focus on endotracheal suctioning, which is dramatically different to that of nasopharyngeal suctioning. Little of the literature discussed non-pharmacological analgesia for this stressful and painful procedure or any improvement in respiratory status or supplemental oxygen requirement post suctioning. There needs to be further research performed to determine the effect suctioning and frequency have on premature infants requiring CPAP and supplemental oxygen requirement, to establish whether suctioning is beneficial without causing any adverse outcomes.

Conclusion

This chapter has discussed the rationale for the research and a literature review was presented, demonstrating the lack of empirical evidence to support current practises of less frequent suctioning of infants, who are breathing spontaneously with CPAP as respiratory support. The need for research pertaining to the specific needs of this group is highlighted throughout the review, due to the vastly different modalities of ventilation and differences between premature infants and paediatric patients. The evidence used for practice needs to reflect the population it is intended for. The following chapter will outline the research methodology and methods that underpin this study and were utilised to elicit some evidence.

Chapter Three

Research Design

Introduction

The previous chapter outlined the problems associated with premature infants' lungs, and the benefits and controversies surrounding respiratory support and suctioning of these fragile infants. The literature review demonstrated the lack of empirical research or evidence to support best practice in the suctioning of infants on CPAP and the need for research to support this. This chapter presents the methodology and methods underpinning this research.

Research Process

In planning research, identifying, discussing and analysing the limitations and strengths of various research designs and methods aid in determining the best option to answer the research question posed (Peat, Mellis, Williams, & Xuan, 2002). In addition, the underlying theoretical assumptions that are implicit to a research methodology and methods are important to understand, as they justify the process involved (Crotty, 1998). The approach taken in this study was decided after consultation with the medical and senior nursing team, of a level three metropolitan NNU in New Zealand, an overseas neonatal nurse specialist and a biostatistician. The outcome desired was to ensure the most ethical and appropriate way of determining the effect of suctioning and frequency of suctioning had on oxygen requirement and desaturations in premature infants on CPAP.

Formations of the methods used for a research project are reliant on the methodology, which in turn informs the theoretical perspective, having primarily been derived from the epistemological stance (Crotty, 1998). Epistemology is the theory of knowledge, and is rooted within the theoretical perspective, the philosophical stance or assumptions, which provides the background for the methodology and thus the methods to be used in the research (Crotty, 1998). Quantitative research methods were chosen to best understand the topic under investigation.

Quantitative research is a positivist approach to research, used to produce results that will generate the most compelling evidence to answer a research question (Creswell, 2009; Polit & Beck, 2008). Positivism is the theoretical perspective of objectivism, with the assumption that there is the ability to gain meaning and truth that is precise and reliable (Crotty, 1998). Positivism is said to have originated from Comte, who saw scientific meaning as encompassing more than just fact and that it could not be viewed in isolation (Crotty, 1998). Within quantitative research, objectivism is the epistemological stance, in that objects subsist separately to experience and perception (Crotty, 1998): objectivism is the epistemological position underpinning this study. The gold standard of research is viewed by many to be the randomised controlled trial (RCT) and is quantitative and experimental in nature (Sandelowski, 2000; Yang et al., 2010). Therefore, an observational study and a randomised cross-over pilot study, were employed as it was felt that these methods best supported researching the effect of suctioning on premature infants on CPAP and the impact frequency had on oxygen requirement, bradycardias and desaturations utilising quantitative research.

Research Question

What is the effect of suctioning and suctioning frequency on oxygenation and bradycardias in infants ≤30 weeks gestation requiring bubble Continuous Positive Airway Pressure (CPAP).

Aim

To determine the effect nasopharyngeal and oral suctioning has on infants ≤30weeks gestation requiring CPAP and if frequency plays a role in reducing supplemental oxygen requirement, desaturations and bradycardic events.

Methodology

A two part approach was chosen to best answer the research question, as no research was found on suctioning specific to this population of premature infants requiring CPAP. Firstly, an understanding of the effect of suctioning was required to demonstrate the impact of suctioning on this population, prior to performing a secondary research study on the impact of frequency of suctioning. The first part, an observational descriptive study looked at the effect suctioning had on infants ≤30 weeks gestation on CPAP. The second part, a randomised cross-over method, determined what impact the frequency of suctioning had on oxygen requirement, desaturations and bradycardias on infants ≤30 weeks gestation on CPAP with a supplemental oxygen requirement.

Part One: Observational study

A descriptive observational study was utilised to look at the effect naso and oropharyngeal suctioning had on oxygen requirement desaturations and bradycardias, with infants ≤30weeks gestation requiring CPAP at 2 weeks of age. As no previous studies had been found on the study topic, an understanding of the effects was sought. Observational research is non-experimental, and analytical or descriptive in nature. Observational research is described as supporting practice, by providing evidence for susceptible populations, as no intervention is required, and therefore is considered a valuable resource of significant information and often termed as “real-world” studies (Dreyer et al, 2010a; Fleurence, Naci, & Jansen, 2010; Yang et al, 2010).

The use of observational studies is said to have originated from epidemiology, which was first described in the 17th century (Fos. 2011). Epidemiological research assists in the prevention and control of injury, disease and supports public policy (Merrill, 2010). An observational research design is used to determine if there is a relationship linking a risk factor to a disease and can be used to “evaluate preventative therapeutic and intervention activities” (Fos, 2011, p.29). The descriptive study type used in the present research was a case series study. This method describes and reviews clinical features, disease prognoses and progression within a small group and is a form of non-experimental research (Merrill, 2010).

Non-experimental research can be seen as less valid than experimental research due to the inability to show causality (Cook & Cook, 2008; Thompson, Diamond, McWilliam, Snyder, & Snyder, 2005). This is true even when results show a statistically significant relationship (Fitzgerald, Rumrill, & Schenker, 2004). Bias and confounding variables may lead to inaccurate results, which can be resolved by randomisation in controlled trials (Dreyer et al., 2010b; Fleurence et al., 2010; Yang et al., 2010). However, within non-experimental research, inaccurate results can be reduced by close attention to the design and the analysis of data, identifying the confounding variables and accounting for them in analysis (Dreyer et al., 2010b; Yang et al., 2010). The reduction of confounding variables can be achieved by using multivariable adjustment (Wunsch, Linde-Zwirble, & Angus, 2006).

Observational studies are useful where it may be unethical to perform a RCT and can provide larger numbers of participants to study (Yang et al., 2010). Another reason for using the observational method of study is when there is little known about a specific phenomenon to allow an RCT to be performed (Meiniger, 2012). Hence, an observational research method was seen as an appropriate, non-interventional process to determine the effect of suctioning in this population.

Part Two: Randomised cross-over pilot study

Randomised Crossover study (RCS) design was utilised to look at the effect that frequency of suctioning had on oxygen requirement, desaturations and bradycardias, with infants' ≤30weeks gestation requiring CPAP, at 2 weeks of age with a supplemental oxygen requirement. Cross-over research is an experimental research method and can be used to study the effect or variances between differing treatments with one subject (Senn, 2002). However, RCT is the most powerful instrument in research (Stolberg, Norman, & Trop, 2004). With high internal validity RCTs can demonstrate that the treatment given elicits a change in the patient and is not related to other factors, with randomisation minimising the differences between groups (Fleurence et al., 2010). The first RCT in neonates was performed in the 1950's (Robertson, 2003). However, RCTs require larger numbers of participants, at times, to show a small effect (Stolberg et al., 2004). This poses a problem when studying premature infants, due to the small population size.

A cross-over design requires fewer participants compared to other forms of interventional studies and subjects are exposed to both interventions, thus allowing the research of two differing treatments on one subject (Everett & Palmer, 2011; Senn, 2002). Two-treatment/two-crossover designs are viewed as the best form of cross-over design to limit the carry-over from the previous intervention (Senn, 2002). Hence, a cross-over design has been chosen to determine the effects suctioning frequency has on supplemental oxygen, desaturations and bradycardias on infants, due to the small population being studied and the timeframe for study. Although the two-treatment design was utilised, only one cross-over period was performed, as this was felt to be sufficient to demonstrate a difference within the study sample.

Carry-over effects are described as outcomes from the previous intervention or study period, which may distort or influence the results of the second intervention, lingering into the second period or intervention, affecting the outcome or results of the study

(Senn, 2002). Washout periods were used to diminish this effect; within this study, a day was placed between each intervention to try to mitigate any risk of carry-over effect. Each intervention may have a different effect on the infant. Improvement of airway management, through more frequent suctioning, could lead to the reduction in oxygen requirement, desaturations, and bradycardias. Whereas less frequent suctioning may lead to a reduction in exposure to the stress of suctioning and handling for the infants; reducing the likelihood of a stress response. Randomisation was used to minimise any cross-over effect in the study, with the infants receiving either 2 hourly or 4 hourly suctioning first.

Although RCT studies are seen as the gold standard and aid in assessing entrenched practices to provide evidence based care, not all research questions can be answered using the RCT method (Dreyer et al., 2010a; Dreyer et al., 2010b). An aspect of this would be that findings from a study may not be generalised amongst a wider population, due to inclusion and exclusion criteria being stringent, and vulnerable populations not included (Yang et al., 2010). This was demonstrated in the study by Wilson et al. (1991) who studied only stable infants. This issue may be overcome with the use of comparative effectiveness research, where RCT is combined with observational research. The observational research compliments the draw backs of RCT and validates the outcomes of both methods of research, one with the other, thus providing generalisability of research findings amongst the wider population (Dreyer et al., 2010b; Fleurence et al., 2010; Yang et al., 2010). Utilising the findings from one method to provide further research answers in the other, giving more clarity and efficacy around the topic being researched, and providing a more concise outcome.

Study Population

The study population of infants ≤30 weeks, was determined due to their need for respiratory support and to reflect the study populations used in the studies reviewed of premature infants requiring ETT suctioning. The age in days of the study population was determined from the research undertaken by Laughon et al. (2009), which discussed the progression of respiratory disease in premature infants. Laughon et al. (2009) identified respiratory deterioration and increased necessity of supplemental oxygen with extremely low birth weight (premature) infants during the second week of life, with the risk of 50% developing BPD. This population, as previously discussed, are also at higher risk of BPD, due to requiring respiratory support and oxygen.

Part One: Observational study

Convenience sampling was utilised, with all infants ≤30 weeks gestation born between 1st September and 30th November 2011, then between 1st July and 30th November 2012 and admitted to the study NNU, requiring CPAP at 14 days old, were recruited. The second period was utilised due to small numbers of infants recruited during the first period, after seeking an extension from the ethics committee. Participants recruited within the second period comprised of infants who did not meet the criteria for Part Two of the research study, as set out below, or where parents did not consent for Part Two of the study or the infants were deemed unstable to participate in Part Two of the study by the medical team. Parents' permission was sought to include their infant in the study. Infants were excluded from the study if they required intubation during the study period, or had a congenital abnormality (excluding PDA), or required surgical treatment.

Part Two: Randomised cross-over pilot study

Convenience sampling was utilised. To ensure enough infants were recruited to demonstrate significance, the sample size was adapted from data obtained from Part One of the study. Any infants ≤30 weeks gestation, born between 1st January 2012 and 30th November 2012 and admitted to the NNU, requiring CPAP at 14 days old and supplemental oxygen requirement, with parental consent to participate in this part of the study, were recruited. The study period had been extended, after approval from the ethics committee, to increase the timeframe and include infants on air, for the purpose of increasing numbers of participants. However, infants on air were recruited to Part One, due to low numbers. Infants were randomised using a block of four, a simple method of randomisation when two treatments methods are being studied, where the two regimes are alternated in a sequence for infants as they are recruited to the study (Everett & Palmer, 2011). There are six sequences available, however, only four blocks were utilised, as numbers of participants were uncertain during the planning of the research. Randomisation was stratified by gender, to start either 2 hourly or 4 hourly suctioning (see Table 1 and 2). These two regimes were selected as they were within the parameters of the suctioning routine of the study NNU. The researcher felt that due to anecdotal evidence and experience that it could also be unethical to extend the suctioning frequency beyond current unit practice for the study.

Table 1
Randomisation Table Part Two-Female

Intervention	Frequency	Percent	Cumulative Frequency	Cumulative Percent
ABAB	2	25	2	25
ABBA	2	25	4	50
BABA	2	25	6	75
BBAA	2	25	8	100

Note. A=2 hourly, B=4 hourly

Table 2
Randomisation Table Part Two-Male

Intervention	Frequency	Percent	Cumulative Frequency	Cumulative Percent
AABB	2	25	2	25
ABBA	1	12.5	3	37.5
BAAB	2	25	5	62.5
BABA	1	12.5	6	75
BBAA	2	25	8	100

Note. A=2 hourly, B=4 hourly

The cross over to the new regime of suctioning frequency occurred after 4 days, with one extra day provided in the new regime, to prevent any residual effects of previous regime (washout day), affecting the last 4 days of suctioning in the new regime. A total of 9 days of data were collected for each infant in the study, with data only being utilised from the first 4 days and last 4 days of study period. Infants were excluded if they had more than three apnoeas and bradycardia with major prolonged desaturations ≤60% within an hour, required resuscitation, the presence of sepsis, were hypovolaemic, had substantial changes in health, or if there were lots of interruptions i.e.: increased handling or frequency of suctioning. Research has found that most premature infants at 2-4 weeks of age, have on average approximately three desaturations <80% for >10 seconds per hour, hence the number of "above three" has been used, as this will be more than would be expected (Di Fiore et al., 2010).

Data Collection

Part One: Observational study

The main outcomes that were identified for the study were; percentage of time in target saturation zone (88-92%), amount of daily supplementary oxygen and the hourly desaturation frequency. The demographic and clinical factors that could be associated with the outcomes were; the daily frequency of suctioning, percentage of time in target saturation zone for gestation (88-92%) and bradycardias, relationship between FiO_2, percentage of time outside target saturation zone (88-92%), gender, gestation, ethnicity, and weight.

Other data that were recorded, as they may influence the requirement for respiratory support, included antenatal steroids-whether a full course or not, signs of amnionitis, apgars, patent ductus arteriosus (PDA) - with treatment, intraventicular haemorrhage (IVH) – with grade, caffeine given, doxapram use, time to full oral feeds, days on CPAP, CPAP pressure, other modes of respiratory support, intubation, hours on supplemental oxygen, fraction of inspired oxygen on those days, haemoglobin-initial and subsequent results, blood transfusion, delayed cord clamping/cord milking, length of stay in NNU, grade of ROP, necrotising entercolitis, sucrose during data collection, procedures performed, during study period, nasal trauma scores, signs of respiratory illness, skin to skin interaction with parents and frequency of suction throughout study period. The rationales for these variables are discussed later within this chapter.

Data one hour prior to suctioning, the lowest recordings during suctioning and then the time taken to return to the presuction baseline were noted, with the number of bradycardias and desaturations each 4 hour period and between suctioning episodes. Percentage of time in target saturation zones, as previously mentioned, the amount of daily supplementary oxygen and hourly desaturation frequency were identified as areas to be analysed within the study.

Part Two: Randomised cross-over pilot study

All data that were identified within Part One of the study were recorded; Percentage of time in target saturation zone, amount of daily supplementary oxygen and hourly desaturation frequency. Secondary outcomes for the following analysed; length of time requiring supplemental oxygen, numbers of bradycardias and desaturations each 4 hour period and between suctioning in relation to frequency of suctioning. The mean for FiO_2 was used with standard deviations for the time frame of the data being analysed. Data from “washout” day between the two frequency regimes was not analysed.

Data Recorded

Data were recorded and downloaded from Masimo Radical and Radical 7 saturation monitors (Masimo Corp., Irvine, CA) for heart rate, desaturations and percentage of time in target saturation zone for gestation (88-92%). Both of these saturation monitors are routinely used within neonatal care and are recognised as being accurate (Baquero, Alviz, Castillo, Neira, & Sola, 2011; Hay et al., 2002). CPAP pressure and FiO_2 was recorded and downloaded from Fisher & Paykel Data loggers prototypes (Fisher &

Paykel Healthcare Limited, Auckland, New Zealand). Staff caring for the infants were asked to push the “mark event” button on Philips Intellivue MP70 monitors (Philips Healthcare, Andover, MA) to establish the starting time of each suctioning episode. Data on observation sheets about parent interaction, handling and procedures performed were also recorded.

Statistical Analysis

In the management of data, software programmes were utilised to aid in the analysis. SAS version 2.15.2, R version 2.15.2 and WinBUGS version 14 were used. SAS is a recognised statistical programme for organising and analysing data, as is WinBUGS, which works from a windows platform, utilising Markov chain Monte Carlo (MCMC) methods on statistical problems to determine Bayesian inference (Lesaffre & Lawson, 2012). R is a free online statistical analysis programme (Everitt & Hothorn, 2006).

The continuous measures including; the percentage of time in oxygen saturation target zone, percentage of time requiring supplementary oxygen, percentage of supplemental oxygen, heart rate, CPAP pressure and oxygen saturation were summarised using the mean for every suctioning interval, each day, during the study period for each infant. The categorical measures, including episodes of desaturation and bradycardia, were summarised by the hourly frequencies in the suctioning intervals. Each day there were multiple records of the summary outcomes, for each infant, corresponding to the suctioning intervals. The summary data for the suctioning intervals were then summarised across each day of the study, for each infant. The distribution of these summary outcome variables were presented by box-plots. An overall summary was provided for each outcome for all the infants across the different days.

The demographics for all the infants included in the study were presented as either mean with standard deviation, median with interquartile range for continuous variables, or count (frequency) for categorical variables. The descriptive summary was also provided for the infants in Part One and Part Two separately. Associations between the frequency of suctioning/demographics/clinical characteristics and primary outcomes were assessed by linear regression model or generalised linear regression models. Linear regression models were used to analyse the relationship between the independent and dependent variable (Liu & Salvendy, 2009).

The linear correlations between the continuous variable (weight, gestational age, hours of CPAP, hours of ventilation, haemoglobin) were presented using Pearson correlational coefficients (Pearson's *r*). Pearson correlational coefficients is a statistical method to gauge the strength of the relationship between two continuous variables that have a linear association (Peat, Barton, & Elliott, 2008), demonstrating that as one variable changes, so does the other variable. When the variables were skewed Spearman's rank-order correlation coefficients (Spearman's rho or *r*) were utilised. Spearman's rho is a correlation coefficient that is non-parametric and is a recognised statistical method that replaces Pearson's *r* when variables stray outside normal parameters (Peat et al., 2008).

The inferential analysis used mixed effect linear regression models to investigate the effect of suctioning frequency and the effect of the other confounding variables on the average amount of supplementary oxygen and their effect on the percentage of time in the oxygen saturation target zone. The co-existing confounders included in the study were; gender, gestational age (weeks), weight (g), antenatal steroids administration and if completed course of antenatal steroid and prolonged rupture of membranes (PROM). Each confounding effect was analysed separately in a simple mixed regression, where random intercept were estimated for each infant and confounders were included as fixed effects. A full mixed effect model, including all identified confounders were also performed to assess the effect of suctioning frequency with the presentation of all other cofounders. Mixed effect models are utilised to understand within the data the effect within-individual correlation and between-individual correlation has and to gauge the effectiveness of treatment (Wu, 2010).

For the outcomes of desaturation and bradycardia episodes, a type mixed effect regressions were utilised under the Bayesian framework. The response variables (hourly desaturations ≥10seconds and ≥60 seconds and hourly bradycardias) had a distribution with spiky zero and long right hand tail. Any standard distribution had not been found to fit the model properly. The Bayesian mixed effect regression model was constructed using a combination of logistical regression for the zero values and a normal linear regression for the non-zero value. The joint posterior distribution of unknown regression parameters were generated via Gibbs sampling. Gibbs sampling was used to the estimate what the posterior distributions are likely to be for the Bayesian method (Suess & Trumbo, 2010). The 95% credible intervals were provided for these regression parameters.

The Bayesian method is an empirical method of data analysis with no assumptions on the posterior distribution of the estimates and is easily implemented for a mixed pattern such as this research (Woodward, 2012). The Bayesian mixed effect regression model is constructed using a combination of logistic regression for the zero values, and a normal linear regression for the non-zero value. The method is based on probability, using MCMC method to derive the estimates for all unknown parameters in the risk model (Woodward, 2012). Winbugs is an established software that enables the implementation of the posterior Gibb sampling to derive the estimates (Lesaffre & Lawson, 2012). The p-value was not used in the Bayesian method and credible intervals are used instead of confidence interval, with the 95% credible intervals being broader than 95% confidence interval (Woodward, 2012). Within analysis, significance was interpreted if the interval contained zero. The reason this method was utilised for the hourly desaturations and bradycardias within this research study, was that these parameters did not have a distribution that could be described to count variables.

Mean with 95% confidence interval, was used to summarise the difference in daily amount of supplementary oxygen (DASO) between two types of interventions. A paired sample t-test was used to assess the difference in DASO between two interventions for the cross-over design. Repeat measure analysis of variance was used to compare the difference in DASO with treatment regime order and baseline variables used as a covariate. The paired sample t-test is a recognised test procedure to analyse data that focuses on the mean and repeat measure analysis is a way of showing inference from the data (Huck, 2012).

To determine the number of participants required in part two of the study and detect a difference of 5% in mean oxygen saturation between the two regimes, a paired *t* test power calculation was performed. This is a recognised method of determining sample size in relation to a statistical power to demonstrate significance (Kelly, Lai, & Wu, 2008). The calculation involved parameters that would demonstrate a statistical power of 85% at a significant level of 0.05.

Reliability and Validity

Reliability and validity within research are seen as crucial to support the information gathered. Reliability relates to the "…accuracy and consistency of the information obtained in a study" (Polit & Beck, 2008, p.196). Therefore, for the information within the study to be reliable, the tools used to measure and collect the information and the documentation of data, need to be consistent. The Massimo saturation monitor is widely used within neonatal care and has been found to be a reliable tool to measure saturation and heart rate in infants (Baquero et al., 2011; Hay et al., 2002). The Fisher & Paykel Data loggers are a prototype monitor, only used for research purposes and have been tested and used for research within the study NNU prior to this study and have been found to be reliable (Bushell, McHugh, & Meyer, 2013).

Data collection issues arise from the consistency and quality of the process and recording of activities (Fitzgerald et al., 2004). Ensuring no bias occurs in the collection and interpretation of the data will reduce this. The researcher meticulously collected all data, striving to maintain consistency and accuracy of the information gathered. However, as with any form of manual recording, error can occur, not only from the researcher, but also from the staff caring for the infants, not recording data accurately, all of which can lead to incomplete data and may have an affect the results of the study.

The results of a study may also be affected by validity, which refers to the robustness of the measurements used to assess the evidence gathered, i.e. the variables (Polit & Beck, 2008). Validity can be identified as internal and external (Creswell, 2009). Internal threats to validity pertain to anything that may affect the data obtained from the population being studied and results drawn from the data (Creswell, 2009). Within the present study threats to internal validity were identified as; maturation and selection. Maturation due to the passage of time, will be evident in the growth of the infants, with possible changes in the condition of the infant over time and any predisposing characteristics that could affect the results or their response to suctioning, such as lung and respiratory centre maturation leading to a lesser need for respiratory support and suctioning. Selection was limited within Part One during the second period of recruitment. This may have altered the outcome, as some of the infants were recruited to Part Two of the study, if they met criteria and consent was given, during this period. Thus, those recruited to Part One during this second period were possible more stable than those recruited during the initial period, as they did not have an oxygen requirement.

External validity occurs when results from a study are generalised inappropriately (Creswell, 2009). Due to the varied and complex nature of the population being studied and the unique setting of the NNU, the results from this study may not be generalisable to other NNUs and further research would need to be performed to support any findings.

Polit and Beck (2008) discuss that threats to external validity are improved by ensuring all significant differences and threats are eliminated during the initial design of the study.

Internal validity is described as the degree to which the study is managed to demonstrate the effect on dependent variables from the independent variable (Berg & Latin, 2004). Aspects of internal validity, within the present study, are counteracted by the nature of the cross-over design of Part Two of the study. Cross-over design is an effective method that can strengthen validity by controlling for extraneous variables (Polit & Beck, 2008).

Variables

Variables are basic elements, parameters or characteristics that may vary within the group being studied and can have an impact on the outcome of a study (Polit & Beck, 2008). The data collected for this study were selected due to the impact these variables have on the respiratory support required. The impact of each of these confounding variables have on the present study are discussed individually to highlight the rationale for inclusion. Confounding variables are elements that can contaminate or influence the research results and need to be controlled (Polit & Beck, 2008). Due to the small sample size for the research, this was not possible. However, within Part Two of the research study the effect of the cross-over study design lessened the effect of these variables.

Part Two of the study looked at the effect that frequency of suction had on oxygen requirement, desaturation and bradycardias. Suctioning frequency is the independent variable with oxygen requirement, desaturations and bradycardia as the dependent variable. The relationship of these variables being that there is an inferred relationship between the two (Polit & Beck, 2008). The confounding variables, may cause a problem in that they may account for some of the effect on results (Bordens & Abbott, 2005). This can be vindicated during analysis of the relative relationship between the variables.

Gender

Gender was noted due to the impact on the need for respiratory support. It has long been established that female infants are less likely to suffer from respiratory morbidity within the neonatal period, compared to male infants (Ambalavanan et al., 2008). Deulofeut, Dudell, and Sola (2007) also found gender differences in the incidence of ROP, BPD and length of stay after the introduction of lower acceptable SaO_2 limits (85-93%).

Ethnicity

Ethnicity was collected to see whether there was any difference between the differing ethnicities within the population being studied. However, research to date has found no relationship between ethnicity and prematurity (Petrova, Mehta, Anwar, Hiatt, & Hegyi, 2003) or that ethnicity impacts on the requirement for respiratory support in premature infants (Hessol & Fuentes-Afflick, 2005). Both of the afore mentioned studies originate in the United States of America and may not be representative of the New Zealand population.

Antenatal steroids

Antenatal steroid administration is known to accelerate the maturation of premature lungs and reduce the risk of respiratory distress syndrome and the requirement for respiratory support (Roberts & Dalziel, 2006). The benefits of antenatal steroids are also seen with studies showing that repeated doses decrease the risk of IVH (Linder et al., 2003).

Chorioamnionitis

Been et al. (2009) found that with amnionitis there was an increased risk of respiratory support required, coupled with the increased risk of BPD (Watterberg, Demers, Scott, & Murphy, 1996). Therefore, this variable was recorded.

Mode of delivery

Controversy exists about the impact of mode of delivery, though Ghi et al. (2010) state there is no difference between normal vaginal and caesarean section delivery. However, this aspect was included.

Apgar scores

Apgar scores at one and five minutes were collected, as these are a recognised tool for the establishment of the general condition of the infant at birth (Rubarth, 2012; Sansoucie & Cavaliere, 2007).

Surfactant

Surfactant therapy was noted due to the beneficial effect giving surfactant has on premature, surfactant depleted lungs, with improved outcomes and reduced requirement for respiratory support (Soll, 2009; Soll & Özek, 2010a; Soll & Özek, 2010b).

Days on CPAP

The number of days on CPAP were recorded to determine the length of time on CPAP, to establish differences and as a comparison for further study.

CPAP pressure

CPAP pressure was noted as this varies between infants. Pressure is changed to ensure appropriate respiratory support is given. Pressure ranges from 5-9cm H_2O within the unit, and is within the parameters of accepted practice (Gomella, Cunningham, & Eyal, 2009).

Hours and fraction of inspired supplemental oxygen

As discussed previously over exposure to oxygen can lead to oxidative stress and increase risk of BPD and ROP. Within the study NNU the practice is to pre-oxygenate infants who have major desaturations during suctioning. This is an established practice and has been found in ETT suctioning to be of benefit in reducing the risk of bradycardia and lessen the degree of desaturation (Cabal, Siassi, Blanco, Plajstek, & Hodgman, 1984). The days on oxygen will relate to the outcomes for BPD and with the length of stay; it will help to correlate the results of this study to previous studies.

Haemoglobin levels (Hb) and blood transfusions

Anaemia is a major problem in premature infants due to blood sampling and their inability to initiate red cell production (Premji, 2007). Therefore, the infant has a lessened ability to transport oxygen, with reduced haemoglobin, and this will affect oxygenation. Due to the difference on the oxygen disassociation curve with fetal haemoglobin compared to adult haemoglobin (Craft et al., 2011), any transfusions of adult blood were documented.

Delayed cord clamping/milking

Delayed cord clamping has been shown to improve haemoglobin in premature infants and reduce the need for transfusion (Rabe, Reynolds, & Diaz-Rossello, 2008). Cord milking showing similar results as above (Rabe et al., 2011). Hence, these data were collected.

Caffeine

Caffeine therapy has been used to support premature infants with apnoea associated with prematurity (Bonner & Mainous, 2008), due to an underdeveloped respiratory drive (Bhatt-Mehta & Schumacher, 2003). The effects of caffeine are that it stimulates the respiratory centre, making it more sensitive to carbon dioxide, to encourage breathing and increases alveoli ventilation (Bhatt-Mehta & Schumacher, 2003) reducing the risk of BPD (Schmidt et al., 2006).

Doxapram

Has been used in neonatal care for over 25 years and is a respiratory stimulant that affects chemoreceptors both centrally and peripherally to promote breathing (Alpin, Eyal, & Sagi, as cited in Prins, Pans, van Weissenbruch, Walther, & Simons, 2013).

Time to full oral feeds

Time to full oral feeds will also influence respirations due to the relative closeness of the stomach to the diaphragm and that infants breathe using their diaphragm. A full stomach can place undue stress on the diaphragm and affect respiration (Lefrak & Lund, 2013).

Nasal trauma scores

Nasal trauma scores were noted due to the impact trauma will have in compromising the airway (Squires & Hyndman, 2009). The score also details if secretions are blood stained due to trauma within the nasal passage.

PDA

Data were collected on whether the infant had a PDA, as PDA can lead to pulmonary oedema and the increased need for respiratory support (Van Marter et al., 2000). PDA may also play a role in the pulmonary deterioration noted by Laughon et al. (2009).

IVH

As previously discussed IVH is stated as one of the risks that may arise for premature infants being suctioned. Therefore, IVH was noted with grade, for the impact on the developmental outcomes and on-going problems for infants (Volpe, 2008).

ROP

Oxygen toxicity or oxidative stress, due to hyperoxia, is recognised as a major cause of neonatal morbidity and ROP and as such this outcome was recorded (Sola et al., 2008).

Necrotising enterocolitis (NEC)

Necrotising enterocolitis is a leading cause of death in premature infants with an incidence of 1-7% (Carter, Holditch-Davis, Tanaka, & Schwartz, 2012). Hypoxia leading to the bowel becoming ischaemic and necrotic, with the risk of developing NEC increasing with the requirement of intensive respiratory support (Gregory, 2008). The incidence within the study group has been noted to measure against outcomes in other studies.

Length of stay

The length of stay was collected to aid in the correlation of the results of the study to previous studies describing the effect of the implementation of the CPAP regime (De Klerk & De Klerk, 2001a).

Procedures performed

Handling and procedures elicit a stress response in premature infants leading to increased risk of apnoea, bradycardia and desaturations (Als et al., 1986). Hence, times were noted to distinguish procedures and handling.

Oxygen saturation probe site

Phattraprayoon, Sardesai, Durand, and Ramanathan (2012) found no difference in saturation probe placement. Therefore, even though this data were collected, the data concerning this were not utilised within the analysis.

Ethical Considerations

Ethics are important in research to ensure that vulnerable populations are not abused (Borbasi, Hengstberger-Sims, & Jackson, 2012). Ethical considerations need to be accounted for within any research study and approval sought as there may be unforeseen or perceived risks. What one person deems as acceptable, may be offensive to another’s values or beliefs, or remove the control/power from the participant. Cram (1998) outlines beliefs on a cultural perspective of ethics; respect, face-to-face meeting, participation, communication, informing, collaboration and sharing the knowledge learnt from research. The principles outlined are transferable to all cultures and domains and have been taken into consideration within this research study.

Infants and their parents/caregivers are recognised as a vulnerable group for research (Thomas, 2009). Performing research on a vulnerable population, requires the stance of beneficence, justice, respect and non-maleficence (Borbasi et al.,2012). Nordentoft and Kappel (2011) describe the ethical dilemma of gaining informed consent from vulnerable groups. Within the research, some parents/caregivers were not approached for consent as they were seen as more vulnerable due to increased anxiety. Although there was no perceived need for consent within the observational part of the study, parents/caregivers were given the option of participation and information on the study given. Singhal, Oberle, Burgess, and Huber-Okrainec (2002) identified parents/caregivers wish to be asked for consent, regardless of the type of study being performed and risk involved with the study.

While research that is dealing with data, as in observational research, may not appear to have any ethical issues, there may be elements that the researcher was not aware of that will affect participants ethically. Nurses can be perceived as being in a position of power, and must avoid the risk of appearing paternalistic in their approach (Williams & Sudia-Robinson, 2007). Having a premature infant can be very stressful for parents/caregivers (Zelkowitz, Papageorgiou, Bardin, & Wang, 2009). Hence, consideration needs to be taken when seeking consent for participation within research within NNUs, to ensure that informed consent is given and parents feel comfortable participating in the study.

In Part One of the study, the observational research, there was no change in care, thus no increased risk was perceived for the infants participating in this part of the study.

Parents/caregivers may have been apprehensive about the extra equipment to record data. However, when the information sheet about the research was given to the parents and permission sought, the equipment to be used was discussed and an opportunity for questions to be asked. During Part Two of the study, the randomised cross-over pilot study, the only change in practice was the set time for suctioning and crossing over between frequencies. The exclusion criteria ensured that there would be minimal harm or risk posed to the infants, as mentioned in the study population, earlier in this chapter. Infants that met these criteria were removed from the study and followed the standard procedure for suctioning within the study NNU.

All parents/caregivers were given time to consider the information given and the opportunity to discuss with family/whanau or a cultural support worker. The principal researcher met with each family to discuss the study and if needed, further opportunities to ask questions. Parents/caregivers were also given the option of having the results of the research sent out to them on completion of the study and analysis.

To ensure that all ethical considerations were met and due to performing a randomised study, where routine care is altered, ethical approval was sought from the Upper South B Regional Ethics Committee, with the Māori Research Committee and Research Department for CMDHB and approval was gained from all. The only condition of approval from the Upper South B Regional Ethics Committee was that cultural aspects be taken into consideration, which was completed. As the research was part of a Master’s programme, the Massey University Human Ethics Committee was notified. Further approval was sought to extend the period and alter the inclusion criteria for Part

Two, due to low participant numbers, to include infants on air, thus, allowing more infants to be included in study. However, the inclusion criteria was never altered; due to the need for more participants in Part One of the study, although the period was extended. The Upper South B Regional Ethics Committee gave permission for the extension and review of criteria.

Confidentiality

Confidentiality was ensured by allocating study numbers to each participant, these number were stored in a locked file. The format of which was a number (1 or 2) to denote which part of the study followed by three other numbers to identify the individual infants, commencing with 100 and increasing for each infant in increments of 10. Information was kept on a netbook which was password secured. No identifying information was used. Data were downloaded from the netbook, once research study was completed for analysis and reporting were completed. At the completion of the study data and results were placed on CD for storage purposes.

Cultural Considerations

The inpatient Te Kaahui Ora (Māori Health Unit) were consulted to ensure that issues that the principal researcher may not have seen as ethical or cultural, were addressed. The Māori Research Review Committee reviewed the research protocol and approved the protocol with the provision that parents/caregivers were allowed to self-determine ethnicity of their infant. The Māori Health Unit were also asked to facilitate in the support of whānau within the unit, if required, to ensure there was understanding of the consent form and research. The involvement of Māori in the initial phases of research can be beneficial in that Māori participate and engage in research that may affect their region or iwi (Health Research Council of New Zealand, 2010).

The district within which the study NNU is situated has the highest population of Māori and Pasifika in New Zealand (CMDHB, 2008). As part of the Māori Health Plan (CMDHB, 2006), CMDHB have a commitment to reduce potentially avoidable hospitalisations. According to unpublished figures, 50% of all “unbooked” women delivering within the district health board area, for the NNU within the study, for the year 2007-8, that had no antenatal care, were Māori, with 38% Pasifika (Shingawa, 2008). Studies have shown a greater risk of morbidity or mortality in infants born to women who receive no antenatal care (Herbst, Mercer, Beazley, Meyer, & Carr, 2003; Vintzileos, Ananth, Smulian, Scorza, & Knuppel, 2002). Hence, this group of infants are at more risk of requiring neonatal care and respiratory support. Therefore, infants born to women, with no antenatal care, would benefit from any measures that would reduce the risk of respiratory support.

Approximately one third of infants born at the gestation being studied, were identified as Māori (Wong, 2010). The findings may demonstrate what frequency of suctioning is appropriate for premature infants on CPAP and any associated change in supplemental oxygen, desaturations and bradycardias, which may reduce risk of lung disease and ROP. Infants born prematurely and with BPD are more prone to respiratory illness, compared to their peers (Hennessy et al., 2008). Māori children are 3 times more likely to develop respiratory disease compared to European children (Byrnes & Trenholme, 2010). By reducing the risk of BPD, with the resulting on going respiratory morbidity, it would be hoped that lengths of stay in hospital and readmission to hospital with respiratory illness would be reduced in an already compromised population. Furthermore, the need for laser surgery, for ROP, could be lessened.

Limitations

Within the study NNU the effect of changes in staff experience and skill have on the outcome cannot be accounted for. Staff skill and expertise are confounding variables that were not reported within this study due to work and time constraints. Acuity and skill mix on individual shifts within the study NNU may have affected the outcomes. Lim et al. (2014) and Petty (2012) found that acuity influenced saturation levels of premature infants. The uniqueness and nature of the infants being studied limit the generalisability of the results of this study. The data recorded on observation charts may not be accurate or have missing data and recorded data were lost in some instances due to errors in downloading. All of these issues impact on the inaccuracy of the results within the research.

Conclusion

Within this chapter the research methodology and methods have been outlined, with the population defined and inclusion and exclusion criteria specified. Data collected was presented and the rationale for these variables given. Outcomes for analysis and the analysis methods were highlighted, with statistical programmes used to analyse the data identified. Information on the cultural and ethical considerations of the study were also laid out. Risks to validity and reliability, as well as the limitations of the study have been identified. The next chapter will present the research findings and analysis of the data.

Chapter Four

Results

Introduction

The previous chapter identified the research design for this study and outlined the methodology, methods, participant selection, variables, data collected and the analysis process, bringing into context the ethical, confidentiality and cultural considerations. This chapter will present the results from the study. The demographics of the participants will be outlined within each part of the study and the results of the data analysis given, exploring the main variables studied; frequency of suctioning, oxygen requirement, desaturations, percentage of time in saturation target zone and bradycardias. A comparison of the study participants will be provided in relation to infants admitted to the study NNU, of the same gestation, over the study period.

Part One

Data collected

Data on oxygen saturation, heart rate, supplemental oxygen and frequency of suctioning, along with other observations, were recorded on infants for 2-7 days, with a total of 971 suctioning episodes recorded. Some infants had fewer days of data recorded due to removal from the study for various reasons: CPAP discontinued, required ventilation or transferred to another neonatal unit. Data collection was discontinued at this point. However, the data generated for the period the infant was in the study was still analysed. A total of nine infants had periods off CPAP during the study and were suctioned less frequently. The time off CPAP ranged from 1 hour to 28 hours (mean 15 hours, standard deviation [SD] 9.36), which resulted in CPAP pressure and supplemental oxygen not being recorded during this time.

