



From Evidence to Practice:

Making CER Findings Work for Providers and Patients

A NEHI Issue Brief – July 2010

Project Sponsor



This issue brief was made possible by generous support from the WellPoint Foundation. The views expressed herein are solely those of the New England Healthcare Institute.

About NEHI:

The New England Healthcare Institute (NEHI) is a nonprofit, health policy institute focused on enabling innovation that will improve health care quality and lower health care costs. Working in partnership with members from across the health care system, NEHI brings an objective, collaborative and fresh voice to health policy.

Introduction

Successful dissemination of the findings from comparative effectiveness research (CER) studies to clinicians and patients is essential if CER is to achieve its desired objectives: improving health care outcomes and reducing U.S. health care spending.

Successful dissemination is thus a high priority of the federal government's new commitment to CER. Successful dissemination will depend not only on how CER findings are communicated, but on whether CER is conducted in ways that yield clear, actionable results that are, in turn, clearly communicated to clinicians and patients.

This issue brief identifies a number of major factors found by NEHI research that could influence the creation of a coherent and effective CER dissemination strategy.

Background: The Patient Protection and Affordable Care Act

Comparative effectiveness research (CER) is an integral part of the strategy for systemic health care reform outlined in the Patient Protection and Affordable Care Act. Building on the \$1.1 billion outlay for CER contained in the 2009 economic stimulus legislation, the 2010 health care reform legislation creates an independent entity (the Patient Centered Outcomes Research Institute – PCORI) to commission new comparative research. It delegates to the Agency for Healthcare Research and Quality (AHRQ) the task of disseminating CER findings to clinicians, patients, health care payers and other stakeholders. AHRQ brings an existing infrastructure to this task based on investments first authorized by the Medicare Part D prescription drug legislation in 2003 (the Medicare Modernization Act).

The Patient Protection and Affordable Care Act stipulates that:

- AHRQ will be responsible for disseminating research produced under PCORI auspices, in consultation with the National Institutes of Health.
- AHRQ's Office of Communication and Knowledge Transfer must disseminate PCORI-produced research within 90 days of receiving the study findings.
- Findings must be disseminated to key stakeholder groups, including clinicians, patients, pharmaceutical companies and health plans.
- Reports disseminated must include appropriate descriptions of patient populations relevant to the research, research methodologies and limitations of the findings. The AHRQ Office of Communication and Knowledge Transfer will reach out directly to developers of

clinical decision support tools to promote timely incorporation of CER findings into decision support at the point of care. The AHRQ Office of Communication and Knowledge Transfer will create other “informational tools” to aid dissemination among physicians, patients, payers, other health care professionals and policymakers. The AHRQ Office of Communication and Knowledge Transfer will develop mechanisms for stakeholder feedback regarding the value and usefulness of CER reports disseminated under the program.

In short, the Patient Protection and Affordable Care Act envisions active roles for PCORI, AHRQ, and the National Institutes of Health in the dissemination of CER findings. However, critical issues regarding dissemination strategy remain to be determined, including:

- ⇒ **How PCORI will choose to report initial findings to AHRQ, and how AHRQ will choose to disseminate findings within the 90 day period called for by the Patient Protection and Affordable Care Act;**
- ⇒ **Whether findings will be translated to convey the strength of underlying evidence, and who will sponsor or carry out the task of evaluating strength of evidence;**
- ⇒ **How findings will be translated and adapted for presentation to distinct audiences (patients, providers, payers, etc.);**
 - **In particular, whether and how CER findings will be communicated directly to the general public and to patients, through mass media and through tools such as decision aids**
- ⇒ **How PCORI-sponsored reports will be different from, complement, or harmonize with CER reports conducted outside of PCORI auspices; and**
- ⇒ **How collaborations will be created between the federal government and groups outside government (medical specialty societies, health care delivery systems, patient groups, etc.) to adapt CER findings for further dissemination, and whether such collaborations will actively promote uptake among clinicians and patients.**

