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Individualized Care Is Superior to Standardized Care for the Majority of Critically Ill Patients

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Abstract

Tools for standardizing patient care can take many forms, including but not limited to, bundles, quality improvement and performance measures, guidelines, and protocols. Each is intended to improve compliance with interventions believed to be supported by the best available evidence, ensuring consistency of management across all patients with the ultimate goal of improving outcomes. However, in the ICU, patients typically present with complex acute illnesses and accompanying comorbidities, requiring careful tailoring of interventions and treatments for each individual patient. The rapidly changing nature of the underlying conditions also demands continuous reassessment and modification of each patient's management on a frequent and sometimes moment-by-moment basis. Disrupting this individualized treatment approach by imposing prescriptive, overly restrictive, "one-size-fits-all" standardized treatments in the critical care setting may prevent the clinician from meeting individual patients' needs and decrease care quality (1). This problem is compounded if the standardization tools adopted are not only inflexible but also have a poorly supported or entirely absent scientific basis. Importantly, identifiable patient subcategories often exist that fit poorly into the populations for which many interventions were developed and tested. Of equal concern, critical care trainees may become dependent on a standardized/cookbook approach to care and fail to recognize and learn how treatments must be tailored for the unique needs of each critically ill patient. Rather than rigidly standardizing critical care, approaches that recognize this complexity and are both scientifically sound and responsive to patient differences should be readily available to critical care clinicians without replacing sensible clinical judgment. Such strategies that acknowledge the limitations of available evidence hold more hope of improving, rather than inadvertently worsening, the outcome.

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Keywords

clinical reasoning; individualized care; protocols; training

RISKS OF STANDARDIZING THE CARE OF CRITICALLY ILL PATIENTS

Proponents for the implementation of standardized care hold that it is possible to define one best “evidence-based” way of managing every disease or syndrome and that variation from this one best way is a consequence of differences in clinician knowledge and experience (2). This premise fails to acknowledge that variability among critically ill patients may reflect and very often dictates the need to individualize care. Standardized protocols and bundles of care, as currently constituted and implemented for broad patient categories, have a poor track record for achieving the commendable goal of “the Right Care, Right Now,” as espoused by the Society of Critical Care Medicine (3). By assuming they do, we risk managing all our patients under an umbrella of “defaults” that can, in fact, be harmful for some of them (4). Notably, a large observational study conducted in 57 ICUs comparing outcomes between highly protocolized and less highly protocolized ICUs reported no net benefit associated with increased protocol use (5). Presuming that standardization of care with protocol implementation had a beneficial effect in some subset of the patients investigated, lack of a net benefit suggests that any advantages of protocol use were offset by harm in other patients. A specific example of this phenomenon is represented by the management of tidal volumes during mechanical ventilation in patients with acute respiratory distress syndrome (ARDS). After a landmark clinical trial suggested a beneficial effect of a “lung-protective” ventilation strategy (6), it was recommended not to use tidal volumes above a rigid threshold of 6 mL/kg for all patients. Of note, this trial did not include a usual care arm, and only compared two tidal volumes (TVs) extremes (6 and 12 mL/kg) of a usually titrated intervention. Preenrollment data from the same trial showed that the tidal volumes clinicians administered were variable but far from random (7), and neither extreme of care studied in the trial improved mortality compared with usual care at the time (7). Usual care was not based on set TVs for all, but rather individualized care; patients with more severe lung injury and less compliant lungs received smaller tidal volumes to minimize excessive airway pressures and further injury, while patients with less severe lung injury and more compliant lungs received larger volumes (7). Notably, more recent recommendations for tidal volume management in ARDS patients recognize this need for titration and suggest a more flexible range, including tidal volumes from 4 to 8 mL/kg (8).

Prioritizing standardization over individualization by encouraging compliance with performance measures and bundles is a prominent trend in healthcare in general, and in critical care in particular. This crusade for compliance and uniformity can have unintended harmful consequences, as it forces clinicians into rigid and prescriptive standards of care that leave little room for clinical judgment and individualization of therapy. Furthermore, it creates a punitive culture that promotes the practice of defensive medicine in which complying with a specific standard becomes an end in itself, instead of an adjunctive instrument to promote better care for patients. In fact, when compliance is sanctioned through incentives or noncompliance is penalized, both the power and the risks of

standardization are multiplied (9). When Centers for Medicare and Medicaid Services (CMS) standardized the care for community-acquired pneumonia and required that all patients receive antibiotics within 4 hours, diagnostic accuracy for the condition decreased (10, 11). Most concerning, in order to meet this standard, physicians reported prescribing antibiotics to patients they did not think had pneumonia despite the widely recognized risks of unnecessary antibiotic use (11).

