



Brandeis University
The Heller School for Social Policy and Management

Health Care Cost Management in Massachusetts: A Discussion of Options

Meeting #6: Comparative Effectiveness

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Comparative Effectiveness: Opportunities for Improved Value

Presenter: **Steve Pearson**, MD, MSc, Institute for Clinical and Economic Review (ICER) and America's Health Insurance Plans

Summary

Drug and device manufacturers spend significant sums developing new medical technologies and bringing them to market. These technologies frequently improve health care quality but also contribute significantly to the growth in health spending. Yet stakeholders in the US spend comparatively little assessing how well these new technologies work in comparison to existing treatment options. In contrast, most other countries have formal processes for evaluating new medical technologies that they use for making coverage decisions.

Comparative effectiveness research (CER) evaluates both the clinical effectiveness and cost effectiveness of alternative treatment options. This research can help patients and providers make more informed treatment decisions and help payers and policymakers make decisions about coverage, reimbursement, and benefit design.

Momentum for funding an organized CER initiative is building at the federal level. Some states, most notably the state of Washington, are beginning to invest in CER to support policy decisions. Expanded availability of CER is thought to be a promising option for improving the value of health services.

Context

Robert Mechanic and Stuart Altman from The Heller School at Brandeis University described the current federal policy context for comparative effectiveness research (CER). Dr. Steven Pearson then presented a framework for assessing comparative clinical effectiveness and value, and discussed federal and state policy options. Dr. Pearson's presentation was followed by participant questions and comments.

- **Comparative effectiveness research helps decision-makers understand "what works."**

The concept of comparative effectiveness research involves gathering evidence on which treatment option works best, usually comparing a new technology to a current one. This research may also examine comparative *cost* effectiveness. CER entails the following types of research:

- *Systematic review*. This involves aggregating and reviewing the existing evidence on a particular subject. The Agency for Healthcare Research and Quality (AHRQ) is a principal funder for this type of evaluation.
- *Prospective head-to-head clinical trials*. These trials directly compare alternative treatment options, for example, stents versus medical management for patients with stable coronary artery disease, or older versus newer anti-hypertensive drugs. These studies are quite expensive.

They are occasionally funded by the National Institutes of Health, or by pharmaceutical companies whose product is a late entrant in a particular drug class.

- **Unlike other developed countries, the US does not have any formal process for CER, but momentum for CER is growing.**

Most of the world's developed countries have formal processes for assessing both clinical and cost effectiveness of new medical technologies. These evaluations are used to determine which new technologies will be covered by the respective national health services; most countries will not approve products whose cost effectiveness falls below a certain threshold.

The US has no centralized CER process or oversight body. While the U.S. spends \$2.1 trillion on health care, AHRQ has just \$30 million allocated for CER research. However, interest in CER is growing at the federal level. The Congressional Budget Office (CBO), Medicare Payment Advisory Committee (MedPAC), America's Health Insurance Plans (AHIP), the Blue Cross Blue Shield Association, and many policy experts support CER. Most stakeholders support creation of a new entity—a public/private partnership funded with \$300 to \$500 million per year—to conduct and oversee CER. Congressional support is also growing with bills under consideration in both the House and Senate. Senator Obama has included CER in his Presidential platform.

Interest in CER is also growing at the state level. State initiatives include:

- *Drug Evaluation Research Project (DERP)*. This is a collaborative effort in which 15 state Medicaid programs have jointly funded systematic reviews of available drugs across a wide range of therapeutic classes. The DERP research is also used by Consumer Reports in its publication, "Best Buy Drugs."
- *Medicaid Evidence-Based Decisions Project (MED)*. This initiative is similar to DERP, but involves gathering data on the clinical effectiveness of procedures, diagnostics, and care management.
- *Washington State Health Care Authority (HCA)*. Washington, which participates in DERP and MED, has created a health technology assessment capability that looks at both clinical and cost effectiveness and uses this data to help make coverage decisions.

