Promoting better weaning practice in PICU:
The development, implementation and evaluation of guidelines for
weaning children from mechanical ventilation.

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Abstract

Introduction: Weaning from mechanical ventilation is defined as the gradual reduction of mechanical support, and replacing this support with spontaneous ventilation. It is a complex process involving assessing the patient’s readiness to wean, optimising factors that can impede the process, selecting the most appropriate weaning mode and continually assessing the patient’s progress. In paediatric intensive care the clinician must also account for the unique physiological and psychosocial needs of the child.

Aim: The aim of the study was to explore the need for, and impact, of guidelines for weaning children from mechanical ventilation on patient outcomes and staff practice.

Method: The study was multi-dimensional using the Model for Improvement as the conceptual framework and decided into four phases.

Phase one: A survey of Australian PICUs in 2000 revealed that over 2500 children were ventilated over a 12 month-period, with a potential population of 625 children experiencing difficulties with weaning from mechanical ventilation. No guidelines for weaning children from mechanical ventilation were identified at the time. Standardising the approach to weaning had proven successful with the adult population.

Phase two: Collaborative guidelines for weaning, based on available evidence and expert opinion, were drawn up, validated by a panel of experts and safely piloted.

Phase three: The guidelines were then tested using a time series design over two years on a PICU at a tertiary referral children’s facility. Results
demonstrated that total ventilation time, weaning duration and length of stay were not significantly improved in the experimental group. However, quality indicators were slightly improved and a survival analysis also showed a slightly reduced probability of long term ventilated patients remaining ventilated. Results also demonstrated a reduction in the fluctuation of outcome variables over time indicating improved consistency in weaning due to the guidelines.

Phase four: A qualitative analysis of focus group interviews with staff about the impact of guidelines on their practice generated themes, centred on practice development, framework, relationships and challenges. Few previous studies have investigated the perceptions of staff regarding use of practice guidelines. This study identified that staff viewed the use of weaning guidelines favourably and perceived that their implementation improved patient outcomes.

Weaning is a relatively neglected area of intensive care because much of the initial focus of management is resuscitation and stabilisation. This study has demonstrated the positive impact that standardised and collaborative practice can have on patient outcome and clinical practice.
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Statement of original authorship

This work contained in this thesis has not been previously submitted for a degree or diploma at any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person, except where due reference is made.

Signed: ________________________________

Date: / /
Declaration of enrolment

I, Samantha Jane Keogh, a candidate of the degree of Doctor of Philosophy at Queensland University of Technology, have not been enrolled for another tertiary award during the term of my PhD candidature without the knowledge and approval of the University’s Research Degrees Committee.

Candidate’s Signature: ______________________________

Date: ______________________________
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Chapter One

Introduction to the study

Respiratory failure is the final common pathway for a variety of disorders that ultimately leads to a deterioration of lung function. Intubation and mechanical ventilatory support then become necessary until the underlying cause of the respiratory failure is improved or resolved. Recent published data confirms that the majority of patients (75%) are easily extubated, however the remaining 25% require a progressive withdrawal of ventilatory support (Brochard et al., 1994; Esteban et al., 1995). The resumption of spontaneous ventilation, commonly referred to as weaning, can often be problematic. Weaning patients involves assessing their readiness to wean, optimising factors that can impede the process, selecting the most appropriate weaning mode and continually assessing each patient’s progress (Weilitz, 1993).

In spite of the complexity of the problem, weaning is usually conducted in an empirical manner and a standardised approach has yet to be agreed. Conflicting evidence also exists about the best weaning mode (Brochard et al., 1994; Esteban et al., 1995). Variations in practice may result in delayed weaning and the associated risks of increased mortality and nosocomial pneumonia (Kollef, Silver, Murphy, & Trovillion, 1995), pulmonary emboli and psychological disturbances (Brochard et al., 1994; Lloyd, 1993a). Related increases in cost of care and demands on health care personnel place enormous burdens on the health care system (Knebel, 1991). It therefore seems prudent, for clinical and economic reasons, that a standardised approach to weaning from mechanical ventilation is adopted to facilitate an expedient and successful weaning process.
1.1 Background and significance of the study

Care of critically ill patients challenges nurses to meet each patient’s complex physiological and psychological needs. Mechanical ventilation constitutes a major therapeutic modality in intensive care, so care of patients requiring ventilatory support is an integral part of the critical care nurse’s role. Esteban et al. (1992 & 1998) noted in their study that 40% of ventilator time is taken up by attempts at weaning. Therefore, ensuring a safe and efficient weaning process is a major concern for these vulnerable patients.

Doctors and nurses tend to carry out the weaning process in an arbitrary manner, based on physician preferences of weaning modes. This variation in practice may lead to inconsistent decision-making about weaning, which has implications for the patient’s physical and mental health, as well as cost (Curley & Fackler, 1998). The reported benefits associated with reduced ventilation times are:

- reduced risk of secondary pneumonia;
- reduced ICU admission time and resultant costs;
- reduction of patient and family stress levels;
- earlier return to normal daily activities and sleep patterns; and
- heightened sense of wellbeing. (Anderson & O’Brien, 1995; Burns, 1998; Clochesy et al., 1997; Knebel, 1991)

Following her review of weaning methods in 1991, Knebel et al. (1994), as part of an American National Study Group, proposed a model for weaning from ventilation and then refined this model in 1998. The model offers nurses a framework outlining the various stages of weaning for the patient, but does not make specific recommendations for the management of the patient within each phase of weaning.

Clement and Buck (1996) conducted a comprehensive review of 12 studies on weaning parameters and strategies. They suggested that the researchers of these studies had not fully utilised methodologies and theoretical definitions. They specifically criticised the lack of a standardised definition of successful weaning, and the very general and inconsistent descriptions of weaning methods used. Clement and Buck’s recommendation for future researchers was to build upon previous research with the ultimate goal of making scientific progress, reducing inconsistencies, and discovering an understanding. Recommendations for practice included the development of a process to determine a patient’s readiness to wean and then an appropriate strategy for the weaning process. The importance of nurses’ ability to analyse and make decisions on a combination of many weaning factors was acknowledged.

Beveridge (1998) reviewed literature on ventilation and weaning and also reflected on her personal experiences as a critical care nurse. She concluded that an ICU protocol for weaning from ventilation was needed to provide a valid framework for advanced practice, increase autonomy and legitimacy and decrease delays in weaning times and associated complications.
Weaning is a complex process and unique to each patient. Wielitz (1993) stated that successful weaning depends on a combination of objective data, clinical judgement and experience. Guidelines would define the necessary criteria for weaning but also allow the nurse to exercise clinical judgement based on experience and knowledge. The importance of nurses’ qualitative judgements regarding how a patient ‘looks’ is often more important than any single number on the vital signs chart (Hazinski, 1992). Reflecting on her clinical practice, the researcher can attest to the value of the nurse/patient relationship. In their study of the concept knowing the patient (Jenny & Logan, 1992) the authors found that nurses’ insight into patients’ resources indicated the strategies likely to succeed and those that were risky. These findings reinforce the need for interdisciplinary collaboration and respect for each profession’s contribution the weaning process.

Despite the studies reviewed, scientifically-based, cogent and universally accepted guidelines remain unavailable or, where available, not instituted in the clinical setting. From personal clinical experience and the literature reviewed this researcher believes that, with the support of research-based guidelines, the critical care nurse would have an increased level of autonomy, be able to expedite the weaning process and therefore reduce the risk of complications, increase patient comfort and contain associated costs.

Most of the clinical research has been conducted on adults and recommendations for practice may be inappropriate for the care of infants or children as major physiological and psychological differences exist in children. It is the paucity of research in this area that has led to the researcher developing this study.
1.2 Goal, objectives and research questions of the study

1.2.1 Goal

The primary aim of the study was to explore the need for these guidelines for weaning children from mechanical ventilation and their impact on patient outcomes and staff practice.

1.2.2 Objectives

The specific objectives of this study were to:

- audit the current status of weaning from artificial ventilation within Australian paediatric intensive care units (PICUs);
- design a set of guidelines for weaning from ventilation;
- evaluate the effect the guidelines had on patient outcomes; and
- analyse staff perceptions of the impact on their practice related to the use of the guidelines.

1.2.3 Research questions

In order to achieve the study’s purpose the following research questions were examined:

1. Is there a standardised approach to weaning children from mechanical ventilation in Australian PICUs?

2. Does the implementation of collaborative guidelines for weaning children from mechanical ventilation significantly improve patient outcomes compared to patients weaned from mechanical ventilation without guidelines? (This question is investigated through the testing of four null hypotheses.)
• **Null Hypotheses 1:** There will be no difference in patients’ total ventilation times after implementation of the guidelines for weaning ventilation.

• **Null Hypotheses 2:** There will be no difference in the weaning duration for patients after the implementation of the guidelines for weaning from ventilation.

• **Null Hypotheses 3:** There will be no difference in the patients’ length of stay in the PICU after the implementation of the guidelines for weaning from ventilation.

• **Null Hypotheses 4:** There will be no difference in the quality indicators (incidence of weaning failure and reintubation) after the implementation of guidelines for weaning from ventilation.

3. What impact on staff practice is associated with the use of guidelines for weaning children from mechanical ventilation?

**1.3 Methodology**

These research questions were addressed through a multi-dimensional study, operating within both quantitative and qualitative paradigms. Langley, Nolan and Nolan’s (1994) *Model for Improvement* provided the conceptual framework for the study. The model was chosen in preference to a change theory model as the researcher was standardising the approach to weaning practice, rather than changing or introducing new practice per se. The *Model for Improvement* provided a framework for teams or individuals to gain and apply knowledge, as well as testing a change in practice. The study was divided into the following four phases:
1. Phase one employed a non-experimental design using a survey, with the primary purpose of auditing current practice in the various national units.

2. Phase two involved the development of the weaning guidelines.

3. In phase three, guidelines were implemented and evaluated on the selected study unit using a time series design.

4. In phase four, focus group interviews were conducted to ascertain nurses’ perceptions of the guidelines in practice.

Chapter four provides a more detailed account of the methodology.

1.4 Limitations and key assumptions

The researcher acknowledges the potential criticism that could be levelled at this study due to the quasi-experimental approach and use of a consecutive sample for phase three and a purposive sample for phase four. However, adhering to the constraints of a randomised, controlled trial of the guidelines would have meant limiting the study to a specific diagnostic group within the ICU population. There was also the risk of control contamination if testing two styles of weaning practice simultaneously within the one study unit. The researcher felt that the guidelines would then have had limited application in the clinical setting. A criticism of randomised controlled trials is that their results may not be applicable to the ‘real’ world setting (Hellman & Hellman, 1991).

The lack of a separate control group did not necessarily discredit the study. A time series design can be used effectively to rule out competing explanations for why an explanation is observed (Brock, Nolan, & Nolan, 1998). Annotating the time
series documented alternative explanations and frequent data collection ensured events and related improvements were clearly noted.

The inclusion of a qualitative approach added another dimension to the study. Qualitative research is based upon the assumption that a method of inner understanding enables a comprehension of human behaviour in greater depth than is afforded through quantitative research. Quantitative research is seldom able to capture the subject’s perspective because of the need to rely on more remote, inferential empirical methods (Denzin & Lincoln, 1994; Rist, 1979). Focus groups are recognised as having high face validity due to the credibility of comments from other members of the group (Nyamthi & Shuler, 1990). Data from the focus group interviews allowed the researcher to better understand the full impact of the guidelines on the clinicians and their practice of weaning on the unit.

1.5 Outline of thesis

This thesis is presented in nine chapters with five of these chapters being in the form of journal articles that have been submitted to international peer-reviewed journals.

- Chapter one provides an introduction to the study, including the background, aims, objectives, research questions, limitations and thesis structure.
- Chapter two comprises of a paper that is under review for publication in the journal Nursing in Critical Care. This paper provides an overview of the development of artificial ventilation throughout history.
- Chapter three consists of a review of the literature on weaning from mechanical ventilation in both adult and paediatric populations. This chapter also includes an exploration of the literature on clinical practice guidelines.
Chapter four provides a description of the *Model for Improvement* (Langley, Nolan, & Nolan, 1994) that provided the conceptual framework for the study. The Model for Improvement enhanced the baseline research process and was particularly sympathetic to testing an intervention within the clinical setting. The chapter also includes a detailed description of the methodology, research designs, research questions and scientific hypotheses, sampling techniques, data collection procedures, outcome and explanatory variables, data analysis and ethical considerations.

Chapter five comprises a paper that is under review for publication within the journal *Neonatal, Paediatric and Child Health Nursing*. The paper provides the results and discussion of phase one of the study.

Chapter six incorporates a paper that has been published in the *Australian Journal of Advanced Nursing*. The paper provides the results and discussion from phase two of the study.

Chapter seven comprises a paper that has been published in the journal *Intensive and Critical Care Nursing*. This paper provides the results and discusses the findings from phase three of the study.

Chapter eight contains a paper that has been prepared for publication in the *Journal of Advanced Nursing*. This paper provides the results and findings from the final and qualitative phase of the study.

Chapter nine concludes the thesis by reviewing and representing all the findings as reported in chapters five to eight. The implications of the study’s findings for nursing practice and research are discussed and recommendations made.
1.6 Summary

Evidence clearly demonstrates the significance of the weaning phase for a critically ill patient. This supports the need for an appraisal of weaning practices in dedicated PICUs and consideration of the implications of this. The complex nature of determining a patient’s readiness to wean, deciding the most appropriate ventilation mode and coordinating the whole process are addressed in the literature review in Chapter three. Prior to a review of more current research related to weaning, Chapter two presents an historical overview of artificial ventilation.
Chapter Two

An overview of artificial ventilation throughout the ages

The previous chapter introduced the study, outlined the subject under investigation and the methods employed to conduct the study. A brief background on the significance of weaning was also provided. The purpose of this chapter is to provide an historical context to the development of mechanical ventilation and its management. Before we examine the direction of future ventilation management it is useful to examine ‘where we have come from’ to help in order to be more appreciative and informed about ‘where we are going’. A summary of the research specific to weaning from mechanical ventilation will then be presented in Chapter three.

This chapter is presented in the format of a journal article that has been submitted to, and is under review by, ‘Nursing in Critical Care’.
This article is not available online. Please consult the hardcopy thesis available from the QUT Library
Chapter Three

Literature review of weaning

This chapter reviews existing research that deals with weaning patients from mechanical ventilation. Weaning from mechanical ventilation is defined as the gradual reduction of mechanical support and replacing this support with spontaneous ventilation (ACCP, 1993). A wide variety of methods and approaches are prescribed for patients, and doctors tend to use weaning techniques based on their experience, preference or consultative advice (Horst, Mouro, Hall-Jenssens, & Pamukov, 1998). In an effort to acquire a better understanding of the physiology of weaning and determine a superior approach, clinicians have conducted research with a variety of different outcome measures. This section of the literature review will discuss these studies under the four main headings of readiness to wean, weaning modes, weaning failure and weaning tools in practice. Reflecting the current research base, this review will include the preponderance of clinical research in the adult population. Research in the paediatric population will be included where available. The final section of this chapter summarises recent literature about healthcare management tools.

3.1 Readiness to wean

The first step in weaning from mechanical ventilation (MV) is to recognise when a patient is ready to be weaned. There is a general consensus in the literature that this is indicated when the following criteria are met:

- resolution or significant improvement in the underlying cause requiring institution of MV
- adequate gas exchange
• requirement for a fraction of inspired oxygen (FiO$_2$) <0.4
• dependence on a positive end expiratory pressure (PEEP) level of <5cm
• appropriate level of consciousness
• stabilisation of non-pulmonary factors (e.g. cardiovascular, metabolic, electrolyte).

(Burns, Burns, & Truwit, 1994; Burns et al., 1995; Burns, Fahey, Barton, & Slack, 1991; Lessard & Brochard, 1996; Mancebo, 1996).

Other factors that may have an impact on a patient’s readiness to wean (but not always considered) include nutritional and gut status, level of pain and comfort, amount of sleep, and level of anxiety (Burns et al., 1998).

In 1991, Burns developed a bedside weaning assessment tool to facilitate daily assessment and measurement of a patient’s readiness to wean that was based on the aforementioned criteria as well as specific respiratory indices (respiratory rate and pattern, cough and swallow, secretions, and tidal volumes). Overall, the Burns Weaning Assessment Program (BWAP) included 26 physiologic variables for adults, with the percentage of ‘yes’ responses for each variable contributing to the final BWAP score. The score provided a useful reference point for the healthcare team to address the impediments to weaning, modulate patient management and perhaps prevent futile weaning attempts (Burns, 1991; Burns et al., 1991).

