



From Evidence to Practice:
A National Strategy for CER Dissemination

A White Paper
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About NEHI

NEHI is an independent, nonprofit national network focused on enabling innovation to improve health care quality and lower health care costs. In partnership with members from all across the health care system, NEHI conducts evidence-based research and stimulates policy change to improve the quality and the value of health care. Together with this unparalleled network of committed health care leaders, NEHI brings an objective, collaborative and fresh voice to health policy.

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The national network for health innovation

A large proportion of the health care Americans receive is not based on rigorously tested empirical evidence. The Affordable Care Act is designed to fill the evidence gap, but effective dissemination of evidence to patients and physicians will be critical to the success of the legislation's expanded CER program.



Introduction

American health care suffers from a pervasive lack of good evidence to support practical decision making by patients and clinicians. It also suffers from a lack of effective dissemination of the evidence that does exist. This is because the process of translating and transmitting research findings to patients and clinicians is highly decentralized, frequently involving a complex interplay among researchers, patient groups, medical specialty societies, providers and others who determine standards of care.

With the enactment of the Affordable Care Act, the federal government's newly expanded comparative effectiveness research (CER) program is charged with generating a new wave of practical medical advice for patients and clinicians. Its success will rest heavily on effective dissemination.

NEHI began its CER research in 2008, focusing on the potential implications of an expanded CER program on innovation throughout the health care system. Its white paper, *Balancing Act: Comparative Effectiveness Research and Innovation in U.S. Health Care* (available at www.nehi.net), was released in April 2009.

Since then, NEHI has been examining the potential avenues for CER dissemination, specifically the existing programs of the Agency for Healthcare Research and Quality (AHRQ) and the newly created Patient-Centered Outcomes Research Institute (PCORI). This white paper takes the position that PCORI must elevate dissemination as a priority, above and beyond the level called for in the Affordable Care Act and in the Institute of Medicine's 2009 report to Congress on CER priorities.

NEHI recommends that PCORI should:

- **Become a highly visible national champion for CER dissemination and effective health care**
- **Build diverse partnerships**
- **Reinforce public understanding of CER**
- **Link CER to major health conditions affecting broad cross-sections of the population**

Over the course of the project NEHI interviewed two dozen national experts on evidence-based medicine and CER, and in July 2010 NEHI convened a diverse array of high-level experts for a roundtable at the National Press Club in Washington, DC. A list of roundtable panelists and other experts consulted by NEHI can be found on page 13. While the views expressed in this white paper are solely those of NEHI, the white paper reflects many experts' strong opinion that the new CER program must forge accountable partnerships with external stakeholder groups. This is of paramount importance if the new CER investment is to have a real impact on improving patient outcomes and – as many hope – on reducing unnecessary or unwarranted medical spending by pushing the health care system to deliver the right treatments to the right patients at the right time.

Dissemination policy must include both the multiple intermediary groups that assess evidence and the multiple channels of communication that reach physicians and patients.



The Challenge of Evidence Dissemination and Dissemination Policy

Medical research in the U.S. is highly decentralized, as is the dissemination of research findings. Both will almost certainly remain so. No one organization has a monopoly on the interpretation of research findings, or on the distribution of guidelines or medical advice to clinicians and patients.

New research findings rarely leap from a journal article straight into clinical practice or into the decision making of an individual patient. Intermediary groups, such as medical societies, typically play an enormous role in translating medical evidence and taking a position on how it should be utilized in the form of medical guidelines, care protocols and other forms of medical advice. Therefore, dissemination strategy should include dissemination to the intermediary groups as well as to the end users (patients and physicians).

Additionally, choices made by researchers regarding the methodology and design of studies can have important implications for the success of dissemination that may occur years later, well after research is completed and findings are reported. For example, the choice of research end points or reported outcomes may make a great difference in whether the findings prove relevant to patients. Research studies typically report on standard measures of mortality and morbidity (e.g. whether the patient survived, for how long and how well).

While patients care about these outcomes, inclusion of other patient-centered considerations that affect quality of life (e.g. how fast they will be able to return to work after undergoing a particular treatment, or whether they will be able to care for children) can also influence dissemination. Successful dissemination involves choices beginning with research and ending with the utilization of research findings at the point of care.

Thus this paper takes an expansive view of CER dissemination policy. In our view CER dissemination begins with the initial decisions on how and why research will be conducted and it ends with patients and physicians using research results in some practical way.

