

Should Weaning Protocols Be Used With All Patients Who Receive Mechanical Ventilation?

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Ventilator weaning protocols have the potential to expedite the weaning process and have been shown to reduce weaning time and the duration of mechanical ventilation in several studies. However, other studies have found no benefits from weaning protocols, and they may be particularly superfluous in highly staffed and structured intensive care units. Furthermore, for a protocol to improve outcomes, the clinicians must have a high rate of adherence to the protocol. Weaning protocols might improve patient care and outcomes, but their implementation should be based on local clinical characteristics and needs, and accompanied by an intensive education effort and measurement of adherence and outcomes. Key words: ventilator, weaning, algorithm, decision support, weaning parameters, weaning predictors, protocol-directed weaning, guidelines. [Respir Care 2007;52(5):609–619. © 2007 Daedalus Enterprises]

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We generally do not know what is right in any absolute sense. We only know, when we have good evidence, what works better than other approaches.

—Alan H Morris MD

Introduction

The weaning process may account for 56–92% of the total duration of mechanical ventilation.¹ Prolonging mechanical ventilation may increase the risk of adverse events, particularly nosocomial pneumonia.² Conversely, extubation failure is also associated with adverse outcomes, including higher hospital mortality, longer hospital stay, higher costs, and greater need for tracheotomy and transfer to post-acute care.³ Therefore, important goals are to recognize weaning readiness and to manage the weaning process efficiently. But intensive care units (ICUs) are complex places. So the problem is, how do humans react to complexity and what is the best way to avoid the errors it creates?

Pro: Weaning Protocols Should Be Used With All Mechanically Ventilated Patients

Problems With Ad Hoc Human Decision Making

Information Overload. The human capacity to store and process information is limited to about 4 variables at a time.⁴ Furthermore, humans possess a propensity to adopt one belief on the basis of less evidence than would be required to believe in an alternative.⁵ Morris estimated that there are more than 236 different variables involved in the care of a typical patient with acute respiratory distress syndrome (ARDS).⁶ Yet, faced with the challenge of adjusting only 4 variables (inspiratory-expiratory ratio, ventilatory rate, inspiratory pressure, and positive end-expiratory pressure) in pressure-controlled inverse-ratio ventilation, experienced ICU physicians did not manage mechanical ventilation as well as did a computerized protocol.⁷

Signal-to-Noise Ratio. Related to the information-overload problem is the issue of signal-to-noise ratio. To detect an association between an input (signal) and an output requires that the signal of interest can be distinguished from other extraneous signals (noise). In the context of this discussion, the signal-to-noise ratio refers to the ratio of useful information to false or irrelevant data. Both the caregiver and the patient contribute to noise; the caregiver by inconsistent decisions and the patient by uncontrollable factors such as disease severity and duration. Given the large background noise in the ICU, the relatively small effects of many clinical interventions produce a low sig-

nal-to-noise ratio and make inferences about the efficacy of a treatment difficult to formulate. This is especially true for uncontrolled, nonexperimental clinical care. Even in controlled experiments, the placebo effect can be associated with a 43–75% positive clinical response, which can produce larger changes in patient outcome than are expected from the study intervention.⁶ Put simply, it is difficult to learn from our routine clinical experience without a systematic effort to do so.

Lack of Standardized Terminology. Medical terminology lacks specificity and standardization. Even in the limited field of mechanical ventilation, it is common to find different meanings for the same term and different terms for the same meaning.⁸ Lack of standardized terminology can lead to different interpretations of the literature, which may lead to unnecessary variation in clinical practice. Examples of this include mechanical ventilation studies, conflicting use of hemodynamic variables, and inconsistent use of terms in fluid and electrolyte assessment.⁶

Limited Experience. Daily decisions made by individuals are limited to each individual's experience. Individual experience augmented by consultation experts (in person or via a reference text) is really team decision making. To the extent that a team of experts makes better decisions than a lone individual, any tool that condenses and makes available such group expertise is a powerful resource (given the appropriate kind of decision to make, as every experienced facilitator knows that some decisions are much more accurately made by individual content experts than by groups). This power can be experienced by using the Internet, with even informal resources such as Wikipedia or Consumer Reports.

Failure to Act. Even when standardized procedures are in place, clinicians often do not follow them.^{9,10} Common objections include claims that patients are unique or more severely ill than anticipated by the standards. At times there appears to be no rational basis for failure to act according to what are apparently obvious indications to do so. Namen et al found that when neurosurgeons were informed of the positive results of spontaneous breathing trials (SBTs), they refused to request extubation in 50–87% of those patients.¹¹ General barriers to adherence include lack of awareness, familiarity, or agreement with the protocol, and the inertia of previous practices.¹²

Practice Variability. Patterns of practice in academic (and other) medical centers are often idiosyncratic and guided more by opinion and local supply of resources than by science.¹³ Unwarranted practice variations are those that cannot be explained by type or severity of illness or by

patient preferences.¹³ Clinical practice variability has at least 2 sources:

1. Physicians demonstrate within-decision-maker inconsistency in their use of physiologic data for decision making.

2. Physicians often fail to adhere to reputable standards.¹⁴

For example, low adherence has been reported for the National Asthma Education and Prevention Program Expert Panel's Guidelines for the Diagnosis and Management of Asthma.¹⁵ Given the above-discussed problems inherent in human decision making, which lead to variations in clinical practice for a given patient population, and given the obvious differences in patient outcomes, then practice variation implies error. If we postulate a strong correlation between treatment and outcome, it follows that poor outcomes must be correlated with poor treatment. And since there is practice variation for a given patient profile, some treatment is therefore good and some bad. (Of course, there may be a weak or absent correlation between treatment and outcome, in which case we are forced to admit that we don't know what we are doing.) Thus, high practice variability implies high error rates. It also follows that error is avoidable if good treatment can be identified and practiced.

Guidelines Versus Protocols

The way to identify and practice good treatment is to develop systematic standardized procedures. Such procedures have been referred to as "guidelines" or "protocols" in the literature. They have been shown to reduce variation and increase adherence to evidence-based interventions and may reduce error, although this has not been formally studied.¹⁴

It is important to make a distinction between guidelines and protocols. Failure to do this is the basis for a lot of misunderstanding and needless resistance. The medical subject headings in Ovid (www.ovid.com) define a guideline as "a set of statements, directions, or principles presenting current or future rules or policy," and a protocol as "a precise and detailed plan for the study of a medical problem or for a regimen of therapy."

Guidelines are general statements. For example, the National Heart Lung and Blood Institute/Hoescht Marion Roussel guideline for controlling hypertension in older women reads, "If the first drug is not tolerated, substitute a different drug from another class."¹⁴ Guidelines omit important details and allow different decisions by different clinicians for the same clinical scenario. Decision-makers must fill in the gaps with their judgment, background, and experience.

A good protocol is not just more explicit than a guideline, it must be "adequately explicit."¹⁴ An adequately explicit protocol provides specific rules for decision mak-

ing, based on patient data. For example, "If the change in P_{aO_2} is > 10 mm Hg, and the time interval is < 2 hours, and the fraction of inspired oxygen is > 0.8 , and positive end-expiratory pressure is < 15 cm H_2O , then increase positive end-expiratory pressure by 2 cm H_2O ." Such a rule, if adhered to, must lead to the same decision by multiple clinicians.