The strength and endurance of the respiratory system seem to be major determinants of weaning outcome, so a measure of the patient’s respiratory system and ventilatory reserve could help identify patients ready to be weaned from MV. Traditional indices reflecting these factors include vital capacity (VC), spontaneous tidal volume (Vt), minute ventilation (Ve), and respiratory frequency (f) (Fiastro,
Habib, Shon, & Campbell, 1988). These factors can be measured at the bedside but require a co-operative patient. Maximal inspiratory pressure (PImax) can be measured in an uncooperative patient by attaching a one-way valve that allows only expiration. The most negative value obtained during an occlusion of 20 seconds is recorded (Marini, Smith, & Lam, 1986).

New and alternative indices to measure and perhaps predict weaning outcome have also been proposed. Yang and Tobin (1991) proposed calculation of the f/Vt (bpm/Litre) ratio—or rapid, shallow breathing index—after observing patients’ patterns of breathing in weaning trials (Tobin et al., 1986). If the f/Vt ratio is greater than 100 breaths per minute per Litre, weaning failure is likely (Yang & Tobin, 1991). Yang and Tobin also developed an integrated index, hypothesising an index that assessed several determinants of weaning might have better predictive value. The CROP index measured compliance, rate, oxygenation and pressure.

The value of these indices was evaluated in a study that assessed the accuracy of each index in 64 adult ICU patients, 44% of whom were already identified as having a high risk of weaning failure. The f/Vt ratio yielded the best predictive power, with a positive and negative predictive value of 0.78 and 0.95 respectively. The more complex CROP index was less accurate in predictive power than the f/Vt or even the simple measurement of Vt.

Having established predictive power of weaning parameters Yang (1992) sought to test the repeatability and validity of the measurement of these parameters on bedside instruments. Before and after weaning trial measurements of PImax, Ve, Vt, VC, and f/Vt were obtained on 30 patients during three trials over a period of 15 minutes. The same individual completed all measurements. Analysis using the
Student’s $t$ test and coefficient of variation (COV) showed no statistical significance in the values of the weaning parameters over three trials, except for VC ($p<0.05$). The VC, however, had the highest COV of 19.6% while $f$ had the lowest at 6.7%. Yang concluded that most weaning parameters could be measured reliably at the bedside (Yang, 1992).

In 1994, Burns and colleagues tested the efficacy of five weaning indices that included the Burns Weaning Assessment Program (BWAP), $f/Vt$ ratio, the CROP and index and a Weaning Index (based on three sets of respiratory variables that measured strength, endurance and gas exchange). Data were collected on 37 adult ICU patients for at least seven days to see if the indices changed and held any predictive powers. With the exception of the BWAP, weaning indices did not change significantly and failed to demonstrate any predictive power related to weaning trial outcomes. All indices had negative predictive value however, so they could prove useful in predicting unsuccessful weaning trials. Burns and colleagues concluded that the BWAP could serve as a useful tool to track trends in progress, keep care planning focused and prevent unsuccessful weaning trials (Burns et al., 1994).

The BWAP forms an integral part of the outcomes-managed approach to weaning (Burns, 1999; Burns et al., 1998). In addition, this approach employs the services of a dedicated outcomes manager, a MV care pathway and weaning protocols. The authors conducted a quasi-experimental study consisting of three components; a retrospective review of 124 adult patients before the implementation of the outcomes-managed approach and then a prospective study of two patient groups. One group was assigned to the outcomes-managed approach ($n=91$) and the other group continued to receive routine care ($n=90$). Statistical analysis failed to demonstrate any significant differences in duration of ventilation and length of stay.
However, a consistent trend towards shorter duration of MV (from 0.5 to 6.9 days across patient groups) and cost savings realised through similar trends in length of stay (mean difference of 2.1 days) was seen as encouraging. The BWAP remained a tool with indices specific to the adult population and no published studies of the BWAP adapted for paediatric population were found.

Two studies examining the efficacy of respiratory indices in predicting a successful extubation outcome (i.e. not reintubated with in 48 hours) in the paediatric population were identified (El-Khatib, Baumeister, Smith, Chatburn, & Blumer, 1996; Khan, Brown, & Venkataraman, 1996). El Khatib and colleagues conducted a prospective study to evaluate the accuracy of the initial negative inspiratory pressure (PI) to maximal negative inspiratory pressure (PImax) ratio in predicting extubation outcome for a sample of 50 infants and children. This measure had previously proven useful in adult patients (Yang, 1993). However, the results from El Khatib and colleagues’ study revealed the PI/PImax ratio was not significantly different between extubation successes and failures, and so not predictive of extubation outcome in children.

Concurrent research by Khan and colleagues (1996) involved a prospective study testing the efficacy of a variety of respiratory indices in predicting extubation outcome in a convenience sample of 208 paediatric patients. Results demonstrated that extubation failure increased significantly with decreasing tidal volume, indexed tidal volume, increasing FiO₂, increasing MAP, increasing O₂ index, increasing fraction of total (ventilator) minute ventilation. Khan and colleagues concluded bedside measurements of respiratory function could predict extubation success and failure in children but integrated indices (useful in adults) did not reliably predict extubation success or failure.
Following this study Baumeister and colleagues (Baumeister, El-Khatib, Smith, & Blumer, 1997) sought to further test the f/Vt ratio and CROP index with the aim of establishing some objective criteria for ending mechanical ventilation in children and infants. Of the 47 available sets of patient data, 38 were collected during successful extubations and 9 during failed extubations. A modified f/Vt index value of ≤ 11 bpm/mL/kg and a modified CROP index value of ≥ 0.1 mL X mmHg/bpm/kg were identified as predictive of successful extubation. Sensitivity and specificity values for both indices were strong (0.79 and 0.78 for f/Vt and 1.0 for both values with the CROP index) (Baumeister et al., 1997). The authors therefore concluded that the modified CROP index was a superior discriminator between successful and unsuccessful extubation.

Farias and colleagues’ (1998) prospective, interventional study examined spontaneous breathing trials in 84 infants and children requiring mechanical ventilation. They also measured the power of respiratory indices with regard to predicting weaning or extubation success or failure. A total of 75 patients (89%) tolerated the spontaneous breathing trial and were extubated. Of these patients, 12 (16%) required reintubation within 48 hours. In nine patients (11%), from the original sample, mechanical ventilation was reinstituted after a median duration of 35 minutes spontaneous breathing.

In this study, of the variety of bedside respiratory measurements taken, only two indices were associated with either weaning or extubation outcome. Tidal volume indexed to body weight was associated with weaning trial failure (odds ratio 2.6, 95%, CI 1.4–24.9). Frequency to tidal volume ratio (f/Vt ratio) was associated with the risk of reintubation (odds ratio, 1.23, CI 1.11–1.36). However, these indices
proved to be poor predictors of weaning failure when sensitivity, specificity and positive and negative predictive values were calculated. The high successful extubation rate following trials of spontaneous breathing led the authors to conclude that a spontaneous breathing trial of up to two hours should be attempted in every clinically stable patient deemed ready to wean. If there are no signs of deterioration of gas exchange or respiratory distress then the probability of successful weaning and extubation will range from 0.60 to 0.80 (Farias, Alia, Esteban, Golubicki, & Olazarri, 1998).

In 1999, Greenough and colleagues sought to test predictors of prolonged ventilator dependence in children. They conducted a retrospective analysis of the compliance of respiratory system (CRS), FiO$_2$ and (Peak Inspiratory Pressure) PIP in 33 paediatric patients. Results revealed patients who required prolonged ventilation had a high CRS (on day one of admission) and required high levels of FiO$_2$ and PIP (throughout their admission). Logistic regression analysis demonstrated a low CRS and a high maximum PIP were significantly correlated with prolonged ventilator dependence. The authors concluded respiratory function measurements have a role in identifying children who would benefit from strategies to prevent long-term ventilator dependence (Greenough, Naik, Kinali, Dimitriou, & Baker, 1999).

A more recent study by Manczur, Greenough and Rafferty (2000) paralleled earlier studies, and compared the predictive value of simple volume measurements to complex combined indices in relation to extubation success or failure. A total of 47 children requiring mechanical ventilation were consecutively enrolled in the study. Respiratory function measurements were made seven hours prior to extubation. Arterial blood gas results were obtained immediately before extubation. Extubation
failed in seven children (14.9%). Results indicated that a tidal volume < 6ml/kg and a minute volume < 180ml/kg were the most sensitive and specific in the prediction of extubation failure (0.71, 0.85 and 0.57, 0.85 respectively). The other combined indices performed poorly with sensitivity for the CROP index and f/Vt ration both at 0.43. The authors stated that respiratory volume measurements could be (relatively) easily measured with minimal handling of the child (Manczur et al., 2000). They concluded that volume measurements in the paediatric intensive care unit may facilitate higher rates of successful extubation.

In spite of the sophisticated measurements discussed the value of careful observation of the patient during the weaning process remains paramount. The use of accessory muscles, supraclavicular and intercostal drawing, paradoxical movement or a rapid shallow breathing pattern indicates the demand imposed on the respiratory system exceeds its capacity (Lessard & Brochard, 1996). Curley and Fackler (1998) sought to identify weaning patterns in young children recovering from acute hypoxaemic respiratory failure. They conducted a secondary analysis of an existing data set to examine patterns of weaning with 10 PICUs contributing data to the American Paediatric Acute Respiratory Distress Syndrome (ARDS) data set. The final study sample was 79. Three distinct patterns of weaning were identified—sprint, consistent and inconsistent (or rapid, steady, & varied). Statistical analysis revealed no significant difference between patients’ demographics, medical history, severity of illness, or lung function. However, patients in the inconsistent subset were more likely to be discharged from the ICU with a moderate or severe disability, have a systemic trigger for ARDS and an increased length of stay in the ICU. Logistic regression analysis then allowed the researchers to determine the probability of membership in a particular subset. This would enable clinicians to identify which
subset a patient would be in and then perhaps enable them to plot and modulate the patient’s weaning trajectory.

Although the predictive value of some of the weaning parameters described is inconclusive; the importance of a formalised, accurate and ongoing patient assessment is clearly demonstrated.

3.2 **Weaning modes**

Mechanical ventilators can be classified into different categories on the basis of their cycling mechanisms. The four types of cycling mechanisms are volume, pressure, flow and time mechanisms (Martin, Bratton, & Walker, 1996). Volume-cycled ventilators maintain a (relatively) constant tidal volume regardless of change in patient compliance or airway resistance. Many of these ventilators have a pressure-limiting safety device. In pressure control ventilation the ventilator delivers gas to a pre-selected pressure limit. A theoretical advantage of this mode is that it may help to reduce barotrauma by reducing the risk of high-pressure ventilation (Lessard & Brochard, 1996). Flow-cycled ventilation terminates inspiration once gas flow falls below a pre-set level (independent of pressure or volume). Time-cycled ventilation controls the variables of inspiratory and expiratory time. Due to the innate reduced compliance of infants’ and children’s lungs pressure- and time- cycled ventilation is preferred (Manczur et al., 2000; Tobin et al., 1998).

A variety of ventilatory weaning modes are available to the clinician. A review of the related literature revealed that weaning modes commonly used synchronised intermittent ventilation (SIMV) and pressure support ventilation (PSV). This next section briefly describes these modes and the ‘trial of spontaneous
breathing method.’ Studies that have compared and evaluated the efficacy of the various weaning modes will then be discussed.

### 3.2.1 Synchronised intermittent mandatory ventilation (SIMV)

SIMV allows for spontaneous patient breaths between ventilator breaths. This mode allows the patient to set the rate and pattern of breathing, reduces the risk of dysynchrony and associated discomfort and increased work of breathing. If the patient does not initiate a breath within a pre-set time then the ventilator delivers a pre-set breath. This mode is often combined with a pressure-cycled mode, as well as pressure support ventilation. The principle underpinning weaning with SIMV is that the ventilator-derived breaths are gradually reduced and the patient’s spontaneous breaths increase until full spontaneous respiration is achieved.

### 3.2.2 Pressure support ventilation

Pressure support ventilation (PSV) is defined as the augmentation of the patient's spontaneous ventilation by a set amount of airway pressures (Richless, 1991). Essentially, the patient breathes spontaneously and triggers the ventilator to deliver a pre-selected amount of pressure support (PS). The pressure support is held constant through inspiration to optimise gas exchange (Witta, 1990). PSV can be used alone or in conjunction with SIMV or continuous positive airway pressure (CPAP). In general, PSV is largely used as a weaning mode. The level of PS is gradually reduced as tolerated by the patient until ventilatory support is no longer required.

The main advantage of this mode is that the patient controls the inspiratory time, rate and tidal volume (Pierce, 1995; Richless, 1991). It is considered a (relatively) more comfortable process of ventilatory support for the patient (Boegner,
1990). It is also believed that the workload of breathing is decreased as the constant
PS overcomes the resistance in the ventilator circuit, valves and endotracheal tube
(MacIntyre, 1986).

3.2.3 Trial of spontaneous breathing

Within this method ventilatory support is removed and the patient allowed to
breathe (with the support of oxygen) through a T-tube circuit or ventilator circuit.
Application of a continuous positive airway pressure of 5cm is recommended to
prevent terminal airway collapse during the trial (Lessard & Brochard, 1996). The
spontaneous trial method is based on the principle of gradually lengthening the
periods of disconnection from the ventilator; progressively building up respiratory
muscle strength and endurance until ventilatory support is no longer required
(Brochard et al., 1994). This is not usually a viable mode for weaning children as,
when they resume the work of breathing, they have to deal with the added burden of
breathing through small (usually nasal) endotracheal tubes and resistant ventilator
circuits (Curley & Fackler, 1998).

In 1994, Brochard and colleagues conducted a randomised trial comparing
three methods of ventilatory weaning modes on 109 patients (43 with SIMV, 31 with
PSV and 35 with T-piece spontaneous trial). Initial analysis showed that a lower
number of weaning failures was found with PSV than the other modes (23% for PSV
versus 42% SIMV and 43% T-piece). After excluding patients whose weaning was
terminated for complications unrelated to the weaning process, the difference became
highly significant (8% for PSV versus 39% SIMV and 33% for T-piece). Weaning
duration and length of stay in the ICU was reduced and, using the Kaplan-Meier
estimate, the probability of remaining ventilated was significantly lower with PSV
for those patients who remained ventilated. Brochard and colleagues therefore
concluded that the outcome of weaning significantly improved when using PSV as a weaning mode.

In 1995, Estaban and colleagues also conducted a randomised trial comparing ventilatory weaning modes. A group of 130 patients were randomly assigned to undergo one of four weaning techniques: SIMV (n=29); PSV (n=37); multiple, daily trials of spontaneous breathing (n=33); and once-daily trials of spontaneous breathing (n=31). The median duration of weaning for once-daily and multiple-daily trials of spontaneous breathing was three days; one and two days less then PSV and SIMV respectively. Regression analysis demonstrated that the rate of successful weaning was higher with a once-daily trial of spontaneous breathing than with PSV or SIMV. There was no significant difference in the rate of success between once-daily and multiple-daily trials. The researchers concluded that a once-daily trial of spontaneous breathing meant that the weaning process could progress three times more quickly than with SIMV and PSV methods. Multiple-daily trials were equally successful (Esteban et al., 1995).

Ely and colleagues (1996 & 1999) also demonstrated that a significant reduction in the duration of MV followed informing physicians that their patients could sustain a two-hour trial of spontaneous breathing. The researchers conducted a randomised, controlled trial of 300 patients. There were 169 patients assigned to the intervention group that underwent daily screening of respiratory function to ascertain suitability to undergo a two-hour trial of spontaneous breathing (either with a T-piece or through the ventilator circuit). Physicians were notified when their patients successfully completed the trials of spontaneous breathing. The control group (n=151) had daily screening but no other interventions.
Analysis showed that patients in the intervention group had median duration of MV of 4.5 days as compared with 6 days in the control group (p=0.003). Complications (patient extubation, reintubation, tracheostomies) occurred in 20% of the intervention group and 41% of the control group (p=0.001). The length of stay in the ICU and the hospital was similar in both groups. The ICU costs and hospital costs were lower, but not significantly. Ely and colleagues concluded that daily screening of (adult) patients receiving MV followed by trials of spontaneous breathing and notification of their physicians when the trials were successful could reduce the duration of ventilation, associated complications and ICU costs.

Manczur and colleagues (2000) studied 40 children, aged one month to 17 years, during the hours prior to extubation. They compared pressure time product readings during a period of synchronised intermittent mandatory ventilation (SIMV) and then a period of continuous positive airway pressure (CPAP). Pressure time product is an estimate of the metabolic work or oxygen consumption of the respiratory muscles. Results demonstrated that O$_2$ consumption and metabolic work of the respiratory muscles was significantly lower when SIMV was employed and CPAP was used. The researchers concluded SIMV was a more efficacious weaning mode in children and that time spent on CPAP should be minimised.

