

THE USE OF A WEANING AND EXTUBATION PROTOCOL TO FACILITATE EFFECTIVE WEANING AND EXTUBATION FROM MECHANICAL VENTILATION IN PATIENTS SUFFERING FROM TRAUMATIC INJURIES

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DECLARATION

I, Natascha Plan, declare that this dissertation is my own work. It is being submitted for the degree of Master of Science (Physiotherapy) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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.....day of, 2010

PRESENTATIONS ARISING FROM THIS STUDY

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ABSTRACT

Introduction

Many patients that have suffered traumatic injuries require admission to Intensive Care Unit (ICU). Mechanical ventilation (MV) is deemed to be the defining event marking many ICU admissions. As many as 30% of admissions, and 90% of all critically ill patients will require at least a short period of MV. There are many risks and complications associated with prolonged MV, such as rate of pneumonia, morbidity and mortality, increased cost, hospital LOS, emotional distress and decreased bed availability. To minimize these risks and complications it is important that patients be weaned and extubated from MV at the earliest possible time. However, just as delayed weaning and extubation carries the risk of complications, premature extubation and subsequent re-intubation should be avoided where possible, as extubation failure leads to an eight-fold higher risk of infection and a twelve-fold increase in mortality. Weaning is the transition from ventilatory support to spontaneous breathing and can often be achieved easily, but may be difficult in up to 25% of patients. Numerous studies have shown the benefit of allied health care worker (nurses and physiotherapists) driven weaning protocols in decreasing MV days and costs.

Purpose

To determine if the use of a nurse and therapist-driven weaning protocol to wean and extubate long-term patients with trauma from MV in an open ICU results in decreased total MV days and ICU length of stay (LOS), and to determine time to spontaneous breathing trial (SBT) failure.

Methods

A weaning protocol was developed by the researcher using clinical guidelines compiled for the American Association for Respiratory Care, American College of Chest Physicians and American College of Critical Care Medicine. A total of 56 mechanically ventilated trauma patients were enrolled in two phases of the study. A prospective cohort of 28 patients (Phase I), weaned according to the protocol, was matched retrospectively with a historical cohort of 28 patients (Phase II), weaned according to physician preference. Pairs in the two groups were matched to be similar for gender, age, type and severity of injury. Data analyzed for both groups were number of MV days, number of ICU days, self-extubation and need for re-intubation. For Phase I patients, time to SBT failure and reason for failure was recorded.

Results and Discussion

With respect to the mean MV days it was found that the two protocol groups did not differ significantly ($p = 0.3$; Phase I = 14.4 days vs Phase II = 16.3 days), although the two day reduction in MV was considered clinically significant in view of the complications associated with additional MV days. The difference of 0.25 days for length of ICU stay between the groups was not statistically significant ($p = 0.9$; Phase I = 20.8 days vs Phase II = 21 days), and demonstrates that a reduction in MV days may not necessarily result in a reduction of ICU LOS. Rate of re-intubation was similar in the two groups (Phase I = 3/28 vs Phase II = 4/28). Eleven patients (39%) in Phase I failed at least one SBT and four of these patients (36%) failed two SBTs prior to successful extubation. Failure of the first SBT occurred an average of 18 hours after onset of SBT. Injury severity scores for these patients were higher than the average for Phase I (16.1 vs 14.5). Mean MV time in this group was 20.5 days as opposed to 14.4 days in the total Phase I group. This indicates that these patients were more critically ill and that they may require longer SBTs than advocated in many studies. All patients failed SBT due to increased RR.

Conclusion

In this study of longer-term ventilated patients who had traumatic injury as reason for admission to ICU and mechanical ventilation, the use of a standardized protocol to assist with weaning and extubation from MV demonstrated a clinically significant reduction in total MV time, even though this did not reach statistical significance. The reduction in MV time did not lead to a reduction in ICU LOS, however it reduces the risks of ventilator-associated complications such as VAP. The use of a weaning and extubation protocol did not lead to a higher rate of re-intubation, demonstrating its safety for use in this patient population. This protocol was driven by nurses and physiotherapists, and the role of physiotherapists and nursing staff in weaning and extubation of patients from MV could be greatly expanded in the majority of ICUs in South Africa.

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LIST OF ABBREVIATIONS

ABG	-	Arterial Blood Gas
ACCP	-	American College of Chest Physicians
AARC	-	American Association for Respiratory Care
APACHE II	-	Acute Physiological Assessment and Chronic Health Evaluation
APRV	-	Airway Pressure Release Ventilation
ARDS	-	Acute Respiratory Distress Syndrome
ASV	-	Adaptive Support Ventilation
ATC	-	Automatic Tube Compensation
BiPAP	-	Biphasic Intermittent Positive Airway Pressure
CMV	-	Controlled Mechanical Ventilation
CNS	-	Central Nervous System
CPAP	-	Continuous Positive Airway Pressure
COPD	-	Chronic Obstructive Pulmonary Disease
CO ₂	-	Carbon Dioxide
ETT	-	Endotracheal Tube
FiO ₂	-	Fraction of Inspired Oxygen
FRC	-	Functional Residual Capacity
f/V _T	-	Frequency Over Tidal Volume
GCS	-	Glasgow Coma Scale
Hb	-	Hemoglobin
H ₂ O	-	Water
ICU	-	Intensive Care Unit
ISS	-	Injury Severity Score
LOS	-	Length of Stay
LRT	-	Lower Respiratory Tract
MIP	-	Maximal Inspiratory Pressure
MV	-	Mechanical Ventilation
MV	-	Minute Volume
NAMDRC	-	National Association for Medical Direction of Respiratory Care
NIP	-	Negative Inspired Pressure
O ₂	-	Oxygen
PaO ₂	-	Partial Pressure of Oxygen in Arterial Blood

PaO ₂ /FiO ₂ ratio	-	Ratio of Partial Pressure of Arterial Oxygen to Fraction of Inspired Oxygen
PAV	-	Proportional-Assist Ventilation
PCV	-	Pressure Control Ventilation
PEEP	-	Positive End Expiratory Pressure
PEF	-	Peak Expiratory Force
Pi _{max}	-	Inspiratory Pressure Maximum
PS	-	Pressure Support
PSV	-	Pressure Support Ventilation
RR	-	Respiratory Rate
RSBI	-	Rapid Shallow Breathing Index
SpO ₂	-	Oxygen Saturation of the Periphery
SBT	-	Spontaneous Breathing Trial
SIMV	-	Synchronized Intermittent Mandatory Ventilation
TV	-	Tidal Volume
VAP	-	Ventilator Associated Pneumonia
VC	-	Vital Capacity
WOB	-	Work of Breathing

CHAPTER 1

1. INTRODUCTION

1.1 BACKGROUND

Between 60 000 and 70 000 injury-related deaths occur each year in South Africa. This accounts for about 12% of all deaths, making trauma the fourth major source of death in South Africa. Particularly homicide and motor vehicle accident mortality is amongst the highest in the world (SA Medical Research Council 2008). In 2004 homicide (45%), transport-related incidents (27%), suicide (10%) and other unintentional injuries, such as burns and poisoning (10%) made up the bulk of injury fatalities. There are approximately 20 non-fatal incidents that result in disability for each violence fatality (SA Medical Research Council 2008; Groenewald et al 2008). Many of these patients are severely or critically injured due to the nature of their injuries (road accidents, gunshot wounds) and require extensive treatment in an intensive care unit (ICU).

Mechanical ventilation (MV) is deemed to be the defining event marking many ICU admissions.

MV is indicated when the lungs cannot supply oxygen (O₂) or remove carbon dioxide (CO₂) effectively through spontaneous breathing. As many as 30% of ICU patients, and 90% of all critically ill patients will require at least a short period of MV (Meade et al 2001b; Frutos-Vivar & Esteban 2003). Recently, improved ICU care has led to more patients surviving acute respiratory failure, resulting in prolonged MV. These patients often exhibit a high burden of underlying co-morbidities and prolonged critical illness increases the risk of acute complications. Up to 20% of patients will require days to weeks to be weaned (Epstein 2007). Their recovery is frequently suboptimal, with only 10% of long-term ventilated patients managed in post-ICU settings achieving functional independence at one year (MacIntyre 2005a).

MV is an invasive procedure and is associated with many adverse physiological and psychological experiences and serious complications (Marellich et al 2000; Blackwood, Wilson-Barnett & Trinder 2004). To minimize these risks and complications, such as increased cost, rate of pneumonia, morbidity and mortality, it is important that patients be weaned and extubated from MV at the earliest possible time (Durbin, Campbell & Branson 1999; Ely et al 2001; MacIntyre et al 2002; Manthous 2002; Blackwood, Wilson-

Barnett & Trinder 2004; Dries et al 2004; Lindgren & Ames 2005; MacIntyre 2005a & b; Rose & Nelson 2006). This will usually be when the conditions that warranted MV in the first place have resolved (MacIntyre et al 2002).

The multiple complications and risks associated with intubation and MV increase over time (Manthous 2002; Newmarch 2006; Rose & Nelson 2006). These complications include sinusitis, injury to the vocal cords, nose, trachea or larynx, tracheal stenosis, haemoptysis, ventilator-associated pneumonia (VAP), increased need for sedation, increased gastro-intestinal stress, skin breakdown and decubitus ulcers, muscle wasting and weakness and pulmonary barotrauma (Durbin, Campbell & Branson 1999; Beckmann & Gillies 2001; Eskandar & Apostolakos 2007). VAP is by far the most serious complication of MV, and is often due to increased number of MV days and the intubation procedure itself, as oral flora is introduced into the trachea and lower respiratory tract (LRT) via the endotracheal tube (ETT) (Vincent et al 1995; Cook, Walter & Cook 1998; Marelich et al 2000). VAP is present in nine to 24% of patients who are ventilated for longer than 24 hours (Morehead & Pinto 2000; Dries et al 2004). In addition, the risk of VAP increases by three percent per MV day in the first week, two percent per MV day in the second week and one percent per MV day thereafter. The risk of death increases twofold per ventilator day (Cook, Walter & Cook 1998) and depending on the organism involved, the mortality rate may be as high as 40% (Dries et al 2004).

The abovementioned direct complications may lead to indirect complications such as increased hospital length of stay (LOS), emotional distress, increased costs, decreased bed availability and increase in patient morbidity and mortality (Fagon et al 1996; Ely et al 1999; MacIntyre et al 2001; Meade et al 2001b; Frutos-Vivar & Esteban 2003; Miwa et al 2003; Walsh, Dodds & McArdle 2004). The daily cost in ICU is estimated to be six fold higher than that of normal wards (Garland 2005). The Krinsley study demonstrated that longer ICU stays were associated with significant cost increases, mostly due to laboratory, pharmacy and imaging charges (Krinsley & Barone 2005). ICU patients requiring long-term MV account for only 10% of patients, but use 50% of ICU resources (Smyrniotis et al 2002). This places a tremendous strain on available resources in the healthcare sector (government and private), and long term patients often require a higher level of care, involving more specialist hours where staff are already in short supply.

Weaning is the transition from ventilatory support to spontaneous breathing (Mancebo 1996). It can often be achieved easily, but may be difficult in up to 25% of patients, especially the critically ill who have been ventilated for a prolonged period of time (Price & Rizk 1999; Blackwood, Wilson-Barnett & Trinder 2004; Eskandar & Apostolakis 2007). Shorter MV time can reduce complications by as much as 50%, and decrease the number of re-intubations (Walsh, Dodds & McArdle 2004; Koch 2007). Some researchers estimate that around 80% of intubated patients can discontinue ventilatory support in a matter of hours (Brochard et al 1994; Esteban et al 1995; Newmarch 2006). However, abnormal lung function or the presence of underlying disease can complicate weaning (Newmarch 2006). Other factors such as critical illness neuromyopathy, prolonged use of sedatives, overloading or underloading respiratory muscles and physician's reluctance to identify weaning and extubation readiness may also delay the process (Caroleo et al 2007; MacIntyre 2007). Finally, many patients report the weaning process as physically and psychologically distressing, which may lead to increased anxiety and delayed extubation (Newmarch 2006; Rosenthal, Kim & Kim 2007).

Weaning and extubation from MV is more complex than the mere manipulation of MV in an attempt to decrease support (Ely et al 2001). To wean a patient from MV, one needs to define and treat the cause of the respiratory insufficiency that necessitated MV on admission. Shapiro and colleagues (1991) suggested that the key to successful weaning from MV is the reversal or significant improvement of the underlying condition that necessitated MV (as cited by Newmarch 2006). One also requires technical competence, extensive knowledge of respiratory and cardiovascular physiology and pathophysiology and their associated interactions, fluid mechanics and the ability to recognize patterns (Brown 2001).

It is important to determine whether a patient is fit for extubation, and what the most effective way of achieving this would be. Numerous studies have shown the benefit of allied health care worker (nurses and physiotherapists) driven weaning protocols over individual physician weaning methods (Brochard, Rauss & Benito 1994; Esteban et al 1999; Kupfer & Tessler 2001; Grap et al 2003; Dries et al 2004; Walsh, Dodds & McArdle 2004).

1.2 **STATEMENT OF PROBLEM AND JUSTIFICATION FOR RESEARCH**

Prolonged MV may lead to complications, which result in increased morbidity, mortality and greater cost. Premature extubation, on the other hand, may lead to re-intubation, which also ultimately result in increased morbidity, mortality and costs. The use of effective and accurate assessment tools, grouped into a weaning protocol, to predict a patient's readiness for weaning and extubation, may reduce these complications. The purpose of this study is to assess the value of a weaning protocol in the process of weaning and extubation of patients who suffered trauma, from MV.

1.3 **RESEARCH QUESTIONS**

Does the use of a weaning protocol to wean and extubate trauma patients from MV in an open ICU result in a decrease in number of days spent on the ventilator compared to that of subjects not weaned according to a protocol? Does the use of a weaning protocol contribute to a decrease in the rate of re-intubation compared to that of subjects not weaned according to a protocol?

1.4 **SIGNIFICANCE OF RESEARCH**

VAP is the most serious complication of MV, and is due to increased number of ventilator days (Marelich et al 2000). As will be discussed in the literature review, the risk of VAP increases every day that a patient is ventilated mechanically. The risk of death increases twofold per ventilator day (Cook, Walter & Cook 1998). It is clear that there will be significant benefit to the patient in terms of complications, morbidity and mortality if the number of ventilator days can be decreased. There may also be a decrease in hospital LOS and cost.

It is therefore felt that the significance of the study outweighs the potential flaw in results due to the study design. The number of patients in each group and the pairing of these patients will ensure that the groups are evenly matched for severity of injury and age.

1.5 **RESEARCH AIMS**

The aim of this study is to assess the usefulness of a weaning protocol to wean and extubate long-term patients with trauma from MV in an open ICU.

1.6 RESEARCH OBJECTIVES

1.6.1 General Objective

1. To establish whether the use of a protocol (Phase I) to wean and extubate patients from MV is more effective than individual weaning methods implemented by physicians (Phase II) in an open ICU.

1.6.2 Specific Objectives

2. To determine whether the use of a weaning and extubation protocol for subjects in Phase I of the trial decreases the number of MV days per patient as opposed to subjects in Phase II of the trial, who were not weaned according to a protocol.
3. To determine whether the use of a weaning and extubation protocol for subjects in Phase I of the trial decreases the number of total ICU days per patient as opposed to subjects in Phase II of the trial, who were not weaned according to a protocol.
4. To determine whether the use of a weaning and extubation protocol for subjects in Phase I of the trial results in a difference in number of re-intubations from subjects in Phase II of the trial, who were not weaned according to a protocol.
5. To determine the time lapsed before spontaneous breathing trial (SBT) failure in the subjects in Phase I of the trial.
6. To determine the reason for SBT failure in the subjects in Phase I of the trial.

1.7 TYPE OF STUDY

Phase I will be a prospective study. The weaning protocol will be implemented and used by all physicians/trauma surgeons working in the ICU at the Union hospital.

Phase II will be a retrospective study. Data will be collected from the files and ICU charts of patients that were admitted to the ICU prior to the introduction of the weaning and extubation protocol (these patients were not weaned according to the set weaning protocol). The patients in Phase II will each be matched to patients in Phase I for age, gender, type of injury and severity of illness using the Injury Severity Score (ISS) scoring system.

1.8 SUMMARY

There are many risks and complications associated with prolonged MV, such as rate of pneumonia, morbidity and mortality, increased cost, hospital LOS, emotional distress and decreased bed availability (Fagon et al 1996; Ely et al 1999; MacIntyre et al 2001; Meade et al 2001b; Frutos-Vivar & Esteban 2003; Miwa et al 2003; Walsh, Dodds & McArdle 2004). Numerous studies have shown the benefit of allied health care worker (nurses and physiotherapists) driven weaning protocols (Brochard et al 1994; Esteban et al 1999; Kupfer & Tessler 2001; Grap et al 2003; Dries et al 2004; Walsh, Dodds & McArdle 2004) and that the use of non-physician driven weaning protocols resulted in a decrease in MV days and costs (Kollef et al 1997; Marelich et al 2000; Ely et al 2001; Dries et al 2004; Walsh, Dodds & McArdle 2004; Tonnelier et al 2005). Decreasing MV time decreases physical and emotional distress for patients.

The aim of this prospective cohort study, which includes a matched historical control group, is to assess the usefulness of a weaning and extubation protocol to wean and extubate patients who suffered trauma from prolonged MV in an open ICU.

Chapter 2 consists of an in-depth discussion of the literature regarding the effects of an allied health worker-driven weaning protocol to wean patients from MV.

CHAPTER 2

2. LITERATURE REVIEW

Articles were sourced from journals by searching Pubmed on the National Center for Biotechnology Information (NCBI) search engine and the Physiotherapy Evidence Database (PEDro). The Google search engine was used to source general non-medical information such as crime statistics in South Africa. Keywords in the searches included “wean”, “mechanical ventilation” and “protocol”. All relevant abstracts of articles dated between 1987 and 2008 were reviewed for inclusion in the literature review.

2.1 THE USE OF PROTOCOLS AND GUIDELINES IN THE CARE OF AN ICU PATIENT

The Free Dictionary by Farflex (www.thefreedictionary.com) defines guidelines as “a rule or principle that provides guidance to appropriate behavior” and protocols as “the plan for a course of medical treatment or for a scientific experiment”. Guidelines are general statements that do not give definite instructions but allow for different decisions for the same scenario. Protocols are explicit and contain specific rules for decision-making, based on specified criteria, by using a multidisciplinary care plan or clinical pathway; therefore there is no variability in outcome (Burns 2004; Chatburn & Deem 2007). The use of protocols provide consistency across all types and levels of health providers and facilitates better communication, leading to timely weaning and extubation (Grap et al 2003). Protocols should not replace clinical judgment, but complement it and be used to guide patient care. Protocols may also be used as default management.

2.1.1 Weaning and Extubation Protocols

Despite numerous studies there are no internationally or locally agreed clinical guidelines or protocols on ventilator weaning, and it is often performed according to the attending clinician’s experience and judgment and influenced by the experience of nursing staff and therapists. If no weaning plan is in place, nurses may delay weaning due to lack of knowledge or confidence. Lack of guidance from senior staff may delay weaning further (Horst et al 1998; Meade et al 2001a; MacIntyre 2005a; Goodman 2006; Hansen & Severinsson 2007). Krishnan and colleagues (2004) found delayed extubation in some cases in their protocol group, due to nurses’ reluctance to disturb doctors on rounds when patients had passed SBT. Alternatively, in very complex critically ill patients, physicians acknowledge that weaning may be delayed due to the process

being physician-led in the absence of adequate staffing (Blackwood, Wilson-Barnett & Trinder 2004). Organizational and external factors such as time of day, staffing levels, multidisciplinary team with rehabilitation capacity, continuity of care and correct patient selection play a role. Inconsistent interdisciplinary communication and documentation of patient progress may also hinder the weaning process (Blackwood, Wilson-Barnett & Trinder 2004; Goodman 2006; Newmarch 2006; Rose & Nelson 2006; Epstein 2007; Hansen & Severinsson 2007).

Chatburn and Deem (2007) in a pro/con presentation on weaning protocols stated that such protocols should be used for all patients, as the human mind only has capacity to store and process information on four variables at a time. Protocols augment individual experience with expert consultation, lead to less variability in practice and stimulates adherence to good practice. Human error is unavoidable, but costly and potentially dangerous. An error rate of only one percent means that every patient in an academic ICU is subjected to an error every second day. Decision-support tools such as protocols may prevent error or minimize risk through early recognition (Grap et al 2003; Chatburn & Deem 2007).

In busy ICUs with many critically ill patients, weaning from MV often has low priority amongst nursing staff and physicians. Weaning procedures are often either too slow or too aggressive. In a study by Bigatello and colleagues (2007) of long-term ventilated patients in a dedicated respiratory unit, they were able to extubate 10% of their admissions within two days and 65% within 10 days, clearly demonstrating that a large number of these patients could have been extubated earlier had there been a focus on weaning and extubation. Weaning protocols should encourage continual assessment of patients and every appropriate patient in ICU should be assessed daily for weaning readiness. This should be combined with daily interruption of sedation to optimally assess their neurological condition (Eskandar & Apostolakos 2007).

Weaning protocols use an algorithm of planned interventions based on scientific evidence and objective clinical data obtained from the patient, combined with 24-hour availability of a team of caregivers with greater autonomy and accountability to impose organization and standardization of the weaning process (Gluck 1996; Caroleo et al 2007; Rose, Presneill & Cade 2007). Strict weaning protocols alleviate physical, mental

and financial distress for patients and their families (Miwa et al 2003). An example of a protocol flow diagram can be seen in Appendix I.