The need for a thoughtful and aggressive dissemination policy has become increasingly more apparent in recent years

as research has shown that medical practice has been slow to absorb evidence-based findings. This research was given special prominence by a series of successive panels convened by the Institute of Medicine. Among the insights:

- A large proportion of the health care Americans receive is not based on rigorously tested empirical evidence.
- A large proportion of the rigorous evidence produced by researchers is not easily or well used by clinicians and patients.
- A small proportion of evidence with practical value is transmitted to clinicians and patients as practical advice that is “valid, relevant, timely, feasible and actionable.”¹
- A small proportion of important, well-grounded research findings make their way into practice.

Harvard Medical School professors Jerry Avorn and Michael Fischer recently characterized the philosophy behind dissemination of most medical evidence as “if you discover it, they will come.” They write, “It is difficult to think of an example of a major biomedical discovery in which this passive posture alone has been followed by adequate practice change.” As examples, they cite the lagged adoption of vaccination against polio, the slow response of practitioners to evidence that mild-to-moderate hypertension requires treatment, and the protracted adoption of statins as a preventive measure against cardiovascular illness.²

The health care system is severely hobbled by these gaps in practical evidence and in the dissemination and uptake of practical evidence. The evidence gaps exact a cost in both dollars and public health. In 2007, the Commonwealth Fund estimated that upwards of \$370 billion could be saved over 10 years through the start-up of an expanded national program of comparative effectiveness research.³ The list of CER priority topics suggested by the Institute of Medicine include many of

1 Tunis, S., Benner, J., & McClellan, M. (2010). Comparative effectiveness research: methods development, research infrastructure, and policy. *Statistics in Medicine*.

2 Avorn, J., Fischer, M. (2010). Bench to behavior: translating comparative effectiveness research into improved clinical practice. *Health Affairs* 29(10): 1891-1900.

3 Schoen, C., Guterman, S., Shih, A., et al. (2007). *Bending the Curve: Options for Achieving Savings and Improving Value in U.S. Health Spending*. The Commonwealth Fund.

the most common and painful health risks faced by Americans, including diabetes, hearing loss, falls, atrial fibrillation, staph infections, low back pain and chronic disease.⁴

CER in the Affordable Care Act

The Obama Administration and the 111th Congress viewed the 2009 economic stimulus legislation and the 2010 health care reform legislation (Affordable Care Act) as opportunities for the federal government to address the gap in evidence and the gap in evidence dissemination. The stimulus bill allocated \$1.1 billion for research grants and for investment in the development of research tools (such as new methodologies) and in infrastructure (such as patient databases) to support the research process. The Affordable Care Act created a permanent CER program funded by new fees on health care plans and large insurers and led by a new, independent governing body, the Patient-Centered Outcomes Research Institute (PCORI).

Five elements of the Affordable Care Act stand out as especially significant for CER dissemination policy:

- **The creation of PCORI**

PCORI is established as an independent organization, albeit funded with federal fee revenues. Its purpose is to “assist patients, clinicians, purchasers and policymakers in making informed health decisions” in several ways, including through the dissemination of research findings.⁵

PCORI is governed by a 21-member board of governors, including 19 members from outside of government appointed by the Comptroller General (with two slots reserved for the directors of the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health). The 19 members are chosen to represent a wide range of interests including: patients, consumers, clinicians, hospital officials, private payers, pharmaceutical, medical device and diagnostic manufacturers, and quality improvement organizations (see sidebar, p.5).

From the standpoint of dissemination policy, PCORI has unique capabilities: budgetary discretion, a governing board that represents multiple stakeholders and broad authority to work closely with AHRQ and to reach beyond AHRQ to stakeholder groups in the field.

- **The preservation of AHRQ’s role**

AHRQ has a lead role in the government’s dissemination of CER findings through its Office of Communications and Knowledge Transfer.

The agency brings a number of existing capabilities to the mission, including its evidence communication programs (such as the Eisenberg Center for Clinical Decisions and Communications Science) and the Effective Health Care Program, the pre-existing CER program authorized by the 2003 legislation that created the Medicare prescription drug benefit (Medicare Modernization Act).

A number of non-governmental organizations are also active in various aspects of evidence translation and dissemination in the U.S., but AHRQ’s portfolio is perhaps the most inclusive. It includes production of reports that synthesize research findings, support for creation of clinical registries and other forms of infrastructure that support comparative research, production or support for creation of materials for use by patients, and research on the development of methods for effective dissemination to diverse patient groups and populations.