The conflicting results of the above studies and the fact that T-piece spontaneous trials are deemed inappropriate weaning methods in paediatrics leave the PICU clinician no better informed about the most appropriate weaning mode. All the researchers commented on the possible benefits and influence the strategic approached to weaning employed as part of the study design. It may be that the team approach, rather than the ventilator mode, is of more consequence.
3.3 Weaning failure

There are a number of different causes of difficult or failed weaning. For the most part, these can be grouped under four headings:

- Inadequate respiratory centre output (e.g. neurologic disorder)
- Increase in respiratory workload
- Respiratory pump failure
- Left ventricular failure. (Lessard & Brochard, 1996)

3.3.1 Neurologic disorder

Head trauma and other neurological disorders (intracranial bleeds, seizures) can depress ventilation. Even when their respiratory efforts resume these patients often have poor airway protection, making weaning and extubating difficult. If this situation persists then a tracheostomy might be appropriate as this affords airway protection allowing weaning from ventilation (Russell, 1998). Residual effects of sedative drugs and their active metabolites must be considered as a cause of difficult weaning.

3.3.2 Increase in respiratory workload

An increase in the minute ventilation translates to an increase in workload (Gil-Murdoch & Cane, 1995; Lessard & Brochard, 1996) and the potential origin of that increase in minute volume is varied. An increase in physiologic dead space (consider the ventilator tubing and placement of endotracheal tube); pain and anxiety; excessive carbohydrate intake leading to increased carbon dioxide production; and infection or sepsis all increase oxygen consumption. Changes in ventilatory demand may explain the difficulties a patient is having with weaning progression.
Increased workload may also result from decreased chest wall or lung compliance (due to underlying disease, prior treatments, or abdominal distension) or a build up of intrinsic positive end expiratory pressure (auto-PEEP). In these patients treating the cause of the reduced compliance or applying external PEEP can decrease the inspiratory threshold load (Ranieri, Guilani, Cinnella, et al., 1993).

The increased resistive workload imposed by the mechanical ventilator, its circuitry, and the artificial airway—as well as any airway obstruction of secretions—need to be acknowledged and minimised. Applying a small amount of pressure support may overcome resistance due to the circuitry or artificial airway (Brochard et al., 1994; Esteban et al., 1995; Ranieri et al., 1993). In addition, the ventilator demand valve should be set to its maximum sensitivity. Nebulised corticosteroids, bronchodilators and saline all help to reduce airway oedema and resistance and facilitate the removal of secretions (ibid).

3.3.3 Respiratory pump failure

Respiratory pump failure may be due to a thoracic wall abnormality (fractured ribs, flail chest, associated pain); peripheral neurologic disorders (phrenic nerve injury, spinal injury, polyneuropathy); or more commonly in the long-term ventilated patient, muscular dysfunction.

Respiratory muscle fatigue or weakness may be associated with muscle catabolism due to underlying sepsis or malnutrition and early treatment and management of these is recommended. Preserving some respiratory muscle activity by minimising the use of neuromuscular blocking agents, using ventilation modes that allow some spontaneous respiration and promoting mobilisation can all prevent
respiratory muscle atrophy and neuropathy (Gil-Murdoch & Cane, 1995; Lessard & Brochard, 1996).

### 3.3.4 Left ventricular failure

Physiologic alterations associated with the transition from MV to spontaneous ventilation can place an excessive burden on the cardiovascular system. Resumption of unassisted breathing results in a reduced intrathoracic pressure. This may be augmented by the inspiratory effort required by the patient to overcome elastic and resistive workload. Increases in oxygen consumption and catecholamine release are also associated with weaning trials. In a patient with pre-existing heart disease, congenital abnormalities or post cardiac surgery, these physiologic alterations may be associated with acute left ventricular failure. Careful assessment of the patient’s readiness to wean and avoiding placement of undue respiratory workload on the patient is advisable for these patients. Diuretic therapy may reduce venous return and preload while nitrates may increase myocardial oxygen supply. Inotropic therapy might also be considered to support the failing left ventricle failure (Gil-Murdoch & Cane, 1995; Lessard & Brochard, 1996).

In summary, the inability of a patient to progress towards or sustain spontaneous ventilation is usually a result of an imbalance between respiratory demand and respiratory muscle capacity. This reiterates the need for a comprehensive and ongoing assessment of the many factors that can potentially impact on or impede weaning progress.

### 3.4 Weaning tools in the literature

In 1990, Knebel conducted a study examining the relationship between dyspnoea and anxiety during the different weaning modes, and the power of the
relationship of these variables to aid in predicting weaning success or failure. The results of the study indicated that pre weaning dyspnoea and anxiety were not accurate predictors in the weaning process. Subjects still reported dyspnoea and anxiety even when their measured inspiratory effort was less using PSV weaning. Knebel concluded that “…the method of weaning may be less important than a systematic approach to withdrawing from ventilator support” (Knebel, 1990 pp 123).

Studies that examined the impact of a weaning protocol on patient outcomes include those by Wood, McLeod and Moffat (1995) and Djunaedi et al. (1997). In these studies comprehensive ventilatory management protocols were developed to allow the respiratory therapists to adjust ventilator settings without physician orders. Both studies employed a pre and posttest design to evaluate the effect of the weaning tool on patient outcomes.

Wood and colleagues (1995) conducted a prospective trial of respiratory therapist (RT) - directed protocol weaning that comprised three phases over nine months. Predetermined outcome data were collected for two months for the control period, then for four months (phase one). The eligibility for RT protocol weaning was then widened and data collected for a further three months (phase two). The results showed that median total ventilation time (TVT) was reduced significantly between the control group (n= 35) where TVT was 18.6 hours and the RT-weaned group (n =55) with a TVT of 16.8 hours (p= 0.02). The median weaning duration (WD) was also reduced by 0.8 hours though this was not significant. In phase two the median TVT was also reduced significantly from a TVT of 19.7 hours for the control (n= 51) to 17.8 hours for the RT-weaned group (n= 70) in phase two (p=0.04). The median WD was reduced by 0.6 hours (p=0.48).
All the RT-weaned patients survived to be discharged from the ICU, with only one patient requiring reintubation and seven patients deemed weaning failures and ultimately physician-weaned. This was compared to three patients who required reintubation (two from the control and one from the physician-weaned group during phase one). By the seventh month of the protocol period there had been a progressive increase in the proportion of patients weaned by RTs from 41% to 90% of all cardiac surgery patients. The reduction in ventilation and weaning, although statistically significant, was minimal in real terms (range 0.6 to 1.9 hours). However, the researchers were able to prove that RTs and nurses could safely wean patients from ventilation with the aid of a protocol (Wood, et al., 1995).

Djunaedi and colleagues (1997) did not report reduced ventilation times but did demonstrate an improvement in patient comfort when weaning was managed by RTs using a protocol. They conducted a retrospective chart review of 50 ventilated patients pre-protocol and 57 patients post-protocol implementation. The protocol had four phases, each with its own distinct goal ranging from optimising and stabilising the patient’s condition, to reducing the ventilator support and actively challenging the patient with intermittent and increasing periods of spontaneous ventilation. The primary outcome measures were the phase one Performance Indicator (measuring rest), Tachypnoea Index and response time to arterial blood gas (ABG) results.

Results demonstrated a reduction of spontaneous breathing time by 22%. This was not statistically significant but it demonstrated an improvement in the ability to rest patients immediately following acute respiratory insult. There was 45% improvement in the Tachypnoea Index indicating an improvement in the level of patient comfort during SIMV rate reduction. The median number of ventilator parameter adjustments was essentially the same between the two groups, however
the best median and worst response times were all significantly shorter in the post-protocol period. The researchers concluded that the introduction of the protocol significantly improved patients’ comfort as evaluated by the reduction in tachypnoeic events and reduction in time to respond to abnormal ABG and SaO$_2$ levels (Djunaedi et al., 1997).

Whilst these studies demonstrated the positive effect of a standardised weaning process, the researchers also hoped to prove that RTs could efficiently manage that weaning process in place of physicians. In the following randomised, controlled studies conducted by Ely et al. (1996) and Kollef et al. (1997) the focus was on the tool not the practitioner.

Ely and colleagues (1996) demonstrated a reduction in mechanical ventilation time for patients who had a successful trial of spontaneous breathing reported to their physician. Results demonstrated significant reductions in the median duration of mechanical ventilation and weaning time, plus slight reductions in length of stay in the ICU and hospital. This was a well-designed study with results that supported a standardised approach to assessing the patient’s readiness for extubation. However, the protocol did not account for the complexities of the weaning process, the concept of waiting for the consultant to respond to the positive trial, and did not utilise the skills and knowledge of all the critical care staff.

In 1996, the Institute for Healthcare Improvement in the USA and Canada carried out a multi centre study (Kollef, Horst, Prang, & Brock, 1998). The overall aim of the study was to improve the outcomes of adult intensive care in a collaborative group of hospitals. Each of the three tertiary referral hospitals developed weaning protocols and, over a two-year period, was able to demonstrate
significant reductions in ventilation duration (up to 48%), length of stay in ICU (28%) and a resultant reduction in costs. The third hospital also reported a 10% decrease in the incidence of ventilator-associated pneumonia when using protocol-directed weaning. However, there was no statistical analysis reported or power calculation in relation to sample sizes that ranged from 35 to 97 patients.

Kollef and colleagues (1997) also demonstrated shorter duration of mechanical ventilation in a randomised, controlled trial comparing patients in the protocol-directed weaning (n=178) to physician-directed weaning (n=178). The median duration of ventilation was significantly shorter for the protocol-directed group (35 hours) compared to the physician-directed group (44 hours). Wilcoxon survival analysis favoured a shorter duration of ventilation amongst the protocol-directed group (p= 0.024). Though it is worth noting that the mean duration of ventilation prior to commencing weaning was significantly less in the protocol-directed group (39.6±81.7) versus 58.3 (±101.1); p=0.029). This was attributed to their lower severity of illness scores. Regression analysis showed that the rate of successful weaning was significantly greater for patients receiving protocol-directed weaning compared to physician-directed weaning (risk ratio 1.31, 95% CI 1.15–1.5; p=0.039) (Kollef et al., 1997). The authors concluded that nurses and respiratory therapists could safely carry out protocol-directed weaning and demonstrated that patients progressed more rapidly towards extubation than physician-directed weaning.

Webster (2000) conducted the first identifiable study that examined the effect of a protocol for nurse-led weaning and extubation in the paediatric setting. Data were first collected on 19 patients post cardiac surgery for the point prevalence of weaning and extubation. A multidisciplinary working party then developed a
protocol and (initially) ten nurses underwent an extensive educational and training program. The protocol was then piloted on 19 infants and children post cardiac surgery, and outcome indicators (specifically reintubation, weaning duration and length of stay) compared with the pre pilot point prevalence study.

Of the 19 patients in the pilot study, all were weaned successfully by nurses using the protocol with 10 of the 19 children extubated by nurses (no comment was made about the remaining nine). No child required reintubation. The author acknowledged that the small sample limited the application of the findings (Webster, 2000). The study also excluded all patients with a respiratory illness as their primary diagnosis. So the findings from this pilot study could not be extrapolated to the general PICU setting.

One of the first studies to develop and examine protocol-directed weaning in the PICU setting was conducted by Schultz and colleagues (Schultz, Lin, & Richard, et. al. 2001). They used a prospective randomised, controlled design to compare the ventilation time between a physician-directed group (n=116) and protocol-directed (n=117) group of patients. The results demonstrated that overall the protocol directed group had shorter total ventilation time (mean score 33.4 hours vs 52.1 hours, p=0.73), weaning time (mean score 5.9 hours vs 25.2 hours, p<0.001), and time on FiO$_2 \geq 0.40$ (mean score 9.7 hours vs 30.2 hours p=0.11). There was apparently a slight increase in the reintubation rate for the protocol-directed group (figures not quoted) but no difference in the 12 and 24 hour risk of mortality. It is difficult to know where to conclusively accept that the protocol-directed weaning results improved outcomes as not all the differences observed were statistically significant, and there is no power statement in the study. Also the data appears to be
highly skewed making the median and related non-parametric analyses more appropriate than the mean scores and parametric tests.

Randolph and colleagues (2002) published the results of their randomised, controlled study (RCT) examining the effect of a ventilator weaning protocol on respiratory outcomes in infants and children (Randolph et al., 2002). Eligible patients were randomised to one of three groups: manual pressure support protocol [PSV] (n=62); automated pressure support protocol [VSV] (n=60); and no protocol (n=60). Results demonstrated that a slight reduction in mean weaning duration, PSV (38.4hrs), VSV (43.2hrs) and no protocol (48hrs). This was not statistically significant, however the mean weaning duration differed by ten hours and this could be clinically significant as it equates to the length of a shift.

Similar to Schultz and colleagues study the reintubation as being higher (15%) in the protocol directed group. This may have been due to the level the respiratory parameters were set to signify the commencement of the respective weaning protocol (i.e. FiO2 ≥ 0.60, PEEP ≤ 8 cm H2O). Although the above studies to not present overwhelming evidence in favour of protocol-directed weaning, the positive trend with some of ventilation times may be increased and the reintubation rate reduced if future protocols amend the readiness to wean criteria.

Criticisms can be levelled at these studies due to the sampling techniques and lack of power, methodologies employed or poor reporting of results. Quasi-experimental studies lack the scientific rigour of randomised, controlled trials. Yet the rigours of a randomised, controlled trial are difficult to apply to the clinical setting. The studies reviewed illustrate an overall positive effect healthcare management tools can have on patient care and outcomes.
3.5 Health care management tools

A growing interest in health management tools and the process of their development and implementation has marked the past decade. This interest has been prompted by the desire to establish best practice patterns, streamline processes and reduce health care costs. These tools have been traditionally based on reported best practice and the consensus of expert opinions. There is now growing recognition that tools guiding clinical practice should be based, where possible, on the systematic identification and synthesis of the best available scientific evidence (NH&MRC, 1998). Health care management tools may include guidelines, protocols, standards of care, or critical pathways and while these terms have been used interchangeably each has its own distinct definition. These definitions need to be considered when developing a health care management tool (HMT).

Guidelines are recommended principles and usually take the form of systematically developed statements aimed at assisting the practitioner in making decisions about health care in specific circumstances (Jaggers, 1996). In general guidelines are broad-based and provide recommendations for care based on the most current research findings (Cole & Houston, 1999). They allow a degree of flexibility and interpretation by the practitioner based on their clinical judgement. Critical appraisals of the relevant literature form the building blocks of this evidence-based approach to practice. More rigorous methodology applied to the analysis and classification of data prior to implementation has facilitated the wider development and acceptance of guidelines in practice (Fuss & Pasquale, 1998). Often developed locally, guidelines are also developed and published by national or speciality organisations.
Protocols are more formal statements, specifying in detail how a process or intervention is to be conducted. They provide a standardised approach to care with a desired outcome (Cole & Houston, 1999). In contrast to guidelines, protocols do not allow for any deviation and the intent is that they are followed verbatim.

Standards of care are accepted principles that help to operationalise patient care processes (ibid) and form the basis of quality assurance measurements. They are often developed from the viewpoint of one particular discipline.

Critical Pathways provide written criteria to guide the care delivery of multiple disciplines. They delineate the optimal sequencing or timing of interventions and procedures by nurses and other staff for a specified patient population (Coffey, Richards, LeRoy, Schoville, & Baldwin, 1992). Deviations or variances from the critical pathway are monitored and can form the basis for quality enhancement efforts as they provide a standard of care for comparing actual with expected patient outcomes (Burns, 1998).

One tool may not be sufficient to standardise practice. Guidelines and protocols often form part of a critical pathway, so a variety of tools are used to guide patient care. The development of any HMT is challenging, but even more so is its successful implementation. Fuss and Pasquale (1998) state that HMTs are without value if they are awkward, verbose and unrealistic to the practitioner in the clinical setting. They need to be succinct, comprehensive, relevant and accessible at the bedside.

Such is the profile of HMTs in healthcare now that in 1999 the British Medical Journal publish a series of papers discussing the advantages and disadvantages of clinical guidelines, method of guideline development, and he legal,
political, and emotional aspects of guidelines. Feder, Eccles, Grol and colleagues (1999) acknowledged the many potential benefits of guidelines to the patient, healthcare professionals and the organisation. But, they also cautioned that their success depended on a number of factors, not least of which was the dissemination and implementation process. The Cochrane Review Group has a body that conducts systematic reviews of interventions designed to improve quality of care thus providing evidence that clinicians can base their implementation processes on as well as the evidence to support the clinical recommendations in the actual guidelines. Strategies to optimise uptake and adherence to clinical guidelines included information seminars and workshops, practice audit and feedback, opportunity for discussion forums to reach consensus of opinion and visual reminders about the presence of guidelines (Bero, Grilli, Grimshaw et. al., 1998).