Existing Hurdles to Evidence Dissemination in the Health Care System

The high priority now placed on dissemination of new CER findings reflects increased awareness that existing medical evidence of all types is haphazardly disseminated throughout the U.S. health care system, and that the uptake of new findings by clinicians and patients is protracted and uneven. The Institute of Medicine’s Roundtable on Evidence-based Medicine (now the Roundtable on Value and Science-Driven Health Care) has drawn attention to this issue repeatedly over the last decade. A frequently cited study suggests that it takes 17 years, on average, for rigorous medical evidence to find its way into common practice.¹

¹ Balas EA, Boren SA. Managing clinical knowledge for health care improvement. In: Bemmel J, McCray AT, editors. Yearbook of Medical Informatics 2000: Patient-Centered Systems. Stuttgart, Germany: Schattauer Verlagsgesellschaft mbH; 2000:65-70.

Analysts cite numerous hurdles to the successful dissemination and uptake of medical evidence by practicing clinicians and patients. They include:

- *Limitations of the scientific evidence:* gaps in the medical evidence due to the limits of scientific knowledge, limitations of study design, or both;
- *Constraints on practicing clinicians:* little or no time to consult evidence or consult colleagues about evidence, limited reimbursement for time spent consulting evidence, and limited skills among some clinicians for consulting electronic data sources;
- *Constraints on patients:* limited understanding of health and health care issues among many patients, and limited capabilities among clinicians and delivery organizations to make health and health care choices comprehensible to typical patients;
- *Limited incentives for clinicians to change practices:* lack of (or weakness of) financial and professional incentives for clinician adherence to evidence-based guidelines or protocols, clinician distrust of an over-reliance on evidence (“cookbook medicine”), and organizational inertia;
- *Limitations in the presentation of evidence:* unclear presentation, inconvenient formats, and lack of clear rationale for action by the clinician or patient; and
- *Limited access to evidence:* uneven distribution of health care information technology infrastructure and other resources that make evidence available in convenient forms to clinicians and patients.

Anticipated Hurdles to CER Dissemination

Proponents see CER study results as a form of data that meets the needs of patients and clinicians in a way that will facilitate the overall uptake of medical evidence.

In theory, well-done comparative research will produce robust findings on the pragmatic alternatives facing clinicians and patients in everyday medical practice. The randomized controlled trials (RCTs) that currently represent the gold standard for conventional medical evidence are typically designed to be internally-valid tests of efficacy of a single intervention. CER studies assess broader topics, comparing and contrasting treatment choices, and thus may be more relevant to actual decision-making.

Nevertheless, factors unique to the conduct of comparative effectiveness research create new hurdles for the dissemination and uptake of the research. Congress and the Institute of Medicine have recognized that new strategies will be needed to disseminate CER evidence, no matter how robust CER findings prove to be. Special hurdles to CER dissemination include:

The public perception of CER and its legitimacy

The debate over CER became the first flash point in the rancorous 2009-2010 debate over national health care reform, and most analysts agree that public concerns over some elements of CER have not been allayed. Consumer research suggests that the public is not well informed about many of the most fundamental concepts of evidence-based medicine, and is not well prepared to understand the case for CER in medical decision-making.²

² Carman KL, Maurer M, Mathews Yeglan J, Dardess, McGee J, Evers M, Marlo K. Evidence That Consumers Are Skeptical About Evidence-based Health Care. *Health Affairs* 29:7 (July 2010).

Clinicians' trust in systematic reviews and observational studies

One of the many tasks facing the new PCORI's Board of Governors will be making decisions on how to allocate CER funding among different forms of research, including prospective trials, systematic reviews and meta-analyses, and observational studies. Given the expense and time required to conduct entirely new trials, it seems likely that systematic reviews (and to a lesser extent, observational studies) will be the dominant form of CER for some time to come.