Morris and colleagues judge a protocol to be adequately explicit when clinicians accept and carry out over 90% of protocol instructions.¹⁴ In practice, paper-based versions of any but the simplest protocols *cannot* be made explicit enough.¹⁶ Adequately explicit *computerized* protocols contain the greatest detail. When used as open-loop control systems (ie, decision support only), computerized protocols may lead to the upper limit of achievable uniformity of clinician decision making.¹⁴ Closed-loop control with computerized protocols eliminates human decision making altogether.¹⁷

Understanding the difference between guidelines and adequately explicit protocols is crucial for logical debate. Guidelines may be what people have in mind when they argue against "cookbook medicine" (ie, treating all patients the same way regardless of the need for individualized care). Some would suggest, however, that a cookbook approach is just what we need:

The best chefs may, through trial and error, create marvelous meals without recipes. But many creations will be flops. We have cookbooks, in part, because most chefs do not have the time or resources to experiment. They want the best consistent outcomes. Recipes may stifle some creativity, but they will give an acceptable result most of the time, if they are good. The worst that happens in cooking, if an experiment goes bad, is the waste of a few ingredients. In medicine, a failed experiment is a bad outcome. Most patients will choose a proven recipe over risking an experiment that could result in a better outcome but is more likely to result in a worse one.¹⁸

Metaphors aside, the only logical way to argue against the decision of an adequately explicit protocol is on the basis of either scientific evidence or (in lieu of evidence) expert consensus. Indeed, such objections, when captured (especially with a computerized system) and analyzed, provide the basis for evolving better protocols. This systematic approach to learning from experience may be the strongest argument of all for protocols.

Criticism of protocol weaning is really a subset of the criticism of evidence-based medicine in general. Critics of evidence-based medicine tend to see medicine as a, "craft . . . in which individual expertise and technique are allowed to shine through and ultimately result in a higher standard of patient care."¹² Aside from the key philosoph-

ical objections raised below, critics of evidence-based medicine also fear that traditional health-care professionals may be replaced by less expensive, less skilled workers. In addition, the use of third parties using guidelines, reinforced by financial or legal incentives, might curtail treatment choice and limit practitioners' autonomy.¹² One author has gone so far as to call evidence-based medicine "a dangerous delusion . . . and a potentially lethal weapon in the hands of misguided regulators and reformers."¹⁹

Benefits of Protocols

Enabling Rigorous Clinical Research. The essence of any satisfactory experiment is that it should be reproducible.²⁰ Protocols are the means to achieve reproducibility by stabilizing the decision making process. The large sample sizes required of many clinical trials frequently necessitate involving many centers over several years. These requirements introduce at least 2 serious challenges to stabilization:

1. Changing co-interventions that naturally occur over time
2. Faltering interest and, hence, decreasing adherence among participating clinicians¹⁴

Computerized protocols offer a solution that could support clinical trials in multiple institutions with adequately explicit methods.⁷ Computerized protocols offer 3 benefits for research:

1. Precise description of patient care (ie, the rules of decision making)
2. Assurance of equal intensity of care
3. Common intermediate end points (eg, therapy regulated to produce the same P_{aO_2} and pH)¹⁴

Morris outlined both the barriers to computerized protocol use and the important steps in protocol development.²¹

Increased Adherence to Evidence-Based Interventions and Reduced Practice Variability. Protocols provide a link between efficacy trials and clinical practice. They can be seen as a mechanism to implement evidence-based medicine. Knowing what to do and how to do it are often 2 different problems. One example is the persistently low adherence to the Guidelines for the Diagnosis and Management of Asthma from the National Asthma Education and Prevention Program.²² A national survey of United States pediatricians showed that only 35% followed widely publicized guidelines, including the asthma guidelines.²³ However, when asthma guidelines were turned into an adequately explicit protocol as an "algoform" (a combination algorithm and patient record that shows the decisions that link patient-assessment data and specific treatments), adherence to evidence-based interventions was facilitated and patient outcomes improved.²⁴

Frank Zappa is reported to have said that "Without deviation from the norm, progress is not possible."²⁵ It is clear that something as basic as biological evolution depends on genetic variability. But the key to the success of evolution is that *Nature notices and rewards useful variation by means of natural selection*. In contrast, most inadvertent clinical variation goes unnoticed. Many purposeful clinical interventions have relatively small effects (odds ratios of ≤ 3.0) that require systematically conducted clinical trials to be recognized.¹⁶ This suggests that small changes in outcomes (good or bad) will be missed if not examined within the systematic framework of an adequately explicit protocol. Thus, it is not variability per se, but *noticing variability* of outcome from standardized treatment that leads to innovation. The obvious example of success here is the "continuous quality improvement" experience in industrial manufacturing.

Everyone on both sides of the protocol argument would agree that clinicians need to respond to the patient's individualized expression of disease. But the pro argument is quite simple and logical on this point:

1. Patients express their individualized needs through their clinical data.
2. Every single iteration of an adequately explicit protocol yields at least one standardized decision *based on the patient's data*.
3. The patient's treatment regimen is the sum of all the standardized decisions over time.
4. *Therefore, the patient's therapy is individualized.*¹⁴

In addition, ethical obligations to deliver individualized care to the research subject are supported as the requirement to reduce differential bias in the experiment is met.²⁶

Improved Outcomes. The evidence that guidelines and explicit decision-support systems improve health care outcomes is consistent with results from systems approaches in other fields.²⁷ Systems approaches to error control, through failure mode and effect analysis and root cause analysis, have been useful in many industries. System stabilization through reduction in practice variation is a prerequisite for continuous quality improvement.²⁸ This is a central theme, for example, in the application of Six Sigma methodology to health care.²⁹

Improved Safety. Human error is unavoidable and costly. For example, an adverse drug event is associated with a significantly prolonged stay, increased economic burden, and an almost 2-fold increased risk of death.³⁰ In a study of drug-related morbidity and mortality from drug-related problems, Ernst and Grizzle found the mean cost for a treatment failure was \$977, and for a combined treatment failure and a resulting new medical problem was \$1,488.³¹ Overall, the cost of drug-related morbidity and mortality exceeded \$177 billion in 2000.³¹

WEANING PROTOCOLS FOR ALL VENTILATED PATIENTS?