Weaning protocols consist of criteria that enable staff to identify patients who have a high probability of being successfully weaned and extubated from MV. It uses a basic screen to establish the level of acuity of illness, the likelihood of hypoxia due to excessive O₂ need or inadequate O₂ delivery and the level of consciousness (Fessler 2006). A standard weaning protocol may consist of three parts: a) individual criteria for weaning, b) screening criteria for SBT and c) criteria for extubation. Individual criteria for weaning may include assessment of haemodynamic stability, neurological status, strength of cough, partial pressure of arterial oxygen (PaO₂), fraction of inspired oxygen (FiO₂) and blood oxygen saturation (SpO₂). It includes measurements of physiologic respiratory parameters (Manthous 2002). Screening criteria for SBT may include level of wakefulness, ability to cough on demand or by reflex, serum electrolyte and blood values, haemodynamic stability, levels of positive end expiratory pressure (PEEP) and pressure support (PS), and ratio of partial pressure of arterial O₂ to fraction of inspired O₂ (PaO₂/FiO₂). Extubation criteria assess the ability to maintain a patent airway, adequate spontaneous ventilation and arterial oxygenation. It takes into account the need for re-intubation and intubation history (Durbin, Campbell & Branson 1999). An example of a standard weaning protocol can be viewed in Appendix II.

There are many identified criteria that have been proven to predict successful weaning to a greater or lesser degree. Criteria should have high specificity, indicating a high likelihood that the outcome, ventilator independence, will occur (MacIntyre et al 2002; Walsh, Dodds & McArdle 2004). Criteria chosen should be cheap, easy to perform and effective and must be individualized for each ICU to suit the patient population (Ely et al 2001; Kupfer & Tessler 2001; MacIntyre et al 2002; Walsh, Dodds & McArdle 2004). Meade and colleagues (2001a) during a systematic review identified 462 weaning criteria that they grouped into six categories – demographic characteristics, subjective signs, haemodynamic variables, lung mechanics, gas exchange and severity of illness measures. They found that many criteria were useless in predicting weaning results. Five criteria were associated with moderate predictive power: rapid shallow breathing index (RSBI) for trials of unassisted breathing, compliance/rate/oxygenation/pressure (CROP) index for trials of extubation, respiratory rate (RR), tidal volume (V_T) and negative inspiratory pressure (NIP). As the use of these criteria was not the focus of this

study, they will not be discussed in depth. Single criteria generally have low predictive power and correlate poorly with success. Multiple criteria organized formally in a protocol have greater accuracy to predict successful weaning and extubation from MV.

Cook and colleagues (1999) demonstrated that standardized weaning protocols were effective to reduce MV time and ICU LOS but noted that protocols might be difficult to institute due to resistance to change from current practice by medical staff. The complexity of patient care may also lead to difficulty in generalizing protocols to all patients (Newmarch 2006). Smyrnios and colleagues (2002) demonstrated significant decreases in ICU and hospital LOS, number of MV days and hospital costs with the implementation of a multifaceted, multidisciplinary hospital-wide protocol. They attributed the great improvement of nearly one week to the fact that many of their patients were long-term ventilated patients, making it easier to show a large improvement. They also credited their systematic approach to care and policy of early transfer of patients to an appropriate site of care for the large improvements. In a trial of patients ventilated for longer than 14 days, D'Arsigny and colleagues (2004) found that the use of a specific weaning protocol decreased MV time and time spent on continuous positive airway pressure (CPAP) significantly, and that the mortality rate dropped from 10 out of 23 to two out of 23 patients. In the French prospective cohort study with historical matching by Tonnelier and colleagues (2005) on longer-term patients (mean MV time in the protocol group was 16.6 ± 13 days) a decrease in MV time and ICU LOS was demonstrated for the weaning protocol group. A trend towards decreased incidence of VAP was also demonstrated. Whilst the extubation failure rate appears high at 31% at first glance, reintubation and initiation of non-invasive ventilation was counted as failed extubation. When considering reintubation alone the rate was 21% which was in line with reports from other ICUs (Tonnelier et al 2005).

Numerous studies have shown the benefit of allied health care worker (nurses and physiotherapists) driven weaning protocols (Brochard et al 1994; Esteban et al 1999; Kupfer & Tessler 2001; Grap et al 2003; Dries et al 2004; Walsh, Dodds & McArdle 2004), and that some of the responsibilities of ventilator weaning could be safely and effectively shifted from physicians to respiratory therapists (Garland 2005). Meade and colleagues (2001), following a systematic review of all randomized trials conducted, stated that the best solution to the question of weaning readiness is the development of a protocol implemented by nurses and respiratory therapists that test for the earliest

opportunity to reduce ventilatory support, a fact reiterated by Frutos-Vivar and Esteban (2003). MacIntyre stated: "...clear evidence that non-physician health care professionals (e.g., respiratory therapists and nurses) can execute protocols that enhance clinical outcomes and reduce costs for critically ill patients" (Ely et al 2001; MacIntyre et al 2002; Dries et al 2004; MacIntyre 2005a). Walsh and colleagues (2004) also demonstrated that the use of a non-physician driven weaning protocol had a major impact on weaning outcomes. Landmark studies of randomized controlled trials by Marelich (2000), Ely (2001) and Kollef (1997) and their colleagues all showed that the use of a non-physician driven weaning protocol resulted in a decrease in MV days and cost in medical, surgical and trauma patients. These results were backed up by several non-randomized controlled trials (Dries et al 2004; Walsh, Dodds & McArdle 2004; Tonnelier et al 2005). Decreasing MV time is significant, even if it does not result in shorter hospital LOS or decreased costs, as it may represent an important quality of life outcome for patients, with intubation being uncomfortable and emotionally distressing.

The protocol designed by Marelich and colleagues (2000) was developed for a medical and trauma ICU by a multidisciplinary team. Respiratory therapists and nurses received training on the protocol prior to implementation and halfway through the study. In this study patients were assessed for immediate SBT if they were ventilated for less than three days. If not, an incremental decrease of RR, PS, PEEP and FiO₂ was performed. SBT was performed a maximum of twice per day, and was successful if completed for 30 minutes. Results showed that MV time was reduced from 232 hours to 78 hours in the medical ICU, and from 52 to 33 hours in the trauma ICU, perhaps due to a weaning protocol already existing in the trauma ICU prior to the study. In the trauma group there was only a difference in MV time in the first 96 hours. In the combined group the decrease in MV time was from 124 to 68 hours. Overall the median duration of MV was decreased by 2.3 days. In the protocol group there was a 70% reduction in MV time from the time discontinuation criteria was met to extubation. If the protocol was violated by the attending physician, patients were excluded from the study, which could potentially exaggerate the results by eliminating patients who would have taken longer to wean (Marelich et al 2000). Mortality and extubation failure rates were similar in the groups. This study demonstrated the feasibility and effectiveness of a single, easily implemented weaning protocol in decreasing MV time in patients with medical conditions or trauma (Marelich et al 2000).

The study by Dries and colleagues (2004) focused on patients who underwent surgery and/or trauma to assess the effect of a nurse and therapist driven weaning protocol on the duration of MV, incidence of VAP and incidence of unplanned reintubation. They demonstrated a decrease in MV days and a lower reintubation rate in the study group despite the fact that patients (after introduction of the weaning protocol) were on average seven years older. This confirms that the use of a protocol results in quicker ventilator discontinuation, and more specifically that it applies to the trauma patient population. Their findings were confirmed in the study by Horst and colleagues (1998) that demonstrated a 46% decrease in the MV time in postoperative patients weaned according to a protocol. This benefit was evident in all patients ventilated for longer than 24 hours. Cost saving in ICU was estimated at \$586 per 24 hours, and ICU LOS decreased by 1.8 days on average (Horst et al 1998). Dries and colleagues also demonstrated a decreased incidence of VAP, a finding confirmed by Horst and colleagues. The patient groups who benefited most were patients who suffered trauma with and without head injury, and patients without trauma who had not undergone cardiovascular procedures (Horst et al 1998; Dries et al 2004).

Ely and colleagues (1996) used a two-step protocol driven by nurses and respiratory therapists that incorporated daily screening and SBT. They reported a 50% reduction in ventilator-related complications, shorter MV time, shorter weaning time and lower ICU cost in patients with medical and/or cardiac conditions who were ventilated for four to six days (Ely et al 1996, Ely et al 2001).

In the study by Kollef and colleagues (1997), three different weaning protocols were compared to physician directed weaning. Despite the differences in protocols, all the protocol-directed groups displayed shorter time to the initiation of weaning and shorter overall MV times. They found that nurses and respiratory therapists, with protocol guidance, initiated weaning earlier and decreased the duration of the weaning process. This suggests a possible delay in clinician's recognition of a patient's readiness to breathe spontaneously and may result in prolonged MV time (Kupfer et al 2001). A drawback of the Kollef study was that patients were only ventilated for a short period of time (Ely et al 2001, Kollef et al 1997).

In the Chatburn and Deem pro/con debate (2007), Deem highlighted various issues around the abovementioned trials; most notably that none of the trials demonstrated a

reduction in hospital LOS or mortality rates. In addition some later trials did not reproduce the findings of shorter duration of MV and lower risk of complications of these early studies. For example, a study done in 2002 on 328 patients who had surgery or suffered trauma, found no decrease in duration of MV, ICU stay, cost or self-extubation rates (Duane et al 2002). Authors speculated that the reasons could have been lack of compliance to the protocol or that a protocol failed to improve on already existing practice. Similarly Martinez and colleagues (2003) found no benefits in protocol weaning on ICU and hospital LOS or mortality (Martinez, Seymour & Nam 2003). Djunaedi and colleagues (1997) tested a therapist-led protocol and found no decrease in MV time, but patients experienced greater comfort with a faster response by medical staff to changes in patient condition. In studies conducted in Australia, the introduction of weaning and sedation protocols prolonged MV, suggesting that protocols may not be beneficial in Australian units that are adequately staffed by highly trained nurses (Keogh et al as cited by Rose & Nelson 2006). Similarly Blackwood found no change in perception of nurses with the introduction of a weaning protocol into a unit where they were already motivated to participate in the weaning process (Blackwood 2006).

Weaning protocols are guidelines that decrease variability and standardize care in ICUs that do not have high levels of staffing or formal treatment plans in place. It may decrease the risk of complications and the overall MV time in these units.

2.1.2 The Role of Allied Health Professionals in Weaning

Traditionally, weaning is the responsibility of medical staff. Clinicians make decisions about weaning and set a series of goals. The nurse or therapist has partial autonomy in achieving these goals, but physicians control much of the process especially if the patient is severely ill (Blackwood Wilson-Barnett & Trinder 2004). In recent years, especially with the adoption of weaning and extubation protocols in many units across the world, experienced nursing, respiratory therapy and physiotherapy staff took over much of this management (Tonnelier et al 2005; Newmarch 2006; Taylor 2006).

Koch (2007) defines a therapist-driven protocol as a patient care plan that is initiated and implemented by credentialed respiratory care practitioners. In North America multidisciplinary weaning teams and respiratory therapists are responsible for weaning and extubation, and they often use protocols or weaning boards and flow sheets to wean patients off MV (Rose & Nelson 2006). In other countries physiotherapists and nurses

fulfill this role and are responsible for respiratory care in ICU. In a study of an Australian closed unit without a weaning protocol, critical care nurses had a high level of accountability and autonomy in the management of MV. In that study an average of six MV and weaning decisions were made per patient per day - 64% of these were made exclusively by nurses and 19% by collaboration between nursing and medical staff. For more critically ill patients, nurse-made decisions were less common. Nurses initiated the onset of weaning in 81% of cases. This model of care resulted in weaning outcomes that are internationally acceptable (Rose et al 2007). In the UK, standard weaning practice is generally a collaborative approach between nurses and doctors. Nursing staff perform weaning steps under broad guidelines from clinicians. There are no formal guidelines and clinical judgment determines the process (Blackwood et al 2006). There are no studies on the responsibilities and involvement in weaning of physiotherapists or nurses in ICU in South Africa, but many units may benefit from a more structured approach, especially in view of the shortage of intensivists in our country.

The role of allied health professionals in weaning patients from MV has not been fully developed in South Africa. The potential exists to create a structure where physiotherapists and nurses can collaborate closely using a weaning protocol to remove patients from MV at the earliest possible opportunity, thereby reducing costs and maximizing resources.

2.1.3 Levels of Care and Impact on Weaning Outcomes

ICUs can be “open” or “closed” units. The term “open ICU” refers to units where patients are not managed exclusively by intensivists or anesthetists. Other specialists are permitted to solely admit and care for patients. Closed units are defined by Garland (2005) as units where all patients at a given time are under the care of a single physician. Pronovost and colleagues (2002) defined closed units as those staffed by intensivists or where intensivist consultations are mandatory. Both authors demonstrated more favorable outcomes with lower mortality and decreased LOS in closed units when compared to open units.

Krishnan and colleagues (2004) demonstrated that closed units with high levels of staffing that use checklists (printed templates) for ward rounds are as effective in improving outcomes in critically ill patients and decreasing mortality as weaning protocols. The checklists, covering each physiological system might prompt teams to

address MV issues daily and thus speed up the weaning process. A weaning protocol was probably unnecessary if it merely codified a set of behaviors already in use. It must be noted however that the unit where the study was done averaged 9.5 physician hours per patient per day as opposed to an average of 3.5 physician hours per patient per day in the other studies it was compared to (Krishnan et al 2004). This unit had also undergone quality assurance improvement to apply standardized methods to interaction with patients that was demonstrated to improve clinical outcomes. Therefore, usual care delivered in unusual environments where systems are employed that demonstrates improved outcome, might decrease the need for a weaning protocol. Tobin stated that "...the question is not what went wrong with protocolized weaning but what was right with usual care" (as cited in Morris 2004).

Those opposed to weaning protocols argue that it restricts clinical discretion and autonomy and discourages individualized care. Lyons went as far as suggesting that it is merely a written form of delegation by medical staff (as cited in Rose et al 2007). Blackwood and colleagues (2004) found that consultants felt that protocols may be followed too rigidly by inexperienced staff and that protocols for long-term management are difficult to develop due to the complex nature of these patients. Critics may also fear that evidence-based medicine may lead to traditional health care professionals being replaced by less expensive, less skilled workers and that it may curtail treatment choice (Chatburn & Deem 2007).

Weaning protocols are useful to save on costly physician time and where physicians are in short supply. It probably speeds up the weaning process by enforcing daily attention to patient readiness to breathe unassisted, avoiding unnecessary delays. Protocols can address specific, uncomplicated problems that occur commonly, and need not be driven by physicians (Krishnan et al 2004; Walsh, Dodds & McArdle 2004).

2.2 COMPONENTS OF THE WEANING PROCESS

Weaning consists of a number of phases with complimenting but separate components. The use of a protocol that consists of daily screening of the respiratory system, the use of a weaning index and SBT, can expedite weaning, specifically by reducing the time spent during the weaning period itself (Lellouche et al 2006; Vassilakopoulos, Zakynthinos & Roussos 2006a).

In 1999 the McMaster University Evidence-Based Practice Centre evaluated ventilator weaning and discontinuation, and a task force was formed by the American College of Chest Physicians (ACCP), the Society for Critical Care Medicine and the American Association for Respiratory Care (AARC) to develop guidelines for weaning based on the McMaster findings (Cook et al 1999, MacIntyre 2005b). The factors that determine successful weaning and extubation from MV are intimately intertwined and may present at different times in the weaning process. A patient may breathe independently but be unable to protect his airway, or be fully awake but unable to sustain adequate ventilation due to respiratory failure. Airway incompetence and respiratory failure is often co-dependent (Siner & Manthous 2007).

The weaning process consists of three phases which will be discussed in the next section. Short-term ventilated patients often bypass the first stage (Meade et al, 2001c, Rose & Nelson 2006) while long-term ventilated patients may spend more time in some of the phases.

2.2.1 Phase I: Progressive Reduction in Ventilatory Support

The ultimate goal of weaning is to optimize respiratory muscle function so that ventilatory demands are met while respiratory muscle fatigue is prevented (Bouley, Froman & Shah 1992; Newmarch 2006). Weaning from MV is the process of reducing the FiO_2 , RR, PS and PEEP that a patient is given to assist breathing, and redirecting the work to the patient (Newmarch 2006).

The weaning phase of MV takes up approximately 42% of the total time spent on MV, and up to 59% of total MV time in patients with chronic obstructive pulmonary disease (COPD). Management strategies that reduce weaning time will minimize costs and risk of complications and decrease the heavy workload for staff (Esteban et al 1994; Kupfer & Tessler 2001; MacIntyre et al 2001; Meade et al 2001a; Blackwood, Wilson-Barnett & Trinder 2004; Restrepo et al 2004; Walsh, Dodds & McArdle 2004; Tonnelier et al 2005; Richardson & Killen 2006; Hansen & Severinsson 2007).

2.2.1.1 Factors that Influence Weaning

The success of weaning from MV depends on the strength of the respiratory muscles and the load applied as well as the respiratory drive to breathe. Unsuccessful weaning may be due to an imbalance between the respiratory muscle pump and load, secondary

to inadequate resolution of the underlying problem, or development of a new problem or complication associated with MV (Miwa et al 2003; Eskandar & Apostolakos 2007). Such problems include respiratory, cardiovascular or central nervous system derangement that causes the ventilatory or gas exchange capabilities of the respiratory system to fail (MacIntyre et al 2001). Derangements include neurological failure, respiratory muscle load malfunctions, metabolic factors such as nutrition, electrolyte or hormonal imbalances, gas exchange factors, cardiovascular and psychological factors (Meade et al 2001b; Eskandar & Apostolakos 2007). Weaning failure is usually due to either oxygenation failure or ventilatory failure. Oxygenation failure is associated with low lung volumes and alveolar filling processes. Ventilatory failure is due to a mechanical or neuromuscular disorder with impaired ventilation and hypercapnia, and often reflects inspiratory muscle fatigue (Price & Rizk 1999).

Other factors that have been independently associated with unsuccessful weaning are low albumin and transferrin levels, increasing age and the physician's estimate of lower weaning likelihood (Dasgupta et al 1999). In contrast, achieving complete ventilator independence was associated with a higher serum albumin level, a nonmedical ICU referral source, cause of respiratory failure other than COPD, and a physician's estimate of higher weaning likelihood (Dasgupta et al 1999). Some co-morbidities, for instance COPD, renal dysfunction or cardiac ischemia may delay weaning. Poor nutritional status may lead to respiratory muscle dysfunction, predisposition to infection and attenuated ventilatory response to gas exchange abnormalities. Abnormal mental status may also delay weaning (MacIntyre 2005b).

Many factors could lead to an increased load on the ventilatory system. This includes excessive secretions, poor patient-ventilator interaction, inappropriate ventilator settings or exacerbation of COPD that causes increased airway resistance. Hyperelastance due to pulmonary edema, pneumonia, dynamic hyperinflation and large effusions or ascites could increase the load further (MacIntyre 2005b; Siner & Manthous 2007). Increased minute ventilation (MV), requiring more mechanical work, could result from systemic inflammatory syndromes or sepsis, withdrawal symptoms or overfeeding, or when dead space is increased due to alveolar hypertension, hypovolemia, pulmonary embolus or emphysema. Ventilatory demands may increase due to increased O₂ demands from sepsis or increased dead space, decreased compliance due to lung edema, infection, inflammation or fibrosis and increased resistance due to bronchoconstriction or airway

inflammation (MacIntyre et al 2001; Eskandar & Apostolakos 2007). Volume overload due to treatment of systemic inflammatory syndromes may lead to decreased functional residual capacity (FRC) and alveolar collapse (Eskandar & Apostolakos 2007).

Neuromuscular weakness could result from neurological syndromes or, more frequently, from muscle dysfunction. Studies by Spitzer and colleagues (1992) and Coakley and colleagues (1998) demonstrated evidence of neuromuscular abnormalities in 60 - 90% of long-term ventilated patients (as cited by MacIntyre et al 2005). Trigger asynchrony in weak patients undergoing prolonged MV is associated with high weaning failure (84%). Chronic muscle overload or overuse, oversedation, sepsis, malnutrition, over feeding, corticosteroids, nerve injury, hyperinflation and deconditioning can all prolong MV (MacIntyre et al 2001; MacIntyre 2005a). Twite (2006) showed that sedation during the first 24 hours of weaning significantly prolonged weaning times. On the other hand, weaning too aggressively can lead to fatigue and cardiovascular instability, which can ultimately delay the weaning process (Meade et al 2001c; Newmarch 2006).

2.2.1.2 Identifying Readiness to Wean

The first part of this section will explore the use of various physiological parameters used in the weaning protocol to identify readiness to initiate weaning. In the remainder of the section the chosen weaning criteria that are included in the weaning protocol will be discussed.

A strategy is needed to rapidly identify the adequate recovery from respiratory failure once the underlying condition that necessitated MV has been resolved. This may be done by using tools to clinically assess a patient's readiness for weaning and extubation (MacIntyre et al 2001; Frutos-Vivar & Esteban 2003; Dries et al 2004; Walsh, Dodds & McArdle 2004). Appendix III summarizes the parameters used in weaning/discontinuation studies to determine weaning readiness in patients on MV, as set out by the MacIntyre taskforce (2002). Even though all values cannot easily be substantiated due to ethical reasons in ICU, most studies agree that the following baseline parameters should be met:

Haemodynamic stability with no or little inotropic support

Patient awake, able to maintain own airway: Glasgow Coma Scale (GCS) score >5/10

Good cough reflex

Satisfactory gas exchange: $\text{PaO}_2 > 60 \text{ mm Hg}$ on $\text{FiO}_2 < 0.5$
 $\text{SpO}_2 > 95\%$

RR within normal limits

(Lindgren & Ames 2005; MacIntyre 2005b; MacIntyre 2007).

