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# comparative effectiveness research: so far, so good

**As anyone who has followed the lengthy debate around the passage of the Affordable Care Act knows, comparative effectiveness research (CER) is now part of healthcare reform.**

As someone who has been pressing the importance of CER as an important building block toward "treating better and spending smarter," I regard its inclusion in the legislation, as well as the recently established Patient Centered Outcomes Research Institute (PCORI), as an early—and important—win.

The key features of the Affordable Care Act provisions on CER are for me, the right ones. The focus is on alternative ways to treat medical conditions, including medical procedures, for various subgroups in the population rather than just comparing drugs and devices in the way some European countries do. The new institute also has as its main functions funding and generating research on CER and disseminating the information that is produced rather than being a decision-making body.

## Learning from ARRA

The American Recovery and Reinvestment Act (ARRA) made an important initial contribution to the CER effort by allocating $1.1 billion for this purpose. It is too early to know the results of the studies funded, but some elements of the effort will be important to keep in place, including outreach and public input in making priority decisions, and transparency in the process used for priority setting.

The response to the early results will be important. Some of these results may be controversial. The strategy and process for disseminating the results, and the degree of sensitivity exhibited in this process, will be important to acceptance of the results. And getting input from the affected parties will be critical. The precedence of including many studies that are not based on randomized clinical trials will also be important in gaining acceptance (or lack of acceptance) of data gathered using observational or other nonexperimental data design strategies.

## The Institute's Structure

PCORI follows the design developed by Sen. Max Baucus (D-Mont.). It is a public-private partnership outside of government whose fundamental role is to set the guidelines and oversee the research that is performed under its sponsorship. Financing of the institute will approximate (although at a slightly lower level) the funding that was available for CER under ARRA. The funding—estimated to provide annual funding $500 million in 2015 (as opposed to $1.1 billion over 18 months under ARRA)—will be a mix of funds from the Medicare Trust Fund and fees assessed on private insurers reflecting their covered lives.

The Government Accountability Office (GAO) recently appointed the 21 members of PCORI's board of governors, reflecting the mix of backgrounds and expertise provided by the legislation.

PCORI will face many challenges, including appointing an experienced and politically savvy executive director and finding the right mix of senior staff to support the board and its activities. It will also need to develop a priority-setting strategy and establish the rules for determining what constitutes "credible evidence." To help it do the latter, the GAO will appoint a methodology committee to establish the parameters for

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"credible evidence" and to report to the board in 18 months. Given some of the concerns that have been raised about the validity of past systematic reviews, the lack of consensus on using various types of nonexperimental designs, and the challenge of studies that are directed to reflect usual care settings, the methodology committee will have more than the usual number of challenges such committees face.

### Making Use of CER

The ultimate challenge will be to find ways to make use of the material generated by PCORI and through other CER-focused efforts. The primary (and officially stated) purpose of CER is to improve health outcomes. These studies should provide important information for patients and clinicians about what works and what doesn't for subgroups in the population when it comes to alternative ways to treat various medical conditions.

Although CER can be expected to provide much important information not previously available, it will be important not to ignore the abundance of information available about past difficulties in changing physician behavior. To avoid repeating these experiences, it will be important to gain acceptance of the process as early as possible from both physicians and the patient or advocacy groups most likely to be affected. This "buy-in" will be especially important if the findings challenge "conventional wisdom." It's hard to forget the public, physician, and media outcry to the report on mammography issued by the U.S. Preventive Services Task Force last November.

The bigger challenge, however, will be to use CER to help moderate spending. I have long believed that CER will be more helpful in setting payment rates than in providing guidance for coverage. If a new medical treatment or device is safe and effective (for the relevant population), its coverage can be justified, but if it doesn't produce better clinical results, why would a payer want to pay more for its use? A trickier issue is deciding how much additional payment is justified if the treatment or device does produce better results (for at least some subpopulations). These considerations suggest that the results of CER might best be incorporated into the payment system through concepts such as value-based payment and insurance that varies copayments and provider reimbursements with expected clinical value.

The problem is that government payers face a variety of prohibitions such as using cost-effectiveness measures to determine coverage, payment, or incentive programs among other things. The Centers for Medicare & Medicaid Services also has no authority to use CER in payment decisions.

One way forward might be to encourage private payers to begin using CER in making their payment decisions along the line of value-based insurance principles, and to promote demonstrations and/or pilots of these principles for Medicare payment.

Whatever next steps are taken, it is clear that the process of incorporating principles of CER into payment decisions will be a long time in the making. ●

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