Collaboration among medical, nursing and other health professionals in HMT development is vital. Knaus, Draper, Wagner, and Zimmerman (1986) demonstrated the importance of effectiveness of multidisciplinary interaction using the APACHE II scoring system to compare outcomes from 13 ICUs. They showed that the level of communication in an ICU was directly related to patient survival (Knaus et al., 1986). The development and use of HMTs can facilitate interdisciplinary collaboration. The tools reflect joint decision-making and responsibility of the health care team involved with a particular patient population (Cole & Houston, 1999). For example, one clinical condition in which collaboration is necessary involves weaning a patient from mechanical ventilation. As discussed previously, there is no conclusive evidence supporting one weaning mode over another, however, there is evidence that the weaning process was improved by a standardised approach to a particular technique.
General criticisms about HMTs are usually related to the development process and the underpinning knowledge basis. In Morin et al.’s (1999) study of research utilisation practices, 32 resource nurses were interviewed and research-based protocols from the nurse’s clinical areas examined. Morin and colleagues found that the majority of protocols submitted, although referenced, were not research-based (Morin et al., 1999). The interview data revealed that many of the participants were confused or unclear about the definition of what constituted a research-based protocol. The authors felt that this issue possibly reflected the quality or content of education programs as well as the apparent lack of administrative support for research and its utilisation (ibid).

Clinicians can anticipate encountering practice guidelines and protocols more often in the future (Callender, 1999). Quality guidelines can aid in making health care more appropriate and effective as they are an ideal mechanism for nurses to facilitate the use of research in practice. The American Institute of Medicine proposed that eight attributes of a high quality guideline were validity, reliability, applicability, flexibility, clarity, development in a multidisciplinary process, scheduled review and careful documentation (Field & Lohr, 1990).

A number of leading agencies have proffered a variety of frameworks for the development of HMTs. Common threads running through all these suggested frameworks encompass: defining the problem, using a (multidisciplinary) team approach, assessing scientific evidence, drafting and validating the tool, and finally implementation and evaluation (AHPR, 1991; NH&MRC, 1998; Paley, 1995). Understanding that HMT development and refinement is an evolutionary process is

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1 Research-based protocols are nursing prescriptions for care described in detail, including processes for assessment, intervention, evaluation, and documentation, and are based on research-based findings (Haber et al., 1994).
important. Callender (1999) also adds that the success of any guideline is dependent on not only its proper development but also its widespread adoption in routine clinical practice.

If appropriately prepared, implemented and reviewed HMTs offer the healthcare team a valuable opportunity to harness best knowledge and practice. Importantly, the implementation of an HMT does not preclude clinical judgement. On the contrary, HMTs assist practitioners by promoting practice patterns associated with good clinical judgement, research-based interventions and improved patient outcome (Cole & Houston, 1999). HMTs encourage professionals to share and define practice to meet common goals.

### 3.5.1 Legal issues with health management tools

The concept of managed care, in all its guises, is increasing and the legal and ethical implications need to be considered. Brennan (1991) opined that practice guidelines would not change the litigation system per se, but that guidelines would be used as evidence to determine the case for negligence. Hyams and colleagues (1995) conducted a two-part study to determine how practice guidelines were being used in malpractice litigation (Hyams, Bradenburg, Lipsitz, Shapiro, & Brennan, 1995). From the 259 claims of medical malpractice received at two major insurance companies in the United States, only 17 involved the use of practice guidelines. In their survey of 560 responding medical malpractice attorneys, 75% were aware of the concept of practice guidelines. A comparable proportion of attorneys (26% versus 30%) reported the use of guidelines influenced their decision whether to take a case or not, and 27% reported that guidelines influenced their decision to settle a case (ibid). Hyams and colleagues (1995) concluded that the findings suggested the concept of guidelines in litigation was spreading through the profession. Further
study of US court cases reported between 1980 and 1994 found 28 cases in which guidelines were used successfully (Hyams, Shapiro, & Brennan, 1996). In the majority of the cases (78%) the guidelines were used for inculpatory purposes (i.e. implicating the defendant). Plaintiffs tended to use guidelines more than defendants.

For practice protocols to be of use in litigation, the protocol must be relevant (Brennan, 1991). Hall and Dadakis (1996) contended that guidelines that are centrally developed by national and government agencies are too general and vague for courtroom dispute. In the case of Quigley v. Jobe in 1992 (cited in Hyams et al., 1996) a guideline was ruled not relevant as a private insurance company promulgated it. Therefore, the impetus for the protocol’s development needs to be considered. Research-based protocols developed to meet the local health care needs are more likely to establish a conclusive standard of care that can be admitted into court as evidence (Hall & Dadakis, 1996).

It can therefore be concluded that although the use of guidelines in medical litigation is as yet limited, it has nevertheless had an impact on the decision-making processes of the attorneys involved. In a review of the liability issues associated with practice protocols, Noonan (1997) stated that protocols offered a decrease in the need to practice defence medicine as well as a method to improve quality of care. From the review of all the medical malpractice cases reviewed, the finding that practice protocols and guidelines did not eliminate the use of expert witnesses was of significance. Protocols, guidelines and critical pathways incorporate, but do not replace physician orders. HMTs require practitioners to use professional judgement by making explicit the rationale for their use (Brown, 1995). Good clinical judgement must prevail.
3.5.2 Ethical consideration with health management tools

Ethical issues related to the use of HMTs are identical to the ethical issues surrounding the use of any therapy or intervention. Four ethical principles need to be considered: nonmaleficence (do no harm), beneficence (do good), autonomy (respect for patient self-direction), and distributive justice (be fair) (Beauchamp & Childress, 1989; Jonsen, Siegler, & Winslade, 1992). Morris et al. (1994) noted that when the decision to treat has been made, the only remaining choice relates to the most appropriate technique or process for delivering treatment. The principles of autonomy and distributive justice become less important, however the importance of nonmaleficence and beneficence remain undiminished. Striking a balance between the principles of nonmaleficence and beneficence is a challenge to the health care practitioner. In essence, a risk-benefit analysis must be done, and is best done when probable estimates of outcome for treatment options are based on sound data (Morris et al., 1994). This statement mounts a convincing case for the use of research-based tools for delivery of care. However, the development and implementation of HMTs can give rise to ethical concerns.

The principle of autonomy requires patient participation and consent. The question then arises as to whether HMTs are considered a new and innovative non-standard therapy. An alternative view is that HMTs are decision support tools that merely formalise and standardise common practice. If the latter argument is used then informed consent is not mandatory. The principle of distributive justice is not an issue as long as the tool is applied to all patients without prejudice (Morris et al., 1994)

When addressing the principles of nonmaleficence and beneficence in regards to HMTs, a shift from the traditional view that the physician is the (only) expert in
his or her knowledge, skills and belief about what is the best available therapy for the patient. The assumption that the consultant is a reliable reflection of best information available does not acknowledge the general human limitations with information processing. (Miller, 1956; Morris, 1992, 1993). The forethought and consensus approach to HMT development means that more consideration and planning is behind decisions made under HMT control than by any individual practitioner (James & Eddy, 1994). The intent to do good, and the belief in a therapeutic decision in the increasingly complex area of critical care, is not always enough. In the absence of credible data concerning outcomes from different therapy options, clinicians are forced to use intent and belief to drive operational decisions, rather than beneficence (Morris et al., 1994). The use and development of standardised approaches to patient care raise ethical issues that are comparable to decisions made in the conventional manner. Indeed, HMTs provide a sound basis to guide clinical decisions and evaluate outcomes for ongoing assessment and quality assurance.

3.6 Summary

The advent and development of mechanical ventilation as a supportive respiratory measure has had profound and lasting effects on the management and outcomes of all critically ill patients. It is obvious in the literature and studies reviewed, however, that for a significant number of ventilated patients resumption of spontaneous respiration is a difficult and protracted task.

Health care professionals seek to assess and address the unique needs of this group of patients in a systematic way. The focus of much of the literature has been on the assessment of the patient in readiness for weaning or comparison of ventilator modes. Much research has perceived the needs for standardising care, and some of
The studies reviewed reported positive results. The focus of this study then was to determine the variability in current weaning practices and the subsequent development, implementation and evaluation of guidelines for weaning from mechanical ventilation on patients and clinical practice in the paediatric intensive care unit.

The next chapter details information about the conceptual framework, research designs, sampling, study variables, data collection and analysis as well as ethical considerations.
Chapter Four

Methodology of the study

The combination of qualitative and quantitative methodologies within one study remains a contentious issue. The research community has historically viewed the two modes as opposites. Frankael (1995) argued that a research paradigm that utilises both qualitative and quantitative methodologies enables the researcher(s) to gain a wider perspective on the issue being examined. Employing both qualitative and quantitative methods can produce a final product that highlights the strengths of both research modalities (Nau, 1995). Critics of the bimodal approach caution researchers against assuming that with this binocular vision they then have all the information—“Objective reality can never be captured” (Denzin & Lincoln, 1994, p. 2).

This study sought to examine a ‘cause and effect’ scenario in relation to the impact of the guidelines for weaning on patient care and to also examine the impact on staff practice. For quality improvement, it was important to consider not only the physical world but to also learn about the experiences of the people involved (Brock et al., 1998). After their review of weaning literature Clement and Buck (1996) recommended that staff perceptions be explored. The strength of any guiding tool in practice is its widespread acceptance by the staff. The use of qualitative inquiry through the focus group interviews in this study produced richer and more revealing data than the use of a closed question survey or observational tool.

4.1 The conceptual framework

Quality improvements should be part of an ongoing process in every organisation. Evidence-based practice should reflect results of current and relevant
research, and the randomised, controlled trial (RCT) is considered the gold standard of research methodology. However the clinical setting does no always lend itself to the exacting conditions of an RCT. Nevertheless, assessment of the efficacy and impact of change needs to be made. The Model for Improvement (Langley, Nolan & Nolan, 1994) offers a pragmatic approach to the assessment of change, striking a balance between the need for action and the need for evidence (Brock et al., 1998)—this is ‘research in action’.

The Model for Improvement proposed by Langley and colleagues in 1994 (see Figure 1), refines a previous model developed for guiding improvement activities introduced by Moen and Nolan (Moen & Nolan, 1987).
The revisions make the improvement framework more widely applicable and easier to learn. However, the underlying principle remains the same. Improvement comes from the application of knowledge, and the model provides a framework for teams or individuals to gain and apply knowledge (Langley et al., 1994).

Generally, the higher the level of (relevant) knowledge, the better the improvements will be. Consequently, any approach to improvement must be based on building knowledge and on applying it appropriately (ibid). This leads to the three
fundamental questions that inform the Model for Improvement’s “trial and learning approach”. They help the researcher focus the research question, current knowledge base and study design.

The three questions aimed at ‘building knowledge’ within this study were:

1. **What were we trying to accomplish?** Weaning has been identified as taking up 40% of patients’ ventilation time and being problematic for approximately 25% of all ventilated patients withdrawing from ventilatory support (Esteban, Alia, Ibanez, Benito, & Tobin, 1994; Esteban et al., 1995). Patients who proved difficult to wean encompassed a population that involved prolonged ventilation times, increased length of stay (LOS) on the PICU and limited reimbursement for the hospital. The process of weaning could be significantly improved, resulting in shorter ventilation times, less inappropriate extubations and cost savings derived from shorter LOS in the PICU.

2. **How did we know that a change was an improvement?** Outcome indicators of total ventilation time (TVT), weaning duration (WD), LOS in the PICU and patient comfort were measured in this study. In addition, reventilation and reintubation rates were monitored. The aim was to expedite the weaning process without sacrificing quality of care.

3. **What changes were made that lead to an improvement?** A review of the national PICUS and literature on weaning from mechanical ventilation (phases one and two) revealed that weaning methods commonly employed a combination of synchronised intermittent ventilation and pressure support ventilation. However, the coordination and management of these techniques varied widely. Therefore the primary change was the implementation and
evaluation of a new set of collaborative guidelines, standardising the approach to weaning patients from mechanical ventilation. A secondary change included the delegation of much of the decision-making process to the critical care nursing staff at the patient’s bedside. When the agreed-upon parameters were reached, the PICU consultant (or attending medical officer) prescribed the appropriate weaning pathway and the weaning process was carried out (primarily, but not exclusively) by the nursing staff using the guidelines for weaning.

4.1.1 Testing a change—the PDSA cycle

The PDSA (Plan-Do-Study-Act) cycle provided a framework for testing and implementing the change. The focus of the cycle is as much about building knowledge as testing the change (Langley et al., 1994). Using a sequence of tests to redesign the system of care is an important feature of the Model for Improvement.

Testing on a small scale does not mean small change. Brock, Nolan and Nolan (1998) state that the change tested could be very innovative and significant though only initially tested on a small subset of patients (Brock et al., 1998). The decision to increase the scale of testing would be made based on the results of previous tests. Hence, the testing of the guidelines and their impact on patient outcomes and clinical practice were conducted in stages, as illustrated in Table 1.
Table 1

Test cycles in study

Cycle 1: Pre tests 1 and 2

Intervention

Cycle 2: Pilot test

Cycle 3: Post-test

Cycle 4: Focus group interviews

Historically, this model was developed to facilitate change in the manufacturing and service industries, but a number of health care studies have since employed the Model for Improvement [or aspects of it] (Brock et al., 1998; Cleghorn & Headrick, 1996; Guinane, Sikes, & Wilson, 1994; Naidoo & McSharry, 1999).

4.2 Research strategy

The research strategy used for this study was multi-dimensional using Langley and colleagues’ (1994) Model for Improvement to provide the conceptual framework. This study was conducted in four phases over two years as outlined below in Figure 2. The methodology for each phase is discussed in the remainder of this chapter.
Figure 2. Flowchart of four phases of study.

4.3 Phase One—National Survey

4.3.1 Aim of study and research question

In this phase a written survey was used with the primary purpose of auditing current weaning practices in the various national units. This design was appropriate for collecting detailed descriptions of the characteristics of an institution and using the data to justify and assess current practice and inform prospective changes in health practices (LoBiondo-Wood & Haber, 1998). The specific research question asked was:

1. *Is there a standardised approach to weaning from mechanical ventilation in Australian PICUs?*
4.3.2 Sample

The target population for phase one was the seven dedicated PICUs within Australia. These were identified through records held by the Australian and New Zealand Paediatric Intensive Care Society (ANZPICS). The purposive sample included all seven units to avoid sampling bias or error and to obtain a national perspective.

4.3.3 Data collection

The survey development and administration was guided by Dillman’s (1978) “Total Design Method” (TDM). Questions in the survey were based on the variables identified in the literature on weaning (modes, presence of guidelines, patient population and diagnoses, staffing ratios and qualifications). The initial version of the survey was piloted with clinical nurse leaders (also entitled nurse unit manages, nurse practice co-ordinators, clinical nurse specialists) in three adult ICUs to test content and face validity (Appendix A). Overall feedback was positive and only minor revisions were required before the final draft of the survey was distributed (Appendix B).

A courtesy call to the clinical nurse leaders of each PICU was made to provide preliminary information concerning the research project and enlist their support. The survey, containing a cover letter, was then forwarded to them. The covering letter explained the rationale and purpose of the study, as well as assuring participants of the confidentiality and anonymity of their reply. A follow up reminder letter was sent to non-responding units approximately two weeks after the initial mail-out, followed by a second reminder letter with a second copy of the survey approximately four weeks after the first reminder. Respondent’s consent was
assumed by return of the completed survey in the reply paid envelope. A copy of the survey’s results was sent to the participating units.

4.3.4 Data analysis

Data from the returned surveys were number coded (for follow up reference and future data checking) and entered into a database. Any qualitative data (i.e. description of weaning if no guidelines and comments) was examined for common themes. To protect anonymity and confidentiality of individual units only aggregate data was analysed and described. Due to small numbers no inferential statistical analysis was conducted.

4.4 Phase Two—Development of guidelines

During this phase the guidelines for weaning from mechanical ventilation were developed. The Australian National Health and Medical Research Council’s “Guide to the development, implementation and evaluation of clinical practice guidelines” provided the framework for the development of weaning guidelines (NH&MRC, 1998). The various steps used and how they related to the present study are presented in the following section.

1. Determine the need and scope of guidelines

The need and scope of the subject was gathered through reflection on current practice, a retrospective analysis (historical control) of weaning outcomes and a national survey of weaning practices in Australian paediatric intensive care units (PICU) (Keogh, 2000).
2. Establish a multidisciplinary working party

In addition to the researcher, a seven-member panel of PICU experts was convened to review the draft of guidelines and the evidence reviewed. The panel consisted of four medical consultants, a nurse leader, a hospital-based nurse educator and university-based nursing lecturer.

3. Define purpose and the target audience for the guidelines

As a reflection of the multidisciplinary nature of the weaning process the guidelines were designed for both medical and nursing staff. As no one particular ventilatory mode had been proven for optimal weaning, the aim was to standardise the (team) approach and keep the weaning process patient-centred.

4. Identify health outcomes

Specific health outcomes measured included total ventilation time (TVT), weaning duration (WD), and length of stay in the PICU (LOS). In addition, weaning failure and reintubation rates were monitored. The aim was to standardise and expedite the weaning process without sacrificing quality of care.

5. Review scientific evidence—Literature Review

An extensive literature search of the CINAHL and MEDLINE databases was conducted to locate studies examining weaning (particularly in the paediatric population), since 1990. This is summarised in Chapter Three.
6. **Formulate guidelines**

A draft of the guidelines, including a weaning algorithm, was drawn up. Guidelines development and refinement is an evolutionary process. The panel met three times over a six-week period and the guidelines were redrafted twice before the final agreed format was ready for piloting on the study unit.