- **Key areas of debate include what criteria are used to measure effectiveness and how the information will be used.**

Most stakeholders support comparative effectiveness research in concept, but different groups see the scope and use of this research differently. The critical CER debates include:

- *What gets measured?* Some stakeholders want CER only to measure *clinical* effectiveness. They argue that evaluation of cost effectiveness will lead to controversy and provoke a backlash if it is perceived as being used to restrict access to treatments. However, others believe that CER must take cost and value into consideration. They argue that failing to consider value will limit the usefulness of CER.
- *How CER information is used.* Most stakeholders support dissemination of CER information to patients and clinicians to inform treatment decisions. More controversial is the use of CER in coverage decisions, reimbursement policy, and value-based insurance design.

Internationally, CER is usually used to support national coverage decisions. This has led some US stakeholders (ranging from drug and device manufacturers to patient advocacy groups) to express concern that US payers would use CER “to say no (to paying for specific treatments).”

Some argue that some evidence is better than none, and that conducting clinical effectiveness research and disseminating the results broadly will improve health care. Others argue that just producing reports with no direct linkage to policy decisions will have little impact on current cost and quality problems.

“If CER just makes information available, but is not tied to reimbursement and coverage, I’m not sure it will make a difference.”

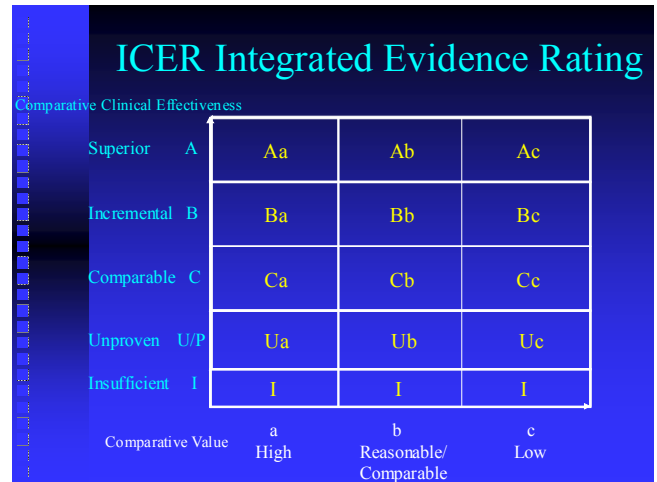
— Stuart Altman

▪ **ICER has developed a framework for assessing clinical effectiveness and comparative value.**

The Institute for Clinical and Economic Review (ICER) has developed a framework (see diagram) to assess new versus existing technologies. The framework aims to establish a simple and consistent language for describing the results of CER. ICER’s Integrated Evidence Rating involves assessing new technologies based on:

- *Comparative clinical effectiveness.* An independent review group rates a technology’s clinical effectiveness. Ratings of a technology versus its alternatives are: Superior, Incremental, Comparable, Unproven, or Insufficient Data.
- *Comparative value.* The same review group also assesses value, defined as the “cost per additional benefit.” The additional benefit of a technology can be measured in several ways such as the cost of a case of cancer prevented, or the cost of a life year gained. A common measure is cost per quality-adjusted life year (QALY). A technology’s comparative value is rated as high, reasonable/comparable, or low.

Dr. Pearson shared the findings an evaluation of two prostate cancer treatments: Intensity Modulated Radiation Therapy (IMRT) versus 3-D Conformal Radiation Therapy (3D-CRT). 3D-CRT had been the state of the art and was reimbursed by



Medicare at a rate of \$10,000 per course of treatment. IMRT was a new form of radiation therapy that Medicare agreed to reimburse at \$42,000 per treatment. As a result, many providers increased their IMRT utilization and total spending for this therapy quickly rose to \$1.5 to 2.0 billion annually. This occurred with no formal evaluation of IMRT in comparison to 3D-CRT.

An evidence review by ICER found that IMRT was no better at curing cancer or prolonging life than 3D-CRT. IMRT did decrease the risk of side effects—moderate proctitis—from about 15% to about 3%.

