Protocols in the management of critical illness
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Abstract
Care of the critically ill patient is becoming increasingly complex. Protocols, which standardize care of patients with similar diseases, represent a potential solution to managing multiple simultaneous problems in critically ill patients. In this article, we examine the advantages and disadvantages to care protocolization, and posit that careful and thoughtful implementation of protocols is likely to benefit patients. We also discuss the potential for unintended consequences, and even harm, with protocolization in critically ill patients using the Critical Illness Outcomes Study as a model to examine the effects of protocolization in large populations of intensive care patients.

Introduction
Care of the critically ill patient is often punctuated with physiologic changes that require immediate attention. Given the frequency of emergent interventions, clinicians may be distracted from important, less urgent tasks that are still essential for optimal patient care. For this and other reasons, the utilization of protocols in the ICU can potentially improve the care of the critically ill patient. Because of the complexities of caring for the critically ill patient, the use of protocols in the ICU has become increasingly common. We will review the definition of a protocol, discuss their advantages, and highlight some of their limitations and potential for harm with their use.

There are multiple definitions for protocols. We prefer that of Fessler and Brower [1], who define protocols as ‘sets of explicit, algorithmic rules, which direct clinical management or research’. Similarly, Alan Morris [2] defined protocols as ‘precise and detailed plans for the study of a medical or biomedical problem and/or for a regimen of therapy’, which should be differentiated from guidelines, defined as ‘a systematic statement of policy rules or principles,’ in which explicit directions for making choices or decisions do not exist. Checklists, by contrast, are lists of things to be completed or checked. A protocol may be implemented by the use of a checklist, and can be used to facilitate specific treatment guidelines. When protocols are properly used, clinicians more frequently treat similar patients in a similar fashion. Protocols have the potential to minimize medical errors, decrease the likelihood of injury, increase patient safety and improve patient outcomes.

How can protocols improve patient care?
Protocols can minimize inconsistencies in the care of similar patients by the myriad healthcare providers in an ICU. Variability in clinician behavior is a product of varied educational backgrounds and experience [3]. In fact, a single physician might even respond to similar patients and situations, at different times, in different fashion [4]. Given these issues, protocols can prove useful when applied in a judicious and thoughtful fashion, as their intent is to reduce unnecessary variations in physician response to patients with defined disease processes [1,5] (Table 1).

Protocols can effect knowledge translation [1]. Outcomes of clinical research do not always readily nor appropriately make their way into clinical practice, and therapies can be both underused or applied to unsuitable candidates [6]. Protocols are one method to more quickly adapt new information to bedside care. A recent example of such delay in knowledge translation involves the ventilator management of patients with acute lung injury (ALI) and acute respiratory distress syndrome (ARDS). Even though the original ARMA trial, comparing tidal volumes of 6 mL/kg versus 12 mL/kg predicted body weight in ALI subjects, was published over a decade ago, only a fraction of patients are being treated with appropriate tidal volumes, even at participating ARDSnet centers [7-9]. The use of a lung protective mechanical ventilation protocol was the factor most likely to be associated with use of appropriate tidal volumes in ALI patients [10]. Explicit instructions for identification of appropriate patients and for setting tidal volumes and positive end-expiratory pressure (PEEP) based on predicted body weight and oxygenation targets has the
Table 1. Advantages and disadvantages of protocols

| Advantages                                      | Disadvantages                                      |
|------------------------------------------------|----------------------------------------------------|
| Reducing unnecessary variability in care       | Use in inappropriate patient                        |
| Quick adoption of new information to the bedside| Loss of individualization of care                   |
| Streamlining of care                            | Potential to be obsolete if not kept current        |
| Educational aids                                | May be designed around low quality evidence         |
| Improved communication                          | May be oversimplified                               |
| Cost containment                                |                                                    |
| Decrease errors and improve patient safety      |                                                    |

potential to prevent errors in which healthcare providers order inappropriate ventilator settings. In so doing, care is improved, and evidence is translated and applied at the bedside.

Likewise, protocols can streamline the care of critically ill patients [1]. It was demonstrated that non-physician providers could easily identify patient readiness for liberation from mechanical ventilator support [11]; 95% of daily assessments were correctly interpreted by respiratory therapists in the absence of physician guidance, and with time, the therapists grew increasingly comfortable with asking intensivists for spontaneous breathing trial orders. This improved use of the multidisciplinary team should allow timely performance of desired therapies while freeing up the physician to focus on other urgent issues.

Additionally, protocols may facilitate the teaching of appropriate clinical management for select diseases [1]. They can become tools used for discussion and education, and those protocols that are multidisciplinary can assist with the teaching of teamwork. Prasad et al. [12], in a retrospective cohort equivalence study, demonstrated that fellows who trained in a highly protocolized environment (defined as critical care units that had two or more protocols for at least 3 years prior to study) performed as well as those who trained in critical care units that were not highly protocolized (no or one protocol), on the subset of questions on the American Board of Internal Medicine Critical Care Boards regarding mechanical ventilation.