Nearly all studies suggest that patients be haemodynamically stable before initiating weaning. Shock increases the work of breathing (WOB) of the respiratory muscles such that nearly 20% of O_2 consumption can be associated with the WOB. However, not all patients with septic shock require MV. Siner and colleagues (2007) found only one abstract that quoted the re-intubation rate as 19% in patients with septic shock who were extubated while receiving vasopressors, similar to what is quoted in many studies of patients on no vasoactive medication (Koh et al 2000; Beckmann & Gillies 2001; Ely et al 2001; Meade et al 2001b; Dries et al 2004; Bouza et al 2007). If verified, this will challenge the notion that patients should not be weaned until cessation of vasopressors occurred (Siner & Manthous 2007).

Weaning and SBT are not considered in patients with bradycardia that require pacemaker placement, sinus tachycardia of >140 beats/minute or sustained tachyarrhythmia. These are commonsense rules for potentially life threatening conditions. Tachycardia is a clinical sign of catecholamine excess and/or electrical excitability of the heart. Weaning often increases catecholamine levels and may therefore exacerbate these tachycardias, with associated risk of hypotension and heart failure (Siner & Manthous 2007). Tachycardia may however be due to patient-ventilator interaction, so the cause must be determined to avoid unnecessary prolonged MV.

During weaning, O_2 consumption may be increased due to increased workload of the respiratory muscles. Anemia, a common co-morbidity in the critically ill, will hamper compensation for the increased O_2 consumption and this could decrease a patient's ability to wean from MV (Hebert et al 2001). Despite this, no significant decrease in

duration of MV has been demonstrated in long or short-term ventilated patients following a liberal transfusion strategy (Hebert et al 2001). In fact, strong data exist that transfusion of hemoglobin (Hb) to $> 10\text{g/dL}$ arbitrarily does not improve general clinical outcome. Therefore, even though Khamiees and colleagues (2001) found that patients with an Hb of $< 10\text{g/dL}$ were five times as likely to fail weaning, it is not considered appropriate to prevent patients starting SBT based on low Hb concentration.

Psychological factors, such as fear of the loss of a life support system, social and family issues and sleep deprivation cannot be neglected when assessing weaning readiness (MacIntyre et al 2001). Adequate communication to alleviate anxiety and fear is vital (Gallimore 2007).

Weaning criteria are incorporated into weaning protocols to predict weaning outcome. They are used as a decision point to determine whether a patient can progress to SBT, as premature SBT may precipitate respiratory muscle fatigue and thereby prolong the duration of MV. Conventional criteria for weaning readiness are easy to use, but the predictive ability is poor. Of the more than 50 known criteria, only eight have been shown to have any predictive capacity. It may be more useful to combine several criteria (Soo Hoo & Park 2002). Even so, some of the more accurate predictors such as vital capacity (VC), maximum voluntary ventilation, oxygenation, and maximal inspiratory pressure (MIP) have significant false positives and negatives, and may be difficult to measure or require special equipment (Eskandar & Apostolakos 2007).

The evaluation of respiratory therapists by Soo Hoo and Park (2002) demonstrated the ad hoc way in which weaning criteria are used. Some criteria (MIP, V_T , RR and MV) are frequently used despite not being highly predictive, whilst frequency over tidal volume (f/V_T), considered to be the most accurate predictor, was used by less than 20% of respondents (Rose & Nelson 2006). Considerable variation exists between different ICUs and between therapists from the same unit in the way that criteria are applied (Manthous 2002; Soo Hoo & Park 2002).

Yang and Tobin (1991) evaluated a number of respiratory weaning parameters, including RR, V_T , oxygenation, and f/V_T (or RSBI) in a landmark study. No variable identified with sufficient accuracy patients that would be successfully weaned from MV, but three parameters predicted failure very well: $f/V_T > 105/\text{min/L}$, $V_T < 325\text{ml}$ and

negative inspired pressure (NIP) >-15 cm H₂O. Yang and Tobin found that whilst MV is well maintained in patients who fail weaning, the individual components of V_T and RR are combined in a way that results in inefficient gas exchange. These patients typically exhibit decreased V_T and increased RR.

Yang and Tobin (1991) found that f/V_T was most consistently and powerfully predictive of SBT and extubation outcomes. The test has negative predictive value, meaning that it accurately predicts weaning failure. Its positive power, to predict successful weaning, is very small (Meade et al 2001a). Overall, it is seldom associated with more than small to moderate changes in the probability of success or failure. Recent studies have questioned the value of this test (Tanios et al 2006; Siner & Manthous). It is less accurate in patients requiring MV for longer than 8 days, and Ely and colleagues found that nearly one third of patients that never passed SBT, often due to failing f/V_T , were successfully extubated (Ely et al 2001; Tanios et al 2006). Manthous successfully extubated 50% of patients with high values for f/V_T (Manthous 2002). Tanios and colleagues (2006) found that the inclusion of f/V_T in their weaning protocol led to longer weaning times and no difference in MV time, ICU or hospital LOS. Re-intubation and mortality rates remained the same. They concluded that outcomes are not improved when f/V_T is used in addition to haemodynamic stability and adequate oxygenation to initiate SBT (Tanios et al 2006; Siner & Manthous 2007). This would indicate that the use of this test is of no value.

Rapid shallow breathing may result from respiratory muscle fatigue, but also from anxiety. It is influenced by female gender, insufficient ETT diameter, sepsis, pneumonia and patient position (Caroleo et al 2007). In elderly patients with cardiopulmonary disease RR is often increased and V_T of each breath decreased to limit energy expenditure and avoid fatigue. Using RSBI in these patients may prolong MV unnecessarily (Kupfer & Tessler 2001).

Weaning from MV requires exact methods to evaluate readiness for weaning (Koh et al 2000; Ely et al 2001; Kupfer & Tessler 2001; Walsh, Dodds & McArdle 2004). Combining a variety of tools that are cheap, easy to use and practical in the form of a weaning protocol to address the issues of weaning ensures a greater chance of predicting weaning success.

No single physiologic parameter predicts with sufficient accuracy who will be successfully extubated. Some studies have demonstrated that traditional weaning parameters, such as RSBI and $\text{PaO}_2/\text{FiO}_2$ ratio are not reliable predictors of extubation and make no difference to outcome, particularly in patients with COPD, pneumonia, obesity and acute respiratory distress syndrome (ARDS) (Khamiees et al 2001; Price & Rizk 1999). Instead, airway parameters such as cough strength and excessive secretions are highly predictive (Smima et al 2003). A strong voluntary cough requires coordination and intact respiratory neuromuscular activity, which is required to sustain long-term spontaneous ventilation and protect one's airway. This might explain the high correlation between mortality and weak cough effort. Meade and colleagues (2001), during a literature review found that the most promising tests to predict successful extubation was $\text{RR} < 38$ breaths/minute, $\text{RSBI} > 100$ breaths/minute/L and APACHE II scores measured on admission. Smima and colleagues (2003) showed that patients with a peak expiratory force (PEF) of 60 L/min or less were 5.1 times as likely to fail extubation and 19.1 times as likely to die during hospitalization as patients with PEF values of greater than 60 L/min. One of the drawbacks of PEF is that it requires co-operation and is dependent on patient effort, making it unsuitable for neurologically impaired patients (Smima et al 2003). In a study by Hernandez and colleagues (2007) patients with a RSBI of > 100 b/L/min were 4.1 times as likely to fail extubation as those with RSBI values of < 100 b/L/min. Serial measurements of variables including f/V_T , respiratory effort, O_2 uptake, dead space, respiratory patterns and time needed to recover basal minute ventilation may be beneficial (Hernandez et al 2007).

2.2.1.3 Modes and Methods of Weaning

The initial reason for intubation, clinician's experience and preference or hospital protocol will influence the method used to wean a patient (Newmarch 2006, Astle & Smith 2007). The most commonly used modes for weaning are a T-piece circuit, synchronized intermittent mandatory ventilation (SIMV) or PSV (Kollef et al 1997; Meade et al 2001c). It appears that the manner in which the ventilation mode is applied is more important than the mode itself. Appendix V summarizes the most commonly used modes of partial ventilator support.

Biphasic intermittent positive airway pressure (BiPAP) is a popular weaning mode from MV. Patients breathe between two preset pressures, PEEP and peak pressure, and generate V_T . A set RR is delivered, but patients may breathe spontaneously anywhere in

the cycle. This increases patient comfort and synchrony and ventilation/perfusion matching allowing a smooth transition to spontaneous breathing and decreasing the need for sedation (Newmarch 2006).

SIMV assists ventilation by delivering a preset RR and V_T or preset RR and pressure. Weaning occurs by decreasing the mandatory RR. Spontaneous breathing is only allowed in between mandatory breaths, to give respiratory muscles the opportunity to rest. Recent evidence showed that the respiratory muscles do not rest during mandatory breaths as originally thought, leading to potential muscle fatigue (Newmarch 2006). WOB is increased by some valve-demand systems and by resistance in the ETT and humidifier. Therefore SIMV is considered the least effective mode for weaning (Brochard et al 1994; Esteban et al 1995; Forrette 2006; Newmarch 2006; Astle & Smith 2007).

PSV is the most frequently used mode of weaning and a consensus conference in 2005 recommended that patients who have failed SBT should be ventilated with PS or assist-control modes of ventilation (Boles et al 2007). All breaths are spontaneous and patient-triggered, and then augmented by positive inspiratory pressure that decreases the WOB and increases comfort. WOB is further decreased as PS overcomes the additional work related to resistance in the ETT. PS typically starts at pressures of 15 to 25 cmH₂O, which is weaned down to 5 – 8 cm H₂O, at which time the patient is ready for a SBT. Newmarch (2006) claims that PS should not be weaned to less than 10 cm H₂O, as the positive pressure will no longer overcome ETT resistance and therefore WOB might increase.

PEEP maintains pressure at the end of expiration, while CPAP provides positive pressure throughout respiration. This prevents atelectasis and increases FRC, reducing the WOB (Newmarch 2006). CPAP may be particularly valuable in patients with ARDS, pulmonary edema and post-operative basal collapse. CPAP can be delivered on the ventilator, or through a high flow CPAP system attached to the ETT or tracheostomy. Tutuncu and colleagues (1996) found that a continuous flow system was superior to ventilator CPAP as it decreased the WOB.

SBT is used as a weaning method when patients perform repeated trials of increasing duration and may be particularly useful in patients who have been ventilated for a long period of time. However, the ETT needs to remain in place in order to connect the T-

piece, thereby losing the benefits of intrinsic PEEP and increasing the risk of atelectasis (Newmarch 2006).

Automated tube compensation (ATC) is a feature on modern ventilators that increases respiratory comfort and promotes a more physiologic breathing pattern than PSV. It decreases WOB by delivering the correct amount of pressure required to overcome the resistance imposed by the ETT during each spontaneous breath. This may allow more marginal patients to tolerate SBT, who could then develop respiratory failure after extubation (Eskandar & Apostolakos 2007). Cohen and colleagues (2002) demonstrated that the use of ATC with CPAP led to more successful SBTs and extubations. Minimizing the WOB during a SBT may positively influence extubation outcome. Haberthur and colleagues (as cited by Cohen et al 2002) found that half the patients who failed SBT with T-piece or PSV were subsequently successfully extubated using ATC.

No studies have demonstrated any benefits of a gradual decrease in MV in order to strengthen respiratory muscles. Conversely, it may prolong total MV time and delay extubation of patients who have recovered from respiratory failure, a fact that was proposed already in 1987 by Hall and Wood (Ely et al 2001; Dries et al 2004). This is particularly true for short-term ventilated patients. Roughly 10% of ventilated patients will undergo tracheostomy (Clec'h et al 2007). The shorter length of the artificial airway reduces the anatomical dead space of the upper airways by approximately 150ml, thereby reducing the WOB. It may also ease secretion removal (Newmarch 2006; Jaeger, Littlewood & Durbin 2002). Although some studies have shown benefits in the use of tracheostomy to wean patients from MV, the results are not uniform (Heffner 2001).

With no clear indication of the benefit of one mode over another, mode selection is often driven by personal preference.

2.2.2 Phase II: Spontaneous Breathing Trial (SBT)

SBT is performed to assess a patient's ability to breathe independently. The best assessment of respiratory capacity is done at the bedside by an experienced clinician during spontaneous breathing. SBT is perhaps the most direct assessment of the load/capacity relationship, utilizing physiological variables and clinical judgment to evaluate factors such as anxiety, discomfort and clinical appearance (MacIntyre 2005b).

Esteban and colleagues (2008) repeated an observational study of ventilation practices that was originally performed in 1998. They demonstrated a trend towards increased use of SBT to assess readiness for extubation. Significantly more patients completed only one SBT trial before successful extubation, suggesting improved screening methods. SBTs are considered very safe if monitored closely by well-trained staff and terminated promptly if the patient fails the trial. There is no evidence that a carefully monitored, but failed SBT is detrimental to weaning outcome (Tanios et al 2006). Failure will occur early on in the majority of short-term ventilated patients, but may occur much later when caused by respiratory muscle fatigue in long-term patients (MacIntyre et al 2002).

During quiet breathing the workload on the respiratory muscles is only five percent of total body O_2 consumption. The total WOB consists of physiological and imposed work. Two thirds of physiological WOB is from elastic forces of the lungs and chest wall, and one third from overcoming airway resistance. Imposed WOB comes from the force required to initiate and terminate gas flow from the ventilator, and to overcome resistance from the ETT and demand valve (Forrette 2006). The resistance in the ETT is influenced by inspiratory flow, ETT diameter and type, presence of secretions, and the presence of a passive humidifier that increases the dead space (Hess 2001).

Some patients may fail SBT due to the increased WOB created by the ETT. For this reason support in the form of pressure support ventilation (PSV) of around 7 cm H_2O , CPAP or PEEP is often used during SBT (MacIntyre 2005a). CPAP provides a continuous small amount of pressure to the airways whereas PSV only provides support on inspiration and therefore cannot compensate for the non-linear, flow-dependant resistant workload of the ETT (Nathan et al 1993). PEEP provides support at the end of expiration. CPAP is thought to maintain FRC at a level similar to that following extubation which may be useful in COPD patients to maintain patency of the small airways, but is of no proven benefit for most other patients (Nathan et al 1993; Frutos-Vivar & Esteban 2003). A risk is that patients with left ventricular failure may develop congestive heart failure post-extubation as the intrathoracic pressure changes from positive to negative with spontaneous ventilation (Nathan et al 1993; Frutos-Vivar & Esteban 2003).

Meade (2001c) concluded that PS or multiple T-piece trials may be superior to SIMV for stepwise reductions in support. In a study of over 500 patients, Esteban and colleagues

(1997) found no difference in re-intubation rate when using a T-piece or PSV for a SBT. The PS group showed better tolerance for weaning and extubation. Low levels of PS during SBT overcome the resistance of the ETT and may enable patients to meet the weaning criteria even if they would not pass a T-piece SBT (Esteban et al 1997; Meade et al 2001c; Dries et al 2004). Ezingard and colleagues (2006) extubated 68% of patients who failed T-piece trials after 30 minutes of SBT with PS. These results may be flawed as the PS trial was performed immediately following failure, and no patients were tested to see if a subsequent T-piece trial would have been successful. The trial demonstrated a particular value in using PS in COPD patients.

A SBT may be performed with the patient on or off the ventilator. If the patient remains on the ventilator, CPAP or PS of up to 7 cm H₂O is applied. The large WOB imposed by unresponsive demand valves in older ventilators has been overcome in the newer generation with features such as flow triggering. Advantages of keeping the patient attached to the ventilator include no additional equipment required, all monitoring and alarm functions on the ventilator available for use and that ventilatory support can be re-established quickly if necessary (Ely et al 2001; Hess 2001). A SBT may be performed by disconnecting patients from the ventilator and placing them on a T-piece through which O₂ is administered with a PEEP-valve set at 5 - 7 cm H₂O. Five centimeters of H₂O is considered to be physiological PEEP (DeTurk & Cahalin 2004) and prevents premature collapse of the airways (Esteban et al 1997). Tutuncu and colleagues (1996) found that a continuous flow system was superior to ventilator CPAP as it decreased the WOB (Tutuncu et al 1996). In the study by Esteban and colleagues (2008) most SBTs were completed as a T-piece trial, even though this did not result in definite improvements in clinical outcome.

2.2.2.1 Criteria Used During SBT

Multiple criteria should be passed to qualify for SBT (MacIntyre et al 2002). These include low levels of PEEP and PS, adequate PaO₂/FiO₂ ratio, and stable haemodynamic and electrolyte values and neurological status (Siner & Manthous 2007). SBT is tolerated if the patient remains haemodynamically stable with good arterial blood gases (ABG), normal respiratory pattern and is comfortable.

Meade and colleagues (2001a) following a literature review concluded that a number of factors could predict SBT failure: a) duration of MV prior to weaning, b) RR > 38

breaths/minute, c) $V_T < 4\text{mL/kg}$, d) $\text{RSBI} > 100$ breaths/minute/L and e) $\text{NIP} < -20\text{cm H}_2\text{O}$. Evidence exists that the optimal threshold value separating success from failure during SBT is RR of 30 – 38 breaths/minute, and V_T of $> 325\text{ml}$ (Tanios et al 2006; Siner & Manthous 2007). An observational study by De Haven and colleagues (1996) found that maximal RR of 30 breaths/minute is too low in patients with trauma. SBTs would be abandoned prematurely and patients denied the opportunity of early extubation. Prolonged shallow breathing leads to atelectasis and hypoxemia, and therefore $V_T < 325\text{ml}$ is associated with SBT failure. The ACCP recommends adequate oxygenation as $\text{PaO}_2/\text{FiO}_2$ of 150 – 200 (Siner & Manthous 2007). Appendix IV lists criteria used in several large trials to define SBT tolerance and include factors such as gas exchange, haemodynamic stability, ventilatory pattern, mental status and patient comfort (MacIntyre et al 2002).

Criteria for SBT failure includes RR > 35 breaths/minute, tachycardia > 140 beats/minute and hypertension defined as systolic blood pressure > 180 mmHg or diastolic blood pressure > 90 mmHg (Siner & Manthous 2007). Development of tachypnea, paradoxical breathing, hypoxemia, tachycardia, haemodynamic instability or severe anxiety indicates that the patient is not ready to discontinue MV (Kupfer & Tessler 2001).

Common causes for failed SBT is respiratory drive failure due to central nervous system (CNS) injury or drugs, oxygenation or O_2 delivery failure, muscle failure due to overload, systemic inflammatory processes, nutritional impairments and metabolic processes associated with ongoing disease (MacIntyre 2007).

2.2.2.2 Duration of SBT

Most studies and guidelines advocate SBT for a period of 30 to 120 minutes, as it is claimed that patients who fail SBT show signs of intolerance early on in the trial (Esteban et al 1999; Frutos-Vivar & Esteban 2003). Esteban and colleagues (1999), when comparing a 30-minute to a 120-minute trial in patients ventilated for an average of 5.5 days, found similar reintubation rates for both groups and that the shorter SBT trials led to significant reductions in ICU and hospital LOS. Two other studies demonstrated similar findings in a group of study patients that were ventilated for a mean of 3.5 days (Martinez, Seymour & Nam 2003; Perren et al 2002). It is unclear whether this would be true for patients who are ventilated for a longer period of time, or whether muscle fatigue would become an important factor. In their study of 44 patients, Koh and colleagues

(2000) found no difference in reintubation rates if patients underwent an additional one-hour T-piece trial after having completed a trial on minimal PS for 30 minutes. They concluded that an additional one-hour trial could in fact delay extubation (Koh et al 2000).

Whilst the role of respiratory muscle fatigue in ventilator dependence is not clearly understood, it is clear that an imbalance between the load imposed on the respiratory muscles and the performance capacity, could cause fatigue. This could be as a result of muscle weakness or loads being too heavy, such as occurs during disuse atrophy, improper remodeling of fibers following inactivity or overuse injury (Pruitt 2006; MacIntyre et al 2001). Recent data does not support the existence of low frequency fatigue that develops over time in patients who fail to wean, despite the excessive respiratory muscle workload (Vassilakopoulos, Zakynthios & Roussos 2006a). This is probably due to the use of stringent criteria for SBT failure that lead to patients being returned to MV from spontaneous breathing well before the onset of low frequency fatigue.

The lack of low frequency respiratory muscle fatigue that requires rest to recover does not mean that the excessive loading associated with weaning failure is not injurious. Breathing against such loads can injure the respiratory muscles, but this injury peaks at about three days after the excessive loading. This coincides with the decline in diaphragmatic force-generating capacity at this point in time (Vassilakopoulos, Zakynthios & Roussos 2006a). Fully developed fatigue can cause oxidant injury to sarcomeres and it takes at least 24 hours for muscle to recover to baseline strength (Fessler 2006). Electromyography in patients ventilated for five to seven days revealed non-specific neuromuscular alterations in 50 – 100% of cases (Caroleo et al 2007). Repeated periods of excessive workload during MV may slow recovery from diaphragmatic fatigue or weakness.

In one of the few studies to assess data related to extubation, 20% of patients required re-intubation within 10 hours – 16% of these due to increased WOB and 16% due to hypoxia (Hernandez et al 2007). These authors reported that patients who failed extubation were older, had a greater incidence of COPD and cardiac failure as co-morbidities and were ventilated for a mean of 6.7 days. Smyrniotis and colleagues (2002) studied a group of patients with a mean of 24 MV days. They did not routinely extubate

patients after a two hour SBT, but allowed up to 24 hours observation on CPAP, as they felt that these patients may fatigue and that reintubation was associated with increased mortality. Longer observation times together with identifying and treating factors that perpetuate fatigue, led to a downward trend in reintubation rates in their study. This is in keeping with SBTs performed in long-term ventilator settings that often involve progressive increases in SBT time well in excess of 120 minutes (MacIntyre 2005a).