7. **Formulate dissemination and implementation strategy**

Prior to piloting the format, all medical and nursing staff were sent an information letter informing them about the study and the guidelines. Education sessions (including didactic lectures and hands-on interactive sessions at the bedside) were scheduled over a four-week period to inform and instruct staff about the weaning guidelines and process in detail and provide them with the opportunity to ask questions. There was concern expressed by some members of the nursing staff that playing a more active role in the weaning process was not within their scope of nursing practice. Consultation of the relevant documentation—from the state nursing registering body’s “Scope of practice decision-making framework” and the national critical care colleges’ competencies guide—indicated that interventions could be undertaken by any nurse in a role for which they had the necessary education, authorisation and competency to perform (ACCCN, 1996; QNC, 1998). The clinical setting also influences the scope for individual practitioners. Care of the ventilated patient is part of the responsibility of the intensive care nurse and assisting the weaning of ventilation is subsequently part of that process. The majority of nurses and doctors welcomed the guidelines. They stated that they merely formalised what many nurses had been doing for years. It seemed that for some staff this was an educational tool ‘expanding’ their role while for others it affirmed their role.
4.4.1 Pilot study

The guidelines were piloted with ten eligible patients (as per criteria for main study) admitted consecutively over a one-month period. Analysis of the demographics demonstrated that the age and PIM scores were comparable between the pilot and control groups (median age 1.7yrs vs 1.6yrs, median PIM 4.8 vs 5.8). However, the gender distribution and primary diagnosis were different (70% male vs 53% male, primary diagnosis being 50% Resp vs 27% Resp). The larger representation of children with a primary respiratory disorder may have explained the longer ventilation times observed (i.e. WD 24.5hrs vs 18.5hrs, TVT 61.75 vs 31.2, LOS 87.5 vs 61.5hrs). However a comparison of quality indicators (weaning failure rate 10 vs 12% and reintubation rate 0 vs 5%) demonstrated that the guidelines could be safely tested on a wider population. Minor revisions were made to the guidelines in response to feedback from staff and the guidelines fully implemented for a 12-month period.

4.5 Phase Three—Implementation and evaluation of guidelines

This phase of the study employed a quasi-experimental approach using a historical control (see Figure 3) using a time series design. Annotating the pre test period with additional analysis (Analysis A) created an additional ‘control’ period that allowed the researcher to explain alternative reasons for changes in outcome data measured (Analysis B).
4.5.1 Setting

The unit in which this study was conducted was an eight-bedded PICU located at tertiary referral children’s hospital admitting patients from 0–16 years of age with a range of diagnoses. The unit had four consultants (two full-time and two part-time), including the medical director. Resident medical staff rotated through the unit as part of ongoing training. There were 50 nursing staff (38.6 full time equivalents) with one Nurse Practice Coordinator, a nurse educator, nine level two registered nurses and 37 level one registered nurses. Post registration qualifications in paediatrics, ICU or PICU were held by 48% of the staff.

4.5.2 Sample

The target population included all ventilated patients within the PICU. All eligible patients (retrospectively and prospectively) were consecutively enrolled in the study. Sample size calculation was based on the main outcome variable of total ventilation time (Bowling, 1997). The figures were drawn from the historical control, as there is no normative reference for ventilated paediatric patients. However, data
was highly skewed and therefore logged before using mean scores in the power calculation. An *a priori* determination of 16 hours (or two clinical shifts) was considered to be of clinical significance. To be able to detect a difference of 16 hours with a Type I error of 5% (two tailed) and 80% power a sample of at least 75 patients was required. By allowing an additional 25% for attrition, non-randomised sampling and multivariate modelling a final sample size of 94 was determined (see Table 2). Exclusion criteria included patients who were post cardiac surgery, with high spinal injuries, congenital myopathies, and those undergoing terminal weaning. The excluded patients either had their own specific weaning agenda or had little chance of ever weaning.

**Table 2**

*Power calculation for testing the difference between two independent means*

\[
\frac{2\sigma^2 \times (sd^2)}{(mean\ 1 – mean\ 2)^2} = N
\]

\[
\frac{2\times 2.8^2 \times (1.2648^2)}{0.5768^2} = 75.3799
\]

\[
0.3328
\]

\[
0.5768 = \log (36.5)
\]

\[
20.5
\]

because \[\log a – \log b = \log (\frac{a}{b})\]

\[
plus\ 25%\ for\ attrition,\ sampling\ and\ modelling\ N = 94
\]
4.5.3 Intervention

The guidelines were developed and subjected to pilot testing as described previously. Minor revisions were made in response to feedback from staff and the guidelines fully implemented for a 12-month period. See Appendix C for a copy of the guidelines.

4.5.4 Research question and scientific hypotheses

The main research question under investigation in this particular phase was:

2. Does the implementation of guidelines for weaning from ventilation significantly improve patient outcome compared to patients who are weaned from ventilation without guidelines?

This was investigated through the testing of the following null hypotheses in phase three.

- Null Hypotheses 1: There will be no difference in patients’ total ventilation times after implementation of the guidelines for weaning ventilation.
- Null Hypotheses 2: There will be no difference in the weaning duration for patients after the implementation of the guidelines for weaning from ventilation.
- Null Hypotheses 3: There will be no difference in the patients’ length of stay in the PICU after the implementation of the guidelines for weaning from ventilation.
- Null Hypotheses 4: There will be no difference in the quality indicators (incidence of weaning failure and reintubation) after the implementation of guidelines for weaning from ventilation.
4.5.5 Outcome measures and data collection

Data for the historical control was obtained through a retrospective audit of patient charts for the 12 months prior to the implementation of the guidelines.

The explanatory variable was the implementation of the guidelines.

The outcome variable was patient outcome. Specifically:

- total ventilation time (TVT)
- weaning duration (WD) (based on time between commencement of weaning and resumption of full spontaneous respiration)
- length of stay in PICU (LOS), and
- quality indicators (incidence of weaning failure and reintubation).

4.5.6 Confounding variables

All the standard demographic and biophysiologic measurements monitored on critical patients were collated, including:

- patient’s date of birth
- gender
- primary diagnosis
- level of acuity (through paediatric index of mortality—PIM) (Shann, Pearson, Slater, & Wilkinson, 1997)

Specific health outcomes measured included total ventilation time (TVT), weaning duration (WD), and length of stay in the PICU (LOS). In addition, weaning failure and reintubation rates were monitored.
Nurses in the study setting routinely collected and recorded standard demographic and biophysiologic patient measurements on a computerised ‘Clinical Information System’ (CIS). Flow sheets for patients in the retrospective, pre intervention group and the prospective, post intervention group were printed and data entered into the Statistical Package for Social Sciences (SPSS version 12.0), for analysis.

### 4.5.7 Data analysis

Inferential statistics were used to analyse the effect of the guidelines on the outcome variables. Continuous variables were compared using Student’s $t$-test for normally distributed variables and Mann-Whitney test for non-normally distributed variables. Chi-square analysis was used for categorical variables. Kaplan-Meier survival analysis was used to gauge the probability of successful weaning over time. Results were then compared for significance using the log rank test.

### 4.6 Phase Four—Analysis of staff perceptions

This was the qualitative phase of the study. Focus group interviews were undertaken to discover the staff on the study unit’s perceptions of the guidelines for weaning from ventilation and what effect they had on their practice. Focus groups have been described as “a carefully planned (group) discussion designed to obtain perceptions on a defined area of interest in a permissive, non-threatening environment” (Kreuger, 1988, p. 18).

The specific research question under investigation within phase four was:

3. **What impact do guidelines for weaning children from mechanical ventilation have on staff practice?**
The use of qualitative inquiry through focus groups produced richer and more revealing data than achievable through the use of a closed question survey or observational survey. The data generated were then subjected to a qualitative-based content analysis to identify any emerging themes.

4.6.1 Setting

The setting for phase four was the same as for phase three—an eight-bedded PICU in a tertiary referral children’s hospital. The unit admitted critically ill children from 0–16 years of age with a range of diagnoses.

4.6.2 Participant selection

The target population for the focus groups was the clinical nursing staff (n=49) and resident medical staff (n= 5) working on the study unit. All staff were sent individual letters explaining the purpose of the focus group interviews and inviting their voluntary participation. The venue for the focus group interviews and a variety of times and dates were included in the information sheet. A total of four focus groups were conducted. A purposive sample of 22 staff volunteered and consented to participate in the focus group interviews. There were two medical staff, six level two/three nurses and 14 level one nurses. The period of time the staff had used the guidelines ranged from three to twelve months.

4.6.3 Data generation

The same semi-structured questions were asked to each of the four focus groups. This ensured a baseline level of answers as well providing the opportunity for an element of discovery as the majority of the discussion was guided by the participants as they reflected on their experience of using the weaning guidelines.
Each interview took place in a room away from the clinical area. The lengths of the interviews varied from 20–40 minutes and were audiotaped to allow for transcription.

### 4.6.4 Data analysis

The data generated were transcribed verbatim from the audiotapes and subjected to content analysis using the guidelines of Burnard (1991) to highlight any significant themes or concepts. Burnard’s guidelines have been adapted from the ‘grounded theory’ approach of Glaser and Strauss (Glaser & Strauss, 1967; Strauss, 1986), from other works on content analysis (Babbie, 1979; Berg, 1989; Couchman & Dawson, 1990; Fox, 1982), and from other sources concerned with the analysis of qualitative data (Bryman, 1988; Field & Morse, 1985). Burnard’s method employs a step-by-step approach to coding and categorising the interview transcripts. The steps are summarised in Table 3.
### Table 3

**Stages of content analysis (Burnard, 1991)**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Transcription of taped interviews</td>
</tr>
<tr>
<td>2.</td>
<td>Transcriptions read and notes made about general themes</td>
</tr>
<tr>
<td>3.</td>
<td>Open Coding—Re-read transcripts and developing descriptive categories</td>
</tr>
<tr>
<td>4.</td>
<td>Grouping of categories from step 3 under higher order headings</td>
</tr>
<tr>
<td>5.</td>
<td>Repetitious categories and headings removed from list made in step 4</td>
</tr>
<tr>
<td>6.</td>
<td>Independent categorisation by two colleagues and comparison of three lists</td>
</tr>
<tr>
<td>7.</td>
<td>Transcripts re-read alongside final list of headings and categories</td>
</tr>
<tr>
<td>8.</td>
<td>Sections of transcript coded under according to the list of category headings</td>
</tr>
<tr>
<td>9.</td>
<td>‘Cut or clip’ (manually or electronically) highlighted transcript sections*</td>
</tr>
<tr>
<td>10.</td>
<td>‘Paste’ sections of transcript under corresponding categories and headings</td>
</tr>
<tr>
<td>11.</td>
<td>Categorisations returned to interviewees to check appropriateness</td>
</tr>
<tr>
<td>12.</td>
<td>Filing of category system with copies of original transcripts</td>
</tr>
<tr>
<td>13.</td>
<td>Systematic writing up of results including direct quotes from transcripts</td>
</tr>
<tr>
<td>14.</td>
<td>Discussion of finding alongside relevant literature and research</td>
</tr>
</tbody>
</table>

* *Maintain copies of complete transcript for future reference.*

#### 4.6.5 Validity and reliability

The traditional concepts of validity and reliability do not translate well into the naturalistic paradigm, as the methods of qualitative research differ fundamentally
from those of quantitative research. In the interest of confirmability, the researcher acknowledged any assumptions or pre-understandings she had about the research topic. In an additional effort to avoid influencing the participants’ recollections of their experience, a semi-structured interview technique was used. Inter-rater reliability was attained through the multiple interpretations of data by the researcher and selected colleagues (as per step 6 in Burnard’s [1991] stages of content analysis). The researcher returned transcribed data and subsequent thematic analyses to the participants for verification (as per step 11, ibid). A description of the ‘decision trail’ taken by the researcher addressed the issue of dependability.

4.7 Ethical considerations for the study

Ethical approval to conduct the study was obtained from the Queensland University of Technology’s Research Ethics Committee (Appendices D\(^1\) and D\(^2\)) and the Hospital’s Ethics Committee (Appendix E).

4.7.1 Informing and gaining consent from participants

The Hospital’s Ethics Committee information about the study (Appendix F) accompanied the survey explaining that return of the completed survey would be an indication of participants’ consent to participate in the study.

*Phase two—Development of guidelines:* PICU clinical experts in Brisbane were invited to be part of the advisory reference group that validated the guidelines for weaning from mechanical ventilation before implementation. No remuneration was offered but, with their permission, their contribution to the project was to be acknowledged in the final thesis and any publications that arose from the study.
Phase three—Pre and post-test of guidelines: The patients and/or their parents were given written and verbal information by the researcher (Appendix G) about the study, and their written consent requested (Appendices H and I).

Phase four—Focus group interviews: Staff on the study unit were given an information sheet (Appendix J) about the study and invited to volunteer for participation in the focus group interviews. Participants were asked to sign a consent form prior to commencement of the interview indicating their permission for the interview to be taped and for the data generated to be used for research and publication purposes (Appendix K).

4.7.2 Potential risks

There were no physical risks involved in this study. The potential risks identified included:

- Phase one—National Survey: The unit leaders completing the national survey may have felt threatened and challenged in their professional practice.
- Phase two—Development of Guidelines: No potential risks were identified for personnel involved in the development of the guidelines.
- Phase three—Pre and post-test of guidelines: No foreseeable physical risks were envisaged. The guidelines were research-based and were validated by clinical experts before their implementation. No new or experimental therapy was prescribed and no treatment was withheld. The researcher acknowledged that the prospect of giving informed consent for participation in a study might have caused additional stress for parents while they were dealing with having a sick child in intensive care.
Phase four—Focus group interviews: The unit staff who were asked to participate in the interviews might have felt intimidated at the prospect of discussing their professional practice openly.

4.7.3 Risk management procedures

All potential risks for participants in all phases of the study were minimised or managed through the following steps:

- Consent to participate in the study was entirely voluntary and participants were free to withdraw from the study at any time without penalty.
- Confidentiality and anonymity was assured. No unit, patient or staff member was identifiable in the final report or subsequent publications.
- In addition to the ongoing support of the researcher and the unit’s clinical leaders, counselling support was available to those individuals who needed it.

4.7.4 Confidentiality and security

The confidentiality and anonymity of all participants was assured throughout the study. Coding mechanisms were applied to the surveys, patient records and transcripts of the taped interviews. No individual unit or person is identifiable within the final report or subsequent publications. All data and information provided has been kept in the strictest confidence in a locked filing cabinet accessible only to the researcher. Records will be in a secure place for the next five years and destroyed after this time.

4.8 Summary

The methodology and range of research design have been described in this chapter. The results of the study are presented in the following four chapters which have also been submitted to international journals for publication.
Chapter Five

Results—Phase One

Weaning from mechanical ventilation:

A national survey of Australian paediatric intensive care units

The results from phase one of the study that examined the status of weaning children from mechanical ventilation as well as unit characteristics and staffing are presented in this chapter.

The chapter is presented in the format of a journal article that has been prepared and submitted to Neonatal, Paediatric and Child Health Nursing.
This article is not available online. Please consult the hardcopy thesis available from the QUT Library.
Chapter Six

Results—Phase Two

Developing and implementing clinical practice tools: The legal and ethical implications

This chapter presents the process and results from phase two of the study. This phase involved an examination of the research on weaning from mechanical ventilation, generation of the guidelines, consultation and subsequent ratification of the guidelines and then the piloting of these guidelines.

This chapter is presented in the format of a journal article that has been published by the *Australian Journal of Advanced Nursing, (2001) 19(2): 14–19*. The paper was co-authored by Professor Mary Courtney who was happy to have it included in this thesis.
This article is not available online. Please consult the hardcopy thesis available from the QUT Library.
Chapter Seven

Results—Phase Three

Weaning from ventilation in paediatric intensive care: An intervention study

The findings from this experimental phase of this study that tested the main research question and four related hypotheses are presented in this chapter. The hypotheses examined the impact the guidelines for weaning children from mechanical ventilation had on weaning duration, total ventilation time, length of stay (in the PICU) and the quality indicators (incidence of weaning failure and reintubation).

This chapter is presented in the format of a journal article published by *Intensive and Critical Care Nursing* (2003) 19, 186–197. The paper was co-authored by Professor Mary Courtney and Fiona Coyer who were happy to have it included in this thesis.
This article is not available online. Please consult the hardcopy thesis available from the QUT Library.
Chapter Eight

Results—Phase Four

Staff perceptions of guidelines for weaning children from mechanical ventilation: A qualitative study

The findings from the qualitative phase of the study exploring staff perceptions of using the guidelines in practice are presented in this chapter. The success of any health care tool lies not just in its development and implementation, but also in its uptake and acceptance by the staff. The use of a qualitative research design produced rich and revealing data.

