Review

Rational use of computerized protocols in the intensive care unit

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Abstract

Excess information in complex ICU environments exceeds human decision making limits, increasing the likelihood of clinical errors. Explicit decision-support tools have favorable effects on clinician and patient outcomes and can reduce the variation in clinical practice that persists even when guidelines based on reputable evidence are available. Computerized protocols used for complex clinical problems generate, at the point-of-care, patient-specific evidence-based therapy instructions that can be carried out by different clinicians with almost no inter-clinician variability. Individualization of patient therapy is preserved by these explicit protocols since they are driven by patient data. Computerized protocols that aid ICU decision-makers should be more widely distributed.

Keywords decision-support, intensive care, protocols, research, safety

Critical care decision-support tools can focus on diagnostic [1], administrative [2], or therapeutic needs. Decision-support tools have been functionally categorized as ‘reminders,’ ‘consultants,’ or ‘educational’ [3]. These three categories do not embrace the intensive care unit (ICU) treatment management or titration protocols used to apply explicit methods of mechanical ventilation [4–6] and fluid and hemodynamic support [7,8] in patients with acute lung injury or acute respiratory distress syndrome (ARDS). In this review I focus on these management or titration protocols and consider several rationales for the use of such explicit detailed computerized protocols in the ICU. I discuss the features of computerized ICU protocols that distinguish them from other decision-support tools such as guidelines, paper protocols, and clinical or nursing or critical paths. These protocols complement, but do not replace, the ICU decision-maker.

Varieties of decision-support tools

Thousands of decision-support tools with different names, foci, and outputs are available but they often lack specific instructions for many of the situations encountered in clinical practice [9]. Most are useful only in a conceptual sense [10–16]. They neither standardize clinical decisions nor lead to a uniform implementation of clinical interventions, although standardization and uniformity are their goals [14,16,17]. For example, it would be difficult to reduce variability with a protocol that required the clinician to determine whether the patient ‘looked septic,’ unless the state ‘looked septic’ were explicitly defined. Computerized protocols used for complex clinical problems can contain much more detail than is possible with textual guidelines or with paper-based flow diagrams [16]. The increased detail allows the generation, at the point of care, of patient-specific therapy instructions that can be performed by different clinicians with almost no inter-clinician variability [18]. This can make both formal clinical inquiries (for example, randomized trials) and informal clinical inquiries (for example, some continuous quality improvement efforts, or clinical practice evaluations) more robust [9,18].

Reducing clinician variability might seem to challenge the importance that clinicians assign to individualized (patient-specific) therapy. Unexpectedly, individualization of patient therapy is preserved when clinical decisions are standardized with explicit, detailed, patient-data-driven, computerized protocols [9,19]. An essential element in achieving this unexpected result is the use of patient data (that is, the patient’s unique expression of the disease) to drive the decision-support tool (protocol) rules. Unlike these specific patient-
data-driven explicit methods [4,5,20–25], time-driven decision-support tools (for example a clinical path that requires discharge of the patient after 3 days of care) raise legitimate concerns about patient-invariant (‘cookbook’) care. Individualizing patient care while standardizing clinical decisions with an explicit method is, in my opinion, one of the most attractive attributes of the point-of-care use of computerized protocols.

Why is there need for protocols in the ICU?

Clinical error rates are common (about 1–50%) [26–53]. This is an expression of the general problem: that human error and injury are unavoidable [27,35,54,55]. Even when ICU errors represent only 1% of clinical decisions [53] and therefore indicate little room for personal improvement (in that 99% of decisions are correct), clinical ICU errors and injuries that threaten patient safety occur with distressing frequency [44,53].