Some data were lost due to lack of documentation, lack of equipment and errors in downloading and transferring of data. Due to inconsistency with documentation, data around procedures and kangaroo cares was not included in the analysis. Increased numbers of eligible infants meeting the entry criteria for Part One simultaneously meant that with limited equipment, the recording data for two infants was incomplete. This meant there was no recording of CPAP pressure and supplemental oxygen for these infants until equipment became available. However, both these infants were on air during the period of the study and required no supplemental oxygen, even during suctioning or handling. There was also no change of CPAP pressure during the study period. In all approximately 2,720 hours of saturation data and suctioning information was gathered.

Participant demographics

In total 21 infants were enrolled in the observational part of the study. Gestations ranged from 24 weeks and 5 days to 29 weeks and 4 days old (mean 28 weeks, SD 1.5) (see Table 3). Weight varied from 730-1600 g, (mean 1195.8 g, SD247.9). Of the 21 infants, four were identified as having intrauterine growth retardation (IUGR). Within the group, there were seven females and 14 males, of varying ethnicity: the majority being of Māori and Pasifika decent (24% and 52% respectively). Antenatal steroids were received by 16 of the 21 infants (76%) with only 12 having completed a full course of 24 hours or more prior to delivery (57%). Delivery mode varied from normal vaginal delivery (13 infants), breech (one infant) and caesarean section (seven infants). Delayed cord clamping and cord milking occurred in 12 and two infants respectively. Prolonged rupture of membranes occurred in five of the infants with 16 mothers receiving antibiotics prior to delivery. Apgar scores for infants at 1 minute and 5 minutes after delivery had a mean of 5 and 7 respectively (1 minute range 1 to 8, 5 minute range 4 to 10).

Within the study group, nine infants (43%) were diagnosed with a PDA and eight received treatment for this. IVH occurred in four of the 21 infants (19%), with one having Grade I IVH, two with Grade II IVH and one with Grade IV IVH plus periventricular leukomylacia. An additional infant had bilateral ventricular cysts that were found to be benign prior to discharge. In all, 16 infants had no evidence of any degree of IVH or cerebral sequelae within the observational study (76%). Time to full oral feeds mean was 15 days (SD 7.6), range 8 to 39 days, with all infants receiving bolus feeds 2 hourly, via an orogastric tube.

Length of stay mean was 91.3 days (SD 31.1), range 54 to 189 days. The incidence of ROP was 48% (10 infants), with five infants having Grade 1 and five with Grade 2. No infants had Grade 3 or required laser surgery within the study group (see Table 4). None of the infants in Part One developed necrotising enterocolitis. Haemoglobin levels were only analysed for the level recorded at birth and was not found to be significant. Further haemoglobin levels and blood transfusions were not included within the analysis of the data.

Table 3
Variables Analysed within Part One

Variable	N	*M*	(SD)	Median	Min	Max
Gestational age (weeks+days)	21	28	(1.5)	28+2	24+5	29+4
Number of days old(at start of study)	21	14.2	(0.4)	14.0	14	15
Weight (g)	21	1195.8	(247.9)	1250.0	730	1600
Apgars 1 minute	21	4.8	(1.9)	5.0	1	8
Apgars 5 minutes	21	6.9	(1.7)	7.0	4	10
Length of stay (days)	21	91.3	(31.1)	91.0	54	189
CPAP (Hours)	21	1168.4	(461.3)	1085.0	399	2597
Ventilation (Hours)	21	64.9	(123.6)	7.0	0	519
HFOV (Hours)	21	37.0	(93.8)	0.0	0	366
High Flow (Hours)	21	171.3	(219.7)	118.0	0	910
Hb level	21	161.0	(25.2)	158.0	102	211

Note. N= number of infants in trial, *M*= mean, SD= standard deviation, Min=minimum, Max=maximum, Hb=Haemoglobin

Respiratory support

CPAP hours varied from 399 hours to 2597 hours, mean 1168.38 hours (SD 461.3). The mean CPAP pressure was 6.3 cmsH_2O (SD 1.4), range 5 to 9 cmsH_2O. Within the study period eight infants were having periods of time off CPAP (cycling). No infants exhibited nasal trauma during the study period. Ventilation was required by only 12 infants, 57%, range 7 hours to 519 hours, mean 64.9 (SD123.6), with 10 (48%) receiving surfactant. This is comparable to all infants admitted to the NNU during the study period, 48%. Of those that received ventilation the mean hours of high frequency oscillatory ventilation was 37 hours (SD 93.8), range zero to 366 hours.

Table 4
Participants Demographics and Characteristics Part One

	n(%) (N=21)
Female	7(33)
Male	14(67)
Asian	1(5)
Māori	5(29)
Pasifika	11(52)
Other European	4(19)
Completed Steroids	12(57)
PROM	3(14)
Maternal Antibiotics	14(67)
Breech	1(5)
LSCS	7(33)
Vaginal	13(62)
IUGR	4(1)9
PDA	9(43)
PDA treated	8(38)
ROP Grade 1	5(24)
ROP Grade 2	5(24)
ROP Grade 3	0(0)
IVH Grade I	1(5)
IVH Grade II	2(9)
IVH Grade III	0(0)
IVH Grade IV	1(5)
Intubated	12(57)
Home oxygen	1(5)

Further respiratory support, in the form of high flow air or oxygen, was given to 13 infants (61.9%) with a mean of 171.3 hours (SD 219.7), range zero to 910 hours. Mild BPD, as classified in appendix B, was found with two infants (10%) compared to severe

BPD (see Appendix B), which was noted in 10 infants (47%). All infants received caffeine within the study and five received doxapram.

Data recorded

In total 1068 suctioning intervals were recorded for the 21 infants enrolled in the study. Due to errors around recording the exact time of suction on the monitor, only 971 suctioning intervals could be utilised in determining the effect of suctioning for oxygen saturation, pulse, desaturations and bradycardia, 970 suctioning intervals for desaturations of ≥10 seconds and 969 suctioning intervals for desaturations ≥60 seconds. A number of infants had periods of air during the recording of data which resulted in only 471 suctioning intervals that could be utilised for time in saturation target zone and 328 suctioning intervals for supplemental oxygen (see Table 5).

Table 5

Outcome Measures Summary Statistics within Suctioning Intervals, Part One.

Variable	n	*M*	95% CI	Median	IQR
Pressure M	770	7	[6, 7]	6	6-8
FiO_2 M	550	25	[24, 25]	22	22-25
spo2mean	971	93	[93, 94]	94	91-96
Heart Rate M	971	168	[167, 168]	169	162-174
Percentage Time FiO_2 M	328	52	[47, 56]	37	9-100
Time Target SaO_2 Zone	471	23	[22, 25]	23	10-33
Desaturation Level	971	83	[78, 87]	64	26-118
Bradycardias Frequency	971	2	[2, 2]	2	0-3
Desaturation ≥10sec	970	9	[9, 10]	5	1-15
Desaturation ≥60sec	969	1	[1, 1]	0	0-2

Note. n = number of suctioning episodes analysed, *M* = Mean, CI = Confidence Interval, IQR = Interquartile Range

Frequency of suctioning

The frequency of suctioning varied from 15 minutes (due to vomiting) to 454 minutes (7 hours 34 minutes), mean was 182 minutes (3 hours 2 minutes) (SD 71.6), median was 174 minutes (2 hours 54 minutes) and mode was 120 minutes (2 hours). Infants who were off CPAP, or more stable were suctioned less frequently and were thus left for longer intervals of suctioning.

Oxygen saturation

The median oxygen saturation was 94% (interquartile range [IQR)], 91–97%). *Figure 2* and Table 6, indicates the median levels of oxygen saturation for infants in Part One, which were 87-98%. The variations in the oxygen saturation level for the infants in the study were similar (IQR, 86–97%).

The analysis of suction frequency and other demographic characteristics in relation to oxygen saturation were tested using linear regression models. In a simple mixed effect linear regression, suctioning frequency, gestational age, weight and length of suctioning interval were separately significantly associated with the average oxygen saturation. In the adjusted full model with every factor presented simultaneously, suctioning frequency and gestational age were both significantly associated with the average oxygen saturation at a 5% significance level (see Table 7).

Table 6

Individual Infants' Oxygen Saturation Means, Part One.

Infant ID	N	*M*	95% CI	Median	IQR
1-100	75	88.8	[88.3, 89.2]	89	87.1-90.1
1-110	47	97.6	[97.2, 98]	97.9	97.4-98.4
1-120	11	94.7	[93.5, 95.8]	94.3	93.2-95.8
1-130	79	89.4	[88.8, 90]	89.4	88-91.4
1-140	48	90.4	[89.8, 90.9]	90.8	88.8-91.8
1-150	71	97	[96.6, 97.3]	97.2	96.1-98
1-160	50	95.6	[95, 96.2	96.2	95-97
1-170	66	87.2	[86.5, 87.8]	87.5	85.6-89.2
1-180	59	91.7	[90.8, 92.6]	91.1	89.7-95.2
1-190	35	93.9	[93.5, 94.4]	93.8	93-95.2
1-200	45	95.6	[95, 96.2]	96	94.3-97.1
1-210	47	92.2	[91.7, 92.7]	92.2	90.9-93.4
1-220	31	96.9	[96.2, 97.6]	97.3	96.4-98
1-230	24	97.1	[96.5, 97.6]	97.3	96.8-97.9
1-240	39	94.9	[94.3, 95.5]	95.4	93.8-96.1
1-250	30	94.1	[93.3, 95]	94.3	93.3-95.6
1-260	48	97	[96.7,97.3]	97.3	96.4-97.6
1-270	40	92.6	[92, 93.3]	92.7	91.3-94.3
1-280	47	94.2	[93.8,94.6]	94.4	93.3-94.8
1-290	30	93.7	[92.9, 94.5]	93.9	92.9-94.7
1-300	49	96.2	[95.8, 96.5]	96.3	95.6-96.9

Table 7

Adjusted Estimates of Average Oxygen Saturations, Part One.

	Estimates	95%CI	*p*-values
Suction frequency	-0.22	[-0.34, -0.10]	.0002*
Gender (Female vs. Male)	-0.62	[-2.9, 1.65]	.59
Gestational age in weeks	1.24	[0.59, 1.90]	.0002*
Completed steroid (Yes vs. No)	-0.60	[-1.65, 2.85]	.6
PROM (Yes vs. No)	-1.56	[-4.28, 1.16]	.26
Day	0.016	['-0.059, 0.092]	.67
Suctioning Interval (hour)	0.094	[-0.044, 0.232]	.18

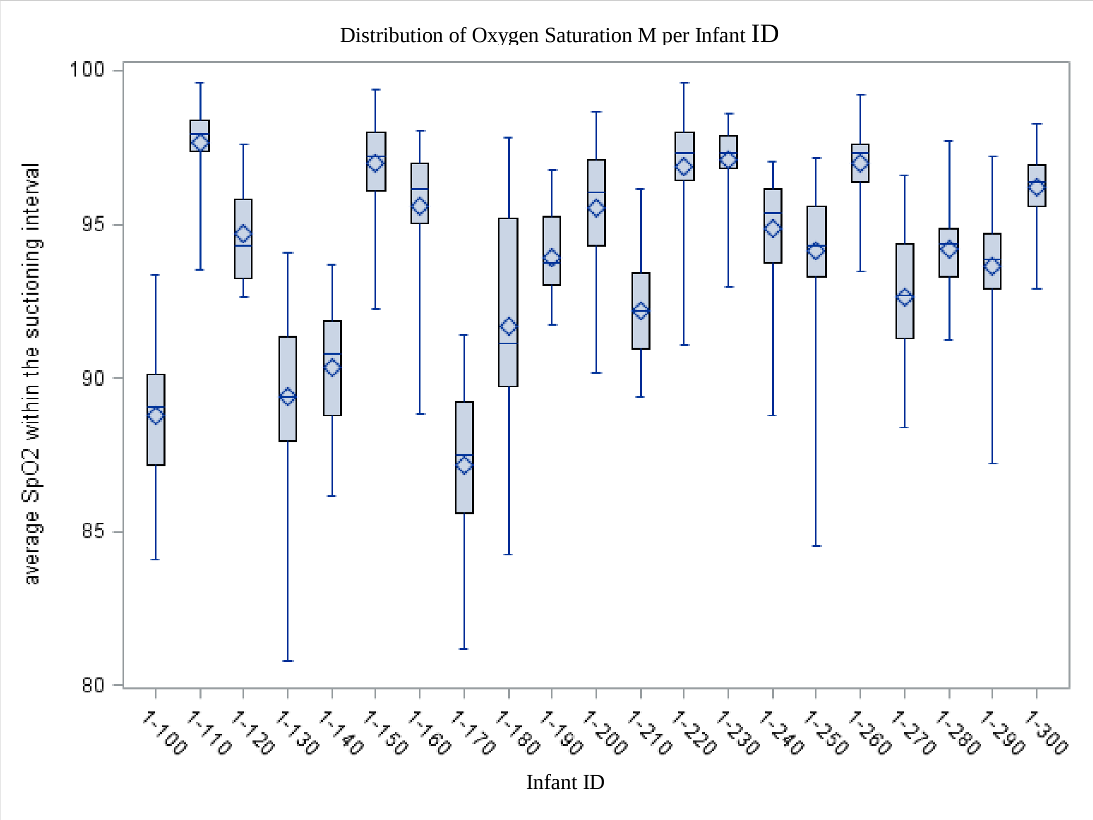

Figure 2. Distribution of Oxygen Saturation Mean, Suctioning Interval per Infant (SpO_2=SaO_2) Part One.

Higher suction frequency was significantly associated with lower average level of oxygen saturation; with every one increase in suctioning episodes per day being associated with a 0.22% decrease in oxygen saturation, 95% confidence interval (CI) [0.1, 0.34], the range of this interval containing the true estimate of 95% chance. Therefore if suctioning episodes increased by four in a 24 hour period the saturation would drop 0.9%. Infants of an older gestation were associated with a higher level of average oxygen saturation, with a one week increase in gestational age resulting in a 1.2% increase in the average oxygen saturation level, the 95% CI [0.59, 1.9]. The absolute measurement error is +/-3%.

The estimates for suctioning frequency and gestational age, even though significant, do not reach clinical significance level at one unit, i.e. if there is only one increase in suctioning within a 24 hour period or one week increase in gestational age. An increase of four episodes of suctioning within a day will result in a decrease in the mean oxygen saturation of 0.9%. An increase of five weeks in gestational age will see an increase in the mean oxygen saturation of 6.2%. Prolonged rupture of membranes is associated with a 2.5% decrease in the average level of mean oxygen saturation, 95% CI [5, 5.2] with estimates of oxygen saturation with PROM being 92% and without PROM 94% (see Table 8).

Table 8
Estimates for PROM. Part One

Effect	PROM	Estimate	SE	95% C.I.
PROM	**No**	94	0.6	[93, 95]
PROM	**Yes**	92	1.2	[90, 95]

Note. PROM=prolonged rupture of membranes, SE= standard error.

Desaturations

The model for desaturations was constructed in two parts. One part was used to explain the probability of having a desaturation (number of desaturations =0). The other part was used to explain the number of desaturations for those where the number of desaturations was >0. Desaturations were analysed as episodes of ≥10 seconds and ≥60 seconds duration, with a total of 970 and 969 suctioning intervals respectively, being reviewed. The mean number of desaturations ≥10 seconds overall, for each suctioning interval, was 9.5 episodes, 95% CI [8.8, 10.2], median 5.0 episodes, (IQR, 1–15 episodes). With desaturations of ≥60 seconds, the mean was 1.2 episodes per suctioning interval, 95% CI for mean [1.1, 1.3], median 0.0, (IQR, 0–2 episodes).

When suctioning intervals were adjusted for length of time of the suctioning intervals, into hourly measurements for ≥10 seconds and ≥60 seconds desaturation, 896 and 895 episodes were reviewed respectively. The mean number of desaturations ≥10 seconds per hour was 3.8 episodes (median 1.5, 95% CI [3.5, 4.1]). Table 9 demonstrates the mean and median number of desaturations ≥10 seconds per hour for each infant in Part One over the study period. With desaturations of ≥60 seconds the mean number of desaturations per hour was 0.5 episodes (median zero, 95% CI [0.5, 0.6]). Table 10 demonstrates the mean and median number of desaturations ≥60 seconds per hour for each infant in Part One over the study period. The box plots for each period are displayed in *Figure 3* and *4*, demonstrating the daily variance for each infant across the study period.

Table 9
Desaturations of ≥10 seconds per Infant, Part One.

Infant ID	**N**	***M***	**95% CI**	**Median**	***IQR***	**Quartile Range**	**Range**
1-100	71	6.8	[5.6, 8]	5.7	2.4-10.3	8	20.9
1-110	46	0.6	[0.4, 0.7]	0.5	0.2-0.7	0.5	3.5
1-120	9	0.5	[0.2, 0.7]	0.3	0.3-0.7	0.5	1.1
1-130	78	8.5	[7.1, 9.8]	6.8	3.5-11.5	8	27.6
1-140	0	.	.	.	.	.	.
1-150	70	1	[0.5, 1.4]	0.3	0-1.1	1.1	11.5
1-160	49	0.5	[0.3, 0.6]	0.3	0-0.8	0.8	2.5
1-170	63	13	[11.8, 14.2]	13.2	9.7-15.8	6.2	26.6
1-180	58	6.8	[5.5, 8.1]	6.1	2.4-9.5	7	24.2
1-190	34	5	[4.2, 5.8]	4.7	3.3-6.5	3.2	9.5
1-200	43	0.5	[0.3, 0.7]	0.3	0-0.6	0.6	2.9
1-210	45	3.8	[3, 4.6]	3.2	2.1-4.7	2.6	11.6
1-220	30	1.5	[0.9, 2.2	1.1	0.7-1.6	0.9	6.7
1-230	23	0.9	[0.5, 1.3]	0.7	0.3-1	0.7	4.2
1-240	38	0.4	[0.2, 0.6]	0.2	0-0.5	0.5	2.4
1-250	30	6.6	[4.7, 8.5]	5.9	3.3-8	4.7	22.7
1-260	47	0.3	[0.2, 0.4]	0.2	0-0.4	0.4	1.3
1-270	39	1.8	[1.3, 2.3]	1.4	0.5-2.8	2.3	5.8
1-280	46	1.8	[1.4, 2.1]	1.5	1.1-2.2	1.1	5.3
1-290	29	3.5	[2.7, 4.4]	2.7	2-5.1	3.1	7.6
1-300	48	0.6	[0.3, 0.9]	0.2	0-0.7	0.7	6.6

To assess the association between frequency of suctioning, demographics and desaturations frequency of ≥10 seconds, the Bayesian fixed effect models were carried out, with infant ID as a random effect in the model. The response variable desaturation was treated with a mixture distribution due to the spiky 0 and long tail. The posterior joint distribution of the unknown parameters include the parameters for the normal distribution for the non-zero value and a binomial distribution for the probability of having non zero number of desaturations.

When hourly blocks of recorded data were analysed, increased suctioning frequency, was significantly associated with more desaturations ≥10 seconds when the desaturation count was >0. Older infants were found to have fewer episodes of ≥10 second desaturations (estimate -0.11, 95% credible interval -0.17 – -0.06) when desaturations were >0 (see Table 11). When estimates were worked out for baseline factors predicating having no desaturations, suction frequency was more likely to be associated with having desaturations (estimate -0.188, 95% credible interval-0.35 – 0.01). For every one increase in suctioning interval, there was the likelihood of 0.188 desaturation of ≥10 seconds. Therefore, an increase of 5.3 suctioning episodes in a day would result in one more episode of desaturation. Longer suctioning hours were more likely to be associated with desaturation (estimate -0.5668, 95% credible interval -0.78 – -0.35). Thus with every 1 hour 40 minutes an infant was left without suctioning there was the likelihood of one desaturation of ≥10 seconds. Female infants were more likely to have desaturations of ≥10 seconds when compared to male (estimate -1.09, 85% credible interval -2.15 – -0.2) (see Table 12).

Table 10
Desaturations of ≥60 seconds per Infant, Part One.

Infant ID	N	*M*	95% CI	Median	IQR	Quartile Range	Range
1-100	70	1.2	[0.9, 1.4]	1	0.5-1.6	1	4.5
1-110	46	0	[0, 0.1]	0	0-0	0	0.4
1-120	9	0.1	[0, 0.2]	0	0-0.2	0.2	0.3
1-130	78	1.2	[1, 1.5]	1	0.5-1.8	1.3	5.5
1-140	0	.	.	.	.	.	.
1-150	70	0	[0, 0.1]	0	0-0	0	1
1-160	49	0.1	[0, 0.2]	0	0-0	0	1
1-170	63	2.2	[1.8, 2.5]	2.1	1.2-3.1	1.9	7.1
1-180	58	1.3	[1, 1.6]	1.1	0.4-1.6	1.2	5.3
1-190	34	0.4	[0.2, 0.5]	0.3	0.2-0.5	0.3	2
1-200	43	0	[0, 0.1]	0	0-0	0	0.5
1-210	45	0.3	[0.2, 0.4]	0.2	0-0.5	0.5	2.1
1-220	30	0.1	[0, 0.2]	0	0-0	0	0.8
1-230	23	0	[0, 0.1]	0	0-0	0	0.5
1-240	38	0	[0, 0.1]	0	0-0	0	0.5
1-250	30	0.3	[0.1, 0.5]	0.1	0-0.3	0.3	3.5
1-260	47	0	[0, 0.1]	0	0-0	0	0.7
1-270	39	0.1	[0, 0.2]	0	0-0.3	0.3	0.6
1-280	46	0.2	[0.1, 0.3]	0	0-0.4	0.4	0.8
1-290	29	0.4	[0.2, 0.7]	0	0-0.5	0.5	3.2
1-300	48	0.1	[0, 0.1]	0	0-0	0	1.3

When desaturations of ≥60 seconds were analysed, as for desaturation ≥10 seconds, estimates for baseline factors predicting the number of these longer desaturation per hour (full model), suctioning frequency was significantly associated with more desaturations ≥60 seconds (estimate 0.112, 95% credible interval 0.063–0.161) (see Table 13). With estimates for baseline factors predicting the likelihood of having longer desaturations per hour when desaturations =0 (full model), older infants were more likely to have no desaturations ≥60 seconds. Suctioning frequency was associated with longer desaturation (estimates -0.14, 95% credible interval -0.27 – -0.1). Consequently an increase in seven suctioning episodes per day leading to one more desaturation of ≥60 seconds. Longer suctioning hours were also more likely to be associated with having longer desaturations (estimates -0.28, 95% credible interval -0.47 – -0.1);

meaning that if the interval for suctioning was 3.5 hours longer, there would be one more episode of desaturation ≥60 seconds. Female infants were also more likely to have longer desaturations (estimates -1.09, 95% credible interval -2.06–0.11) (see Table 14).

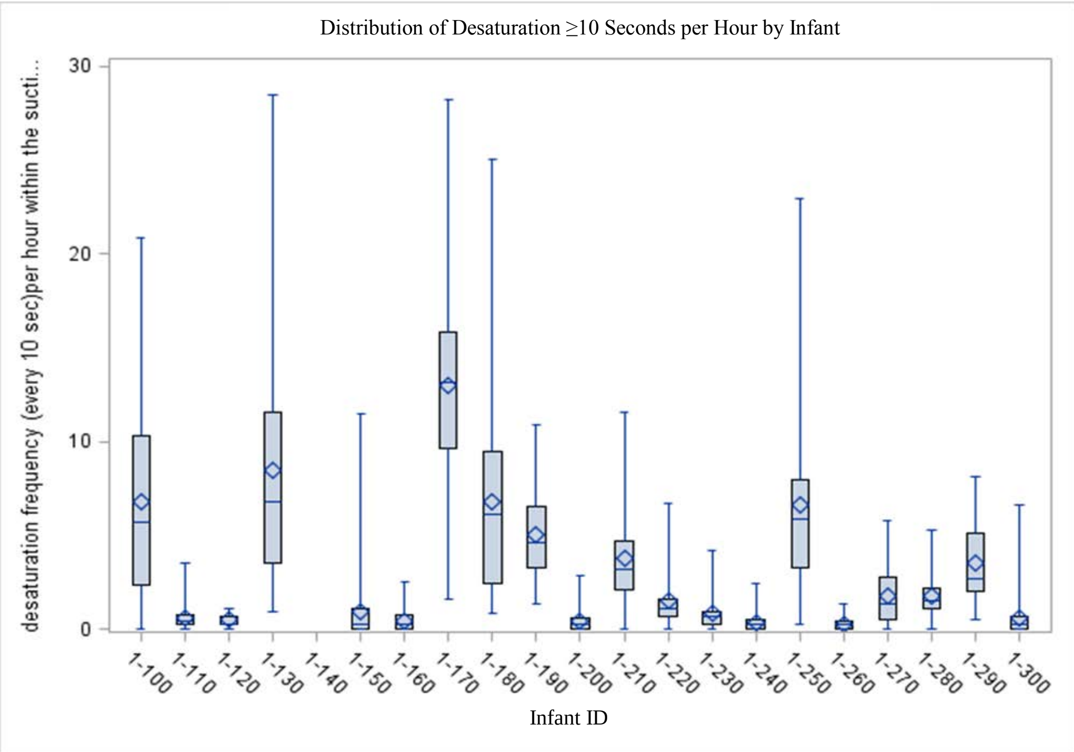

Figure 3. Desaturations of ≥10 seconds per hour for each infant, Part One.

To assess the association between demographics characteristics and desaturation frequency, mixed effect linear regression models were carried out with the infant identification (ID) as the random effects in the model, for all infants in both studies. Gestation, weight, CPAP hours and ventilation hours were all found to have a significant effect on desaturation in the unadjusted model (see Table 15). However, in the full model there were no demographics that were significant (see Table 16).

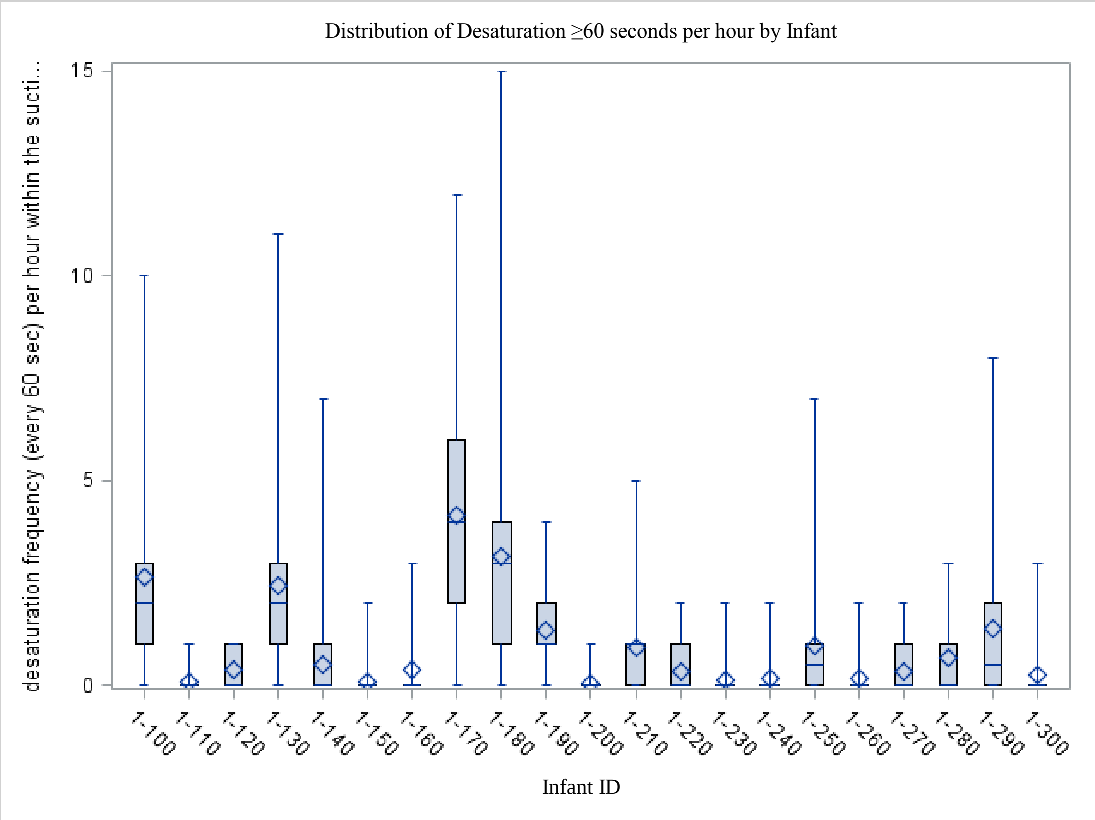

Figure 4. Desaturations of ≥60 seconds per hour for each infant, Part One.

Table 11

Estimates Predicting Number Desaturation ≥10 seconds/hour within Suctioning Interval, (Desaturation count >0), Part One.

	Estimates	95% Credible Interval	
Day	0.35	0.22	0.49*
Suction frequency	0.69	0.54	0.84*
Gender (Female vs. Male)	0.61	-0.43	1.65
Completed steroid (Yes vs. No)	-0.45	-1.47	0.54
PROM (Yes vs. No)	-0.53	-1.69	0.64*
Gestational (Weeks)	-0.11	-0.17	-0.06

Note. * Statistical Significance

Table 12

Estimates Predicting Having No Desaturation ≥10 seconds (Desaturation =0), Part One.

	Estimates	95% Credible Interval	
Suction frequency	-0.188	-0.35	-0.01*
Gender (Female vs. Male)	-1.09	-2.15	-0.02*
Completed steroid (Yes vs. No)	0.1223	-0.89	1.19
PROM (Yes vs. No)	0.2855	-0.88	1.48
Gestational (Weeks)	0.04718	-0.03	0.11
Interval (hours)	-0.5668	-0.78	-0.35*

Note. * Statistical Significance

Table 13

Estimates Predicting Number of Desaturation ≥60 Seconds/Hour (Full Model, Desaturation Count >0), Part One.

	Estimates	95% Credible Interval	
Day	0.022	-0.015	0.058
Suction frequency	0.112	0.063	0.161*
Gender (Female vs. Male)	0.079	-0.852	1.012
Completed steroid (Yes vs. No)	-0.022	-0.948	0.896
PROM (Yes vs. No)	-0.066	-1.136	0.995
Gestational (Weeks)	-0.009	-0.038	0.019

Note. * Statistical Significance

Table 14

Estimates Predicting Having Desaturation ≥60 Seconds/Hour (Full Model, Desaturation Count =0), Part One.

	Estimates	95% Credible Interval	
Suction frequency	-0.14	-0.27	-0.01*
Gender (Female vs. Male)	-1.09	-2.06	-0.11*
Completed steroid (Yes vs. No)	0.03	-0.97	0.99
PROM (Yes vs. No)	-0.23	-1.36	0.87
Gestational (Weeks)	0.10	0.05	0.16*
Interval(hours)	-0.28	-0.47	-0.1*

Note. * Statistical Significance

Table 15
Unadjusted Estimates of Average Bihourly Desaturation Frequency, All Infants Part One and Two.

	Estimates	95% CI	*p* values
Gender (Female vs. Male)	12.3	[-26.0, 50.5]	.5288
IUGR (No vs. Yes)	-29.5	[-79.1, 20.1]	.2436
Mode of delivery (Breech vs. Normal)	25.4	[-27.2, 78]	.6169
Mode of delivery (LSCS vs. Normal)	10.7	[-32.0, 53.3]	
Late infection (No vs. Yes)	36.6	[-12.9, 86.0]	0.1472
Gestational (Weeks)	-11.3	[-21.1, -1.5]	.0237*
Weight (g)	-0.109	[-0.17, -0.5]	.0002*
Apgars 1 minute	3.39	[-7.5, 14.3]	.5427
CPAP (Hours)	0.051	[0.02, 0.08]	.0018*
Ventilation (Hours)	0.036	[-0.04, 0.12]	.3833
Hb level	-0.244	[-1.0, 0.52]	.5296

Note. * Statistical Significance

Supplemental oxygen

The median amount of supplemental oxygen that infants received during the study period was 22.3% (IQR, 21.5–24.9%), individual infants means are presented in Table 17. The box plots indicate the median amounts of supplementary oxygen for the infants in Part One being between 21.4% and 33.2% (see *Figure 5*). When analysed the variations in the supplemental oxygen among the different suctioning intervals vary (IQR, 0–3.2). The range of change between the infants is 0% change in supplemental oxygen and 29.4% change in supplemental oxygen. This is reflected in the box plots, as some of them have long edges while some have no edges. Of note are infants 1-120, 1-150, 1-200, 1-230, 1-240 and 1-260, who were all on air throughout the study. Of the 21 infants within Part One of the study, 16 (76%) were on air on day 14, when the study commenced, 3 (14%) required ≤25% supplemental oxygen and 2 (10%) infants required >25% supplemental oxygen.

Table 16
Unadjusted Estimates of Average Bihourly Desaturation Frequency, Full Model, All Infants Part One and Two

	Estimates	95% CI	*p* values
Gender (Female vs. Male)	21.0	[-21.2, 63.1]	.3291
IUGR (No vs. Yes)	-60.3	[-143.2, 22.5]	.1533
Mode of delivery (Breech vs.Normal)	-38.1	[-100.0, 23.8]	.3035
Mode of delivery (LSCS vs. Normal	-47.8	[-114.2, 18.7]	
Late infection (No vs. Yes)	59.2	[-0.9, 119.3]	.0534
Gestational age (Weeks)	-9.3	[-28.9, 10.3]	.3538
Weight (g)	-0.079	[-0.19, 0.03]	.166
Apgars 1 minute	-4.01	[-18.1, 10.0]	.5756
CPAP (Hours)	0.005	[-0.04, 0.05]	.8392
Ventilation (Hours)	-0.017	[-0.10, 0.07]	.6977
Hb level	0.08	[-0.9, 1.1]	.8677

To assess the association between demographic characteristics and supplementary oxygen, mixed effect linear regression models were carried out with Infant ID as the random effects in the model, for all infants in both studies. The unadjusted estimates demonstrated that gestational age, weight, and CPAP hours were significant, although in the full model there was no significance. However, in the reduced model weight and CPAP hours were found to be significant (see Table 18).

Time in oxygen saturation target zone (SaO_2 88–92%)

Suctioning intervals were looked at for each individual infant and the mean, median and 95% confidence intervals were identified (see *Figure 6* and Table 19). The association between frequency of suctioning, demographic characteristics, and the percentage of time in the target oxygen saturation zone of 88–92%, was demonstrated using mixed effect linear regression models, with infant ID and days as random effects within the model. Tests were carried out on days, adding it as a fixed effect in the model and was found to be significant, indicating that there was an effect of day on trend and hence was included in the model.

Table 17
Supplemental Oxygen percentage, per Infant Part One.

Infant ID	N	*M*	95% CI	Median	IQR	Quartile Range	Range
1-100	66	32.9	[32.2, 33.7]	33.2	31.1-34.3	3.2	20.2
1-110	15	21.5	[21.5, 21.6]	21.5	21.5-21.5	0	0.2
1-120	10	22.3	[22.1, 22.4]	22.4	22.1-22.4	0.3	0.7
1-130	71	23.3	[23, 23.6]	23.1	22.3-24	1.8	5.9
1-140	29	22.2	[21.8, 22.6]	21.8	21.-22.26	0.6	3.4
1-150	79	21.4	.	21.4	21.4-21.4	0	0
1-160	15	21.9	[21.8, 22]	21.9	21.8-22	0.2	0.8
1-170	58	31.7	[30.7, 32.7]	31.5	30.2-32.7	2.5	29.4
1-180	34	23.3	[22.7, 23.9]	23.2	22.4-23.8	1.4	9.5
1-190	21	22.3	[22, 22.7]	22.5	21.8-22.8	1	2.5
1-200	15	22	[22, 22]	22	22-22	0	0.2
1-210	26	23	[22.3, 23.7]	22.2	21.6-24	2.4	5.7
1-220	1	21.9	.	21.9	21.921.9	0	0
1-230	3	21.5	[21.4, 21.6]	21.5	21.4-21.5	0.1	0.1
1-240	0	.	.	.	.	.	.
1-250	16	22.3	[22.1, 22.5]	22.4	22-22.6	0.6	1.3
1-260	20	21.5	[21.5, 21.6]	21.5	21.5-21.5	0	0.4
1-270	20	22.2	[21.9, 22.5]	22.2	21.9-22.4	0.5	2.7
1-280	17	22	[21.7, 22.3]	21.7	21.622.3	0.7	1.9
1-290	21	22.2	[21.9, 22.4]	22.3	21.7-22.5	0.8	1.7
1-300	13	21.8	[21.8, 21.9]	21.9	21.9-21.9	0	0.5

Table 18
Adjusted Estimates of Average Supplementary Oxygen, Reduced Model, All Infants Part One and Two.

	Estimates	95% CI	*p-values*
Weight (g)	0.00617	[0.00342, 0.00892]	<.0001*
CPAP (Hours)	-0.00265	[-0.00397, -0.00134]	<.0001*
Ventilation (Hours)	-0.00288	[-0.00562, -0.00014]	0.0397

Note. * Statistical Significance

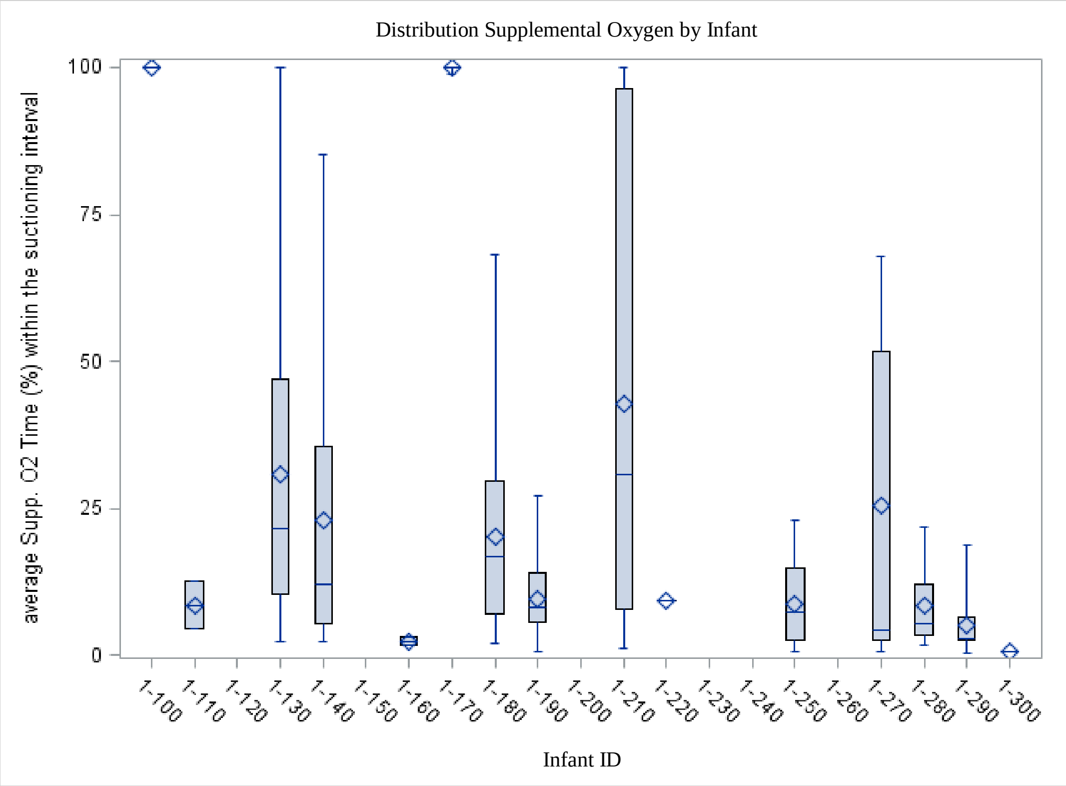

Figure 5. Distribution of Supplemental Oxygen Means by Infant.