This chapter is presented in the format of a journal article prepared for the Journal of Advanced Nursing.
This article is not available online. Please consult the hardcopy thesis available from the QUT Library.
Chapter Nine

Discussion and conclusion

The general aim of this study was to explore the need for, and impact of, guidelines for weaning children from mechanical ventilation on patient outcomes and staff practice. The study was undertaken to increase understanding and knowledge related to the process of weaning critically ill children from ventilation. A specific aim was to determine variability in current weaning practices and subsequently evaluate the impact of the implementation of collaborative, standardised and patient-centred guidelines for this process.

This study contributed to the weaning and ventilation literature in several ways. Previous research had quantified the significant time, effort and resources weaning consumed, from both staff and patient perspectives (Anderson & O'Brien, 1995; Burns, 1998; Burns et al., 1998; Clochesy et al., 1997; Curley & Fackler, 1998; Esteban & Alia, 1998; Esteban, Alia, Ibanez, Benito, & Tobin, 1994; Knebel, 1991). A number of studies had demonstrated the positive impact of a standardised weaning process on patient outcomes (Burns, 1998, 1999; Burns et al., 1998; Djunaedi et al., 1997; Henneman, Dracup, Ganz, Molayeme, & Cooper, 2002; Keogh, Courtney, & Coyer, 2003; Kollef, Horst, Prang, & Brock, 1998; Kollef et al., 1997b; Lessard & Brochard, 1996; Wood, MacLeod, & Moffat, 1995). However, prior to the commencement of this study there had been no published studies examining the effect of weaning guidelines in the paediatric ICU population. At the time of writing there are now two studies that have examined weaning guidelines in the PICU. They both used an RCT design, but were both underpowered and yielded different results and conclusions (Schultz et al., 2001; Randolph et al., 2003).
study examined the effect of weaning guidelines in the general PICU, including the highly varied group of patients admitted for respiratory reasons, using a quasi-experimental design and with slightly different readiness to wean criteria. The results demonstrated that guidelines for weaning children from mechanical ventilation could be used safely and improve consistency of practice.

The study also contributed to the knowledge and understanding of guideline literature as it explored staff perceptions of the effect weaning guidelines had on their specific and general practice.

Langley’s Model for improvement (Langley, Nolan, & Nolan, 1994) guided the study. The model provided a framework for implementing and testing an intervention in the clinical setting. The sequence of tests (pre-, pilot, and post-) employed when re-designing a system of care is an important feature of the model. The decision to increase the scale of testing is based on the results of the previous test as demonstrated in Figure 8.
1. **Goal:** Improved and/or reduced inappropriate weaning.
2. **Outcome measures:** TVT, WD, LOS, QIs and staff perceptions.
3. **Intervention:** Collaborative guidelines for weaning children from mechanical ventilation.

![Adapted Model for Improvement reflecting the phases of the study](image)

_Figure 8._ Adapted Model for Improvement reflecting the phases of the study.

This chapter begins with a review of the major findings from the study. The findings from each phase are discussed in relation to the relevant questions and hypotheses tested. The main conclusions and the theoretical and practical implications of the study are discussed—recommendations are also proposed.
9.1 Review of findings

9.1.1 Phase 1

Phase one of this study, as reported in Chapter five, sought to describe the current status of weaning management in Australian PICUs and, more specifically, ascertain if there was a standardised approach to weaning from mechanical ventilation.

- Research Question 1: Is there a standardised approach to weaning from mechanical ventilation in Australian PICUs?

The survey quantified the number of ventilated children admitted to Australian PICUs over a 12-month period (n= 2587). The majority of units indicated that children with respiratory disorders were the primary reason for admission for ventilatory support to their unit. However, a number of research protocols often exclude this population because of the dynamic nature of each patient’s response to illness. SIMV with PEEP ± PC/PS was cited as the most used weaning mode in the paediatric units. This contrasts with weaning in the adult population where PS with PEEP and CPAP are the preferred weaning modes as they have shown to reduce weaning time and decrease risk of patient-ventilator dysynchrony in the adult population (MacIntyre, 1986; Richless, 1991). Manczur and colleagues’ (2000) study does not support this in the paediatric population. Their study demonstrated there was a decrease in work of breathing and oxygen consumption in children supported by SIMV as opposed to CPAP (Manczur, Greenough, & Rafferty, 2000). Australian PICU survey respondents indicated that they used CPAP as part of a weaning strategy for difficult-to-wean or long-term ventilated patients. One paediatric study concluded that spontaneous breathing trials were a successful weaning mode for
children (Farias, Alia, Esteban, Golubicki, & Olazarri, 1998). However, reintubation rates were higher than in reported in other studies and in the designated study unit for this paper. This indicates possible inappropriate weaning and extubation times for these patients weaned according to response to a spontaneous breathing trial. These inconsistencies within both practice and research highlight the need for more research into comparing weaning modes in the paediatric population.

The results of the national survey demonstrated that while the management of ventilated patients receives a high profile, the management of weaning does not. All units reported having ventilation guidelines, but no unit reported having implemented weaning guidelines. The units collectively reported using similar weaning modes but differing approaches employed, demonstrate the diversity in practice and echoing the conflict and disparity in the research in this area.

A number of studies have developed and evaluated the effect of various weaning tools in the adult population (Djunaedi et al., 1997; Kollef et al., 1997a; Lessard & Brochard, 1996; Wood et al., 1995). All these studies demonstrated a positive impact on patient outcomes measured that included total ventilation time, length of stay (in ICU), patient comfort, and financial costs. Some of the weaning tools were aimed at all members of the health care team, acknowledging the multidisciplinary approach to weaning in intensive care. It would therefore seem prudent, for clinical and economic reasons, that collaborative guidelines for weaning children from mechanical ventilation be developed and implemented into Australian PICUs.

A total of 52% of Australian PICU nurses were identified as holding a postgraduate qualification, with 33% holding a PICU qualification. ANZICS (Faculty of
Intensive Care, 1997) recommend that the majority (i.e. > 50%) of ICU nurses hold specific ICU qualifications. It would not be unreasonable to transpose this recommendation to paediatric intensive care. If weaning a patient from ventilation is considered an extension of the nurses’ role then a specific qualification would be able to address the knowledge and skills required for this. An improvement in the availability and/or accessibility of PICU courses within Australia may help redress the shortfall of specifically PICU-qualified nurses within Australian units. Complementary support from the clinical areas (i.e. financial support, study-leave) would also be required.

9.1.2 Phase 2

Phase two of the study, as reported in Chapter six, detailed the processes involved in the development of the guidelines (as per the NH&MRC framework). The need and scope of the subject had been gathered in the initial study phase. A multidisciplinary working part was established, reflecting the multidisciplinary nature of the weaning process and thus the guidelines. The specific health outcomes measures identified and an extensive literature search of the CINAHL and MEDLINE databases was conducted. A draft of the guidelines, including a weaning algorithm, was drawn up, reviewed and refined over a six-week period before they were considered ready for clinical use.

Prior to piloting the format, all medical and nursing staff were sent an information letter informing them about the study and the guidelines. Education sessions (including didactic lectures and hands-on interactive sessions at the bedside) were scheduled over a four-week period to inform and instruct staff about
the weaning guidelines and process in detail and provide them with the opportunity to ask questions.

The chapter also included an exploration of the legal and ethical implications of incorporating guidelines into practice. Practice guidelines may not change the litigation system per se, but they could be used as evidence to determine the case for negligence (Brennan, 1991). To date, the use of guidelines in medical litigation in Australia is limited. Nevertheless, clinicians need to be aware of the potential impact clinical guidelines may have on the decision-making processes of the attorneys. Guidelines and protocols offer a decrease in the need to practice defensive medicine as well as a method to improve quality of care (Noonan, 1997).

The ethical issues related to the use of practice guidelines are identical to the ethical issues surrounding the use of any therapy or intervention. These being, autonomy, distributive justice, nonmaleficence, and beneficence (Beauchamp & Childress, 1989; Jonsen, Siegler, & Winslade, 1992).

The principle of autonomy requires patient participation and consent. The question of whether guidelines are considered a new and innovative non-standard therapy then arises. Are guidelines decision support tools that merely formalise and standardise common practice? If the latter argument is used then informed consent is not mandatory. The principle of distributive justice is not an issue as long as the tool is applied to all patients without prejudice (Morris et al., 1994).

Striking a balance between the principles of nonmaleficence and beneficence is a challenge to the health care practitioner. In essence, a risk-benefit analysis must be undertaken, and is best done when probable estimates of outcome for treatment options are based on sound data. When addressing the principles of nonmaleficence
and beneficence in regards to guidelines, the assumption that physician belief is a reliable reflection of best information available does not acknowledge the general human limitations with information processing (Miller, 1956; Morris, 1992, 1993). The forethought and consensus approach to guideline development means that more consideration and planning underpin decisions made under guideline control than by any individual practitioner (James & Eddy, 1994). The intent to do good and the belief in a therapeutic decision within the increasingly complex area of critical care is not always enough.

No specific research question or hypotheses were tested in this phase. However, the guidelines were piloted to test for validity and safety in the clinical setting.

9.1.3 Pilot study

The guidelines were piloted on ten patients over a one-month period. Outcomes measured included total ventilation time (TVT), weaning duration (WD), length of stay (LOS), as well as quality indicators (weaning failure, reintubation and reventilation rates). Results from the pilot sample were compared to the retrospective analysis and the outcome measures were comparable. The pilot sample was too small for application of statistical analysis; however, the pilot test demonstrated that the multidisciplinary weaning guidelines were a safe clinical practice tool. Minor revisions were made to the guidelines in response to feedback from staff and the guidelines fully implemented for a 12-month period.

9.1.4 Phase 3

The results from the third phase of this study are discussed in Chapter seven. The aim of this phase was to implement and evaluate the collaborative guidelines for
weaning children from mechanical ventilation. The main research question under investigation in this phase of the study was:

- **Research Question 2: Did the implementation of collaborative guidelines for weaning children from mechanical ventilation significantly improve patient outcomes compared to patients weaned from ventilation without guidelines?**

Phase one had ascertained the lack of guidelines in PICUs and identified the annual population of ventilated children in Australia. Standardised approaches to weaning that were facilitated through protocols or guidelines in both adult and paediatric populations had proven successful (Burns, 1999; Burns et al., 1998; Djunaedi et al., 1997; Kollef et al., 1998; Kollef et al., 1997b; Lessard & Brochard, 1996; Wood et al., 1995). These studies demonstrated that the use of weaning guidelines reduced ventilation, weaning, weaning and reintubation rates, ICU admission times, and associated costs. Guidelines also improved nurse response time and patient comfort levels. In phase two, the evidence and expert opinion on weaning from mechanical ventilation was reviewed, guidelines drawn up and then safely piloted.

Phase three employed a quasi-experimental time series design using an historical control. The primary purpose of this phase of the study was to evaluate the impact of collaborative guidelines for weaning children from mechanical ventilation on patient outcomes. A total of 220 patients (pre intervention n=107 and post intervention n=113) were studied. Specific health outcomes monitored and measured were as for the pilot study (TV, WD, LOS, weaning failure, and reintubation rates).

These outcomes were each investigated through the testing of the following null hypotheses:
Null Hypothesis 1: There will be no difference in patients’ total ventilation times, after implementation of the guidelines for weaning from ventilation.

This hypothesis was not supported. TVT was longer post intervention, but this was not statistically significant (mean difference TVT-15.5hrs p<0.068). The prolonged time observed in the post intervention analysis, however, was relatively reduced compared to the baseline measurement (relative difference equalled 14.95hrs for TVT). This relative reduction in ventilation times indicates (a) the guidelines had not prolonged the time further, (b) the guidelines appear to have contributed to the relative reduction observed and (c) that an improvement in the consistency of practice has occurred.

Null Hypothesis 2: There will be no difference in the weaning duration for patients after the implementation of the guidelines for weaning from ventilation.

Weaning duration was comparable between groups (Median difference WD–1.5hrs p<0.427). However, the relative difference between the pre-test control and post-test was 12.5hrs, indicating at least a minimising of fluctuation of this variable over time and an improvement in consistency of practice in relation to the guidelines.

Null Hypothesis 3: There will be no difference in the patients’ length of stay in the PICU after the implementation of the guidelines for weaning from ventilation.

This hypothesis was not supported. The LOS was longer post intervention, but this was not statistically significant (mean difference LOS–23.75hrs p<0.088). However, similar to the TVT outcome, the mean post intervention LOS time was
relatively reduced compared to the baseline measurement (12.25hrs for LOS). This indicates that the guidelines had not prolonged the time further and they appear to have contributed to the relative reduction observed and more consistency in weaning management.

- **Hypothesis 4:** There will be no difference in the quality indicators (incidence of weaning failures and reintubation) after the guidelines for weaning from ventilation have been implemented in to practice.

The results indicated limited support for the relationship between improved quality indicators and the use of weaning guidelines in children. There was a slight improvement in the quality indicators [weaning failures 13(12%) versus 9 (7.9%), $\chi^2 p=0.371$ and reintubation rates 5(4.6%) versus 4 (3.5%), $\chi^2 p=0.743$]. Although not statistically significant, the improvement indicated a positive trend for patients weaned according to the guidelines.

A reduction in the reintubation rate is clinically significant because of the reported increase in morbidity and mortality rates associated with reintubation (Estaban et al., 1999). Farias and colleagues (1998) had reported that spontaneous T-piece trials were a successful weaning mode. However, the reintubation rate was 16%—three to four times the rate in this study. In summary, a more rapid approach to weaning and extubation may not always be the most prudent. A systematic and coordinated approach to weaning children from mechanical ventilation may prolong TVT, WD and LOS for some, but the risk of weaning failure and reintubation is reduced.

The Kaplan-Meier plots of probability of successful weaning over time visually clarified weaning practice in paediatrics (see Figure 7). The analysis
demonstrated an increased probability of remaining ventilated for short- to medium-term ventilated patients (i.e. 2–200 hours or 8 days) weaned according to guidelines. This could be because the implementation of guidelines imposed a process and evaluation of patient parameters not overtly followed before. However, there was a slightly reduced probability of remaining ventilated for long-term ventilated patients (i.e. more than 200 hours or 8 days) when weaned according to the guidelines. This demonstrates the positive impact of a cohesive and coordinated approach to the management of weaning patients from mechanical ventilation.

9.1.5 Phase 4

The aim of phase four was to ascertain and analyse staff perceptions of using collaborative weaning guidelines in practice. A qualitative methodology was employed for this study to gain the fullest understanding of the participants’ experience of using the guidelines. The use of qualitative inquiry through the focus group interviews in this study produced richer and more revealing data than possible by the use of a closed question survey or observational tool. The data generated from the focus groups were subjected to a thematic content analysis to identify any emerging themes. The research question that was the focus for this phase of the study was:

- Research Question 3: What impact did guidelines for weaning children from mechanical ventilation have on staff practice?

Staff feedback on the use of the weaning guidelines in practice that was captured in focus group interviews added another dimension to the overall evaluation of the impact of the guidelines. One principal category of ‘Practice’ emerged with four related sub-categories called framework, development,
relationships/communication and challenges. These are outlined in Table 10 along with related transcript excerpts. Each subcategory will be discussed in the following section and the data compared with themes that have emerged from literature on guidelines to date. Direct quotations from the transcripts are used to give further insight into participants’ experience and demonstrate the credibility or ‘truth value’ of the data analysis.

9.1.6 Practice Framework

This was the most dominant sub-category with participants overwhelmingly positive and appreciative that the guidelines gave them a framework on which to base their weaning practice. One participant said, “. . . it’s very easy to follow. It’s straightforward” while another identified “(T)here’s some sort of uniformity as to the approach at the bedside. . . it assists decision-making”.

This positive attitude is echoed in a number of studies examining nurses’ and doctors’ attitudes towards clinical practice guidelines. In a survey of 391 general practitioners (GPs) in the south of England the results demonstrated that the GPs found guidelines a useful method of accessing expert information and enabled safe delegation of care (Watkins, Harvey, Langley, Gray, & Faulkner, 1999). In another qualitative study examining doctors’ and nurses’ perceptions of clinical protocols, these tools were seen as a useful method to standardise practice, manage risk and facilitate the inclusion of both evidence and policy into practice (Lawton & Parker, 1999). Other quotes from the focus group interviews that related to this sub-category were “(I)t was great to have consistency for things that we are doing. . . it was based on the patient rather than ward convenience’.
9.1.7 Practice development

The next sub-category that featured highly in the interviews was practice development. Participants commented on how they believed the weaning guidelines had increased their input into patient care and thus improved their levels of confidence and autonomy in clinical practice (both nurses and junior medical staff). Participants stated, “(I) found I had more confidence to question more... gives us, the nurses, more autonomy in our practice”. Participants stated that the guidelines had enhanced their knowledge and awareness about the weaning process. Senior medical staff commented that the collaborative guidelines reflected the merging of (clinical) roles and the team effort involved in caring for a critically ill patient. One participant said “(I)t’s another evolutionary process along with this independent practice, with an enhanced understanding of what we’re doing”.

