significantly alter the trajectory of CF lung disease and will need to be applied before irreparable airway damage has occurred. Thus, the patients with CF who most likely will benefit from these therapies are the youngest. As safety and measures of efficacy are demonstrated in adult subjects and older children, clinical trials during infancy will be an essential future step. If successful, the course of CF lung disease could be forever changed. In that case, change would be good.

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Moving the Science of Quality Improvement in Critical Care Medicine Forward

In order for patients to reap the benefits of bench and clinical research, we must develop effective strategies that translate this knowledge into clinical practice. Delivering quality care to patients has two goals: increasing the likelihood of desired health outcomes and ensuring concordance with current evidence (1). Quality improvement is the scientific discipline that accompanies this so-called T3 activity, focusing on the structures, processes, and outcomes of healthcare delivery (2). A primary motivator of quality improvement is the reduction of medical error, which has emerged as a major problem in modern healthcare, estimated to cause up to 98,000 preventable hospital deaths in the United States each year at a cost of $17–29 billion (3). The ICU poses unique challenges to effective healthcare delivery and is an ideal setting for rigorous quality improvement inquiry.

Changes in the structure of care, such as the institution of an intensivist model for critical care, and improvements in the process of care have led to significant improvements in health care outcomes (4). These strategies need not be complex. For example, a checklist is a simplification tool that coalesces a large slice of the ICU (e.g., central venous catheter insertion techniques, physician education, nurse–physician communication, data collection systems) into an actionable problem. Despite their apparent simplicity, checklists have proven remarkably effective at improving multiple healthcare outcomes, from reducing catheter-related bloodstream infections to enhancing provider communication (5).

While the randomized controlled trial (RCT) is widely given the highest grade of evidence, RCTs in the ICU may be impractical, and data derived from them are often lacking (6). Indeed, most published quality improvement research employs an observational design (7). Even when the evidence is strong, widespread implementation of a quality improvement intervention is often suboptimal. Clinical practice guidelines are meant to standardize medical care according to the best available evidence, yet compliance with these guidelines in clinical settings is poor (8). As a result, many opportunities to improve outcomes in critically ill patients are missed (9).

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One approach to improve healthcare delivery in the intensive care unit is to adopt quality improvement strategies that have proven effective in industry. One of the fathers of modern industrial quality improvement, W. Edwards Deming, employed an early form of complex system analysis to generate the Plan-Do-Study-Act cycle for understanding and improving the performance of organizations and processes (10). This and other industry-derived approaches, such as Six-Sigma and Toyota Production Systems' LEAN thinking, have been employed successfully in many healthcare settings (11).

Healthcare, however, differs from industrial settings in several fundamental ways, including its global scale and complexity, the importance placed on experimental evidence, and clinical and experiential—as opposed to operational—value (12). We contend that complex system analysis offers one promising approach to address these problems. In general, a complex system contains a vast number of interrelated and interacting elements with fluid governing rules, and displays organization without an organizing principle (13). Complex system analysis has been used to model far-ranging systems such as human correspondence activity (14).

In healthcare, complex system research has led to significant new insights in areas such as ICU monitoring (15). For example, investigators have used complex system analysis to generate bioinformatics systems that detect variations in a system of clinical variables from their steady-state values to more promptly identify clinically meaningful changes (16). Clinical decision support is another area in which complex system analysis can lead to improvements in critical care quality. Recently, investigators have focused not only on data integration but on its transmission to the appropriate decision maker (17).

Properly addressing these challenges will require the commitment of substantial resources. Unfortunately, funding for quality improvement research in healthcare is low compared with that of other industries. The Federal Aviation Administration (FAA) levies a 7.5% tax on airline tickets, a significant proportion of which is spent on air traffic control and safety (18). With annual U.S. healthcare spending amounting to approximately $2.3 trillion, the equivalent investment in safety would be on the order of $170 billion (19). The recently increased budget request of the Agency for Healthcare Research and Quality (AHRQ) is $611 million, with only $479 million devoted to the Research on Health Care Costs, Quality, and Outcomes program (20). Health care advocates and legislators have considered tying reimbursements to quality outcomes, notifying consumers of standardized outcomes by hospital or provider, federally mandated safety standards, and increased federal funding for quality research as mechanisms to encourage the industry to fully fund and implement quality improvement programs.

In summary, the ICU is a complex system that must be considered more than the sum of its parts. With an aging population and an explosion of data, the ICU will become ever more complex, and the critically ill more susceptible to medical error. While quality improvement science has led to significant advances, significant limitations persist. Innovative points of view such as a complex system approach, a renewed focus on implementation, and increased funding will be needed to advance the field. The implementation of new knowledge gained from the bench and from clinical trials requires a high-performance healthcare delivery system that can rapidly and efficiently bring these advances to the bedside.

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