Vallverdu and colleagues (1998) found that almost 25% of patients failed SBT after 60 minutes. Vitacca and colleagues (2001), in a study of patients with COPD ventilated for longer than 15 days, found that 60% failed T-piece trials after a median of two hours. This contradicts the study by Esteban and colleagues (1999) that found 30 minutes of SBT sufficient to indicate extubation readiness. These studies make a strong case for the fact that SBT of two hours may not be long enough to adequately assess breathing readiness in long-term ventilated patients with co-morbidities.

2.2.2.3 Management of SBT Failure

If a patient fails SBT, the cause for failure and its reversibility must be established. Causes could include cardiac insufficiency, inadequate pain control, over-sedation, fluid status and other physiological reasons (MacIntyre 2005a). While a 77% success rate is achieved in short-term ventilated patients, up to 35% of patients fail their first SBT and may require a gradual decrease of MV support (MacIntyre et al 2002; Frutos-Vivar & Esteban 2003). These patients must be identified early in order to start appropriate weaning steps.

Patients who fail SBT should be reconnected to the ventilator with enough support to decrease WOB, promote comfort and prevent muscle overload, allowing them to rest and recuperate. Ventilator management should focus on avoiding ventilator-induced lung injury and proper loading of the respiratory muscles to avoid atrophy and fatigue (MacIntyre et al 2002; MacIntyre 2005b; MacIntyre 2007). As muscles, once fatigued, need at least 24 hours to recover, a SBT should only be attempted once a day (Frutos-Vivar & Esteban 2003). Failed SBT is often due to persistent respiratory system mechanical abnormalities that are unlikely to reverse rapidly (MacIntyre et al 2002). However, new evidence suggests that muscle fatigue may recover much more rapidly than previously thought (Tanios et al 2006).

2.2.3 Phase III: Extubation

The experience of nursing staff, availability of physicians and time of day can delay extubation even if weaning protocols are used (Restrepo et al 2004). Siner and Manthous (2007) found that two thirds of patients in large weaning trials were successfully extubated on the first day of SBT suggesting that weaning had been slow due to overly stringent criteria. Siner (2007) states that "...clinicians created many plausible but unproven prerequisites for commencing SBTs, thus binding patients unnecessarily to ventilators".

According to various models (Perren et al 2002, Soo Hoo & Park 2002, Scales & Pilsworth 2007), extubation should be performed during normal working hours when senior medical assistance is available. In the evaluation of respiratory therapists by Soo Hoo and Park (2002), 32% of respondents indicated that they followed this practice. This clearly poses problems of delayed extubation for example over weekends. It is considered better to extubate patients during daytime and it should be planned around patient workload of the whole unit, as these patients must be monitored closely. Up to 9.5 percent of patients do not experience complications immediately following extubation, but only later on (Perren et al 2002, Soo Hoo & Park 2002, Scales & Pilsworth 2007).

There is a risk of increased complications and higher costs with delayed extubation but also with premature extubation and subsequent re-intubation. Many authors have studied mortality rates in patients who fail extubation and claim mortality rates of 6.4 to 12 times higher than in patients who are successfully extubated (Epstein, Ciubotaru & Wong 1997; Walsh, Dodds & McArdle 2004). Perren and colleagues (2002) stated that this might reflect the gravity of the underlying disease. Extubation failure is associated with longer ICU and hospital LOS and higher costs (Ely et al 2001; Meade et al 2001b; MacIntyre et al 2002; Perren et al 2002; Frutos-Vivar & Esteban 2003; Martinez, Seymour & Nam 2003; Smima et al 2003; Walsh, Dodds & McArdle 2004). Epstein and colleagues (1997) showed that re-intubation added 12 days to MV time, 17 days to ICU stay and increased mortality by 31% (Epstein, Ciubotaru & Wong 1997).

Up to 50% of unintentional extubations do not require re-intubation (Kupfer & Tessler 2001). In the study by Krinsley and Barone (2005) there was a 6.6 percent rate of unplanned extubation and 44% of these patients required re-intubation. All the

unplanned extubation patients had longer ICU and hospitals LOS, but interestingly lower mortality rates. This was attributed to the fact that 56% of these patients did not require reintubation and were therefore ready for extubation. The group that required reintubation demonstrated markedly longer ICU and hospital LOS, a fivefold increase in mortality and significant increase in infection rate. The longer ICU LOS was associated with significant cost increases. In a similar study Bouza and colleagues (2007) confirmed these findings. Of the overall 10% of patients that had unplanned extubation, 29% were due to accidental extubation, and 90% of these required reintubation. The other 71% was due to self-extubation. Only 20% of them required reintubation, indicating that extubation was possibly unnecessarily delayed in these patients. Reintubated patients had significantly longer MV and ICU stay and showed a trend towards higher mortality. Up to 15% of patients will require re-intubation in the first 48 hours despite having met all the weaning and extubation criteria (Koh et al 2000).

Re-intubation rates vary widely between studies, suggesting that investigators use different criteria for assessment of extubation readiness (Meade et al 2001a). Depending on the ICU population, four to 20% of patients will require re-intubation not related to accidental extubation. This rate rises to 33% in patients with altered neurological status or impairment (Beckmann & Gillies 2001; Ely et al 2001) and drops to five percent in patients who suffer trauma or are recovering from general or cardiothoracic surgery if they do not suffer co-morbidities (Caroleo et al 2007). Some feel that an ICU that does not re-intubate at least 10 – 15% of its patients is not extubating aggressively enough (Koch 2007). Clinicians who choose a high threshold for weaning and extubation readiness will likely reduce the number of failed trials and extubations but risk the complications of longer MV time (Meade et al 2001a).

The continued need for an ETT must be considered once a patient has passed a SBT. This includes the capacity for adequate gas exchange during spontaneous ventilation and the ability to protect the airway. Substantial respiratory reserve is required immediately post-extubation to cope with the workload of unassisted breathing, which may be increased due to reduced FRC and secretion retention (Koh et al 2000). Sufficient airway reflexes are required to prevent secretions from above the glottis to drip into the trachea and to clear secretions. Excessive or tenacious secretions could overwhelm competent airways. Subjective dyspnoea and discomfort, accessory muscle use, tachycardia and abdominal paradox should be considered (MacIntyre 2007). FiO_2

and PEEP requirement, decreased $\text{PaO}_2/\text{FiO}_2$ ratio and RSBI may indicate progressive hypoxemia or hypercapnia (Ramachandran, Grap & Sessler 2005).

Patient anxiety may delay extubation. Any possible causes, such as hypoxemia, metabolic abnormalities, adverse drug reactions or cerebral hypoperfusion should be ruled out first. Anxiety may be countered by the judicious use of anxiolytics (Lindgren & Ames 2005).

Extubation failure may be due to upper airway obstruction, excessive secretions and a weak cough, cardiac dysfunction, encephalopathy or an imbalance between respiratory muscle capacity and WOB (Frutos-Vivar & Esteban 2003; Dries et al 2004). A weak or absent cough response correlates with a fourfold increase in extubation failure and in the presence of excessive secretions, this increases 32-fold (Khamiees et al 2001). Khamiees and colleagues (2001) also found that 69% of patients who require tracheal suctioning at least two hourly and who have a weak cough failed extubation and that up to 82% of these patients were likely to have unsuccessful extubations despite passing a SBT. Siner and Manthous (2007) stated that the post-test probability of extubation failure was nearly 50% in patients who had passed SBT but had two out of three of the following negative prognostic signs: a) excessive secretions, b) weak cough and c) gross neurological dysfunction. This may lead to decreased capacity to protect and maintain a patent airway and clear secretions and an inability to maintain adequate spontaneous ventilation. Smima and colleagues (2003) did not find any correlation between amount of secretions and extubation outcome; however this might be due to careful patient selection. However, patients with neurological problems were 3.3 times as likely to fail extubation as they often lack gag reflexes, are not fully awake and cannot follow commands. A variety of factors such as older age, female gender, the presence of COPD or anemia and prolonged ventilation and sedation increases the risk of extubation failure (MacIntyre et al 2002; Martinez, Seymour & Nam 2003; Dries et al 2004). Patients who require late re-intubation appear to have high APACHE II scores and multiple co-morbidities. They also require dialysis more often for acute renal failure (Epstein, Ciubotaru & Wong 1997).

One of the major concerns surrounding unsuccessful extubation is reluctance to re-intubate and difficulty in re-establishing an airway due to upper airway edema, respiratory distress and patient anxiety (Koh et al 2000). This leads to significant clinical

deterioration - compromised gas exchange, severe respiratory muscle fatigue, cardiac complications, lung injury - and increased mortality (Burns et al 1995; Epstein, Ciubotaru & Wong 1997; Meade et al 2001b; MacIntyre et al 2002). Patients are at risk of infection due to micro-aspiration of gastric contents and re-intubation which introduces oral flora into the airway (Dries et al 2004). Torres and colleagues (1995) found that 47% of re-intubated patients developed nosocomial pneumonia, and 35% died from it.

There are clearly a variety of factors that must be considered at various stages of the weaning process to allow a patient to progress smoothly to successful extubation. Weaning protocols put these factors into an easily understood and executed framework to allow as many patients as possible to be extubated in the shortest time with the least complications.

2.3 THE IMPLEMENTATION OF NEW PRACTICES

Evidence based medicine (EBM) is “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients,” and promotes practice that is effective, efficient, and based on research (Chan et al 2001; Vincent 2004). Guidelines and protocols based on best practice and research reduces undesirable variations and improves the quality of care. The level of institutional commitment to improving clinical outcomes and the healthcare team's persistence and consistency in implementing protocols will determine their success (Ely et al 2001). However, a gap often exists between best evidence and best practice.

The implementation of weaning protocols is a complex process. It involves practitioner behavior, and methods of organizing and delivering those behaviors (Blackwood 2006). Many of the structures and processes used in ICU function at a systems level and promote hierarchical and discipline specific decision-making, meaning that change needs to occur at systems rather than personal level (Hansen & Severinsson 2007). In order to successfully alter established practices, one must demonstrate the evidence for the change, taking into account existing culture and the suitability of the proposed change in a local context. To ensure compliance, success and sustainability, the use of multidisciplinary team members involved in patient care to develop a protocol for a unit is important and ongoing training of all relevant parties is essential (Chan et al 2001).

Barriers to learning include limited knowledge (only 10 – 20% of medical practice is supported by rigorous studies), understanding and interpretation of the literature by

clinicians who lack the skills of critical evaluation. Solutions include regular review of the literature, the creation of clinical practice guidelines as a standard of care and the installation of practicable strategies (Garland 2005). Physicians often receive little or no education on new concepts, may view data from studies as being inaccurate, question the generalizability of a single-centre study to their patient population and usually resist proposals that may abridge their professional autonomy, even when research clearly supports a practice change (Ely et al 2001; Garland 2005; Esteban et al 2008). They may not regard guidelines as legitimate or identify with the rules written for them by members of other social groups (Hansen & Severinsson 2007). They frequently fail to make use of allied health professional's experience, knowledge and familiarity with patients to initiate weaning.

The introduction of protocols can create resentment and frustration amongst health care professionals who think it removes clinical judgment without considering all facets of patient care. People may be generally resistant to practice change amid fears about competence (Blackwood, Wilson-Barnett & Trinder 2004). Even with a protocol, a range of cultural, personal and conceptual factors, such as relationships, hierarchy, power, leadership, education, experience and responsibility influence nurses' decision-making (Hancock & Easen 2006; Kollef et al 1997). However, improvement of staff perceptions about a protocol is associated with decreased number of errors, LOS and employee attrition (Blackwood, Wilson-Barnett & Trinder 2004). When investigating factors that led to the initiation of nurse-led weaning, Gelsthorpe and Crocker (2004) and Hansen and colleagues (2007) found that nurses rely on past experience and knowledge rather than written protocol. Even though nurses in their study unit underwent a yearly ventilator knowledge certification that included a weaning protocol, the protocol was rarely referred to or used, despite the fact that respondents felt the protocol was useful. It allowed nursing staff to act in the absence of a physician, created a sense of independence and was timesaving. The protocol was frequently used at inception, after which its use gradually decreased.

Compliance with protocols is notoriously bad, with Ely and colleagues (1999) reporting only 25 – 36% adherence, and Chatburn and colleagues (2007) 66% in a pediatric unit. However, after training Ely and colleagues demonstrated compliance of 81% in medical and 63% in surgical ICUs (as cited by Lellouche, Mancebo & Jolliet 2006). McLean and colleagues (2006) estimated adherence to an evidence-based protocol that decreased

unsuccessful extubation, VAP rate and MV time to be less than 1 percent one year after introduction. They assessed staff perceptions regarding the protocol. After training, staff did not feel safer using the protocol but understanding of and adherence to it had increased to 21%. Improved compliance over time is possible with continued training and reinforcement (Chan et al 2001; Scheinhorn et al 2001). Kupfer & Tessler (2001) state that “inservicing” and intensive education of all personnel is crucial to achieve success.

Clearly there are many barriers to the successful, sustained implementation of a weaning protocol. This can be overcome with good evidence, continued training and commitment from health professionals to drive such a change for better patient outcomes.

2.4 **INJURY SEVERITY SCORE**

The Injury Severity Score (ISS) is an anatomical scoring system that provides an overall score for patients with multiple injuries. Each injury is assigned an Abbreviated Injury Scale (AIS) score and is allocated to one of six body regions: Head, Face, Chest, Abdomen, Extremities (including Pelvis), or External. The highest AIS score in each body region is used. The 3 most severely injured body regions have their score squared and added together to produce the ISS score. An example of the ISS calculation is shown in Appendix VI.

The ISS score takes values from 0 to 75. If an injury is assigned an AIS of 6 (unsurvivable injury), the ISS score is automatically assigned to 75. The ISS score is virtually the only anatomical scoring system in use and correlates linearly with mortality, morbidity, hospital stay and other measures of severity.

Its weaknesses are that any error in AIS scoring increases the ISS error, many different injury patterns can yield the same ISS score and injuries to different body regions are not weighted (Baker et al 1974).

2.5 SUMMARY

It is clear that weaning patients from MV is a complex issue. The weaning process itself can be divided into three stages and in each stage there are multiple factors that directly and indirectly influence outcome. Furthermore, individual patients with differing characteristics may respond in different ways to treatment techniques. Some patients may require more physician attention, while others will do well with minimal clinician intervention.

However, even in the face of such a diverse patient population, using protocols and guidelines to ensure standardized care has been proven to be beneficial. It promotes multidisciplinary care and has been proven to be particularly useful in units where no standardized care exists. Protocols are a logical stepwise process of thinking. Furthermore, it has been proven that these protocols can be used safely and effectively by a range of health care providers caring for a patient. This includes nursing staff and physiotherapists who spend a large amount of time with individual patients and are well placed to make decisions regarding management.

Protocols are not designed to remove autonomy from clinicians, but rather as tools to assist in managing patients effectively along agreed lines. Therefore most protocols require a clinician's order to initiate and patients may be withdrawn from the protocol treatment at any time. Protocols must be tailored to the needs of specific patient populations in specific units. It appears that how we reach the final outcome may not be as important as that a method is in place that continually focuses attention on the need to assess readiness for weaning and extubation and that this is done in a systematic way.

Chapter 3 of this dissertation will describe the methodological process that was followed in order to conduct the proposed study.

CHAPTER 3

3. METHODOLOGY

This chapter describes the study design, variables, hypothesis tested and the sample selected. It gives a detailed description of the data collection, as well as the methods used for data analysis. The ethical considerations related to the study are presented at the end of the chapter.

3.1 STUDY DESIGN

This was a non-randomized trial. The study consisted of retrospective and prospective phases. Phase I was a prospective cohort study of patients who were mechanically ventilated and weaned according to the weaning protocol.

Phase II of the study was retrospective, analyzing a cohort of mechanically ventilated patients in the ICU before the implementation of the weaning protocol. The patients in Phase II were not weaned according to a set weaning protocol, but according to physician preference. Data such as number of MV days, self-extubation and need for re-intubation were retrieved and analyzed from patient files held at the physiotherapy practice of Sklaar, Laidler and Partners, and ICU charts.

The patients in Phase II were each matched and paired to a patient in Phase I according to age, gender, type of injury and severity of illness (rated using the ISS score).

3.2 SAMPLE SELECTION

Patients who suffered trauma and were admitted to the ICU of the Union Hospital in Alberton, and mechanically ventilated participated in this study. All patients were treated by the physiotherapy practice of Sklaar, Laidler and Partners.

3.3 INCLUSION CRITERIA

Patients who suffered trauma, regardless of age, gender, type of injury or ISS score, who were mechanically ventilated for a period of longer than three days before weaning commenced, but no longer than 30 days from date of intubation were eligible for inclusion in Phase I of the study.

3.4 **EXCLUSION CRITERIA**

Patients with partial or complete spinal cord injuries were excluded from the study, as the literature suggests that these patients cannot be weaned according to any protocol and require specialized care.

Patients with a history of cardiac disease or cardiac contusion were excluded from the study.

Patients with unrecoverable brain injuries as confirmed by a neurosurgeon through CT-scan or brainstem testing were also excluded, as were patients with brain injuries who failed SBT on more than three occasions.

3.5 **VARIABLES**

In this study the independent variable was the success and effectiveness of a weaning and extubation protocol to wean and extubate patients who suffered trauma, from MV.

There were a number of dependent variables, which were closely related to one another:

- Total time spent on MV;
- Total number of days spent in the ICU;
- Total number of patients that required re-intubation following extubation;
- Number of patients that extubated themselves;
- Number of self-extubated patients that required re-intubation.
- Total time elapsed before SBT failure in patients in Phase I of the study who failed SBT;
- Reason for SBT failure in patients in Phase I of the study.

3.6 **HYPOTHESIS**

- a) The use of a weaning and extubation protocol to wean and extubate patients from MV results in a decrease in number of days spent on the ventilator and in ICU compared to that of subjects not weaned according to a protocol.
- b) The use of a weaning and extubation protocol decreases the total number of re-intubations of subjects in comparison to subjects not weaned according to a protocol.

3.7 **SAMPLE SIZE**

The sample size of 27 matched pairs was determined by the statistician by evaluating the actual number of patients and average number of ventilator days per patient in the Union Hospital ICU over a period of 3 months prior to the implementation of the weaning and extubation protocol. Finally 28 pairs were included in the study.

A sample size of 27 pairs will have 80% power to detect a clinically relevant difference in length of ventilation and stay of 3 days, under the assumption that the standard deviation (SD) is 6,1 ($SD = \sqrt{2} \times 4,3$) using a one-sided paired t-test with a 0,05 level of significance.

3.8 **RESEARCH METHOD**

The Union Hospital in Alberton, South Africa is a private hospital that houses a 30-bed trauma, medical and surgical ICU. The standard procedure for weaning in the ICU of this hospital prior to September 2006 was according to physician preference. As a trauma patient frequently had multiple attending physicians, this could lead to potentially conflicting orders to nursing staff.

Due to difficulties in conducting a randomized controlled trial that will be discussed in Chapter 5, the study was conducted as a prospective cohort study with historical matching. Two groups of patients were analyzed: one group of patients that were mechanically ventilated prior to the implementation of the weaning and extubation protocol was studied retrospectively, and the other group that was weaned according the weaning and extubation protocol were studied prospectively.

3.8.1 **Development of Protocol**

The Union Hospital Trauma Unit team holds monthly management meetings. At a meeting in May 2004 the team requested the researcher to develop a weaning protocol for weaning patients from MV, as it was recognized that attending physicians and trauma surgeons gave conflicting orders regarding weaning and that this caused confusion and distress for nursing staff. Evidence from the literature also supported the use of a weaning protocol tailored to the patient population of the ICU to wean patients from MV.

Thorough research of all available literature and guidelines was undertaken by a task force that included the researcher and a protocol for weaning and extubation was

developed (Appendix VII). The protocol was based on the guidelines compiled by MacIntyre et al for weaning and by Durbin et al for the removal of the ETT (Durbin et al 1999, MacIntyre et al 2002). The protocol was refined for use by the trauma unit at Union hospital, taking into account the specific patient characteristics of the ICU. Criteria were used that were deemed to be simple, cheap and practical to implement, but were still strong predictors of successful liberation from MV.

A notable deviation from other weaning protocols described in the literature was the decision to extend the duration of the SBT beyond two hours in patients who undergo MV for longer than three days. The majority of trauma patients at the Union Hospital are long-term ventilated patients with co-morbidities (average MV time for patients in Phase II was 16.3 days). The trauma unit management group felt that SBT of two hours may not be long enough to adequately assess breathing readiness in these patients.

The protocol was presented at a subsequent trauma unit management meeting and circulated to all team members for review and comment. The protocol was reviewed by members of the ICU nursing staff and discussed again at the following management meeting. Proposed changes were discussed, agreed upon and implemented. All attending physicians, trauma surgeons and the unit manager of the ICU agreed with and signed off on the final version during a management meeting.

Prior to implementation of the weaning and extubation protocol, training was undertaken with all nursing staff. Nursing staff at the Union Hospital work 12-hour shifts, so there are two shifts per day. Each shift loosely consists of two teams that alternate. Four training sessions were undertaken: two for day shifts and two for night shifts, held on different days. By conducting two training sessions on different days, for each shift, it was possible to ensure that most staff underwent training on the weaning protocol. In addition, any staff member that was not present at the training sessions could receive individual training, and this was mandatory when they were nursing a ventilated patient who was ready for weaning.