Similar comments about how the guidelines were linked to practice development were found in the literature. As nursing and medicine become more specialised then practitioners’ skills may require professional and organisational support in the form of guidelines (Workman, 2000). Guidelines may also facilitate the explicit codification of the scientific basis of work, and thus enhance the practitioner’s status (Harrison, Dodswell, & Wright, 2002). Senior clinicians and physicians perceived guidelines as being valuable in enabling safe delegation of care to other health professionals, supporting specialist roles as well as providing an interface between the movement towards evidence-based practice (Carr, Bethea, & Hancock, 2001; Dykes, 2003; Harrison et al., 2002).

9.1.8 Practice interaction

Staff in the study commented on how they believed the guidelines enhanced communication both within and between disciplines. For example: “talk more openly
between staff, well doctors and nurses. . . smooths out discrepancies. . . it is a good communicative tool”. They felt that the guidelines helped raise the awareness of each other’s roles and capabilities and encouraged a more team-focused approach to the care of the patient. In one similar study GPs felt more confident in delegating aspects of care to other health care professionals if they had access to guidelines (Watkins et al., 1999). Guidelines could facilitate a collaborative decision-making approach to patient care, particularly if the guidelines were developed collaboratively (Dykes, 2003). The guidelines were also a valuable tool to facilitate the sharing of decision-making with patients (Watkins et al., 1999). Staff in this study echoed this view with one participant stating, “( I) think it helps you to explain, clarify, issues to the parents”.

9.1.9 Practice challenges

Staff also made comment on the less positive aspects of the guidelines (as they perceived them). Some staff comments betrayed a simple resistance to change. For example, “(H)assle. . . I think it challenged their comfort zone”. Yet others embraced the concept wholeheartedly but apparently at the expense of their clinical judgement reflecting a ‘blind following’ of the tool. For example, “people went with, you know, what was said it (the guideline) without really thinking whether the child was really able—like coping”. This was never the intent of the guidelines. Indeed the introduction to the tool contained a preface that stated: “These guidelines are a guide for the PICU practitioner during the weaning process. They do not replace sound clinical judgement at the bedside”. Dykes (2003) suggested that questions remain as to the format of practice guidelines that grant autonomy whilst offering recommendations that are clear and measurable.
9.2 Summary of findings

The national survey of Australian PICUs, demonstrated the need and scope for guidelines for weaning children from mechanical ventilation. Variations in weaning management may lead to inconsistencies in care, therefore guidelines for weaning children from ventilation were developed to standardise the approach to weaning in the PICU.

The results of the experimental phase of the study demonstrated that collaborative guidelines could be used safely to guide the weaning process for the paediatric population in intensive care. An explicit, coordinated and systematic approach to weaning from mechanical ventilation may prolong ventilation and concurrent PICU admission times, but the risk of weaning failure and reintubation was slightly reduced. Therefore faster weaning approaches may not always prudent. The relative reduction in outcomes (TVT, WD AND LOS) observed demonstrated that guidelines facilitated the desired standardised approach to management of weaning and as a result minimised the fluctuation of outcome variables over time.

The overall staff feedback about guidelines use was positive. Staff perceived that improved patient outcomes resulted from the implementation of the guidelines. They also felt that the guidelines standardised the approach to weaning, enhanced communication, promoted thinking and autonomy, and assisted the beginning practitioner. However, some staff felt that this level of autonomy challenged their comfort zone, and there was a need to clarify some terms to minimise confusion about readiness to wean. This positive experience of guideline use may help promote wider use of guidelines for other areas of practice that would benefit from a collaborative, cohesive and research-based approach.
9.3 **Strengths and limitations of the study**

A quasi-experimental in preference to a experimental design was chosen for this study. If a randomised, controlled trial had been employed it would have proved difficult to reduce contamination of the control due to shared clinical management within the one study unit. Use of a second unit would have potentially introduced even more confounding variables. This study used both a historical and time series control, with the aim of avoiding experiment group contamination and providing a baseline measurement of variable fluctuation. This allows the researcher to explain alternative reasons for any changes in outcome variables measured post intervention.

Although the overall analysis was by intention to treat, guidelines compliance was also monitored. The number of children who completed the weaning guidelines was 92 of 113 (81%) in the post intervention group. Of the 21 children whose weaning and/or extubation was unplanned, or occurred before consent for the study, none failed weaning or extubation. Adherence to the weaning guidelines by staff was observed retrospectively during data collection. Essentially, the pattern of weaning was anecdotally compared to the guideline recommendations. A more thorough examination of guidelines adherence would only be possible if the intervention was computerised and a staff acceptance or rejection of the guidelines’ recommendations collated by the computer program. Unit staff turnover was minimal on the unit, and any new staff (medical and nursing) were orientated to the study and weaning guidelines to ensure inter-rater reliability of guidelines application.

The traditional concepts of validity and reliability do not translate well into the naturalistic paradigm employed for the phase four of the study. To establish a sense of credibility reliability of data interpretation was confirmed by both
independent research colleagues and participants. A detailed description of the data analysis addressed the issue of dependability. A semi-structured interview technique was used to minimise the researcher’s influence on successive interviews.

9.4 Implications for nursing practice

The greatest value of this study is the development of practice guidelines to optimise patient outcomes and staff practice in the clinical setting. Variation in weaning practice may lead to inconsistent decision-making about weaning, which has implications for the patient’s physical and mental health and related costs (Curley & Fackler, 1998). Too rapid or inappropriate weaning may lead to premature weaning and/or extubation prone to failure. Reintubation rates have correlated with poor outcome including increased mortality (Esteban et al., 1999). The results of this study demonstrated a reduction in outcome variable fluctuation due to the implementation of a guideline. The guidelines provided a framework for decision-making and patient assessment during the weaning process. As well as articulating a common action plan and goal for each patient the guidelines also kept the weaning process patient-centred (as opposed to ‘doctor- or nurse-centred’).

Health care professionals have a duty to assess and address the unique needs of this group of patients in a systematic way. Based on the results from this study PICU staff need to consider adopting a coordinated and collaborative approach to weaning to improve consistency of weaning management and optimise patient outcomes. Guidelines should be aimed at specific patient groups and tailored accordingly. Clinicians need to discriminate between short- to medium- term ventilated patients (up to eight days) and long-term (greater than eight days) ventilated patients.
As the role and responsibilities of critical care nurses expand so must supportive education and training. If Australia is to achieve the recommended level of formally qualified PICU nurses there needs to be an increase in the number of courses available, and a change to more flexible modes of study to facilitate uptake of the courses. The improved availability and/or accessibility of PICU courses would require complementary support from the clinical areas.

9.5 Implications for nursing research

This study was conducted in one unit that appeared to be representative of the other PICU (in relation to activity, admission criteria, staffing profiles). However, as this remains one of the first and few studies examining weaning in this area, a larger and multi-site study would be welcomed. It is recommended that future research into weaning acknowledges the different patient populations, and examine them separately (e.g. short, medium and long-term ventilation).

In addition to the testing of weaning approaches, limited and conflicting evidence about optimal weaning modes and predictive indices in the paediatric population remains. Therefore, there is also a need for more research into weaning modes and predictors for children on mechanical ventilation.

Much of the previous research examined specific predictive mechanisms, modes and/or approaches aimed at specific staff groups (i.e. nurses, respiratory therapists or doctors). Any weaning tool should be patient-focused and involving all members of the health care team in the process should optimise every unit’s most valuable resource—its staff.
9.6 Recommendations

Based on the results of this study it is recommended that national guidelines for weaning paediatric patients from mechanical ventilation be developed and disseminated. Guidelines should be tailored to meet the needs of specific patient groups, these may then be adapted to meet local needs and implemented and evaluated.

Universities, nursing colleges, and the hospitals need to support further and ongoing education of nurses in paediatric intensive care. An increase in availability and accessibility (through external or online modes) of PICU courses will make the courses more attractive to nurses. The increased cost of providing this support needs to be weighed against the (potential) improvement in outcomes and quality of care provided in Australian PICUs.

There is a need for more research into weaning children from mechanical ventilation. SIMV was the most frequently used weaning mode, however, PS and CPAP were also used for some patients. The limited research found and the literature to date is inconclusive and more research comparing weaning modes in paediatric population is required.

9.7 Conclusions

In this research project, the need and scope for guidelines for weaning children was ascertained, guidelines developed (based on available evidence and expert opinion). The guidelines were implemented and then evaluated for their impact on patient outcomes and staff practice.

The national survey provided some insight into the management of weaning from mechanical ventilation in Australian PICUs as well as a brief overview of unit
characteristics and staffing. No unit reported having implemented weaning guidelines.

In phase two, the development of the guidelines as per the NH&MRC guidelines was described alongside a broader discussion of the legal and ethical considerations associated with clinical practice guidelines. The impact of guidelines has already been realised in the medical litigation process. However, an increasing litigious environment should not be the impetus for clinical guideline development. Quality guidelines can aid in making health care more appropriate and effective. The ethical issues to be considered when using guidelines compare to those associated with conventional clinical decision-making processes. Guidelines can assist practitioners by providing a framework that promotes practice patterns associated with good clinical judgement, research-based interventions and results in improved patient care and outcomes.

Phase three tested the effect of the guidelines in the clinical setting using a quasi-experimental design. The results from this phase of the study demonstrated that collaborative guidelines could be used safely and effectively when weaning children from mechanical ventilation. An explicit, coordinated and systematic approach to weaning helps improve the consistency of weaning management and care, and thus improves the quality indicators for weaning outcomes. Therefore, faster weaning approaches may not always be prudent.

The final phase of the study explored and analysed staff perceptions of using collaborative weaning guidelines in practice—the overall staff feedback was positive. Four sub-categories relating to the principal category of ‘Practice’
emerged—framework, development, interactions and challenges. Staff perceived that improved patient outcomes resulted from the implementation of the guidelines.

This study has contributed to the body of knowledge on ventilation and weaning by:

- describing the practice for weaning nationally,
- developing a weaning tool for use in the paediatric population,
- providing a framework to promote consistency in weaning practice,
- demonstrating its safe and effective use in the clinical setting,
- clarifying weaning practice in paediatrics, and
- exploring staff experiences of their use in practice.

The modern ICU is an important focus for quality improvement efforts. Guidelines cannot automatically guarantee improved quality of care; however, they do direct the clinician in the pursuit of this objective.
Appendices
Appendix A: Pilot letter and questionnaire
APPENDIX A
Centre for Nursing Research
QUT

Date

Clinical Nurse Consultant
Intensive Care Unit
Hospital
Street
City
State PC

A study of the effect of guidelines for weaning from artificial ventilation on patient outcomes and nursing practice in the paediatric intensive care unit.

Dear

Thank you for considering your inclusion in the pilot study phase of this project. This research forms the basis of my dissertation for a Doctorate of Philosophy being undertaken at the Queensland University of Technology in Brisbane.

As part of the pilot study sample I am keen to obtain your comments on the structure and content of the survey itself. Your contribution as a clinical expert is to ensure the content of the survey is valid. The data generated by your answers to the questions will not be included in the data analysed or the final report. Please be assured that all information provided by you will be anonymous and treated as strictly confidential. Participation in this pilot study is voluntary and you are free to withdraw from the study at any time without penalty or comment. By completing this survey and returning it in the enclosed stamped and addressed envelope you are deemed to have agreed to participate in this study.

The purpose of this survey is to collect demographic and utilisation data on the seven dedicated paediatric intensive care units in Australia, and ascertain current practice pertaining to weaning from artificial ventilation. The results of the survey will be used in conjunction with an extensive literature search and used in the development of guidelines for weaning from artificial ventilation. The guidelines will then be implemented and evaluated for their effect on patient outcomes and nursing practice on the chosen study unit.

If you have any queries feel free to contact me at the above address and telephone, or my academic supervisor Professor Mary Courtney on (07) 3864 3887. If you have any concerns about the ethical conduct of this research please contact the Queensland University of Technology's Registrar, on (07) 3864 1056.

Yours sincerely

Samantha Keogh RN BSc(Hons)
Pilot study questionnaire

As outlined in the cover letter, the main purpose of this pilot study is to obtain your comments on the structure and layout of the survey. After you have completed the survey please answer the questions below and make any additional comments. (Please tick the appropriate answer.)

Did the direction of the questioning flow logically? YES o NO o
Comment: ____________________________________________________________

Were the instructions about answering questions clear? YES o NO o
Comment: ____________________________________________________________

Did you find the questions clear and concise? YES o NO o
Comment: ____________________________________________________________

Were there any questions difficult to answer? YES o NO o
Comment: ____________________________________________________________

Was there any data that was difficult to obtain? YES o NO o
Comment: ____________________________________________________________

Did you feel that the questions asked were relevant to the area being researched? YES o NO o
Comment: ____________________________________________________________

Did you find the length of the survey..... Too short o
Just right o
Too long o

What was your overall impression of the presentation and layout of the survey?
Appendix B: National Survey
APPENDIX B

NATIONAL SURVEY OF AUSTRALIAN PAEDIATRIC INTENSIVE CARE UNITS
Thank you for agreeing to participate in this survey. The primary aim is to ascertain current practice pertaining to weaning from artificial ventilation, as well as collect general demographic and utilisation data. Please answer in your own words where space is provided or circle appropriate response where indicated.

Unit demographics and activity
1. a) How many patient beds are there on your unit? _______________

   b) Of this number how many of the following types of beds are on your unit?

   Ventilated ICU _______________
   Non-ventilated ICU _______________
   High dependency _______________
   Other (please specify) _______________

2. a) How many patients were admitted to your unit between 1st July 1998 and 31st June 1999? _______________

   b) Of this number how many patients were ventilated on your unit between 1st July 1998 and 31st June 1999? _______________

3. What are the three(3) most frequent indications for artificial ventilation of patients on your unit. Choose only three of the following and rank 1, 2 & 3 in descending order of frequency, i.e. 1 equals most frequent indication for admission for ventilation.

   Respiratory ( ) Gastroenterology ( )
   Cardiac ( ) Renal ( )
   Neurological ( ) Hepatic ( )
   Trauma ( ) Oncology ( )
   Burns ( ) Other (please specify) ( )

4. What types of ventilators are in use on your unit? (Please list)

   ______________________________________________________________
   ______________________________________________________________
   ______________________________________________________________
   ______________________________________________________________
   ______________________________________________________________
APPENDIX B

Management of weaning process

5. Do you have written guidelines for care of the ventilated patient on your unit?

Please circle Yes No

If yes please enclose a copy when you return the survey.

6. Do you have written guidelines for weaning patients from ventilation?

Please circle Yes No

If yes please enclose a copy when you return this survey.

If no please go to question 8.

7. a) To whom are the guidelines directed?

Please circle Nurse Doctor Both Other (please specify)

b) Where on the unit can staff access these guidelines?

Please circle the most appropriate response.

Always Frequently Sometimes Hardly ever Never

Please go to question 9.

8. a) Please briefly describe the weaning process practiced on your unit.

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

b) Who is responsible for determining changes to ventilation parameters during the weaning process?

Please circle Nurse Doctor Both Other (please specify)

c) Who adjusts ventilation parameters during the weaning process?

Please circle Nurse Doctor Both Other (please specify)
APPENDIX B

Staffing demographics

9. How many nursing staff on your unit? ________________

10. How many full time equivalents (FTEs) does this equal? ________________

11. How many of the staff hold the following qualifications?
   
   Paediatric only ________________
   Paediatric ICU only ________________
   General ICU only ________________
   Both Paed & ICU ________________
   Other (please specify) ________________

12. Briefly describe any other aspects of care related to ventilation or weaning on your unit that you feel are innovative and may be relevant to this study.

   ______________________________________
   ______________________________________
   ______________________________________
   ______________________________________
   ______________________________________
   ______________________________________
   ______________________________________
   ______________________________________
   ______________________________________

   Thankyou for completing this survey. Your participation is appreciated.
   Please return in the envelope provided by 26th November 1999.
Appendix C: Copy of the guidelines
GUIDELINES FOR WEANING PAEDIATRIC PATIENTS FROM MECHANICAL VENTILATION
APPENDIX C

Introduction
The aim of these guidelines is to standardise the approach to weaning paediatric patients from mechanical ventilation. Weaning is a complex process that involves assessing the patient's readiness to wean, optimising factors that can impede the process, selecting the most appropriate weaning mode, and continually assessing the patient's progress. A combination of pulmonary and non-pulmonary factors need to be assessed and optimised to give the patient the best chance of being successfully weaned from mechanical ventilation. These guidelines are a guide for PICU practitioners during the weaning process. They do not replace sound clinical judgement at the bedside.

The first step in weaning from mechanical ventilation is to recognise when a patient is ready to be weaned.