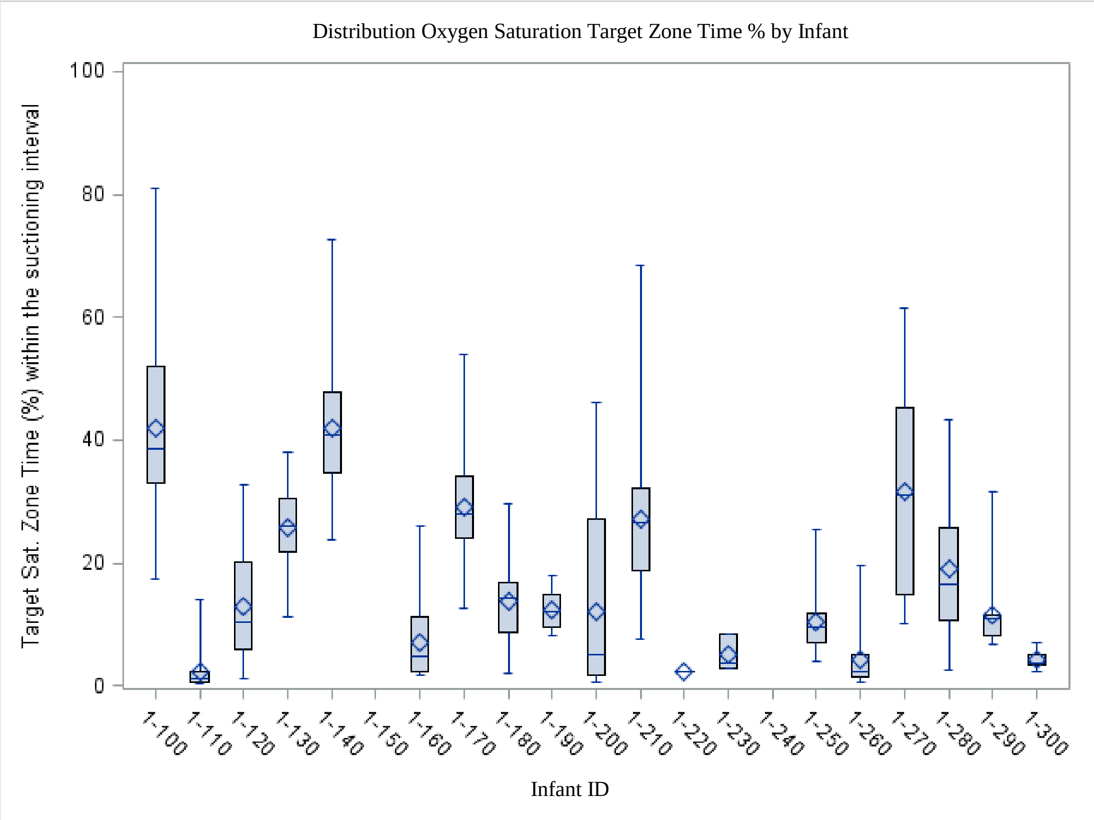

Figure 6. Percentage of Time in Oxygen Saturation Target Zone per Infant Part One.

Analysis demonstrated that in both unadjusted and adjusted estimates, increased suctioning frequency lead to a higher percentage of time within the saturation target zone of 88–92% (unadjusted estimate 0.66, 95% CI [0.24, 1.08], *p* value .002 and adjusted estimate 0.79, 95% CI [0.33, 1.25]). Therefore, in the adjusted model, for every one increase in suctioning frequency there was a 0.8% increase in the time an infant spent within the target saturation zone. Infants of smaller weight were also more likely to have a higher percentage of time in the target saturation zone in the unadjusted model (estimate -2.76, 95% CI [-0.054, 0.018], *p* value .0001) (see Table 20 and 21). The mean time in the oxygen saturation target zone, when the periods where infants who were on air were removed, was 18%.

Table 19

Percentage of Time in Oxygen Saturation Target Zone per Infant, Part One.

Infant Id	N	*M*	95% CI	Median	IQR
1-100	66	41.9	[38.6, 45.1]	38.6	33-52.1
1-110	15	2.1	[0.3, 4]	1	0.7-2.3
1-120	10	12.8	[5.5, 20.1]	10.3	5.8-20.2
1-130	71	25.7	[24.2, 27.1]	25.9	21.8-30.4
1-140	29	41.8	[37.7, 46]	40.7	34.6-47.7
1-150	0	.	.	.	.
1-160	15	7.1	[3.5, 10.8]	4.7	2.2-11.2
1-170	58	29.1	[27, 31.3]	27.9	24-34.1
1-180	34	13.8	[11.4, 16.1]	14.2	8.7-16.9
1-190	21	12.3	[10.9, 13.7]	11.9	9.6-14.7
1-200	15	11.9	[3.6, 20.3]	5	1.8-27.2
1-210	26	27.2	[22.4, 32.1]	26.6	18.8-32.2
1-220	1	2.3	.	2.3	2.3-2.3
1-230	3	5	[-2.4, 12.4]	3.7	2.9-8.4
1-240	0	.	.	.	.
1-250	16	10.5	[7.7, 13.3]	9.7	7.1-11.9
1-260	20	4.3	[2, 6.6]	2.4	1.3-5
1-270	20	31.6	[23.6, 39.6]	30.9	14.8-45.2
1-280	17	19.2	[13, 25.3]	16.6	10.8-25.6
1-290	21	11.5	[9, 14]	10.9	8.1-11.6
1-300	13	4.2	[3.3, 5.1]	3.6	3.3-5.2

Within the adjusted model, older gestational age infants were associated with a lower percentage of time in the target saturation zone (estimate -3.52, 95% CI [-6.51, -0.53], *p* value .020). This was a 3.5% increase in time outside the target saturation zone for each one week increase in gestational age. Length of stay was associated with lower percentage of time within the target saturation zone, within the adjusted model (estimate -0.61, 95% CI [-0.91, -0.32], *p* value <0.0001). With every additional day spent in the NNU, the infant had 0.6% less time in the target saturation zone (see Tables 20 and 21).

Table 20

Unadjusted Estimates of Percentage of Time in Oxygen Saturation Target Saturation Zone. Part One.

	Estimates	**95% CI**	***p*-values**
Suction frequency	0.66	[0.24, 1.08]	.002*
Gender (Female vs. Male)	2.86	[-9.34, 15.05]	.65
Gestational (Weeks)	-2.76	[-6.34, 0.81]	.13
Weight (g)	-0.036	[-0.054, -0.018]	.0001*
Steroid (Yes vs. No)	1.91	[-11.42, 15.24]	.78
Completed steroid (Yes vs. No)	4.36	[-7.4, 16.11]	.47
PROM (Yes vs. No)	10.61	[-1.8, 23.03]	.094
Suctioning interval (hour)	0.78	[0.01, 1.55]	.05

Note. * Statistical Significance

Table 21

Adjusted Estimates of Percentage of Time in Oxygen Saturation Target Zone, Full Model. Part One

	Estimates	***95% CI***	***p-values***
Suction frequency	0.79	[0.33, 1.25]	.0007*
Gender (Female vs. Male)	2.81	[-7.55, 13.16]	.6
Gestational (Weeks)	-3.52	[-6.51, -0.53]	.02*
Completed steroid (Yes vs. No)	2.07	[-8.16, 12.29]	.69
PROM (Yes vs. No)	7.56	[-4.8, 19.92]	.23
days	-0.61	[-0.91, -0.32]	<.0001*
Suctioning interval	-0.17	[-0.71, 0.37]	.54

Note. * Statistical Significance

Bradycardias

Heart rate was recorded every 2 seconds and bradycardias were identified when the heart rate dropped below 90 bpm. The median number of bradycardias were identified for each suctioning interval for individual infants and is represented in *Figure 7*. This information was then adjusted to represent the median number of bradycardias hourly for each infant and is represented in *Figure* 8 and Table 22.

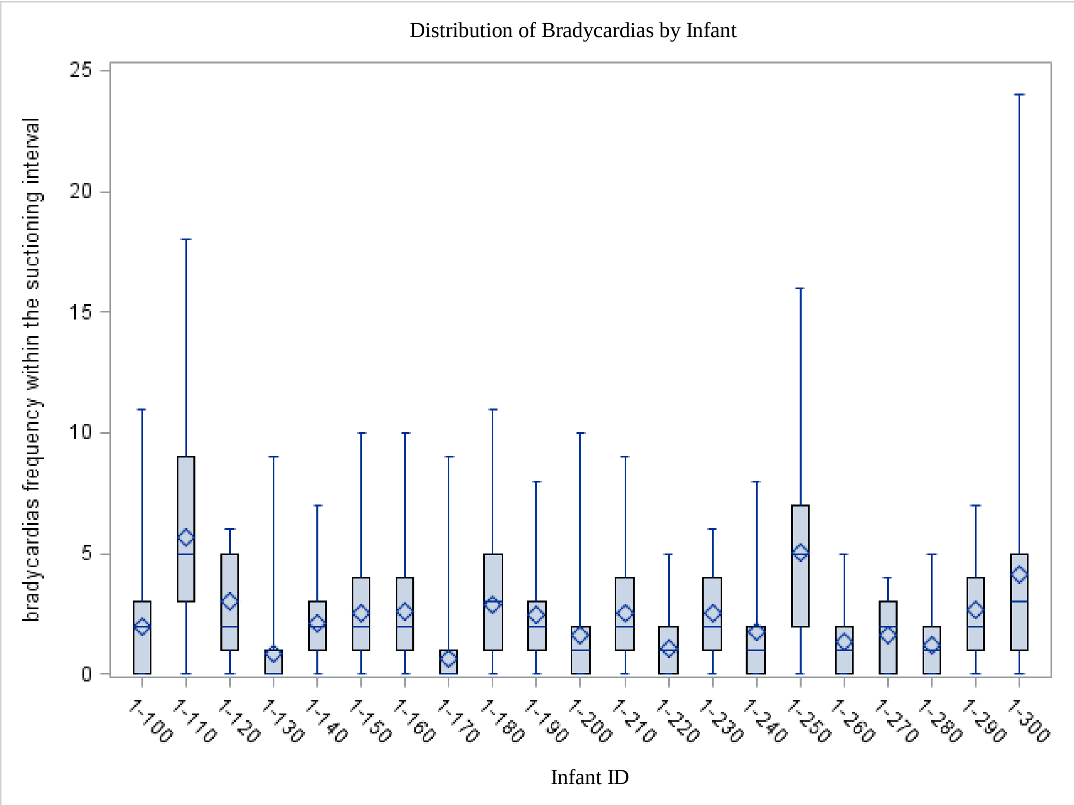

Figure 7. Distribution of Median Number of Bradycardias within Suctioning Interval per Infant Part One.

The median number of bradycardias for all infants was 0.5 per hour, one bradycardia every 2 hours (IQR, 0.0–1.0). The box plots in *Figure 8* indicate the median hourly rate in infants in Part One being between 0.0 (minimum) and 2.3 (maximum).

In the participating infants, the variations in the number of bradycardias among the different suctioning intervals are very different (IQR, 0.2–1.4). The extent of the range (maximum-minimum) is between 1 (minimum) and 7 (maximum). These differences are clearly demonstrated with the box plots which have long edges, while others have short edges.

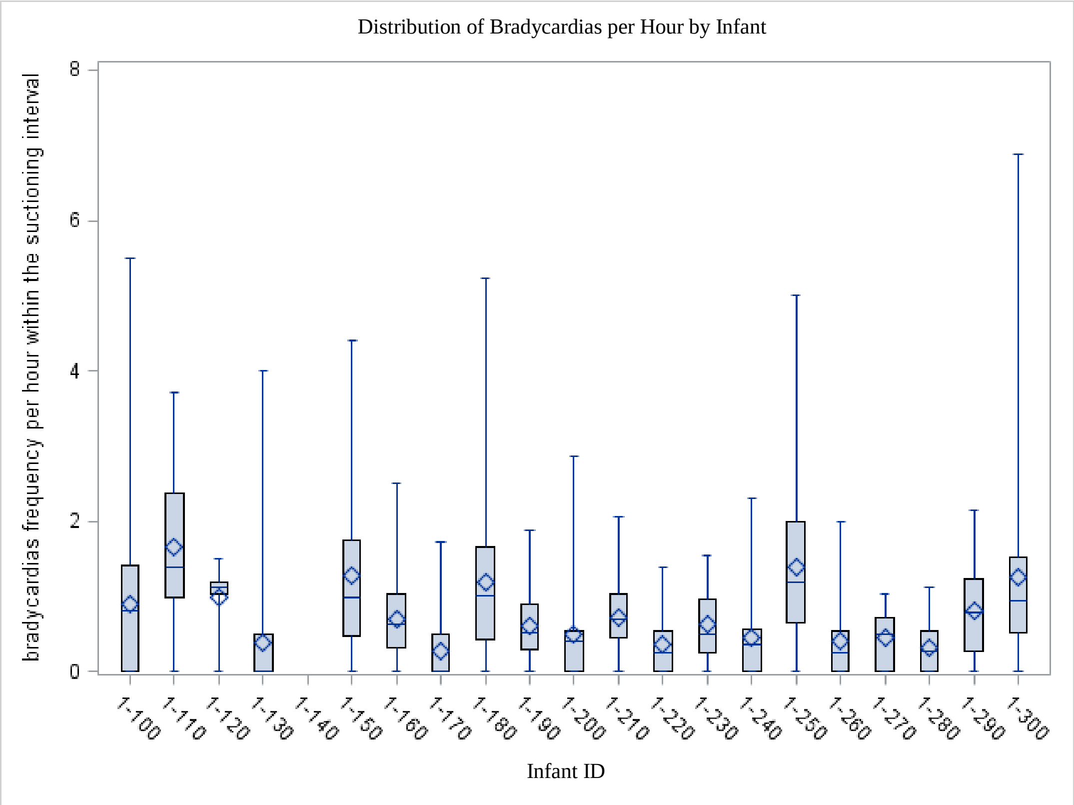

Figure 8. Distribution of Median Number of Bradycardias Adjusted by Interval to Hourly per Infant Part One.

When the data were analysed using the Bayesian method, an increase in suctioning frequency was demonstrated to be significantly related to an increase in the number of bradycardias in the unadjusted full model (see Table 23). This was in relation to predicting the number of bradycardias per hour (where bradycardia >0). When there was an increase of 15 suctioning episodes a day, there was one more bradycardia per hour, although this was not demonstrated within the model where bradycardia =0 (meaning the likelihood of the infant having a bradycardia). In this model the length of time between suctioning, and the interval, was found to be significant in the likelihood of having a bradycardia (see Table 24). The odds for the likelihood of having a bradycardia, if the interval increases one hour is 1.9, 95% CI [1.6, 2.3].

Table 22

Bradycardias Adjusted for Hourly Frequency per Infant, Part One

Infant ID	N	Mean	95% CI	Median	IQR	Quartile Range	Range
1-100	71	0.9	[0.7, 1.1]	0.8	0-1.4	1.4	5.5
1-110	46	1.6	[1.4, 1.9]	1.4	1-2.4	1.4	3.7
1-120	9	1	[0.6, 1.3]	1.1	1-1.2	0.2	1.5
1-130	78	0.4	[0.2, 0.5]	0	0-0.5	0.5	4
1-140	0	.	.	.	.	.	.
1-150	70	1.3	[1, 1.6]	1	0.5-1.8	1.3	4.4
1-160	49	0.7	[0.5, 0.9]	0.6	0.3-1	0.7	2.5
1-170	63	0.3	[0.2, 0.4]	0	0-0.5	0.5	1.7
1-180	58	1.2	[0.9, 1.4]	1	0.4-1.7	1.2	5.2
1-190	34	0.6	[0.5, 0.8]	0.5	0.3-0.9	0.6	1.9
1-200	43	0.5	[0.3, 0.7]	0.4	0-0.5	0.5	2.9
1-210	46	0.7	[0.6, 0.9]	0.7	0.4-1	0.6	2.1
1-220	30	0.4	[0.2, 0.5]	0.2	0-0.5	0.5	1.4
1-230	23	0.6	[0.4, 0.8]	0.5	0.2-1	0.7	1.6
1-240	38	0.4	[0.3, 0.6]	0.4	0-0.6	0.6	2.3
1-250	30	1.4	[1, 1.8]	1.2	0.6-2	1.3	5
1-260	47	0.4	[0.3, 0.5]	0.3	0-0.5	0.5	2
1-270	39	0.4	[0.3, 0.5]	0.5	0-0.7	0.7	1
1-280	46	0.3	[0.2, 0.4]	0.3	0-0.5	0.5	1.1
1-290	29	0.8	[0.6, 1]	0.8	0.3-1.2	1	2.1
1-300	48	1.2	[0.9, 1.6]	0.9	0.5-1.5	1	6.9

Table 23

Estimates of Bradycardias/Hour Predicting the Number of Bradycardias frequency/Hour (Full Model, Bradycardia >0), Part One.

	Estimates	95% Credible Interval	
Day	0.020	-0.009	0.050
Suction frequency	0.065	0.022	0.108*
Gender (Female vs. Male)	0.197	-0.749	1.127
Completed steroid (Yes vs. No)	-0.158	-1.073	0.764
PROM(Yes vs. No)	-0.025	-1.088	1.044
Gestational (Weeks)	0.014	-0.013	0.041

Note. * Statistical Significance

Table 24

Estimates of Bradycardias/Hour Predicting Bradycardias/Hour (Full Model, Bradycardias counts =0), Part One.

	Estimates	95% Credible Interval	
Suction frequency	-0.023	-0.136	0.117
Gender (Female vs. Male)	-0.563	-1.538	0.354
Completed steroid (Yes vs. No)	0.290	-0.562	1.297
PROM (Yes vs. No)	0.201	-0.942	1.343
Gestational (Weeks)	0.028	-0.030	0.075
Interval(hours)	-0.644	-0.829	-0.444*

Note. * Statistical Significance

Effect of suctioning

The effect of suctioning was analysed using the mean level from the previous suctioning interval for supplemental oxygen, oxygen saturation, and heart rate. These were then compared to the highest supplemental oxygen, lowest oxygen saturation, and lowest heart rate during a period of 10 minutes from the start of the subsequent suctioning episode, to determining the length of time for recovery to the previous suctioning interval means. Recovery was said to have occurred when the previous mean levels were reached and maintained for 80% of the time, for a minimum of 2 minutes. Oxygen saturation levels were sustained above the lower parameter of the target oxygen saturation zone of 88% during this period. Where the previous oxygen saturation mean was below the target saturation zone, recovery was defined as when the oxygen saturation level returned to 88%.

There were 574 periods available where all the data were available for both the previous suctioning interval and the current suctioning episode. Of these periods, 104 periods demonstrated a difference in supplemental oxygen, 308 periods where there was a difference in the heart rate and 466 periods where the oxygen saturation level altered between the previous suctioning interval and the current suctioning episode. Recovery time for supplemental oxygen was recorded in minutes due to the length of time to recovery and as the data were recorded in 30 second segments. The mean length of time for the recovery of supplemental oxygen to the previous suctioning interval mean was 16.5 minutes (SD 20), for those periods where there was a difference. The median was 9 minutes (IQR, 4–19 minutes). The maximum times for recovery to the previous suctioning interval mean being 89 minutes maximum and the minimum time to recover being 0 minutes (see Table 25).

When there was a difference for supplemental oxygen between the previous suctioning interval and the current suctioning episode and the level of supplemental oxygen did not alter throughout the whole of the current suctioning interval, “no change” was marked for the episode. This meant that for the whole suctioning interval the supplemental oxygen level remained at the new level and was marked as “0” on analysis for minimum time.

Recovery time for heart rate and oxygen saturation were recorded in seconds, as data were recorded in 2 second blocks, which reflected the speed in which the heart rate and oxygen saturation recovered. The mean time for the heart rate to recover was 41.3 seconds (SD 70.6), and the median 18 seconds (IQR, 2–38 seconds). The shortest length of time for recovery was 2 seconds and the longest time to recover was 570 seconds. In some instances the mean from the previous suctioning interval was higher or at the higher end of normal parameters for heart rate. In those instances where the time to reach that heart rate was greater than 20 minutes, the recovery time was recorded when the heart rate returned to within 20 beats of the mean heart rate of the previous suctioning interval.

Within the recovery time for desaturations, the mean was 82.8 seconds (SD 98.2), and the median 50 seconds (IQR, 16–112 seconds). The minimum time for recovery of oxygen saturation to the mean of the previous suctioning interval, being 2 seconds and the maximum, 612 seconds. There were also instances where the oxygen saturation in the previous suctioning interval was higher than the target oxygen saturation zone. When this occurred and recovery time exceeded 20 minutes, the time it took for the infant to recover to 88% oxygen saturation were recorded.

Table 25

Recovery to Previous Suctioning Episode Means, Part One.

N Obs	Variable	n	*M* (SD)	Median	IQR	Min	Max
574	Recover Time FiO_2 (min)	104	16.5 (20)	9	4-19	0	89
	Recover Time HR (sec)	308	41.3 (70.6)	18	10-38	2	570
	Recover Time SaO_2 (sec)	466	82.8 (98.2)	50	16-112	2	612

Note. Min=minute, sec=seconds

Differences between the means of the previous suctioning interval and the highest supplemental oxygen and lowest heart rate and oxygen saturation level in the current suction episode varied greatly. The mean change in supplemental oxygen was 0.8% (SD 4.1), median being 0 (IQR, -0.2%–0.3%) and minimum being -12.1% and maximum 47.4% increase in supplemental oxygen over the suctioning episode compared to previous suctioning interval. Within the heart rate, differences were noted to be -133 bpm (a drop of 133) and 23 bpm (an increase of 23) when compared to the mean heart rate for the previous suctioning interval. The mean difference being -35 bpm (SD 33), median -26 bpm (IQR, -63– -7 bpm). When oxygen saturation was analysed, differences varied from -80% (lowest) to 4% (highest), mean change in oxygen saturation being -20% (SD 15), median change in oxygen saturation being -17% (IQR, -28– -9%) (see Table 26).

Generally, the heart rate recovered quicker than oxygen saturation and the supplemental oxygen level remained unchanged within the majority of suctioning intervals. Where there were desaturations, only 22% of the suctioning intervals reviewed had supplemental oxygen changed during the time period. These findings led to further analysis of the data, to examine these periods and understand the process. Periods of prolonged desaturations were reviewed where the oxygen saturation recovery time was ≥250 seconds, as it was felt that infants should have completed suctioning at this time and should have recovered. This assumption was based on research by Singh et al. (1991) and Kerem et al. (1990). In all, within Part One, 25 instances were noted where the infant took ≥250 seconds to recover to the mean oxygen saturation of the previous suctioning interval, during the suctioning episode. The means from the previous suctioning intervals varied from 85–95% SaO_2, with mean 93% (SD 3), median 93% (IQR, 92–95%).

Table 26
Differences between previous suction interval means and suctioning episode, Part One.

N Obs	Variables	n	*M* (SD)	Median	IQR	Min	Max
574	**Difference between the highest FiO2 and average of the pre-suction**	571	0.8 (4.1)	0.0	-0.2-0.3	-12.1	47.4
	Difference between the lowest heart rate and the average of the pre-suction heart rate	569	-35 (33)	-27	-62- -7	-133	23
	Difference between the lowest SaO_2 and the average of the pre-suction Sa O2	569	-20 (15)	-15	-28- -9	-80	19

When data were reviewed to determine the time frame the infant took to recover to within target oxygen saturation zone, it was found that this varied from 10 seconds to 586 seconds, mean 296 seconds (SD 138), median 276 seconds (IQR, 194–374 seconds). The majority of the time the oxygen saturations remained within the 70-80% range. The most interesting aspect noted was that during the periods of prolonged desaturations the amount of supplemental oxygen administered to the infants did not alter greatly. The range being -3% to 3% difference between the previous suctioning interval and the current suctioning episode. The median change being 0% (IQR, 0%–0%).

Also of note were the number of desaturations within this recovery period. Due to the nature of data analysis, the desaturations were logged as blocks of five recording of <80% SaO_2, as recorded on the Masimo saturation monitor. This was to account for the 2 second recording blocks of these parameters. Therefore, when an infant's SaO_2 was <80% for 10 seconds or more, this was marked as a desaturation. However, if the saturation returned to ≥80% for 2 seconds or more then dropped <80% again this was counted as another desaturation. Within these periods of prolonged recovery there were a number of desaturations noted ranging from zero to nine ≥10 seconds duration and zero to four for ≥60 seconds duration. The median being three for ≥10 seconds duration (IQR, 2–5) and zero for ≥60 seconds duration (IQR, 0–1) (see Table 27).

Associations of the covariates

When all the data were analysed the association of the covariates was performed using Pearson correlation coefficients. This was performed on infants' variables from both Part One and Part Two. Gestational age was found to be negatively associated with hours of ventilation, with older gestational age infants having less ventilation hours (Spearman's r=-.35, *p-value* <.0001). The weight of the infant was positively associated with the gestational age but negatively associated with hours of CPAP and ventilation. Thus indicating the older infants had higher weight (Pearson's r =.65, *p-value* <.0001), and the heavier infants had less hours of CPAP and ventilation (Pearson's r =-.55, *p-value* <.001).

It was noted that the Apgar score at one and five minutes had no association with the hours of ventilation of CPAP. Of interest was the haemoglobin level of the infant on admission, that it was weakly associated with the hours of CPAP (Pearson's r =-.25, *p-value* <.0001). Haemoglobin level at birth was weakly associated with the hours of CPAP (Pearson's r = -.25, *-value* <.0001).

Table 27

Episodes of Prolonged Desaturation with Time to Recover to ≥88% SaO_2, Part One.

Time recover Sao2 (sec)	Difference in FiO_2%	Desats during recovery ≥10sec	Desats during recovery ≥60sec	Probe off Number	Time recover SaO_2 88% (Sec)	Range of SaO_2
612	1	3	0		542	70s
280	0	0	0		126	low 80s
392	-3	5	1		392	70s
294	2	2	1		194	70s-low 80s
316	0	3	1		334	70s
316	-1	0	0		266	70s-low 80s
280	0	2	0		176	70s-low 80s
570	0	3	1		566	70s-low 80s
284	2	6	0		284	70s-low 80s
532	0	3	0		332	70s
294	0	2	0		190	low 80s
556	3	8	4		332	70s-low 80s
294	0	5	1	1	292	70s-low 80s
256	0	2	0		214	70s
550	0	1	0		228	mid 80s
356	0	4	0	1	222	low 80s
416	0	0	0		10	mid 80s
586	0	8	2		586	70s
388	0	7	1		374	70s
428	-1	3	2		276	70s-low 80s
302	2	2	0		272	70s-low 80s
400	-1	2	1		160	low 80s
512	0	9	3		460	70s-low 80s
258	0	4	0	1	186	mid 80s
428	0	6	1		388	70s-low 80s

Part Two

Sample size calculation

Statistical analysis from Part One was utilised to determine the number of infants required within Part Two of the study to demonstrate significance. A paired sample *t* test was utilised to detect a difference of 5% for the mean oxygen saturation, between the two frequencies of suctioning. Within Part One the mean oxygen saturation was 93.3% (SD 3.2). The result found that 10 infants were required within each group of either starting two hourly or four hourly suctioning, for a statistical power of 85% at a significant level of 0.05. Requiring 20 infants enrolled within this part of the study.

Data collected

Data on oxygen saturation, heart rate, supplemental oxygen and frequency of suctioning, along with other observations, were recorded on infants for 2-9 days, with a total of 394 suctioning episodes recorded. Some infants had fewer days of data recorded due to removal from the study as they did not meet the inclusion criteria. In these cases data collection were discontinued at this point. However, the data generated for the period the infant was in the study was still analysed. Some data were lost due to lack of documentation and errors in downloading and transferring of data, leaving 386 suctioning intervals for the six infants enrolled in the study. Some of infants had periods of air during the recording of data, which resulted in only 304 suctioning intervals for supplemental oxygen (see Table 28). Due to inconsistency with documentation, data around procedures and kangaroo cares were not included in the analysis.

Table 28
Outcome Measures Bihoury, Part Two

Variable	n	*M*	95% CI	Median	IQR
Bihourly spO2	386	90	[90, 90]	90	89-92
Bihourly Supp. O2 Time (%)	304	63	[58, 67]	94	15-100
Bihourly Target Sat. Zone Time (%)	386	28	[28, 28]	28	22-34
Bihourly Desaturation frequencies (≥10 sec)	386	21	[19.3, 22.7]	17	9-28
Bihourly Desaturation frequencies (≥60 sec)	386	2.7	[2.5, 3.0]	2	1-4

Participant demographics

Within Part Two of the study six infants, who met the criteria, were enrolled, which was not enough to ensure significance would be found within the results. Gestations ranged from 25 weeks to 26 weeks 3 days old (mean 25.5 weeks, SD 0.5) (see Table 30). Weight varied from 730-950 g (mean 873.8 g, SD 83.5, median 912.5g). Of the six infants, none were identified as having intrauterine growth retardation (IUGR). Within the group, there were two females and four males, of varying ethnicity: two Māori (33%) and two of Pasifika decent (33%), one Asian (2%) and one European (2%). Antenatal steroids were received by four of the six infants' mothers (67%), with all of the infants who received steroids having completed a full course of 24 hours or more prior to delivery (67%). Delivery mode varied; normal vaginal delivery three infants (50%), and breech delivery three infants (50%). Delayed cord clamping and cord milking occurred in two and one infants respectively. Prolonged rupture of membranes occurred in two of the infants with five mothers receiving antibiotics prior to delivery. Apgar scores for infants were recorded at one minute and five minutes, the means being 5 and 7 respectively (one minute 4–6, five minute 5–10).

Within the study group, all six infants (100%) were diagnosed with a PDA and five received treatment for this. None of the infants within Part Two of the study were diagnosed with IVH, with all head ultrasound scans showing no abnormality or bleeding within the brain. Time to full oral feeds mean was 15 days (range 9-29 days, SD 8.2, IQR, 10–14 days), with all infants receiving bolus feeds 2 hourly, via an orogastric tube, at the commencement of the study. Length of stay mean was 125 days (range 88-149 days, SD 26.6, median 139, IQR, 106–143 days).

The incidence of ROP was 80%, (four of the five infants, who survived to discharge), with two infants having Grade 1 ROP (40%) and two with Grade 2 ROP (40%). No infants had Grade 3 ROP or required laser surgery within the study group (see Table 29). Of the infants in Part Two, one infant developed necrotising enterocolitis and later died. Haemoglobin levels were only analysed for the level recorded at birth and was not found to be significant. Further haemoglobin levels and blood transfusions were not included within the analysis of the data.

Respiratory support

CPAP hours varied from 926 hours to 2302 hours (mean 1590.3, SD 514.9, median 1551 hours) (see Table 30). The mean CPAP pressure was 8 cmsH_2O (7-9 cmsH_2O, SD 0.4, median 8 cmH_2O with IQR, 8–8 cmH_2O). Nasal trauma was not evident amongst the participants during the study period. Ventilation was required by five infants, 83%, (10 hours to 1044 hours, mean 365.4 hours, SD 396.8), with four (67%) receiving surfactant. Only one infant received high frequency oscillatory ventilation for 20 hours. Further respiratory support, in the form of high flow air or oxygen, was given to four infants (67%) with a mean of 166 hours (87-721 hours, SD 241.4). BPD, as classified as an oxygen requirement for at least 28 days, was found with four infants (66.7%) compared to the definition of respiratory support at 36 weeks gestation, which was noted in five infants (83.3%). All infants received caffeine and only one was not given doxapram.

Table 29
Participants Demographics and Characteristics Part Two

	n(%) (N=6)
Female	2(33)
Male	4(67)
Asian	1(17)
Māori	2(33)
Pasifika	2(33)
Other European	1(17)
Completed Steroids	4(67)
PROM	1(33)
Maternal Antibiotics	5(83)
Breech	3(50)
LSCS	0(0)
Vaginal	3(50)
IUGR	0(0)
PDA	6(100)
PDA treated	5(83)
ROP Grade 1	2(40)
ROP Grade 2	2(40)
ROP Grade 3	0(0)
IVH Grade I	0(0)
IVH Grade II	0(0)
IVH Grade III	0(0)
IVH Grade IV	0(0)
Intubated	5(83)
Home oxygen	0(0)

Table 30
Variables Analysed within Part Two.

Variable	N	*M*	(SD)	Median	Minimum	Maximum
Gestational age (weeks+days)	6	25+3	(0.5)	25+3	25+1	26+3
Number of days old (at start of study)	6	14.5	(0.8)	14.0	14	16
Weight (g)	6	873.8	(83.5)	912.5	730	930
Apgars 1 minute	6	5	(1.9)	5	4	6
Apgars 5 minutes	6	7	(1.7)	7	5	10
Length of stay (days)	6	125	(26.6)	139	88	149
CPAP (Hours)	6	1590.3	(514.9)	1551.0	926	2302
Ventilation (Hours)	6	304.5	(385)	221	0	1044
HFOV (Hours)	6	3.30	(8.2)	0.0	0	20
High Flow (Hours)	6	285	(257.1)	262	0	721
Hb level	6	150.8	(19.8)	147	133	178

Frequency of suctioning randomisation

Within Part Two of the study three infants commenced on 2 hourly suctioning frequency for 4 days, changing over to 4 hourly on Day 5 for a total of 5 days of 4 hourly suctioning. The remaining three infants commenced on 4 hourly suctioning frequency changing to 2 hourly as above. In relation to gender both suctioning frequency regimes were demonstrated, 50% of females and 50% of males commencing on 2 hourly and 4 hourly suctioning frequency (see Table 31).

Table 31
Infant ID Identifying Gender and Suctioning Regime Part Two

Infant ID	Gender	Regime
2-100	Male	2 hourly
2-110	Female	2 hourly
2-120	Male	2 hourly
2-130	Male	4 hourly
2-140	Female	4 hourly
2-150	Male	4 hourly

Infants commenced the study at 6am on Day 1 and at 6am on Day 5 changed to the new regime, giving 5 days in the new regime to account for the washout day. The study was concluded at 6am on Day 10, unless they met the criteria to be withdrawn from the study prior to this. Of the infants enrolled in the study, 2 required to be withdrawn due to requiring ventilatory support on Day 2 and Day 5 respectively. Suction frequency was maintained within the 2 hour or 4 hour period, with some variance in time to work in with workloads and unit requirements.

Oxygen saturation

Oxygen saturation was recorded in 2 second periods over the duration of study and means calculated for each suctioning interval. The means for these suctioning intervals varied across the infants from 86% (minimum) to 93% (maximum), the overall mean for all infants being 90% (SD 1.5). Within the suctioning interval mean oxygen saturations, the median was 91% (IQR, 89–91%). *Figure 9* and Table 32, both indicate the mean levels of oxygen saturation for infants in Part Two, which were 86–93%. Estimates for the predicted oxygen saturation for each infant within each suctioning interval are presented in Table 32. As infant 2-100 and 2-150 did not complete the full crossover trial, only the analysis of the other infants are presented.

Desaturations

Desaturations were analysed as episodes of ≥10 seconds and ≥60 seconds duration, with a total of 386 suctioning intervals reviewed. The results were set out in bihourly intervals with the mean number of desaturations ≥10 seconds overall, for each bihourly interval being 21 episodes 95% CI [19, 23], median 17 episodes (IQR, 9 to 28). With desaturations of ≥60 seconds, the mean was 3 episodes per bihourly interval 95% CI [2, 3], median 2, (IQR, 1–4). The box plots in *Figures 10* and *11*, identify the individual infants' variations between ≥10 seconds and ≥60 seconds desaturation frequency per hour within the study period.

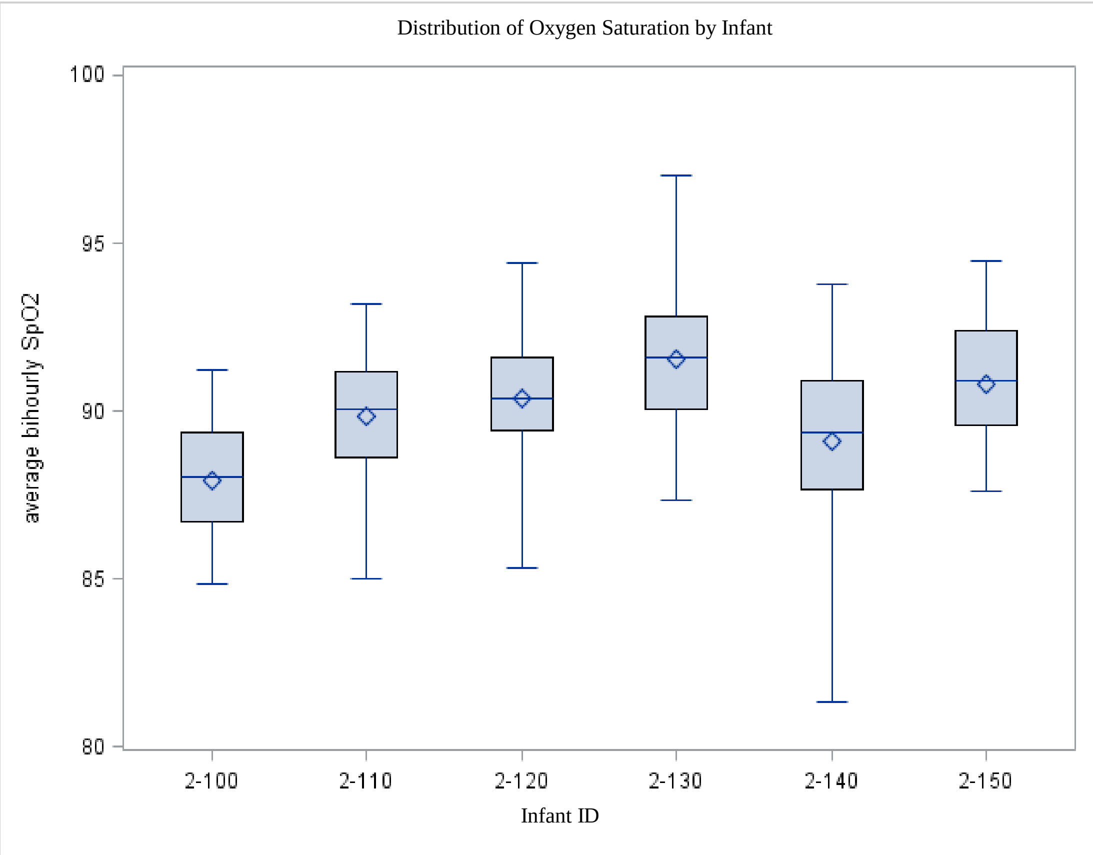

Figure 9. Distribution of Oxygen Saturation Mean for Suctioning Interval per Infant Part Two (SpO2-SaO_2)

Data for desaturation means were analysed to estimate the fixed effect, which was an estimate for all infants, of the difference between 4 hourly and 2 hourly suctioning. Amongst the six infants, the fixed effect demonstrated that there were 7.3 more episodes of desaturation ≥10 seconds with 4 hourly suctioning (standard error [SE]: 2.1 and 95% CI [1.2, 13.4]), compared to 2 hourly suctioning (see Table 33).