Table 1. Trials of Ventilator Weaning Protocols

First Author	Year	n	Groups*	Duration of Ventilation (d)	Hospital Stay (d)
Randomized Controlled Trials					
Ely ³⁵	1996	300	Physician-directed vs not physician-directed	4.5 vs 6 (p = 0.003)	NS
Kollef ³⁶	1997	357	Physician-directed vs not physician-directed	2.9 vs 4.3 (p = 0.03)	NS
Marellich ³⁷	2000	335	Physician-directed vs not physician-directed	2.8 vs 5.2 (p = 0.001)	NR
Shultz ³⁸	2001	223	Physician-directed vs not physician-directed	NS	NR
McKinley ^{†39}	2001	67	Physician-directed vs not physician-directed	NS	NS
Namen ¹¹	2001	100	Physician-directed vs not physician-directed	NS	NS
Randolph ⁴⁰	2002	182	Physician-directed vs not physician-directed		NS
Krishnan ⁴¹	2004	299	Physician-directed vs not physician-directed	NS	NR
Hendrix ⁴²	2006	20	Computer-driven (closed-loop) vs physician-directed	NS	NR
Lellouche ⁴³	2006	144	Computer-driven (closed-loop) vs physician-directed	7.5 vs 12 (p = 0.01)	NS
Nonrandomized Trials (Cohort or Observational)					
Foster ⁴⁴	1984	63	Protocol vs concurrent controls	0.45 vs 0.75 (p < 0.01)	NR
Wood ⁴⁵	1995	284	Protocol vs historical controls	NS	NS
Saura ⁴⁶	1996	101	Protocol vs historical controls	10.4 vs 14.4 (p < 0.05)	NR
Djunaedi ⁴⁷	1997	107	Protocol vs historical controls	NS	NR
Burns ⁴⁸	1998	409	Protocol vs historical controls	NS	NS
Horst ⁴⁹	1998	893	Protocol vs historical controls	4.7 vs 7.1 (p < 0.001)	NR
Ely ⁵⁰	1999	1,167	Observational/temporal trends after protocol	NS	NR
Dries ⁵¹	2004	650	Observational/temporal trends after protocol	3 vs 5 (p < 0.001)	NR
Tonnelier ⁵²	2005	104	Protocol vs historical controls	16.6 vs 25.5 (p = 0.02)	NR

*Non-physician directed may include open-loop computerized protocols

†Subgroup analysis of a larger, prospective controlled trial

NS = nonsignificant difference

NR = not reported

Clinical error rates range from 1% to 50%.²⁷ Even when the error rate was only 1%, every patient in one academic ICU was subjected to an error that threatened life or limb *every other day*.³² A systems approach, rather than educational programs, would be needed to improve the performance of caregivers who already perform correctly 99% of the time.¹⁶ Explicit decision-support tools increase the signal-to-noise ratio in clinical practice and may enhance our ability to prevent errors or at least recognize them early enough to minimize adverse effects. Strong evidence suggests that some computer-based clinical decision-support systems can improve physician performance.³³ Computerized protocols improved clinical outcomes in hospital pharmacy and infectious disease departments, and in both out-patient and in-patient hospital practice.²⁷

Enhanced Education. Critics of evidence-based medicine suggest that standardization may lead to de-skilling practitioners, because following protocols will encourage clinicians to stop using clinical judgment and treat all patients as if they were interchangeable.¹² However, explicit decision-support instruments can be effective teaching tools. Such tools specify the important variables to be

considered and the rules for using them to make decisions. This approach is often lacking in traditional health-care education programs. To be fair, validated, evidence-based algorithms are available for only a very limited set of clinical procedures. So far, only such interventions as mechanical ventilation, antibiotic choices, intravenous fluid therapy, and hemodynamic support have been addressed with explicit support tools.²⁷ Computerized systems offer the advantage of being able to explain the rationale for the decisions they make when queried by the user,³⁴ which provides additional educational support.

Weaning From Mechanical Ventilation; Literature Review

Controlled Trials. Table 1 lists 19 trials, spanning 22 years, that have examined the use of protocols for weaning from mechanical ventilation, and have reported the duration of mechanical ventilation.^{11,35–52} Three additional trials reported “weaning time” but not duration of mechanical ventilation.^{53–55} There have been objections to some of the positive studies (which will be mentioned in the con argument below).⁵⁶ In addition, there have been trials that

showed negative results, and those studies have generated objections as well. For example, the study by McKinley et al failed to show a difference in survival or hospital stay but did document less ventilator-induced lung damage and multiple-organ failure in the computerized-decision-support group.³⁹ In addition that group had significantly less exposure to potentially toxic oxygen levels (ie, $\geq 60\%$). Finally, the “control group” in this study started using permissive hypercapnia as the trial progressed, potentially confounding the definition of “usual care.” The study by Randolph et al did not control for the use of sedation, which is known to affect weaning rate.^{40,57} Other problems with that study include the fact that protocol adherence was only 66% and extubation was delayed > 4 hours for 25 of the protocol patients. The study by Krishnan et al⁴¹ has generated several objections about the study design and how the data should be interpreted.^{58,59}

Other Supporting Research

Ely et al summarized the results of 9 nonrandomized trials published between 1984 and 1998. These authors (all well known experts on the topic) concluded that the results of those studies were generally consistent with the results of randomized controlled trials that have found statistically significant reductions or trends in the duration of mechanical ventilation, ICU stay, and other favorable outcomes, such as fewer blood gas analyses.⁶⁰ Ely et al recommended that “ICU clinicians utilize protocols for liberating patients from [mechanical ventilation], in order to safely reduce the duration of [mechanical ventilation].” That same year (2001), a collective task force facilitated by the American College of Chest Physicians, the American Association for Respiratory Care, and the American College of Critical Care Medicine developed evidence-based guidelines for weaning and discontinuing ventilatory support. The guidelines recommended: “Weaning/discontinuation protocols that are designed for nonphysician health-care professionals should be developed and implemented by ICUs.”⁶¹

Summary of Pro Argument

Several studies show that protocols improve outcomes over ad hoc or “usual care” decisions made by clinicians. Some other studies that showed no benefit from protocols had design flaws. And even if a properly designed and implemented study showed no benefit from a weaning protocol, the implication is not clear. Tobin suggested that in such a case, the question is not, What went wrong with protocolized weaning? but, What was right with usual care?⁵⁹ If this is true, then all the studies mentioned in this paper may be no more than a bucket of red herrings. The larger question is whether we believe we can learn from

our experience and thus improve the quality of care. If we believe we can, then the question is how. An argument can be made that adequately explicit protocols, implemented with computers, is the best choice described so far. The widespread implicit belief in protocols is evidenced by the effort expended to design clinical research plans and maintain adherence to their directions. The need to learn from experience while assuring a reproducible standard of care is no less pressing in daily clinical practice than it is for research.

The only things that evolve by themselves in an organization are disorder, friction, and malperformance.”

—Peter F Drucker

Con: Weaning Protocols Should Not Be Used With All Patients Who Receive Mechanical Ventilation

As mentioned in the previous section, a task force of pulmonary and critical care experts issued guidelines in 2001 on weaning and discontinuing ventilator support.⁶¹ Recommendation 8 stated that, “Weaning/discontinuation protocols that are designed for nonphysician health-care professionals should be developed and implemented by ICUs.” This recommendation was given an “A” grade, which corresponds to the following description: “Scientific evidence that is provided by well-designed, well-controlled trials (randomized and nonrandomized) with statistically significant results that support the recommendation.” The document goes on to provide evidence from 3 prospective randomized trials that support Recommendation 8.

The following discussion will critically evaluate the key studies that support the use of weaning protocols, in addition to several negative trials. In addition, this section will make a more general case that “protocolized” medicine is as likely to be harmful as helpful, and that this approach to medical practice should be viewed with considerable skepticism.

