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### Protocolised Versus Non-Protocolised Weaning From Mechanical Ventilation in Adult Critical Care

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#### Author

**Gavin G. Lavery, MD, FFARCSI, FJFICM**  
*ICU Consultant Regional Intensive Care Unit  
Royal Hospitals; and Clinical Director  
HSC Safety Forum Public Health Agency  
Belfast, Northern Ireland*  
[gavin.lavery@belfasttrust.hscni.net](mailto:gavin.lavery@belfasttrust.hscni.net)

**Bronagh Blackwood, PhD, M.Sc**  
*Lecturer  
School of Nursing and Midwifery, Queen's University Belfast  
Belfast, Northern Ireland*

Although mechanical ventilation (MV) provides physiological benefit during critical illness, it may also predispose to respiratory infection, lung injury, cardiovascular instability, limited communication, the need for sedation, and delirium. Reduction and discontinuation of ventilator support (a process termed weaning) as soon as the patient can sustain spontaneous breathing, is an important goal in critical care. Patients in whom weaning is difficult or prolonged have higher rates of mortality (Mancebo 1996), ventilator-associated pneumonia (Vincent et al. 1995), and lung injury. Timely and safe cessation of ventilation facilitates desirable outcomes for patients, clinicians and the healthcare system.

In the UK, weaning is usually a collaborative task. Nurses use general guidance from medical staff to advance or delay weaning according to the patient's response. Often there are no specific (written) criteria to determine the best time to start weaning and no formal guidelines for reducing support. Nurses' engagement in weaning may be influenced by experience, personal preference or the ICU culture. The overall result is wide variability in weaning practices.

Deciding when and how to wean a patient is influenced by the judgment and experience of the doctor. Predictions, based on judgment alone, have low sensitivity and specificity – the ability to predict success and failure. Until recently, there have been few weaning standards based on sound data and so a wide variation exists in weaning practice. Weaning methods include:

- Intermittent T-piece trials,
- Reduction of synchronised intermittent mandatory ventilation or pressure support ventilation, and
- Spontaneous breathing through a ventilator circuit with reducing continuous positive airway pressure.

Combinations of these and newer modes, such as bi-level, positive airway pressure are also used. There is little evidence of superiority for any of these methods, although synchronised intermittent mechanical ventilation may be least effective.

#### What is a Weaning Protocol?

There is increasing interest in promoting more consistent weaning practices within ICU by developing protocols providing structured guidance. Protocols should improve efficiency of practice by using expert consensus to reduce variation produced by the application of individual judgment and experience. They typically have up to 3 components (Figure 1).

While most weaning protocols or guidance used in ICUs are written, advances in microprocessor technology have enabled development of computer-assisted management of ventilation and weaning. These systems measure and interpret respiratory data in real time and provide continual adjustment of the level of assistance within targeted values. By enabling 'interaction' between the patient and the ventilator, such closed loop systems may improve tolerance of ventilation and reduce work of breathing (Burns et al. 2008). Several commercial computerised ventilation and weaning programmes have been developed, including adaptive support ventilation,

proportional assist ventilation and pressure support ventilation (Rose et al. 2007) [SmartCare].

## Evidence from the Literature

There is evidence suggesting that weaning protocol use improves outcomes, and/or reduces the duration of ventilation (Marelích et al. 2000; Strickland Jr and Hasson 1993). From 2000 to 2003, two of the largest general adult Intensive Care Units (ICU) in our region collaborated in a study of protocolised weaning from mechanical ventilation, the first in the UK to use a prospective, controlled comparison of the effectiveness of weaning protocols on patient outcomes (Blackwood et al. 2006). The study found that admission APACHE II score and diagnostic category were significant predictors for MV time, intubation time and ICU stay, but the use of protocolised weaning was not - findings that failed to support previous studies. There are several potential reasons for such disagreement.

It has been reported that patients who successfully complete a spontaneous breathing trial (SBT) can be extubated two hours after determining their ability to wean rather than having a stepwise reduction in ventilatory support (Ely 2001). Studies incorporating daily assessments of readiness to wean and SBTs in their protocols

demonstrated significant reductions in MV time (Marelích et al. 2000; Grap et al. 2003; Saura et al. 1996). Our weaning protocols did not incorporate an SBT due to lack of ICU consultant agreement (Blackwood et al. 2004). Reasons included the perceived need to maintain control of weaning in a widely variable group of patients and unease about protocols being applied by inexperienced staff.

Randomised controlled trials which have shown significant reductions in MV times (Marelích et al. 2000) based their intervention on structured protocols versus "no weaning unless directed" - a bipolar manipulation representing two extremes of a continuum which makes detection of differences more likely. This type of manipulation is clearly suited to ICUs where patients are managed by 'attendings' and where nurses do not progress weaning without a medical order. In contrast, in our units (as in most of the UK) there is closer collaboration on weaning between the 'on-site' ICU consultants/doctors-in-training and nurses. Some nurses are proactive in reducing ventilatory support. In most UK ICUs, there is frequent medical review during the day. This was 'usual practice' for both ICUs in our study. These factors may have resulted in the manipulation being less bipolar than in studies suggesting protocolised weaning reduced weaning time or time on MV.