- **The focus on clinical effectiveness**

The political debate over CER centered largely on whether Congress would support one or both types of comparative health research — research on comparative *clinical* effectiveness or research on comparative *cost* effectiveness. While the Affordable Care Act does not outright prohibit federal support for cost effectiveness research, it does prohibit PCORI from supporting analyses utilizing quality-adjusted life years, and otherwise strongly emphasizes federal support for clinical effectiveness research. Under the legislation, the mission of the new CER program is to ramp up a pipeline of practical medical advice for use by clinicians and patients, irrespective of cost considerations.

⁴ Institute of Medicine (2009). 100 Initial Priority Topics for Comparative Effectiveness Research.

⁵ 42 U.S.C. §1320e (P.L. 111-148, Sec 6301(a)).

- **The prohibition of linkages to payment policy**

The Affordable Care Act attempts to sever any direct link between the use of CER findings and coverage or reimbursement decisions.

The Centers for Medicare and Medicaid Services (CMS) is prohibited from using CER studies as the sole basis for decisions. Private payers such as health plans and large employers are free to consider CER findings, at least as one source of information among many, and private payers may continue to make value-based coverage and reimbursement decisions based on CER. But there is no link between government-sponsored CER and government-mandated payment policies.

- **Support for broadly scoped CER studies**

The Affordable Care Act directs PCORI to address broad or wide-ranging medical needs in the U.S. population.

This includes comparisons of entire modes of health care treatment or entire modes of health care delivery, as opposed to a sole focus on narrow comparisons of one treatment or medical technology to another. A narrow approach is more typical of the kind of health technology assessment employed by European national health systems, systems that are frequently criticized by CER opponents for restricting access to new technologies.

PCORI Board of Governors

PCORI is governed by a 21-member board, including 19 members from outside of government.

Debra Barksdale, PhD, RN, University of North Carolina (UNC) at Chapel Hill School of Nursing

Kerry Barnett, JD, The Regence Group

Lawrence Becker, Xerox Corporation

Carolyn Clancy, Agency for Healthcare Research and Quality

Francis Collins, National Institutes of Health

Allen Douma, MD, Empower, LLC

Arnold Epstein, MD, Harvard University School of Public Health

Christine Goertz, DC, PhD, Palmer Center for Chiropractic Research

Leah Hole-Curry, JD, Washington State Health Care Authority

Gail Hunt, National Alliance for Caregiving

Robert Jesse, MD, PhD, Department of Veterans Affairs

Harlan Krumholz, MD, Yale University School of Medicine

Richard E. Kuntz, MD, Medtronic, Inc.