Importantly, protocols can improve patient safety by decreasing errors of both omission (a failure to perform beneficial actions) and commission (implementation of injurious actions despite appropriate intentions). That is, protocols can increase the likelihood that needed therapies are not overlooked, and that they are implemented as intended. Patient safety could potentially be enhanced by protocolizing other processes, such as provider-to-provider communication and hand-offs (“the transfer of patient care from one health care provider to another” [13]), especially in an era in which resident physicians have limits on their work hours, outpatient doctors are relinquishing inpatient care to hospitalists, and many ICUs are adopting a shift work schedule in order to maximize coverage by attending physicians. Communication becomes vital to ensure that no details are missed, and a protocol for hand-offs could help assure this. In a recent review of the literature looking at transition of care from one physician to another, the most cited solution to poor quality hand-offs was standardization, although this and other proposed solutions still require careful study [13].

Protocols could potentially help contain costs by reducing inconsistencies in practice since variability in clinical practice results not only in variable outcomes, but also in variable costs. In a prospective, observational study of nine intensivists at a single university ICU, physicians were the third biggest driver of cost variation behind severity of illness and type of critical illness [14]. By formalizing care for complex disease processes, unnecessary tests might be avoided, complications from incorrect and unneeded therapies could be minimized, and resource utilization might be improved. Kress et al. [15], by protocolizing sedation interruption, showed a reduction in the length of mechanical ventilatory support from 7.3 to 4.9 days, and a reduction in ICU length of stay (LOS) from 9.9 days to 6.4 days. Ely et al. [16] demonstrated a reduction in ICU costs from a median of $20,890 (interquartile range $11,501 to $37,570) to $15,740 (interquartile range $7,873 to $33,035) per patient using a respiratory therapy driven weaning protocol.

Weaning protocols and their effects on multiple outcomes were recently examined in a Cochrane review, in assessing how patients might benefit from an algorithmic approach to care [17]. The primary outcome was duration of mechanical ventilation, while the secondary outcomes included ICU and hospital mortality, adverse events (re-intubation, tracheostomy, prolonged ventilation), duration of weaning, ICU and hospital LOS, and cost. No pre-specified outcomes were adversely affected while duration of mechanical ventilation was reduced by 25% (95% confidence interval of 9 to 39%, \( P = 0.006 \) in 10 studies), duration of weaning was reduced by 78% (31 to
93%, \( P = 0.009 \) in 6 studies), and ICU LOS was reduced by 10% (2 to 19%, \( P = 0.02 \) in 8 studies). In addition to weaning, other protocols that have been developed are those involving daily awakening, lung protective ventilation, and severe sepsis/septic shock, anemia, ischemic stroke, and hypothermia after cardiac arrest [7,11,15,16,18-24] (Table 2).

Outcomes of selected interventions that might be considered for protocolization are shown in Table 3.

### Caveats to protocolized care

In addition to their advantages, we list some potential downsides to implementing protocols in the ICU in Table 1. Protocols might be used in patients who would not benefit from their use as clinicians less familiar with their elements or suspected illness may incorrectly use them or inappropriately adapt their use. Perhaps automated, non-physician ordered protocols may be viewed as a solution, by some institutions, to ensuring the use of protocols. This risks, however, the implementation in inappropriate patients since many protocols require careful consideration with regards to whether they should be implemented. Because protocols are generally based on evidence in the literature, they are truly only applicable to the patient populations in which they were originally studied, so care must be taken to avoid applying protocols to inappropriate patients. For instance, a septic shock protocol might not be appropriate in cardiogenic or hemorrhagic shock patients even though all these patients are grossly similar. Likewise, a daily awakening and spontaneous breathing trial protocol may work less well, or even be inappropriate, for a neurosurgical or cardiac patient compared to a medically critically ill patient.

Medicine evolves, as shown by changes in the data about glycemic control, steroids and activated protein C in the past decade [21,25-31]. For instance, tight glucose control protocols were soon developed at many medical centers after the initial publication showing benefit of strict glycemic control in surgical critical care patients [31]. Follow-up studies, however, could not confirm the benefit of the initial study, and in fact showed harm [28,29]. Protocols need to be ‘living documents’: They should be developed in rational fashion using best evidence, avoiding the incorporation of low quality recommendations and guidelines, and kept current, all by careful review of the literature and data [32]. Protocols are only as good as the evidence from which they are derived.

If protocols are complex and difficult to follow, clinicians will resist them, or perhaps even only incorporate selective portions [33]. For example, even easily followed protocols for PEEP might not always be used, and almost certainly, complex PEEP protocols are rarely followed outside of the research setting [7,34]. Protocols may be inadvertently simplified to the point that they no longer apply to many patient populations or that they no longer account for complex physiology.