Using ICER’s Evidence Rating framework, the review group deemed IMRT’s clinical effectiveness as “incremental” and its comparative value as “low” (based on a cost/QALY of \$700,000). The review group thus gave IMRT a rating of “Bc.”

▪ **Dr. Pearson hopes stakeholders can use this framework to make rational medical policy decisions.**

Once ICER or another entity assesses the clinical effectiveness and comparative value of treatment alternatives, results can be used to shape medical policy. For example, a payer could create a tiered benefit design. For a clinically superior, high-value technology, there could be a \$0 co-pay along with financial incentives for the provider (e.g., pay-for-performance) for using this technology. Simultaneously, for a technology with comparable effectiveness but higher cost (i.e., low value), there could be higher patient co-pays, lower reimbursement, and negative provider financial incentives.

▪ **States can move forward with CER without federal action.**

As the experience in Washington State demonstrates, states can use CER. To move forward, states should consider:



- *Developing trusted data sources.* Device manufacturers, government payers and health plans are not generally considered trusted sources of information by all stakeholders. A federal CER entity could, if organized correctly, be trusted by a wide range of stakeholders. Many states currently view entities like DERP and MED as trusted data sources.
- *Developing approaches to apply CER now via innovative coverage and benefit policies, rather than just "yes or no" coverage decisions.* While Washington State is using CER data for coverage decisions, states can also use this data to create tiered benefit designs.
- *Deciding where to start.* The best approach is to go after "low-hanging fruit" and avoid controversial areas. For example, don't focus on interventions that are life-or-death for patients (such as one kind of drug for a particular kind of cancer), or technologies that are the "financial lifeblood" for physician specialties; targeting such technologies will result in backlash. Start where there are multiple treatment alternatives.
- *Building a foundation for honest public dialogue.* This is a long-term dialogue focused on using evidence to make better decisions. It is important to initiate dialogue in a way that builds public support.

Participant Comments

- **CER can have real impact.** In Dr. Altman's view, among the many potential options being discussed for control health care spending growth and improving outcomes, CER has strong potential for making a significant impact.
- **Medicare can't consider cost.** Currently Medicare is prohibited from considering cost/value in coverage decisions. Legislative change would be required for Medicare to benefit from comparative value studies.
- **Involve clinicians in CER.** Multiple participants emphasized the importance of involving clinicians in the CER process.

Physician input is necessary to give credibility to the CER process and to encourage discussion of this information with patients.

- **Patient subgroups.** There are often technologies that are not effective, on average, for a patient population with a particular illness, but that are highly effective for certain subgroups. It is important that researchers try to identify subgroups that might be more likely to benefit from a therapy when designing research protocols.
- **Engaging consumers.** The UK has a formal process for engaging consumers in the CER process through a Citizen's Council that advises the government. In the US, Consumer's Union is trying to disseminate CER to patients more effectively through its publication of Consumer Reports' "Best Buy Drugs."
- **The risk of doing nothing.** Given the unsustainable rate of health care spending, cost control measures are inevitable. The alternative to investment in CER and decision making based on value will be more blunt cost management strategies such as freezing coverage of expensive drugs or applying high co-payments. These types of controls are potentially harmful to patients, and are likely to be controversial.
- **Impact on innovation.** Some participants expressed concern that CER could inhibit innovation by drug and device makers. Dr. Pearson disagreed, stating that CER provides a clear set of ground rules for innovation. Innovations that are of low value and do not provide superior clinical effectiveness will not be rewarded, but innovations that are clinically effective and of high value will have an objective way to demonstrate their superiority.
- **Setting prices.** In some countries, CER is used to determine the price at which a new technology would be a good value. This data may also be used to establish reimbursement rates or negotiate with manufacturers. Under the current US political climate, this type of negotiation is more likely to occur with private plans than government payers.

For more information about this series:

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Additional materials are available at:

www.heller.brandeis.edu/costmanagement