Sharon Levine, MD, The Permanente Medical Group of Northern California

Freda Lewis-Hall, MD, Pfizer Medical Division

Steven Lipstein, MHA, BJC Health Care

Grayson Norquist, MD, MSPH, University of Mississippi Medical Center

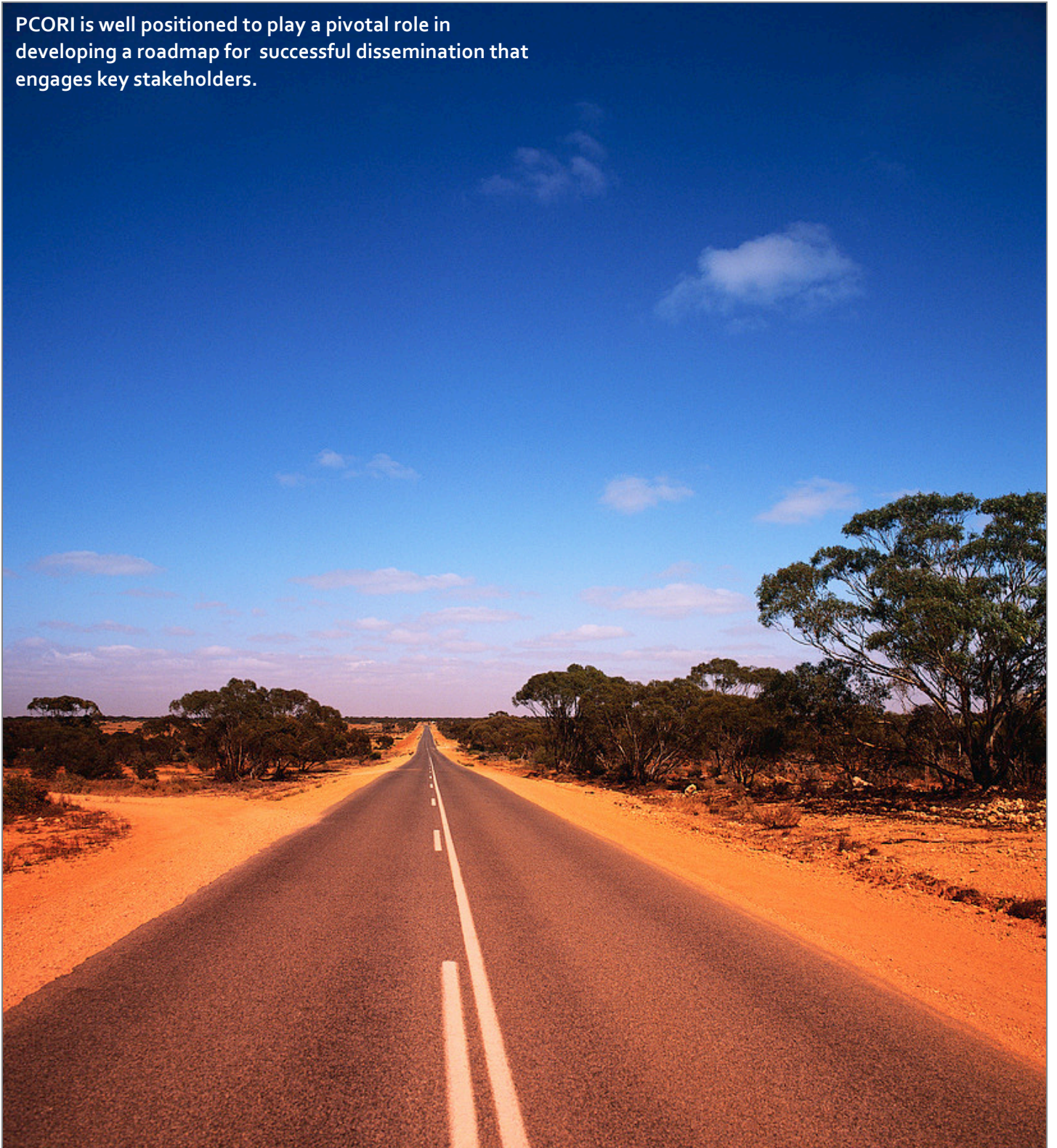
Ellen Sigal, PhD, Friends of Cancer Research

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Harlan Weisman, MD, Johnson & Johnson

Robert Zwolak, MD, PhD, Dartmouth Medical School

PCORI is well positioned to play a pivotal role in developing a roadmap for successful dissemination that engages key stakeholders.



Recommendations for a National CER Dissemination Strategy

The five principal elements of the new CER program discussed in the previous section could become the basis for a coherent dissemination strategy. If managed effectively, the elements could leverage PCORI's broad convening authority to attract voluntary participation of external stakeholders while utilizing AHRQ's existing program as a building block.

The strategy would center on the application of findings on clinical effectiveness to major, highly prevalent medical conditions that affect large numbers of Americans — a strategy to generate practical medical advice for the common medical problems of real people.

NEHI's own recommendations for a national CER dissemination strategy center on a vital role for PCORI, including the following:

Policy Recommendation 1: PCORI should become a highly visible national champion for CER dissemination and effective health care

Because of the highly decentralized nature of consensus building and medical guideline development and the lack of direct links between CER findings and payment policy, CER dissemination will need a visible champion. The success of CER dissemination will depend upon gaining active, voluntary participation in the dissemination process by clinicians, patients, provider organizations and other independent groups. This will require strong and visible leadership, and PCORI should play that role.

As noted earlier, dissemination is part of the broad statement of purpose within PCORI's enabling language in the Affordable Care Act. AHRQ's Office of Communications and Knowledge Transfer is charged with a specific role in disseminating research commissioned by PCORI, but there is an opportunity — and a need — for PCORI to play a more visible and comprehensive role, for two reasons:

- **PCORI is best positioned to lead because of its independent structure**

PCORI is well positioned to seize a public role in CER dissemination in a way that other organizations,

including AHRQ, are not. AHRQ's role in dissemination is essential: PCORI would have to replicate much of AHRQ's existing capabilities if they did not exist already. But as a line agency of the government, AHRQ is less well positioned to claim a highly visible public role in promoting CER dissemination when the very legitimacy of the new CER program is still disputed by opponents.

As an independent, non-profit organization, PCORI can operate at arm's length from government agencies and government policies. Its board of governors includes multiple interests (patients, providers, manufacturers, payers and others) and include several with expertise in the health and health care of minority groups and small patient populations. Thus, PCORI is positioned to become a trusted authority on CER.