Weaning Protocols: The Evidence

The gold standard of evidence-based medicine is the randomized controlled trial. Thus, although a number of trials have supported weaning protocols, the 2001 task force focused on 3 randomized controlled trials when it made its grade A recommendation in support of weaning protocols. Although each of these trials reported statistically significant results that were consistent with the task force’s recommendation, the clinical importance of the results is less clear. In addition, there were design flaws in two of the trials that cast considerable doubt on the generalizability of their findings.

In the landmark 1996 study by Ely et al, patients were randomized to protocolized weaning, consisting of readiness assessment plus an SBT, versus usual care. The trial found that weaning time was shortened by a median of 2 days, and that time to liberation from mechanical ventilation was reduced by 1.5 days.³⁵ However, more meaningful outcomes, such as ICU stay, hospital stay, hospital costs, and mortality were unaffected by the weaning protocol. Furthermore, the odds were heavily stacked in favor of any intervention, given that SBTs were not performed as part of weaning in the control group. This was despite the fact that failure to successfully pass an SBT was a key entry criteria for 2 prospective randomized trials of ventilator weaning published in the year prior to beginning their protocol trial.^{62,63} Furthermore, given that 75% of the patients in the Ely et al study were ventilated with intermittent mandatory ventilation (IMV), it seems likely that IMV was used for weaning in at least some, if not the majority, of patients. Given that IMV weaning had previously been shown to take approximately 2 days longer than weaning with SBTs, the results from Ely et al are not surprising.⁶³

The next published randomized controlled trial of ventilator weaning is even more difficult to interpret in terms of application to clinical practice. The trial used 3 different weaning techniques (IMV, pressure support, or daily SBTs) and involved 3 different protocols in 3 different ICUs.³⁶ These diverse groups were combined into one "protocol" versus one "physician-directed" weaning group for comparison. The duration of mechanical ventilation was 1.4 days less in the protocol group, but this benefit was largely realized in the "pre-weaning" phase, which included identification of readiness for weaning. Furthermore, there were no differences in other more meaningful end points, including duration of stay, costs, or mortality. Paradoxically, benefits from protocolized weaning were realized in those patients weaned with IMV and pressure support; there was no benefit to protocolized weaning using daily SBTs! Thus, the results of this trial directly contradict those of other studies that suggest that daily SBTs are a key component of accelerated liberation from mechanical ventilation.^{35,63}

The third trial, by Marelich et al, randomized patients to either physician-directed weaning or twice-daily screening followed by SBTs.³⁷ Protocolized weaning reduced the duration of mechanical ventilation by approximately 2.5 days, but duration of stay and cost data were not reported. In addition, there was a trend toward higher mortality in the protocol group.

Since the publication of the weaning guidelines in 2001, several additional randomized controlled trials have been published (see Table 1). A prospective randomized trial that compared protocolized weaning to physician-directed weaning in neurosurgical patients found no difference in

the duration of mechanical ventilation or any other outcome between the 2 groups.¹¹ A study of pediatric patients found no benefit to nonphysician-directed protocols in that population.⁴⁰ A subgroup analysis of trauma patients included in a randomized controlled trial of computer-assisted (open-loop) protocolized ventilator management versus physician-directed care found no effect of protocol use on duration of mechanical ventilation or stay.³⁹

A small randomized controlled trial that compared computer-directed weaning to physician-directed weaning in patients recovering from cardiac surgery found an approximately 2-hour reduction in the time to extubation with the protocol, but this difference was not statistically significant.⁴² A large randomized controlled trial of protocolized versus physician-directed weaning in a high-intensity-staffing medical ICU service found no differences in duration of mechanical ventilation or other outcomes between the groups.⁴¹

Minimizing human involvement from medical practice might be considered the pinnacle of protocolized medicine, as exemplified by a recent trial of computer-driven weaning from mechanical ventilation.⁴³ In this multicenter trial, 144 patients were randomized to weaning via a closed-loop knowledge-based system, versus usual care (control), after passing an initial screening test. The closed-loop system, which was integrated into a standard ventilator, reduced the pressure support level based on feedback from measurements of tidal volume, respiratory rate, and end-tidal P_{CO_2} . Usual care weaning used guidelines in 4 of 5 centers. Computer-driven weaning resulted in an impressive 4.5-day reduction in the total duration of mechanical ventilation, and a 3.5-day reduction in ICU stay. However, there was no significant reduction in hospital stay, and cost data were not reported.

Of multiple nonrandomized controlled trials that examined weaning protocols, several found no significant benefits from protocol use, and none reported shorter hospital stay (see Table 1). A compelling case against protocols is illustrated by a report from Ely et al on the large-scale implementation of weaning protocols at Vanderbilt hospital.⁵⁰ There was no significant change in the duration of mechanical ventilation during the year of protocol implementation; in fact the trend was toward a longer duration of ventilation.

In summary, these studies hardly provide robust evidence for the widespread application of nonphysician-directed weaning protocols. None of the studies found shorter hospital stay or lower costs with protocols, and 3 randomized studies reported trends toward higher mortality in the protocol groups.^{11,37,43} None of the data documents cost savings from weaning protocols. Although weaning protocols appear to provide benefits in some institutions and models of critical care delivery, they do not provide benefits in all institutions and models. These data are similar

to those regarding other computer-based clinical decision tools, which in one systematic review were found to be associated with improved patient outcomes in only 3 of 10 studies.³³

Protocols and Evidence-Based Medicine

Evidence-based medicine: The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine requires the integration of individual clinical expertise with the best available external clinical evidence from systematic research and our patient's unique values and circumstances.⁶⁴

Although the term "evidence-based medicine" has become popular only within the past 2 decades, it is clear from the above definition that the concept is not new. Individual clinical expertise combined with the best available clinical evidence has been applied to patient care since the birth of medicine as a profession. It is also clear that evidence-based medicine can be practiced without the use of protocols; in fact, the inclusion of "individual clinical expertise" in the definition would seem to exclude protocol use from best practice, given the inherent heterogeneity introduced by a multitude of individuals. In reality, the only new concept that evidence-based medicine has introduced is the hierarchical ranking of evidence, with the randomized controlled trial held as the standard by which all other evidence is judged. Whether this hierarchy is appropriate is a matter for another debate; however, it is clear that an argument against widespread protocol application is not an argument against the use of evidence in medicine. In contrast, medical protocols should be held to the same standards as other aspects of treatment, and their utility proven in randomized controlled trials. As discussed in detail above, ventilator weaning protocols have failed to sufficiently meet this standard, particularly in regards to recommending their application to all patients in all settings.

Protocols: Panacea or Poison Pill?

Simply put, a protocol is a precise and detailed plan, or, in computer language, a means of communication between 2 unrelated objects. It is difficult to argue against planning and communication, and the proponents of protocolized medicine suggest that protocols increase the efficiency and uniformity of care, reduce error rates, increase application of proven therapies, and ultimately improve outcomes.²⁷ However, there are theoretical negative aspects to protocols that cannot be dismissed, including inflexibility and removal of thought and judgment from clinical decision

making. This aspect will result in some patients being harmed while others benefit, and will probably impair clinical medical education. This latter effect will become more obvious with the broader acceptance and implementation of closed-loop, computer-driven protocols, wherein the clinician is effectively removed from the feedback loop, as opposed to open-loop, computer-assisted protocols, which include the clinician in the decision process. Furthermore, there is little evidence to support the notion that increased uniformity of care is in fact beneficial, particularly in regard to critical care medicine.

