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Implementation Research: A Critical Component of Realizing the Benefits of Comparative Effectiveness Research

David Atkins, MD, MPH, Joel Kupersmith, MD

Office of Research and Development, US Department of Veterans Affairs, Washington, District of Columbia, USA.

ABSTRACT

Comparative effectiveness research (CER) holds the promise of improving patient-centered care and increasing value in the healthcare system. Achieving these goals, however, depends on effectively implementing the findings of CER. In this article, we draw on lessons from implementation research and our experience in the Veterans Administration (VA) healthcare system to offer recommendations about what is needed to support implementation of CER. There is no single strategy for successful implementation. Implementation efforts must take into account the nature of the evidence, the type of change being implemented, the clinical context in which the findings are being applied, and the specific barriers and facilitators to implementing new practices. The experience of the VA illustrates the importance of taking a systems approach that aligns numerous elements of the healthcare system—guidelines, decision support, performance measures, financial incentives, coverage and benefits policy, and health information technology—to support implementation:. We illustrate these principles with an example of implementing a new model of evidence-based depression care.

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The growing support for comparative effectiveness research (CER) rests on an underlying premise that better information comparing the benefits and harms of alternative therapeutic or diagnostic strategies will enable patients, providers, and policymakers to make better choices.[1] This should produce more patient-centered care, more effective treatments, less waste, and higher-value healthcare. Increasing the output of comparative information will not, however, produce any of these desired results unless concerted efforts are made to implement the findings of CER.[2] A recent call for research proposals from Agency for Healthcare Research and Quality (AHRQ) has highlighted the need for studies to demonstrate effective implementation of CER.[3] Implementation needs to be considered an integral part of CER, however, not relegated to an afterthought to be considered only when CER research produces actionable results. In this article, we review possible lessons from implementation research for the design and conduct of CER, reflect on our experience trying to foster implementation through the Quality Enhancement Research Initiative (QUERI) program in the Veterans Health Administration (VHA), and offer suggestions for how CER might improve the chances that its results will be taken up in practice.

The emerging interest in "translation research" and "implementation science" coincided with attention to pervasive problems in the quality, safety, and consistency of healthcare in the United States.[4,5] The "quality chasm" identified by the Institute of Medicine reflected fundamental problems that went far beyond knowledge gaps about effective treatments, diagnostics, and preventive interventions. The long lag between initial efficacy research and widespread adop-

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Requests for reprints should be addressed to David Atkins, MD, MPH, Health Services Research and Development ProgramOffice of Research and Development, US Department of Veterans Affairs, 810 Vermont Ave NW (124), Washington, District of Columbia 20420.

E-mail address: David.atkins@va.gov.

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tion of new treatments is well known[6] and has been attributed to "blocks" in the translation process. The initial focus of funders such as the US National Institutes of Health (NIH) has been on improving the transformation of basic science advances into potential clinical interventions (T1) and translating promising interventions into patient-specific evidence of effective care (T2).[7] Health services researchers identified a third (T3) activity needed to ensure that proven interventions are delivered consistently and reliably throughout the healthcare system.[8] Successful T3 translation requires much more than traditional dissemination efforts. It involves improving our ability to measure delivery of effective care, ensuring accountability and aligning incentives for effective care at various levels in the healthcare system, redesigning practice delivery to make "doing the right thing the easy thing," leveraging technology such as electronic health records (EHRs) and decision support, engaging patients so that decisions reflect their priorities, and improving our ability to spread improvements from well-resourced early adopters to a more diverse set of delivery sites and providers.

Many efforts to implement evidence continue to focus on traditional dissemination and education approaches aimed at both providers and patients. This in part reflects the limited points of leverage for the professional societies or public health organizations that produce guidelines to promote changes in clinical practice, given the current fragmented nature of healthcare delivery in the United States. Evidence suggests that simple dissemination and education efforts, while necessary, often have small effects and are rarely sufficient by themselves to promote lasting changes in practice.[9] More comprehensive organizational change, including changing financial incentives for patients and providers, restructuring care processes, using performance reporting and feedback, and optimizing health information technology for both providers and patients, have been much more effective in promoting desired practices such as immunizations, preventive screenings, and post–myocardial infarction (MI) care.[10]

While multifaceted approaches are usually necessary to support implementation, a sustainable implementation strategy requires that we match the most effective strategies to the specific needs of the situation. For example, electronic reminders are useful for simple practices such as giving a vaccination but less so for more complex intervention such as obtaining a Pap smear,[10] and if used indiscriminately they can overload clinicians. Implementation science applies a framework to understand the implementation process so that we can identify overarching principles that help explain when and why implementation efforts succeed or fail.[11,12] By understanding the factors that contribute to successful implementation, we can develop more targeted and effective implementation strategies matched to the specific practice being implemented, the clinical setting, and barriers to adoption.

LESSONS FROM IMPLEMENTATION SCIENCE

A wide variety of theories and frameworks have been offered to explain the implementation process, and each has its own strengths and limitations.[13-17] Although the different frameworks may use different constructs and terminology, they share a number of common elements that are relevant to CER.

Evidence

Implementation is much easier when there is clear compelling evidence, for example, when benefits are large and when downsides are small.[17] It is not surprising that the use of many cardiovascular treatments, such as lipid-lowering drugs and aspirin after MI, has increased dramatically as large clinical trials demonstrated clear benefits on mortality and few harms.[18] Changing practice is likely to be harder where the tradeoff between benefit and risk is closer and where evidence is derived from nonrandomized studies or from selected settings. This has important implications for CER in 2 respects. First, our ability to implement will be influenced by the quality (or perceived quality) of the evidence produced by CER. This will require improving the consensus on using clinically robust registries and observational databases to answer CER.[19] Where questions are particularly controversial, we may need to invest in more compelling evidence from direct comparative trials with clinical outcomes (for example, prostatectomy versus watchful waiting for early prostate cancer).[20] Second, because CER often compares one active treatment to another rather than to placebo, we will frequently face evidence that involves smaller differences between options or more complex tradeoffs (for example, differences between open prostatectomy and minimally invasive surgery).[21]

Context

The second insight is the importance of context.[15-17] Each change occurs in a unique context that is a function of the nature of the intervention or change, the setting in which it occurs, and the particular targets of the change. Sometimes the practice implications of CER findings will be relatively simple—for example, changing the preferred dose of a given drug—but others may involve substantial changes to the delivery system. Numerous studies had documented that collaborative care for depression was a more effective model than conventional referral from primary care providers,[22] but implementing these new models of care required a more organized process of supporting implementation (see below).

Comparative effectiveness results may create important shifts in who delivers care for certain conditions—for example, a shift from primary care physician to specialist (or vice versa) or from surgeon to radiation oncologist. In a fee-for-service system, this can create potential "winners" or "losers," and in capitated systems it can create challenges in workload, both of which can complicate implementation.