- **PCORI has a unique end-to-end perspective of CER and the CER dissemination process**

PCORI is also positioned to take a holistic view of CER dissemination that starts with decisions made about the design and conduct of CER studies and extends to the distribution of CER findings to clinicians and patients.¹

Decisions on CER design and outcomes can have a decisive impact on how well resulting findings can be disseminated and utilized. Research questions need to be designed to address the most practical concerns of clinicians in daily practice. Outcomes need to be defined to incorporate measures that match the practical concerns of physicians and patients; these concerns may extend beyond standard measures of mortality and morbidity to patient-reported outcomes related to the patient's ability to conduct daily activities at work and home. Appropriate research methodologies need to be adopted to incorporate these concerns.

Likewise, key stakeholder groups should be involved at an early point in the research process in order to identify potential downstream issues in dissemination, and to plan strategies to address them. The Affordable Care Act directs PCORI to develop highly transparent processes that will allow stakeholders to observe and comment on research methods

¹ NEHI (2010). From Evidence to Practice: making CER Findings Work for Providers and Patients. Available at <http://www.nehi.net/publications/>.

and the conduct of CER studies. PCORI has full authority to convene advisory groups in order to ensure full transparency. This same emphasis should be extended to concerns about dissemination, so that advisory groups can comment early on measures that will enhance the use of findings from studies commissioned by PCORI.

All in all, dissemination should be seen from end-to-end, and PCORI should utilize its convening authority, and its status as an independent, multi-stakeholder panel, to engage stakeholder groups in early definition and execution of dissemination strategies.

Policy Recommendation 2: PCORI should build diverse partnerships

Successful dissemination of CER evidence will require collaboration, almost by definition. Given the highly decentralized nature of evidence dissemination, collaboration and consensus building will be critical even when CER produces findings that seem to be clear and unambiguous.

Stakeholder groups that are not part of a consensus-building process are less likely to become active advocates for the dissemination of guidelines or other evidence-based aids to decision making or may in fact become active opponents of guidelines. The 2009 controversy over the U.S. Preventive Services Task Force's recommendations on mammography screenings is a case in point. While it is not clear that the Task Force's recommendations on mammography screening would have been better accepted if the American Cancer Society and other patient groups had been involved earlier, their lack of involvement in the process clearly helped to fuel opposition to the recommendations. The Task Force's mission and operating procedures, previously held up as a model for other organizations, were thrown into serious dispute.

Among the potential partners for PCORI:

- **National medical societies and patient groups**

National organizations, such as national medical specialty societies and patient advocacy organizations, stand out as potential partners for PCORI. Many national organizations operate programs to identify and disseminate standards of practice. However, few have specifically focused on the

development of mechanisms to build rapid consensus and expedite the use of good evidence. Limited funding and the complexity of bringing experts together can constrain the consensus-building process, as evidenced by the National Institutes of Health Consensus Development Program, which releases no more than three or four consensus statements per year.²

Then again, stakeholder groups may disagree on the implications of evidence even when the evidence seems clear. Recently, for example, the American College of Chest Physicians and the American Academy of Orthopedic Surgeons took markedly different positions on the outcomes to be used in defining the efficacy of measures to prevent thromboembolisms during hip and knee surgery.³

In contrast, the cardiology community offers an example of a more distributed or stakeholder-based model for expedited translation and dissemination of evidence. Collaboration among cardiologists and hospitals led to the creation of the Cardiovascular Research Network, one of the largest networks of clinical registries in the country, with access to clinical data on more than 11 million patients. Collaboration between the American College of Cardiology and the American Heart Association has focused on development of guidelines that address clinical situations rather than guidelines that simply enumerate steps in process or procedure. Cardiologists have recognized the need to speak with one voice by involving multiple interested parties, including the European Society of Cardiology, in the guideline development process. Guideline-writing committees have evolved into "living committees" that remain in place to update guidelines as new evidence becomes available.

Bridging the evidence gap has proven difficult. For all its success, the U.S. cardiology community has not pushed adherence to its guidelines above 55 percent.⁴ Many analysts

2 Steinbrook, R. (2007). Guidance for guidelines. *N Engl J Med* 356(4): 331-3.

3 Cushner, F.D., Nett, M.P. (2009). Unanswered questions, unmet needs in venous thromboprophylaxis. *Orthopedics* 32(12 Suppl):62-66.