Variability in Practice: Good or Bad?

Arguments against practice variability largely center on variability in surgical procedure volumes between medical centers and variability in simple, explicit interventions such as β -blocker administration after acute myocardial infarction.¹³ However, there is no evidence that variability in the complex decision making processes involved in critical care medicine results in worse outcomes. In addition, it is not necessarily true that high practice variability implies a high error rate. Many practices in critical care are equivalent (or nearly so) in efficacy, and there are therefore multiple routes to a good outcome. In addition, although it may be that practice quality is associated with outcomes, it does not necessarily follow that for the individual patient a bad outcome was due to bad practice. In fact, bad outcomes occur in a large percentage of critically ill patients despite what might be defined as "best practice." These bad outcomes will occur with or without protocols; such is the nature of critical illness.

In a recent thought-provoking book, Surowiecki used examples from animal and human behavior, sports, and business to support an argument for "the wisdom of crowds."⁶⁵ Surowiecki distilled the information that supports a hypothesis first reported more than a hundred years ago, that groups are more intelligent than the smartest individuals in them. The corollaries to this are that the best way for a group to be smart is for each person in it to act and think as independently as possible. This "collective intelligence" will produce better results than a small group of experts (or a protocol) because of diversity of opinion, independence, and decentralization (where errors balance out).

There is reason to believe that "the wisdom of crowds" has relevance in the field of medicine. The principle implies that a large group (all critical care providers) will perform better (provide better patient care) than the experts (or expert-designed protocols) within it. This contrasts directly with the idea that increased uniformity of care will produce better outcomes. The wisdom of crowds probably applies at the local level as well, where a small group (multidisciplinary team) will perform better than a

single expert (physician leader). This may also apply to protocol development, in that the protocol will perform better if designed by a large, diverse group rather than a small group of experts.

Practices from the automobile industry and other industries have been enthusiastically endorsed to achieve uniformity of practice and thereby improve the efficiency and quality of health care.⁶⁶ However, it requires a considerable stretch of the imagination to accept that what applies to the manufacture of assembly-line products, which by design are as identical as possible, also applies to the care of patients, each genotypically and phenotypically unique.

Adherence to Protocols

The introduction of protocols into an institution or ICU does not guarantee that the protocol will be used, or used correctly. Even with minimization of human involvement through the use of closed-loop computer-driven protocols, the protocol must be initiated by a clinician.⁴³ Protocol adherence is difficult to achieve and costly to monitor. Adherence was only 66% in one randomized controlled trial of weaning protocols in pediatric patients, which is striking, given the rigid structure of a randomized controlled trial.⁴⁰ In the weaning protocol implementation study by Ely et al, intensive physician and nonphysician education and feedback were used to promote protocol adherence, but, despite those efforts, protocol adherence was only 25–36% over the final 6 months of implementation.⁵⁰ The failure to perform an SBT once the screening test was passed was attributable to decisions (or lack thereof) by both respiratory therapists and physicians. It is thus not surprising that these investigators were unable to document a reduction in the duration of mechanical ventilation in association with protocol implementation. It is evident that if the intent of the protocol is to improve patient outcomes, intense education and monitoring are necessary to achieve even minimal protocol adherence. This may be less of an issue if the protocol is implemented only in response to a guideline or a benchmark publication, as discussed below.

Protocols and the “Standard of Care”

Another problem related to the propagation of protocolized medicine is that therapies that are inherently appealing become institutionalized before they are rigorously proven to improve outcomes, and they become a “standard of care” that is difficult to reverse. An important example of this is the “ventilator bundle” endorsed by the Institute for Healthcare Improvement’s 100,000 Lives Campaign, one component of which is the recommendation for the use of weaning and sedation protocols (Table 2). The Institute for Healthcare Improvement Web site states that,

Table 2. Key Components of the Institute for Healthcare Improvement “Ventilator Bundle”

Elevation of the head of bed
Daily interruption of sedation and evaluation of readiness for extubation
Peptic ulcer disease prophylaxis
Deep venous thrombosis prophylaxis

“The ventilator bundle is a series of interventions related to mechanical ventilation, that when implemented together, will achieve significantly better outcomes than when implemented individually.” Unfortunately, there is absolutely no evidence that that statement is true. Furthermore, key components of the ventilator bundle are based on single, small trials, with results that were not reproduced in follow-up studies.^{67,68} Nonetheless, the ventilator bundle has been widely promoted and adopted, and serves as a benchmark for quality care delivery. The money spent on these efforts might be better directed elsewhere.

Another recent example of over-enthusiastic promotion of unproven interventions is the “rapid response team” for management of urgent in-hospital situations.⁶⁹ Rapid response teams are advocated by the 100,000 Lives Campaign and may become a measure of patient safety with the Joint Commission (formerly known as the Joint Commission on Accreditation of Health Care Organizations). The largest prospective randomized trial (23 medical centers, 125,000 patients) found no benefit from rapid response teams,⁷⁰ but rapid response teams are nonetheless viewed by some experts as a standard of care.

Summary

Ventilator weaning protocols have the potential to expedite the weaning process and have been shown to reduce weaning time and the duration of mechanical ventilation in several studies. However, other studies have found no benefits to protocol use, and no study has documented shorter hospital stay or lower mortality with weaning protocols. They may be particularly superfluous in highly staffed and structured ICUs. This limitation and other potential negative aspects of weaning protocols should be evaluated when considering their implementation in specific settings. Furthermore, for a protocol to improve outcomes, a high adherence rate is necessary. Thus, implementing a protocol requires intensive clinician education and measurement of clinician adherence and outcomes.

REFERENCES

1. Esteban A, Anzueto A, Frutos F, Alia I, Brochard L, Stewart TE, et al; Mechanical Ventilation International Study Group. Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. *JAMA* 2002;287(3):345–355.