The volume of systematic reviews and meta-analyses has increased markedly in recent years, but questions remain as to how powerful they have proven to be in influencing medical practice. Among the factors that inhibit full acceptance of systematic reviews are (a) the relative youth of the field, and (b) the necessity for researchers performing the views to utilize statistical and decision analytic methods that may be foreign to most clinicians and thus not entirely transparent to them. The use of these methods also poses a challenge to external peer review of systematic reviews, as peer reviewers must be experts who are capable of understanding both review methodologies and the judgments made by the researchers conducting the systematic reviews. Currently, AHRQ's Effective Health Care program encourages, but does not require, the external publication of AHRQ-funded reviews in peer-reviewed journals. The Patient Protection and Affordable Care Act makes provisions for the utilization of medical journal peer review for PCORI-sponsored research.

Lack of standard methodologies

Clinician uncertainty about systematic reviews and observational studies is only one aspect of a larger sense of uncertainty regarding CER methodologies. While there is broad recognition throughout the medical community that findings from RCTs have significant limitations for use in everyday practice, they nevertheless remain the gold standard of medical evidence. As of yet, there are no widely-accepted standards for methodologies designed for the conduct of systematic reviews, meta-analyses and observational studies, although many clinicians believe that such studies yield important practical insights, and these studies are far less expensive and time-consuming to conduct compared to RCTs. Physicians and health care delivery organizations are less likely to consider and act on CER findings if they do not entirely trust the methodologies used to generate the data.

The authors of the Patient Protection and Affordable Care Act clearly recognized the urgency of methodology development. The act directs the PCORI to create a Methodologies Committee that will report back on methodology development within 18 months of its creation.

Trust in CER methodologies among patients and the general public will also be an important factor in the acceptance of CER as a guide to patient decision-making. This was underscored for many CER analysts by the public uproar over the U.S. Preventive Services Task Force mammography guidelines in the summer of 2009, as well as in the hostile reaction of some members of Congress to use of analytical tools such as the quality-adjusted life year as a tool for CER.

Speed of change in the evidence base

One of the inherent limitations of CER studies is that they provide data for only a snapshot-in-time. Constant changes in medical technology and rapid changes in biomedical science create a need to revise CER findings to reflect these changes. (Authors of practice guidelines and

treatment protocols face the same challenge.) Some fields change more rapidly than others (oncology, for example). Sound dissemination policy will need to accommodate timely revisions of findings, and may need to create revision procedures tailored to specific fields.

Strength of evidence

Comparative analysis of any given topic may not yield evidence of a large or clear effect between one compared intervention or another, and evidence of a clear effect may rest on relatively weak data or weak studies. As of yet there are no generally accepted criteria for grading studies on their strength. CER studies that report minor or ambiguous differences among competing options are less likely to be disseminated successfully or to seriously influence medical practice.

Heterogeneity of treatment effects

All forms of medical evidence are challenged by heterogeneity of treatment effects: The results of any given medical study are not applicable to every patient. The impact on, and the very existence of, population subgroups is frequently unknown or poorly understood.

As mentioned above, acceptance of evidence-based medicine is frequently hampered by the perception that it represents “cookbook medicine.” The threat that new federally-supported CER findings will similarly create “one size fits all medicine” was a flashpoint in the 2009 debate over CER. Yet CER proponents point out that well-done CER studies that are based on the best available data should have the opposite effect: they will begin to detect heterogeneous effects that previous research has been unable to identify.

Drivers of CER Dissemination

In its June 2009 report to Congress, the Institute of Medicine recommended that the national CER program should actively support research on CER dissemination -- an acknowledgment that there is little consensus on best practices for CER dissemination that are pertinent to broad audiences of clinicians and patients.

In fact, communication of all forms of health care information is a rapidly changing and highly entrepreneurial domain. Health care information technology and other innovations have vastly expanded the channels for distributing evidence and the formats in which it can be delivered. Customization of CER findings in formats appropriate for different audiences is a goal of the current AHRQ Effective Health Care program, and a task called out specifically by the Patient Protection and Affordable Care Act.