4 Lauer, M.S., Skarlatos, S. (2010). Translational research for cardiovascular diseases at the National Heart, Lung, and Blood Institute: moving from bench to bedside and from bedside to community. *Circulation* 121(7):929-933; McGlynn, E.A., Asch, S.M., Adams, J., et al. (2003). The quality of health care delivered to adults in the United States. *N Engl J Med* 348(26):2635-2645.

still doubt just how effective adherence to guidelines can be without strong links to payment policy.⁵ Nevertheless, the cardiology community has demonstrated that partners working collaboratively can upgrade their capacity to find consensus around evidence and expedite the dissemination of findings.⁶ PCORI's objective should be to challenge similar communities of interest to rally around a common approach to consensus building and the dissemination of appropriate guidelines.

- **Learning health care systems**

Highly-integrated, self-identified "learning health care systems" around the country can be valuable allies and partners in the demonstration of successful CER dissemination. While still relatively few and at an early stage of development, learning health care systems are demonstrating that important findings in medical evidence can be generated from patient data, independent of government or private payer policy.

Intermountain Health Care, Cleveland Clinic, Mayo Clinic, the VA health care system and others have become learning systems by creating sophisticated ways to track patient data, to analyze and learn from data on patient outcomes, and to continuously feed this knowledge back into a re-evaluation of not only what works best, but what works best for particular patients in their particular delivery system. This process is comparative and always involves a consideration of what approaches work better than others for particular patients. It creates contextualized findings based on the real characteristics of real patient populations and their health care outcomes, as affected by the idiosyncrasies of local conditions and local health care delivery. All of these systems would admit that they still face significant gaps in evidence-based practice, but their goal is to create an individualized approach to care. These systems exemplify that it is clearly not a one-size-fits-all approach, and one that is clearly not directed by a central authority, federal or otherwise.

5 Avorn, J., Fischer, M. (2010). Bench to behavior: translating comparative effectiveness research into improved clinical practice. *Health Affairs* 29(10): 1891-1900; Winstein, K. (2010 February 11). A simple health-care fix fizzles out. *Wall Street Journal*.

6 New England Healthcare Institute (2008). Improving Physician Adherence to Clinical Practice Guidelines. Available at <http://www.nehi.net/publications/>.

Expedited development and dissemination of medical evidence, therefore, is a major objective of the learning health care paradigm, as enunciated by the Institute of Medicine's Evidence-based Medicine Roundtable and by integrated health care systems — such as the Intermountain and Geisinger systems — that have emerged as national leaders in quality improvement. As such, these systems represent valuable partners for PCORI to expedite the use of CER findings in practice. Recently a number of leading organizations (Dartmouth-Hitchcock Medical Center, Intermountain Health Care, Mayo Clinic, Cleveland Clinic, Geisinger Health System and Denver Health) announced a formal partnership to identify and disseminate best practices for the care of eight highly prevalent conditions that are also responsible for rapidly increasing health care costs.⁷ This is an approach that clearly would be consistent with a targeted dissemination strategy enunciated by PCORI.

- **State and regional medical societies, quality organizations and patient groups**

The vast majority of health care settings in the country clearly do not have access to the analytical capabilities of the learning health care systems. But organizations working together at the state or regional level can collaborate to create capabilities that will allow them to contextualize CER findings within their own settings.

One current example is a new initiative in Massachusetts that is translating comparative effectiveness findings on prostate cancer into decision aids for patients through direct collaboration with local clinicians. The Institute for Clinical and Economic Review (ICER) has designed a web site and related materials with direct input from clinicians at five Boston-area hospitals and physician practices. The clinicians themselves appear in the materials and are using them in daily practice.⁸

As state and regional health information exchanges continue to grow, they may create a new capacity to develop patient databases that will support comparative analysis. The

7 Dartmouth Institute for Health Policy & Clinical Practice (2010, December 15). Leading health care organizations announce collaborative effort to improve care, lower costs. Press release.

8 Institute for Clinical and Economic Review (2010 October 18). Employer Action Coalition on Healthcare and Institute for Clinical and Economic Review Launch Prostate Cancer Decision Aid Website. Press release.

continued deployment of electronic health records creates a means to forward data to exchanges, as well as a platform for the deployment of clinical decision support systems in which localized findings can be embedded. State or regional-level health care quality improvement organizations can be incorporated to develop and monitor standards of practice and viable health care improvement goals.

All of these organizations are a resource that can be used to reverse the lagging number of clinical trials underway in the U.S., a point recently made by Dr. Janet Woodcock of the FDA.⁹ Here again, PCORI should challenge state and regional organizations to step forward to create a mutual partnership that will focus on achieving measurable health improvement goals.