All physiotherapists from the practice of Sklaar, Laidler and Partners who treated patients in the Union ICU received training in the weaning and extubation protocol.

The researcher, unit manager or one of the physiotherapists checked every patient on MV each morning, and routinely asked whether the staff member nursing the patient had undergone training. All staff were offered the opportunity to have individual training on the day of nursing their first patient who was ready to wean.

In September 2006 the weaning and extubation protocol was adopted for use on all trauma patients admitted to the ICU of the Union Hospital. Copies of the protocol was laminated and fixed to the chart table at each bed in ICU.

3.8.2 Pilot Study

A data collection sheet (Appendix IX) was developed by the researcher, and nursing staff was given individual training on its use when they were nursing a patient that was ready to wean. The data collection sheet consisted of a checklist of the criteria in the weaning protocol, with a date column.

A patient would be assessed daily for readiness to wean using the checklist (Appendix VIII). This list was shown to the attending physicians each morning. When a patient fulfilled all the criteria, they were considered ready to wean and the physician would give the order to implement the weaning protocol.

Patients were weaned according to the protocol and when they fulfilled the criteria, the physician was informed, who could give the order to extubate.

The protocol was initially tested randomly on five mechanically ventilated patients with diverse pathologies. The aim was to assess the practical implementation of a weaning protocol and its usefulness in different patient types. These patients had very different pathologies and were all severely ill. All five patients were successfully monitored and extubated as soon as possible with no complications. This demonstrated that severely ill patients could be successfully weaned and extubated according to the protocol without unnecessary delay. There were no adverse outcomes and the nursing staff and physiotherapists understood and implemented the protocol well.

3.9 THE DATA COLLECTION PROCEDURE

3.9.1 Phase I: Prospective

Trauma patients admitted to the Union Hospital ICU between end September 2006 and April 2008 were observed for eligibility for inclusion in the study using the checklist developed for the pilot study if they were mechanically ventilated.

Each morning the treating physiotherapist would assess the patient for weaning and extubation readiness, and follow their progress using the checklist and filling in the data collection sheet, noting the date and time. The physiotherapist would discuss the protocol with the nurse looking after the patient. The data collection sheet was explained and left with the nurse to complete if necessary throughout the day.

The unit manager of the ICU or the researcher showed the printed checklist to the attending physician every morning on his/her ward round, together with the data collection sheet that indicated the parameters achieved for each patient. The physician gave the order to initiate the weaning protocol once all goals were met. Once the order was given, the protocol was initiated and followed through to extubation, using the checklist as needed to progress to the next phase. If at any time the physician felt that the weaning and extubation protocol was no longer appropriate for the patient, the patient could be withdrawn from the protocol and the study.

When the patient passed all criteria for extubation readiness, the physician was alerted. If given permission, the patient was extubated. The time and date was noted on the data collection sheet. Patients were observed by the physiotherapist for 72 hours following extubation. The need for re-intubation was noted in this period. A note of the patient's date of discharge from ICU was made.

The data of 28 trauma patients who were admitted to the ICU of Union Hospital in Alberton from September 2006 was collected prospectively over a period of 18 months. It was initially anticipated that it would take six to eight months to collect the data. However, the researcher relocated overseas six months following the implementation of the protocol. Due to the big disturbance this created in the Sklaar, Laidler and Partners physiotherapy practice, no data was collected for a period of eight months. The weaning and extubation protocol however remained in use unchanged in the ICU of the Union

Hospital. The remaining patients were recruited into Phase I of the study from February 2008 until April 2008.

3.9.2 Phase II: Retrospective

Data from the physiotherapy practice of Sklaar, Laidler and Partners for all trauma patients treated by the practice from January 2005 to 1 September 2006 was reviewed to identify 28 patients who could be matched and paired to the subjects in Phase I of the study for age, gender, type of injury and severity of injury as indicated by the ISS score. The data on number of MV days, self-extubation and re-intubation is available from practice records and was crosschecked with ICU charts that were requested from the hospital archives.

Pairing was done by the researcher and recorded on a matching sheet. For the purpose of matching, the age classification from the ISS scoring system was used. Patients are divided into three groups:

- Younger than 15 years;
- Aged 15 to 55 years;
- Older than 55 years

Patients were further matched according to gender and severity of injury according to the ISS scoring system (Appendix VI).

Through analysis of the patient records, 24 patients were included in Phase II of the study. Four patients were found to provide matching for more than one patient in Phase I of the study, thereby creating 24 clusters of patients to match the 28 patients in Phase I of the study.

The researcher counted total MV and ICU days for both groups. The researcher recorded the number of unplanned re-intubations in each group. An unplanned re-intubation was defined as any re-intubation occurring within 72 hours after extubation and not due to a planned event, e.g. taking a patient to the operating theatre. This included self-extubation and failed planned extubation. The researcher recorded the number of failed planned extubations and self-extubations in each group as well as the number of self-extubated patients who required re-intubation.

For Phase I, the hours lapsed prior to a patient's failure of SBT was recorded, as well as the reason for failing the trial. This was only done for subjects in Phase I, as SBT forms part of the weaning and extubation protocol, but was not used by all the physicians consistently for patients in Phase II of the trial.

3.10 DATA ANALYSIS

In a comparison of protocols demographic data were matched between individuals in each group. In four of the 'matched groups', which are referred to as 'clusters', there were two Protocol I patients for one Protocol II patient. Therefore results are reported for 24 matched groups and data are correlated within clusters.

Protocols were compared using random effects maximum likelihood regression, taking into account the dependency of observations. Logistic regression and Kaplan-Meier survival estimates was used to analyze the relationship between age, gender, type and severity of injury and total MV time and ICU LOS respectively in the two groups. When submitted to testing, it was confirmed that the proportional hazards assumption was valid for both MV time and ICU LOS. Log-rank testing was applied to compare outcomes for MV and ICU LOS in the two groups.

Odds ratio analysis was used to describe the relationship between re-intubations in each group.

Data was analyzed using the STATA 9 software package.

3.11 ETHICAL CONSIDERATIONS

Ethical clearance for this study was obtained from the University of the Witwatersrand Ethics Committee under Ethical Clearance number M060361, issued on 2006/06/03 (Appendix XII).

All attending physicians and trauma surgeons at the Union Hospital trauma unit signed consent to take part in the study and have their patients included (Appendix XI). The study was approved by the trauma unit management group at the Union Hospital and the General Manager of the Union Hospital (Appendix XIII).

All patients in Phase I gave written, informed consent to have their data included in the study. If the patient was unable to give consent, a family member was asked to give consent for the patient's data to be used in the study (Appendix X).

Patient confidentiality was maintained by using an alphanumerical system to code patients in Phase I and Phase II of the trial. All patients remained anonymous, with numbers being allocated to files to track data should the need arise.

CHAPTER 4

4. RESULTS

The main hypothesis for the study was that the use of a weaning and extubation protocol to wean and extubate patients from MV would result in a decrease in number of days spent on the ventilator and in ICU compared to that of subjects not weaned according to a protocol.

It was also hypothesized that the use of a weaning and extubation protocol would decrease the total number of re-intubations of subjects in comparison to subjects not weaned according to a protocol.

In this chapter the results of the study are described. In Section 4.1 an overview of the baseline data for the patient sample is given. The results for each of the objectives are described in Sections 4.2 to 4.5.

4.1 BASELINE DATA OF THE SAMPLE

A total of 56 mechanically ventilated trauma patients were enrolled in two phases of the study. A historical cohort of 28 patients (Phase II) was matched retrospectively with a prospective cohort of 28 patients (Phase I). Due to the small sample size, each patient in Phase I was paired with a patient in Phase II of the study, so that the pairs were similar in terms of gender, age, type and severity of injury. There were four patients of Phase II that matched more than one patient in Phase I. Therefore, there were 24 clusters of data reported for the 28 pairs of patients.

Patients enrolled in the study presented with various types of injury. Mostly patients presented with polytrauma, although ten patients presented with isolated head injuries. Other injuries included fractures of long bones, ribs, pelvis and spine, as well as soft tissue and organ injuries. Two patients suffered burns.

Patients with spinal cord injury, underlying cardiac disease or cardiac contusion or unrecoverable brain injury were not eligible for entry into the study. All other patients, regardless of age, gender, type or severity of injury who were mechanically ventilated for

a period of longer than three days before weaning commenced, but no longer than thirty days from date of intubation were eligible for inclusion in Phase I of the study.

For the purpose of matching, the age categories used in the ISS scoring systems were utilized. Patients were divided into three groups according to age – less than 15 years of age, aged 15 to 55 years, and greater than 55 years of age. In terms of total ISS score, patients were classified into groups according to the predicted mortality rate associated with their injuries and age. This is in keeping with the parameters used by Tonnelier and colleagues (Tonnelier et al 2005).

Table 4.1: Demographic Characteristics of Patients: Age, Gender, Severity of Injury

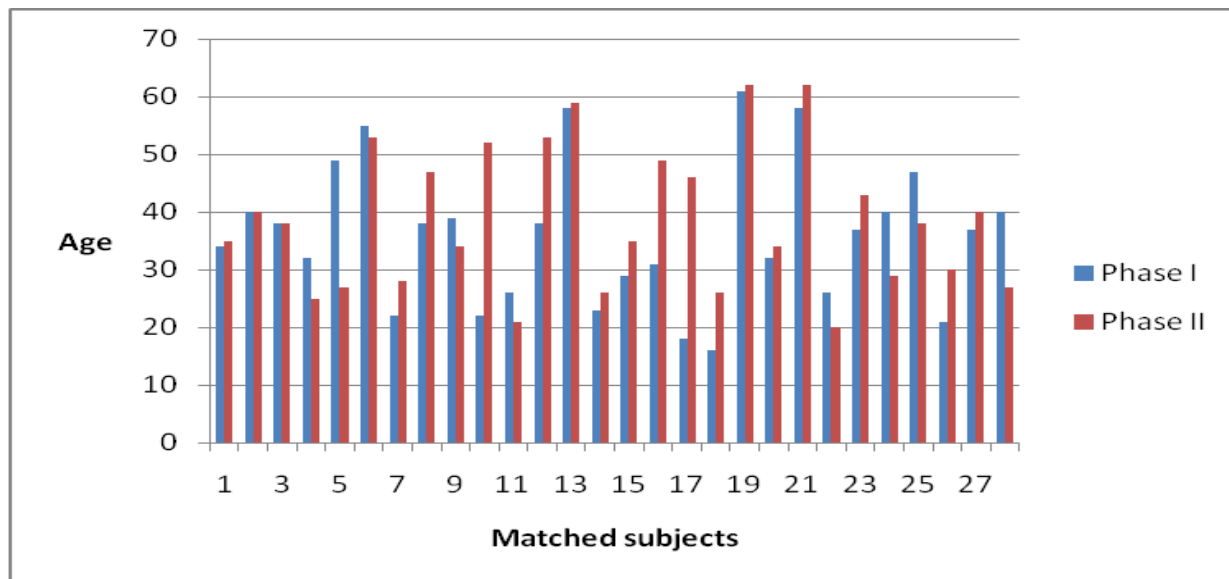
Variables	Phase I (n = 28)	Phase II (n = 28)
Mean Age (years)(SD)	36 (12.37)	38.5 (11.99)
Gender:		
▪ Male	26	26
▪ Female	2	2
Mean ISS (SD)	14.53 (4.56)	14.68 (5.70)
Admission Diagnoses:		
▪ MVA	16	15
▪ GSW	6	3
▪ Burns	1	1
▪ Falls	1	0
▪ MBA	3	4
▪ Assault	1	4
▪ PVA	0	1

ISS = Injury severity score, MVA = motor vehicle accident, GSW = gunshot wound, MBA = motorbike accident, PVA = pedestrian vehicle accident

Each group consisted of 26 males (92.8%) and two females (7.2 percent). The small number of females in this study group is compensated for by the fact that patients were paired and matched for gender in the groups so that females are compared to females.

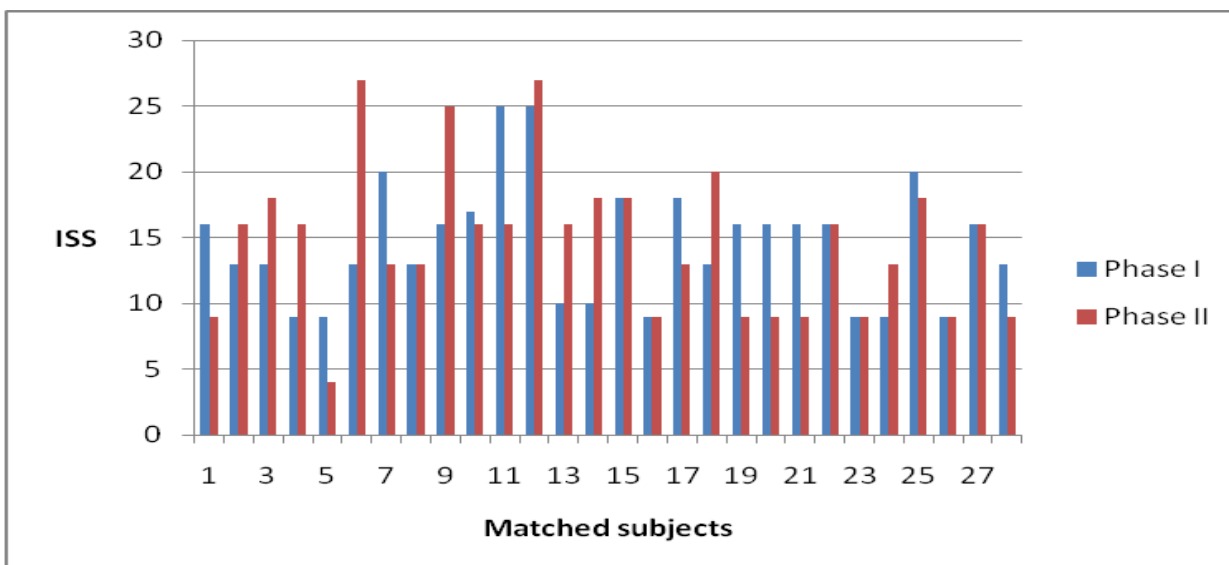
The mean age of patients in Phase I was 36 years. The average age of patients in Phase II was 38.5 years (see Table 4.1).

Figure 4.1.1: Ages of patients in Phase I and II of the study

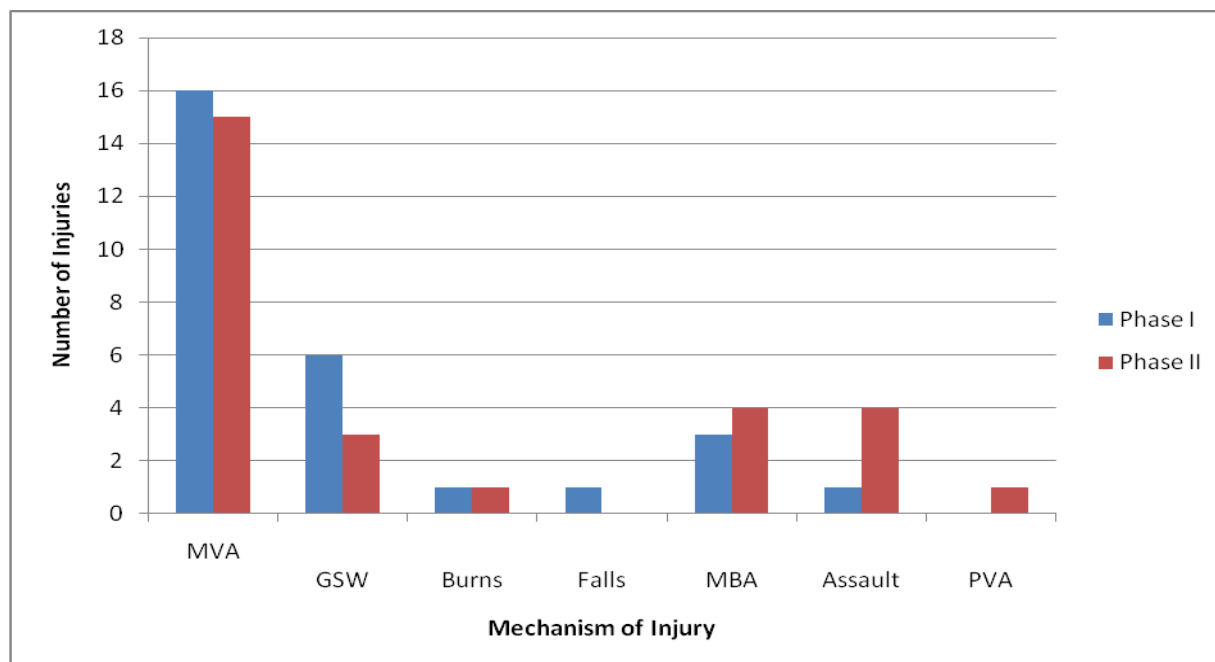


The ISS scores for both groups were comparable, with ISS being a mean of 14.5 in Phase I patients and a mean of 14.7 in Phase II patients.

Figure 4.1.2: ISS scores of patients in Phase and II of the study



When assessing mechanism of injury that led to ICU admission, there were seven major types of injury. Predictably, the majority of admissions were as a result of motor vehicle accidents.

Figure 4.1.3: Mechanism of Injury

MVA = motor vehicle accident, GSW = gunshot wound, MBA = motorbike accident, PVA = pedestrian vehicle accident

4.2 THE EFFECT OF THE USE OF A WEANING AND EXTUBATION PROTOCOL ON THE NUMBER OF MV DAYS AND ICU LOS PER PATIENT

In this study the independent variable was the success and effectiveness of a weaning and extubation protocol to wean and extubate trauma patients from MV. The main aim was to establish whether using a weaning protocol to wean and extubate patients from MV is more effective than individual weaning methods implemented by physicians in terms of total MV days, total ICU LOS and rate of re-intubation. Table 4.2 summarizes the comparisons between the groups in terms of MV days, ICU LOS and age.

Table 4.2: Comparison of number of MV and ICU days between protocols
Protocol I

Variable	Observed	Mean	Std. Dev.	Min	Max
Age	28	36.0	12.4	16	61
MV Days	28	14.4	8.4	3	30
ICU Days	28	21	11.0	4	40

Protocol II

Variable	Observed	Mean	Std. Dev.	Min	Max
Age	24	36.9	12.0	20	62
MV Days	24	16.3	9.5	4	33
ICU Days	24	20.8	11.6	5	43

The time that patients spent on MV was a dependent variable. There was a difference of 2 days in mean number of ventilator days. Although this represented a trend towards reduction in MV days, it was not statistically significant for the study population ($p = 0.3$). There was a difference of 0.3 days for length of ICU stay between the groups ($p = 1.0$).

Figure 4.2.1 displays the Kaplan - Meier estimates for time to end of MV. The two graphs did not differ significantly ($p = 0.2$; Log-rank test).

Figure 4.2.1: Kaplan-Meier Estimates for Duration of MV

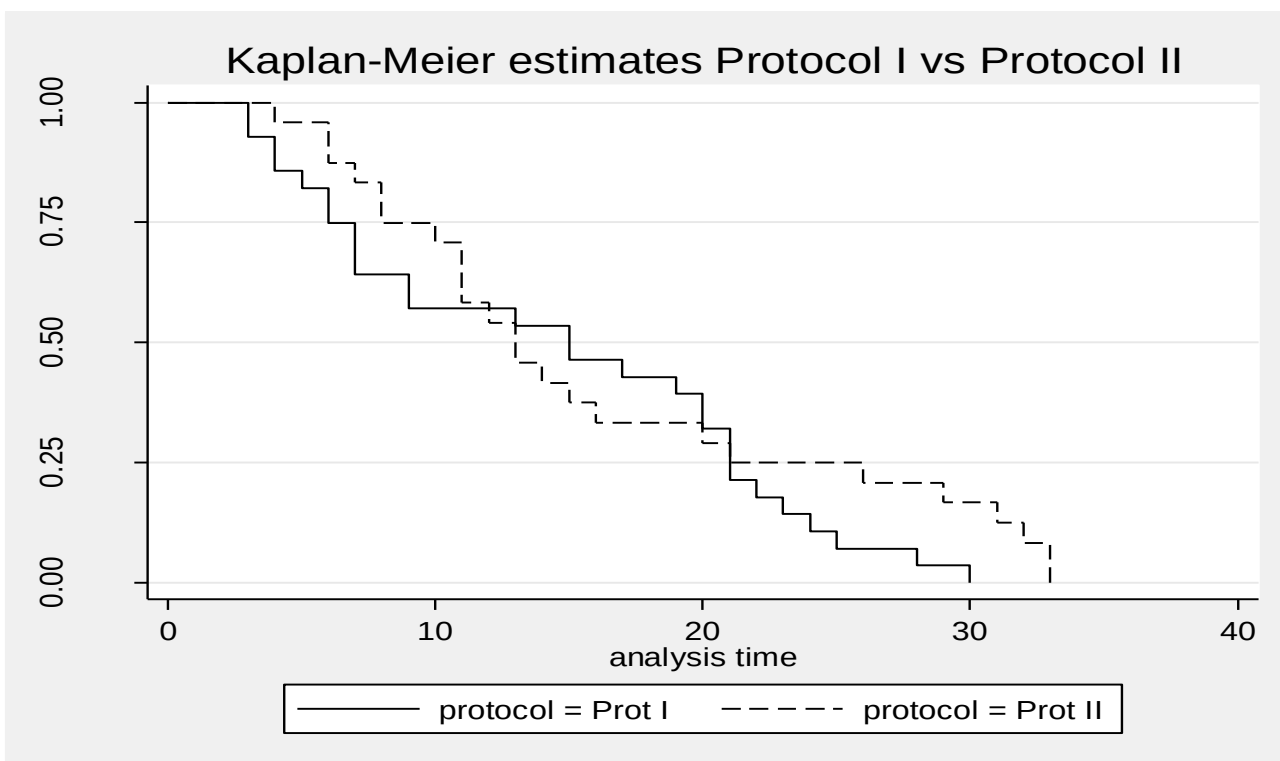
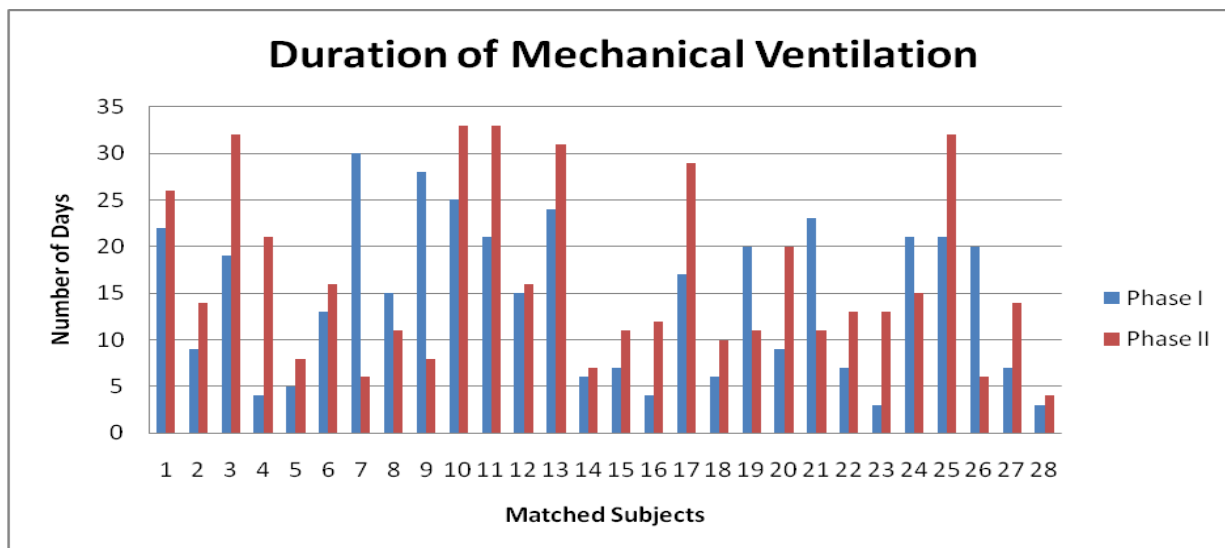


Figure 4.2.2: Duration of Mechanical Ventilation



Patients in Phase I of the study spent an average of 14.4 days on MV, while the patients in Phase II of the study were ventilated for an average of 16.3 days. With respect to the mean MV days it was found that the two protocol groups did not differ significantly ($p = 0.3$; 14.4 days vs 16.3 days).

