

rations care far more than comparative studies ever could.

The assault took on a more Orwellian tone 10 days later when Betsy McCaughey, a former lieutenant governor of New York, linked funding for CER with the stimulus bill's provisions supporting the use of electronic medical records. She warned that the inclusion of both initiatives was designed to enable electronic monitoring of individual patient-care decisions by the federal government and punishment of clinicians who fail to comply with imminent rationing guidelines.<sup>4</sup> The radio talk-show host Rush Limbaugh then disseminated this message to millions of listeners, warning that once the stimulus bill "computerizes everybody's health record," a new federal bureaucracy "will monitor treatments to make sure your doctor is doing what the federal government deems appropriate."<sup>5</sup>

This avalanche of nonfacts did not succeed in derailing the stimulus bill or its CER funding. Although these commentaries painted caricatures of new federal powers that were not in the bill, they were a shot across the bow of the entire CER enterprise. As the debate continues, we are likely to see more diatribes designed to further an ideological or commer-

cial agenda. But CER also raises important issues that warrant the continuing attention of thoughtful clinicians and policymakers. For instance, although such research may well determine the first-line approach most likely to benefit a typical patient, what is the best way to individualize treatment for "outlier" patients for whom that approach turns out not to be the best strategy? For some medications, pharmacogenetics may give us an evidence-based way to identify these patients prospectively, but that science is not ready to be applied to most therapeutic decisions. Moreover, cost-effectiveness is a concept laden with difficult ethical and methodologic issues that we cannot dismiss simply on the basis of an appeal to utilitarianism. What is the moral responsibility of the physician to care for a patient for whom the best therapy may not meet conventional standards of cost-effectiveness? These aspects of the debate will need to continue as we begin to implement CER with this vital new funding.

Fortunately, Congress did not let warnings of a dystopian scientific police state undercut the nation's need to learn what works best in medicine. Given the quality and cost crises we face, preserving ignorance would have been

a poor strategy for improving the effectiveness, safety, and affordability of health care. Although CER dodged a barrage of well-coordinated bullets this time, the debate is bound to continue. To engage in it responsibly, we must stay focused on the methodologic, practical, and ethical issues we will face in the new era of CER, while avoiding the disinformation and distractions that seek to equate generating new knowledge with denial of care.

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## The Neglected Purpose of Comparative-Effectiveness Research

Aanand D. Naik, M.D., and Laura A. Petersen, M.D., M.P.H.

On February 17, 2009, President Barack Obama signed into law an initiative providing \$1.1 billion to support research on the comparative effectiveness of drugs, medical devices, surgical procedures, and other treat-

ments for various conditions. This comparative-effectiveness research (CER) initiative has generated considerable controversy. Industry and free-market advocates have expressed concerns about the role of cost-effectiveness analyses within

CER and subsequent governmental intrusion into doctor-patient decisions.

Despite such controversy, the broad consensus is that although the amount of funding the federal government provides for re-

The Three Translations Required to Improve the Quality of Primary Percutaneous Coronary Intervention (PCI) in Patients with Acute Myocardial Infarction.		
Translational Tier	Type of Research	Products of Research
T1	Clinical efficacy research	Proof that primary PCI is more effective than fibrinolytic therapy in controlled clinical trials
T2	Comparative-effectiveness and health services research	Establishment of a 90-minute standard for the interval between arrival in the emergency department and the initiation of coronary intervention
T3	Implementation research	Identification of hospital-based strategies to reduce the time to PCI and establishment of consortium to guide local integration of strategies

search is already large, the translation of this investment into practice, enabling new laboratory discoveries to reach patients' bedsides, is frustratingly slow. Furthermore, much of the government's research funding goes toward randomized clinical trials that evaluate the efficacy of new drugs, devices, and treatments within highly controlled environments. Doctors are most concerned about the relative benefits and harms of one treatment as compared with another for a particular patient, but randomized trials are seldom designed to answer these types of practical questions.<sup>1</sup> Therefore, health policymakers, health insurers, and providers are increasingly interested in the information that could be obtained from studies of the comparative effectiveness of various treatments for specific conditions.

Surprisingly little attention has been paid to what we believe is the most critical question facing CER: Will its results significantly improve the quality and safety of the health care received by the average patient? Policymakers and research funders, such as the National Institutes of Health, often assume that the final steps in the translation of clinical research — the decision to act on new medical evidence and its im-

plementation in routine care — are seamless and automatic, whereas we know that changing the behavior of physicians and patients is difficult.<sup>2</sup> Though we agree that the need for CER is clear, many of the assumptions regarding the most important aspect of such research — the ultimate implementation of its findings into health care — have little empirical support.