Finally, the intervention guidelines dictated that having determined patients' readiness to wean using a daily screening tool, nurses had to obtain agreement from the duty consultant before proceeding to wean. Hence, it is possible that, at times, usual practice (experienced nurses autonomously reducing support) may have been inhibited by the constraints of the protocol.

Thus, the nature of the (weaning) intervention, the pre-existing ICU culture and how the intervention "fits" into existing practices may all be important influences on the success (or failure) of protocolised weaning.

A recent systematic review assessed evidence from randomised and quasi-randomised controlled trials comparing protocolised versus non-protocolised weaning on the duration of MV (via a nasotracheal or orotracheal tube) in critically ill adults (Blackwood et al. 2010; Blackwood et al. 2011). From a total of 6,016 citations retrieved from electronic databases, 14 trials were reviewed in full and further information was obtained on seven unpublished trials. 11 trials, involving 1,971 patients met the inclusion criteria.

In these 11 trials, protocolised weaning led to statistically significant reductions in geometric mean values; 25% for the total duration of mechanical ventilation; 78% for weaning duration, and 10% for ICU LOS. Data from a large epidemiological study (N = 5183) of characteristics and outcomes in patients receiving mechanical ventilation (Esteban et al. 2002) showed a mean value for the risk of duration of mechanical ventilation of 144 hours. Applying the effect estimates in the systematic review to these data, protocolised weaning would reduce the assumed risk for:

- total duration of mechanical ventilation from 144 hours to 108 hours (95% CI 87.8 - 131 hours);
- weaning duration from 96 hours to 21 hours (95% CI 6.7 - 66.2 hours);
- and ICU LOS from 11.2 days to 10.1 days (95% CI 9.07 - 10.97 days).

Whilst the above appears to support a benefit from protocolised weaning, the review authors were cautious in their conclusions. While the included trials were methodologically sound and had a low risk of bias based on GRADE (Guyatt et al. 2008), the quality of evidence was low; mainly due to the significant heterogeneity among the included studies, particularly in relation to total duration of MV ( $I^2 = 58\%$ ), and weaning duration ( $I^2 = 97\%$ ). Trial methodology was limited by the inability to blind clinical staff to the method of weaning, potentially leading to biased estimates of treatment effect. However, following assessment of the blinding of those collecting outcome data, the risk of bias was viewed as low in eight out of 11 included studies. Six of 11 studies originated in the US, potentially limiting the applicability or relevance of the findings to other healthcare systems.

The use of weaning protocols did not adversely impact on ICU or hospital mortality. Protocol use did not appear to increase the frequency of adverse events including reintubation, self-extubation, tracheostomy and protracted weaning. However, the meta-analysis was underpowered to investigate the impact of the interventions on these infrequent outcomes.

## Clinical Implications

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Ventilator weaning is a complex process. The discordance in results among studies may be due to contextual factors (differences in patient populations and usual practice within units) or intervention factors (differences in determining readiness to wean; ventilator modes and parameters used in weaning protocols). Clearly, weaning a surgical ICU patient following elective major surgery is often a more straightforward process than weaning a medical ICU patient with respiratory failure due to acute exacerbation of chronic pulmonary disease.

Another important contextual factor is the use of the 'usual care' group as a control in randomised trials (Thompson and Schoenfeld, 2007). Usual care in ICUs may encompass a wide variety of practices. It may be based on high-level evidence, representing best practice, or it may be highly variable, including unfavourable practices. If usual care in an ICU involves a consistent high quality approach to weaning, albeit not formally laid out in guidelines, then it may not differ greatly from that delivered by a weaning protocol. The study by Marelich et al. (2000) was conducted in two ICUs with differing weaning practice and found that the surgical ICU, but not the medical ICU, had a standardised approach to weaning. While combined data demonstrated protocol use decreased the duration of MV, unit data, analysed separately, showed a statistically significant reduction only in the medical ICU (where no previous standard approach to weaning existed). Similarly, Rose et al. (2008) attributed their lack of effect to the usual practice in their ICU: Unlimited assessment of weaning by experienced autonomous nurses; a 1:1 nurse to patient ratio supported by 24-hour medical staff and twice-daily intensivists rounds.

## **Conclusion**

Protocolised weaning may decrease total duration of MV, weaning and ICU length of stay due to consistent application of objective criteria for determining readiness to wean and a guided approach to reducing support. Reduced duration of MV may lead, in turn, to reduced requirements for tracheostomy. However, in settings where objective criteria and guided approaches are already incorporated into standard weaning practice, the beneficial effects of protocolised weaning on the above may not be realised.

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