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- Rello J, Allegri C, Rodriguez A, Vidaur L, Sirgo G, Gomez F, et al. Risk factors for ventilator-associated pneumonia by *Pseudomonas aeruginosa* in presence of recent antibiotic exposure. *Anesthesiology* 2006;105(4):709–714.
- Epstein SK. Extubation failure: an outcome to be avoided. *Crit Care* 2004;8(5):310–312.
- Cowan N. The magical number 4 in short-term memory: a reconsideration of mental storage capacity. *Behav Brain Sci* 2001;24(1):87–114; discussion 114–185.
- Haselton MG, Nettle D. The paranoid optimist: an integrative evolutionary model of cognitive biases. *Pers Soc Psychol Rev* 2006;10(1):47–66.
- Morris AH. Algorithm-based decision making. In: Tobin MJ, editor. *Principles and practice of intensive care monitoring*. New York: McGraw-Hill; 1998:1355–1381.
- East TD, Bohm SH, Wallace CJ, Clemmer TP, Weaver LK, Orme JF Jr, Morris AH. A successful computerized protocol for clinical management of pressure control inverse ratio ventilation in ARDS patients. *Chest* 1992;101(3):697–710.
- Chatburn RL, Chatburn RL. Classification of ventilator modes: update and proposal for implementation. *Respir Care*. 2007; 52(3):301–323.
- Redman BK. Clinical practice guidelines as tools of public policy: conflicts of purpose, issues of autonomy, and justice. *J Clin Ethics* 1994;5(4):303–309.
- Safran C, Rind DM, Davis RB, Ives D, Sands DZ, Currier J, et al. Effects of a knowledge-based electronic patient record in adherence to practice guidelines. *MD Comput* 1996;13(1):55–63.
- Namen AM, Ely EW, Tatter SB, Case LD, Lucia MA, Smith A, et al. Predictors of successful extubation in neurosurgical patients. *Am J Respir Crit Care Med* 2001;163(3 Pt 1):658–664.
- Timmermans S, Mauck A. The promises and pitfalls of evidence-based medicine. *Health Affairs (Millwood)* 2005;24(1):18–28.
- Wennberg JE. Unwarranted variations in healthcare delivery: implications for academic medical centres. *BMJ* 2002;325(7370):961–964.
- Morris AH. The importance of protocol-directed patient management for research on lung-protective ventilation. In: Dreyfuss D, Saumon G, Hubmayr R, editors. *Ventilator-induced lung injury*. New York: Marcel-Dekker; 2006: 537–610.
- Legorreta AP, Christian-Herman J, O'Connor RD, Hasan MM, Evans R, Leung KM. Compliance with national asthma management guidelines and specialty care: a health maintenance organization experience. *Arch Intern Med* 1998;158(5):457–464.
- Morris AH. Rational use of computerized protocols in the intensive care unit. *Crit Care* 2001;5(5):249–254.
- Chatburn RL. Computer control of mechanical ventilation. *Respir Care* 2004;49(5):507–517.
- Harding J. Cookbook medicine — advisability and efficacy of practice guidelines. [Internet]. 1994. Available at http://www.findarticles.com/p/articles/mi_m0843/is_n8_v20/ai_15786956/pg_1. (Accessed March 19, 2007)
- Charlton BG. Restoring the balance: evidence-based medicine put in its place (editorial). *J Eval Clin Pract* 1997;3(2):87–98.
- Beveridge W. *The art of scientific investigation*. New York: Vintage Books; 1953.
- Morris AH. Developing and implementing computerized protocols for standardization of clinical decisions. *Ann Intern Med* 2000;132(5):373–383.
- National Heart, Lung, and Blood Institute. Expert Panel Report: Guidelines for the diagnosis and management of asthma — update on selected topics 2002. [Internet]. Available at <http://www.nhlbi.nih.gov/guidelines/asthma/asthupdt.htm>. (Accessed March 19, 2007)
- Flores G, Lee M, Bauchner H, Kastner B. Pediatricians' attitudes, beliefs, and practices regarding clinical practice guidelines: a national survey. *Pediatrics* 2000;105(3 Pt 1):496–501.
- McDowell KM, Chatburn RL, Myers TR, O'Riordan MA, Kerckmar CM. A cost-saving algorithm for children hospitalized for status asthmaticus. *Arch Pediatr Adolesc Med* 1998;152(10):977–984.
- Frank Zappa quotes. [Internet]. http://www.brainyquote.com/quotes/authors/f/frank_zappa.html. (Last accessed March 21, 2007)
- Morris AH. Ethical implications of standardizing clinical decisions with computerized protocols. In: Vincent J-L, editor. *Yearbook of intensive care and emergency medicine*. Berlin: Springer;1999: 691–697.
- Morris AH. Decision support and safety of clinical environments. *Qual Saf Health Care* 2002;11(1):69–75.
- Deming W. *Out of the crisis*. Cambridge: Massachusetts Institute of Technology, Center for Advanced Engineering Study; 1982.
- Six Sigma. [Internet]. http://en.wikipedia.org/wiki/Six_sigma. (Last accessed March 21, 2007)
- Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events in hospitalized patients: excess length of stay, extra costs, and attributable mortality. *JAMA* 1997;277(4):301–306.
- Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. *J Am Pharm Assoc (Wash)* 2001;41(2):192–199.
- Donchin Y, Gopher D, Olin M, Badihi Y, Biesky M, Sprung CL, et al. A look into the nature and causes of human errors in the intensive care unit. *Crit Care Med* 1995;23(2):294–300.
- Johnston ME, Langton KB, Haynes RB, Mathieu A. Effects of computer-based clinical decision support systems on clinician performance and patient outcome: a critical appraisal of research. *Ann Intern Med* 1994;120(2):135–142.
- Carlo WA, Pacifico L, Chatburn RL, Fanaroff AA. Efficacy of computer-assisted management of respiratory failure in neonates. *Pediatrics* 1986;78(1):139–143.
- Ely EW, Baker AM, Dunagan DP, Burke HL, Smith AC, Kelly PT, et al. Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously. *N Engl J Med* 1996;335(25):1864–1869.
- Kollef MH, Shapiro SD, Silver P, St John RE, Prentice D, Sauer S, et al. A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation. *Crit Care Med* 1997;25(4):567–574.
- Marelich GP, Murin S, Battistella F, Inciardi J, Vierra T, Roby M. Protocol weaning of mechanical ventilation in medical and surgical patients by respiratory care practitioners and nurses: effect on weaning time and incidence of ventilator-associated pneumonia. *Chest* 2000;118(2):459–467.
- Schultz TR, Lin RJ, Watzman HM, Durning SM, Hales R, Woodson A, et al. Weaning children from mechanical ventilation: a prospective randomized trial of protocol-directed versus physician-directed weaning. *Respir Care* 2001;46(8):772–782.
- McKinley BA, Moore FA, Sailors RM, Cocanour CS, Marquez A, Wright RK, et al. Computerized decision support for mechanical ventilation of trauma induced ARDS: results of a randomized clinical trial. *J Trauma* 2001;50(3):415–424; discussion 425.
- Randolph AG, Wypij D, Venkataraman ST, Hanson JH, Gedeit RG, Meert KL, et al; Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network. Effect of mechanical ventilator weaning protocols on respiratory outcomes in infants and children: a randomized controlled trial. *JAMA* 2002;288(20):2561–2568.
- Krishnan JA, Moore D, Robeson C, Rand CS, Fessler HE. A prospective, controlled trial of a protocol-based strategy to discontinue mechanical ventilation. *Am J Respir Crit Care Med* 2004;169(6):673–678.
- Hendrix H, Kaiser ME, Yusen RD, Merk J. A randomized trial of automated versus conventional protocol-driven weaning from me-