However, the difference was less in desaturations of ≥60 seconds, the fixed effect demonstrated that there were 0.65 more episodes of desaturation ≥60 seconds with 4 hourly suctioning (SE: 0.39 and 95% CI [-0.4, 1.7]), compared to 2 hourly suctioning, as demonstrated in *figures 12* and *13* and Tables 34 and 35.

Table 32
Estimate of Saturations for Each Infant, for Each Frequency of Suctioning, Part Two.

Oxygen Saturation		**Estimate**	**SE**	**Predicted Oxygen Saturation**
	Fixed effect	-0.032	0.72	
Predicted random effect for each baby				
2-100	**Four hourly**	0.00	1.13	90.0
	Two hourly	-1.82	0.59	88.2
2-110	**Four hourly**	-0.79	0.63	89.2
	Two hourly	0.08	0.53	90.1
2-120	**Four hourly**	0.66	0.59	90.6
	Two hourly	0.12	0.53	90.1
2-130	**Four hourly**	0.25	0.61	90.2
	Two hourly	1.88	0.52	91.9
2-140	**Four hourly**	-0.84	0.58	89.2
	Two hourly	-0.85	0.53	89.2
2-150	**Four hourly**	0.72	0.61	90.7
	Two hourly	0.58	0.61	90.6

When compared individually for desaturations ≥10 seconds (Table 34), infant 2-110 had a predicted hourly desaturation rate of 21.5 (SE: 2.0) in the 4 hourly regime and 7.0 (SE: 1.6) in the 2 hourly regime. Infant 2-120 had a predicted hourly desaturation rate of 14.1 (SE: 1.8) in the 4 hourly regime and 7.3 (SE: 1.6) in the 2 hourly regime. Infant 2-130 had a predicted hourly desaturation rate of 13.0 (SE: 1.9) in the 4 hourly regime and

5.3 (SE: 1.6) in the 2 hourly regime. Infant 2-140 had a predicted hourly desaturation rate of 14.1 (SE: 1.8) in the 4 hourly regime and 11.3 (SE: 1.8) in the 2 hourly regime. Infants 2-100 and 2-150 did not complete all days of the study period, with infant 2-100 only receiving 2 hourly suctioning for less than 2 days and infant 2-150 having 4 days of 4 hourly suctioning regime and then only 1 day of 2 hourly suctioning regime. Therefore, only four infants who completed the study are presented here.

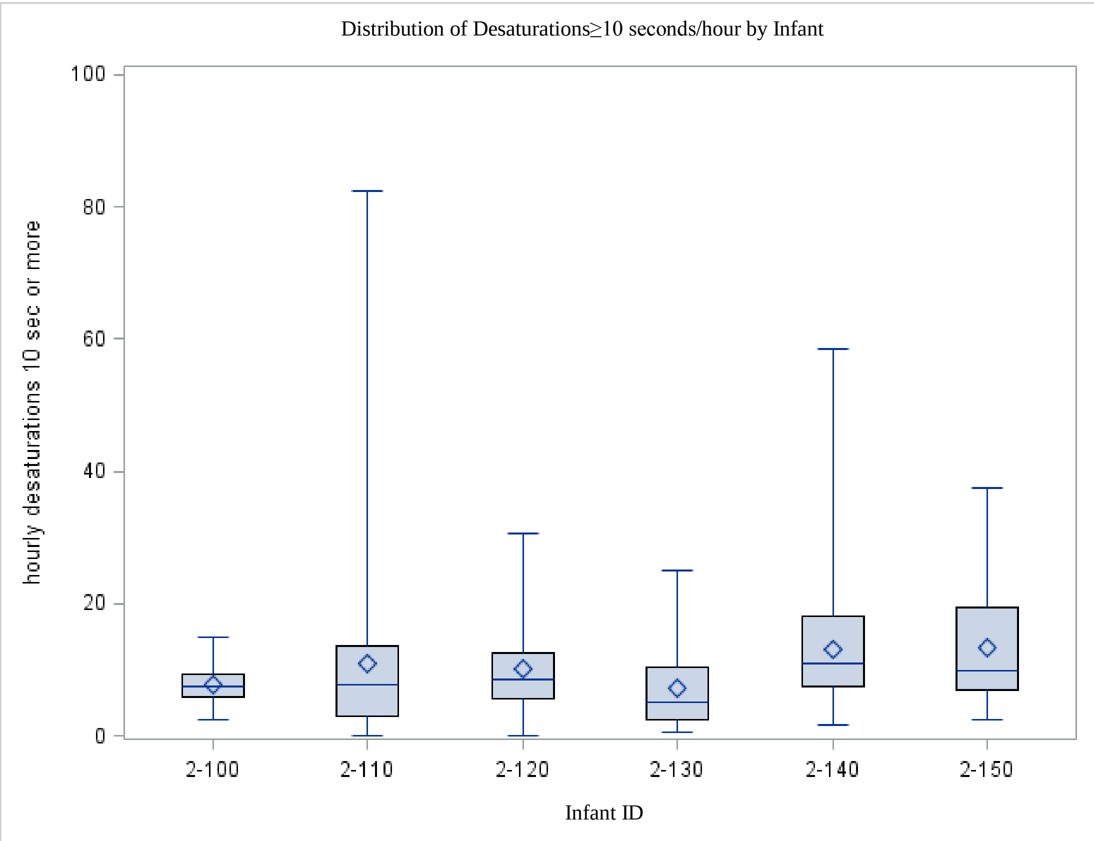

Figure 10. Distribution of Desaturations ≥10 seconds/hour for each Infant, Part Two

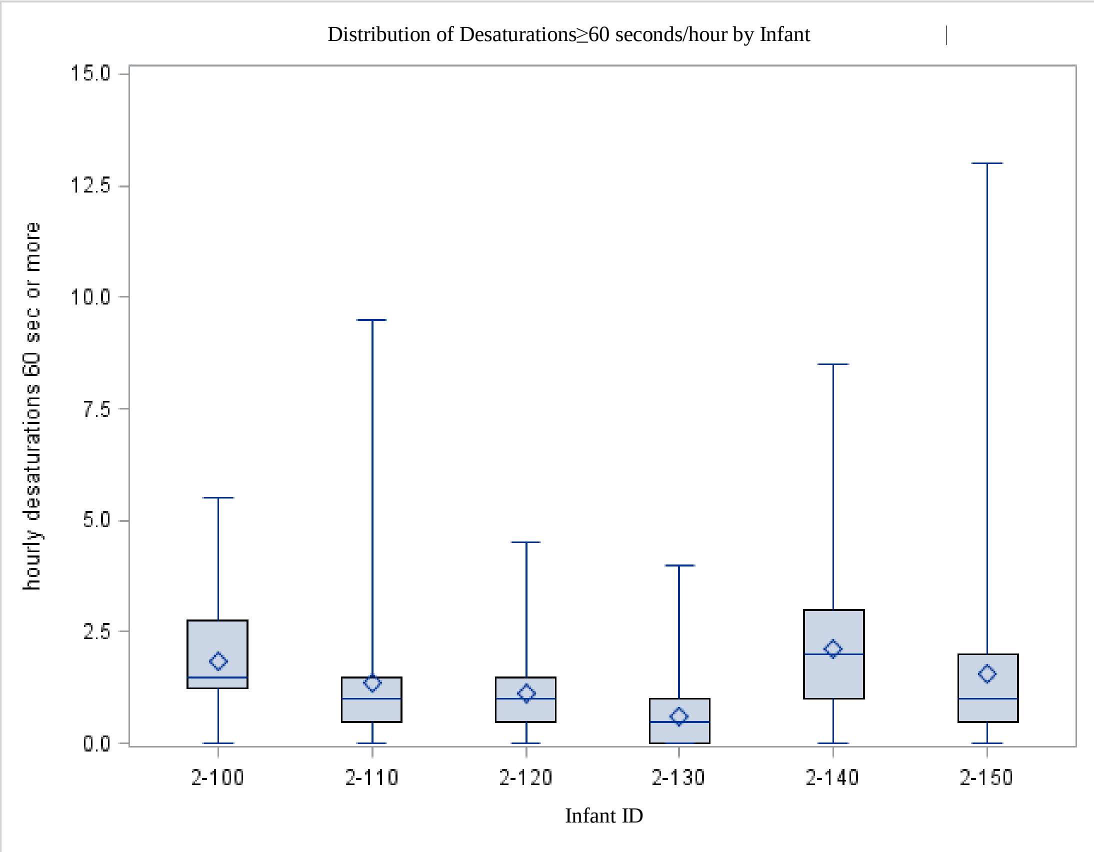

Figure 11. Distribution of Desaturations ≥60 seconds/hour for each Infant, Part Two

Table 33

Desaturations ≥10 seconds/hour Estimate Comparing 4 hourly to 2 hourly Suctioning for all Infants. Fixed Effect. Part Two.

Effect	Actual Treatment	Estimate	SE	DF	t Value	Pr > |t|	Alpha	95% CI
Intercept		8.4	1.5	4	5.73	0.0046	0.05	[4.3, 12.4]
Actual Treatment	**Four hourly**	7.3	2.2	4	3.34	0.0288	0.05	[1.2, 13.4]
Actual Treatment	**Two hourly**	0						

Table 34

Estimate and Prediction of Desaturations ≥10 seconds/hourly Period Comparing 4 hourly to 2 hourly Suctioning for each Infant, Part Two.

Effect	Infant ID	Actual Treatment	Estimate	SE Pred	DF	t Value	Pr > |t|	Predicted Hourly Desat
Intercept	**2-100**		0.0	.	.	.	.	
Actual Treatment	**2-100**	**Four hourly**	0.0	3.2	374	0	1	
Actual Treatment	**2-100**	**Two hourly**	0.0	1.9	374	-0.01	0.9903	
Intercept	**2-110**		0.0	.	.	.	.	
Actual Treatment	**2-110**	**Four hourly**	5.8	2.0	374	3	0.0029	**21.5**
Actual Treatment	**2-110**	**Two hourly**	-1.4	1.6	374	-0.85	0.3943	**7.0**
Intercept	**2-120**		0.0	.	.	.	.	
Actual Treatment	**2-120**	**Four hourly**	-1.6	1.8	374	-0.87	0.3861	**14.1**
Actual Treatment	**2-120**	**Two hourly**	-1.1	1.6	374	-0.66	0.5101	**7.3**
Intercept	**2-130**		0.0	.	.	.	.	
Actual Treatment	**2-130**	**Four hourly**	-2.6	1.9	374	-1.36	0.1754	**13.0**
Actual Treatment	**2-130**	**Two hourly**	-3.1	1.6	374	-1.96	0.0503	**5.3**
Intercept	**2-140**		0.0	.	.	.	.	
Actual Treatment	**2-140**	**Four hourly**	-1.5	1.8	374	-0.86	0.393	**14.1**
Actual Treatment	**2-140**	**Two hourly**	3.0	1.8	374	1.64	0.1015	**11.3**
Intercept	**2-150**		0.0	.	.	.	.	
Actual Treatment	**2-150**	**Four hourly**	-0.1	2.0	374	-0.05	0.9635	**15.6**
Actual Treatment	**2-150**	**Two hourly**	2.6	1.9	374	1.35	0.1778	**10.9**

Note. SE Pred=Standard Error Predicted, DF=Degree of Freedom, Desat=Desaturation

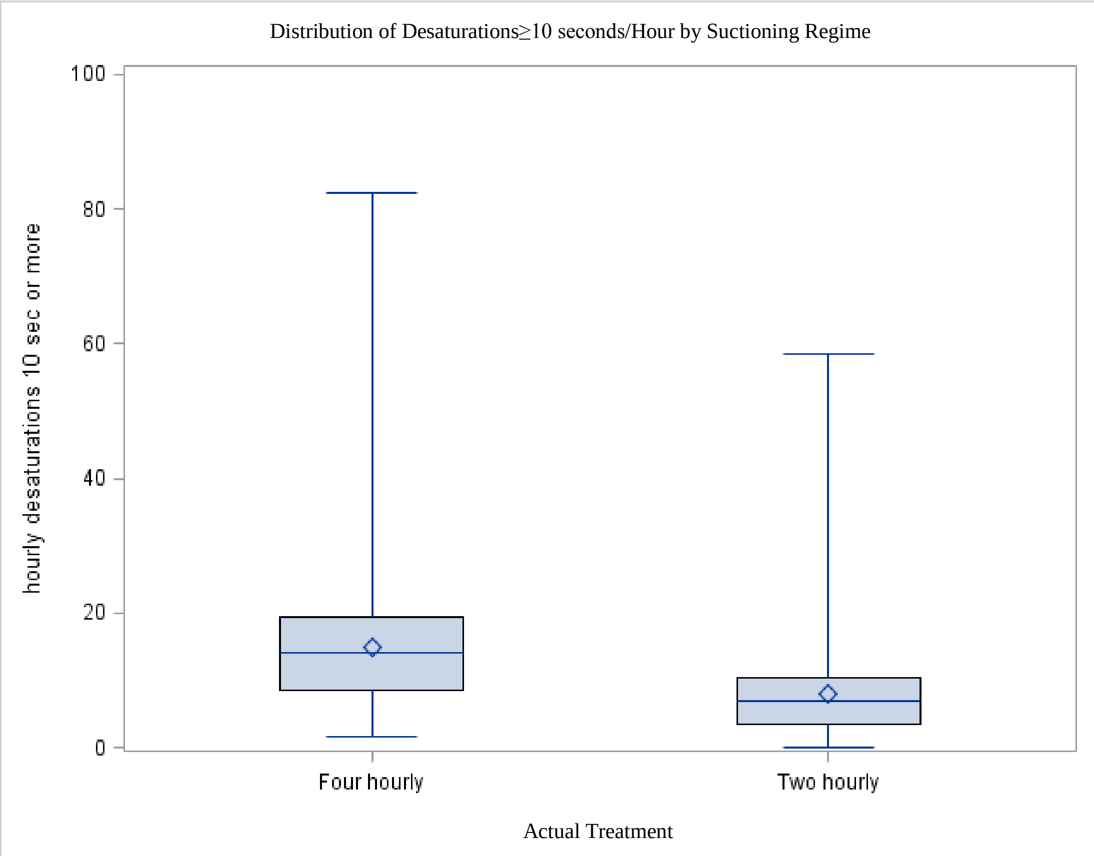

Figure 12. Distribution of Desaturation ≥10 seconds/hour for all Infants According to Suctioning Regime Part Two.

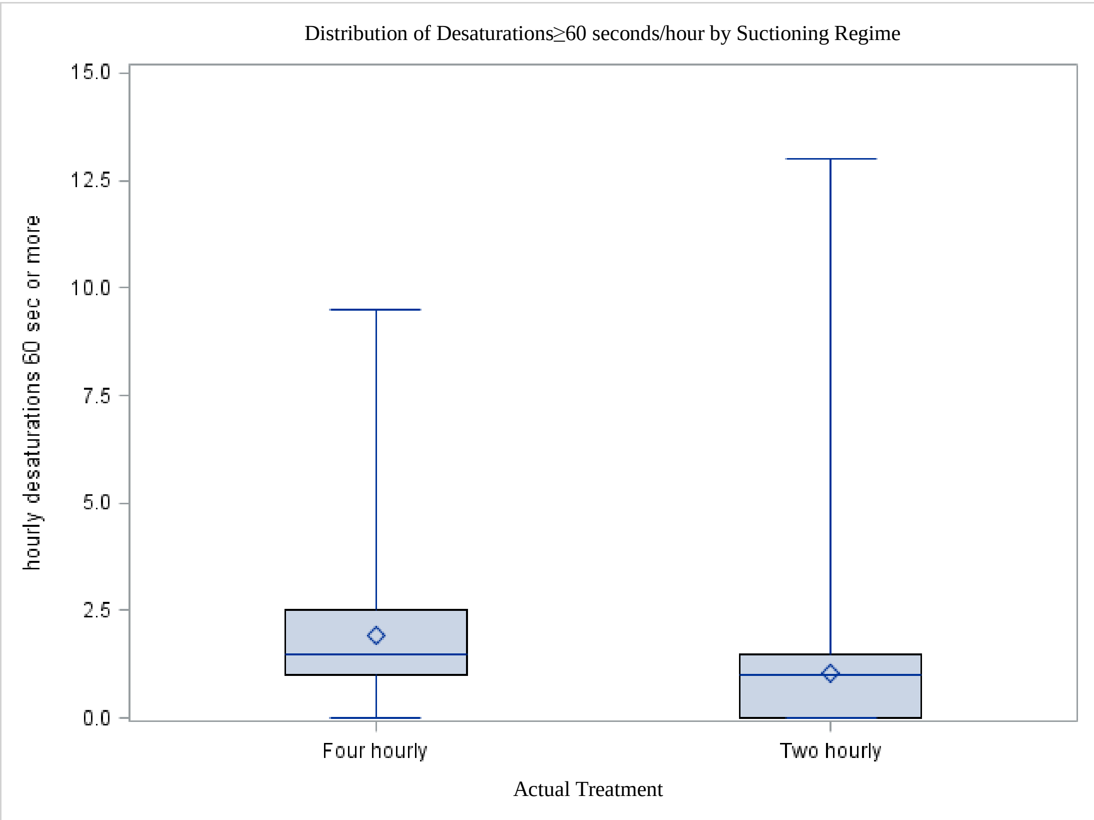

Figure 13. Distribution of Desaturation ≥60 seconds/hour for all Infants According to Suctioning Regime Part Two.

Table 35
Estimate and Prediction of Desaturations ≥60 seconds/hourly Period Comparing 4 hourly to 2 hourly Suctioning for each Infant, Part Two.

Effect	Infant ID	Actual Treatment	Estimate	Std Err Pred	DF	t Value	Pr > |t|	Predicted Hourly Desat
Intercept	**2-100**		0.1	0.2	375	0.29	0.7742	
Actual Treatment	**2-100**	**Four hourly**	0.0	0.6	375	0	1	**1.9**
Actual Treatment	**2-100**	**Two hourly**	0.4	0.4	375	1.19	0.2333	**1.7**
Intercept	**2-110**		0.0	0.2	375	0.19	0.8523	
Actual Treatment	**2-110**	**Four hourly**	0.7	0.4	375	1.75	0.0807	**2.6**
Actual Treatment	**2-110**	**Two hourly**	-0.4	0.3	375	-1.17	0.2415	**0.9**
Intercept	**2-120**		-0.1	0.2	375	-0.41	0.6852	
Actual Treatment	**2-120**	**Four hourly**	-0.3	0.4	375	-0.7	0.4835	**1.6**
Actual Treatment	**2-120**	**Two hourly**	-0.3	0.3	375	-1	0.3156	**0.9**
Intercept	**2-130**		-0.1	0.2	375	-0.67	0.503	
Actual Treatment	**2-130**	**Four hourly**	-0.2	0.4	375	-0.64	0.5239	**1.7**
Actual Treatment	**2-130**	**Two hourly**	-0.7	0.3	375	-2.24	0.0256	**0.5**
Intercept	**2-140**		0.1	0.2	375	0.56	0.5778	
Actual Treatment	**2-140**	**Four hourly**	0.3	0.4	375	0.93	0.3552	**2.2**
Actual Treatment	**2-140**	**Two hourly**	0.5	0.3	375	1.44	0.1504	**1.7**
Intercept	**2-150**		0.0	0.2	375	0.03	0.9736	
Actual Treatment	**2-150**	**Four hourly**	-0.5	0.4	375	-1.35	0.1778	**1.4**
Actual Treatment	**2-150**	**Two hourly**	0.6	0.4	375	1.48	0.1399	**1.8**

When desaturations of ≥60 seconds were compared individually for the four infants (Table 35), infant 2-110 had a predicted hourly desaturation rate of 2.6 (SE: 0.4) in the 4 hourly regime and 0.9 (SE: 0.3) in the 2 hourly regime. Infant 2-120 had a predicted hourly desaturation rate of 1.6 (SE: 0.4) in the 4 hourly regime and 0.9 (SE: 0.3) in the 2 hourly regime. Infant 2-130 had a predicted hourly desaturation rate of 1.7 (SE: 0.4) in the 4 hourly regime and 0.5 (SE: 0.3) in the 2 hourly regime. Infant 2-140 had a predicted hourly desaturation rate of 2.2 (SE: 0.4) in the 4 hourly regime and 1.7 (SE: 0.3) in the 2 hourly regime. Overall, there was an increase in ≥10 seconds desaturations each hour for all infants within the 4 hourly suctioning regime compared to the 2 hourly suctioning regime. Table 36 demonstrates the estimation of desaturations being higher with 4 hourly suctioning. However, this was not significant.

Table 36
Estimate of Desaturations ≥60 seconds/hourly Period Comparing 4 hourly to 2 hourly, Suctioning for all Infants, Part Two.

Effect	Actual Treatment	Estimate	SE	DF	t Value	Pr > |t|	Alpha	95% CI
Intercept		1.2484	0.276	4	4.52	0.0106	0.05	[0.48, 2.01]
Actual Treatment	**Four hourly**	0.6526	0.3915	4	1.67	0.1709	0.05	[-0.43, 1.74]
Actual Treatment	**Two hourly**	0						

Supplemental oxygen

Mean supplemental oxygen levels within the suctioning intervals, between the infants in Part Two varied from 21% (minimum) to 61% (maximum). The mean for all infants, of the combined means being 27% (SD 5.3, median 25%, [IQR, 22–30%]). Individual means for the infants over the study period can be seen in Table 37.

Table 37
Mean Levels of Supplemental Oxygen per Infant Part Two.

Analysis Variable: Mean FiO_2			
Infant ID	**M (SD)**	**Median**	**IQR**
2-100	32.3(2.7)	32.4	30.5-33.8
2-110	23.3(1.8)	22.8	21.9-24
2-120	24.4(2.3)	23.4	22.3-25.9
2-130	22.6(1.3)	22.2	21.8-23.4
2-140	32.5(5)	31.3	29.7-34.2
2-150	28.5(3.9)	29.3	25.6-31.3
Overall	26.7(5.3)	25	22.3-30.1

The percentage in time in supplemental oxygen varied daily from 2% of the time (minimum) to 100% of the time (mean 61% of the time, SD 38.6, median 70% of the time (IQR 17–100%). This can be seen in *Figure 14*.

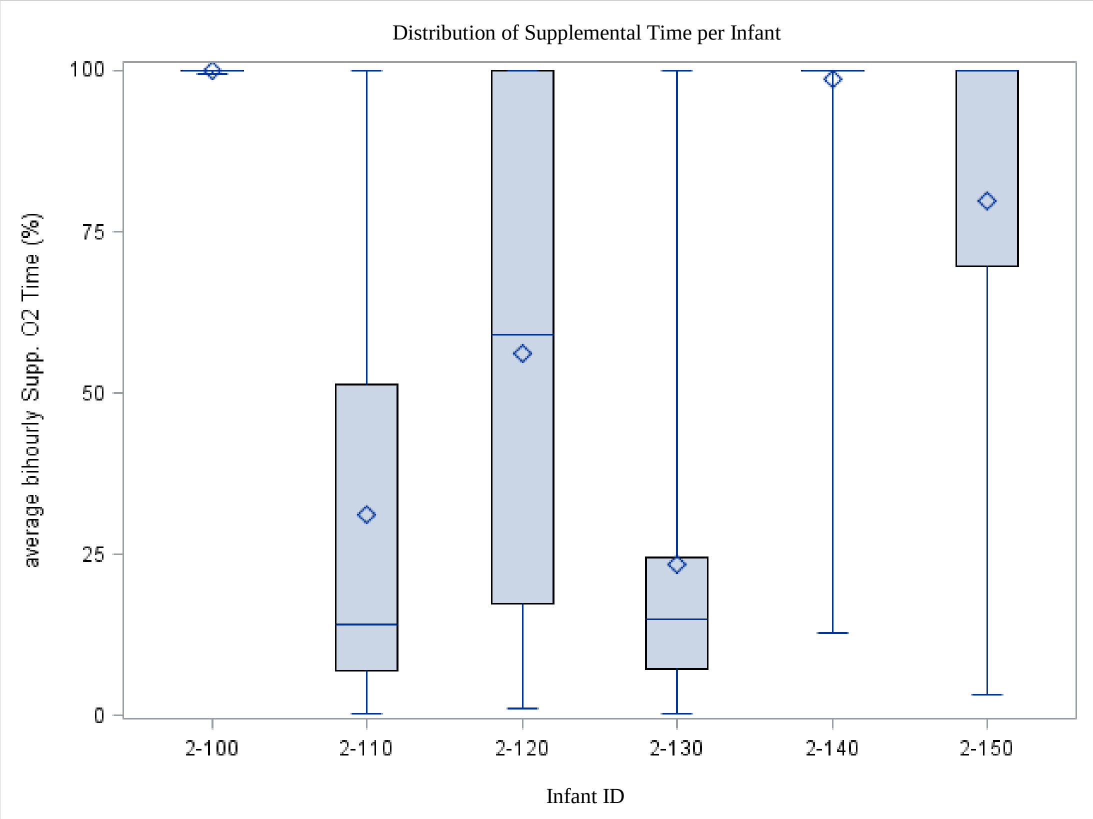

Figure 14. Distribution of Percentage of Time in Supplemental Oxygen Bihourly per Infant Part Two.

When data were analysed for the fixed effects estimates amongst the six infants, three infants demonstrated a reduced supplementary oxygen requirement and the other three demonstrated an increased supplementary oxygen requirement within the 2 hourly suctioning regime. However, the standard errors are larger than the random effect estimates for the difference between the 4 hourly and 2 hourly suctioning regimes, in all infants. The fixed effect, which is the estimate for all infants, for the difference in time in supplemental oxygen is between 4 hourly and 2 hourly is 0.32 (SE: 0.52) (see Table 38). The fixed effect is the mean difference between two groups. The random effect for each infant is the variation this infant deviates from the grant mean of the group.

Time in oxygen saturation target zone (SaO_2 88-92%)

Amongst the six infants, two of them showed a higher percentage of time in the targeted oxygen saturation zone in the 2 hourly suctioning regime and one had a higher percentage of time in the targeted oxygen saturation zone in the 4 hourly suctioning regime. The fixed effect, which is an estimate for all infants, of the difference between 4 and 2 hourly is 1.24 (SE: 2.88). Infant 2-100 only received 2 hourly suctioning, so effect cannot be determined and infant 2-150 only had 1 day in 2 hourly suctioning, which was a wash out day and thus is inconclusive. Compared with the random effect, the variation across the infants and between groups can be seen (see Table 39). However, the fixed effect is very small and so conclusions cannot be drawn.

Table 38
Fixed Effect, Predicted Random Effect and Predicted Level for Supplemental Oxygen for each Infant, for each Suctioning Frequency per Infant Part Two.

Supplemental Oxygen			**Estimate**	**SE**	
		Fixed effect	0.12	3.25	
Predicted random effect for each baby					**Predicted Oxygen Level**
	2-100	**Four hourly**	0.00	5.31	26.2
		Two hourly	6.07	2.31	32.1
	2-110	**Four hourly**	-8.53	2.52	17.6
		Two hourly	-2.65	2.24	23.4
	2-120	**Four hourly**	-0.19	2.46	26.0
		Two hourly	-3.29	2.26	22.8
	2-130	**Four hourly**	-2.07	2.49	24.1
		Two hourly	-3.95	2.23	22.1
	2-140	**Four hourly**	6.77	2.45	32.9
		Two hourly	5.89	2.24	31.9
	2-150	**Four hourly**	4.01	2.49	30.2
		Two hourly	-2.07	2.35	24.0

The percentage of time in the target oxygen saturation zone of 88-92% differed between the infants. The daily mean from bihourly recorded data were 15% of the time (minimum) to 41% of the time (maximum) (mean 28%, SD 5.7, median 27.6% [IQR, 27–32%]). The distribution of the daily means is demonstrated in *Figure* 15.

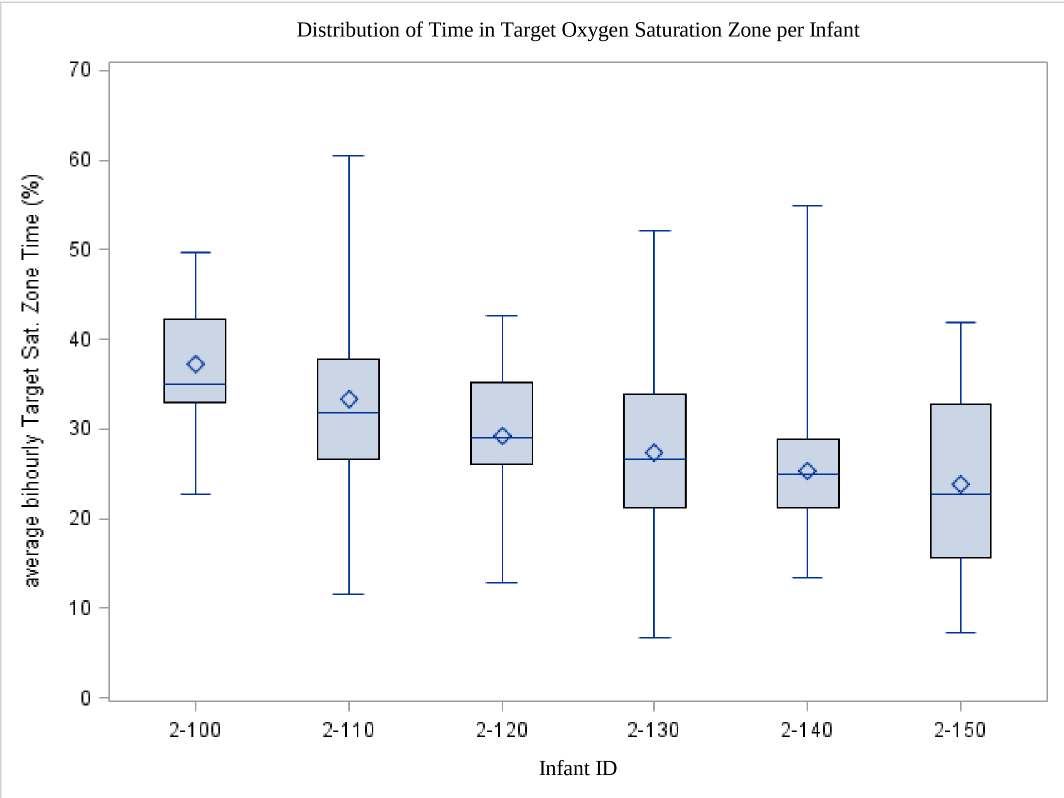

Figure 15. Distribution of Percentage of Time in Oxygen Saturation Zone for Bihourly Interval per Infant Part Two.

Bradycardias

Heart rate was recorded every 2 seconds and bradycardias were identified when the heart rate dropped below 90 bpm. The median number of bradycardias were identified hourly for individual infants and is represented in *Figure 16*. The daily hourly mean number of bradycardias ranging 0 (minimum) to 6 (maximum). The mean number of bradycardias for all infants was 1.1 per hour (SD 1.2, median 0.7 [IQR, 0.4–1.4]).

Table 39

Fixed Effect, Predicted Random Effect and Predicted Percentages for Percentage of Time in Oxygen Saturation Target Zone for each Infant, Part Two.

Oxygen Saturation Target Zone %		**Estimate**	**SE**	**Predicted Oxygen Targeted Zone %**
	Fixed effect	-1.36	2.99	
Predicted random effect for each baby				
2-100	**Four hourly**	0.00	4.66	27.75
	Two hourly	6.23	2.46	35.34
2-110	**Four hourly**	0.25	2.59	28.00
	Two hourly	5.54	2.17	34.65
2-120	**Four hourly**	-0.92	2.45	26.82
	Two hourly	2.12	2.20	31.24
2-130	**Four hourly**	4.27	2.59	32.02
	Two hourly	-3.17	2.14	25.95
2-140	**Four hourly**	-2.03	2.44	25.72
	Two hourly	-3.42	2.39	25.70
2-150	**Four hourly**	-1.57	2.66	26.18
	Two hourly	-7.31	2.48	21.80

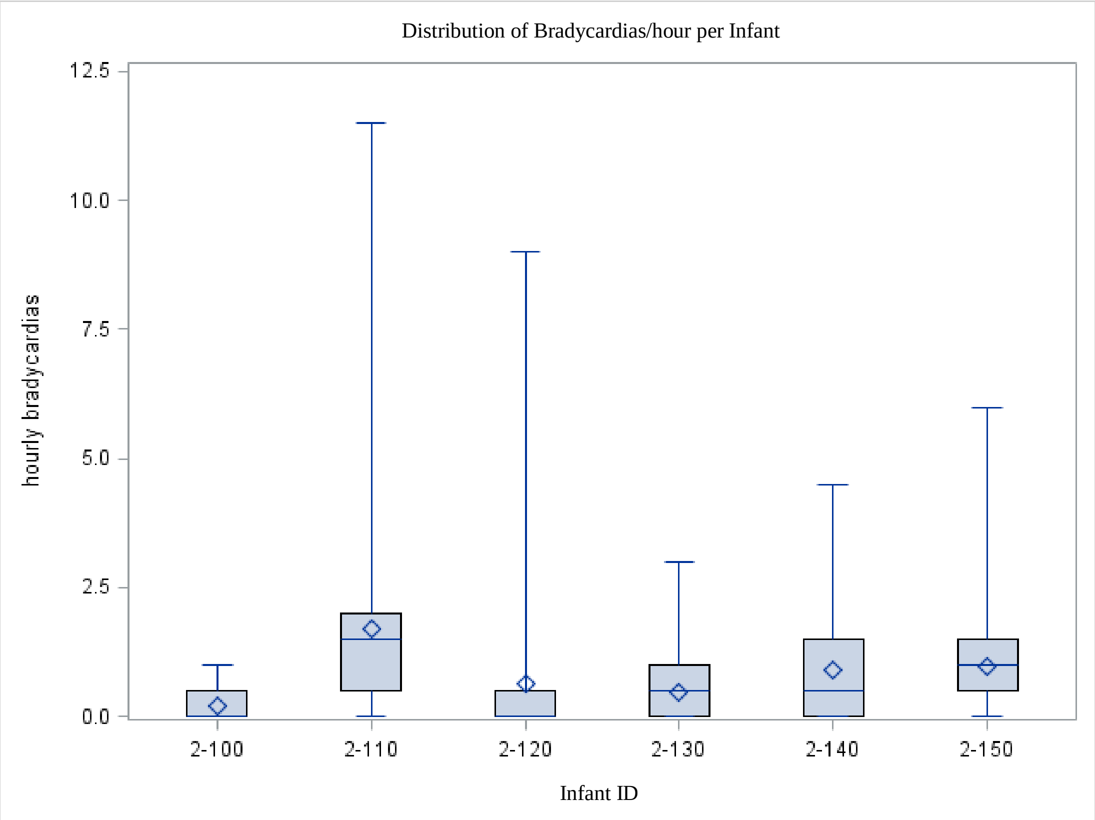

Figure 16. Distribution of Bradycardias/hour per Infant Part Two.

When analysed for estimation of fixed effect, there was a statistically significant trend in hourly bradycardia episodes between 4 hourly and 2 hourly suctioning regimes. Amongst the six infants, the fixed effect demonstrated that there were 0.7 more bradycardias per hour with 4 hourly suctioning (SE: 0.2 and 95% CI [-0.003, 1.3]), compared to 2 hourly suctioning (see Table 40). As demonstrated in *Figure 17*, when bradycardias were separated into suctioning regimes, there were fewer bradycardias within the 2 hourly suctioning regime than the 4 hourly.

Table 40
Estimate of Predicted Hourly Bradycardias for 4 and 2 hourly Suctioning Part Two.

Effect	Actual Treatment	Estimate	SE	DF	t Value	Pr > |t|	Alpha	95% CI
Intercept		0.6208	0.23	4	2.67	0.0555	0.05	[-0.02, 1.27]
Actual Treatment	**Four hourly**	0.7	0.2	4	2.76	0.0507	0.05	[-0.003, 1.32]
Actual Treatment	**Two hourly**	0	.	.	.	.	.	. .

When compared individually for bradycardias, infants 2-110 and 2-130 had a higher predicted hourly bradycardia rate for 2 hourly suctioning compared to 4 hourly suctioning; 0.9 (SE: .03) and 0.5 (SE: 0.3) in the 4 hourly regime and 1.4 (SE: 0.3) and 1.3 (SE: 0.3) in the 2 hourly regime, respectively. However, infants 2-120 and 2-140 had a lower predicted hourly bradycardia rate in 2 hourly suctioning when compared to 4 hourly suctioning; 1.4 (SE: 0.3) and 1.3 (SE: 0.3) in the 4 hourly regime and 0.4 (SE: 0.3) and 0.5 (SE: 0.3) in the 2 hourly regime, respectively (see Table 41). Infant 2-100 and 2-150 did not participate in the full study period. The estimate between both 2 hourly and 4 hourly suctioning regimes in Table 41, demonstrate conflicting results for the two suctioning regimes.

Based on the pilot study of six infants, it is not conclusive if the 2 hourly suctioning frequency achieves better outcomes when compared to the 4 hourly suctioning frequency, although the hourly desaturation demonstrates a statistical significant difference in favour of the 2 hourly suctioning regime, and a statistically significant trend in hourly bradycardias episodes.

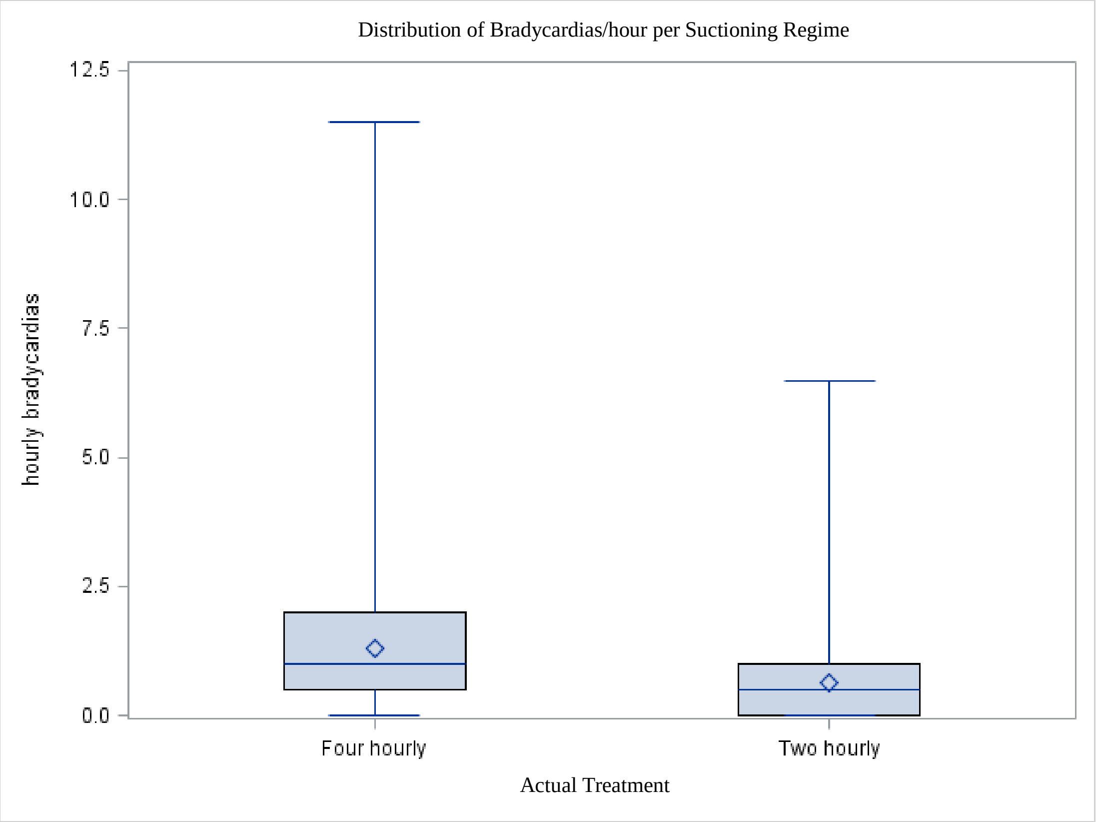

Figure 17 Distribution of Bradycardias for all Infants According to Suctioning Regime Part Two.