<table>
<thead>
<tr>
<th>(1) Criteria for commencement of weaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parents/patient consented for study</td>
</tr>
<tr>
<td>Secure endotracheal tube (ETT)</td>
</tr>
<tr>
<td>Acceptable arterial blood gases</td>
</tr>
<tr>
<td>• PaO$_2$ ≥ 80 mmHg on FiO$_2$ ≤ 0.4</td>
</tr>
<tr>
<td>• PaCO$_2$ 30 - 50 mmHg if pH 7.35 - 7.5</td>
</tr>
<tr>
<td>PEEP level ≤ 5 cm H$^2$O</td>
</tr>
<tr>
<td>Resp Rate &lt; 1.5 X Max for age</td>
</tr>
<tr>
<td>Resp effort score 0 or 0-1</td>
</tr>
<tr>
<td>Haemodynamically stable (in absence of inotropic support)</td>
</tr>
<tr>
<td>Sedation Score 1-3</td>
</tr>
<tr>
<td>Medical order to commence weaning and consideration of other factors</td>
</tr>
<tr>
<td>• Resolution or significant improvement in the cause of institution of MV</td>
</tr>
<tr>
<td>• Chest X-ray improving</td>
</tr>
<tr>
<td>• Stabilisation of non-pulmonary factors (CVS, metabolic, electrolytes)</td>
</tr>
</tbody>
</table>


Other factors that can impact on the patient's readiness to wean and may also need to be considered include:

- Nutritional and gut status;
- Fluid balance;
- Abdominal distension;
- Level of pain and comfort;
- Amount of sleep; and
- Level of anxiety.

*** COMMENCE ALGORITHM FOR WEANING FROM MECHANICAL VENTILATION ***
APPENDIX C

1. Refer to age related table for range of acceptable values expected of patient
2. Discontinue weaning if respiratory indices not adequate (SaO₂, RR & ABG).
3. Notify MO if respiratory indices remain suboptimal; respiratory effort increases; patient becomes haemodynamically unstable; patient is agitated or excessively anxious or upset, patient becomes excessively lethargic or sleepy.
4. For patients expected to be ventilated ≤ 8 hours the rate and pace of weaning can be accelerated e.g. 2-5 breaths every 30-60 minutes.
5. The decision to extubate remains a medical one.

Patient on SIMV with PEEP +/- PCIPS

- Does patient meet criteria for weaning?
  - YES: Wean SIMV rate 2bpm and assess patient response within 30 mins
  - NO: Return patient to previous rate and reassess in 2 hours

- Is SaO₂ ≥ 95% and RR < 1.5 X max for age?
  - YES: Continue to wean SIMV rate by 2bpm every 1-2 hours till rate 4bpm assessing patient response after each change.
  - NO: Return to previous rate and reassess in 2 hours

- Is SaO₂ ≥ 95% and RR < 1.5 X max for age?
  - YES: Does patient meet criteria for completion of weaning?
    - YES: Ventilate on PS with PEEP.
      - Wean PS 1-2cm every 1-2 hours to 5cm assessing patient response after each change
    - NO: Is SaO₂ ≥ 95% and RR < 1.5 X max for age?
      - YES: Weaning complete; Document time
      - NO: CPAP as per medical orders

Check ABG; Notify MO

Has patient stabilised?

Return patient to previous rate and reassess in 2 hours
 Criteria for completion of weaning

- \( \text{SaO}_2 \geq 95\% \text{ on } \text{FiO}_2 \leq 0.4 \)
- SIMV rate \( \leq \) 4 bpm and/or PS \( \leq \) 5 cm H\( \text{O} \)
- PEEP \( \leq \) 5 cm H\( \text{O} \)
- Spontaneous Vt \( > \) 5 ml/kg
- Acceptable ABG
  - \( \text{PaO}_2 \geq 60\text{mmHg on } \text{FiO}_2 \leq 0.4 \)
  - \( \text{PaCO}_2 \) 30 - 50 mmHg if pH 7.35 - 7.5
- Resp rate \( < \) 1.5 x max for age
- Resp effort score 0 or 0-1
- Haemodynamically stable
- Sedation score 1-3
- Adequate cough & swallow reflexes
- Adequate respiratory drive

N.B. The decision to extubate remains a medical one.

<table>
<thead>
<tr>
<th></th>
<th>Newborn</th>
<th>1 to 6 months</th>
<th>6 months to 3 years</th>
<th>6 to 12 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory rate</td>
<td>40-60</td>
<td>20-45</td>
<td>20-40</td>
<td>15-30</td>
</tr>
<tr>
<td>(breaths/minute)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>100-160</td>
<td>80-160</td>
<td>80-140</td>
<td>70-110</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>60-90</td>
<td>75-100</td>
<td>80-115</td>
<td>85-120</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>20-60</td>
<td>50-70</td>
<td>50-80</td>
<td>55-80</td>
</tr>
</tbody>
</table>


Glossary

- ABG: Arterial blood gas
- BP: Blood pressure
- BPM: Beats per minute
- CPAP: Continuous positive airway pressure
- CVS: Cardiovascular system
- ETT: Endotracheal tube
- FiO\( \text{2} \): Fraction of inspired oxygen
- IMV: Intermittent mandatory ventilation
- MV: Minute volume
- PC: Pressure control
- PEEP: Positive end expiratory pressure
- PIP: Positive inspired pressure
- PS: Pressure support
- PSV: Pressure support ventilation
- RR: Respiratory rate
- SaO\( \text{2} \): Oxygen Saturation
- SIMV: Synchronised intermittent mandatory ventilation
- VT: Tidal volume

For more information about this study and weaning see: G ICU/Research/Weaning on hard drive of unit PCs or hardcopy folder at desk.

References

- Bloedel Smith, J. (Ed.) (1983) Paediatric Critical Care, Delmar Publishers, New York USA
- Rogers, M. C. (Ed.) (1987) Textbook of Paediatric Intensive Care, Williams & Wilkins, Baltimore USA.
Appendix D1 & D2:   Approval from University Ethics Committee
APPENDIX D1

QUT MEMORANDUM

To Ms Samantha Jane Keogh, School of Nursing
From Secretary, University Human Research Ethics Committee
Date 23 September 1999
Re Conditional Approval – 1771H

I write further to information received in relation to your project, 'The effect of guidelines for weaning from ventilation on patient outcomes and nursing practice in the paediatric intensive care unit' (QUT Ref No: 1771H).

The Deputy Chairperson of the University Human Research Ethics Committee (UHREC) has considered your response and asked that I respond on her behalf. The Deputy Chairperson has decided, under executive powers, that your response has addressed the Committee's requests / concerns.

This decision is subject to ratification at the 19 October 1999 meeting of the Committee. However, you are authorised to proceed with your project on this basis.

Please do not hesitate to contact me if you have any further queries in relation to this matter.

Gary Allen
Secretariat
Phone: 2902
Facsimile: 1818
Email: gx.allen@qut.edu.au
http://www.qut.edu.au/draa/or/ethics.html
APPENDIX D2

UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

Ms Jane Keogh
Centre of Nursing Research
QUT Kelvin Grove

21 October 1999

Dear Ms Keogh

At its 19 October 1999 meeting, the University Human Research Ethics Committee considered the additional information/revisions you provided in relation to your project "The effect of guidelines for weaning from ventilation on patient outcomes and nursing practice in the paediatric intensive care unit" (Ref No QUT 1771H).

The Committee is satisfied that the information provided addresses its concerns.

Please do not hesitate to contact me if you have any further queries in relation to this matter.

Yours sincerely

Gary Allen
Secretary, University Human Research Ethics Committee
QUT Secretariat
Telephone: (07) 3864 2902
Facsimile: (07) 3864 1818
Email: gx.allen@qut.edu.au
http://www.qut.edu.au/drae/or/ethics.html

Cc: Prof Mary Courtney, School of Nursing Kelvin Grove
Appendix E: Approval from Hospital’s Ethics Committee
Ms. Samantha Keogh,

Dear Ms. Keogh,

A study of the effect of guidelines for weaning from artificial ventilation - patient outcomes - nursing practice - paediatric intensive care

Many thanks for your submissions for the above project to the Ethics Committee. I am pleased to say that the Royal Children's Hospital & District Ethics Committee has approved all phases of the project. Members join with me in sending all best wishes for this important study.

With kindest regards,

Professor John Pearn.
Chair,

Royal Children's Hospital and District Health Service Ethics Committee.

c.c. Ethics Committee files (Professor John Pearn).
Members of the Ethics Committee.
Dr. R. McCrossin, Executive Director of Medical Services, R.C.H.
Appendix F: Copy of cover letter to survey participants
APPENDIX F

Centre for Nursing Research

Chief Investigator: Samantha Keogh
QUT School Of Nursing
Victoria Park Road
N Block, Level 3
Kelvin Grove Qld 4059
(07) 3864 3832
email: s2keogh@qut.edu.au

1st November 1999

Name
Clinical Nurse Leader
Paediatric Intensive Care Unit
Royal Children’s Hospital
Address

A study of the effect of guidelines for weaning from artificial ventilation on patient outcomes and nursing practice in the paediatric intensive care unit.

Dear

This research forms the basis of my dissertation for a Doctorate of Philosophy being undertaken at the Queensland University of Technology in Brisbane.

The purpose of this survey is to collect demographic and utilisation data on the seven dedicated paediatric intensive care units in Australia, and ascertain current practice pertaining to weaning from artificial ventilation. The results of the survey will be used in conjunction with an extensive literature search in the development of guidelines for weaning from artificial ventilation. The guidelines will then be implemented and evaluated for their effect on patient outcomes and nursing practice on the chosen study unit.

As one of only seven PICUs in Australia your response would be greatly appreciated. Only aggregate data will be published and all information provided by you will be anonymous and treated as strictly confidential. All records will be maintained in a locked filing cabinet only accessible to the researcher. A summary of the results will be forwarded to you after the final analysis is complete – approximately February 2000.

Participation in this research is voluntary and you are free to withdraw from the study at any time without penalty or comment. By completing this survey and returning it in the enclosed stamped and addressed envelope you are deemed to have agreed to participate in this project.

Thank you for considering your inclusion in this study. If you have any queries feel free to contact me at the above address and telephone, or my academic supervisor Professor Mary Courtney on (07) 3864 3887. If you have any concerns about the ethical conduct of this research please contact the Queensland University of Technology’s Registrar, on (07) 3864 1056.

Yours sincerely

Samantha Keogh RN BSc(Hons)

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APPENDIX G

Centre for Nursing Research

The development, implementation and evaluation of guidelines for weaning paediatric patients from mechanical ventilation.

Information for parents

This study forms the basis of my dissertation for a Doctorate of Philosophy (PhD) being undertaken at Queensland University of Technology (QUT) in Brisbane.

The purpose of this study is to evaluate the effect of guidelines for weaning from ventilation on the patient’s outcome. Weaning from ventilation is a necessary process for all ventilated patients to help them resume breathing by themselves. It is hoped that by standardising the approach to weaning and enhancing the decision making process at the bedside, staff will be able to respond to changes in your child’s condition better, and make your child’s weaning process more comfortable, less stressful and speedier.

The guidelines do not deviate from established practice. They are based on an extensive literature review and expert opinion. The guidelines do not advocate PICU staff to follow any new or experimental method of weaning, nor will any treatment be withheld. The information necessary for this study is currently collected as part of the routine care of the PICU patient. Information about your child will only be required for the duration of the weaning process; that is, until they are breathing without the support of the ventilator. There are no foreseeable risks to your child by being included in this study. Should you have any concerns for your child or yourself whilst they are on the study or in the PICU you could discuss these with myself, Desley Horn (Nurse Practice Coordinator), or Jenny Rich (unit social worker (07) 3253 8558, pager no. 64086).

Your consent to allow your child’s participation in and throughout this study is voluntary. You are free to withdraw your child from the study at any time and this will not affect the care your child subsequently receives. Information obtained about your child will remain confidential and secure at all times. Your child will not be identifiable in the final written report or any publications arising from the study. Should you wish to obtain a summary of the final results this will be available from me by the end of next year (2001).

Thank you for taking the time to consider your child’s inclusion in this study. If you wish to discuss any aspect of the study feel free to contact me on the numbers below or my academic supervisor Professor Mary Courtney on (07) 3864 3887. If you have any concerns about the ethical conduct of the study you may contact the University Registrar on (07) 3864 1056.

Yours sincerely

Samantha Keogh

QUT (07) 3864 3832
RCH (07) 3252 7957
Appendix H: Parent consent form—phase three
APPENDIX H
Centre for Nursing Research

The development, implementation and evaluation of guidelines for weaning paediatric patients from mechanical ventilation.

Consent Form

Chief Investigator: Samantha Keogh
(07) 3864 3832

The investigator conducting this research project abides by the principles governing the ethical conduct of research, and at all times, avows to protect the interests, comfort and safety of all participants.

Your signature below will indicate that:

1. you have read and understood the participant information sheet outlining the nature and purpose of the study;

2. you clearly understand the extent of your child’s involvement and possible risks involved;

3. your consent to allow your child’s inclusion in the study is voluntary and may be terminated by you at any time without comment or penalty, and without jeopardising the ongoing care of your child;

4. you understand that the information obtained will be kept confidential, and that your child will not be identifiable in the final report or subsequent publications;

5. you consent for your child to be included in the study.

Participant’s name: ...........................................................................

Signature: ........................................ Date: ..............................

Researcher’s signature: ................................................ Date: ..............................
Appendix I:  Child’s information letter and consent form—

phase three
Hello, my name is Sam and I am a nurse.

This letter tells you about a project I am doing at University.

At the moment you have a tube in your nose/mouth and this tube is attached to a machine by your bed that does your breathing for you. To help you breathe by yourself again we need to slowly turn the machine breaths down and get you to breathe for yourself.

For my project I have written a new list for nurses and doctors to use as they help you breathe by yourself again. Starting to breathe by yourself might make you tired but will not hurt you.

I need to know if you are happy for the nurse to use the list. Please tick yes or no at the bottom of the page by your name. Your name will not be in my project so people who read it will not know who you are. I will also talk to your mum and dad about this project.

If you have any questions, just ask me, Sam.

NAME: ___________________________ YES □ NO □
Appendix J: Staff information sheet

(focus group interviews)—phase four
Dear

I am now 7 months into the 12-month guideline evaluation period. I would like to take this opportunity to thank you for your assistance with the study to date. The patient evaluation will be in progress till October. The final phase of the study is to explore your experience of using the guidelines for weaning from ventilation. The strength of any tool guiding clinical practice is its widespread acceptance by the staff. Therefore, the final phase of this study is to analyse how staff perceived the effect of using the guidelines on their practice of weaning patients from ventilation.

You are invited to participate in a focus group interview with myself and (up to) six of your clinical peers to discuss your experience of using the guidelines for weaning. Please note that all members of the PICU staff are being invited to participate in the focus group interviews and that no individuals have been singled out. The interviews will be conducted in the unit’s seminar room in work time as indicated on the inservice board (as agreed with the clinical leader). It is anticipated that the interview will last no more than 30 minutes and will be audio-taped so that I can later transcribe the conversations verbatim.

No foreseeable risk to you is envisaged through your participation in the interview. However should the interview process worry or concern you in any way please feel free to discuss this further with myself, your clinical leader (Desley Horn).

Participation in and throughout the study is voluntary. You are free to stop the interview and/or leave the study at any time without comment or penalty. All data will be kept secure and confidential. Transcriptions will be coded to maintain anonymity. You will not be identified within the final written report or subsequent publications. A summary of the results of the focus group interviews will be available to you after the final analysis – approximately October 2001.

If you wish to discuss any aspect of this study feel free to contact me on the numbers below, or my academic supervisor Professor Mary Courtney on (07) 3863 3887. Should you have any concerns about the ethical conduct of the study you may contact the QUT Registrar on (07) 3864 1056.

Yours sincerely

Samantha Keogh
Telephone: RCH (07) 3253 7957
QUT (07) 3864 3832
Appendix K: Staff consent form (focus group interviews)—phase four
APPENDIX K

Centre for Nursing Research

The development, implementation and evaluation of guidelines for weaning from mechanical ventilation in the paediatric intensive care unit.

Chief Investigator:  Samantha Keogh
                  (07) 3864 3832

The investigator conducting this research project abides by the principles governing the ethical conduct of research, and at all times, avows to protect the interests, comfort and safety of all participants.

Your signature below will indicate that:

1. you have read and understood the participant information sheet outlining the nature and purpose of the study;

2. you clearly understand the extent of your involvement and possible risks involved;

3. your consent to participate in the study is voluntary and may be terminated by you at any time without comment or penalty;

4. you understand that the information obtained will be kept confidential, and that you will not be identifiable in the final report or subsequent publications;

5. you consent to be included in the study.

Participant’s name:..............................................

Signature:......................................................... Date:......................

Researcher’s signature:......................................... Date:......................
References


end-expiratory pressure in patients with chronic obstructive pulmonary
disease during acute ventilatory failure and controlled mechanical ventilation.
*American Review of Respiratory Disease, 141*, 281-289.