- chanical ventilation following coronary artery bypass surgery. *Eur J Cardiothorac Surg* 2006;29(6):957–963.
43. Lellouche F, Mancebo J, Jolliet P, Roeseler J, Schortgen F, Dojat M, et al. A multicenter randomized trial of computer-driven protocolized weaning from mechanical ventilation. *Am J Respir Crit Care Med* 2006;174(8):894–900.
 44. Foster GH, Conway WA, Pamulkov N, Lester JL, Magilligan DJ Jr. Early extubation after coronary artery bypass: brief report. *Crit Care Med* 1984;12(11):994–996.
 45. Wood G, MacLeod B, Moffatt S. Weaning from mechanical ventilation: physician-directed vs a respiratory-therapist-directed protocol. *Respir Care* 1995;40(3):219–224.
 46. Saura P, Blanch L, Mestre J, Valles J, Artigas A, Fernandez R. Clinical consequences of the implementation of a weaning protocol. *Intensive Care Med* 1996;22(10):1052–1056.
 47. Djunaedi H, Cardinal P, Greffe-Laliberte G, Jones G, Pham B, Snell CC. Does a ventilatory management protocol improve the care of ventilated patients? *Respir Care* 1997;42(6):604–610.
 48. Burns SM, Marshall M, Burns JE, Ryan B, Wilmoth D, Carpenter R, et al. Design, testing, and results of an outcomes-managed approach to patients requiring prolonged mechanical ventilation. *Am J Crit Care* 1998;7(1):45–57; quiz 58–59.
 49. Horst HM, Mouro D, Hall-Jenssens RA, Pamukov N. Decrease in ventilation time with a standardized weaning process. *Arch Surg* 1998;133(5):483–488; discussion 488–489.
 50. Ely EW, Bennett PA, Bowton DL, Murphy SM, Florance AM, Haponik EF. Large scale implementation of a respiratory therapist-driven protocol for ventilator weaning. *Am J Respir Crit Care Med* 1999;159(2):439–446.
 51. Dries DJ, McGonigal MD, Malian MS, Bor BJ, Sullivan C. Protocol-driven ventilator weaning reduces use of mechanical ventilation, rate of early reintubation, and ventilator-associated pneumonia. *J Trauma* 2004;56(5):943–951; discussion 951–952.
 52. Tonnelier JM, Prat G, Le Gal G, Gut-Gobert C, Renault A, Boles JM, L'Her E. Impact of a nurses' protocol-directed weaning procedure on outcomes in patients undergoing mechanical ventilation for longer than 48 hours: a prospective cohort study with a matched historical control group. *Crit Care* 2005;9(2):R83–R89.
 53. Rotello LC, Warren J, Jastremski MS, Milewski A. A nurse-directed protocol using pulse oximetry to wean mechanically ventilated patients from toxic oxygen concentrations. *Chest* 1992;102(6):1833–1835.
 54. Strickland JH Jr, Hasson JH. A computer-controlled ventilator weaning system: a clinical trial. *Chest* 1993;103(4):1220–1226.
 55. Bumroongkit C, Liwsrisakun C, Deesomchok A, Theerakittikul T, Pothirat C. Efficacy of weaning protocol in medical intensive care unit of tertiary care center. *J Med Assoc Thai* 2005;88(1):52–57.
 56. Tobin MJ, Jubran A. Weaning from mechanical ventilation. In: Tobin MJ, editor. *Principles and practice of mechanical ventilation*, 2nd ed. New York: McGraw-Hill; 2006.
 57. Meade MO, Ely EW. Protocols to improve the care of critically ill pediatric and adult patients (editorial). *JAMA* 2002;288(20):2601–2603.
 58. Morris AH. Clinical trial of a weaning protocol. *Crit Care* 2004;8(4):207–209.
 59. Tobin MJ. Of principles and protocols and weaning (editorial). *Am J Respir Crit Care Med* 2004;169(6):661–662.
 60. Ely EW, Meade MO, Haponik EF, Kollef MH, Cook DJ, Guyatt GH, Stoller JK. Mechanical ventilator weaning protocols driven by non-physician health-care professionals: evidence-based clinical practice guidelines. *Chest* 2001;120(6 Suppl):454S–463S.
 61. MacIntyre NR, Cook DJ, Ely EW Jr, Epstein SK, Fink JB, Heffner JE, et al. Evidence-based guidelines for weaning and discontinuing ventilatory support: a collective task force facilitated by the American College of Chest Physicians; the American Association for Respiratory Care; and the American College of Critical Care Medicine. *Chest* 2001;120(6 Suppl):375S–395S.
 62. Brochard L, Rauss A, Benito S, Conti G, Mancebo J, Rekić N, et al. Comparison of three methods of gradual withdrawal from ventilatory support during weaning from mechanical ventilation. *Am J Respir Crit Care Med* 1994;150(4):896–903.
 63. Esteban A, Frutos F, Tobin MJ, Alia I, Solsona JF, Valverde I, et al. A comparison of four methods of weaning patients from mechanical ventilation. Spanish Lung Failure Collaborative Group. *N Engl J Med* 1995;332(6):345–350.
 64. Glossary of terms in evidence-based medicine. Centre for Evidence-Based Medicine. [Internet]. <http://www.cebm.net/glossary.asp>. (Last accessed Mar 21, 2007)
 65. Surowiecki J. *The wisdom of crowds: why the many are smarter than the few and how collective wisdom shapes business, economies, societies and nations*. New York: Random House; 2005.
 66. Chalice R. *Stop rising healthcare costs using Toyota lean production methods: 38 steps for improvement*. Milwaukee: ASQ Quality Press; 2005.
 67. de Wit M, Jenvey WI, Gennings C, Greenblatt DJ, Epstein SK. Randomized trial comparing the impact of daily interruption of sedation and sedation algorithm on duration of mechanical ventilation. *Proc Am Thorac Soc* 2006;3:A216.
 68. van Nieuwenhoven CA, Vandenbroucke-Grauls C, van Tiel FH, Joore HC, van Schijndel RJ, van der Tweel I, et al. Feasibility and effects of the semirecumbent position to prevent ventilator-associated pneumonia: a randomized study. *Crit Care Med* 2006;34(2):396–402.
 69. Winters BD, Pham J, Pronovost PJ. Rapid response teams—walk, don't run. *JAMA* 2006;296(13):1645–1647.
 70. Hillman K, Chen J, Cretikos M, Bellomo R, Brown D, Doig G, et al; MERIT study investigators. Introduction of the medical emergency team (MET) system: a cluster-randomised controlled trial. *Lancet* 2005;365(9477):2091–2097. *Erratum in: Lancet* 2005;366(9492):1164.

Discussion

Kacmarek: You went over the initial randomized controlled trial that showed benefit from weaning protocols,¹ and you commented that the approach to weaning in the control group was not up to standards so the study was probably not a good study. I would counter that by saying that that was the purpose of the study—to demonstrate

that the care in many institutions that do not use weaning protocols is not at the standard-of-care level, and that there are multiple different approaches, or approaches that have proven ineffective, that are still commonly used.

In addition, institutions such as Hank's [Fessler],² who found no benefit from protocols nevertheless actually use protocols! I'm sure that the way Hank operates on rounds is equiv-

alent to a protocol. Do you use a checklist to identify different things that you should cover every day in rounds? Do you make sure that there's a discussion about weanability of patients? Do you discuss all the specific categories that go into deciding whether a patient is ready to wean? Is that not a protocol? When I read your paper,² I thought you were comparing one protocol to another protocol, and they

ended up being equal. That does not condemn the use of protocols in the ICU. I'm a little disturbed by the mortality data in the Lellouche et al study.³ I didn't think that was a good study; there were a lot of problems with the protocol group, but I missed the fact that mortality was higher in the protocol group.