The second dependant variable, which was closely related to the first, was the total number of days spent in the ICU by each patient. The number of ICU days for both groups were counted.

In Figure 4.2.3 the Kaplan - Meier estimates for time to end of ICU LOS is displayed. The two graphs did not differ significantly ($p = 0.7$; Log-rank test).

Figure 4.2.3: Kaplan-Meier Estimates for ICU LOS

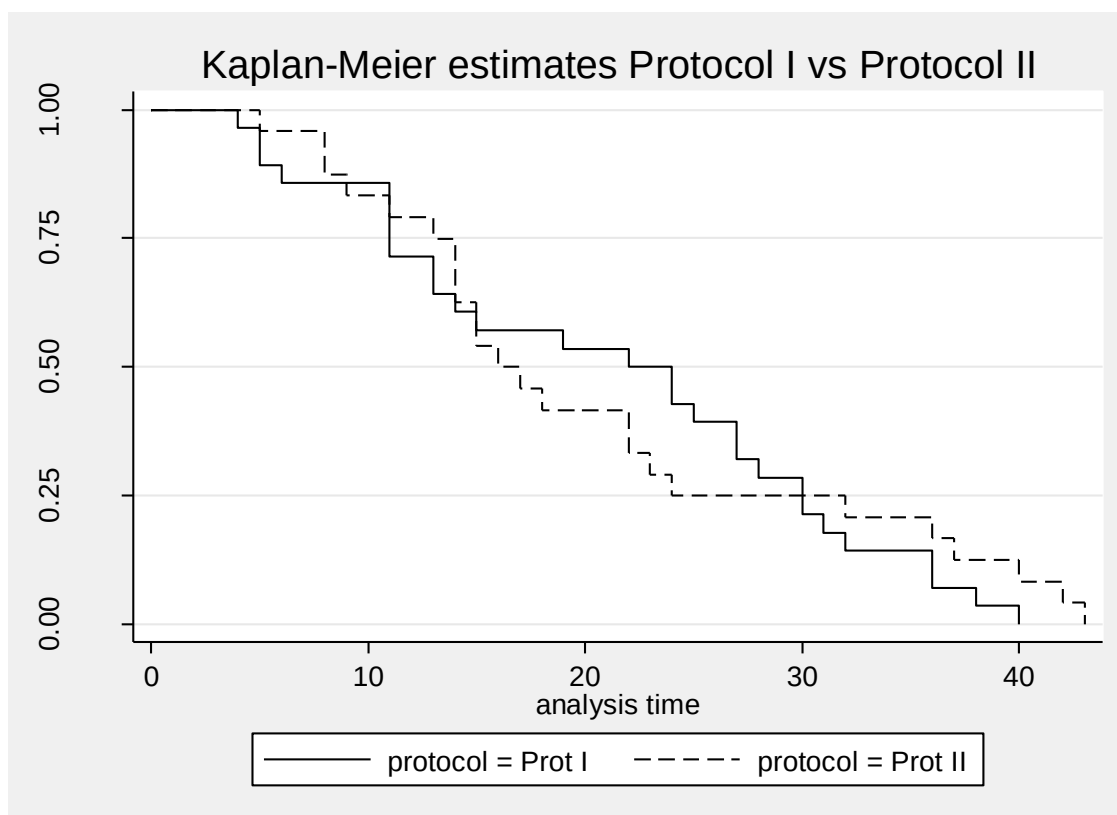
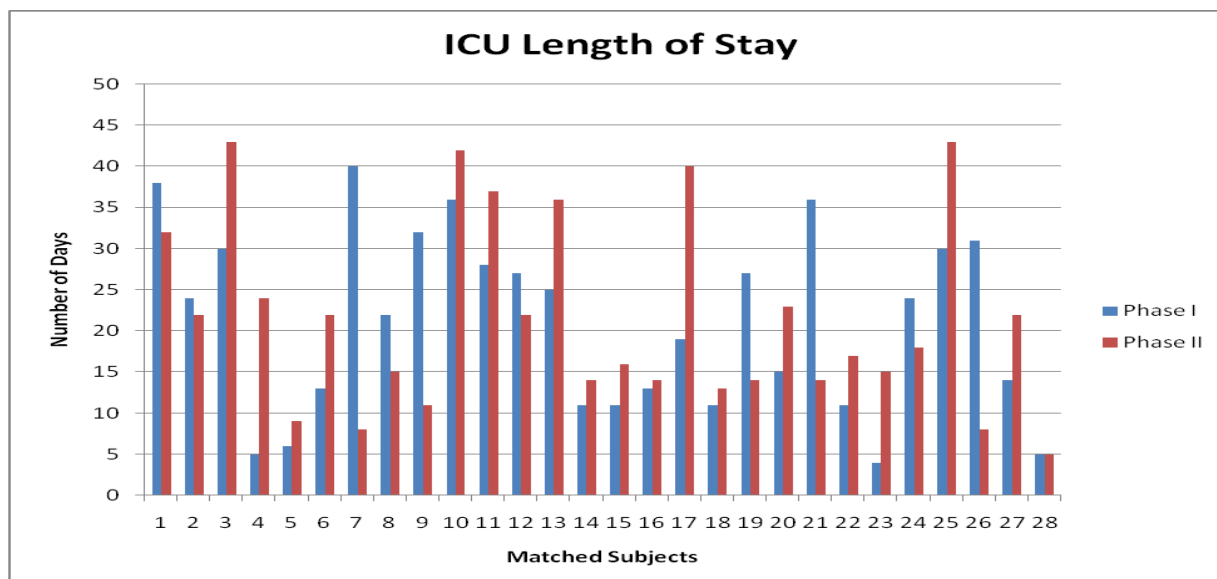


Figure 4.2.4 : ICU Length of Stay



Patients in Phase I of the study spent an average of 21 days in ICU, as opposed to patients in Phase II of the study, who spent 20.8 days in ICU. It was found that with respect to the mean number of ICU days the two protocol groups did not differ

significantly ($p = 1.0$; 21 days vs 20.8 days). This demonstrates that a reduction in MV days may not necessarily result in a reduction of ICU LOS.

4.3 THE EFFECT OF THE USE OF A WEANING AND EXTUBATION PROTOCOL ON THE NUMBER OF PATIENTS REQUIRING RE-INTUBATION

The third dependent variable was the total number of patients that required re-intubation following extubation. This included patients who extubated themselves and patients who were accidentally extubated, classified as “unplanned extubations”. It included patients who were intentionally extubated as they were considered ready and suitable for extubation, but who then subsequently failed extubation.

There were a total of three patients (10.7%) who required re-intubation in Phase I of the study, two (66%) due to self-extubation and none due to accidental extubation. One of these patients extubated himself on day 24, after four days on T-piece, and did not require re-intubation. The third patient was considered ready for extubation and failed after nine hours. Four patients (14%) in Phase II required re-intubation. All these patients were self-extubations, and therefore there were no incidences of patients in Phase II being extubated too early or failing planned extubation.

From a random-effects logistic regression the odds ratio (OR) of 0.6 suggests that relative to Protocol II, Protocol I is protective of reintubation as an odds ratio less than 1 indicates that the condition or event is less likely to occur in the first group. However, this was not found to be statistically significant ($p = 0.5$).

The rate of re-intubation was similar in the two groups. Whilst the use of a weaning and extubation protocol did not reduce the number of re-intubations in the study group, it was demonstrated that weaning and extubation protocols can be used safely and effectively to accelerate the weaning process without any adverse outcomes.

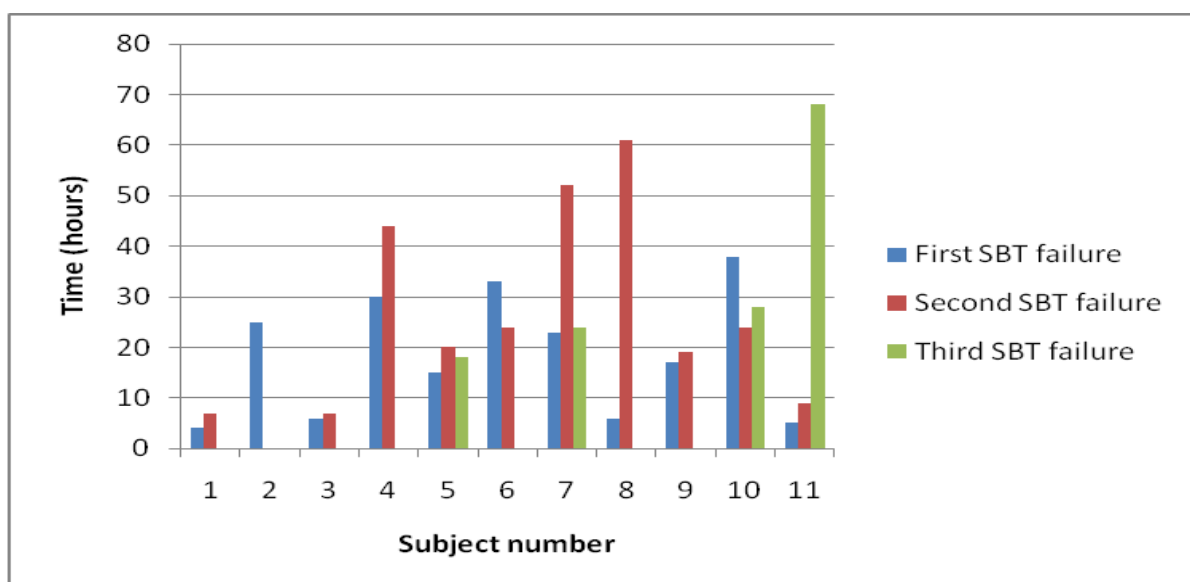
4.4 TIME ELAPSED BEFORE SBT FAILURE AND REASON FOR FAILURE IN SUBJECTS IN PHASE I

The hours lapsed prior to a patient's failure of SBT was recorded as well as the reason for failing the trial. This was only done for subjects in Phase I, as SBT forms part of the weaning and extubation protocol, and was not used consistently by all the physicians for patients in Phase II of the trial.

Table 4.4: Analysis of SBT Failure for Subjects in Phase I

Patient Number	Days of MV	Time to first SBT failure (hours)	Time to second SBT failure (hours)	Time to third SBT failure (hours)
1	9	4	7	
2	30	25		
3	15	6	7	
4	28	30	44	
5	25	15	20	18
6	15	33	24	
7	24	23	52	24
8	17	6	61	
9	20	17	19	
10	21	38	24	28
11	21	5	9	68

Figure 4.4: Comparison graph of SBT Failure for subjects in Phase I



Eleven patients (39%) in Phase I failed at least one SBT and four of these patients (36%) failed two SBTs prior to successful extubation. Failure of the first SBT occurred between 4 and 38 hours from the onset of the trial, with an average of 18 hours. All patients failed their SBT due to increased RR.

In analysis of age of the patients with SBT failure, eight out of 11 were aged between 22 and 47 years. One patient was 18 years of age, one 58 years of age, and one 68 years of age. Therefore, nine out of 11 patients fell in the second age category according to the ISS scoring system (15 to 55 years of age), and two fell in the third age category (greater than 55 years of age).

The mean ISS score for the patients in Phase I who failed SBT was 16.1. This is substantially higher than the mean ISS of 14.5 for the total Phase I population. It therefore appears that sicker patients may have a greater potential to fail SBT initially.

Days of MV in the SBT failure group ranged between 9 and 28, with an average of 20.5 days. This MV rate in patients in Phase I who failed SBT is longer than the average rate of MV in the total Phase I group of 14.4 days, once again possibly indicating the severity of illness.

Patients were not considered to have failed SBT if tracheostomies were kept to protect the airways only.

CHAPTER 5

5. DISCUSSION

Prolonged MV as well as premature extubation may ultimately lead to complications, which can result in increased morbidity, mortality and greater costs. VAP is by far the most serious complication of MV, and is due to increased number of MV days (Marelich et al 2000). The risk of VAP increases for every day that a patient is subjected to MV. The risk of death increases twofold per ventilator day (Cook, Walter & Cook 1998). It is clear that there may be significant benefit to the patient in terms of complications, morbidity and mortality if the number of MV days can be decreased. Additionally, there may also be a decrease in hospital LOS and cost.

The use of effective and accurate assessment measures, grouped into a weaning protocol, to predict a patient's readiness for weaning and extubation, may reduce MV time and therefore complications. Every ICU is inherently different due to the characteristics of the patient population and a set of criteria that is suitable for the population, while still cheap, easy to use and effective must be identified (Ely et al 2001; Kupfer & Tessler 2001; MacIntyre et al 2002; Walsh, Dodds & McArdle 2004). Other studies on protocols to guide the weaning process have mostly been performed on short-term MV patients, and have not focused exclusively on trauma patients. The aim of this prospective cohort study was to assess the usefulness of a weaning protocol to wean and extubate long-term trauma patients from MV in an open ICU.

Usefulness of the weaning protocol was assessed in terms of decreased number of MV and ICU days, and decreased incidence of re-intubation. The findings demonstrate the potential usefulness of a weaning and extubation protocol, as there was a trend towards reduction of MV days. Even though this reduction was not statistically significant, it was considered to be clinically significant in view of the complications associated with increased MV time. Despite a reduction in MV time, there was however not a significant associated reduction in ICU LOS.

In this chapter each of the research objectives will be discussed in terms of the research question posed, the findings and explanations for the findings and comparisons with other studies.

5.1 **DEMOGRAPHIC CHARACTERISTICS OF PATIENT POPULATION**

In an analysis of a larger sample of trauma patients at the Union Hospital, the average percentage of females in that group was 20%. This is in keeping with trauma statistics from South Africa published by the Medical Research Council that show that 81% of all non-natural deaths occur in males (Medical Research Council Policy Brief 2004, National Injury Mortality Surveillance System). Meel found that the ratio of violent and traumatic deaths in males compared to females were 3.3:1 (Meel 2004). There are no incidence statistics on live trauma patients. There are very few ventilation studies conducted on an exclusive trauma population, but Barquist and colleagues conducted such a study in 2006. Their patient population consisted of 69% males in the one and 84% males in the other study group.

The mean age of patients in Phase I of this study was 36 years (SD = 12.4), and that of patients in Phase II 37 years (SD = 12.0). This would seem to correlate with the data from Meel on trauma patients, when he found that nearly 50% of the violent and/or traumatic deaths occurred in the 21- to 40-year age group (Meel 2004).

5.2 **THE EFFECT OF A WEANING AND EXTUBATION PROTOCOL ON TOTAL NUMBER OF MV DAYS AND ICU LOS**

In this study, the use of a weaning and extubation protocol led to a decrease in the number of days that patients spend on MV, but not a decrease in the ICU LOS.

The reduction in MV days between patients in Phase I and Phase II of the study was two days. This reduction was not statistically significant ($p = 0.3$), however, the trend toward reduction in MV days was considered to be clinically significant. This is primarily in view of the statistics around VAP, which clearly demonstrates increased risk of complications with each additional ventilator day (Cook, Walter & Cook 1998).

One of the possibilities for the trend towards reduction of total MV days not reaching statistical significance may be that some of the values for parameters chosen for the weaning and extubation protocols were quite strict. As discussed in the literature review, there are many criteria to select from, and the Trauma Unit representatives and doctors were given the opportunity to select values for the criteria that they felt comfortable with.

Therefore, it is possible that review of the protocol and the moderation of some of the criteria may lead to faster weaning and extubation. A change in critical values for parameters such as RR, blood pressure, or $\text{PaO}_2/\text{FiO}_2$ ratio could feasibly decrease weaning time.

The weaning protocol was driven by the physiotherapists in the ICU and undertaken by the nursing staff once the order to start weaning was given by the physician. Having each patient assessed for weaning readiness daily, and the ability to safely continue weaning by using a checklist with clearly defined parameters even in the absence of a physician, resulted in a trend of reduction of MV days in patients in Phase I of the study.

Meade and colleagues (2001) and Frutos-Vivar and Esteban (2003) demonstrated significant reductions in MV days when using a weaning protocol. Reduced weaning times could be attributed to the use of a protocol, or to the increased role of respiratory therapists and nurses in the weaning process (Price as cited by Taylor 2006). Positive outcomes of weaning protocols may simply be due to the earlier recognition of patients who are ready to breathe spontaneously (Rose & Nelson 2006). Krishnan and colleagues (2004) agreed that the use of a weaning protocol could improve outcomes, but felt that it may vary with staff and patient characteristics.

The decreased number of MV days in this study is likened to the findings of many other researchers. Studies on weaning protocols in general by Cook and colleagues (1999), Smyrniotis and colleagues (2002) and D'Arsigny and colleagues (2004) all demonstrated significant decreases in MV days and ICU LOS, as well as decreased mortality rates, costs and incidence of VAP in some studies. Other studies, focusing on weaning protocols driven specifically by allied health workers (nurses and physiotherapists) demonstrated similar findings (Brochard et al 1994; Kollef et al 1997; Esteban et al 1999; Marelich et al 2000; Ely et al 2001; Kupfer & Tessler 2001; Grap et al 2003; Dries et al 2004; Walsh, Dodds & McArdle 2004; Tonnelier et al 2005).

These researchers did acknowledge the problems inherent to the use of protocols such as resistance to institute and generalize them to all patients (Newmarch 2006). They noted the fact that bigger changes can be made with careful patient selection (Smyrniotis et al 2002).

The mean number of total MV days for patients in this study differs substantially from those in other studies. This is probably due to the specificity of the trauma patient population and the severity of injury as indicated by the relatively high ISS scores, which was on average 14.6, placing patients in the serious to severe categories. The number of MV days in this study is still less than the average number of total MV days reported in Tonnelier's study (2005), and in line with the study by D'Arsigny and colleagues (2004), both of which demonstrated a large reduction of nearly six MV days in the study group of patients who were ventilated for an average of 22.5 days and more than 14 days respectively.

The weaning process is reported by many patients to be physically and psychologically distressing, and can easily lead to increased anxiety. This is compounded by a number of factors related to ICU stay, including medications, sleep deprivation and the psychological stress resulting from coping with severe illness (Newmarch 2006; Rosenthal, Kim & Kim 2007). In addition patients may feel anxiety and distress due to being surrounded by other patients who are critically ill. Therefore extended ICU LOS could place severe additional psychological and emotional burdens on patients, and should be avoided. This subjective feeling of distress is however very difficult to measure. In the general wards patients would also be able to interact more with family and friends, as visiting hours are generally less restricted than in ICU.

Even though the study demonstrated a reduction in total MV days, this did not lead to any reduction in the total ICU LOS. This is contrary to what many researchers found in earlier studies, where a decrease in MV days led to decreased ICU LOS (Cook et al 1999; Smyrniotis et al 2002; Tonnelier et al 2005). Ideally, decreased MV time should result in decreased ICU LOS, but even if it does not, the overall benefit is that reduced MV time represents an important quality of life outcome for patients, as they are more comfortable and can communicate better than if they are intubated. In addition there is decreased risk of complications associated with MV. More aggressive discharge of patients may lead to decreased costs and a better sense of well being for patients.