Policy Recommendation 3: PCORI should reinforce public understanding of CER

Most Americans are still not aware of what CER is, and those who are may be as apt to distrust it as support it. In fact, recent surveys have revealed public distrust of evidence-based medicine in general.¹⁰

Public perception of the role of CER in health care improvement has been muddied because of the debate over cost effectiveness. Now that the Affordable Care Act has firmly linked federal support of CER to research on clinical effectiveness, CER's role in improving U.S. health care should be re-established and reinforced with patients and the general public.

The reframing of CER began in earnest with the choice of "Patient-Centered Outcomes Research Institute" as the name for what Senate CER legislation had previously termed the "Health Care Comparative Effectiveness Research Institute." This is a meaningful change of terms since it associates comparative effectiveness research with patient-centric trends such as the movement for patient-centered medical homes and increased patient engagement in health care decision making.

⁹ Giffin, R., Woodcock, J. (2010). Comparative effectiveness research: who will do the studies? *Health Affairs* 29(11): 2075-2081.

¹⁰ Gerber, A., Patashnik, E., Doherty, D. et al. (2010). A national survey reveals public skepticism about research-based treatment guidelines. *Health Affairs* 29(10): 1882-1884.

However, rebranding CER is not enough. It must be visibly supported by major stakeholder groups that the public trusts on questions of health care, such as medical professional societies and patient advocacy groups. These stakeholder groups should be challenged to express their support for the clinical effectiveness mission of the CER program, but actions speak louder than words: PCORI should also challenge stakeholder groups to come together around partnerships for visible and measurable improvement of patient care.

Two specific recommendations for PCORI to increase credibility with the public are:

- **Avoid endorsing research findings**

PCORI's overriding mission is to create a CER process that is transparent and meets the highest standards of research integrity. Endorsement of CER findings would prove a distraction from this mission and a deterrent to efforts to forge collaboration with the stakeholder groups that will end up serving as the final arbiters of standards of practice.

- **Support the development of personalized medicine**

During the initial 2009 debate over CER, a number of patient and industry groups voiced fears that an expanded federal CER program would generate one-size-fits-all recommendations that would overlook the benefits from genetics-guided treatments or treatments that help small patient populations, and would otherwise inhibit the future development of personalized medical therapies. Since the passage of the Affordable Care Act, leaders at AHRQ, NIH and a number of interested organizations have advocated to continue building consensus on the relationship between CER and personalized medicine.

Many observers see an opportunity for CER to support the development of personalized medicine. The infusion of new federal support into comparative research may create an opportunity for researchers to conduct prospective research that takes advantage of new genomic data and seeks out evidence of heterogeneity in patient characteristics. The new CER program is an opportunity to apply new tools to the analysis of existing data in order to unveil disparities in patient characteristics and treatment responses.

Personalized medicine holds promise that is not yet realized in the relatively few personalized therapies currently available to patients. Personalized therapies are seen as the best long-term hope for cancer patients, and perhaps the only realistic path of development for the pharmaceutical and biotechnology industries. A compelling demonstration that CER will not merely co-exist with but enhance personalized medicine would therefore help underscore PCORI's essential mission of improving the effectiveness of health care.

Policy Recommendation 4: PCORI should link CER to major health conditions affecting broad cross-sections of the population

One of the most straightforward ways to organize the end-to-end approach to research described earlier is to link it to major health problems that affect broad cross-sections of the public. This would serve to address significant public health issues facing the country and build support and awareness of CER.

A dissemination strategy targeted at highly prevalent conditions such as diabetes, heart disease, depression and hospital-acquired infections would offer PCORI several advantages. It would make it easier for the organization to communicate what CER is and to emphasize its role in improving the clinical effectiveness of health care. It would also create a tangible goal around which key stakeholder groups can rally. Highly visible goals may also engender a greater sense of shared responsibility and accountability for successful dissemination and uptake of evidence-based research findings in practice.

In choosing to focus on specific targets for dissemination strategy, PCORI must first decide on a set of selection criteria. There is a strong case to be made that the choice should be based on the demonstrated willingness of stakeholder groups to organize, to partner with PCORI and to be held accountable for the results of the targeted dissemination strategy. In return, PCORI should offer these groups a guarantee of a well-funded program that will encompass both research and support for dissemination activities (e.g. translation of research findings, development of guidelines and forms of clinical decision support, as well as development of materials for use by patients, such as decision aids). Stakeholder groups

will need to bring a formal partnership to the table with measurable goals, including those supporting the expedited dissemination and uptake of CER findings by clinicians and patients in daily decision making.