1. Ely EW, Baker AM, Dunagan DP, Burke HL, Smith AC, Kelly PT, et al. Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously. *New Engl J Med* 1996; 335(25):1864-1869.
2. Krishnan JA, Moore D, Robeson C, Rand CS, Fessler HE. A prospective, controlled trial of a protocol-based strategy to discontinue mechanical ventilation. *Am J Respir Crit Care Med* 2004;169(6):673-678.
3. Lellouche F, Mancebo J, Joliet P, Roeseler J, Schortgen F, Dojat M, et al. A multicenter randomized trial of computer-driven protocolized weaning from mechanical ventilation. *Am J Respir Crit Care Med* 2006; 174(8):894-900.

Deem: It was glossed over in the discussion of several of the other studies that there was a trend toward higher mortality in the protocol groups. Although the differences between the groups were nonsignificant, that doesn't mean we should ignore the differences, because that's a troubling signal.

MacIntyre: Why are we allowed to ignore mortality data when it's not significant, as in the Derdek et al trial,¹ but we get all lathered up about mortality differences here that are also not significant?

1. Derdak S, Mehta S, Stewart TE, Smith T, Rogers M, Buchman TG, et al. High-frequency oscillatory ventilation for acute respiratory distress syndrome in adults: a randomized, controlled trial. *Am J Respir Crit Care Med* 2002;166(6):801-808.

Deem: I think the difference is that we have guidelines that suggest that we should use protocols. We are being graded on that, and yet there is this troubling background signal that suggests that there may be difficulties or harm with this approach that we

haven't fully explored. About the Ely et al study,¹ with regard to the control group not receiving the standard of care, I'll buy your argument to an extent, except that it appears that nobody there was using what had been shown at that point to be the best way to wean patients. That is an unusual circumstance, I think, for a university hospital.

1. Ely EW, Baker AM, Dunagan DP, Burke HL, Smith AC, Kelly PT, et al. Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously. *New Engl J Med* 1996; 335(25):1864-1869.

Kacmarek: But I think you'd have a little difficulty arriving at agreement on the best way to wean patients. You had 2 big studies with opposite outcomes. One that favored T-piece trial and one that favored pressure support as the right approach to weaning.

Deem: They weren't really opposite outcomes, and the corollary is that all those patients had SBTs before they were enrolled in the protocol.

Kacmarek: I'm not disagreeing with your conclusion. I'm simply stating that I'm not sure that there was enough data available at the time of the study to definitively make the statement that SBT is the way everybody should be managing ICU patients.

Deem: I think most of us believed that IMV was not the correct way to wean patients at that point. Maybe I'm wrong there, but I think that most of us had come to that conclusion, and I have to assume that they did some IMV weaning, but it wasn't reported.

Kacmarek: Would you come and talk to our cardiac surgeons?

Deem: We're not talking about surgeons here.

Fessler: I would not want the conclusion from our study to be inter-

preted that we're against the use of protocols, or that we think protocols don't work. I think the conclusion from our study is that understaffing of ICUs doesn't work. That is a major aspect of the conditions under which the Ely et al study was done. It's perhaps the best designed study in this group, and it had some of the most significant results.

However, their ICU service ranged between about 20 and 30 patients; they were spread over up to 6 ICUs on 3 different floors. It was staffed by one attending, one fellow, and 3 house officers, and there was one house officer on call at night, responsible for all of those patients. So I think that those physicians basically spent their day running from disaster to disaster. The patients who needed nothing more than weaning were at the bottom of everybody's to-do list.

I think protocols *are* valuable, and they become more valuable under conditions of low physician staffing, or when the physician's knowledge base is smaller.

Kacmarek: I didn't realize that you have such good physician staffing—probably better than you have nursing or respiratory therapy staffing in your ICU. Fourteen beds and 12 physicians? That's pretty great staffing. You guys *should* do a good job weaning patients. One physician can spend the whole day at the bedside of each patient considered ready for weaning.

Fessler: You're right. I haven't compared the physician numbers to our nursing.

Kacmarek: I bet that on most days you've got more doctors than nurses, or at least as many.

Fessler: Well, maybe, but certainly on a per bed per day basis, we had 2-3 times the physician staffing that they had in the Marelich et al study,¹ the Kollef et al study,² or the Ely et al study.³ And yes, we do run our rounds

off of what is essentially a checklist, on which we go through every system. Weaning gets talked about on every patient, every day. I don't think protocols are the only way that you can achieve these ends, but under many circumstances they are the simplest and most reliable way.

1. Marelich GP, Murin S, Battistella F, Inciardi J, Vierra T, Roby M. Protocol weaning of mechanical ventilation in medical and surgical patients by respiratory care practitioners and nurses: effect on weaning time and incidence of ventilator-associated pneumonia. *Chest* 2000;118(2):459-467.
2. Kollef MH, Shapiro SD, Silver P, St John RE, Prentice D, Sauer S, et al. A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation *Crit Care Med* 1997; 25(4):567-574.
3. Ely EW, Baker AM, Dunagan DP, Burke HL, Smith AC, Kelly PT, et al. Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously. *New Engl J Med* 1996; 335(25):1864-1869.

Deem: I want to reiterate that, as Hank pointed out, the Ely et al study was probably done in the best possible circumstances, and I find the results unimpressive: a day and a half

less on the ventilator, but no less time in the ICU or in the hospital, no difference in mortality, and no difference in cost. So what does that mean in terms of benefit?

Kallet: I think days less on mechanical ventilation is important. There are a number of things that factor into the ICU duration of stay, such as lack of availability of beds on the ward, and need for intensive wound care. I think what we have to use is the absolute duration of mechanical ventilation.

One of the drawbacks with protocols is that they sometimes dull critical thinking, in the sense that if a patient repeatedly fails an SBT, clinicians often don't question why and pursue less salient reasons for failure. Sometimes it's obvious: a minute ventilation of 15 L and a pulmonary compliance like particle board. But a lot of times it's less obvious things, such as electrolyte disorders, and clinicians don't think through the other things that need to be considered.

Chatburn: Martin Tobin pointed out that in studies where you don't see a difference between a protocol and

usual care, it doesn't indicate so much what's wrong with the protocol, but what's right with the usual care.¹ If that's true, then all these studies are just a big bucket of red herrings.

I think we're missing the bigger philosophical issue here, which is, do we believe it's possible to learn from experience and continually improve? If we do, what's the best way to do that? I think the best way is with an adequately explicit protocol. And you all believe that too, because if you didn't you wouldn't spend so much time designing them for your randomized controlled trials, and making sure that people follow them.

1. Tobin MJ. Of principles and protocols and weaning (editorial). *Am J Respir Crit Care Med* 2004;169(6):661-662.

Myers: Yes, it is challenging to get the staff and the patients to adhere to the protocol, especially if it requires certain actions at certain times of day. You've got to take both the patients and clinicians in hand.