One encouraging example of the fruits of linking CER with implementation research is the remarkable improvement in the safety and quality of primary percutaneous coronary intervention (PCI) during acute myocardial infarction. Numerous randomized trials in the early 1990s established the clear superiority of primary PCI over fibrinolytic therapy in controlled, clinical laboratory settings. Subsequent comparative-effectiveness studies examining the characteristics of patients and systems that were associated with the time from presentation to primary PCI showed that delays common in most real-world settings attenuated the benefits of therapy.<sup>3</sup> Ten years after the publication of the first efficacy studies, less than one third of hospitals were achieving the average time from diagnosis to PCI (90 minutes or less) associated with high-quality care. Recent efforts

to understand and ameliorate this quality gap have relied on implementation science, using qualitative and survey research methods to identify hospital-based strategies associated with faster times to primary PCI. Implementation researchers have worked in partnership with health care organizations and professional societies to develop a tool kit to facilitate hospitals' implementation of strategies that reduce these times.<sup>3</sup>

Given that the experience with PCI is uncommon — research results are rarely implemented into routine health care — it is time to revisit our expectations of what CER will produce. CER is the centerpiece of the Effective Health Care Program of the Agency for Healthcare Research and Quality (AHRQ) ([www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov)) whose creation was mandated by the Medicare Modernization Act of 2003. Leaders within the AHRQ recently described the need for three tiers of evidence translation: the first translating basic science into clinical efficacy data (T1), the second (T2) using patient-oriented outcomes and health services research to develop knowledge about clinical effectiveness, and the third (T3) using implementation research for continuous measurement and refinement of treatment

implementation.<sup>4</sup> (See the table for an overview of these tiers as applied to primary PCI.)

These leaders argue that an earlier emphasis on creating informational tools for organizing and disseminating CER findings has given way to an imperative to develop connections between researchers and practitioners through measurement, experimentation, and dissemination of information about the best ways of delivering effective care.<sup>4</sup> Similarly, the Department of Veterans Affairs (VA) has developed the Quality Enhancement Research Initiative (QUERI; [www.queri.research.va.gov](http://www.queri.research.va.gov)) for disseminating research findings to VA policymakers, providers, and patients and has created a dedicated resource center, the Center for Implementation Practice and Research Support (CIPRS; [www.queri.research.va.gov/ciprs/default.cfm](http://www.queri.research.va.gov/ciprs/default.cfm)), to accelerate improvement in the quality and performance of VA health care through implementation research and practice.

These efforts suggest that some researchers and policymakers guiding the three tiers of evidence translation have come to understand that a shift is needed from the “science of recommendation to a science of implementation.”<sup>2</sup> The creation of a CER initiative focused on developing and disseminating effectiveness reviews is an essential, but not a sufficient, step toward the routine provision of safe, high-quality health care to all Americans. We also need evidence-based methods for discovering and describing how the findings of clinical trials and CER can be efficiently implemented and incorporated into routine practice.<sup>5</sup> Harnessing the promise of CER by ensuring the efficient and effective im-

plementation of its findings into practice requires substantial investment and planning that will involve health care providers, patients, and other local stakeholders.

An implementation research and development program designed for this purpose could fulfill three important objectives: it could accelerate the translation of evidence into everyday care, enhance the opportunities for doctors and patients to define value (balancing expected benefits with costs) on the basis of their understanding of local contexts and constraints, and allow providers and patients to communicate with researchers and policymakers about clinically important issues earlier in the research process. In efforts to reduce the average time to primary PCI, for example, hospitals are encouraged to use several core strategies that define high-quality primary PCI care, but they are given substantial latitude in determining the best methods of applying these strategies.<sup>3</sup> Local factors such as infrastructure, existing processes, the degree of buy-in by clinicians and administrators, and the costs associated with change may vary widely among hospitals and regions. Stakeholders determine how best to integrate the core strategies into local practice, given the value of the action steps required for implementation. Decisions that are not informed by a recognition of local constraints are likely to be poorly received and ineffective.

As demonstrated by the example of primary PCI, implementation research and development are critical for achieving the objectives of CER. The Federal Coordinating Council for Comparative Effectiveness Research need

look no further than the VA's QUERI program, CIPRS, and the AHRQ's John M. Eisenberg Clinical Decisions and Communications Science Center for useful models. These programs are well positioned to achieve the three objectives of implementation research. Above all, the Federal Coordinating Council must remain mindful that the primary goal of CER is to enhance the translation of new medical discoveries into safe and high-quality health care for all Americans. This goal can be achieved only if our renewed investment in CER includes a commitment to implementation research.

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