- **Create accountable partnerships**

This approach brings the challenge of creating accountable partnerships front and center within the national policy discussion around CER dissemination. Many experts consulted by NEHI, including experts assembled for a July 2010 roundtable at the National Press Club in Washington, DC, identified accountability as the single biggest challenge to successful dissemination of CER and other forms of medical evidence. Evidence development, translation and dissemination is a highly fragmented process in the health care system (notwithstanding the performance of some exceptional delivery systems); financial incentives for evidence-based care are in their infancy, at best; and linkages between use of CER findings and financial incentives remain controversial. For these reasons, it is essential for CER dissemination to rest upon strong and accountable collaborations among PCORI, federal agencies and interested parties such as medical professional societies and patient organizations.

Many observers have suggested that PCORI needs an early win in order to establish its credibility and authority, particularly in what may be a hostile political atmosphere. Putting forth a successful challenge that spurs stakeholder groups to accountability and action is a realistic way for PCORI to achieve this. After all, it will be difficult for PCORI to demonstrate a measurable impact on health and health care practices in the near term. To do so would require PCORI to muster up new research, or repackage existing research, identify clear and actionable findings, and expedite the measurable use of those findings, none of which is likely to happen soon. A more practical goal for PCORI is to create visible and meaningful partnerships that make measurable progress toward an end-to-end strategy targeting major health and health care problems.

PCORI should approach this in a clear and dramatic way. One potential approach:

- **Wrap CER research and dissemination strategy into “grand challenges”**

PCORI should galvanize public and stakeholder support for targeted CER dissemination by adopting the kind of grand challenge approach that has characterized U.S. science policy over the decades.

The term grand challenge has typically been applied to a large, collaborative effort to answer major questions in science and engineering. The Apollo program, the 1970s-era War on Cancer and the Human Genome Project were all organized as grand challenges in which the federal government played a role as the chief underwriter of research. More recently the National Academy of Engineering identified 14 grand challenges in engineering, including the challenge of engineering innovations to rapidly develop personalized medicines. The Obama White House has solicited ideas for a new round of grand challenges that will become part of overall U.S. science and innovation policy.

Non-governmental and private organizations have issued their own challenges in the health care sector. The Gates Foundation has underwritten a Grand Challenges in Global Health program that seeks to develop breakthrough innovations for treatment of infectious disease and other health threats found in the developing world. Under Dr. Donald Berwick’s leadership, the Institute for Healthcare Improvement conceived and executed the “100,000 Lives” campaign, in collaboration with hospitals, to reduce patient deaths and illness due to unsafe conditions in hospitals.

While these approaches have had critics, they have the advantage of historical precedent and they convey clear, vivid goals to the public and policymakers. A grand challenge specifically related to CER and dissemination offers the advantage, once again, of clearly associating CER with the health problems Americans care about most.

Grand challenges could be sponsored by PCORI directly, or by PCORI in partnership with other federal health agencies such as the National Institutes of Health or the Centers for Disease Control and Prevention, or with national initiatives such as

the Healthy People 2020 program, which recently outlined the latest 10-year national plan for achievement of major health improvement in the country. The challenge should extend to other federal agencies administering programs that will enhance the health care system’s capabilities to utilize evidence, such as the Office of the National Coordinator for Health Information Technology, charged with implementing federal support for the deployment of electronic medical records and clinical data infrastructure.

Conclusion

The rancorous national debate over the Affordable Care Act has raised the hurdles to the successful dissemination of comparative effectiveness research findings by creating public skepticism over the mission and value of CER. Yet the central thrust of the CER mission as outlined in the law is one that should command broad support: a mission to improve health care for individual patients by finding more effective ways to treat illness and deliver care. Only through the effective dissemination of CER results, which yield better evidence for providers and patients at the point of care, can CER fully achieve this promising mission.

To reach these goals, PCORI must take a visible leadership role by fostering better public understanding of CER and its mission; by promoting the development and dissemination of CER that targets major health care needs; and by rallying critically-needed participation from patient and clinician groups, as well as other critical stakeholder organizations. Taken together, these steps will enable CER to achieve the vision of providing valuable evidence of what works best for patients, and ultimately improving the quality of health care in the United States.

Contributors

Roundtable Panelists

From Evidence to Practice: Making CER Findings Work for Providers and Patients, July 8, 2010, National Press Club, Washington, DC

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