Effect of suctioning

The effect of suctioning was analysed, as in Part One, using the mean level from the previous suctioning interval for supplemental oxygen, oxygen saturation, and heart rate. These were then compared to the highest supplemental oxygen, lowest oxygen saturation and lowest heart rate during a period of 10 minutes within the current suctioning episode and determining the length of time to recover to these previous suctioning interval means. Recovery was said to have occurred when the previous mean levels were reached and remained constant, above lower parameter of the target oxygen saturation zone of 88% for 80% of the time, for 2 minutes minimum. Where the previous oxygen saturation mean was below the target saturation zone, recovery was defined as when the oxygen saturation level returned to 88%.

Table 41
Estimate of and Predicted Bradycardias per Hourly Period Comparing 4 hourly to 2 hourly Suctioning for each Infant, Part Two.

Effect	Infant ID	Actual Treatment	Estimate	SE	DF	t Valu e	Pr > |t|	Predicted Hourly Bradycardia
Intercept	**2-100**		-0.2171	0.318	374	-0.68	0.4946	
Actual Treatment	**2-100**	**Four hourly**	0.0	0.3	374	0	1	**1.3**
Actual Treatment	**2-100**	**Two hourly**	-0.1	0.3	374	-0.47	0.6402	**0.5**
Intercept	**2-110**		0.7	0.3	374	2.47	0.014	**2.0**
Actual Treatment	**2-110**	**Four hourly**	0.3	0.3	374	1.09	0.2762	**0.9**
Actual Treatment	**2-110**	**Two hourly**	0.1	0.3	374	0.48	0.632	**1.4**
Intercept	**2-120**		-0.2	0.3	374	-0.62	0.5356	**0.5**
Actual Treatment	**2-120**	**Four hourly**	0.1	0.3	374	0.54	0.5926	**1.4**
Actual Treatment	**2-120**	**Two hourly**	-0.2	0.3	374	-0.95	0.3428	**0.4**
Intercept	**2-130**		-0.3	0.3	374	-0.96	0.3367	**1.0**
Actual Treatment	**2-130**	**Four hourly**	-0.2	0.3	374	-0.62	0.5383	**0.5**
Actual Treatment	**2-130**	**Two hourly**	0.0	0.3	374	0.01	0.9928	**1.3**
Intercept	**2-140**		0.0	0.3	374	-0.14	0.8922	**0.6**
Actual Treatment	**2-140**	**Four hourly**	0.1	0.3	374	0.25	0.8032	**1.3**
Actual Treatment	**2-140**	**Two hourly**	-0.1	0.3	374	-0.34	0.733	**0.5**
Intercept	**2-150**		0.0	0.3	374	0.03	0.9795	**1.3**
Actual Treatment	**2-150**	**Four hourly**	-0.3	0.3	374	-1.24	0.2155	**0.3**
Actual Treatment	**2-150**	**Two hourly**	0.3	0.3	374	1.25	0.211	**1.6**

There were 257 periods available where all the data were available for both the previous suctioning interval and the current suctioning episode. Of these periods, 83 periods demonstrated a difference in supplemental oxygen, 190 periods where there was a difference in the heart rate and 254 periods where the oxygen saturation level altered between the previous suctioning interval and the current suctioning episode. Recovery time for supplemental oxygen was recorded in minutes due to the length of time to recovery and as the data were recorded in 30 second segments. The mean length of time for the recovery of supplemental oxygen to the previous suctioning interval mean was 26.1 minutes (SD 26.1), for those periods where there was a difference. The median was 15 minutes (IQR 7–36 minutes). The maximum times for recovery to the previous suctioning interval mean being 96 minutes maximum and the minimum time to recover being 0 minutes.

"No change" was marked for an episode when the level of supplemental oxygen did not alter throughout the whole of the current suctioning interval, even when there was a difference in supplemental oxygen between the previous suctioning interval and the current suctioning episode. This meant that for the whole suctioning interval the supplemental oxygen level remained at the new level and was marked as "0" on analysis for minimum time.

Recovery time for heart rate and oxygen saturation were recorded in seconds, as data were recorded in 2 second blocks and was more reflective of the speed the heart rate and oxygen saturation recovered. The mean time for the heart rate to recover was 80.8 seconds (SD 130.2), and the median 31 seconds (IQR, 14–78 seconds). The shortest length of time for recovery was 4 seconds and the longest time to recover was 826 seconds. In some instances, the mean from the previous suctioning interval was higher or at the higher end of normal parameters for heart rate. In those instances where the time to reach that heart rate was greater than 20 minutes, the recovery time was recorded when the heart rate returned to within 20 beats of the mean heart rate of the previous suctioning interval.

Within the recovery time for desaturations, the mean was 128.2 seconds (SD 133.2), and the median 93 seconds (IQR, 42–170 seconds). The minimum time for recovery of oxygen saturation to the mean of the previous suctioning interval, being 2 seconds and the maximum, 846 seconds. There were also instances where the oxygen saturation in the previous suctioning interval was higher than the target oxygen saturation zone. When this occurred and recovery time exceeded 20 minutes, the time it took for the infant to recover to 88% oxygen saturation was recorded.

Table 42
Time to Recover to Previous Suctioning Episode Means, Part Two.

Phase	N Obs	Variable	n	*M*(SD)	Median	IQR	Min	Max
2	**257**	**Time to Recover FiO_2 (min)**	83	26.1 (26.1)	15.0	7-36	0.0	96
		Time to Recover HR (sec)	190	80.8 (130.2)	31.0	14-78	4.0	826
		Time to Recover SaO_2 (sec)	254	128.2 (133.2)	93.0	42-170	2.0	846

Differences between the means of the previous suctioning interval and the highest supplemental oxygen and lowest heart rate and oxygen saturation level in the current suction episode varied greatly. The mean change in supplemental oxygen was 2% (SD 8.3), median being 0 (IQR, -1–2%) and minimum being -29% and maximum 56% increase in supplemental oxygen over the suctioning episode compared to previous suctioning interval. Within the heart rate, differences were noted to be -108 bpm (a drop of 108) and 13 bpm (an increase of 13) when compared to the mean heart rate for the previous suctioning interval. The mean difference being -44 bpm (SD 29), median -43 bpm (IQR, -67 bpm to -20 bpm). When oxygen saturation was analysed differences varied from -84 (lowest) to 0 (highest), mean change in oxygen saturation being -29% (SD 16), median change in oxygen saturation being -27% (IQR, -36%–-18%) (see Table 43).

Table 43
Differences Between Previous Suction Interval Means and Suctioning Episode Part Two.

N Obs	Variable	n	*M* (SD)	Median	IQR	Min	Max
257	**Difference between the highest FiO2 and average of the pre-suction**	257	2 (8.3)	0.0	-1.2 to 2.2	-29.	55.8
	Difference between the lowest heart rate and the average of the pre-suction heart rate	257	-44 (29)	-43	-67 to -20	-108	13
	Difference between the lowest SaO_2 and the average of the pre-suction Sa O2	257	-29 (16)	-27	-36to -18	-84	0

Generally, heart rate recovered quicker than oxygen saturation and the supplemental oxygen level remained unchanged within the majority of suctioning intervals. When there were desaturations, only 33% of the suctioning intervals reviewed had supplemental oxygen changed during the time period. These findings lead to further analysis of the data, to examine these periods and understand the process. Periods of prolonged desaturations were reviewed, where the oxygen saturation recovery time was ≥250 seconds, as it was felt that infants should have completed suctioning at this time and should have recovered. In all, within Part Two, 30 instances were noted where the infant took ≥250 seconds to recover to the mean oxygen saturation of the previous suctioning interval, during the suctioning episode. The means from the previous suctioning intervals varied from 81-94% SaO_2, with mean 90% (SD 3), median 90% (IQR, 89–91%).

The time frame for the infants' oxygen saturations to recover to be within the target oxygen saturation zone, varied from 114 seconds to 846 seconds, mean 128 seconds (SD 166.9), median 350 seconds (IQR 271–476 seconds). The majority of the time the oxygen saturations were sitting within the 70-80% range. During these episodes there were a varied range of supplemental oxygen differences between the previous suctioning interval and the supplemental oxygen given during these prolonged desaturations, -5% (minimum) and 16% (maximum). However, considering the duration of the desaturation and the lowest desaturation, the supplemental oxygen levels did not alter greatly. The median being 0% change (IQR -1–2%) (see Table 44).

Also of note were the numbers of desaturations within this recovery period. Due to the nature of data analysis, the desaturations were logged as blocks of five of <80% SaO_2, as recorded on the saturation monitor. This was to account for the 2 second recording blocks of these parameters. Therefore, when an infant's SaO_2 was <80% for 10 seconds or more, this was marked as a desaturation. However, if the saturation returned to ≥80% for 2 seconds or more then dropped <80% again this was counted as another desaturation. Within these periods of prolonged recovery there were a number of desaturations noted ranging from 1 (minimum) to 18 (maximum) ≥10 seconds duration and 0 (minimum) to 5 (maximum) for ≥60 seconds duration. The median being 4 for ≥10 seconds duration (IQR, 3–7) and 2 for ≥60 seconds duration (IQR, 1–2.75).

Table 44

Episodes of Prolonged Desaturation with Time to Return to ≥88% SaO_2, Part Two.

Time recover Sao_2 (sec)	**Difference in FiO_2%**	**Desats during recovery ≥10sec**	**Desats during recovery ≥60sec**	**Probe off Number**	**Time recover SaO_2 88% (Sec)**	**Range SaO_2 Level**
428	2	7	5		428	70s
356	0	4	2		356	70s-low 80s
846	4	11	5		846	low 80s
540	16	5	2		540	70s-low 80s
705	-1	14	3		706	70s-low 80s
428	-1	11	2		428	70s-low 80s
260	3	2	2		252	70s-low 80s
322	0	5	0		260	low 80s
570	0	18	4		570	70s-low 80s
328	0	2	2		328	70s-low 80s
280	-2	3	1		268	70s-low 80s
274	15	3	1	1	114	70s
578	-1	6	3		576	70s
296	-2	4	0		256	70s-low 80s
292	-1	11	1		292	70s-low 80s
488	0	4	1		404	70s-low 80s
400	0	1	0		326	low 80s
278	-1	5	0		254	mid 80s
510	-	2	1		468	70s-low 80s
390	-5	2	1		386	70s-low 80s
514	-1	4	2	1	500	70s-low 80s
770	5	10	3	1	766	70s
308	0	9	4	2	308	70s-low 80s
484	2	3	3		466	70s-low 80s
364	11	4	2		344	70s-low 80s
262	-1	3	2		262	60s-70s
424	-1	4	2		416	70s-low 80
282	-3	4	1		282	70s-low 80s
292	2	5	0		238	70s-low 80s
360	7	7	2		340	70s-low 80s

Demographics of all infants <30 weeks gestation admitted during the study period

Demographics were obtained for all infants admitted during the study period of 1st September 2011 and 30th November 2012. This was to allow comparison of study group to general population of age group, within the unit during that period. A total of 75 infants ≤30 weeks gestation, were admitted to the study NNU. These infants consisted of 32 females and 43 males with a mean gestation of 27.4 weeks, median 28 (SD 1.91, 23 weeks minimum and 29+6 weeks maximum). The mean weight was 1081.6 g (median 1020, SD 313, 480 g minimum and 1820 g maximum). Ethnicity within this group was identified by the family as being 21 Māori (28%), 31 Pasifika (41%), 13 Asian (17%) and 10 European (13%). Antenatal steroids were received by 59 mothers (79%) and 45 (60%) received antibiotics prior to delivery. Thirty five infants (47%) had normal vaginal deliveries, 12 (16%) were breech deliveries and 28 (37%) were delivered by LSCS. During the first 14 days 8 infants died (11%) (see Table 45).

In regards to respiratory support (see Table 46) 45 (60%) were intubated and mean ventilation hours 73.2 (SD 156.8, median 8, zero hours minimum and 1044 hours maximum). Of these hours the mean for HFOV was 25.5 (SD 78.9, median zero hours, zero hours minimum and 440 hours maximum). Some infants were given high flow oxygen or air, with the mean hours being 93.2 (SD 172.5, median zero hours, zero hours minimum and 910 hours maximum). Surfactant was given to 37 infants (49%).

Respiratory support for infants who survived to 14 days of age varied with 14 self-ventilating (21%), 51 on CPAP (76%), eight of whom were cycling on and off CPAP, and two requiring ventilation (3%). Of these infants 54 were on air (80%), seven required 21-25% supplemental oxygen (10%) and six required >25% supplemental oxygen (10%), meaning that 20% of the infants admitted during the study period required supplementary oxygen at 14 days of age.

Table 45

Participants Demographics and Characteristics, All Admission, Study Period

	All Infants n(%) (N=75)	**Part One n(%) (N=21)**	**Part Two n(%) (N=6)**
Female	32(43)	7(33)	2(33)
Male	45(57)	14(67)	4(67)
Asian	12(17)%	1(5)	1(17)
Māori	20(28)	5(29)	2(33)
Pasifika	32(41)	11(52)	2(33)
Other European	11(13)	4(19)	1(17)
Completed Steroids	59(79)	12(57)	4(67)
PROM	18(24)	3(14)	2(33)
Maternal Antibiotics	45(60)	14(67)	5(83)
Breech	12(16)	1(5)	3(50)
LSCS	28(37)	7(33)	0(0)
Vaginal	35(47)	13(62)	3(50)
IUGR	11(15)	4(19)	0(0)
PDA	33(45)	9(43)	6(100)
PDA treated	26(35)	8(38)	5(83)
ROP Stage 1	17(27)	5(24)	2(40)
ROP Stage 2	18(28)	5(24)	2(40)
ROP Stage 3	1(2)	0(0)	0(0)
IVH Grade I	6(10)	1(5)	0(0)
IVH Grade II	3(5)	2(9)	0(0)
IVH Grade III	1(2)	0(0)	0(0)
IVH Grade IV	2(3)	1(5)	0(0)
Intubated	45(60)	12(57)	5(83)
Home oxygen	2(3)	1(5)	0(0)

Of those who survived (n=62) 13 infants (21%) had an oxygen requirement of at least 28 days. When the infants were 36 weeks corrected gestation (n=62) 39 infants (63%) were self-ventilating and 25 infants (37%) required some form of respiratory support. CPAP pressure varied from 5 cmH_2O to 9 cm H_20 (mean 6 cm H_2O, SD 1.3, median 6 cm H_2O, [IQR, 5–8 cm H_2O]). Of the 62 infants who survived to discharge, only two (3%) were discharged home on supplementary oxygen. A separate table to define some of the characteristics of infants admitted during the study period, but were not in the cohort of participants is given in Table 47.

Table 46
Variables for all Infants Admitted During Study Period.

Variable	N	*M*(SD)	Median	Min	Max
Gestational age (weeks+days)	75	27+2(1.91)	28	23	29+6
Weight (g)	75	1081.6(313)	1020	480	1820
Apgars 1 minute	74	5(2.1)	5	1	9
Apgars 5 minutes	73	7(2.3)	7	0	10
Length of stay (days)	62	89(44.4)	79	42	364
CPAP (Hours)	74	877.9(595.1)	922	0	2597
Ventilation (Hours)	73	73.2(156.8)	8	0	446
HFOV (Hours)	73	25.5(78.9)	0.0	0	20
High Flow (Hours)	74	93.2(172.7)	0	0	910

Necrotising enterocolitis was diagnosed in three infants (4%), with two requiring surgery and one receiving medical treatment. PDA was present in 33 infants (45%) and 26 (35%) required treatment. ROP was absent in 27 infants (44%); Grade 1 ROP was diagnosed in 16 infants (26%), Grade 2 ROP being diagnosed with 17 infants (26%), and Grade 3 ROP diagnosed with one infant (2%). A further one infant having Grade 1 in one eye and Grade 2 in the other (2%). Full oral feeds were reached in 64 infants by 7 days minimum to 44 days maximum, (mean 14.3 days, SD 8, median 12, [IQR, 10–14 days]). In the infants that survived to discharge, IVH was diagnosed in 12 infants (20%), six infants having Grade I (10%), three infants with Grade II (5%), one infant with Grade III (2%) and two infants with Grade IV (3%), one of whom also had PVL. Benign bilateral ventricular cysts were diagnosed in one further infant. Length of stay varied amongst the infants from 42 days to 364 days (mean 89 days, SD44, median 79 days, [IQR, 67–96 days]).

Table 47
Variables for Infants Admitted During Study Period, Not in the Study.

Variable	N	*M*(SD)	Median	Min	Max
Gestational age (weeks+days)	48	27+2(2.03)	28	23	29+6
Weight (g)	48	1057.2(339.4)	1020	480	1820
Apgars 1 minute	47	5(2.3)	5	1	9
Apgars 5 minutes	46	7(2.6)	7	0	10
Length of stay (days)	36	82.8(50.8)	74	42	364
CPAP (Hours)	47	657.1(535)	667	0	1814
Ventilation (Hours)	46	46.8(90.6)	5.5	0	446
HFOV (Hours)	46	23.1(76.9)	0	0	440
High Flow (Hours)	47	33.9(88.8)	0	0	384

Conclusion

The results of the research were presented within this chapter, categorised into each of the study parts with subheadings to identify the differential findings for each of the outcomes investigated. Demographics for each study group were described and the main outcomes identified for the study; percentage of time in target saturation zone (88-92%), amount of daily supplementary oxygen and the hourly desaturation and bradycardia frequency, were exhibited. Secondary outcomes were reported and the comparison of the study group to the general population of infants admitted to the study NNU ≤30 weeks gestation, during the study period, given. Figures and tables were used within the chapter to support these results.

Chapter Five

Discussion

Introduction

In the previous chapter, the results from the analysis of the data were presented together with tables and figures to demonstrate the findings. Within this chapter these findings will now be examined, exploring the outcomes identified from the data, comparing these to current literature and research. The aim of the study will be discussed in relation to these findings. Identification of the limitations of the study, the implications for practice, as well as recommendations for future studies in the area of suctioning premature infants requiring CPAP will also be reviewed.

Part One

Demographics

Infants who participated within Part One of the research had similar characteristics when compared with all other infants admitted during the study period that were ≤30 weeks gestation. The gestation mean in the rest of the population was 28 weeks compared to 27.4 weeks in the study group. Gender, weight, antenatal steroids, apgars, IUGR, intubation and PDA, were also similar. Ethnicity was similar to all admissions during the study period. However, it is important to note the percentages of the infants ethnicity compared to the demographics of the community. The local community for the study NNU has the highest population of Māori and Pasifika in New Zealand with Māori representing 17% of the population, Pasifika 21%, Asian 16% and other

(European being a component of this) 46% (CMDHB, 2008). The study population for Part One comprised of Māori 24%, Pasifika 52%, Asian 5% and other/European 19%. Of note are the over representation of Māori and Pasifika infants within the study group when compared to their ethnic representation within the community, nearly double. Unpublished figures, show 50% of all women who sought no antenatal care, delivering at the maternity unit attached to the study NNU, in 2007-8, were Māori, with 38% Pasifika (Shingawa, 2008). When compared with total deliveries; 21% were Māori and 30% Pasifika (Shingawa, 2008). Studies have shown a greater risk of morbidity or mortality in infants born to women who receive no antenatal care increasing the likelihood of requiring neonatal unit admission (Herbst et al., 2003; Vintzileos et al., 2002). This may be the rationale for the over representation of these two ethnicities within the study group.

IVH within Part One of the study occurred in 19% of the infants with none having Grade III and 5% grade IV. Groenendaal, Termote, van der Heide-Jalving, van Haastert, and de Vries (2010), found in infants 25-30 weeks gestation that 5.7% of infants had Grade III and 5.7% had Grade IV IVH. There have been studies that discuss the role suctioning can have on intracranial pressure and the risk of IVH (Durand et al, 1989; Fanconi & Duc, 1987; Kaiser et al., 2008; Singh et al., 1991). However, Linder et al. (2003) found lower grades of IVH (15% overall) in infants who received increased suctioning frequency. Within Part One IVH was present in 19% of infants, which is slightly higher than the Linder et al. (2003) study, yet still may be comparable. Though Linder et al.'s (2003) study focused on ETT suctioning, which may be more stressful than nasopharyngeal suctioning, parallels may be taken from the study to support the practice of frequent suctioning to maintain a patent airway.

The results within Part One of this study demonstrated lower rates of Grade III-IV IVH (5%) compared to Groenendaal et al. (2010) and Linder et al. (2003) with 5.7% and 5.6% respectively. Linder et al. (2003) found that 9.5 % of infants had Grade I-II, compared to 14.2% in Part One of the study. Due to the small numbers within the study, it would be difficult to draw conclusions. Nevertheless, the higher number of Grade I-II may reflect a reduction in severity of IVH amongst infants receiving frequent suctioning. However, the results from this study would be better compared to similar populations within Australasia and research that is more current, to draw conclusions on this aspect of the findings.

Isaza, Arora, Bal, and Chaudhary (2013) found the incidence of ROP in infants 25-30 weeks gestation to be 10.5% for Stage 1, 29.8% for Stage 2 and 12.8% for Stage 3, with 63% having no ROP. When compared to the overall findings for admissions for the study period for the same population group 43% had no ROP, 27 % had Stage 1, 3 % had Stage 1 in one eye and Stage 2 in the other, 28% had Stage 2 and 2% had Stage 3. Overall there were more infants in the study NNU with ROP, although they had less Stage 3 and more Stage 1 compared to Isaza et al. (2013), which may be reflective of the amount of supplemental oxygen given. Though again, small numbers may limit the conclusiveness of the results.

All the demographics were analysed for both parts of the study, using association of the covariates and found that only gestational age weight, haemoglobin, CPAP hours and ventilation hours had any correlation. Older infants were found to not require as much ventilation as those of a lesser gestation as with heavier infants not requiring as many hours of CPAP and ventilation. This would be expected, as the older gestational age infants are more often heavier and have more mature lungs, requiring less respiratory support. Haemoglobin level on admission was found to be weakly associated with the hours of CPAP, which would be reflective of the oxygen carrying capacity of the blood. The higher haemoglobin levels could mean the better oxygenated the infant and thus possibly less need for respiratory support.

Respiratory support

The most significant areas of difference was observed in the hours of CPAP (657.1 hours in all other infants compared to Part One infants with 877.9 hours), ventilation (46.8 hours compared to 73.2 hours) and high flow air or oxygen (33.9 hours and 93.2 hours), along with length of stay within the unit (64.47 days compared to 91.3 days). However, this does not account for one infant who was still admitted in the unit at the end of the study period and remained in the unit for 364 days, due to BPD. The increased length of stay would have been reflective of the need of the infants admitted to the study who required respiratory support and consequently the effect that respiratory support then had on lung development and the risk of BPD.

The rate of BPD was 37% for all infants born ≤30weeks gestation who were admitted during the study period, and survived to discharge (including study participants). When compared to the infants in Part One of the study, 48% of those infants had respiratory support at 36 weeks and thus diagnosed with BPD. Of these infants, 7 were born prior to 28 weeks with 2 requiring respiratory support at 36 weeks (29%). However, when all infants born < 28 weeks, who were admitted to the unit during the study period were included, 45% required respiratory support at 36 weeks gestation. Laughon et al. (2009) found that 51% of infants born prior to 28 weeks developed BPD. The study demonstrated a lower level of BPD for the infants within Part One, which may be reflective of the way respiratory support is delivered and care practices within the study NNU. Of the other infants in Part One of the study, 6 (43%) required respiratory support compared to 13 (33%) of 40 infants ≥28-≤30 weeks gestation admitted during the study period. The overall BPD rate was 37% (23 of the 62) in infants who survived to discharge. There was no concise data to compare the overall results with, hence the infants' were categorised into gestation weeks. Nonetheless, there was an obvious reduction on in infants with BPD compared to other research, although, due to the small number of participants the results may not be conclusive.

When compared to an oxygen requirement for at least 28 days, Part One had two infants out of 21, who had an oxygen requirement (one <28 weeks gestation and one ≥28 to ≤30 weeks gestation), yet 10 infants went on to have respiratory support at 36 weeks gestation. Of the rest of admissions during the study period, a further seven infants had an oxygen requirement for at least 28 days, two of whom died prior to reaching 36 weeks gestation. Of interest were the five infants who received doxapram during the study to support their continuation on CPAP. Of these infants, two had been on air at the commencement of the study and then developed an oxygen requirement and subsequently required respiratory support at 36 weeks and diagnosed with BPD. Both these infants were male and 28 weeks gestation. Only one other infant had respiratory support at 36 weeks gestation after doxapram, who was male and 25 weeks gestation. The other two infants were a male and a female at 24+5 weeks and 24+6 weeks gestation respectively, whom had an oxygen requirement at 14 days but no diagnosis of

BPD. It would be interesting to complete further studies on the outcomes of infants who received doxapram in relation to oxygen requirement at 14 days, gestation and subsequent diagnosis of BPD. Prins et al. (2013) found that doxapram reduced the number of infants requiring ventilation (64.8%), which is similar to the statistics found within Part One of the study. However, no research could be found in relation to doxapram and influence of BPD.

Frequency of suctioning

There was a wide variance of suctioning intervals, although the interval was mostly around 3 hours (mean) and reliability of the timing was dependent on staff remembering to push the monitor button prior to suctioning to record the time. Due to workloads and human error, this was not always accomplished. Hence, large amounts of data were not utilised. The impact of the frequency of suctioning will be discussed within each parameter in the subheadings. However, overall the difference between the suctioning frequencies may have been too little and having a larger difference between the frequencies may have seen a more significant result in the analysis.

Oxygen Saturation

Overall, there was a reduction in the average level of oxygen saturation with increased suctioning frequency. However, even though this was seen as significant, there was only a minimal effect. With every increase in one suctioning interval per day, the mean oxygen saturation dropped 0.22%. Hence, there needed to be an increase in suctioning frequency of 4.5 per day to get a 1% decrease in mean oxygen saturation. The median oxygen saturation was 94% for the infants in Part One, which is above the target oxygen saturation level. The current levels aimed for within the study unit were 88–92%, this being the oxygen saturation target zone commonly used by many neonatal units within New Zealand (König & Holberton, 2012). During data analysis, oxygen saturation levels were found to be low for prolonged periods after suctioning, with minimal or no increase in supplemental oxygen during this time. This may account for some of the effect in the reduction of oxygen saturation around suctioning, as the more frequent an infant was suctioned and left to slowly recover with minimal supplemental oxygen, the lower the overall oxygen saturation would be. Hence, frequency of suctioning may have had a lesser impact on oxygen saturation within the study than the results suggest, due to this phenomenon within the study NNU’s practice.

If the reduction in saturation was related to the frequency of suctioning, the results may be more significant due to research demonstrating that higher levels should now be sought for premature infants, of above 90%. This is due to results from the BOOSTII study that demonstrated the increased incidence of mortality with lower saturations in infants <28 weeks (Stenson et al., 2013). The mortality rate for Part One was 0%, as all infants in this part of the study survived to discharge. However, the mortality rate for all infants admitted during the study period was 17% (13 infants). When all admissions during the study period are broken down into those infants <28 weeks, the rate changes to 35% (12 infants died out of 34 infants delivered <28 weeks gestation). This is higher than the rate found by Stenson et al. (2013) of 23.1%, although infants were excluded from their data if they were not expected to survive and with congenital abnormalities. It was also unclear if they included any infants’ ≤24 weeks.

If the infants in the study NNU born ≤24 weeks and those not expected to survive were removed from the statistics, the mortality rate dropped to 29%. This is still higher than Stenson et al. (2013) discovered and it is unclear if this would be significant, due to the small numbers within the study. Nevertheless, there may be a need to review the oxygen saturation target zone to determine if higher levels should be instigated, though being conscious of the increased risk of oxidative stress resulting from increased levels of oxygen circulating in the blood with higher oxygen saturation levels (Castillo et al., 2008).

When individual infants oxygen saturation means were reviewed, three infants' overall means were below 90%, 1-100 (28+5 weeks gestation), 1-130 (24+5 weeks gestation) and 1-170 (25 weeks gestation). The mean oxygen saturation for 1-130 and 1-170 were the lowest oxygen saturation of all the infants in Part One. However, only 1-100 and 1-170 went on to require respiratory support at 36 weeks, with 1-100 requiring home oxygen. Of note was that both 1-130 and 1-170 had the largest number of desaturations ≥10 seconds, and all 3 had a larger number of desaturations ≥60 seconds, although not the highest amongst the infants in Part One. These desaturations may account for the lower mean oxygen saturation levels. Interestingly 1-100 was >28 weeks and was the infant that went home on oxygen. It would have been expected that the other lesser gestation infants, that had lower means, would require home oxygen.

Gestational age was found to be of significance in that the older the infant the higher the oxygen saturation level. The increase of 1.2% per week increase in age, resulting in a 6% increase in oxygen saturation with 5 weeks increase in gestation. This finding may result from the increased respiratory drive with the older gestational aged infant and the improved lung development. Bhatt-Mehta and Schumacher (2003) discussed that apnoeas resulting from an immature respiratory centre were related inversely to gestational age and would thus explain this effect of gestational age on oxygen saturation level. This outcome was contradicted in the older gestational infant mentioned above, having a similar lower oxygen saturation mean to infants whom were almost 4 weeks younger than that particular infant was. However, PROM was associated with a decrease in the oxygen saturation, and increased risk of chorioamnionitis, which increases the risk of respiratory support and BPD (Been et al., 2009; Watterberg et al., 1996). The aforementioned infant had been exposed to PROM for 4 weeks, which may be the reason behind the lower oxygen saturation means and respiratory support.

Desaturations

Increased frequency of suctioning was found to be significantly associated with increased desaturations of ≥10 seconds, in the hourly model when the desaturation count was =0. However, 5.3 more suctioning intervals were required within a day to predict the chance of having one desaturation of ≥10 seconds per hour. This would be almost the equivalent of the difference in intervals between 2 hourly and 4 hourly suctioning an infant. With desaturations ≥60 seconds the outcome was similar with the estimation that predicted the number of desaturations ≥60 seconds to be 0.112 for every one increase in suctioning frequency per day, when desaturations were >0. Thus there would need to be 8.9 more suctioning interval per day for there to be one more desaturation ≥60 seconds per hour in that day. When desaturations were =0 then there was an increased chance of having a desaturation ≥60 seconds in a hour, with an increase of 7 suctioning intervals.

As expected the older the infant the less desaturations ≥10 seconds they had and the likelihood to have no desaturations ≥60 seconds each hour, when desaturation were >0. For every 1 week increase in gestational age there was 0.11 less of a desaturations ≥10 seconds. Interestingly female infants were more likely to experience longer desaturations than males, a slight contradiction to other research and anecdotal evidence that female infants have better respiratory outcomes than males (Ambalavanan et al., 2008), although there is no rationale as to why this occurred.

One of the key findings and of interest was that increasing the interval between suctioning, increased the risk of desaturation. This was evident both for desaturation ≥10 seconds and ≥60 seconds, when desaturation were =0. With every 1 hour 40 minutes an infant was left without suctioning there was an increase in the likelihood of another desaturation ≥10 seconds per hour and for every 3 hours 30 minutes increase in interval there was another desaturation ≥60 seconds per hour. These findings indicate the need to ensure suctioning be performed frequently enough to ensure infants are not compromised with the risk of increased desaturations.

Wallace (1998) discusses the need to base the requirement for suctioning around the condition of the infant and that research should support practice. This is a valid point and demonstrates the importance of ensuring suctioning is appropriate. The findings of this study suggest that less frequent suctioning may be beneficial. However, in relation to the number of desaturations that each infant had in each suctioning interval, the data from the secondary outcomes needs to be taken into consideration. When the data recorded for the effect of suctioning on each infant were analysed, it was noted that there were prolonged periods that the infants were left to recover during suctioning, without any increase in supplemental oxygen. During these periods there were a number of desaturations recorded. However, there were only 25 periods of prolonged recovery (≥250 seconds), but only 22% of desaturations recorded were associated with having the oxygen altered, leaving 88% of suctioning episodes where there was no increase in supplemental oxygen. Therefore, a number of desaturations could be attributed to the effect of insufficient oxygen, poor lung expansion or collapse due to the removal of the CPAP.

Lim et al. (2014) found that there were increased numbers of prolonged desaturations when infants were cared for by experienced nurses. The possible explanation given for this being that more experienced staff use a degree of patience, allowing the infant to recover themselves without alterations to supplemental oxygen. This could account for the results seen within this study. Although staff experience was not noted within the study, there were a number of instances where infants were left to recover for long periods of time. It is unclear if prolonged recovery times would impact on the outcomes of suctioning frequency.

Increased suctioning frequency would be affected more by this occurrence than longer suctioning intervals. As the more instances where CPAP was removed and lung expansion compromised, the more likely the infant would have been to desaturate; this effect being amplified by the lack of or minimal increase in supplemental oxygen. It would therefore be interesting to know what effect adequate supplemental oxygen administration would have had on the number of desaturations the infants had around the time of suctioning and whether this affected the outcome of the study. Also of interest would be the use of two staff while suctioning unstable infants, to ensure the period of CPAP removal during suctioning was minimised and supplemental oxygen administered during the procedure. Kerem et al. (1990) found that preoxygenation was most effective in reducing desaturation related to suctioning, yet this appeared to not be practiced or used minimally within the study NNU. The result of this being prolonged desaturations for some of these infants.

Therefore, the numbers of desaturations increased with more frequent suctioning, though this may be reflective of practices within the study NNU. In addition, it was found that when suctioning intervals were prolonged, the likelihood of desaturations was significantly increased within this population. However, the group studied were infants that required respiratory support and therefore were more at risk of desaturations and bradycardias. It would have been of interest to determine the effect and benefit frequency of suctioning had between the infants on air and those on supplemental oxygen.

Supplemental oxygen

Overall, the mean amount of supplemental oxygen that infants within Part One of the study received was minimal (median 22%). There was no analysis done on the effect suctioning had on the amount of supplemental oxygen, due to the volume of data to be analysed. However, this would have been of interest, as the level of supplemental oxygen appears low when compared to other research. Of the 21 infants in Part One, 8 infants (38%) received no supplemental oxygen throughout the study period. Of these infants seven were < 28 weeks, 4 (57%) of whom were on air at 14 days of age. Laughon et al. (2009) found in their study that only 20% of infants <28 weeks had consistently low levels (<23%) of supplemental oxygen. Of all infants born <28 weeks gestation within the study period, who survived to 14 days, 15 (58%) were on air at 14 days, five (19%) required ≤25% supplemental oxygen and six (23%) >25% supplemental oxygen, with eight infants (24%) who died prior to day 14. When compared to the results that Laughon et al. (2009) found, where 38% requiring >21% to ≤25% supplemental oxygen and 43% requiring >25% supplemental oxygen, the results from the study NNU are considerably lower. These differing results could be attributed to the method of respiratory support and the diligent airway management within the study NNU, with frequent suctioning. However, numbers within the study were small and therefore the results may not be conclusive.

Of all infants admitted during the study period, 16% required at least 28 days of supplemental oxygen. Overall 37% required respiratory support at 36 weeks gestation. The respiratory support was either CPAP or high flow, which may have been utilised with air or supplemental oxygen. Ehrenkranz et al. (2005) found that 77% of infants <32 weeks and <1000g had at least 28 days of supplemental oxygen, but only 39% required supplementary oxygen or respiratory support at 36 weeks. It would be difficult to compare this study with the research undertaken, as the population differs and it would be difficult to interpret the differences between each gestation age. Still some aspects can be discussed, such as the rate of respiratory support at 36 weeks being similar in both studies, although within the study NNU there were less infants requiring at least 28 days of supplemental oxygen. Again, this may be due to the respiratory support and airway management leading to less infants developing mild BPD, although this is not conclusive.

Severe BPD can lead to a need for home oxygen (Lagatta, Clark, Brousseau, Hoffmann, & Spitzer, 2013). Home oxygen was required for only one infant (4%) in Part One, with a total of two infants (3%) of all those born in the study period and surviving to discharge, requiring home oxygen. Lagatta et al. (2013) found that 27.6% of infants <29 weeks required home oxygen. In comparison the infants of similar gestation in Part One, only 7% went home on oxygen and for all infants admitted over the study period <29 weeks, only 5% of infants required home oxygen. This is a very significant difference and could be reflective of practices within the unit around respiratory support and care, although the inclusion of more infants would give more definitive results and comparisons.

Time in oxygen saturation target zone (SaO_2 88–92%)

Analysis demonstrated that there was a significant relationship between increased suctioning frequency and percentage time in the oxygen saturation zone, both in the unadjusted and adjusted models. The more suctioning an infant received within a 24 hour period led to an increase in the time spent within the oxygen saturation target zone by 0.8%. Hence, a change in suctioning from 4 hourly to 2 hourly would see an increase of 4.8% more time in the oxygen saturation target zone. When the data for time in oxygen saturation target zone of the infants who were solely on air throughout the study were removed, the mean percentage time in the target zone was 18%. However, saturation is not solely dependent on airway management. Supplemental oxygen administration, respiratory support, infant's condition, artefact (resulting from poor signal pick through the probe) and care that disturbs the infant, all have a role in the resulting oxygen saturation level.

Lim et al. (2014) found in their observational study that preterm infants of 27 to 32 weeks gestation were within the target zone of 88-92% SaO_2 for 31% of the time, which was comparable to other studies, and higher than what was found within this study. However, they noted that when nurses were caring for more than one infant that the frequency of prolonged periods of hyperoxia increased and the more infants they were responsible for higher the number of episodes of higher SaO_2 (Lim et al., 2014). The assumption being that nurses in their study only cared for one infant at a time. Petty (2012) found similar results, in a descriptive analysis of the relationship of nurse:patient ratios when caring for infants <29 weeks.

Within the study NNU, most of the staff were responsible for the care of two to three infants requiring CPAP. This may be reflective of the lower time in oxygen saturation target zone found in the study. It would be useful to determine during the periods when infants were not within the oxygen saturation target zone, if the oxygen saturation levels were above the upper limits or below lower limits of the target zone. However, this would require reviewing and further analysis of the data. Nevertheless, this would aid in the understanding of practice and support standards around care and nurse:patient ratios, to better maintain oxygen saturation levels. In addition, being aware of whether the prolonged recovery times impacted on the length of time outside the oxygen saturation target zone below the expected level 88-92%, due to prolonged desaturation and minimal supplemental oxygen. These parameters were not identified within the initial analysis of the data and information on nurse:patient ratios were not collected. Further research would be required to determine this effect.