Variation in clinical practice persists even when guidelines based on reputable evidence are available [28,29], and patients can be harmed when clinicians do not comply with standard practice [9,30,31]. Widespread distribution of evidence-based guidelines [35,36] and education programs [24,37–40] has had only a limited effect on low compliance by clinicians. Variability is fostered by incorrect perceptions. The perceptions of physicians in their use of physiological data and the actual use of such data in decision-making for cardiac problems in the ICU are internally inconsistent (within-decision-maker inconsistency) [56]. This is in part due to the use of ill-defined terms or statements such as ‘...caution should be exercised when PAOP [pulmonary artery occlusion pressure] becomes increased to the extent that pulmonary edema is a risk’ [57]. This particular inconsistency appeared in a journal issue containing three articles that presented mutually contradictory sets of recommendations about hemodynamic monitoring (between-decision-maker inconsistency) [58].

Variation in practices with ICU fluids and electrolytes illustrates the confusion propagated by the imprecise use of words and concepts in medicine. An analytical scheme addressing three major factors in fluid and electrolyte evaluation (1, effectiveness of the arterial circulation; 2, extracellular fluid volume [ECF]; and 3, state of hydration [59]) is compatible with widely taught precepts [60–67]. Evaluating these three concepts separately is important for clarifying problems with fluids and electrolytes and thereby for reducing unnecessary variation. Use of fluid and electrolyte terms in a nonstandardized manner leads to confusion. An American Medical Association Council report cites isotonic, hypertonic, and hypotonic dehydration, thereby confusing the evaluation of the state of the ECF and the state of hydration [68]. Cardiovascular evaluation is also (inappropriately) included in the evaluation of hydration, thereby confusing the evaluation of the effectiveness of the arterial circulation (cardiovascular evaluation) with the evaluation of the state of hydration. Hypernatremic dehydration (a tautology if standard definitions are used) was used to describe both dehydration (hypernatremia) and ECF contraction [69]. For patients with traumatic brain injury, dehydration was used in two contradictory ways [70]. First, the authors recommended inducing dehydration with mannitol (producing dehydration or underhydration according to the standard terminology) because it was effective in reducing intracranial pressure. They then recommended avoiding dehydration with diuretics (producing ECF contraction due to negative fluid balance). Therefore it was ineffective in reducing intracranial pressure [70]. The use and the teaching of terms in such contradictory ways probably contribute to the uncertainty surrounding fluid and electrolyte therapy for sepsis [71], shock [72–74] and ARDS [75]. Fluid and electrolyte therapy is an important and uncontrolled co-intervention that can influence patient outcome and obscure the effects of therapeutic interventions in clinical trials.

Protocols enhance efficiency, safety, and efficacy of care

Efficiency is the term assigned to the evaluation of resource consumption for a clinical intervention accepted as part of routine practice. At the individual patient level, standardization enhances efficiency by making the clinical plan explicit to all providers dealing with that patient. Nurses, therapist, and physicians thereby achieve a level of uniformity of approach and goals for the specific patient. This reduces within-patient variability of decision-making. However, this does not reduce unnecessary variation between patients and between physicians. Standardized clinical decisions are important at several levels within the healthcare delivery system.

Human decision-making limitations, perceptual inaccuracies, and variation in the use and in the interpretation of important clinical variables all make clinicians unable to consistently generate therapeutic decisions that are coherent, that consider all appropriate options, and that are based on the relevant scientific evidence [27,34,35,43,44,46,76–79]. For example, adverse drug events are common, costly, and largely preventable causes of excess morbidity and mortality in ICU patients [25,80–82]. Estimates of the annual national cost of adverse drug events in the USA run as high as US $79 billion to US $136 billion [25,83]. Unfortunately, adverse drug events are generally undetected. Traditional screening for in-hospital adverse drug events detects only 1% and voluntary reporting only 12% of the adverse drug events detected by automated computerized screening of an integrated electronic clinical database [84].