On analysis of the results it is unclear why the reduction in MV days did not lead to a reduction in ICU LOS. A possibility is that clinicians felt uncomfortable discharging patients who were critically ill to the ward earlier in light of the severity of their injuries and total MV times. Another possibility is that no formal protocol was in place for

discharge of patients from ICU. The decision was left to the treating clinicians and not based on any guidelines or specific criteria.

Therefore, protocol based weaning and extubation led to decreased MV times, but this was not augmented with measures in place to assess readiness for discharge to the ward. In addition, clinicians may have felt that patients were not being harmed by additional days in ICU to ensure that it was safe to discharge them to the ward. Even though patients remained in the same unit, they would be downgraded to the “high care” section of the unit as soon as they were well enough. High care is more cost effective as the nursing ratio is lower than that for the rest of the ICU. This approach however needs to be weighed against the additional costs that are still incurred by stay in a specialized unit.

In a non- randomized trial, Blackwood and colleagues (2006) used an intervention and non-intervention ICU to examine practice changes over time. This design was used because a randomized controlled trial would have been difficult considering possible contamination if nurses were engaged in both experimental and control arms of the study. The non-intervention ICU served as external reference for practice changes over time. The study results demonstrated that there were no changes in outcomes in the reference unit, and that the intervention unit patients in fact had longer ICU LOS. This was attributed to the longer LOS between extubation and ICU discharge, for which the reason was not clear (Blackwood et al 2006).

Some later studies such as the one by Duane and colleagues (2002), Martinez and colleagues (2003) and Djunaedi and colleagues (1997) did not reproduce the findings of the earlier studies in terms of MV days and ICU LOS. The reason for this could have been non-compliance to the protocol or that the protocol failed to improve on existing practice (Duane et al 2002; Blackwood 2006; Keogh et al as cited by Rose & Nelson 2006). In addition, Deem (Chatburn & Deem 2007) reminded people that virtually none of the studies (except for the one by Tonnelier and colleagues, 2005) demonstrated decreased mortality rates and hospital LOS, and therefore questioned the importance of a decrease in MV days.

Whilst not resulting in an objective cost saving, the possibility of a more subjective improvement in quality of life cannot be ignored, as intubation is emotionally distressing for patients and their families.

5.3 THE EFFECT OF A WEANING PROTOCOL ON THE NUMBER OF RE-INTUBATIONS

Three patients in Phase I of the study (10.7%) required re-intubation compared to four in Phase II (14%). This figure is at the lower end of the average of five to 33% reported in other studies (Beckmann & Gillies 2001; Ely et al 2001; Meade et al 2001b; Frutos-Vivar et al 2006; Caroleo et al 2007).

The number of re-intubations in each group of this study was comparable, indicating that the use of a weaning protocol driven by physiotherapists and executed by nurses does not cause worse adverse outcomes than clinician-led weaning. On the other hand the use of a weaning and extubation protocol did not lead to a reduced number of re-intubations as expected in patients in Phase I of this study.

Re-intubation rates vary widely between studies, suggesting that investigators use different criteria for assessment of extubation readiness. Stricter criteria for weaning and extubation readiness will likely reduce the number of failed extubations but may risk the complications of longer MV time (Meade et al 2001a; Meade et al 2001b). One patient in Phase I of the study failed intentional extubation after nine hours; the other two patients who required re-intubation extubated themselves, indicating that re-intubation was generally (66%) not as a result of poor decision-making or of the weaning protocol being too liberal.

The reason for the low re-intubation rate is likely to be that the criteria used in the weaning protocol ensured that all patients were ready for extubation. The question then arises whether the weaning protocol is aggressive enough or whether it should be accelerated further to encourage faster extubation. In fact one patient in Phase I extubated himself on day 24, after four days on T-piece, and did not require re-intubation. This indicates that there may be potential for the criteria in the protocol to be relaxed, as patients may indeed qualify for and cope with extubation earlier than provided for in the current protocol.

It would be difficult to assess this given the nature and severity of illness of this cohort of

ICU patients and the ethical issues around certain assumed safe values. One also has to consider the fact that whilst clinicians and nurses may feel comfortable with the critical values set in this protocol, they may feel less so if the values are less stringent and could potentially place patients at risk.

Up to 50% of unintentional extubations do not require re-intubation (Kupfer & Tessler 2001; Krinsley & Barone 2005). All patients involved in unplanned extubation, irrespective of whether they required re-intubation or not, had longer ICU and hospital LOS, but interestingly lower mortality rates, perhaps due to the fact that at least half of these patients do not require re-intubation and are therefore ready for extubation. Bouza and colleagues (2007) demonstrated that 9 out of every 10 unplanned extubations required re-intubation, but that only 20% of self-extubated patients required re-intubation. Patients experience severe physiological distress prior to re-intubation, and the most important consequence is increased morbidity due to complications such as pneumonia and cardiac complications (Meade et al 2001a).

If patients require re-intubation they demonstrate markedly longer ICU and hospital LOS, a large increase in mortality (six to 12-fold) and significant increase in infection rate, notably VAP (8-fold higher risk). The longer ICU LOS is also associated with significant cost increases (Torres et al 1995; Epstein, Ciabotaru & Wong 1997; Beckman & Gillies 2001; Ely et al 2001; Khamiees et al 2001; MacIntyre et al 2002; Meade et al 2001b; Perren et al 2002; Frutos-Vivar & Esteban 2003; Martinez, Seymour and Nam 2003; Smima et al 2003; Dries et al 2004; Walsh, Dodds & McArdle 2004; Krinsley & Barone 2005; Bouza et al 2007).

Given that all but one of the extubations were self-extubations it raises the issue of the judicious use of sedation. It is obvious that less sedation will lead to more alert patients who are ready to be weaned and extubated, but some patients may be anxious or confused and the more alert state promotes self-extubation. For instance, Girard and colleagues (2008) assessed the use of a SBT and sedation protocol as opposed to the use of SBT alone in a randomized controlled trial. They demonstrated that a paired sedation and weaning protocol led to decreased MV days and hospital LOS as patients were more alert earlier. Patients in the paired protocol group were more alert, passed their first SBT more often. The researcher felt that the trend in reduction of MV days in

the Phase I group may have been due to one of the screening criteria for SBT that stated that patients had to be awake and able to maintain their own airway.

However, as two out of three (66%) of the patients requiring re-intubation in Phase I of the trial extubated themselves, it does demonstrate that there is risk associated with patients being awake and alert on the ventilator while still fully ventilated. Patient anxiety could contribute to this. In most cases good communication in the form of frequent explanations and reassurance about clinical improvement and medical stability will alleviate these feelings of anxiety over time (Newmarch 2006; Rosenthal, Kim & Kim 2007). It highlights the need for excellent communication especially by the allied health professionals who spend a significant amount of time with the patient.

Studies by Beckmann and Gillies (2001) and Frutos-Vivar and colleagues (2006) found that some patients are at higher risk for unplanned extubation than others. These included men, patients with COPD, patients on weaning trials and non-sedated patients. Intentional unplanned extubation was more common during weaning and at night, indicating that perhaps high-risk patients were not monitored as closely on the night shift. The reintubation group was also older and more likely to have had pneumonia as the primary reason for MV. They were more likely to have had a positive fluid balance in the 24 hours prior to extubation. This is similar to findings of other studies. They did not find an association between cough strength, amount of secretions or level of consciousness and extubation success (Beckmann & Gillies 2001; Frutos-Vivar et al 2006).

Similarly, all the patients in this study who required re-intubation following unplanned extubation were male, and four out of six were older than 55 years. The mean age of these patients was 48 years, well above the mean age for Phase I and II of 36 and 37 years respectively. The patients in Phase I that were unplanned intubations were aged 55 and 58 respectively, and the patient that failed planned extubation was much younger, at 38 years of age. These results correlate with the findings of Beckmann and Gillies (2001) and Frutos-Vivar and colleagues (2006).

Unlike the studies mentioned above, most patients in this study extubated themselves during the day shift, indicating that patients were monitored closely at night. It may also indicate that patients received less sedation during daytime hours when weaning was

performed, as per the protocol, leading to increased wakefulness and therefore increasing the risk of self-extubation.

The findings in the study demonstrate that there is no inherent additional risk associated with the earlier ventilator discontinuation that resulted from the use of the weaning protocol compared to physician directed weaning. Conversely, the use of a weaning and extubation protocol did not lead to fewer re-intubations, indicating that the decision making regarding extubation during clinician led weaning was not poorer than with the use of a protocol. However cognizance needs to be taken of the state of wakefulness of these patients while they are still receiving a significant amount of MV and the potential for them to therefore prematurely extubate themselves.

5.4 TIME BEFORE SBT FAILURE IN PATIENTS IN PHASE I OF THE TRIAL AND REASONS FOR FAILURE

In this trauma population (Phase I) with a mean MV time of 14.4 days, 12 patients failed SBT and the average time that elapsed prior to SBT failure was 18.6 hours, significantly longer than the 90 to 120 minutes commonly advocated in the literature (Esteban et al 1995, Esteban et al 1997). Days of total MV ranged between 9 and 28, with a mean of 18.8 days. This duration of MV in patients in Phase I who failed SBT is longer than the mean duration of MV in the total Phase I group of 14.4 days.

Even in the patients who did not fail SBT in Phase I, clinicians often did not follow the protocol for SBT times according to number of days of MV. Of the 16 patients who only required one SBT, eight (50%) underwent SBT for longer than 12 hours, irrespective of the number of total MV days. Only three out of the remaining eight (38%) patients underwent SBT according to protocol for their number of MV days.

This could be due to the fact that many patients were perceived to have severe injuries by their clinicians, and that clinicians wanted to ensure that patients would not fail extubation. Another factor for the delayed extubation could be the rule in the protocol that states that no patients are to be extubated at night. Therefore, if a patient passed a 12-hour SBT in the evening they would wait until the following morning for extubation. Nursing staff may have also waited for doctor's rounds in the morning instead of contacting the clinician to confirm that patients could be extubated.

This is a possible flaw in the protocol which could lead to significantly longer MV time. It could be addressed by clinicians and nursing staff having greater confidence in the protocol itself, and perhaps by increased availability of clinicians via telephone, so that nursing staff would feel free to phone and inform them if a patient passed SBT.

All twelve patients who failed SBT did so longer than two hours after initiation of SBT. In fact, the shortest SBT failure time was four hours in a patient who was ventilated for nine days. The average MV time for patients who failed SBT was 19 days. The reason for SBT failure in all the patients in Phase I of the trial was increased RR. This ultimately resulted in fatigue over a long period of time. The findings demonstrate that muscle fatigue takes longer to develop in long-term MV patients, and that this group is indeed at great risk of failing extubation if a short SBT is used.

The total WOB, consisting of physiological and imposed work, results in O_2 consumption that is minimal under resting conditions. WOB is made up of elastic forces of the lungs and chest wall, airway resistance and resistance from the ventilator circuit (Forrette 2006). If any of the components of WOB become unbalanced, the patient would be able to compensate for this in the early stages, but could be placed in a position where O_2 demand would ultimately outstrip the ability to supply O_2 . This would lead to exhaustion and the inability to maintain adequate spontaneous ventilation. EMG studies have demonstrated that diaphragmatic fatigue already occurs during the first day in all patients on MV. Those who recovered went on to be successfully extubated, while patients continuing to exhibit fatigue ultimately required re-intubation (Eskandar & Apostolakos 2007).

Steady-state breathing during wakefulness is characterized by variability, which tends to be reduced when sleeping or when loaded chemically or mechanically. Such variability is indicative of a healthy system. During weaning, sudden loading of the respiratory muscles, for instance during SBT, could reduce breath-by-breath variability by adding elastic or resistive loads, perhaps promoting microatelectasis. Wysocki and colleagues (2006) demonstrated that breathing variability during a 60-minute SBT was decreased in patients who failed, indicating a more monotonous respiratory pattern that is not sustainable over long periods of time.

The premise exists that the cause of weaning failure during spontaneous breathing without ventilator assistance is muscle fatigue which requires rest to recover. Recent data does not support the existence of this type of low frequency fatigue, which develops over time, in patients who fail to wean, despite the excessive respiratory muscle workload. This may however be due to criteria for SBT failure that lead to patients being returned to MV from spontaneous breathing well before the onset of such low frequency fatigue (Vassilakopoulos et al 2006a). As muscles fatigue over time, especially if placed under unusual force, it is reasonable to expect in long-term MV patients that this fatigue may set in later. A SBT trial that is too short could lead to premature extubation in these patients. Whilst there is no reason for an extended SBT in patients who undergo MV for a short period of time, the use of longer SBT in long-term MV patients is useful in preventing premature extubation and subsequent re-intubation. No patients in this study required re-intubation following intentional extubation, demonstrating the effectiveness of longer SBTs in this patient population.

In this study the reason for SBT failure was linked to fatigue that developed over a period of time, specifically in a group of patients that were ventilated for a longer period of time. The fact that only one patient undergoing intentional extubation required re-intubation indicates a minimization of this risk, but one has to consider whether in some cases this was overcautious and led to unnecessary prolonged MV.

5.5 **PROTOCOLS DRIVEN BY ALLIED HEALTH PROFESSIONALS**

The weaning and extubation protocol used at the Union Hospital was developed and agreed upon by a multidisciplinary group of health providers, which included physicians, physiotherapists, surgeons and nursing staff. Once developed, the protocol was initiated on the orders of the physician, but driven by the physiotherapists, who evaluated each patient for weaning, SBT and extubation each morning, and the nursing staff, who were responsible for the actual weaning of the patient. This correlated with findings in numerous other studies (Brochard et al 1994; Esteban et al 1999; Kupfer & Tessler 2001; Grap et al 2003; Dries et al 2004; Walsh, Dodds & McArdle 2004) that allied health driven protocols can be used successfully and that some of the responsibilities of ventilator weaning could be safely and effectively shifted from physicians to respiratory therapists (Garland 2005).

Protocols could be developed and led by clinicians, but can then be safely implemented daily by non-physician allied health professionals (Ely et al 2001). Scheinhorn and colleagues (2001) found the most variance in their protocol was due to clinicians halting the weaning process as patients' medical status was deteriorating. In many cases the daily screens in the protocol would have automatically halted the process. Nursing staff who are present 24 hours a day, or physiotherapists who spend significant time in the unit treating patients, are ideally placed to continually perform screening for weaning readiness and pathophysiological changes and correct these. As confidence and experience increases they can make more decisions, for instance regarding initiation of a SBT (Grap et al 2003). With a protocol a specific, evidence-based approach without variations is used to make decisions and take action. Goodman (2006) stated that the majority of nurses surveyed found that protocols were easy to follow, an accurate indicator of weaning readiness, useful and improved nurses' autonomy and improved communication between multidisciplinary team members.

This study demonstrates that scope exists in many ICUs in South Africa to better utilize the skills of well-trained physiotherapists and nursing staff to drive weaning and extubation protocols. This will enable quicker weaning from MV and may decrease the risks of complications associated with prolonged MV. If the weaning protocols are combined with protocols regarding readiness for discharge from ICU, it may further lead to decreased ICU LOS and therefore decreased costs.

CHAPTER 6

6. LIMITATIONS AND RECOMMENDATIONS

6.1 LIMITATIONS

The non-randomized study design is a major limitation of this study. Even though the patients were matched for age, gender and type and severity of injury, selection bias cannot be totally eliminated in a prospective study with a historical cohort. On the other hand it would have been impossible not to create some crossover effect if the same nursing staff and physicians would treat patients in the two groups differently. Decision-making would inherently be influenced as people became familiar with the weaning process, and therefore one would not be able to guarantee that the physicians treating the control group would not unwittingly apply some of the weaning protocol criteria to the control groups. It was also felt that placing clinicians in different groups, where some weaned according to the protocol and some according to their personal preference, would in effect test the clinicians' ability to wean patients and not the protocol itself.

The sample size for the study was small, and therefore caution must be exercised when generalizing the outcomes of this study to the general trauma population. The small study size was in part countered by the matching of patient pairs instead of comparing the two large groups to each other. However, this may have contributed to average data being biased one way or another. For instance, if even one patient had a significantly increased MV duration compared to his match, it could alter the results. In addition, it is difficult to match trauma patients exactly in terms of type and severity of injury. One must also consider that trauma patients form a very specific subgroup of ICU patients, and that final outcomes for them may be dependent on additional factors such as pre-existing co-morbidities.

There were only two females included in each group. This constituted 7.4 percent of the study population, which is below the average of 20% in other studies (Meel 2004; Barquist et al 2006). Again, matching for gender eliminated this problem to some extent as the groups were equal for gender.

The timeframe over which the study was conducted was very long, especially considering the small amount of patients. However, in the total time no other major new

protocols or changes to patient treatment were incorporated into the ICU. This meant that changes to the main outcomes were due to the introduction of the weaning protocol in the ICU. An indirect benefit of the long time to complete the study was the observation that the protocol remained in use in the unit for all patients. It indicates a successful, sustained change in patient management.

The absence of the researcher from the study site due to relocation overseas created some difficulties in the collection and collation of data, for which research assistants had to be employed. It also led to further delays in completing the thesis.

6.2 **RECOMMENDATIONS**

The number of subjects included in this study was small. It would be useful to repeat the study with a larger cohort of patients, possibly in a number of ICUs to reiterate the findings of this study.

It is possible that the absolute values for criteria used in the weaning and extubation protocol could be further refined, to investigate whether it would result in further decreases in MV time. Similarly the criteria for longer SBT (MV of more than three days) were arbitrarily chosen to ensure patient safety and confidence of staff in executing the protocol. It may be possible to refine a value for number of days ventilated before requiring a longer SBT.

It is recommended that the weaning and extubation protocol be reviewed in terms of the apparent delays in extubation due to nursing staff waiting for doctors to do rounds instead of contacting them when patients have passed SBT. Clear direction on this issue could result in further reduction in MV time.

The reduction in MV days did not result in a reduction in ICU LOS. This may be due to physicians preferring to keep critically ill patients under close observation until they feel comfortable that they are no longer at risk for complications, or to the fact that there was no checklist developed to assess readiness for discharge to the ward. It is recommended that the possibility of developing a protocol to assess patient readiness for discharge from ICU be explored.

The pilot study indicated that the use of this weaning and extubation protocol could be

useful in patient populations other than long-term trauma. Further study is recommended to ascertain the usefulness of this particular protocol in other patient populations.

CHAPTER 7

7. CONCLUSIONS

In this study of longer-term ventilated patients who had traumatic injury as reason for admission to ICU and MV, the use of a standardized protocol to assist with weaning and extubation from MV demonstrated a clinically significant reduction in total MV time, even though this did not reach statistical significance. These findings correlate with the findings of a number of other studies worldwide.

The reduction in MV time did not lead to a reduction in ICU LOS; however it reduces the risks of ventilator-associated complications such as VAP, and has a potentially important quality of life implication for patients, who experience ventilation as physiologically and psychologically distressing.

The use of a weaning and extubation protocol did not lead to a higher rate of re-intubation, demonstrating its safety for use in this patient population. The fact that only one patient in the study group failed intentional extubation does raise the question of whether the chosen protocol values are too conservative and could be reviewed.

In conclusion, this study on the effectiveness of a weaning and extubation protocol to wean and extubate patients from MV proves that such a protocol could be used successfully in the management of trauma patients. The protocol could be developed by a multidisciplinary team, and driven by physiotherapists and nursing staff. The role of physiotherapists and nursing staff in weaning and extubation of patients from MV could be greatly expanded in the majority of ICUs in South Africa. This will be useful in very busy units or in units where intensivists are in short supply.