Lim et al. (2014) also noted that the time within target zone was negatively related to the experience of the nurses caring for the infants. Therefore if a nurse was more experienced, the infants were outside the target zone of 88-92% more of the time. The experience of nursing staff was not documented within this study and hence could not be accounted for within the analysis. However, on reviewing the data recorded, it was noted that some infants were left with low oxygen saturations, to recover for prolonged periods of time, maximum 612 seconds (10 minutes), with minimal or no change in supplementary oxygen during the desaturation. In some instances, the supplementary oxygen was 3% less than the previous episode mean and the level of supplementary oxygen was not always altered to meet the needs of the infant within recovery period. Other studies have found that infants returned to baseline recording levels within 150 seconds to 5 minutes post suctioning (Kerem et al., 1990; Singh et al., 1991). This slow recovery meant that in some instances there would have been less time in the oxygen saturation target zone. This effect may have been reduced if there had been an increase in the supplemental oxygen given to the infants during these desaturations and this would have impacted the outcomes within the study.

Effect of suctioning

The effects of suctioning, in the prolonged periods of recovery noted on analysis of the data, have already been discussed in oxygen saturation, desaturations and percentage of time in oxygen saturation target zone, as the results influenced those outcomes. However, recovery time after suctioning was on average less than previously found in other studies (Kerem et al., 1990; Singh et al., 1991). The heart rate recovering in 41.3 seconds (mean) and oxygen saturation recovering in 82.8 seconds (mean). As previously identified adequate supplemental oxygen during suctioning may have improved oxygen saturation levels and minimised the number ≥10 seconds and ≥60 second desaturations recorded and the time within the oxygen saturation target zone. Experience and inexperience of the nurses caring for the infants may be been a factor in these results. Lake et al. (2010) discussed in their study of nurses' education, experience and infant outcomes that the more experience a registered nurse had the better the outcomes for the infant. Further research into the experience of staff caring for these infants, as well as suctioning practices may give a clearer picture of the impact suctioning frequency has on outcomes.

Part Two

Demographics

The fact that there were only six infants who participated in the study, affects the percentages within the group greatly and the significance of the results, due to the small number. The sample size calculation demonstrated that 20 infants would be required to demonstrate significance. Hence statistical significance cannot be demonstrated within this part of the study. However, inferences can be made in relation to these outcomes and those found within Part One.

Of those infants recruited to Part Two of the study Māori and Pasifika ethnicity were still highly represented within the group with 33% each. Other demographics in Part Two were similar to those in Part One, in relation to most of the variables except, gestational age, mode of delivery, weight, PDA, ROP, length of stay, and respiratory support. The gestational age and weight are probably reflective of the necessity for respiratory support and supplemental oxygen requirement within Part Two. Infants of a younger gestational age are more at risk of pulmonary deterioration as noted by an increased supplemental oxygen requirement around 14 days of age (Laughon et al., 2009). The differences in respiratory support would also be reflective of their gestational age and impact on the other variables that that were also different.

Respiratory support

All infants who participated within Part Two of the study were 25-26 weeks gestation, more premature than the infants in part one and the other infants admitted during the study period. Within Part Two there was a greater number of hours for all respiratory support; CPAP, ventilation, HFOV and high flow. This would be reflective of the infants gestation age and pulmonary deterioration around 14 days, increasing the risk of BPD and respiratory support, as previously discussed (Laughon et al., 2009). As the need for supplemental oxygen was a requirement for the study, this may have also impacted on the increased requirement for respiratory support, due to the oxidative stress from supplemental oxygen leading to increased risk of BPD (Araujo et al., 1998; Clark et al., 2001; Saugstad, 2010; Van Marter et al., 2000; Vento et al., 2009).

Respiratory support in the form of doxapram was only given to one of the six infants; of interest this was the only infant not to require respiratory support at 36 weeks gestation, which may be reflective of the degree of BPD. This infant required <25% supplemental oxygen at 14 days and minimal CPAP pressures compared to the other infants (6 cmH_2O compared to 8cm H_20). Comparing rates of BPD within this group, 80% of all infants surviving to discharge had respiratory support at 36 weeks, which is greater than previously quoted figures from the literature (Laughon et al., 2009). This is also higher when related to 48% BPD rate for all infants admitted to the NNU during the study period. The small number of infants within the study and the lower gestational age, which have a higher risk of developing BPD, may be the only explanation for this (Belik, 2008; Saugstad, 2010).

Frequency of suctioning

Both suctioning regimes were represented equally within the study, with three infants commencing in each regime. However, within each regime males were represented more with two males and one female in each. Of the six infants that began the study two infants did not complete the whole study period, being withdrawn in line with the exclusion criteria. One infant had a high number of prolonged desaturations <60% and the other infant required intubation and ventilation. This, combined with the small number of participants, meant it was difficult to draw conclusive evidence from the data. The effects of suctioning frequency were discussed within the outcomes to follow.

Saturations

Overall, the median and mean oxygen saturations were lower than those in Part One, with all daily means being of lower values with some periods being outside the oxygen saturation target zone. Therefore, there would be more risk associated with these lower levels in regards to mortality (Stenson et al., 2013). The mortality rate was higher within this group with one infant (20%) dying prior to discharge, having developed necrotising enterocolitis. The data for this infant demonstrated one of the higher levels of mean oxygen saturation, though one of the lower levels for supplemental oxygen and this infant was the oldest in the group, at 26weeks and 3 days gestation. However, the small numbers within the group make the analysis of these results inconclusive.

Desaturations

Analysis of the data for desaturations, using fixed effects, found that there was an increased risk of desaturations ≥10 seconds with 4 hourly suctioning compared to 2 hourly suctioning when estimated for all infants. The effect was that there were 7.3 more desaturations with the 4 hourly regime. The same effect was also seen with desaturations ≥60 seconds, though not to the same extent. This was interesting in that it was the opposite for Part One, where there was significant increases in desaturations with 2 hourly suctioning. The difference could be related to these infants requiring more respiratory support and supplemental oxygen. Hence, the more frequent suctioning ensured airway patency, reducing the effort of breathing, by reducing the resistance in the airways (Grinnan & Truwit, 2005). Nonetheless, there were too few infants within the study to draw definitive results and therefore any results can only be conjecture.

Of interest is the individual predicted desaturation of ≥10 seconds for each infant, which was higher within 4 hourly for all infants, but more so with three infants, where the difference was a factor of 1.9 to 3 times more desaturations with 4 hourly compared to 2 hourly suctioning. One of the infants that had a higher proportion of desaturations with 4 hourly suctioning was not on doxapram and had no BPD. With the other two infants both had doxapram and one died prior to discharge. The other two infants only had a predicted difference of 0.4 to 1.4 times more desaturations with 4 hourly suctioning. A similar distribution was seen for desaturations of ≥60 seconds also, with a comparable factor distribution of desaturations within suctioning regimes, for each infant when compared to desaturations of ≥10 seconds. Although, the number of desaturations of ≥60 seconds was much less when compared to Part One. The mean number of desaturations ≥10 seconds in Part Two was 12.7 per hour, which is higher than the 9.5 per hour in Part One. Again, this may be reflective of the respiratory support the infants required and the increased risk of BPD.

Di Fiore et al. (2010) found that increased desaturation lead to increased severity of ROP in 24-27 week gestation infants, where desaturations ≤80% were ≥10 seconds. The increased number of desaturations in Part Two then may account for the increase in ROP, though the limited number of participants may not make the results reflective of the population.

Supplemental oxygen

The median level of supplemental oxygen was higher in Part Two than in Part One, with infants receiving 25% supplemental oxygen in Part Two compared to 22.3%

supplemental oxygen in Part One. This was expected as the infants enrolled in Part Two were required to be on supplemental oxygen to participate in this part of the study. The mean time in supplemental oxygen was also higher being 61% in Part Two compared to 19% in Part One. Part Two had 4 infants with an oxygen requirement for at least 28 days and all 4 went on to require respiratory support at 36 weeks gestation. This may be reflective of their initial oxygen requirement at 14 days, a phenomenon discussed by Laughon et al. (2012), where infants <28 weeks gestation who demonstrated a degree of respiratory deterioration at 14 days old were more likely to develop BPD. The effect of frequency of suctioning on supplemental oxygen was mixed with two infants requiring less oxygen when suctioned 2 hourly and two infants requiring more with 2 hourly suctioning. However, again due to there being too few infants no conclusions can be drawn.

Time in oxygen saturation target zone (SaO_2 88–92%)

The mean percentage of time in the oxygen saturation target zone was higher in Part Two compared to Part One, 28% compared to 18%. The mean percentage of time in oxygen saturation target zone in Part Two was more in line with the findings of Lim et al. (2014) where infants were within the oxygen saturation target zone 31% of the time. There is no clear rationale as to why this was so and only summation can be given. The higher level of time within the oxygen saturation target zone may be a reflection of the infants already requiring oxygen, their instability, as demonstrated in the use of doxapram, or that they were allocated a more experienced nurse. The more experienced nurse may have monitored them more closely; although this would contradict other studies that found infants were more likely to be outside the oxygen saturation target zone with more experienced staff (Lim et al., 2014; Petty, 2012). It would have been interesting to have recorded data to identify this aspect of the study.

Individually, two infants demonstrated a higher percentage of time in the oxygen saturation target zone with 2 hourly suctioning, one infant had no difference between suctioning regimes and the other two had a higher percentage of time in the oxygen saturation target zone when suctioned 4 hourly. However, only four infants completed the full crossover programme for Part Two. Irrefutable evidence cannot be forth coming due to the small numbers of participants within the study.

Bradycardias

The mean number of bradycardias in Part Two were also higher than in Part One with 1.1 per hour compared to 0.5 per hour. As discussed prior this may be due to the gestational age and respiratory support requirements of the infants within the group. Overall, there were 0.7 more bradycardias per hour with 4 hourly suctioning compared to 2 hourly suctioning. As discussed with desaturations, this may reflect the overall improvement of airway resistance due to suctioning. While individually the infants had varying results, two infants had more bradycardias with 2 hourly suctioning and two had more bradycardias with 4 hourly suctioning. Although the analysis demonstrated statistical significance in favour of 2 hourly suctioning regime, no conclusive result can be made due to numbers.

Effect of suctioning

As with Part One there were a number of periods of prolonged recovery that may have impacted on the results of the study. Within Part Two there were proportionally more episodes per infant possibly due to their increased respiratory requirements; higher CPAP pressure, lesser gestation, requirement for doxapram and supplemental oxygen. Recovery times overall were longer on average with heart rate recovery mean 80.8 seconds and oxygen saturation recovery time mean 128.2 seconds, though still within parameters found from other studies (Kerem et al., 1990; Singh et al., 1991). Overall, there was a greater variance in supplemental oxygen use. Infants in Part Two were given more oxygen for longer periods, which may account for the effect of the percentage of time within the oxygen saturation target zone. However, of note again are the proportions of changes in supplemental oxygen during desaturation within suction episodes. Only 33% of all episodes of suctioning where there was a desaturation had the supplemental oxygen altered.

Overall, the percentage of supplemental oxygen was lowered less during a suctioning interval when compared to the previous suctioning interval in Part Two, in contrast to Part One. Nonetheless, the majority of the prolonged recovery periods had no change in the supplemental oxygen level given. In one instance, the recovery time was 706 seconds (11 minutes 46 seconds) with no change in supplemental oxygen, lowest oxygen saturation recorded for this interval was 62% and the previous oxygen saturation was 90%. During this suctioning interval recovery period there were 14 desaturations of ≥10 seconds and 3 desaturations of ≥60 seconds. More prudent use of supplemental oxygen may have reduced these desaturations and given a clearer understanding of the effect suctioning had on infants ≤30 weeks requiring CPAP. This may have led to an alteration in the mean oxygen saturation levels, the number of desaturations and bradycardias the infants experienced, the amount of supplemental oxygen required and the percentage of time within the oxygen saturation target zone. Thus, the ability for the research to ascertain the effect of the suctioning regime on these infants has been affected by the practices within the study NNU, that until this study have not become known. However, due to the limited number of infants recruited into the study, it would be difficult to form conclusive results from this data.

Overall comparison of study group and all infants admitted during study period

Aspects of the demographics for all infants admitted during the study period have already been discussed within this chapter, in comparison to the infants in Part One and two of the study. Due to the limited participants recruited in Part Two, it was difficult to draw similarities between the groups. Generally, the infants in Part One were similar to all other infants admitted to the study NNU during the time of the research. The only differences noted between Part One and all admissions, was respiratory support. Although, there were similarities here, probably due to the data from infants in Part Two being included with all infants, which would have skewed some of the results.

More infants in Part One had normal vaginal deliveries 70% compared to 47% for all other admissions. The LSCS rate for Part One was 3% with 37% LSCS rate in all admissions. Whether this had an impact on respiratory outcomes is unclear, although there is no evidence to support any difference in outcomes between the two modes of delivery (Ghi et al., 2010). Of interest was that there were less infants in Part One whose mothers had received full dose steroids antenatally, 57% compared to 79% of all admissions during the study period. For Part Two the results were slightly lower than for all admission at 67% receiving a full dose of steroids. This lower incidence of antenatal steroids may have influenced the requirement for respiratory support amongst the study group. There may also be a relationship between lower uptake of antenatal steroids and antenatal care. As described previously, poor antenatal care can affect morbidity and mortality for infants (Herbst et al., 2003; Vintzileos et al., 2002). Due to incomplete data around mothers being booked and receiving antenatal care, this aspect could not be analysed or compared with antenatal steroid uptake or outcomes. Nonetheless, this would have been an interesting aspect to review in terms of neonatal care and respiratory support.

With respiratory support, a point of interest was when data were analysed for BPD. It was noted that five infants, admitted during the study period, whom were on air at 14 days then developed a supplemental oxygen requirement for at least 28 days and went on to require respiratory support at 36 weeks, were all female. This is contradictory to other findings that females have less respiratory morbidity (Ambalavanan et al., 2008; Deulofeut et al., 2007). Overall, there were no other major differences within the demographics. NEC was diagnosed in three infants (4%) admitted over the study period. With perforation of the bowel occurring in two infants (3%), a higher percentage than described by Groenendaal et al. (2010) who found that 1.7% of infants 25-30 weeks gestation had perforated the bowel due to necrotising enterocolitis. Length of stay overall was distorted in all infants due to one infant remaining for 364 days.

The aim of the study was to determine the effect of suctioning and frequency on oxygenation, desaturation, and bradycardias in these premature infants requiring CPAP. Overall, the recovery time mean for heart rate and oxygen saturation were lower than in previous studies. This could be reflective of the differences between respiratory support methods, CPAP as oppose to ventilation, and the suctioning technique practiced within the study NNU, described in chapter one. Frequency of suctioning was found to increase desaturations and bradycardias in Part One, which was contrary to the findings in Part Two. However, the effect of prolonged periods between suctioning was probably of greater interest in demonstrating the effect of frequency on desaturations and bradycardias.

Within the study it was unclear precisely the impact that the suctioning regimes had on outcomes for the infants within the unit due to limited numbers of participants, lost data within the study, and practices that may have influenced the outcomes. The frequency of suctioning utilised within the unit is not a trend peculiar to the study NNU. Mann, Sweet, Knupp, Buck, and Chipps, (2013) found that 65.1% of registered nurses suctioned infants both routinely and when needed compared to just when needed or routinely, with 35.7% performing suction 3-4 hourly or less. These findings are similar to those within the study NNU. Suctioning guidelines state that suctioning infants within the study parameters, should be undertaken 2-4 hourly, dependent on the infants condition and oxygen requirement (CMDHB, 2012).

Limitations

Limitations identify the restrictions and boundaries of the study, which are present in all research designs (Marshall & Rossman, 2011). Within this study limitations related to; aspects of the study design, number of participants recruited within both parts of the study, data collection, and generalisability of the findings due to the uniqueness of the population, convenience sampling and study setting. There were many other variables within the study that were not analysed, which could have influenced the outcomes analysed such as; touch, noise, stress, parental interaction (Symington & Pinelli, 2006), antenatal care (Herbst et al., 2003; Vintzileos et al., 2002), staff experience, and nurse:patient ratios (Lim et al., 2014; Petty, 2012). All could not be controlled or accounted for within the current study and may have affected the results, although the amount of data and findings obtained from the study has led to a greater understanding of the population, outcomes, and practices within the study NNU. However, outcomes and findings were possibly affected due to some unforeseen practices within the study NNU, with infants being left to recover for prolonged periods.

The research methods chosen sought to contribute to understanding the effect of suctioning on these fragile infants and the impact of frequency on oxygenation, desaturations, and bradycardias. It was anticipated that results from each method would support the outcomes of the other (Dreyer et al., 2010b; Fleurence et al., 2010; Yang et al., 2010). However, there were areas of conflict, as well as areas of commonality. While comparisons were limited due the small numbers of participants, there were areas of note around suctioning intervals and some morbidities amongst the population, between both studies. Utilisation of data from Part One to support the sample size calculation for Part Two demonstrated that there were too few infants recruited into Part Two to show significance.

The number of participants recruited was small in both parts of the study, especially in Part Two, with only six infants. Convenience sampling was utilised to ensure that participants met the criteria for the study, although as a result, limited the generalisability of the study findings. Results from this study are reflective of the uniqueness of this particular population and thus may not apply to all premature infants in other NNUs. The low numbers of participants recruited were indicative of the limited population available to study. Larger numbers would have been obtained by prolonging the research or including more NNUs within the research. However, this was not feasible, as other NNUs do not practice CPAP in the same manner as the study NNU. In addition, after already extending the study period, time constraints on completing the research for masters study meant the study period could not be extended further. In hindsight the gestation of the study population should have been limited to <28 weeks gestation, to be more reflective of the current literature, provide a comparison and discussion, although, this would have limited the number of participants further. The population within the study area had a higher proportion of Māori and Pasifika, which were over represented within the participants of the study and may not be representative of, or transferrable to, other areas.

Data lost from instruments, due to errors in recording and downloading, reduced the number of suction intervals that were available to be analysed. Lack of documentation, led to a further reduction in the number of episodes available for analysis within the study, particularly in Part One, resulting in less data that could be correlated for analysis. This led to the inability to review all suctioning intervals for each infant and a reduction in data analysed, which may have portrayed a different result within the study. However, with more time, accurate documentation, data recording, inclusion of staff experience, nurse:patient ratios and larger numbers of participants, may result in more accurate outcomes that are significant.

Implications for Practice

Suctioning is an important aspect of nursing care for premature infants on CPAP (Aly, 2001). This study has demonstrated that there may be benefits in frequent suctioning in certain circumstances. Results have revealed that some infants responded well with 2 hourly suctioning, having fewer desaturation and bradycardias, yet others were found to have fewer with 4 hourly suctioning. Outcomes demonstrate that suctioning practices within the study NNU lead to lower levels of IVH, less BPD, lower levels of supplemental oxygen and fewer infants requiring home oxygen.

Prolonged recovery times may have influenced the outcomes within the study around increased desaturations and bradycardias associated with increased frequency. Therefore, prudent use of supplemental oxygen during suctioning should be encouraged to minimise desaturations and bradycardias, resulting from the removal of CPAP, coupled with the stress of the suctioning procedure (Kerem et al., 1990). However, there needs to be careful consideration of oxygenation prior to and during suctioning to limit the effects of oxidative stress (Sola et al., 2008; Walsh et al., 2009). Infants within the study that were left for longer periods between suctioning demonstrated increased desaturations and bradycardias, indicating the need for nurses to suction infants frequently enough to prevent this, although what the ideal interval should be is unclear. Nurses need to ensure infants are monitored closely to determine the need for suctioning in response to increased desaturations and bradycardias, resulting from increased secretions.

Recommendations

Further research needs to be undertaken that includes larger numbers of infants to determine the impact of suctioning frequency. Future research recommendations include increasing the suctioning interval difference of frequencies to comparing 2 hourly and 6 hourly. This may demonstrate more significance between the frequency regimes and give a clear indication for practice. However, this may have ethical implications, with findings of this research study demonstrating that prolonged intervals between suctioning increased the incidence of desaturations and bradycardias.

Further research is required around the use of preoxygenation with premature infants on CPAP, prior to suctioning and during suctioning. This would aid in determining the level of increase in supplemental oxygen required that would minimise any morbidity. This would hopefully reduce the risk of prolonged recoveries and give a clearer representation of the impact suctioning frequency has on infants ≤30 weeks gestation requiring bubble CPAP. Another area of research to be considered would be around the use of two staff to support the each other in performing suctioning on infants with a supplemental oxygen requirement and unstable infants. It would be of interest as to whether this is beneficial with this fragile population and reduces desaturations and bradycardias.

Concluding Statement

Suctioning practices with premature infants to date have focused on research performed around ETT suctioning, with outcomes that may differ from those for premature infants on CPAP. This study set out to gain a better understanding of these differences and to establish if practices within the study NNU around frequency of suctioning influenced the outcomes. Results demonstrated in Part One that more frequent suctioning lowered the mean oxygen saturation level and increased the risk of having desaturations and bradycardias. However, the data analysed demonstrated periods of prolonged recovery with minimal supplemental oxygen utilisation and resultant desaturations and bradycardias, which may have impacted on the aforementioned outcomes. Other findings were that the length of time the infants spent within the oxygen saturation target zone improved with increased suctioning frequency. However, this was less than outcomes from other studies. This could be attributed to lower nurse:patient ratios, when caring for premature infants on CPAP.

Of most interest and relevance to care were the results around prolonged intervals between suctioning. When infants were left for longer periods between suctioning, the incidence of desaturation and bradycardia were more significant, than that found with increased frequency. These findings are probably of more significance than those from increased frequency, as findings would be influenced less by the effect of prolonged recovery. These finding supporting the practice of frequent suctioning and speculation that the other significant results around frequency found in Part One, were attributed to the effect of the prolonged recovery period. If the infants who were exposed to the prolonged recovery period were given an increased level of supplemental oxygen, there is the possibility that there would have been fewer desaturations and bradycardias, higher mean saturations and increased time within the oxygen saturation target zone.

Part Two demonstrated improved outcomes within all areas of analysis for infants during the 2 hourly suctioning regime. The effect of which was felt to be reflective of their increased need for respiratory support and supplemental oxygen requirement due to respiratory deterioration. However, there was difficulty in establishing significance within Part Two due to the low numbers in the study. Infants were found to have more prolonged periods of recovery in comparison to Part One, although infants within Part Two received more supplemental oxygen.

While the aims of this study have been met for some of the outcomes, issues have been identified that may have influenced the findings. Unrecognised practices within the study NNU may have affected the results of the research with nurse:patient ratios and prolonged recovery times. Further research is required to identify these issues and the impact they have on nursing care for these fragile infants. Practice needs to ensure delivery of care that is supported by research to provide evidenced based care and improve outcomes. Overall, the approach taken with CPAP and aspects of care around the frequency of suctioning infants on CPAP within the study NNU have been supported by the findings of this study and the improved outcomes. However, further research is required to explore further the findings of this study

References

Als, H., Duffy, F., McAnulty, G., Rivkin, M., Vajapeyam, S., Mulkern, R., & Eichenwald, E. (2004). Early experience alters brain function and structure. *Pediatrics 113*(4), 846-857. doi: 10.1542/peds.113.4.846

Als, H., Lawhon, G., Brown, E., Gibes, R., Duffy, F.H., McAnulty, G., & Blickman, J.G. (1986). Individualized behavioural and environmental care for the very low birth weight preterm infant at high risk for bronchopulmonary dysplasia: Neonatal intensive care unit and developmental outcome. *Pediatrics, 78*(6), 1123-1132.

Aly, H.Z. (2001). Nasal prong continuous positive airway pressure: A simple yet powerful tool, *Pediatrics, 108,* 759-761. doi: 10.1542/peds.108.3.759

Ambalavanan, N., Van Meurs, K., Perritt, R., Carlo, W., Ehrenkranz, R., Stevenson, D., & Higgins, R. (2008). Predictors of death or bronchopulmonary dysplasia in preterm infants with respiratory failure. *Journal of Perinatology*, *28*(6), 420-426. doi: 10.1038/jp.2008.18

Araujo, V.V., Ruiz, E.E., Llovera, M.M., Tokashiki, N.N., Abellan, C.C., & Dominguez, C.C. (1998). Impact of oxygen therapy on antioxidant status in newborns. Relationship with infection risk. *Biofactors, 8*(1-2), 143-147. doi:10.1002/biof.5520080124

Aschengrau, A., & Seage, G.R. (2014). *Essentials of Epidemiology in Public Health* (3rd ed.). Burlington, MA: Jones & Bartlett Learning.

Avery, M.E., Tooley, W.H., Keller, J.B., Hurd, S.S., Bryan, M.H., Cotton, R.B., … Wung, J. (1987). Is chronic lung disease in low birth weight infants preventable? A survey of eight centres. *Pediatrics, 79*(1), 26-30.

Axelin, A., Ojajärvi, U., Viitanen, J., & Lehtonen, L. (2009). Promoting shorter duration of ventilator treatment decreases the number of painful procedures in preterm infants. *Acta Paediatrica, 98*(11), 1751-1755. doi: 10.1111/j.1651-2227.2009.01446.x

Baquero, H., Alviz, R., Castillo, A., Neira, F., & Sola, A. (2011). Avoiding hyperoxemia during neonatal resuscitation: Time to response of different SpO2 monitors. *Acta Paediatrica, 100*(4), 515-518. doi: 10.1111/j.1651-2227.2010.02097.x

Been, J., Rours, I., Kornelisse, R., Lima Passos, V., Kramer, B., Schneider, T., & Zimmermann, L. (2009). Histologic chorioamnionitis, fetal involvement, and antenatal steroids: Effects on neonatal outcome in preterm infants. *American Journal Of Obstetrics & Gynecology, 201*(6), 587.e1-587.e8. doi: 10.1016/j.ajog.2009.06.025

Belik, J. (2008). Susceptibility of the immature lung to oxidative and mechanical injury. In E, Bancalari, (Ed.), *The newborn lung.* (pp. 101-118). Philadelphia, PA: Saunders.

Berg, K.E. & Latin, R.W. (2004). *Essentials of research methods in health, physical education, exercise science, and recreation.* Philadelphia, PA: Lippincott, Williams & Wilkins.

Bhatt-Mehta, V., & Schumacher, R.E. (2003). Treatment of apnoea of prematurity. *Pediatric Drugs, 5*(3), 195-210. doi: 10.2165/00128072-200305030-00006

Bonner, K.M., & Mainous, R.O. (2008). The nursing care of the infant receiving bubble CPAP therapy. *Advances in Neonatal Care, 8*(2), 78-95. doi: 10.1097/01.ANC.0000317256.76201.72

Borbasi, S., Hengstberger-Sims, C., & Jackson, D. (2012). Quantitative research: Summing it up. In S. Borbasi & D. Jackson, *Navigating the maze of research: Enhancing nursing and midwifery practice* (3rd ed., pp. 79-122). Sydney, Australia: Mosby Elsevier.

Bordens, K.S., & Abbot, B.B. (2005). *Research design and methods* (6th ed.). New York, NY: McGraw-Hill.

Bushell, T., McHugh, C., & Meyer, M. (2013). A comparison of two nasal continuous positive airway pressure interfaces-a randomized crossover study. *Journal of Neonatal-Perinatal Medicine, 6*(1), 53-59. doi: 10.3233/NPM-1363612

Byrnes, C., & Trenholme, A. (2010). Respiratory infections in Tamariki (children) and Taitamariki (young people) Māori, New Zealand. *Journal of Paediatrics & Child Health, 46*(9), 521-526. doi: 10.1111/j.1440-1754.2010.01853.x

Cabal, L.A., Siassi, B., Blanco, C., Plajstek, C., & Hodgman, J.E. (1984). Cardiac rate and rhythm changes during airway suctioning in premature infants with RDS. *Journal of the California Perinatal Association, 4*(1), 45-48.

Carrasco, M., Martell, M., & Estol, P. (1997). Oronasopharyngeal suction at birth: Effects on arterial oxygen saturation. *The Journal of Pediatrics, 130*(5), 832-834. doi: 10.1016/S0022-3476(97)80031-5

Carter, B., Holditch-Davis, D., Tanaka, D., & Schwartz, T. (2012). Relationship of neonatal treatments with the development of necrotizing enterocolitis in preterm infants. *Nursing Research, 61*(2), 96-102. doi: 10.1097/NNR.0b013e3182410d33

Castillo, A., Sola, A., Baquero, H., Neira, F., Alvis, R., Deulofeut, R., & Critz, A. (2008). Pulse oxygen saturation levels and arterial oxygen tension values in newborns receiving oxygen therapy in the neonatal intensive care unit: Is 85% to 93% an acceptable range? *Pediatrics, 121*(5), 882-889. doi: 10.1542/peds.2007-0117

Clark, R.H., Gerstmann, D.R., Jobe, A.H., Moffit, S.T., Slutsky, A.S., & Yoder, B.A. (2001). Lung injury in neonates: Causes, strategies for prevention and long-term consequences. *Journal of Pediatrics*, *139*(4), 478-486. doi: 10.1067/mpd.2001.118201

Clifton-Koeppel, R. (2006). Endotracheal tube suctioning in the newborn: A review of the literature. *Newborn and Infant Nursing Reviews, 6*(2), 94-99. doi: 10.1053/j.nainr.2006.03.006

Cook, B., & Cook, L. (2008). Nonexperimental quantitative research and its role in guiding instruction. *Intervention in School & Clinic*, *44*(2), 98-104. doi: 10.1177/1053451208321565

Cordero, L., Sananes, M., & Ayers, L.W. (2000). Comparison of closed (TrachCare MAC) with an open endotracheal suction system in small premature infants. *Journal of Perinatology, 20*(3), 151-156.

Cordero, L., Sananes, M., & Ayers, L.W. (2001). A comparison of two airway suctioning frequencies in mechanically ventilated, very-low-birthweight infants. *Respiratory Care, 46*(8), 783-788.

Counties Manukau Health. (2012). *Population profile.* Retrieved from http://www.countiesmanukau.health.nz/About_CMDHB/Overview /population-profile.htm

Counties Manukau Health Board. (2006). *Whaanau Ora Plan*. Retrieved from http://www.cmdhb.org.nz/About_CMDHB/Planning/Māori-Health-Plan/WhanauOraPlan.pdf

Counties Manukau Health Board. (2008). *The changing demography of Counties Manukau district health board.* Retrieved from http://www.cmdhb.org.nz/About_CMDHB/Planning/Health-Status/Population/2008/changing-demography-report.pdf

Counties Manukau District Health Board. (2012). *Suctioning with CPAP.* Auckland, New Zealand: Author.

Cram, R. (1998). Rangahau Māori: Tona tika, tona pono- Validity and integrity of Māori research. In M. Tolich (Ed.), *Research ethics in Aotearoa New Zealand* (pp. 35-52). Auckland, New Zealand: Pearson Education.

Creswell, J.W. (2009). *Research Design: Qualitative, quantitative, and mixed methods approaches* (3rd ed.). Thousand Oakes, CA: Sage Publications.

Craft, J., Gordon, C., & Tiziani, A. (2011). *Understanding pathophysiology*. Sydney, Australia: Mosby Elsevier.

Crotty, M. (1998). *The foundations of social research: Meaning and perspective in the research process.* Sydney, Australia: Allen and Unwin.

Cunningham, M.L., Baun, M.M., & Nelson, R.M. (1984). Endotracheal suctioning of premature neonates. *Journal of the California Perinatal Association, 4*(1), 49–52.

Dall'Alba, P., & Burns, Y. (1990). The relationship between arterial blood gases and removal of airway secretions in neonates. *Physiotherapy Theory & Practice*, *6*(3), 107-116. doi: 10.3109/09593989009037788

De Klerk, A.M., & De Klerk, R.K. (2001a). Nasal continuous positive airway pressure and outcomes of preterm infants. *Journal of Pediatrics and Child Health, 37*(2), 161-167. doi: 10.1046/j.1440-1754.2001.00624.x

De Klerk, A.M., & De Klerk, R.K. (2001b). Use of continuous positive airway pressure in preterm infants: Comments and experience from New Zealand. *Pediatrics, 108*(3), 761-762. doi: 10.1542/peds.108.3.761

De Paoli, A.G., Morley, C. & Davis, P.G. (2003). Nasal CPAP for neonates: What do we know in 2003? *Archives of Disease In Childhood-Fetal & Neonatal Edition, 88*, F168-F172. doi: 10.1136/fn.88.3.F168

Deulofeut, R., Dudell, G., & Sola, A. (2007). Treatment by gender effect when aiming to avoid hyperoxia in preterm infants in the NICU. *Acta Paediatrica*, *96*(7), 990-994. doi: 10.1111/j.1651-2227.2007.00365.x

Di Blasi, R. (2009). Nasal continuous positive airway pressure (CPAP) for the respiratory care of the newborn infant. *Respiratory Care, 54*(9), 1209-1235. Retrieved from http://rc.rcjournal.com/content/54/9/1209

Di Fiore, J.M., Bloom, J.N., Orge, F., Schutt, A. Schluchter, M., Cheruvu, V.K., … Martin, R.J. (2010). A higher incidence of intermittent hypoxemic episodes is associated with severe retinopathy of prematurity. *The Journal of Pediatrics, 157*(1), 69–73. doi: 10.1016/j.jpeds.2010.01.046

Dreyer, N., Schneeweiss, S., McNeil, B., Berger, M., Walker, A., Ollendorf, D., & Gliklich, R. (2010a). GRACE principles: Recognizing high-quality observational studies of comparative effectiveness. *American Journal of Managed Care*, *16*(6), 467-471. Retrieved from http://www.ajmc.com/

Dreyer, N., Tunis, S., Berger, M., Ollendorf, D., Mattox, P., & Gliklich, R. (2010b). Why observational studies should be among the tools used in comparative effectiveness research. *Health Affairs*, *29*(10), 1818-1825. doi: 10.1377/hlthaff.2010.0666

Dunn, P. (1990). Dr von Reuss on continuous positive airway pressure in 1914. *Archives of Disease In Childhood, 65*(1), 68. doi: 10.1136/adc.65.1_Spec_No.68

Dunn, P. (2007). Dr Mary Crosse, OBE, MD (1900-1972) and the premature baby. *Archives of Disease In Childhood-Fetal & Neonatal Edition, 92*(2), F151-3. doi: 10.1136/adc.2005.077529

Durand, M., Sangha, B., Cabal, L., Hoppenbrouwers, T., & Hodgman, J. (1989). Cardiopulmonary and intracranial pressure changes related to endotracheal suctioning in preterm infants. *Critical Care Medicine*, *17*(6), 506-510. doi: 10.1097/00003246-198906000-00004

Ehrenkranz, R., Walsh, M., Vohr, B., Jobe, A., Wright, L., Fanaroff, A., ... Poole, K. (2005). Validation of the National Institutes of Health consensus definition of bronchopulmonary dysplasia. *Pediatrics*, *116*(6), 1353-1360.

Estol, P., Piriz, H., Basalo, S., Simini, F., & Grela, C. (1992). Oro-naso-pharyngeal suction at birth: Effects on respiratory adaptation of normal term vaginally born infants. *Journal of Perinatal Medicine, 20*(4), 297-305. doi: 10.1515/jpme.1992.20.4.297

Everitt, B.S., & Hothorn, T. (2006). *A handbook of statistical analyses using R.* Boca Raton, FL: Chapman & Hall/CRC.

Everett, B.S., & Palmer, C.R. (Eds.). (2011). *Encyclopaedic companion to medical statistics.* Chichester, England: Wiley.

Fanconi, S., & Duc, G. (1987). Intratracheal suctioning in sick preterm infants: Prevention of intracranial hypertension and cerebral hypoperfusion by muscle paralysis. *Pediatrics, 79*(4), 538-543.

Finer, N., Carlo, W., Walsh, M., Rich, W., Gantz, M., Laptook, A., & Higgins, R. (2010). Early CPAP versus surfactant in extremely preterm infants. *New England Journal Of Medicine, 362*(21), 1970-1979. doi: 10.1056/NEJMoa0911783

Fitzgerald, S.M., Rumrill, P.D., & Schenker, J.D. (2004). Correlational designs in rehabilitation research. *Journal of Vocational Rehabilitation, 20,* 143-150. Retrieved from http://www.ebscohost.com

Fleurence, R., Naci, H., & Jansen, J. (2010). The critical role of observational evidence in comparative effectiveness research. *Health Affairs, 29*(10), 1826-1833. doi: 10.1377/hlthaff.2010.0630

Fos, P.J. (2010). *Epidemiology foundations*: *The science of public health* [EBL version]. Retrieved from http://www.massey.elib.com.au

Gardiner, D.L., & Shirland, L. (2009). Evidence-based guideline for suctioning the intubated infant. *Neonatal Network, 28(*5), 281-302. Retrieved from http://www.ebscohost.com

Ghi, T., Maroni, E., Arcangeli, T., Alessandroni, R., Stella, M., Youssef, A., ... Pelusi, G. (2010). Mode of delivery in the preterm gestation and maternal and neonatal outcome. *Journal of Maternal-Fetal & Neonatal Medicine, 23*(12), 1424-1428. doi: 10.3109/14767051003678259

Gien, J., & Kinsella, J. (2011). Pathogenesis and treatment of bronchopulmonary dysplasia. *Current Opinion in Pediatrics, 23*(3), 305-313. doi: 10.1097/MOP.0b013e328346577f

Gilbert, M. (1999). Assessing the need for endotracheal suction. *Paediatric Nursing, 11*(1), 14-17.

Gomella, T., Cunningham, M., & Eyal, F. (2009). *Neonatology: Management, procedures, on-call problems, diseases, and drugs* (6th ed.). New York, NY: McGraw-Hill.

Gregory, G., Kitterman, J., Phibbs, R., Tooley, W., & Hamilton, W. (1971). Treatment of the idiopathic respiratory-distress syndrome with continuous positive airway pressure. *The New England Journal of Medicine, 284*(24), 1333-1340.

Gregory, K. (2008). Clinical predictors of necrotizing enterocolitis in premature infants. *Nursing Research, 57*(4), 260-270. Retrieved from http://journals.lww.com/nursingresearchonline/pages/default.aspx

Groenendaal, F., Termote, J., van der Heide-Jalving, M., van Haastert, I., & de Vries, L. (2010). Complications affecting preterm neonates from 1991 to 2006: what have we gained?. *Acta Paediatrica, 99*(3), 354-358. doi: 10.1111/j.1651-2227.2009.01648.x

Grinnan, D.C., & Truwit, J.D. (2005). Clinical review: Respiratory mechanics in spontaneous and assisted ventilation. *Critical Care, 9*(5), 472-84.

Gungor, S., Kurt, E., Teksoz, E., Goktolga, U., Ceyhan, T., & Baser, I. (2006). Oronasopharyngeal suction versus no suction in normal and term infants delivered by elective cesarean section: A prospective randomized controlled trial. *Gynecologic and Obstetric Investigation*, *61*(1), 9-14. doi: 10.1159/000087604

Gungor, S., Teksoz, E., Ceyhan, T., Kurt, E., Goktolga, U., & Baser, I. (2005). Oronasopharyngeal suction versus no suction in normal, term and vaginally born infants: A prospective randomised controlled trial. *Australian & New Zealand Journal of Obstetrics & Gynaecology, 45*(5), 453-456. doi: 10.1111/j.1479-828X.2005.00452.x

Hay, W.W., Rodden, D.J., Collins, S.M., Melara, D.L., Hale, K.A., & Fashaw, L.M. (2002). Reliability of conventional and new pulse oximetry in neonatal patients. *Journal of Perinatology, 22*(5):360-366. doi: 10.1038/sj.jp.7210740

Hayes, J.S., Czarnecki, M.L., & Kaucic, C.L. (1999). Infant nasal-pharyngeal suctioning: Is it beneficial? *Pediatric Nursing*, *25*(2), 193-197.

