

WILL COMPARATIVE EFFECTIVENESS RESEARCH INCREASE PATIENT SAFETY IN INTENSIVE CARE UNITS?

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According to the Institute of Medicine's (IOM's) Web site, comparative effectiveness research (CER) "identifies what works best for which patients under what circumstances."¹ In a recent article published in the *Annals of Internal Medicine*, Sox and Greenfield² describe the concept in more detail:

CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition, or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.

Ideally, CER will provide useful practice data beyond the scope of information generated by a typical 2-arm randomized intervention vs placebo study.

The American Recovery and Reinvestment Act of 2009 contained a provision to establish the Federal Coordinating Council for Comparative Effectiveness Research and included \$1.1 billion for CER. The stimulus bill signed in February 2009 directed the IOM to create a congressional prioritization list of potential areas of need for CER. One hundred high-priority topics were identified by the committee.^{1,3} As shown in the Table, several topics impacting critical care received a high rating, particularly health care delivery.³ Given the high resource use of critical care and associated high mortality within intensive care units (ICUs), critical care is positioned to make an essential contribution to nationwide CER efforts.

The implications for critical care research, particularly for critical care nursing research, are significant. Using CER, critical care researchers will learn how to interpret from the more global ICU-related research structures to render information specific to

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individual ICU patients. CER could help bedside critical care clinicians deliver the care most befitting our individual ICU patients' needs and preferences.⁴

Understanding Safety Implications of Efficacy and Effectiveness

The typical framework in efficacy research is the randomized controlled trial. Usually, the benefits and risks are reported for a well-defined intervention group compared with a similarly characterized placebo group, and both are confined to a narrowly defined population. This design minimizes variability to allow a good chance that only the intervention is the cause for outcome differences between groups. Experts have argued that efficacy research has limited generalizability: a concern that in turn gave rise to the concept of CER.

This issue relates to care decisions at the bedside because clinicians regularly care for patients whose characteristics would exclude them from a typical intervention vs placebo clinical trial. For example, if an efficacy study examined whether a certain drug were an effective treatment for stroke but excluded patients who had chronic dialysis needs, upon approval it would be unclear whether the drug would be safe for ICU patients who present with both stroke and chronic dialysis.

CER is designed to provide critical care personnel with practical diagnostic and treatment options that can guide health care choices for individual patients. Even in those areas already represented by efficacy-structured clinical trials, broad interpretation across patient subpopulations is challenging. After data are in, we are often left with uncertainty.⁴

Why Is Safety a Priority For CER?

Technology at the ICU bedside is pervasive. In many ways, technological advances have driven the

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Table

IOM Top 10 Combined Primary and Secondary Research Areas

Health care delivery systems
Racial and ethnic disparities
Functional limitations and disabilities
Cardiovascular and peripheral vascular disease
Geriatrics
Psychiatric disorders
Neurologic disorders
Pediatrics
Endocrinologic and metabolism disorders
Musculoskeletal disorders

Adapted from: Iglehart JK. Prioritizing comparative-effectiveness research—IOM recommendations. *N Engl J Med*. 2009;361(4):325-328.

field of intensive care. And because we often administer to life-threatening disorders in the ICU, there is an increasing chance that our patients will experience environment-related complications.

A recent report on patient safety described 2 dimensions of safe practice interpretation in the ICU⁵: the “individual patient level” and the “collective level.” On the one hand, safe practice designs can be evaluated at a specific, individual patient outcome level; on the other, an entire ICU can be measured for its impact on all patients. Certain critical care practices could increase or decrease the “effectiveness of our interventions” through a unit safety measurement.⁵ Characterizing organization and unit structure and examining processes of care within the organization or unit structure will be an aspect of CER. But reporting safety only in terms of per-patient errors shortchanges our ability to improve care delivery. These 2 important characterizations could capture a more global ICU safety viewpoint, amounting to a “systems” level analysis.⁵

There are several links between the potential answers from CER and the need for critical care professionals to prioritize ICU patient safety. Health care providers in ICU environments are familiar with multiple organ dysfunctions and higher mortality rates compared to other hospital in-patient areas. Because of their high exposure to near-death and death, critical care personnel commonly struggle to

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maintain patients' and families' wishes in the forefront of decision making and care delivery.

We realize that great variation exists across religious, cultural, and other demographic categories concerning the appropriateness and duration of ICU care administration. The expectation for refinement of care delivery that CER promises therefore may emerge through an important growth within safety practices. The reinforcement of ICU patient safety as a priority for CER may add to our abilities to choose most appropriately from the wealth of ICU technologies available in a very patient-specific manner.

Medical Error and Patient Safety in the ICU

Several reports have helped our field focus appropriate concern on the issue of ICU patient safety.^{6,8} A safety task force has recently asked, "What are the causes of an unsafe ICU and how can we improve the safety culture and environment within our intensive care units?" The task force also proposed that a multiple critical care society consider mechanisms for improvements.⁵ Much CER may take the form of observational studies that lead to better understanding of how ICU safe practice can be promoted.

Observational CER will require tools such as collections of detailed electronic patient records.² Observational ICU studies from large databases may support the principles of CER through daily examination of records from representative ICU patient populations. In the context of a large number of records, it should become easier to contrast subgroups of patients by a variety of characteristics to help identify those with a positive response to specific care practices.²

CER and the Future: Translating CER Findings Into Patient Safety

Many are hopeful that CER will augment our knowledge about the causes for lack of safety in the ICU environment.⁵ Through ICU database development and prospective ICU studies, proponents of CER seek to improve our understanding of how failure to

provide safe ICU processes of care and ICU organization affects both patients and health care professionals.⁵ An important part of the CER process involves prioritizing the public interest, and in so doing there is a hope that clearer information for the public will be associated with safer outcomes.

With CER, there is also the hope that improved decision making by ICU patients and their families will reduce suffering and promote realistic outcomes. Safer outcomes will be linked to ICU professionals' abilities to translate CER into improvements in specific daily ICU care practices.²

The statements and opinions contained in this editorial are solely those of the coeditors.

KEYWORDS: comparative effectiveness research, Institute of Medicine, intensive care, critical care, critical illness, randomized controlled trial, patient safety

FINANCIAL DISCLOSURES

None reported.

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