Experts point to three current trends that are potential drivers for CER dissemination:

The “Learning Health Care System” concept and the contextualization of evidence

The Institute of Medicine’s Roundtable on Value and Science-driven Health Care (formerly the Roundtable on Evidence-based Medicine) has popularized the so-called learning health care system. In this system, existing medical evidence (such as CER findings) are continuously tested and evaluated against outcomes observed in real-life medical practice, such as outcomes evaluated from electronic medical records and patient databases compiled by health care providers. In this way, evidence is continually revised to fit the context of actual patient populations and the actual settings in which the patients receive care.

Leading integrated health care systems such as the Veterans Administration, Intermountain Health Care, the Mayo Clinic and Geisinger Health System are demonstrating the capabilities

of a learning system by utilizing patient records, databases and sophisticated analytical capabilities to create and revise their own care treatment protocols. Assuming steady implementation in the future, the deployment of health care information technology throughout the country under the stimulus bill's HITECH Act for funding health IT promises to extend these same capabilities further throughout the system.

Patient-centered health care

Patient-centered care is a stated goal of health reform. It is endorsed in many provisions of the Patient Protection and Affordable Care Act, including provisions that promote adoption of the patient-centered medical home and the utilization of shared decision-making techniques among clinicians and patients.

Patient-centered care is expected to influence CER dissemination in at least two ways. First, it will drive demand for patient education programming and materials, and the creation of decision aids that support improved patient-clinician communication and improved patient decision-making. Second, it will influence (or should influence) the conduct of CER itself, in that patient-centered research will (or should) yield findings that go beyond typical clinical concerns such as mortality and morbidity, and address issues of patient preference, lifestyle and values, such as activities of daily living, the ability to adhere to treatments, the impact of treatments on work life, and so on.

Mass media

Mass media, including the Internet and electronic media, are increasingly influential channels for the delivery of health care information. Social media networks to exchange health and medical information are increasingly common. Health care-related web sites are now among the most heavily trafficked sites on the Internet. A recent Pew Research Center study report found that 66% of Internet users get their health care information online, and that all Internet users would like to see more news coverage of health and health care issues.

Building a Coherent Strategy for Dissemination: Policy Choices

CER policymakers and health care leaders face a seemingly unlimited array of choices for creating a comprehensive CER dissemination policy in the U.S. As a general principle, the Patient Protection and Affordable Care Act directs PCORI and AHRQ to ensure that CER products are customized to the needs of appropriate patient sub-populations. Beyond this, recommendations from experts suggest six key components for optimizing CER dissemination:

Use consistent evidence ratings

Experts have recommended the creation of systematic, rigorous evidence ratings that could be applied to CER findings.³ The U.S. Preventive Services Task Force employs letter grades (A, B, C, etc.) to communicate the strength of evidence of effectiveness of recommended measures of preventive medicine. The Institute for Clinical and Economic Review (ICER) employs a "bond rating" style that communicates information on both the level of clinical effectiveness associated with a given intervention, and the strength of the underlying evidence.

³ Pearson S, From Better Evidence to Better Care: Using Comparative Effectiveness Research to Guide Practice and Policy, in *Implementing Comparative Effectiveness Research: Priorities, Methods, and Impact*, Brookings Institution, June 2009.

Create partnerships with stakeholder groups

Sponsors of CER (PCORI, AHRQ, NIH, academic researchers) could create formal partnerships with stakeholder groups to shape both the conduct of research and appropriate dissemination strategy. Formal partnerships – if successful – would lend legitimacy to CER findings through their association with trusted organizations, and would enhance the level of physician and patient buy-in necessary to ensure appropriate uptake of CER findings.

Potential partnerships could include:

- Partnerships with organizations such as medical professional societies that develop medical practice guidelines;
- Partnerships with health care delivery organizations, such as physician practices and hospitals, including conversion of CER findings into each organization’s practice protocols; and
- Partnerships with patient advocacy organizations, to win endorsement for standards of care supported by patient advocates.