As protocols are inherently rigid, there is concern that individualized care is ignored. In the absence of highly sophisticated artificial intelligence systems, they will never be as good as the best, well-trained, seasoned clinicians who can respond quickly to changing conditions. There are no protocols that can effectively deal with all clinical scenarios, and patients with rare diseases or those with unusual presentations of common diseases may not be well served by a protocol that was not designed to fit their specific situation. For example, differences in drug metabolism across patients may lead to differences in response to particular medication protocols. Obesity, for instance, can affect drug distribution and metabolism in a difficult to predict fashion because of increased adiposity, and changes in physiology (increased cardiac output and blood volume, altered liver

| Table 2. Interventions/processes amenable to protocolization |
|-------------------------------------------------------------|
| Ventilator weaning                                          |
| Acute lung injury/lung protective ventilation               |
| Sepsis                                                      |
| Rapid antibiotic administration                             |
| Daily interruption of sedation                              |
| Other sedation                                              |
| Catheter placement                                          |
| Venous thromboembolism prophylaxis                          |
| Early mobility                                              |
| Stress ulcer prevention                                     |
| Nutrition                                                   |
| Transfusion restriction                                      |
| Massive transfusion                                         |
| Hypothermia after cardiac arrest                             |
| Ventilator-associated pneumonia prevention                  |
| Delirium assessment                                          |
| Delirium treatment                                           |
| Palliative care/end of life                                 |
| Electrolyte replacement                                     |
| Acute coronary syndrome                                     |
| Acute brain injury                                          |
| Stroke                                                      |
| Intracerebral hemorrhage                                    |
| Glucose control                                             |
| Critical care code/Advanced Cardiac Life Support (ACLS)     |
| Oral hygiene                                                |
and renal metabolism, and changes in serum protein levels) [35]. Likewise, drug metabolism in the elderly can be unpredictable given age-related changes in organ function, multiple chronic illnesses and polypharmacy [36]. Additionally, many critically ill states, such as severe sepsis and septic shock, result in abnormal regional blood flow.

To summarize, the successful protocolization of medicine requires rapid and correct identification of disease processes, the need for thoughtful consideration of the inclusion and exclusion criteria for application of protocols to appropriate patients, and algorithms derived from good quality evidence.

Future directions

Computers and artificial intelligence systems will likely play an increasing role in clinical medicine. Sophisticated, commercially available computer-driven protocols for weaning and liberating patients from mechanical ventilator support already exist, although studies demonstrate mixed results with regards to their performance, possibly related to their application in inappropriate patient populations [37,38]. Certainly, there seems to be potential for these and similar systems to improve the care of carefully selected patient populations. Likewise, Computer Physician Order Entry (CPOE) systems may facilitate the use of protocols via prompts, and could allow for flexibility as clinicians could select or de-select appropriate therapies within the bounds of a protocol. Given enough information, it might be possible to design an intelligent system in order to both identify patients to whom protocols would be applicable and prevent use in patients with exclusion criteria.

Understanding the effects of ICU protocolization

Many institutions, in an attempt to improve care, have adapted protocols without strong supporting evidence. More research about specific protocols, and, more generally, about the role of protocols in patient care needs to be performed. We need to determine whether patient safety, outcomes and costs are reliably improved by protocols. As an initial step, the Critical Illness Outcomes Study (CIOS), organized through the US Critical Illness and Injuries Trials (USCIIT) Group, is being conducted to examine organizational and structural factors in adult ICUs, and to determine their association with patient-related treatments and outcomes [39]. CIOS will enhance our understanding of the relationship between ICU protocols, both availability and utilization, and clinical outcomes.

Weiss et al. [40] recently demonstrated that verbal prompts to use a checklist resulted in significantly decreased mortality and significantly shorter LOS when compared to the control in which checklists were used without prompts. While checklists are not as explicit as protocols (and although they can be used to improve protocol initiation), their purpose, similar to protocols, is to improve patient care processes.

The next logical step, if protocols can be shown to be reliably beneficial, is their widespread implementation into the community. Fessler and Brower [1] and Morris et al. [41] elegantly outline necessary steps in generating explicit and valid protocols, and in clinician acceptance of protocols.

Conclusion

Because of the complexities of the critically ill patient, the ICU is a logical place in which to implement...
protocols. We believe that most patients are best served in ICUs that emphasize multidisciplinary, team-based care and conscientious application of protocols. The advantages of protocols can be maximized by their careful development and implementation, by the proper identification of appropriate patient populations, and through incorporation of educational components. We are not aware of reliable data showing worsening of outcomes with protocols, but we believe that more research is still necessary to fully understand their role in ICU patient care.

Abbreviations
ALL, acute lung injury; ARDS, acute respiratory distress syndrome; COOS, Critical Illness Outcomes Study; IOS, length of stay; PEEP, positive end-expiratory pressure.

Competing interests
The authors declare that they have no competing interests.

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