Even when the healthcare community understands the proper approach, compliance of physicians with evidence-based treatments or guidelines is low across a broad range of healthcare topics [20,85–89]. Patient [90] and hospital [91] compliance is approximately as low. Only about 50% of patients with chronic diseases receive effective delivery of their therapy [90]. Like low compliance by clinicians, this seems to be a feature of our human condition. In contrast,
both paper-based and computerized decision-support tools that provide explicit, point-of-care (point-of-decision-making) instructions to clinicians have overcome many problems and have achieved clinician compliance rates of 90–95% [5,19,92]. However, the absence of requisite infrastructure in the ICU environment is an important obstacle to the adoption of clinical decision-support tools such as those demonstrated to produce a favorable clinical outcome in a multicenter randomized clinical trial [5,6].

Protocols enable rigorous clinical research
Modern medicine has fostered the development of undoubted advances. In spite of these and other obvious benefits, only a small fraction of current clinical practice has been shown to produce more good than harm [18,32–34]. Some important problems in critical care have long resisted resolution. While our understanding of underlying mechanisms of injury and inflammation in sepsis and ARDS has blossomed, our understanding of clinical management of sepsis and ARDS has not. Several clinical trials of promising therapeutic agents have consistently failed to identify the promised advances in therapy [21,93–98]. The absence of a clear benefit from this broad spectrum of tested interventions suggests that the clinical problems are insoluble and cannot be improved, or that the needed interventions have not yet been tested, or that our clinical investigative strategy is not sound. We have all been encouraged by recent advances in the treatment of patients needing mechanical ventilation [92] and those with sepsis [99], but our success rate with clinical trials that produce important clinical advances is disappointingly low.

Standardization of clinical decisions is needed not only for clinical practice but also for rigorous clinical research [49]. Many interventions of clinical value have relatively small effects, with odds ratios of 3.0 or less [50]. Systematically conducted clinical trials are necessary for these small effects to be recognized and for ineffective clinical care elements to be identified [50,51]. However, without explicit methods the fundamental scientific requirement of replicability of results [48,49] cannot be achieved. An explicit method, driven by patient data, contains enough detail to generate specific instructions (patient-specific orders) without requiring judgments by a clinician. Any form of guideline or protocol can theoretically contain enough detail to constitute an explicit method. In practice, however, paper-based versions of any protocols except the simplest (for example, vaccination schedules or treatment of hypokalemia in a patient receiving digitalis and diuretics) cannot be made explicit and therefore remain dependent on the judgment of a clinician.

Protocols enhance education
If explicit computerized protocols lead clinical trainees to abandon critical thinking, they might contribute to the production of clinicians less prepared for the rigorous intellectual challenge of healthcare delivery. For those afraid of demeaning the clinical training of students and house officers, I respond that an explicit method, when used wisely, can be an effective tool for teaching students the principles both of decision-making and of clinical practice. Unlike much traditional clinical teaching, explicit decision-support tools articulate both the variables considered and the decision rules. In an environment dedicated to training, explicit methods can be an asset. In an environment that pays little heed to training, they could be a disadvantage. Like any tool, guidelines can be misused. Finally, many physicians are concerned about a reduction of their role in medical practice and of the potential disenchantment of physicians with medicine that could follow the widespread mandatory use of guidelines and protocols [15]. Standardization might be perceived as an attack on clinicians’ assumption that they possess special and ineffable wisdom in clinical matters and on its corollary that patients receive the best outcome when physicians independently use their best clinical judgment [100,101]. It is this belief, namely that expert ICU physicians possess special and ineffable wisdom, that interferes with the education of young physicians, by avoiding the challenge of articulating precisely how decisions should be made.

Summary
The excess information in complex ICU environments exceeds human decision-making limits, increasing the likelihood of clinical errors. Explicit decision-support tools have favorable effects on the clinician and on patient outcomes. They have been implemented in diverse clinical environments and have been successfully transferred and used in geographically dispersed ICUs that were not involved in their initial development. However, various human factors and the paucity of distributed electronic clinical databases impede the widespread distribution of clinical decision-support tools. Notwithstanding these challenges, the documented benefit of the application of decision-support tools in the ICU and the rapid expansion of electronic ICU databases promise an increasingly favorable environment for the development, implementation, and use of computerized protocols to aid clinical decision-makers in the ICU.

Competing interests
None declared.

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