One of the most prominent examples of a broad, collaborative approach to development of actionable CER findings is the process utilized by the Cochrane Collaboration to create and revise systematic reviews.⁴

Select high priority targets for dissemination

Coordinated and intensive dissemination strategies could be devised to support dissemination of evidence regarding specific medical interventions or types of medical interventions.⁵ Targets might include highly prevalent disease states, costly disease states or health conditions that represent significant threats to public health. Coordinated strategies would entail identifying specific barriers to the uptake of evidence relative to these diseases or conditions, and the creation of specific strategies to overcome them. Such a strategy might be particularly relevant to disease states in which patient engagement and adherence are important, and in which good clinician performance is not sufficient to ensure good outcomes. One model of targeted dissemination is the “Get With the Guidelines” program, sponsored by the American Heart Association to promote consistent application of the most recent scientific guidelines for heart disease and stroke treatment in both inpatient and outpatient settings.

Integrate CER dissemination into the deployment of health care information technology

The Department of Health and Human Services has promulgated “meaningful use” criteria for the adoption of electronic medical records and health care information technology that will be reimbursable by the Department under the HITECH act. Utilization of electronic clinical decision support is a primary goal of the meaningful use criteria, and thus federally supported health care information technology deployment creates a major opportunity to integrate CER findings into clinical decision support at the point of care.

⁴ As described in the Cochrane Collaboration manual, “In contrast to the practices of most print journals, review authors do not, in general, approach the Cochrane Review Group with their finished review. Rather, the Review Group’s editorial base provides an input to the review process from the very beginning. Suggested review titles are thoroughly discussed with the Review Group’s editorial team; authors are then encouraged to attend a protocol workshop, which leads to the preparation and subsequent publication of a protocol, i.e. a plan of how the review will be carried out.”

Utilize patient and clinician incentives to promote comparative clinical effectiveness

The language of the Patient Protection and Affordable Care Act reflects strong Congressional sentiment that federally supported CER should focus on demonstrating the clinical, and not the cost, effectiveness of competing interventions. The Centers for Medicare and Medicaid Services is restricted in its ability to use even comparative clinical effectiveness findings in making coverage decisions.

Private payers, however, are not restricted in considering comparative clinical effectiveness data in making coverage and reimbursement decisions, and many already do so through value-based insurance design (VBID) and provider incentives such as pay-for-performance plans. Payers and purchasers are likely to remain extremely interested in applying CER findings to coverage and reimbursement decisions, and their decisions will inevitably influence support for CER among clinicians and patients. Thus, controversial or not, outreach to payers and purchasers could be an essential step in the dissemination of CER findings.

Communicate directly with the public and with patients

While all government-funded research, including CER, is available to the public, it is not traditionally disseminated widely. To be successful, the new CER program will need to develop new strategies and channels to communicate findings in ways that are comprehensible and useful to individual citizens-as-patients, but also to citizens in their roles as taxpayers and stakeholders in health care improvement and system reform. As noted earlier, public understanding of evidence-based medicine is low, and the public debate over CER may have diminished support for both EBM and CER. Communication to the public may need to clearly delineate both the strengths and the limitations of CER findings, and perhaps be tied to a stronger effort by credible authorities (such as physician organizations) to educate the public on the case for grounding medical decision-making on evidence.

Conclusion

The federal government's new commitment to comparative effectiveness research creates a need for broad thinking about the dissemination of comparative effectiveness findings and other forms of medical evidence in the U.S. health care system. CER promises to assist patients and clinicians by giving them information that is pragmatic and actionable. But CER policy must still overcome existing limitations of comparative research that could inhibit dissemination, and it must address an increasing demand for medical evidence that informs individual patients and supports patient decision making. CER dissemination policy should take full advantage of other trends in health care improvement, most particularly the deployment of health care Information Technology. In the end, thoughtful and comprehensive dissemination policy will not only support the use of CER, but should go far to improve the utilization of all forms of scientific evidence in the health care system.