Health Research Council of New Zealand. (2010). *Guidelines for researchers on health research involving Māori, version 2.* Retrieved from http://www.hrc.govt.nz/sites/default/files/Guidelines%20for%20HR%20on%20Māori-%20Jul10%20revised%20for%20Te%20Ara%20Tika%20v2%20FINAL[1].pdf

Hennessy, E., Bracewell, M., Wood, N., Wolke, D., Costeloe, K., Gibson, A., & Marlow, N. (2008). Respiratory health in pre-school and school age children following extremely preterm birth. *Archives of Disease in Childhood, 93*(12), 1037-1043. doi: 10.1136%2Fadc.2008.140830

Herbst, M.A., Mercer, B.M., Beazley, D., Meyer, N. & Carr, T. (2003). Relationship of prenatal care and perinatal morbidity in low-birth-weight infants. *American Journal of Obstetrics and Gynecology,* 189, 930-933. doi: 10.1067%2FS0002-9378%2803%2901055-X

Hessol, N., & Fuentes-Afflick, E. (2005). Ethnic differences in neonatal and postneonatal mortality. *Pediatrics*, *115*(1), e44-51. doi: 10.1542/peds.2004-0478

Hislop, A.A. (2003). Fetal and postnatal anatomical lung development. In A. Greenough & A.D. Milner (Eds.), *Neonatal respiratory disorders* (2nd ed., pp. 3-11). London, England: Arnold.

Ho, J.J., Subramaniam, P., Henderson-Smart, D.J., & Davis, P.G. (2002). Continuous distending pressure for respiratory distress in preterm infants. *Cochrane Database of Systematic Reviews,* 2002(2). doi: 10.1002/14651858.CD002271.

Hodgman, J., Gonzalez, F., Hoppenbrouwers, T., & Cabal, L. (1990). Apnea, transient episodes of bradycardia, and periodic breathing in preterm infants. *American Journal of Diseases of Children (1960), 144(*1), 54-57. Retrieved from http://www.ebscohost.com

Huck, S.W. (2012). *Reading statistics and research* (6th ed.). Boston, MA: Pearson.

Isaza, G., Arora, S., Bal, M., & Chaudhary, V. (2013). Incidence of retinopathy of prematurity and risk factors among premature infants at a neonatal intensive care unit in Canada. *Journal of Pediatric Ophthalmology and Strabismus, 50*(1), 27-32. doi: 10.3928/01913913-20121127-02

Jobe, A. (2011). The new bronchopulmonary dysplasia. *Current Opinion in Pediatrics, 23*(2), 167-172. doi: 10.1097%2FMOP.0b013e3283423e6b

Jobe, A., & Bancalari, E. (2001). Bronchopulmonary dysplasia. *American Journal of Respiratory and Critical Care Medicine, 163*(7), 1723-1729. doi: 10.1164%2Fajrccm.163.7.2011060

Kaiser, J., Gauss, C., & Williams, D. (2008). Tracheal suctioning is associated with prolonged disturbances of cerebral hemodynamics in very low birth weight infants. *Journal of Perinatology, 28*(1), 34-41. doi: 10.1038%2Fsj.jp.7211848

Kattwinkel, J., Perlman, J., Aziz, K., Colby, C., Fairchild, K., Gallagher, J., & Zaichkin, J. (2010). Neonatal resuscitation: 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Pediatrics, 126*(5), e1400-e1413. doi: 10.1542%2Fpeds.2010-2972E

Kelly, K. Lai, K., & Wu, P. (2008). Using R for data structural equation modelling. In J.W. Osborne (Ed.), *Best practices in quantitative methods* (pp. 535-572). Thousand Oaks, CA: Sage Publications Inc.

Kerem, E., Yatsiv, I., & Goitein, K. (1990). Effect of endotracheal suctioning on arterial blood gases in children. *Intensive Care Medicine*, 16(2), 95-99.

Kerr, M., Menzel, L., & Rudy, E. (1991). Suctioning practices in the pediatric intensive care unit [Abstract]. *Heart and Lung, 20*(3), 300.

Knox, T. (2011). Practical aspects of oronasopharyngeal suction in children. *Nursing Children & Young People*, *23*(7), 14-17. Retrieved from http://rcnpublishing.com/journal/ncyp

Kondoh, Y. (2004). Effects of a flexed posture in the prone position with boundaries following endotracheal suction in very low birthweight infants. *Japan Journal of Nursing Science*, 1(1), 47-55. doi: 10.1111%2Fj.1742-7924.2004.00009.x

König, K., & Holberton, J. (2012). Current practice of pulse oxygen saturation targets and limits in neonatal intensive care units in Australia and New Zealand. *Acta Paediatrica, 101*(6), e253-5. doi: 10.1111/j.1651-2227.2012.02628.x

Lagatta, J., Clark, R., Brousseau, D., Hoffmann, R., & Spitzer, A. (2013). Varying patterns of home oxygen use in infants at 23-43 weeks' gestation discharged from United States neonatal intensive care units. *Journal of Pediatrics, 163*(4), 976-982.e2. doi: 10.1016/j.jpeds.2013.04.067

Lake, E., Patrick, T., Rogowski, J., Horbar, J., Staiger, D., Cheung, R., & Kenny, M. (2010). The three Es: How neonatal staff nurses' education, experience, and environments affect infant outcomes. *Journal of Obstetric, Gynecologic & Neonatal Nursing, 39,* S98. doi: 10.1111/j.1552-6909.2010.01125

Laughon, M., Allred, E., Bose, C., O'Shea, T., Van Marter, L., Ehrenkranz, R., & Leviton, A. (2009). Patterns of respiratory disease during the first 2 postnatal weeks in extremely premature infants. *Pediatrics, 123*(4), 1124-1131. doi: 10.1542%2Fpeds.2008-0862

Lefkowitz, W., & Rosenberg, S. (2008). Bronchopulmonary dysplasia: Pathway from disease to long-term outcome. *Journal of Perinatology, 28*(12), 837-840. doi: 10.1038%2Fjp.2008.110

Lefrak, L., & Lund, L.H. (2013). Nurisng practice in the neonatal intensive care unit. In A.A. Fanaroff & J.M. Fanaroff (Eds.) *Klaus & Fanaroff's care of the high risk neonate* (6th ed., pp. 225-243). Philadelphia, PA: Elsevier Saunders.

Lesaffre, E., & Lawson, A.B. (2012). *Bayesian biostatistics.* Chichester, England: Wiley.

Lim, K., Wheeler, K., Gale, T., Jackson, H., Kihlstrand, J., Sand, C., ... Dargaville, P. (2014). Oxygen saturation targeting in preterm infants receiving continuous positive airway pressure. *The Journal of Pediatrics*, *64*(4), 730-736.e1. doi: 10.1016/j.jpeds.2013.11.072

Linder, N., Haskin, O., Levit, O., Klinger, G., Prince, T., Naor, N., & Karmazyn, B. (2003). Risk factors for intraventricular hemorrhage in very low birth weight premature infants: A retrospective case-control study. *Pediatrics, 111*(5), e590-e595. doi: 10.1542%2Fpeds.111.5.e590

Liu, Y., & Salvendy, G. (2009). Effects of measurement errors on psychometric measurements in ergonomics studies: implications for correlations, ANOVA, linear regression, factor analysis, and linear discriminant analysis. *Ergonomics, 52*(5), 499-511. doi: 10.1080/00140130802392999

Manilal-Reddy, P.I., & Al-Jumaily, A.M. (2009). Understanding the use of continuous oscillating positive airway pressure (bubble CPAP) to treat neonatal respiratory disease: An engineering approach. *Journal of Medical Engineering & Technology, 33*(3), 214-222. doi: 10.1080%2F03091900601164838

Mann, B., Sweet, M., Knupp, A., Buck, J., & Chipps, E. (2013). Nasal continuous positive airway pressure: a multisite study of suctioning practices within NICUs. Advances in neonatal care: *Official Journal of The National Association of Neonatal Nurses, 13*(2), E1-E9. doi: 10.1097/ANC.0b013e3182863eaf

Marshall, C., & Rossman, G.B. (2011). *Designing qualitative research.* Thousand Oaks, CA: Sage Publications.

McHugh, C. (2009). *Review of Neonatal Unit suctioning frequencies and oxygen requirement.* Auckland, New Zealand: Author.

Meeks, M., & Hallsworth, M. (2010). Normal adaptation to the post-natal environment. In M. Meeks, M. Hallsworth, & H, Yeo (Eds.), *Nursing the neonate* (2nd ed., pp. 39-50). Chichester, England: Wiley-Blackwell.

Meiniger, J.C. (2012). Observational research. In J.J. Fitzpatrick & M.W. Kazer (Eds.), *Enclyclopedia of nursing research* (3rd ed., pp. 355-357). New York, NY: Springer.

Merrill, R.M. (2010). *Introduction to epidemiology* (5th ed.). Ontario, Canada: Jones and Bartlett.

Meyer, M., Mildenhall, L., & Wong, M. (2004). Outcomes for infants weighing less than 1000 grams cared for with nasal continuous positive airway pressure-based strategy. *Journal of Pediatrics and Child Health, 40,* 38-41. doi: 10.1111%2Fj.1440-1754.2004.00287.x

Milner, A., & Greenough, A. (2004). The role of the upper airway in neonatal apnoea. *Seminars in Neonatology: SN*, 9(3), 213-219. doi: 10.1016%2Fj.siny.2003.11.005

Morley, C., & Davis, P. (2004). Continuous positive airway pressure: Current controversies. *Current Opinion in Pediatrics*, *16*(2), 141-145. doi: 10.1097%2F00008480-200404000-00004

Morley, C.J., Lau, R., De Paoli, A., & Davis, P.G. (2005). Nasal continuous positive airway pressure: Does bubbling improve gas exchange? *Archives of Disease in Childhood Fetal and Neonatal Edition, 90*, F343-344. doi: 10.1136%2Fadc.2004.062588

Morrow, B., Futter, M., & Argent, A. (2006). Effect of endotracheal suction on lung dynamics in mechanically-ventilated paediatric patients. *Australian Journal of Physiotherapy, 52*(2), 121-126. doi: 10.1016%2FS0004-9514%2806%2970047-2

Morrow, B.M., & Argent, C.A. (2008). A comprehensive review of pediatric endotracheal suctioning: Effects, indications, and clinical practice. *Pediatric Critical Care Medicine, 9*(5), 465-477. doi: 10.1097%2FPCC.0b013e31818499cc

Narendran, V., Donovan, E., Hoath, S., Akinbi, H., Steichen, J., & Jobe, A. (2003). Early bubble CPAP and outcomes in ELBW preterm infants. *Journal of Perinatology: Official Journal of The California Perinatal Association*, *23*(3), 195-199. doi: 10.1038%2Fsj.jp.7210904

Neonate. *The Oxford advanced learners dictionary* (7th ed., p. 1021). (2005). Oxford, England: Oxford University Press.

New Zealand Resuscitation Council. (2010). *Guideline 13.4 airway management and mask ventilation of the newborn infant.* Retrieved from http://www.nzrc.org.nz/assets/Uploads/New-Guidelines/guideline-13-4dec10.pdf

Nordentoft, H., & Kappel, N. (2011). Vulnerable participants in health research: Methodological and ethical challenges. *Journal of Social Work Practice, 25*(3), 365-376. doi: 10.1080/02650533.2011.597188

Northway, W., Rosan, R., & Porter, D. (1967). Pulmonary disease following respiratory therapy of hyaline-membrane disease. Bronchopulmonary dysplasia. *The New England Journal of Medicine, 276*(7), 357-368.

Peat, J., Barton, B., & Elliott, E., (2008). *Statistics workbook for evidence-based health care*. Oxford, England: BMJ Books, Wiley-Blackwell

Peat, J., Mellis, C.,Williams, K., & Xuan W. (2002). *Health science research: A handbook of quantitative methods*. London, England: Sage Publications.

Petrova, A., Mehta, R., Anwar, M., Hiatt, M., & Hegyi, T. (2003). Impact of race and ethnicity on the outcome of preterm infants below 32 weeks gestation. *Journal of Perinatology, 23*(5), 404-408. doi: 10.1038%2Fsj.jp.7210934

Petty, J. (2012). Nurse:patient ratios influence the achievement of oxygen saturation targets in premature infants. *Evidence Based Nursing, 15*(1), 15-16. doi: 10.1136/ebnurs-2011-100029

Phattraprayoon, N., Sardesai, M., Durand, S., & Ramanathan, R. (2012). Accuracy of pulse oximeter readings from probe placement on newborn wrist and ankle. *Journal of Perinatology, 32*(4), 276-280. doi:10.1038/jp.2011.90

Polin, R.A., & Sahni, R. (2002) Newer experience with CPAP. *Seminars in Neonatology, 7,* 379-389. doi: 10.1053%2Fsiny.2002.0132

Polit, D.F., & Beck, C. (2008). *Nursing research: Generating and assessing evidence for nursing practice* (8th ed.). Philadelphia, PA: Wolters Kluwer Health/Lippincott, Williams, & Wilkins.

Premji, S. (2007). In C. Kenner & J.W. Lott (Eds.), *Comprehensive neonatal care: An interdisciplinary approach* (4th ed., pp. 437-447). St. Louis, MO: Saunders, Elsevier.

Prendiville, A., Thomson, A., & Silverman, M. (1986). Effect of tracheobronchial suction on respiratory resistance in intubated preterm babies. *Archives of Disease in Childhood, 61*(12), 1178–1183.

Prins, S., Pans, S., van Weissenbruch, M., Walther, F., & Simons, S. (2013). Doxapram use for apnoea of prematurity in neonatal intensive care. *International Journal of Pediatrics, 2013*(251047) 1-5. doi:10.1155/2013/251047

Rabe, H., Jewison, A., Alvarez, R., Crook, D., Stilton, D., Bradley, R., & Holden, D. (2011). Milking compared with delayed cord clamping to increase placental transfusion in preterm neonates: A randomized controlled trial. *Obstetrics & Gynecology, 117*(2 Pt 1), 205-211. doi: 10.1097%2FAOG.0b013e3181fe46ff

Rabe, H., Reynolds, G., & Diaz-Rossello, J. (2008). A systematic review and meta-analysis of a brief delay in clamping the umbilical cord of preterm infants. *Neonatology 93*(2), 138–44. doi: 10.1159%2F000108764

Roberts, D, & Dalziel, S.R. (2006). Antenatal corticosteroids for accelerating fetal lung maturation for women at risk of preterm birth. *Cochrane Database of Systematic Reviews*, 2006(3). doi: 10.1002/14651858.CD004454.pub2.

Robertson, A. F. (2003). Reflections on errors in neonatology: I. The "hands-off" years, 1920 to 1950. *Journal of Perinatology, 23*(1), 48-55. doi: 10.1038%2Fsj.jp.7210842

Rubarth, L. (2012). Back to basics: The apgar score: Simple yet complex. *Neonatal Network*, *31*(3), 169-177. doi: 10.1891/0730-0832.31.3.169

Salmond, S.W. (2007). Advancing evidence-based practice: A primer. *Orthopaedic Nursing, 26*(2), 114-123. doi: 10.1097%2F01.NOR.0000265869.72265.0a

Samson, N., Duvareille, C., St-Hilaire, M., Clapperton, V., & Praud, J. (2008). CPAP inhibits non-nutritive swallowing through stimulation of bronchopulmonary receptors. *Advances in Experimental Medicine and Biology*, *605*, 418-422. doi: 10.1007%2F978-0-387-73693-8_73

Samson, N., St-Hilaire, M., Nsegbe, E., Reix, P., Moreau-Bussière, F., & Praud, J. (2005). Effect of nasal continuous or intermittent positive airway pressure on nonnutritive swallowing in the newborn lamb. *Journal of Applied Physiology (Bethesda, Md.: 1985),* 99(5), 1636-1642. doi: 10.1152%2Fjapplphysiol.00464.2005

Sandelowski, M. (2000). Focus on research methods. Whatever happened to qualitative description?. *Research in nursing & health*, *23*(4), 334-340. doi: 10.1002%2Fnur.4770170611

Sankar, M., Sankar, J., Agarwal, R., Paul, V., & Deorari, A. (2008). Protocol for administering continuous positive airway pressure in neonates. *Indian Journal of Pediatrics*, *75*(5), 471-478.

Sansoucie, D.A., & Cavaliere, T.A. (2007). In C. Kenner & J.W. Lott (Eds.), *Comprehensive neonatal care: An interdisciplinary approach* (4th ed., pp. 677-718). St. Louis, MO: Saunders Elsevier.

Saugstad, O.D. (2010). Oxygen and oxidative stress in bronchopulmonary dysplasia. *Journal of Perinatal Medicine*, 38(6), 571-577. doi: 10.1515%2Fjpm.2010.108

Schmidt, B., Roberts, R., Davis, P., Doyle, L., Barrington, K., Ohlsson, A., & Tin, W. (2006). Caffeine therapy for apnoea of prematurity. *New England Journal of Medicine*, *354*(20), 2112-2121. doi: 10.1056%2FNEJMoa054065

Senn, S. (2002). *Cross-over trials in clinical research* (2nd ed.). Chichester, England: J. Wiley.

Shingawa, C. (2008). *Counties Manukau District Health Board Women's Health deliveries and unbooked deliveries, 2007-8*. Auckland, New Zealand: Author

Singh, N., Kissoon, N., Frewen, T., & Tiffin, N. (1991). Physiological responses to endotracheal and oral suctioning in paediatric patients: The influence of endotracheal tube sizes and suction pressures. *Clinical Intensive Care: International Journal of Critical & Coronary Care Medicine*, *2*(6), 345-350.

Singhal, N., Oberle, K., Burgess, E. & Huber-Okrainec, J. (2002). Parents' perceptions of research with newborns. *Journal of Perinatology, 22*(1), 57-63. doi: 10.1038%2Fsj.jp.7210608

Sola, A., Rogido, M.R., & Deulofeut, R. (2007). Oxygen as a neonatal health hazard: Call for détente in clinical practice. *Acta Paediatrica;96*, 798-800. doi: 10.1111%2Fj.1651-2227.2007.00287.x

Sola, A., Saldeno, Y., & Favareto, V. (2008). Clinical practices in neonatal oxygenation: Where have we failed? What can we do?. *Journal of Perinatology, 28,* S28-34. doi: 10.1038%2Fjp.2008.47

Soll, R. (1998). Synthetic surfactant for respiratory distress syndrome in preterm infants. *Cochrane Database of Systematic Reviews,* 1998(3). doi: 10.1002/14651858.CD001149

Soll, R., & Özek, E. (1997). Prophylactic animal derived surfactant extract for preventing morbidity and mortality in preterm infants. *Cochrane Database of Systematic Reviews,* 1997(4). doi: 10.1002/14651858.CD000511

Soll, R., & Özek, E. (2010). Prophylactic protein free synthetic surfactant for preventing morbidity and mortality in preterm infants. *Cochrane Database of Systematic Reviews,* 2010(1). doi: 10.1002/14651858.CD001079.pub2

Squires, A., & Hyndman, M. (2009). Prevention of nasal injuries secondary to NCPAP application in the ELBW infant. *Neonatal Network, 28*(1), 13-27. doi: 10.1891%2F0730-0832.28.1.13

Stenson, B., Tarnow-Mordi, W., Darlow, B., Simes, J., Juszczak, E., Askie, L., ... Brocklehurst, P. (2013). Oxygen saturation and outcomes in preterm infants. *New England Journal of Medicine, 368*(22), 2094-2104. doi: 10.1056/NEJMoa1302298

Stocks, J., & Godfrey, S. S. (1976). The role of artificial ventilation, oxygen, and CPAP in the pathogenesis of lung damage in neonates: Assessment by serial measurements of lung function. *Pediatrics*, 57(3), 352

Stolberg, H.O., Norman, G., & Trop, I. (2004). Randomized controlled trials. *American Journal of Roentgenology*, *183*, 1539-1544. doi: 10.2214/ajr.183.6.01831539

Suess, E.A., & Trumbo, B.E. (2010). *Introduction to probability simulation and Gibbs sampling with R.* New York, NY: Springer.

Symington, A., & Pinelli, J. (2006). Developmental care for promoting development and preventing morbidity in preterm infants. *Cochrane Database of Systematic Reviews,* 2006(2). doi: 10.1002/14651858.CD001814.pub2

Thibeault, D., Mabry, S., Ekekezie, I., & Truog, W. (2000). Lung elastic tissue maturation and perturbations during the evolution of chronic lung disease. *Pediatrics, 106*(6), 1452-1459. doi: 10.1542%2Fpeds.106.6.1452

Thomas, K. (2009). When neonatal ICU infants participate in research: Special protections for special subjects. *Critical Care Nursing Clinics of North America, 21*(2), 277-281. doi: 10.1016%2Fj.ccell.2009.01.007

Thomas, M., & Fothergill-Bourbonnais, F. (2005). Clinical judgements about endotracheal suctioning: What cues do expert pediatric critical care nurses consider? *Critical Care Nursing Clinical of North America, 17,* 329-340. doi: 10.1016%2Fj.ccell.2005.08.002

Thompson, B., Diamond, K., McWilliam, R., Snyder, P., & Snyder, S. (2005). Evaluating the quality of evidence from correlational research for evidence-based practice. *Exceptional Children, 71*(2), 181.

Touch, S., Shaffer, T., & Greenspan, J. (2002). Managing our first breaths: A reflection on the past several decades of neonatal pulmonary therapy. *Neonatal Network, 21*(5), 13-20. doi: 10.1891%2F0730-0832.21.5.13

Van Marter, L.J., Allred, E.N., Pagano, M., Sanocka, U., Parad, R., Moore, M., … Leviton, A. (2000). Do clinical markers of barotrauma and oxygen toxicity explain interhospital variations in rates of chronic lung disease? *Pediatrics*, *105,* 1194-1201. doi: 10.1542%2Fpeds.105.6.1194

Vento, M., Moro, M., Escrig, R., Arruza, L., Villar, G., Izquierdo, I., & Asensi, M. (2009). Preterm resuscitation with low oxygen causes less oxidative stress, inflammation, and chronic lung disease. *Pediatrics*, *124*(3), e439-49. doi: 10.1542%2Fpeds.2009-0434

Vintzileos, A.M., Ananth, C.V., Smulian, J.G., Scorza, W.E., & Knuppel, R.A. (2002). The impact of prenatal care on neonatal deaths in the presence and absence of antenatal high-risk conditions. *American Journal of Obstetrics and Gynecology, 186*, 1011-1016. doi: 10.1067%2Fmob.2002.127140

Volpe, J.J. (2008). *Neurology of the newborn*. (5th ed.). Philadelphia, PA. Saunders Elsevier.

Wallace, J. (1998). Suctioning–A two-edged sword: Reducing the theory-practice gap. *Journal of Neonatal Nursing*, *4*(6), 12.

Walsh, B., Brooks, T., & Grenier, B. (2009). Oxygen therapy in the neonatal care environment. *Respiratory Care*, *54*(9), 1193-1202. Retrieved from http://rc.rcjournal.com/

Watterberg, K., Demers, L., Scott, S., & Murphy, S. (1996). Chorioamnionitis and early lung inflammation in infants in whom bronchopulmonary dysplasia develops. *Pediatrics*, *97(*2), 210-215.

Ward-Larson, C., Horn, R., & Gosnell, F. (2004). The efficacy of facilitated tucking for relieving procedural pain of endotracheal suctioning in very low birthweight infants. *MCN: The American Journal of Maternal Child Nursing, 29*(3), 151-158. doi: 10.1097%2F00005721-200405000-00004

West, J.B. (2012). *Respiratory physiology: The essential*, (8th ed.). Baltimore, MD: Lippincott, Williams, & Wilkins.

Williams, P.H., & Sudia-Robinson, T. (2007). In C. Kenner & J.W. Lott (Eds.), *Comprehensive Neonatal Care: An interdisciplinary approach* (4th ed., pp. 606-614). St. Louis, MI: Saunders Elsevier.

Wilson, G., Hughes, G., Rennie, J., & Morley, C. (1992). Evaluation of two endotracheal suction regimes in babies ventilated for respiratory distress syndrome. *Early Human Development*, *25*(2), 87-90. doi: 10.1016%2F0378-3782%2891%2990187-8

Woodward, P. (2012). *Bayesian analysis made simple: An Excel GUI for WinBUGS*. Boca Raton, FL: Taylor & Francis Group.

Wu, L. (2010). *Mixed effects models for complex data*. Boca Raton, FL: Taylor & Francis Group.

Wong, M. (2010). *Australia New Zealand Neonatal Network Data*. Auckland, New Zealand.: Author.

Wung, J., Driscoll, J., Epstein, R., & Hyman, A. (1975). A new device for CPAP by nasal route. *Critical Care Medicine, 3*(2), 76-78.

Wunsch, H., Linde-Zwirble, W., & Angus, D. (2006). Methods to adjust for bias and confounding in critical care health services research involving observational data. *Journal of Critical Care*, *21*(1), 1-7. doi: 10.1016%2Fj.jcrc.2006.01.004

Yang, W., Zilov, A., Soewondo, P., Bech, O.M., Sekkal, F., & Home, P.D. (2010). Observational studies: Going beyond the boundaries of randomized controlled trials. *Diabetes Research and Clinical Practice*, *88*(Suppl. 1), S1-S9. doi: 10.1016%2FS0168-8227%2810%2970002-4

Zelkowitz, P., Papageorgiou, A., Bardin, C., & Wang, T. (2009). Persistent maternal anxiety affects the interaction between mothers and their very low birthweight children at 24 months. *Early Human Development*, *85*(1), 51-58. doi: 10.1016%2Fj.earlhumdev.2008.06.010

Zemlicka-Dunn, T. (2001, December 3). *AARC: Nasopharyngeal suctioning reduces oxygen requirements in pediatric bronchiolitis patients.* Paper presented at the 47th International Respiratory Congress of the American Association for Respiratory Care, San Antonio, TX.

Appendix A

Literature Review Tables

1. Cordero, L., Sananes, M. & Ayers, L.W. (2001). A Comparison of Two Airway Suctioning Frequencies in Mechanically Ventilated, Very-Low-Birthweight Infants. Respiratory Care, 46(8), 783-788.

Country	Setting	Subjects	Design and methods	Results / conclusions	Critique / limitations of study
USA	NICU	180 infants ≤1500grms consecutive admission pre & post change in suction practice, requiring mechanical ventilation for 7 days	Sequential retrospective study. Convenience sampling of last 90 infants admitted on mechanical ventilation for 7 days, prior to change in practice, suctioned 4hourly (plus as needed). First 90 infants admitted on mechanical ventilation for 7 days, post change in practice, suctioned 8hourly (plus as needed).	No significant difference in gestational age, birthweight, days of ventilation 29 and 27 days Less suctioning per patient in 8 hourly group. Less bacterial colonisation of lung infections in 8hourly group. No significant difference in re-intubation or blocked tubes.	Consecutively running a study on open and closed suctioning in post-practice change period though did indicate no significant effect. Didn't mention experience of staff performing the procedure in each group. More reflective of premature infant population as covered the whole period of ventilation. Though limited to ventilation

2. Durand, M., Sangha, B., Cabal, L., Hoppenbrouwers, T., & Hodgman, J. (1989). Cardiopulmonary and intracranial pressure changes related to endotracheal suctioning in preterm infants. *Critical Care Medicine, 17*(6), 506-510.

Country	Setting	Subjects	Design and methods	Results / conclusions	Critique / limitations of study
USA	NICU	15 infants <1500grms ≤30 days (13 ≤ 14 days old) Ventilated	Observational study. No sedation or paralysis used, 10 infants had mild sedation. Standard procedure for suctioning-supine closed system. Measurements monitored prior during and for 1 minute intervals post till 5 minutes: Heart rate Arterial BP TcPO2 TcPCO2 ICP CPP calculated Suction pressure set at 80-120mmHg.	Significant lowering of heart rate and increase in BP and ICP. TcPCO2 dropped, although not significantly. Stated that phasic increases in ICP CPP and mean BP and increase the risk of IVH. TcPO2 lowered during suctioning, was felt to reflect the closed system used, as the results didn't correlate to other studies results. The TcPCO2 rose slightly Discuss the possibility that increased ICP may be due to tracheal stimulation and increased intrathoracic pressure which may impede venous return during suction. Mean arterial BP was found to be a significant determinant of the CPP.	ET tube suctioning, which may be more traumatic to infants that oro or nasopharyngeal suctioning, due to the introduction of a catheter into a larger airway and the partial occlusion of that airway. Low number of infants. One infant was studied twice. All infants were suctioned supine, a position that is now know to increase stress in preterm infants. There is no breakdown of the gestation of the infants in the study, or discussion around the characteristics of the population or outcomes. There discussion around risk of IVH with increasing mean BP, ICP and CPP differs from other studies which show that CPP lowered with increased ICP-though there was no change in the mean BP in the other study. There is no graph or statement of significance for the changes in CPP. If the increase in ICP is related to tracheal stimulation the results of this research may not be applicable to oro/nasopharyngeal suctioning. No discussion around the pressures used in each individual session and whether this impacted on the results.

3. Fanconi, S., & Duc, G. (1987). Intratracheal suctioning in sick preterm infants: prevention of intracranial hypertension and cerebral hypoperfusion by muscle paralysis. *Pediatrics, 79*(4), 538-543.

Country	**Setting**	**Subjects**	**Design and methods**	**Results / conclusions**	**Critique / limitations of study**
Switzerland	NICU	28 infants <36 weeks ventilated. 28-36 weeks 780-2900grms	Prospective cross over study. Infants suctioned 3 time without muscle paralysis and 3 times with muscle paralysis. Sedation also given on a regular basis. Measurement taken of : BP Heart rate Transcutaneous O2 and CO2(TcPO2 & TcPCO2) Intracranial pressure (ICP) Cerebral perfusion pressure (CPP) was calculated from mean BP and ICP.	Average gestation of infants was 31 weeks. Suctioned every hour and measurements taken one to three times a day. Measurements performed until infant extubated. Only infants with fontanelles >10mm had intracranial measurements done. Sharp increase in ICP in non-paralysed infants associated with suctioning. This reflected in a sharp reduction of CPP. No significant change in heart rate or BP prior or post suctioning, either with or without paralysis. Significant drop in TcPO2 in both groups with no difference between the groups. Though this was adjusted with the use of FiO2 No significant changes in TcPO2 prior or post in either paralysed or not paralysed. Felt to be too short a period to determine any changes. Any changes in BP heart rate and TcPO2 detected during suctioning procedure was resolved within 2 minutes and the peak of the ICP resolved straight away. No correlation found between any parameters, even ICP and the risk of IVH. Though discussed the possibility that sustained increases in ICP leading to reduced CPP could increase the risk of IVH. Found that muscle paralysis reduced the risk of increased ICP.	ET tube suctioning, which may be more traumatic to infants that oro or nasopharyngeal suctioning, due to the introduction of a catheter into a larger airway and the partial occlusion of that airway. Old study with practices that may not be relevant for today, such as suctioning that is not indicated. Doesn't state how many infants didn't have ICP measured. If it was due to smaller size of fontanelle, this would be more likely to be extremely low birth weight infants, who are more prone to IVH Sedation may have resulted in the lack of change in heart rate and BP with suctioning. There was no analysis within the group of infants placing them in to more recognised groups for gestation ie 24-28 weeks, 28-32 weeks and 32-<36. This may have shown a much different picture, as extremely low birth weight infants have less ability for cerebral auto regulation and more fragile vessels. CPAP infants are not usually sedated and this may also have an impact on responses of infants during suction. So hard to apply this research to suctioning of CPAP infants, measuring ICP is not standard procedure and may pose difficulties in application with bubble CPAP with the placement on the transducer and maintaining the placement of CPAP equipment on infant. It would hard to tell also if the fact that an instrument was in situ may aggravate the infants response also. There was no discussion on when each suctioning episode took place; time may play a role in the outcomes, as well as illness. The researchers mentioned sicker infants may not respond as well as well infants.

4. Gilbert, M. (1999). Assessing the need for endotracheal suction. Paediatric Nursing, 11(1), 14-17.

Country	Setting	Subjects	Design and methods	Results / conclusions	Critique / limitations of study
UK	4 Paediatric Intensive Care Units	12 RNs caring for 12 children till extubation.	Mixed method, using observational research and content analysis. 12 staff approached to participate. Procedure observed by researcher and then staff questioned n rationale for suctioning episode. 92 episodes observed during 8-16.00 over 4 days. Patients included 3 long term awake ventilated children, 5 weaning from the ventilator and rousable, and 4 fully ventilated and heavily sedated.	Data on reason for suctioning was analysed with the majority of reasons being related to an alteration in child's clinical condition. Result showed that nurses assess the need for suctioning on certain clinical changes, that assessment is complex and that training and education of staff on suctioning ETT is essential.	Study only performed during 8.00-16.00 May have observer bias and practices may have altered due to observation. Selection bias in approaching staff to participate in study. Experience of staff not noted or discussed in relation to skill and expertise in procedure. Small sample size. No rationale given for need for education discussed. Focussed on ETT suctioning.

5. Hayes, J., Czarnecki, M., & Kaucic, C. (1999). Infant Nasal-Pharyngeal Suctioning: Is it Beneficial? Pediatric Nursing, 25(2), 193.

Country	Setting	Subjects	Design and methods	Results / conclusions	Critique / limitations of study
USA	Two Paediatric Medical Unit Infant unit	46 RN's from medical unit, in 2 units completing questionnaire. 33 infants' ≤6months old admitted to infant unit with Bronchiolitis, RSV, bronchospasm or pneumonia, receiving Albuterol aerosol treatments and requiring nasopharyngeal (NP) suctioning.	**Research question-** Study was divided into two parts. 1. What respiratory assessment parameters do nurses identify as indicating need for NP suctioning? 2. What respiratory assessment parameters show statistical significant improvement after NP suctioning? 3. What the relationship between what the nurses thinks is important when deciding whether or not to suction and what physiological improvements are actually found after NP suctioning? **Study 1** Descriptive study using questionnaires to ask staff to identify and rank order of assessment parameters used in NP suctioning decision. **Study 2** One group, pretest-posttest design to determine effect of NP suctioning on individual infants. Infants were their own control, with the intervention being suctioning episode.	Study 1-Most frequently used and highly ranked, cues for suctioning were presence of audible secretions, visible secretions and a decrease in pulse oximeter readings. Study 2-19males and 14 females, 2-22weeks of age. 3 indicators improved from pre to post testing: presence of audible secretions, presence of visible secretions and pulse oximeter readings. Pulse oximetry showed greatest improvement. Results from study 2 validate the findings of study 1.	Study 1-Apparent misinterpretation of years of experience and therefore data not reported. This could have a bearing on reason for suctioning and thus on results. An important part of the research has been missed out altogether. Study 2-single assessment of each infant. Infants not requiring CPAP and not premature infants, so results not easily transferrable to that population. Half of the data of pulse oximetry was missing so may have led to misleading findings. Small sample size means the significance may not be relevant. Restricted to sick infants and needs further research. Results may be different dependent on experience of staff. Data collected not clearly defined, only the parameters found to correlate with survey findings identified. Unclear if staff who completed the questionnaire worked in the same unit where the infants were studied and whether this would have an effect on results.

6. Kaiser, J., Gauss, C., & Williams, D. (2008). Tracheal suctioning is associated with prolonged disturbances of cerebral hemodynamics in very low birth weight infants. *Journal of Perinatology, 28*(1), 34-41.

Country	Setting	Subjects	Design and methods	Results / conclusions	Critique / limitations of study
USA	NICU	73 infants 25-29 weeks ≤1500grms with normal head ultrasound scan Born between July 2002 to June 2005 Requiring ventilation	Observational study looking at the acute effects of suctioning when clinically indicated on cerebral hemodynamics. All received surfactant, ventilator settings recorded, FiO2 to maintain SaO2 >90%. Mean arterial BP recorded continuously via arterial line and used for blood gas monitoring also. Cerebral blood flow (CBF) was monitored transcranially. BP, PaO2, PaCO2 and cerebral blood flow were continuously monitored prior during and post each suctioning episode for the first week of life. 15 minutes prior to 45 minutes post suctioning episode.	A total of 202 suctioning episodes. One third of sessions were when infants were on high frequency oscillatory ventilation, which was found to cause a higher CBF, though not significant. Overall the increase in CBF was 31% following suction and stayed elevated for 25 minutes. Felt that although infants studied had good cerebral autoregulation, that infants that didn't may have increased risk of IVH. That more frequent suctioning may lead to increased risk of IVH also. PaCO2 was a good predictor for CBP. That increases in mean arterial BP may increase the CBP in infants with reduced cerebral auto regulation.	ET tube suctioning, which may be more traumatic to infants that oro or nasopharyngeal suctioning, due to the introduction of a catheter into a larger airway and the partial occlusion of that airway. Not many suctioning episodes for 73 infants over 7 days. Used open suction technique, as opposed to closed suction, which may have some effect on the results. Transcranial monitoring may not be as accurate as other methods of measuring CBF, plus not a readily available tool for most units to use. No discussion if sedation or analgesia was used, position of infants or swaddling/comfort given during the procedure. Number of times suction catheter was passed or quantity of secretions not mentioned. Infant could have been compromised at the start of suctioning procedure, as procedure only performed when indicated. There may also be discrepancies amongst the staff as to when to suction, experience and skill of staff in the performing the procedure. Didn't discuss how long infants required ventilation and CLD for these infants, which is morbidity associated with prolonged ventilation FiO2 levels were documented but no comparison of pre and post suction, to elicit if there was improvement from the procedure.

7. Kerem, E., Yatsiv, I., & Goitein, K. (1990). Effect of endotracheal suctioning on arterial blood gases in children. *Intensive Care Medicine, 16*(2), 95-99.

Country	Setting	Subjects	Design and methods	Results / conclusions	Critique / limitations of study
Israel	PICU	25 infant/children 1 day to 10 years old Intubated with severe respiratory failure. Various conditions	Randomised case control study, with infants acting as own control. Looking at the best method to reduce hypoxia and hypercarbia due to suctioning. Each infant was suction 4 times and a different protocol used each time. Each episode was 30 minutes apart. Looking at the effect of FiO_2 prior or hyperinflation of the lungs pre or post had on the arterial blood gas results. 1-arterial blood gas (ABG) taken pre-test, patient suctioned, post ABG, returned to ventilator, ABG taken 5 and 10 minutes post suction. 2- ABG taken pre-test, FiO_2 100% administered for 1 minute, patient suctioned, post ABG, returned to ventilator, ABG taken 5 and 10 minutes post suction. 3- ABG taken pre-test, Hyperinflation, patient suctioned, post ABG, returned to ventilator, ABG taken 5 and 10 minutes post suction. 4- ABG taken pre-test, patient suctioned, post ABG, Hyperinflation, returned to ventilator, ABG taken 5 and 10 minutes post suction.	97 studies performed of a maximum of 100. Highly significant decrease in PO_2 was noted post suctioning in the control group, with a similar fall in SaO_2, returning to pre suctioning level within 5 minutes. There was no significant change in PCO_2. With pre-oxygenation there was significantly high post suction PO_2. Hyperinflation saw a significantly higher pre suction PO_2 and still a dramatic fall post suction. With hyperinflation post showing a significant increase post suction, above pre suction levels. Suggest delivering 100% oxygen to patients 1 minute prior to suctioning to lessen effects of suctioning, with no indication for hyperinflation prior, as there was no change in PCO_2. Hyperinflation post, may restore PO_2 quickly but will not prevent hypoxia during suctioning.	ET tube suctioning, which may be more traumatic to infants that oro or nasopharyngeal suctioning, due to the introduction of a catheter into a larger airway and the partial occlusion of that airway. As the patient was serially suctioned, it would be difficult to appreciate the true effects of each suctioning protocol, as there may have been residual effect left from the previous episode. However, the initial ABG prior to each suctioning period, may counter this and the fact that they randomised the sequence. Very small numbers for randomisation may not show true effect. No breakdown of differing ages and response to suctioning. Would have been interesting due to the large gap in ages, only median age given. No reason given for the missing results or on which patients and protocol they were. Due to oxidative stress and resulting organ compromise, it would not be advisable to deliver 100% to preterm infants as suggested In this study.