Importantly, any set of interventions implemented as a rule will only be as good or as bad, as the quality of the evidence that supports it (12). Ideally, standardized care should encompass interventions supported by high-quality evidence or wide clinical acceptance. If this standardized care includes a bundle of interventions, these same criteria should apply to each bundle component, as well as to the performance of these components when used together. Some bundles meet these criteria, such as the Central Line Bundle to prevent catheter-related bloodstream infections (13). However, other measures have been adopted that do not conform to this rigorous level of proof (14–16). One example in the ICU setting is the Severe Sepsis and Septic Shock Performance Measure bundle (known as SEP-1), which was instituted by CMS to standardize care for severe sepsis and septic shock. This measure has raised numerous concerns and criticism and illustrates the risks and potential harm of care standardization for very heterogeneous and complex syndromes (17–19). This bundle, which is now being enforced via its inclusion in the Hospital Compare program, requires all patients with suspected sepsis to be managed by adhering to a set of prescriptive rules. Some of the core elements of SEP-1, including the hemodynamic interventions, are not supported by any high-quality reproducible data showing consistent benefit even in a general population. Even with recent modifications to SEP-1, current fixed fluid and lactate level (itself an unreliable marker of volume status) requirements, which risk excessive fluid administration in patients with underlying comorbidities like congestive heart failure or kidney disease, are not backed by high or even moderate quality evidence. Overall, SEP-1 requirements represent a strict “one-size-fits-all” approach that ignores evidence that differences in the usual care of septic patients actually reflects purposeful individualization of care (19–22).

Notably, many trials testing ICU interventions are well known to exclude a large proportion of critically ill patients and the populations enrolled in the trial often do not reflect the general ICU population to which the intervention may eventually be recommended and applied. A potential mismatch between the context in which a recommended treatment is developed and the setting in which it is deployed needs to be accounted for in any tools directed at standardization of care (23). If recommendations lack flexibility, they risk benefiting some patients while harming others. Allowing individualized care, in contrast, empowers providers to utilize all available evidence, while still exercising their clinical expertise to provide the very best care for individual patients.

RISKS OF AN OVEREMPHASIS ON STANDARDIZED CARE IN CRITICAL CARE TRAINING PROGRAMS

Emphasizing a standardized treatment approach to the exclusion of recognizing and expertly managing exceptions undermines physician training and may promote a cookbook, less thoughtful approach to medicine. Unexamined adherence to a rigid standardized set of directives leads to the assumption that the ideal way of practicing medicine is dependent on a faithful devotion to prescriptive rules. The alternative is a careful assessment of each patient as an individual, integrating available knowledge with management adjusted accordingly on a case-by-case basis (24). Over-confidence from repetitively applying a standardized, rote approach to care risks inattention to important patient data and ultimately failing to learn how to individualize treatment when necessary. A study evaluating the effects of training in a highly protocolized ICU environment on trainee performance taking a certification exam showed no improvement over those training in an environment with fewer or no protocols (25).

INTEGRATING NONPRESCRIPTIVE STANDARDS INTO INDIVIDUALIZATION OF CARE

At odds with the emphasis on standardized care with bundles and performance measures is the evolving trend towards personalized medicine that emphasizes the importance of underlying pathophysiologic and biological differences among patients when making therapeutic decisions. Current cancer patient management reflects how this approach is possible and beneficial for individual patients (26). In fact, recommendations for oncological therapies are usually based on thoughtful discussions by tumor boards where evidence-based, standardized protocols are evaluated and adapted to the individual characteristics of each patient and their condition. It is understood that deviations from these standard protocols are sometimes required and justified and that patients benefit from this individualized treatment (26).

In critical care, there are alternatives to defaulting to a standardization of care. The simplest one would be nonprescriptive checklists in the form of simple aides or reminders of steps to consider. Other potentially beneficial initiatives could focus on standardizing aspects of care that are more suitable for a homogeneous approach, such as care team communication or administrative tasks (27). It has also been noted that efforts to standardize some aspects of care can be tempered by allowing exceptions based on the individual setting and needs of the patient (28). Importantly, the medical and scientific community should continue to focus on understanding and preventing poor outcomes by addressing root causes, rather than dogmatically embracing standardization, a trumped-up panacea (23).

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