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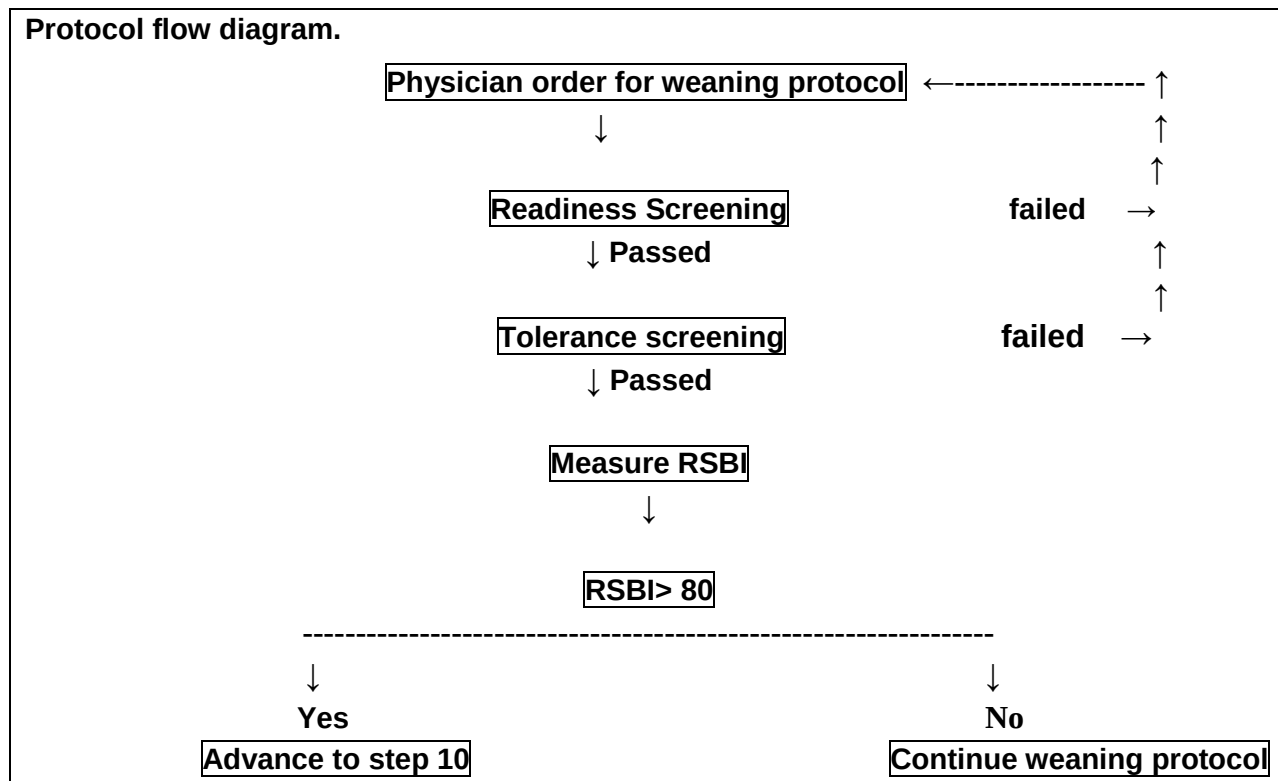
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APPENDIX I

PROTOCOL FLOW DIAGRAM



(Chao & Scheinhorn 2007 Determining the best threshold of rapid shallow breathing index in a therapist-implemented patient-specific weaning protocol. *Respiratory Care* 52: 159-165)

APPENDIX II

AN EXAMPLE OF A STANDARD WEANING PROTOCOL

1. WEANING CRITERIA

Haemodynamically stable with no inotropic support except low dose Dobutrex
 GCS of $> 5/10$
 Good cough reflex
 $\text{PaO}_2 > 60\text{mm Hg}$
 $\text{FiO}_2 < 0.5$
 $\text{SpO}_2 > 95\%$

**GCS = Glasgow Coma Scale, PaO_2 = Partial pressure of arterial oxygen,
 FiO_2 = Fraction of inspired oxygen, SpO_2 = Percentage saturation of oxygen**

2. DAILY SCREENING CRITERIA FOR SBT

Patient awake and able to maintain own airway
 Able to cough on demand, or good cough reflex with suctioning
 Normal serum electrolyte values
 Haemodynamically stable with no inotropic support except low dose Dobutrex
 $\text{PEEP} = 5 - 8 \text{ cm H}_2\text{O}$
 Pressure support < 8
 Mandatory ventilation rate $< 4 \text{ b/min}$
 Total respiratory rate $< 25 \text{ b/min}$
 $\text{P/F ratio} > 200$
 Respiratory rate/tidal volume (f/TV) < 105
 Heart rate $< 110/\text{min}$
 Systolic blood pressure $90 - 145 \text{ mmHg}$
 $\text{SpO}_2 > 95\%$
 $\text{pH} > 7.25$
 $\text{Hb} > 8$
 Temperature $< 38^\circ\text{C}$

PEEP = Positive end expiratory pressure, P/F ratio = Ratio of partial pressure of arterial oxygen to fraction of inspired oxygen, pH = acidity or alkalinity of blood, Hb = hemoglobin concentration in blood

3. EXTUBATION CRITERIA

Able to maintain patent airway
 Able to maintain adequate spontaneous ventilation
 Normal arterial oxygenation
 No immediate need for re-intubation
 No previous difficulty with intubation
 Haemodynamically stable
 Stable non-respiratory function
 Normal electrolyte values
 $\text{PEEP} < 10\text{mmHg}$
 $\text{FiO}_2 < 0.4$

(Durbin CG, Campbell RS, Branson RD 1999 Removal of the endotracheal tube. *Respiratory Care* 44: 85-90)

APPENDIX III

CRITERIA USED IN WEANING/DISCONTINUATION STUDIES TO DETERMINE WHETHER PATIENTS RECEIVING HIGH LEVELS OF VENTILATORY SUPPORT CAN BE CONSIDERED FOR DISCONTINUATION

Criteria	Description
Objective measurements	Adequate oxygenation (eg, $PO_2 \geq 60$ mm Hg on $FIO_2 \leq 0.4$; $PEEP \leq 5$ – 10 cm H_2O ; $PO_2/FIO_2 \geq 150$ – 300);
	Stable cardiovascular system (eg, $HR \leq 140$; stable BP; no or minimal pressors)
	Afebrile (temperature $< 38^\circ C$)
	No significant respiratory acidosis
	Adequate hemoglobin (eg, $Hgb \geq 8$ – 10 g/dL)
	Adequate mentation (eg, arousable, $GCS \geq 13$, no continuous sedative infusions)
	Stable metabolic status (eg, acceptable electrolytes)
Subjective clinical assessments	Resolution of disease acute phase; physician believes discontinuation possible; adequate cough

Hgb = hemoglobin; HR = heart rate; GCS = Glasgow coma scale.

(MacIntyre NR, Cook DJ, Ely EW, Epstein SK and task force 2002 Evidence-based guidelines for weaning and discontinuing ventilatory support. *Respiratory Care* 47: 69-90)

APPENDIX IV

CRITERIA USED IN SEVERAL LARGE TRIALS TO DEFINE TOLERANCE OF AN SBT

Criteria	Description
Objective measurements indicating tolerance/success	Gas exchange acceptability ($\text{SpO}_2 \geq 85\text{--}90\%$; $\text{PO}_2 \geq 50\text{--}60$ mm Hg; $\text{pH} \geq 7.32$; increase in $\text{PaCO}_2 \leq 10$ mm Hg);
	Hemodynamic stability ($\text{HR} < 120\text{--}140$ beats/min; HR not changed $> 20\%$; systolic BP $< 180\text{--}200$ and > 90 mm Hg; BP not changed $> 20\%$, no pressors required)
	Stable ventilatory pattern (eg, $\text{RR} \leq 30\text{--}35$ breaths/min; RR not changed $> 50\%$)
Subjective clinical assessments indicating intolerance/failure	Change in mental status (eg, somnolence, coma, agitation, anxiety);
	Onset or worsening of discomfort
	Diaphoresis
	Signs of increased work of breathing (use of accessory respiratory muscles, and thoracoabdominal paradox)

HR = heart rate; SpO_2 = hemoglobin oxygen saturation.

(MacIntyre NR, Cook DJ, Ely EW, Epstein SK and task force 2002 Evidence-based guidelines for weaning and discontinuing ventilatory support. *Respiratory Care* 47: 69-90)

APPENDIX V

MOST COMMONLY USED MODES OF PARTIAL VENTILATOR SUPPORT

Mode	Patient Work Adjusted By
SIMV	No. of machine breaths supplied (<i>ie</i> , the fewer the No. of machine breaths, the more spontaneous breaths are required)
PSV	Level of inspiratory pressure assistance with spontaneous efforts
SIMV + PSV	Combining the adjustments of SIMV and PSV
VS	PSV with a "guaranteed" minimal tidal volume (PSV level adjusts automatically according to clinician tidal volume setting)
VAPS(PA)	PSV with "guaranteed" minimal VT (additional flow is supplied at end inspiration if necessary to provide clinician VT setting)
MMV	SIMV with a "guaranteed" $\dot{V}_E$ (machine breath rate automatically adjusts according to clinician $\dot{V}_E$ setting)
APRV	Pressure difference between inflation and release (<i>ie</i> , the less the pressure difference, the more spontaneous breaths are required)

SIMV = synchronized intermittent mandatory ventilation; PSV = pressure support ventilation; VS = volume support; VAPS(PA) = volume assured pressure support (pressure augmentation); MMV = mandatory minute ventilation; APRV = airway pressure release ventilation.

(MacIntyre NR, Cook DJ, Ely EW, Epstein SK and task force 2002 Evidence-based guidelines for weaning and discontinuing ventilatory support. *Respiratory Care* 47: 69-90)

APPENDIX VI

AN EXAMPLE OF THE ISS SCORING SYSTEM

Region	Injury Description	AIS	Square Top Three
Head & Neck	Cerebral Contusion	3	9
Face	No Injury	0	
Chest	Flail Chest	4	16
Abdomen	Minor Contusion of Liver Complex Rupture Spleen	2 5	25
Extremity	Fractured femur	3	
External	No Injury	0	
Injury Severity Score:			50

APPENDIX VII

WEANING AND EXTUBATION PROTOCOL USED AT UNION HOSPITAL

1 WEANING PATIENTS from MECHANICAL VENTILATION

1. The consulting physician will give the instruction for weaning to commence.
2. Ensure that the following criteria are met before commencing with weaning:

- a. Patient haemodynamically stable with no inotropic support (except low dose Dobutrex)
- b. Patient has Glasgow Coma Scale of $> 5/10$, with a good cough reflex.
- c. $\text{PaO}_2 > 60$ mmHg on a FiO_2 of < 0.50
- d. $\text{SpO}_2 > 95\%$

3. Start weaning the patient, adhering to the following principles:

- a. Wean the set ventilatory rate to 4 breaths per minute in increments of 2 breaths at a time
- b. Once the rate is weaned, wean pressure support to 8 cmH₂O in increments of 2 cmH₂O at a time (Ensuring patient maintains a spontaneous Tidal Volume of 4 - 6 ml/kg).
- c. Once the above is reached, then only wean PEEP to 5 – 8cm H₂O
- d. NEVER wean PEEP before pressure support or respiratory rate, unless otherwise specified by the doctor
- e. Sedation and analgesic administration should be kept at a minimum, but keep patient comfortable and pain free.
- f. Wean at pace that patient is comfortable at without causing distress
- g. If patient is tachypneic, increase the set respiratory rate.
- h. If tidal volumes are low, increase pressure support

2 WEANING INTOLERANCE INDICATORS:

If patient exhibits any of the following signs, revert back to ventilation settings prior to onset:

- a. $\uparrow$ or $\downarrow$ in Heart Rate of > 20 beats/min from baseline
- b. $\uparrow$ or $\downarrow$ in Blood Pressure of > 20 mmHg from baseline
- c. $\uparrow$ in Respiratory Rate of > 10 above Baseline
- d. Tidal Volumes of < 250 ml
- e. $\uparrow$ in Minute Volume of > 5 L/min
- f. Diaphoresis
- g. Restlessness
- h. $\text{SpO}_2 < 90\%$
- i. $\text{PaO}_2 < 60$ mmHg

4. Once patient has been successfully weaned to the above parameters screening for spontaneous breathing trial should be performed daily

3 DAILY SCREENING CRITERIA FOR CPAP and EXTUBATION

1. Screen each patient that has weaned to parameters for the following:

- a. Patient awake and able to protect own airway.
- b. Able to cough on demand, or has good cough reflex during endotracheal suctioning
- c. Normal serum electrolyte values
- d. Haemodynamically stable with no inotropic support (except low dose Dobutrex)
- e. PEEP: 5 – 8 cmH₂O
- f. Pressure Support: ≤ 8
- g. Mandatory Ventilation Rate: ≤ 4 breaths / min
- h. Total Respiratory Rate : < 25 breaths/min
- i. PaO₂ / FiO₂ Ratio (P/F Ratio) > 200
- j. Respiratory rate / Tidal Volume (f / TV) < 105 L/min
- k. Heart Rate < 110 beat / minute
- l. Systolic Blood Pressure 90 – 145 mmHg
- m. SpO₂ > 95 %
- n. pH > 7.25 mmHg
- o. Hb > 8.0
- p. Temperature < 38 °C

- 2. If the patient meets the above criteria, a spontaneous breathing trial should be performed on **wall CPAP**.
- 3. Place patient on wall CPAP with a PEEP of 5 cmH₂O and FiO₂ of 0.4
- 4. Once the patient has passed the spontaneous breathing trial, he/she can be extubated with chest physiotherapy.

Notes

- 1 If the patient was ventilated for less than 72 hours, a breathing trial of 2 hours should be performed.
- 2 If the patient was ventilated for > 72 hours, had ARDS or multiple surgical procedures, the spontaneous breathing trial should be continued for 8 – 12 hours.
- 3 All sedation must be stopped prior to extubation.
- 4 Patients should not be extubated in the late afternoon or evening.
- 5 If the spontaneous breathing trial is failed, the patient should be placed back onto the last ventilator settings maintained prior to the breathing trial, and monitored for acceptable values.
- 6 The patient should only be screened for another spontaneous breathing trial the next morning
- 7 ONLY ONE (1) SPONTANEOUS BREATHING TRIAL TO BE DONE PER DAY

Spontaneous Breathing Trial will be failed if any of the following occur:

- a. Respiratory Rate > 35 breaths / minute
- b. SpO₂ < 90 %
- c. Heart Rate > 140 beats / minute or sustained ↑ or ↓ by more than 20 from baseline
- d. Systolic BP > 180 mmHg or < 90 mmHg
- e. Anxiety or Sweating
- f. pH < 7.25
- g. PaO₂ < 70 mmHg
- h. PaCO₂ < 35 mmHg or > 45 mmHg

APPENDIX VIII

CHECKLIST FOR WEANING AND EXTUBATION USED AT UNION HOSPITAL

(Laminated copy to be shown to physician each morning)

1. WEANING CRITERIA TEMPLATE UNION HOSPITAL ICU

Haemodynamically stable with no inotropic support except low dose Dobutrex
 GCS of $> 5/10$
 Good cough reflex
 $\text{PaO}_2 > 60\text{mm Hg}$
 $\text{FiO}_2 < 0.5$
 $\text{SpO}_2 > 95\%$

2. DAILY SCREENING CRITERIA FOR SBT AT UNION HOSPITAL

Patient awake and able to maintain own airway
 Able to cough on demand, or good cough reflex with suctioning
 Normal serum electrolyte values
 Haemodynamically stable with no inotropic support except low dose Dobutrex
 $\text{PEEP} = 5 - 8 \text{ cm H}_2\text{O}$
 Pressure support < 8
 Mandatory ventilation rate $< 4 \text{ b/min}$
 Total respiratory rate $< 25 \text{ b/min}$
 $\text{P/F ratio} > 200$
 Respiratory rate/tidal volume (f/TV) < 105
 Heart rate $< 110/\text{min}$
 Systolic blood pressure $90 - 145 \text{ mmHg}$
 $\text{SpO}_2 > 95\%$
 $\text{pH} > 7.25$
 $\text{Hb} > 8$
 Temperature $< 38^\circ\text{C}$

3. EXTUBATION CRITERIA

Able to maintain patent airway
 Able to maintain adequate spontaneous ventilation
 Normal arterial oxygenation
 No immediate need for re-intubation
 No previous difficulty with intubation
 Haemodynamically stable
 Stable non-respiratory function
 Normal electrolyte values
 $\text{PEEP} < 10\text{mmHg}$
 $\text{FiO}_2 < 0.4$

APPENDIX IX

PATIENT DATA COLLECTION SHEET USED AT UNION HOSPITAL

1. WEANING CRITERIA TEMPLATE UNION HOSPITAL ICU

DATE				
Haemodynamically stable with no inotropic support except low dose Dobutrex				
GCS of > 5/10				
Good cough reflex				
PaO ₂ >60mm Hg				
FiO ₂ < 0.5				
SpO ₂ > 95%				

2. DAILY SCREENING CRITERIA FOR SBT AT UNION HOSPITAL

DATE				
Patient awake and able to maintain own airway				
Able to cough on demand, or good cough reflex with suctioning				
Normal serum electrolyte values				
Haemodynamically stable with no inotropic support except low dose Dobutrex				
PEEP = 5 – 8 cm H ₂ O				
Pressure support < 8 cm H ₂ O				
Mandatory ventilation rate < 4 b/min				
Total respiratory rate < 25 b/min				
P/F ratio >200				
Respiratory rate/tidal volume (f/TV) <105				
Heart rate < 110/min				
Systolic blood pressure 90 – 145 mmHg				
SpO ₂ > 95%				
pH > 7.25				
Hb > 8				
Temperature < 38°C				

3. TABLE 3: EXTUBATION CRITERIA

DATE				
Able to maintain patent airway				
Able to maintain adequate spontaneous ventilation				
Normal arterial oxygenation				
No immediate need for re-intubation				
No previous difficulty with intubation				
Haemodynamically stable				
Stable non-respiratory function				
Normal electrolyte values				
PEEP < 10mmHg				
FiO ₂ < 0.4				

APPENDIX X

SUBJECT INFORMATION SHEET AND CONSENT FORM

Dear patient,

Hello, I am Natascha Plani. I am registered as a postgraduate student at the University of the Witwatersrand. As part of a Masters of Science degree in physiotherapy, I am studying the most effective way of taking a patient off the ventilator (or breathing machine). This is called weaning.

Many patients who are admitted to the Intensive Care Unit (ICU) need some help breathing during the initial part of their illness. This is done with the help of a mechanical ventilator. As their health improves, we let them do more and more of the breathing on their own, with less help from the ventilator. This process is called weaning.

If weaning takes too long, patients run the risk of infections, and end up spending a longer period of time in ICU. This can lead to weakness and even depression.

On the other hand, if weaning is rushed and the ventilator removed too early, patients might not be strong enough to breathe on their own, and the ventilator may need to be replaced.

The study aims to see if using a specific protocol (or recipe) is better than each doctor using his or her own strategies.

The study will look at how long it takes to remove the patients from the ventilator, and if any patients need to be ventilated again after removal of the machine.

All patients admitted to this unit following trauma and placed on a ventilator for three days or longer, were asked to take part in this study, as long as they did not have heart problems.

The method used to wean you from the ventilator depended on whether you were assigned to Phase I (where the doctors wean individually) or to Phase II (where the doctors use the weaning protocol).

The patients in Phase I (the first part of the study) were allocated to this group as they were admitted to the ICU. For this group, the doctors independently gave orders to wean patients from the ventilator.

The next set of patients was allocated to Phase II of the trial as they were admitted to ICU. In the Phase II group, the doctor was shown a form each morning, indicating your progress in terms of breathing on your own in the form of tick boxes. Using this information, the doctor decided on weaning you according to a set of rules (weaning protocol) for the nursing staff to follow. The aim of this weaning protocol was to remove you from the ventilator as soon as possible, but still have many safety features built in to warn us if we were moving too fast.

The weaning protocol was developed for our unit in May of 2004 and was agreed upon by all the doctors involved in patient care in the ICU. Most doctors are applying the principles of the protocol, but just not in a formal way. This study wants to see if there are any benefits to adopting a more formal approach.

You were closely monitored for any changes in your condition. If at any time the doctor felt that you needed different care, you would have been withdrawn from the study immediately.

As you are now conscious and can make decisions yourself, I need your consent to use the information gathered about your responses to the weaning protocol in my study. Your consent will be greatly appreciated. If you decide not to agree to have your information used, you will be withdrawn from the study, and we will still give you the best possible care.

More information is available on request from the researcher, Natascha Plani, who can be contacted on 082-448-6673 at all times.

CONSENT

I understand the information above. I had a chance to discuss the study and any questions I had have been answered.

I understand that by signing this document I give consent for my information to be used in this study.

I, _____, consent to the inclusion of my information in the study.

Signature

Signature researcher

Witness

Date

Date

Date

APPENDIX XI

DOCTORS CONSENT TO PARTICIPATE IN STUDY

THE USE OF A WEANING PROTOCOL TO WEAN AND EXTUBATE PATIENTS FROM MECHANICAL VENTILATION

Dear Doctor

As part of my Masters degree in Physiotherapy at the University of the Witwatersrand, I am required to complete a patient study.

I have chosen as my topic to evaluate the difference in total ventilator days between patients weaned from mechanical ventilation strictly according to the weaning protocol (designed for the Union Hospital in 2004 – copy enclosed), and patients weaned according to individual methods by doctors.

The study will take the form of a randomised controlled trial, with patients assigned to either the control group (weaned according to individual methods) or the experimental group (weaned according to the weaning protocol).

All patients ventilated for a period of longer than eight days, with no cardiac dysfunction and no unrecoverable head injury will be included in the study if the relatives sign informed consent.

For the experimental group, you will be shown a checklist (copy enclosed) daily, consisting of criteria deeming the patient fit to start on the weaning protocol. The weaning protocol will be initiated on your order.

If at any time you consider the weaning protocol unsuitable to the patient, the patient will be immediately withdrawn from the study, and ventilation commenced at the level you wish.

For the control group, you will wean and extubate patients according to your personal choice. The unit manager or shift leader will inform you as to which group the patient has been assigned to, and show you the checklist each morning.

Your participation in this study will be greatly appreciated.

Yours sincerely

Natascha Plani

CONSENT FOR STUDY – WEANING PROTOCOL

Dr J Goosen

Dr F Plani

Dr S Moeng

Dr A Arain

Dr D Somwe

Dr A Kok

Dr A Stavrides

Dr B Botha

APPENDIX XII

ETHICS CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

R14/49 Plani

CLEARANCE CERTIFICATE

PROTOCOL NUMBER M060361

PROJECT

The Use of a Weaning Protocol to Effectively Liberate Patients from Mechanical Ventilation

INVESTIGATORS

Ms N Plani

DEPARTMENT

Department of Physiotherapy

DATE CONSIDERED

06.03.31

DECISION OF THE COMMITTEE*

Approved unconditionally

+

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

DATE 06.06.03

CHAIRPERSON
(Professor M Vorster)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof C Eales

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX XIII

LETTER FROM UNION HOSPITAL MANAGEMENT CONSENTING TO STUDY BEING CONDUCTED AT UNION HOSPITAL

We understand and approve the following study at the Union Hospital, after having read the research proposal included with this letter.

Researcher : Natascha Plani

Title : The use of a Weaning Protocol to Facilitate Effective Liberation from Mechanical Ventilation

We understand that all patient confidentiality will be maintained, and that there will be no additional costs to the hospital or to the patients.

Signature Hospital Manager/ Head of Unit – Union Hospital