8. Kerr, M., Menzel, L., & Rudy, E. (1991). Suctioning Practices in the Pediatric Intensive Care Unit [Abstract]. *Heart and Lung, 20*(3), 300.

Country	Setting	Subjects	Design and methods	Results / conclusions	Critique / limitations of study
USA	Paediatric Intensive Care Unit	24 ventilated children	Observational study. Children 2weeks–6years of age mean 18.8 months. Variables observed were oxygen delivery, glove technique, head position, type of suction, number of breaths and catheter insertions, secretion amount and suctioning rationale. Data collected using precoded instrument.	Significant variance in suctioning practise, with large numbers of suction catheter insertions and breaths delivered, highlighted that practice at that time may not be optimal. Rationale for suctioning was noted as being routine, congested lung sounds, mucous in tube, high pressure alarm on ventilator sounding and physician request.	Limited as only an abstract was available for this study. Focuses on ETT suctioning. No indication of any significance noted. Limited report on research. A window on suctioning practices at this time.

9. Morrow, B., Futter, M., & Argent, A. (2006). Effect of endotracheal suction on lung dynamics in mechanically-ventilated paediatric patients. *Australian Journal of Physiotherapy*, 52(2), 121-126

Country	**Setting**	**Subjects**	**Design and methods**	**Results / conclusions**	**Critique / limitations of study**
South Africa	PICU Children's hospital	78 intubated infant/children 0.3 to 25 months old 24 removed due to large Et tube leaks, leaving 54	Observational study looking at lung compliance after suctioning, using dynamic compliance to show this. All patients were sedated and given analgesia. Ventilator settings, FiO_2, ET tube size, age, weight, respiratory rate, PaO_2, oxygen index and ventilation index. Continuous cardiac and saO_2 monitoring. Preoxygenated with 100% FiO_2 prior to suctioning. FiO_2 reduced as SaO_2 recovered. Connected to a CO_2 monitor for 5 minutes prior and 5 minutes post one episode of suctioning. Ratio of internal diameter of ET tube to external diameter of suction catheter noted. Adverse events were recorded. Suction episode was a routine procedure, not when indicated.	Patients had a significant drop in dynamic compliance after suction. However, patients with secretions had improved lung compliance after suction and patients with "stiff" lungs had less reduction in compliance. Significant decrease in compliance when larger suction catheter used. Conclusion was that endotracheal suctioning drops dynamic lung compliance with small ET tubes. Did state that a third of the patients displayed an improvement when there were obstructive secretions. Though what obstructive secretions were was not identified.	Reasonable number of patients, patients act as own control with baseline observations. Relates to ET suctioning and also larger patients than premature infants. No indication of the effect that suctioning had on heart rate or saturation levels during the procedure, though these were monitored, or the length of time for recovery. The recovery time may also indicate the extent to which the infant was compromised and could have been correlated with the dynamic compliance results. Only mentioned one patient suffering a "transient relative bradycardia", though this has been cited by other authors as one of the side effects of suctioning. As there is no record of the heart rate during the study, could this mean that suctioning in this instance did not cause bradycardias. Also discussed three patients having desaturations below 85%, another side effect mentioned for suctioning by other authors. One patient was removed prior to analysis as the results were far outside the parameters. This was thought to be due to measurement error, though could have been a true result. It was stated that this didn't alter the results, though this would be difficult to verify. The quantity of secretions was not mentioned and could have had some impact on the results. The suction catheter was also only passed the once. If a patient has copious secretions, sometimes several insertions of the suction catheter are required. Suction was performed as a routine procedure and found that when secretions were present that there was improved compliance. Therefore, if suctioning was only performed when secretions were noted the results would contradict the conclusion the study presented.

10. Singh, N., Kissoon, N., Frewen, T., & Tiffin, N. (1991). Physiological responses to endotracheal and oral suctioning in paediatric patients: the influence of endotracheal tube sizes and suction pressures. *Clinical Intensive Care: International Journal Of Critical & Coronary Care Medicine, 2*(6), 345-350.

Country	Setting	Subjects	Design and methods	Results / conclusions	Critique / limitations of study
Canada	PICU Children's Hospital	17 intubated infants Approx. 6.5 months old	Prospective observational study. Suctioned when indicated. Using open suctioning. Suction catheters used were documented giving the internal diameter of ET tube to external diameter of suction catheter ratio. Varying suction pressures were used from 80-120mmHg. Some suctioning episodes required multiple insertions to clear secretions. Measurements monitored prior and 30 second intervals till recording back to baseline: Heart rate Respiratory rate Arterial BP Oxygen Saturation (SaO2) ICP	4 patients had invasive ICP. 9 patients were sedated and 3 paralysed. Each patient had nine suctioning episodes over 24-48 hour period. Significant changes in heart rate, SaO2 and ICP. Mean Arterial BP and respiratory rate showed no significant change, though there was a rise in BP and drop in respiratory rate initially. No significant difference between paralysed and not paralysed or between sedation in either group. No difference was found when different suction pressures were used. Oral suctioning was performed also using 100mmHg and similar recordings made. Found that there were comparable results between the two methods, with less likelihood of desaturation	ET tube suctioning, which may be more traumatic to infants that oro or nasopharyngeal suctioning, due to the introduction of a catheter into a larger airway and the partial occlusion of that airway. Low number of infants. There is no breakdown of the gestation of the infants in the study, or discussion around the characteristics of the population or outcomes. Though oral suctioning was looked at in this study, it is not clear if this was performed straight after ET suctioning or at a different time. Also no indication is given as to if the infant was allowed to fully recover from the ET suctioning prior to initiating the oral suctioning. The baselines for all parameters recorded are different for ET compared to oral suctioning except ICP. This could be an effect of the timing of oral suctioning in relation to ET suctioning, as the parameter baselines are, as a majority, lower for ET suction compared to oral. Oral suctioning is also being performed on an infant with an ET tube in situ, which may impede the infants response to oral suctioning. No indication of how long it took infants to recover from suctioning episode, or if the number of insertions of the suction catheter or if ET tube and suction catheter ratio had an impact on the readings and results. There is no mention of containment or swaddling to help reduce the stresses of the procedure.

11. Ward-Larson, C., Horn, R., & Gosnell, F. (2004). The efficacy of facilitated tucking for relieving procedural pain of endotracheal suctioning in very low birthweight infants. *MCN: The American Journal of Maternal Child Nursing, 29*(3), 151-158.

Country	**Setting**	**Subjects**	**Design and methods**	**Results / conclusions**	**Critique / limitations of study**
USA	NICU	40 infants intubated. 23-32 weeks	Prospective randomised crossover design. Infant own control. Ventilated infant ≤ 28 days old at start of study. Three measurement tools used to assess pain and stress: Premature infant pain profile. Neonatal therapeutic intervention scoring system. Score for neonatal acute physiology. Infants' score obtain prior and post suctioning episode, one where facilitated tucking was used and one without over a 12 hour period. Period of observation post suctioning was 30 seconds.	2-4 hours between each suctioning episode observed. Results showed that facilitated tucking appeared to be effective in significantly reducing the stress and pain associated with ET suctioning.	ET tube suctioning, which may be more traumatic to infants that oro or nasopharyngeal suctioning, due to the introduction of a catheter into a larger airway and the partial occlusion of that airway. There is no breakdown of the gestation of the infants in the study, or discussion around the characteristics of the population or outcomes. Though heart rate and SaO2 were used within the assessment tools there is no breakdown of these recordings in response to the procedure with and without facilitated tucking. This would have been an interesting comparison with other studies using sedation and paralysis. The period of observation post suctioning appears very short at 30 seconds, as most studies have noted that infants took up to 2 minutes for observations to return to baseline. Though three methods of scoring are discussed only one method is analysed within the research. There is no clear indication as to why this is. There was no breakdown on the differing ages in days for the infants. It would be interesting to note whether this had an impact on the results

12. Wilson, G., Hughes, G., Rennie, J., & Morley, C. (1992). Evaluation of two endotracheal suction regimes in babies ventilated for respiratory distress syndrome. *Early Human Development*, *25*(2), 87-90.

Country	Setting	Subjects	Design and methods	Results / conclusions	Critique / limitations of study
UK	NICU	97 infants <2.5kg requiring admission to unit and mechanical ventilation via ETT	Objective- -an evaluation of the effect of reducing endotracheal lavage to 12 hourly on time on ventilation and the incidence of pneumothorax or blocked endotracheal tubes in uncomplicated cases of respiratory distress syndrome. Case-control study Random assignment of consecutive admissions from February 1987 and April 1988, to 12hourly research group or current practice, 6 hourly, control group. Study was only performed on infants for first 3 days of ventilation. Mortality and IVH recorded Exclusion of any infant with respiratory sequelae.	No significant difference in gestational age, birthweight, surfactant, ventilation requirements or respiratory outcome. No significant difference in mortality, IVH or respiratory sequelae. 2 blocked tubes occurred in 6hourly suctioning group compared to nil in 12hourly group. 1 infant moved from research group due to requirement of increased suctioning. That 12hourly suctioning alright in ventilated infants without initial respiratory sequelae, within first 3 days of ventilation, Study would need to be carried out on more infants to determine true benefit of less frequent suctioning.	Limited to only first 3 days of ventilation and not with sicker more complex infants with respiratory sequelae, who tend to be the infants most ventilated. No may not be representative of neonatal population. As pointed out by researcher, more participants would be required to show a more significant result. Didn't mention experience of staff performing the procedure in each group, as this could have an effect on the procedure and recovery post suctioning. No information on how data collected and volume of secretions aspirated. Limited to ventilation

13. Zemlicka-Dunn, T. (2001, December 3). [AARC: Nasopharyngeal Suctioning Reduces Oxygen Requirements in Pediatric Bronchiolitis Patients]. Presentation at the 47th International Respiratory Congress of the American Association for Respiratory Care, San Antonio, TX. [Transcript]. Retrieved from http://www.docguide.com/dg.nsf/PrintPrint/158AF86B59018B4D85256B170052F8C1

Country	Setting	Subjects	Design and methods	Results / conclusions	Critique / limitations of study
USA	unsure	421 infants ≤24 months old.	Retrospective observational study. To quantify the effect that nasopharyngeal suction had on the ability to wean oxygen. Review data of infants suctioned while receiving supplemental oxygen. Collecting data from patients notes: FiO2 Suctioning episodes Suctioning related morbidities	1141 suctioning episodes. Resulted in weaning oxygen in 31% post first suction, 24% post second suction and 24% post third suction. Oxygen was weaned if SaO2 was ≥88%.	Very limited as unable to get full study, only conference proceedings. Interesting to note the decrease in FiO2 after suctioning. This has not been noted in any study so far reviewed. No breakdown of infants ages or response to suctioning. Would have liked to have learned more about this research. On older self-ventilating infants and not fragile premature infants requiring CPAP as support Retrospective study-data only as reliable as information documented at time.

Appendix B

Key Concepts and Definitions

BPD (CLD)

Brochopulmonary Dysplasia, also identified as Chronic Lung Disease (CLD), was first described by Northway, Rosan, & Porter in 1967, as a disease associated with prolonged ventilation and exposure to high levels of supplemental oxygen. Northway et al., (1967), identified 4 stages, resulting in damage to the lungs impeding gas exchange due to parenchymal fibrosis, airway injury and inflammation (Jobe & Bancalari, 2001), and cardiomegaly (Northway et al., 1967).

There has since been many studies done to determine the cause of BPD development and to establish practice to reduce the risk. The cause of BPD has been found to multifactorial with prematurity, inflammation/infection, PDA/fluid management, vascular maldevelopment, arrested development, genetics, nutrition and the intrauterine environment all felt to play a role in the development of BPD (Gien & Kinsella, 2011; Jobe & Bancalari, 2001).

The pathophysiology of BPD has appeared to change over the decades as a result of more premature infants surviving and requiring respiratory support. This change has been described as the “new BPD” (Jobe & Bancalari, 2001), with the physiological state of the lung damage being an increase in elasticity relational to the severity of the disease, with fewer and larger alveoli, indicative of a disruption of septation and in some cases the development of pulmonary microvasculature is reduced (Thibeault, Mabry, Ekekezie, & Truog, 2000). The abnormal development of the pulmonary vasculature and increased pulmonary pressure being associated with severe BPD (Jobe & Bancalari, 2001). Through the years the definition of BPD and criteria for classification have been debated due to the poor predictability of terms to identify poor long-term respiratory outcomes for infants, with BPD being used interchangeably with CLD (Lefkowitz & Rosenberg, 2008). Validation of the definitions was performed by Ehrenkranz et al. (2005), and has been presented in Table 56.

Table B1
Definition of BPD.

Gestational age <32 weeks:	
At 36 weeks post menstrual age or at discharge home, whichever comes first, having had treatment with oxygen >21% for at least 28 days plus-	
Mild BPD	Breathing room Air
Moderate BPD	Need for <30% oxygen
Severe BPD	Need for ≥30% oxygen and/or positive pressure (Respiratory support)

Note. Adapted from Ehrenkranz et al. (2005), p.1354.

Bradycardia

A transient drop of the heart rate to 90 beats per minute (bpm) as defined by Hodgman et al. (1990).

CPAP

CPAP is described as a “non-invasive method of applying a constant distending pressure” (DiBlasi, 2009, p.1210). CPAP is delivered in many differing ways (Polin & Sahni, 2002), with the one goal of introducing pressure into the airways. Supporting spontaneous respirations, gas exchange, reducing apnoea and maintaining a functional residual capacity, thus reducing the work of breathing and the risk of lung injury

(DiBlasi, 2009). CPAP can reduce the risk of mechanical stress and inappropriate lung distension, with studies using models suggesting the oscillatory effect of bubble CPAP may be beneficial (Manilal-Reddy & Al-Jumaily, 2009), though other research has shown no change in oxygen saturation when the amplitude and rate of the bubble is decreased (Morley, Lau, De Paoli, & Davis, 2005). The system used at Study NNU is represented in *Figure B1* below. Application of the system is crucial to the success of CPAP delivery, such as right sized prongs and snug fitting hat (Bonner & Mainous, 2008).

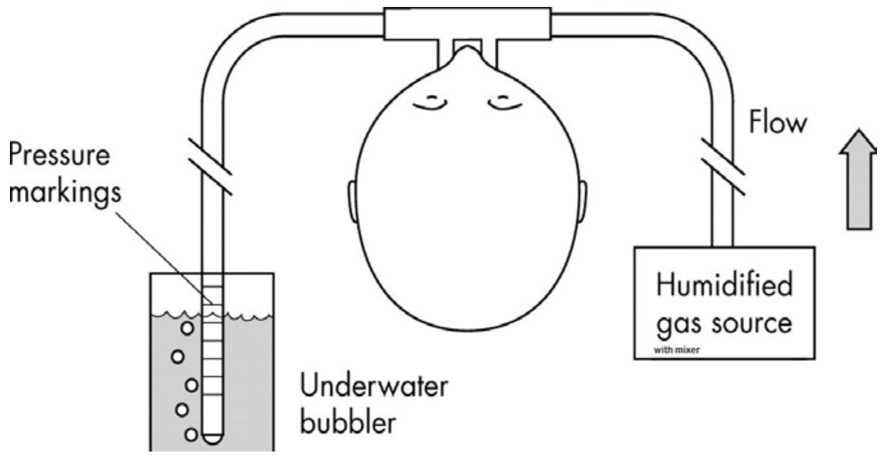

Figure B1. Bubble CPAP. Adapted from Morley et al. (2005), p. F343.

Desaturation

Desaturations are defined, within this study, as a drop in saturation levels ≤80% for a period of ≥10 seconds (Di Fiore et al., 2010). Research has found that most premature infants, at 2-4 weeks of age, average approximately 2-3 desaturations ≤80% for 10 seconds per hour (Di Fiore et al., 2010), hence the number of 3 or more prolonged desaturations was used within the study for withdrawal from Part Two, as this was more than would have been expected.

Developmental care

Developmental care for premature infants requiring respiratory support to reduce the risk of respiratory disease, was first discussed by Als et al. (1987), and consists of observing behavioural cues that indicate stress and using strategies such as nesting, flexed positioning, clustering cares to cues, reducing stimulation and use of facilitated tucking. Thus allowing infants to transition between sleep and awake states smoothly and prevent undue stress, reducing risk of apnoea and oxygen requirement. Developmental care has also been found to support brain development in premature infants (Als et al., (2004).

Doxapram

Has been used in neonatal care for over 25 years and is a respiratory stimulant that affects chemoreceptors both centrally and peripherally to promote breathing (Alpin, Eyal, & Sagi, as cited in Prins et al., 2013).

Infant (Neonate)

The Oxford Advanced Learners Dictionary (2005) defines a neonate as an infant up to 4 weeks of age. As many of the premature infants remain in neonatal unit for many months, infant will be the term used throughout this thesis. An infant being described as one requiring care within the neonatal unit.

Lung compliance

Lung compliance is described by West (2012), as the change in volume in the lung per unit change in pressure and is dependent on the size of the lungs. Compliance is improved with a lower surface tension within the alveoli, reducing the effort of breathing (West, 2012).

Oxygen saturation (SaO_2)

The use of a monitor to determine percentage of haemoglobin saturated with oxygen. This is a recognised way of monitoring the status of oxygenation, though there is uncertainty about what the appropriate range of SaO_2 for premature infants requiring supplemental oxygen (Walsh et al., 2009).

Suctioning

Suctioning is the use of negative pressure to remove secretions from airways to optimise the airway (Wallace, 1998). The maximum pressure used is the Neonatal unit in the study was 100mmHg, with size 6-7FG suction catheter used (CMDHB, 2012).

Supplemental oxygen

Oxygen used to prevent hypoxia and is the most commonly used drug in neonatology (Sola et al., 2008)

Appendix C

Ethical Approval

Health and Disability Ethics Committees

Upper South B Regional Ethics Committee
c/- Ministry of Health
6 Hazeldean Road, Level 1 Montgomery Watson Building
Addington, Christchurch
Phone: (03) 974 2305
Email: uppersouthb_ethicscommittee@moh.govt.nz

29 August 2011

Ms Su Greensill
Counties-Manukau District Health Board
Neonatal Unit
Middlemore Hospital
Private Bag 93311
Otahuhu, Auckland

Dear Ms Greensill

Re:	Ethics ref:	**URB/11/07/024** (please quote in all correspondence)
	Study title:	What is the effect of suctioning and frequency on oxygenation and bradycardias in infants ≤30 weeks gestation requiring Bubble Continuous Positive Airway Pressure (CPAP).
	Investigators:	Ms Su Greensill

This study was given ethical approval by the Upper South B Regional Ethics Committee on 29 August 2011. A list of members of the Committee is attached.

<u>Approved Documents</u>

- Information Sheet and Consent Form for Infants Part One version 4 dated 11 August 2011
- Information Sheet and Consent Form for Infants Part Two version 5 dated 11 August 2011

This approval is valid until 30 November 2012, provided that Annual Progress Reports are submitted (see below).

<u>Access to ACC</u>

For the purposes of section 32 of the Accident Compensation Act 2001, the Committee is satisfied that this study is not being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is being carried out. Participants injured as a result of treatment received in this trial will therefore be eligible to be considered for compensation in respect of those injuries under the ACC scheme.

Health and Disability Ethics Committees

Upper South B Regional Ethics Committee
c/- Ministry of Health
6 Hazeldean Road, Level 1 Montgomery Watson Building
Addington, Christchurch
Phone: (03) 974 2305
Email: uppersouthb_ethicscommittee@moh.govt.nz

Amendments and Protocol Deviations

All significant amendments to this proposal must receive prior approval from the Committee. Significant amendments include (but are not limited to) changes to:

- the researcher responsible for the conduct of the study at a study site
- the addition of an extra study site
- the design or duration of the study
- the method of recruitment
- information sheets and informed consent procedures.

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

Annual Progress Reports and Final Reports

The first Annual Progress Report for this study is due to the Committee by 31 August 2012. The Annual Report Form that should be used is available at www.ethicscommittees.health.govt.nz. Please note that if you do not provide a progress report by this date, ethical approval may be withdrawn.

A Final Report is also required at the conclusion of the study. The Final Report Form is also available at www.ethicscommittees.health.govt.nz.

Requirements for the Reporting of Serious Adverse Events (SAEs)

SAEs occurring in this study must be individually reported to the Committee within 7-15 days only where they:

- are *unexpected* because they are not outlined in the investigator's brochure, and
- are not defined study end-points (e.g. death or hospitalisation), and
- occur in patients located in New Zealand, and
- if the study involves blinding, result in a decision to break the study code.

There is no requirement for the individual reporting to ethics committees of SAEs that do not meet all of these criteria. However, if your study is overseen by a data monitoring committee, copies of its letters of recommendation to the Principal Investigator should be forwarded to the Committee as soon as possible.

Please see www.ethicscommittees.health.govt.nz for more information on the reporting of SAEs, and to download the SAE Report Form.

Health and Disability Ethics Committees

Upper South B Regional Ethics Committee
c/- Ministry of Health
6 Hazeldean Road, Level 1 Montgomery Watson Building
Addington, Christchurch
Phone: (03) 974 2305
Email: uppersouthb_ethicscommittee@moh.govt.nz

<u>Statement of compliance</u>
The committee is constituted in accordance with its Terms of Reference. It complies with the *Operational Standard for Ethics Committees* and the principles of international good clinical practice.

The committee is approved by the Health Research Council's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990.

We wish you all the best with your study.

Yours sincerely

Diana T. Whipp

Mrs Diana Whipp
Administrator Upper South B Regional Ethics Committee
Email: uppersouthb_ethicscommittee@moh.govt.nz

Health and Disability Ethics Committees

Upper South B Regional Ethics Committee
c/- Ministry of Health
6 Hazeldean Road, Level 1 Montgomery Watson Building
Addington, Christchurch
Phone: (03) 974 2305
Email: uppersouthb_ethicscommittee@moh.govt.nz

2 April 2012

Ms Su Greensill
Counties-Manukau District Health BoardHB
Neonatal Unit
Middlemore Hospital
Private Bag 93311
Otahuhu, Auckland

Dear Ms Greensill

Ethics ref:	**URB/11/07/024** (please quote in all correspondence)
Study title:	What is the effect of suctioning and frequency on oxygenation and bradycardias in infants ≤30 weeks gestation requiring Bubble Continuous Positive Airway Pressure (CPAP).

Thank you for submitting a request to extend the length of the above study. The Chairperson of the Upper South B Regional Ethics Committee, under delegated authority, has confirmed ethical approval until 28 February 2013.

The Committee looks forward to receiving a further progress report at that time.

Yours sincerely

Diana T. Whipp

Mrs Diana Whipp
Administrator Upper South B Regional Ethics Committee
Email: uppersouthb_ethicscommittee@moh.govt.nz

8 June 2011

Ref: June_app_08

Su Greensill
Neonatal Unit,
Middlemore Hospital,
Private Bag 93311,
Otahuhu

Email: sgreensill@middlemore.co.nz

Teenaa koe Su

Ngaa mihi rangatira mo ouu whakaaro ki teenei kaupapa rangahau hauora

Re: What is the effect of suctioning and frequency on oxygenation and bradycardias in infants ≤30 weeks gestation requiring Bubble Continuous Positive Airway Pressure(CPAP)

The Counties Manukau Maaori Research Review Committee reviewed your research application at its meeting on 1st June 2011 and offer the following comments:

a. The committee would like to acknowledge the importance of this research for our Counties Manukau population, and commend the development of local research relevant to our community. Thank you for providing all the relevant information requested for our consideration, and the high quality of your application.

b. We note that you intend to collect ethnicity data. Consistency in collecting ethnicity information is particularly important for Maaori health outcomes. We consider it appropriate to collect ethnicity data using sector standard methodology to be able to adequately describe the study population (see http://www.moh.govt.nz/ moh.nsf/indexmh/ethnicity-data-protocols-feb1994).

The CMDHB Maaori Research Review Committee has appreciated the opportunity to engage with you regarding the relevance of this research for Maaori. The committee is able to approve your research project to be conducted in the auspices of CMDHB with the expectation that our concern raised in ‘b’ will be addressed.

We wish you every success in your research and the Committee would appreciate a copy of any research publications produced as an outcome of this research.

Kia piki te ora,

Karla Rika-Heke
Chair
Maaori Research Review Committee
CMDHB

MASSEY UNIVERSITY

20 July 2011

Susan Greensill
126 McRobbie Road
RD1
PAPAKURA

Dear Susan

Re: What is the effect of suctioning and frequency on oxygenation and bradycardias in infants ≤ 30 weeks gestation requiring Bubble Continuous Positive Airway Pressure (CPAP)

Thank you for your HDEC Notification which was received on 19 July 2011.

Your project has been recorded on the database for applications referred to HDECs which is reported in the Annual Report of the Massey University Human Ethics Committees.

Please note that if your research project involves the use of invasive procedures you must also contact the Insurance Officer (G.D.Storrier@massey.ac.nz) for advice on the University's insurance cover.

Please advise this office of any changes required by the approving HDEC. These will be placed on your file. Please also supply to the office a copy of the approval letter from the approving HDEC, when received.

Best wishes for your research.

Yours sincerely

J O'Neill

Professor John O'Neill
Director, Research Ethics
Chair, Massey University Human Ethics Chairs Committee

cc Dr Stephen Neville
School of Health & Social Services
ALBANY

Prof Steve LaGrow, HoS
School of Health & Social Services
PN371

Massey University Human Ethics Committee
Accredited by the Health Research Council

Te Kunenga ki Pūrehuroa

Research Ethics Office, Massey University, Private Bag 11222, Palmerston North 4442, New Zealand
T +64 6 350 5573 +64 6 350 5575 F +64 6 350 5622
E humanethics@massey.ac.nz animalethics@massey.ac.nz gtc@massey.ac.nz
www.massey.ac.nz

Appendix D

Consent Forms

COUNTIES MANUKAU DISTRICT HEALTH BOARD
A Community Partnership

Participant Information Sheet for Infants Part 1

Study Title
What is the effect of suctioning and frequency in oxygenation and bradycardias in infants ≤30 weeks gestation requiring Bubble Continuous Positive Airway Pressure(CPAP).

Lay Title:
What does suctioning do to premature infants needing help with their breathing and does how often they are suctioned make a difference?

Investigators		
Su Greensill	Associate Clinical Nurse Manager	Principal Investigator

Introduction:

Your infant is involved in a clinical audit that is recording how they react to suctioning. This information sheet contains detailed information about the audit. This is part one of a two part study. The second part looks at the effect the amount of suctioning has on infants with oxygen and is not part of this audit.

Please take your time to read this information sheet, ask any questions you may have, and feel free to discuss the audit with your whanau, family, friends or health-care professional.

Why is this audit being done?

At present there is no research that shows how a premature infant, needing support with breathing by CPAP, copes with the removal of secretions with suctioning . There is a need to understand how infants like yours respond to suctioning .

How long is my infant needed for?

We will be monitoring your infant for 7 days. During this time we will record, on monitors, what your infant is doing in response to suctioning. We will look at heart rate, oxygen level in the air and in the blood.

What are the benefits of being in the audit?

There will be no change in the care that your infant will receive during this audit. Information and knowledge gained from this audit may help us to do further study and adapt care for other infants in the future.

What are the risks of being in the audit?

There is no risk to your infant with this audit. We are just recording your infants heart rate, the pressure of CPAP, the oxygen level your infant is breathing and oxygen levels in the blood.

Will the care my Infant gets be any different?

There is no difference in the care your infant is receiving; we are just monitoring the response to suctioning.

Privacy, confidentiality and disclosure of information

Any information obtained in connection with this audit which may identify your infant will remain confidential to those involved with the audit and will only be used for the purpose of this audit. Any information which may identify your infant will only be disclosed with your permission, except as required by law.

Your infant's medical records, the data on the monitors used and any other information obtained during the audit may be inspected (in order to verify processes and procedures) by an auditor approved by the Upper South B Regional Ethics Committee.

In any publication associated with this audit, your infant's identity will remain anonymous. Your infant's information will be kept for 26 years. Your infant's personal information, which we collect for the audit, will be kept in a secure location, where we keep other confidential information.

Payment

There is no payment for taking part in this audit.

Participation is voluntary

If you wish your infant to stop being in the audit you are free to leave the audit at any point. However, if you wish to do this, please let one of the charge nurses know. If you do decide to withdraw it will not affect your care or future care in any way.

Ethical approval

This audit has received ethical approval from the Upper South B Regional Ethics Committee, ethics reference number URB/11/07/024.

Results of the audit

The research team involved with this audit will share any new information or findings of the audit with you. If you wish to receive a final report of the audit, please indicate below on the form and provide us with your address.

Injury

In the unlikely event of a physical injury as a result of your infants participation in this audit, your infant may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act. ACC cover is not automatic, and your infants case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and

Compensation Act (2002) to determine whether you qualify. Even if your infants claim is accepted by ACC, your infant still might not receive compensation. 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.

Where can I get further information about the audit?

If you wish to have more information about this audit please contact the Principal Investigator.

Su Greensill, Associate Clinical Nurse Manager, Neonatal Unit (Principal Investigator) 276 0044 Ext 8363

Maori Health Support

Please contact Whanau Support, Maori Health Services at Middlemore Hospital if you have any concerns or issues relating to Maori Health arising from this audit. Phone 276 0000 x8138, or ask the charge nurse to contact the service.

General support

If you have any queries or concerns regarding your rights as a participant in this audit, 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

Please feel free to contact a member of the staff if you wish to discuss matters further.

I/we would like a copy of this trial in lay language	YES / NO

Please identify your infant's ethnicity:

- ☐ Maori
- ☐ New Zealand European
- ☐ European
- ☐ Samoan
- ☐ Cook Island maori
- ☐ Tongan
- ☐ Nuain
- ☐ Fijian
- ☐ Tikelauan
- ☐ Other Pacific Peoples ______________________
- ☐ Chinese
- ☐ Indian
- ☐ Other Asian _________________________
- ☐ Middle Eastern
- ☐ Latin American
- ☐ African
- ☐ Other ___________________________

Please tick the box that you identify with for your infant, you may tick more than one. If your ethnicity is not identified above, please write it in the space provided.

Thank you for providing this information.

(Adapted from the Statistical Standards for Ethnicity for Statistics New Zealand: http://www2.stats.govt.nz/domino/external/web/carsweb.nsf/55d63ae38ba3a25e4c2567e6007f6686/35d9b7e17a1d6151cc25701100031353?OpenDocument.)

Participants should be advised that a significant delay may occur between data collection and publication of the results.

Name: ……………………………………………………………………

Address: ……………………………………………………………………

……………………………………………………………………

……………………………………………………………………

……………………………………………………………………

COUNTIES MANUKAU DISTRICT HEALTH BOARD
A Community Partnership

Participant Information Sheet for Infants Part 2

Study Title
What is the effect of suctioning and frequency on oxygenation and bradycardias in infants ≤30 weeks gestation requiring Bubble Continuous Positive Airway Pressure(CPAP).

Lay Title:
What does suctioning do to premature infants needing help with their breathing and does how often they are suctioned make a difference?

Investigators		
Su Greensill	Associate Clinical Nurse Manager	Principal Investigator

This participant information sheet and the attached consent form and ethnicity identification forms are 10 pages long. Please make sure you have all the pages and enough time to read them.

Introduction:

You and your infant are being invited to take part in a clinical research study, but we will only include you in this research study if you choose to take part. This information sheet contains detailed information about the study.

Please take your time to read this information sheet, ask any questions you may have, and feel free to discuss your decision to take part in the study with your whanau, family, friends or health-care professional.

Once you understand what the study is about, and you are willing for your infant to participate, you will be asked to sign the consent form. Signing the consent form confirms that you understand what the study is about and that you are happy for your infant to take part in it. You will be able to keep a copy of this patient information sheet and the consent form that you sign.

Why is this study being done?

At present there is no research that shows how a premature infant, who needs help with their breathing with CPAP, copes with the removal of secretions with suctioning, or what is the best length of time to leave infants between suctioning (frequency). Most of the studies that have been performed have been on infants with a breathing tube into their lungs and show that less frequent suctioning with these infants does not cause any harm. There is a need to understand how infants like yours respond to suctioning and if the frequency of 2 or 4 hourly suctioning makes a difference.

How long is my infant needed for?

We will talk with you about the study and if you agree, we will ask you as the parent/guardian to sign consent to be a part of the study. When your infant is 2 weeks old we will randomly put them in a group to receive either 2 or 4 hourly suctioning for 4 days followed by 4 or 2 hourly suctioning for 5 days. An extra day of the second suctioning frequency in between has been added, called a washout day, to try and get an accurate picture of the effect each different frequency has. The total number of days your infant will be studied for is 9 days.

During this time we will record, on specific monitors, what your infant is doing in response to the study. We will look at heart rate, CPAP pressure, oxygen level your baby is breathing and oxygen levels in the blood.

What are the benefits of being in the study?

We cannot guarantee or promise that your infant will receive any benefit from this study because we do not know yet if it will be effective. Information and knowledge gained from this study may help us to treat other patients in the future.

What are the risks of being in the study?

At present we suction infants, who have an oxygen requirement, 2 hourly or more frequently, if needed. Infants who are on CPAP breathing air are suctioned 3-4 hourly. It is not known which one is best for premature infants on CPAP.

Infants born prematurely have problems with their breathing, in their first few months of life, causing them to occasionally stop breathing (apnoea), their heart rate to drop (bradycardia) or the oxygen level in the blood to drop (desaturation) and we use CPAP to support them with their breathing and suction to keep the airway clear. This breathing problem is normal for premature infants, though sometimes when they are sick it may get worse. There is also the risk, that during either of the suctioning frequencies, your infant may have more of these episodes or require extra help with their breathing for other reasons. If this were to happen we would ensure the safety of your infant takes priority and not place them at any risk. They would be removed from the study and given care according to our procedures and guidelines.

Alternatives to participation

You may choose not to participate in this study. If so, your infant will receive the standard, routine care.

Will the care my Infant gets be any different?

If you choose to take part your infant will receive the same care and expertise as normal, the only difference will be the frequency of suctioning during the 9 day period.

Privacy, confidentiality and disclosure of information

Any information obtained in connection with this study which may identify your infant will remain confidential to those involved with the study and will only be used for the purpose of this study. Any information which may identify your infant will only be disclosed with your permission, except as required by law.

Your infant's medical records, the data on the monitors used and any other information obtained during the study may be inspected (in order to verify processes and procedures) by an auditor approved by the Upper South B Regional Ethics Committee. By signing the attached consent form you authorise the release of and access to this confidential information to the relevant study personnel and regulatory authorities outlined above.

In any publication associated with this study, your infant's identity will remain anonymous. Your infant's information will be kept for 26 years. Your infant's personal information, which we collect for the study, will be kept in a secure location, where we keep other confidential information.

Payment

There is no payment for taking part in this study.

Participation is voluntary

If you wish your infant to stop being in the study you are free to leave the study at any point. However, if you wish to do this, please let one of the charge nurses know. If you do decide to withdraw it will not affect your care or future care in any way.

Ethical approval

This study has received ethical approval from the Upper South B Regional Ethics Committee, ethics reference number URB/11/07/024.

Results of the study

The research team involved with this study will share any new information or findings of the study with you and your infant. You have the right to request this information be sent to your General Practitioner. If you wish to receive a final report of the study, please indicate this on the consent form and provide us with your address.

Injury

In the unlikely event of a physical injury as a result of your infant's participation in this study, your infant may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act. ACC cover is not automatic, and your infant's case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act (2002) to determine whether you qualify. Even if your infants claim is accepted by ACC, your infant still might not receive compensation. 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.

Where can I get further information about the study?

If you wish to have more information about this study please contact the Principal Investigator.

Su Greensill, Associate Clinical Nurse Manager, Neonatal Unit (Principal Investigator) 276 0044 Ext 8363

Maori Health Support

Please contact Whanau Support, Maori Health Services at Middlemore Hospital if you have any concerns or issues relating to Maori Health arising from this study. Phone 276 0000 x8138, or ask the charge nurse to contact the service.

General support

If you have any 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

Please feel free to contact a member of staff if you wish to discuss matters further.

COUNTIES MANUKAU DISTRICT HEALTH BOARD
A Community Partnership

Participant Consent form

Study Title
What is the effect of suctioning and frequency on oxygenation and bradycardias in infants ≤30 weeks gestation requiring Bubble Continuous Positive Airway Pressure(CPAP).

Investigators		
Su Greensill	Associate Clinical Nurse Manager	Principal Investigator

REQUEST FOR INTERPRETER

English	I wish to have an interpreter	Yes	No
Maori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Maori	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
Samoan	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
If you have a hearing impairment and require a sign language interpreter please indicate your need here		Yes	No

I/we have read, or have had read to me/us in my/our first language, and understand the information sheet Version 5 dated 11th August 2011 for volunteers taking part in the study designed to investigate the effect of suctioning and frequency suctioning and frequency on oxygenation and bradycardias in infants ≤30 weeks gestation requiring Bubble Continuous Positive Airway Pressure(CPAP).

I/we have had the opportunity to discuss this study with staff involved with the trial and I/we are satisfied with the answers that I/we have been given.

I/we have had the opportunity to use whanau support or a friend to help me/us ask questions and understand the study.

Should my/our infant be withdrawn, it won't affect their future health care. I/we understand that taking part in this study is voluntary (my/our choice) and I/we know I/we can withdraw my/our infant at any time and it won't affect their future health care.

I/we understand that my/our participation in this study is confidential and that no material that could identify my/our infant will be used in any reports on this study.

I/we understand that my/our infant's medical notes will be reviewed for information relevant to this study.

I/we understand that this study has received ethical approval from the Upper South B Regional Ethics Committee and that this committee may check that the study is following ethical procedures at any time.

I/we know who to contact if I/we have any questions about this study.

I/we would like a copy of this trial in lay language YES / NO

Participants should be advised that a significant delay may occur between data collection and publication of the results.

Address:

I agree to my GP being informed of my infants participation in this study Yes/No

I (Parent/Guardian)
Of (name of infant)
hereby consent to take part in this study.

Signature
Date

Project explained by:
Project role:

Signature:
Date

Name of Interpreter: Language:

Signature:
Date

Please identify your infant's ethnicity:

- ☐ Maori
- ☐ New Zealand European
- ☐ European
- ☐ Samoan
- ☐ Cook Island maori
- ☐ Tongan
- ☐ Nuain
- ☐ Fijian
- ☐ Tikelauan
- ☐ Other Pacific Peoples ______________________
- ☐ Chinese
- ☐ Indian
- ☐ Other Asian _________________________
- ☐ Middle Eastern
- ☐ Latin American
- ☐ African
- ☐ Other ___________________________

Please tick the box that you identify with for your infant, you may tick more than one. If your ethnicity is not identified above, please write it in the space provided.

Thank you for providing this information.

(Adapted from the Statistical Standards for Ethnicity for Statistics New Zealand: http://www2.stats.govt.nz/domino/external/web/carsweb.nsf/55d63ae38ba3a25e4c2567e6007f6686/35d9b7e17a1d6151cc25701100031353?OpenDocument.)