

# Editorial

## NARROWING THE 17-YEAR RESEARCH TO PRACTICE GAP

By Cindy L. Munro, RN, PhD, ANP, and Richard H. Savel, MD



**D**eveloping evidence to improve clinical practice and disseminating it to be used by clinicians to improve outcomes for individual patients is important. How long does it take to get evidence into practice? The standard refrain of “17 years to move evidence into practice” is repeated by researchers and clinicians alike with despair.<sup>1,2</sup> Rather than accepting the inevitability of a long lag in translating research to the bedside, we believe it is worthwhile to examine the origin of the “17-year gap,” to scrutinize how it applies to interdisciplinary research in critical care, and to suggest ways to close that gap.

In March of 2001, the Institute of Medicine report *Crossing the Quality Chasm*<sup>3</sup> stated, “It now takes an average of 17 years for new knowledge generated by randomized controlled trials to be incorporated into practice, and even then application is highly uneven.” Recently, the National Institutes of Health (NIH) strategic plan<sup>4</sup> estimated that moving a new drug or medical device from conception to market takes 14 years and costs \$2 billion. This includes 6.5 years for laboratory-based drug discovery and preclinical testing, 6 years for clinical trials of promising drug candidates, and 1.5 years for US Food and Drug Administration (FDA) approval of those that are brought to market.

### The Investigative Process

Traditional clinical investigations proceed through multiple sequential steps. The process of planning a project, completing it, and disseminating results can be lengthy. A testable idea must be formulated and refined, and a research team assembled. Preliminary data may need to be gathered to guide a larger investigation. Permissions must be obtained and regulatory requirements met. Support must be obtained for essential resources such as personnel and supplies, which may entail seeking internal and external grant funding. Subjects must be enrolled, interventions delivered, data collected, and analyses performed. The final step for an individual research project entails dissemination of the findings through presentations and publications. Each of these steps is essential, and each takes time.

For pharmaceuticals, basic and preclinical research require a large investment of time and money. Only 5% of compounds initially screened in early research will move forward to market.<sup>4</sup> Fortunately, not all critical care research involves pharmaceuticals, and not all critical care research requires lengthy accumulation of basic science and preclinical studies prior to development of clinically relevant research questions. Where FDA approval is not required, the process can move more quickly.

### Assessing the Evidence

After research studies are completed, additional time is needed for the scientific community to amass

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and assess evidence from multiple studies examining an area of intervention. In developing clinical guidelines that translate evidence to practice, both the quantity and quality of available evidence must be evaluated. GRADE (Grading of Recommendations Assessment, Development and Evaluation Working Group)<sup>5</sup> and the American Association of Critical-Care Nurses (AACN) evidence-leveling hierarchy<sup>6</sup> provide standardized approaches to developing clinical practice guidelines and rating the strength of recommendations. Few clinical questions are definitively answered in a short amount of time. More frequently, clinical questions are addressed in an iterative series of research studies, progressing from early observational studies to randomized controlled trials and meta-analyses. Guideline developers must make sense of a body of literature that includes diverse study designs, heterogeneous subject samples, differences in interventions, and a variety of outcome measures. New evidence may contradict or alter the interpretation of previous research, resulting in a need for continuous review and updating of existing guidelines.

Critical care research, including nursing and interdisciplinary research, regularly focuses on patient's problems and interventions that do not involve drugs or devices and that have a rapid uptake in clinical practice. As an example, early mobility in the intensive care unit (ICU) has been the subject of research for less than a decade, but mobility protocols already have been widely implemented. Based on currently available evidence, mobility projects have been instituted in 11 ICUs through the AACN Clinical Scene Investigator (AACN CSI) Academy. Project summaries, final presentations, and implementation toolkits are posted at the AACN CSI website.<sup>7</sup> Research in oral care, support of families in the ICU, infection control, communication, and optimizing team processes have had similar rapid translation to clinical practice and have been regularly updated as evidence evolves.

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### National Initiatives

National initiatives are under way to narrow the research to practice gap. In 2012, the NIH established the National Center for Advancing Translational Sciences (NCATS).<sup>8</sup> NCATS is responsible for accelerating the timeline for converting basic science research to testable clinical products (Type 1 translation) and from clinical research into practice (Type 2 translation). As a leader in translational science, NCATS focuses on the process of translating research into safe and effective treatments for patients, and seeks to understand the science underlying that process rather than any specific disease.

Whereas quality improvement at the local level remains important, more emphasis should be placed on translational science. Translational science is distinct from local quality improvement. Translational science seeks to implement practice change broadly throughout the health care system, using scientific and operational principles. It seeks to change all clinical practice. Quality improvement projects at the local level seek to optimize clinical practice within a local context. Quality improvement is most efficient and effective when based not only on high quality basic and clinical research, but on translational science as well. Generalizable knowledge about how research findings should be applied in clinical practice, resulting from translational research, provides a jumpstart for local quality improvement efforts.

The 21st Century Cures Act, proposed by Congress, is a more controversial approach to resolving the research to practice gap.<sup>9</sup> The version of the 21st Century Cures Act recently passed by the House and referred to the Senate (Committee on Health, Education, Labor, and Pensions) has 3 important components: additional funding for the NIH, in part to support young investigators and precision medicine initiatives; acceleration of the FDA approval process for drugs and devices, including use of evidence from clinical experience rather than reliance on randomized clinical trials, and use of biomarkers and other surrogate markers as outcome measures; and increased after-market monitoring of drugs and devices. There are concerns that the acceleration of FDA approval may compromise safety. We have written before about the consequences of moving pharmaceutical agents into practice without the evidence of multiple randomized trials to verify effectiveness and safety<sup>10</sup>; reducing the level of evidence

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required for drug approval may speed more pharmaceuticals to market, but also may be associated with increased harm.

## Conclusion

Critical care researchers and clinicians can contribute to narrowing the research to practice gap. Conducting larger, multisite studies rather than small single site studies would narrow the gap by enrolling required subjects more quickly and reducing the time required to complete research. Multisite studies also would provide more generalizable data, speeding translation to practice. New experimental designs such as adaptive trials, stepped wedge designs, and comparative effectiveness trials may increase efficiency of clinical research. Further, critical care researchers can narrow the research to practice gap by presenting results in a way that provides actionable information to authors of guidelines and to clinicians. Clinicians should seek and use high quality evidence for their practice, including guidelines that synthesize the available evidence.

We value the crucial contribution the *American Journal of Critical Care* makes in disseminating high quality research that provides clear guidance for interdisciplinary clinical practice with high potential for improving outcomes for critically ill patients. Moving research into practice is a delicate balance of incorporating new findings quickly enough to maximally benefit patients, but not so quickly that we expose patients to unnecessary harm. Critical care practice has built on clinical and translational research since its inception, and we can lead the way in narrowing the research to practice gap.

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

## FINANCIAL DISCLOSURES

None reported.

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