Minnesota Physician
The Independent Medical Business Newspaper
Volume XXIV, No. 4
July 2010

Comparative effectiveness research

Checking it twice

By Kent Bottles, MD

Comparative effectiveness research, or CER, is a hot topic in medicine these days. CER is hardly a new concept; anyone who has been involved in evidence-based medicine has been aware of it for a long time. What is new is that now there is federal money available to support this kind of research.

Just what is comparative effectiveness research? The federal government has defined for the first time what it means: CER is "research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat, and monitor health conditions in 'real world' settings."

Why should practicing Minnesota physicians care about CER? Federal funding will mean that more and more of what we do clinically will be subjected to research to determine what works and what is unnecessary care.

CER and health reform legislation

The Obama administration included $1.1 billion for comparative effectiveness research in the American Recovery and Reinvestment Act of 2009, the

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Physician engagement

Serving organizations, communities to improve health

By Irving Lerner, MD

It was more than 40 years ago that Prof. B.J. Kennedy called me, immediately after I began my practice following my fellowship at the University of Minnesota, to broach the concept of volunteerism. B.J., who was my oncology professor there, was a wonderful teacher, mentor, and friend—so I took any suggestion from him seriously. He explained that, in addition to a physician's obvious primary role in caring for patients, he felt it was a responsibility of a cancer physician to be involved in community activities dealing with cancer.

B.J. directed me to the American Cancer Society (ACS). At the time, I had about as much knowledge of the ACS as other folks. I felt it was basically a good organization, but I didn't know why, and I had no real working knowledge of what the society actually did. I asked B.J. why he

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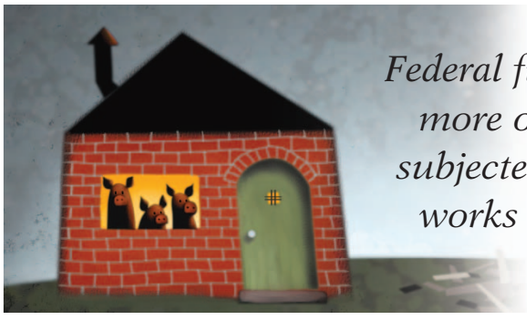
***Research** from cover*

stimulus package that was applied to the U.S. economy after the global recession of autumn and winter 2008. Included in this congressionally approved legislation was $300 million for the Agency for Healthcare Research and Quality (AHRQ), $400 million for the National Institutes of Health (NIH), and $400 million for the Office of the Secretary of Health and Human Services (HHS).

The Patient Protection and Affordable Care Act passed by Congress and signed by President Obama in March establishes a nonprofit Patient-Centered Outcomes Research Institute to identify research priorities and conduct research to compare clinical effectiveness of medical treatments. Although there is not complete agreement about how comparative effectiveness research should be implemented in "real world" settings, there is agreement that in the future physicians, patients, government, and researchers will have to find a way to decrease the per-capita cost of care and increase the quality of the care delivered. Medicare and Medicaid provide funding for more than half of all medical care in the U.S., and at the current pace these programs will be bankrupt in about eight years.

The unprecedented administrative and legislative support for comparative effectiveness research stems from what is perceived as its key role in solving both the health care delivery crisis and stimulating the recovery of the U.S. economy. Director of the Office of Management and Budget Peter Orszag has long believed that rising health care costs are the single most important challenge for the U.S. economy in the future.



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Orszag is convinced that the federal government can save enough money to make Medicare solvent by determining which medical treatments and procedures really work and thus are worth having Medicare pay for them. He also believes that CER can help persuade doctors to become more efficient and thereby save billions of dollars for the federal government.

An example is COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation), a five-year study (1999–2004) involving 2,287 people at 50 centers across North America. The results were published in the New England Journal of Medicine in 2007. The researchers concluded that chronic chest pain patients usually received no benefits from stents when used with drug therapy, and that cardiac stress testing should be done before stent placement. In a Feb. 11, 2010, Wall Street Journal article, experts estimated the nation would save $5 billion to $8 billion a year if we followed the evidence-based COURAGE medical guidelines.

And therein lies part of the problem: As we know, doctors and patients don't always select the best treatments and follow evidence-based medicine guidelines. Knowledge gaps, skills gaps, system barriers, technology barriers, and misaligned financial incentives are all part of the problem. Increased federal funding can address knowledge gaps, but the other factors must also be dealt with. We are only at the beginning of transforming health care so that it will truly bring costs under control while ensuring proper care. The newly established Patient-Centered Outcomes Research Institute is a step on the road to consistent, high-quality, cost-effective care.

What CER will—and won't—do

Not everyone agrees with Orszag's approach. Common criticisms of comparative effectiveness research include the following:

- The federal government should not micromanage the doctor/patient relationship.
- CER discounts clinical experience and does not value tacit knowledge as opposed to evidence-based scientific knowledge.
- CER will result in "cookbook medicine" that will erode the physician's role in medical decision-making.
- CER will lead to rationing of care; more costly treatments will be disallowed.
- Insurers will be encouraged to deny payment or treatment based on CER findings.
- The CER approach disadvantages certain groups that have been under-researched (e.g., minority groups and women).
- CER will discourage innovation in medicine, especially in pharmaceuticals and medical devices, because companies will not want to spend the money necessary for R&D on new therapies/products that might not compare well against other therapies/products (especially in terms of cost-effectiveness).

The health policy, employer, consumer-driven health advo-

cates, and evidence-based medicine proponents of CER view each of the above bulleted items from a different perspective.

- Since the federal government pays for more than half of all health care, and since the federal government is in a deficit, it makes sense for it to try to control unnecessary costs.
- Since the American public only receives about 55 percent of scientifically indicated care, it makes sense to decrease variability in care delivery.
- Check lists, evidence-based guidelines, and decision trees have made significant contributions to increased quality and safety in the airline and nuclear power industries.
- CER will replace the current ad hoc system of rationing care with a more thoughtful scientific approach.
- Using CER findings to pay only for effective interventions makes sense clinically and fiscally.
- CER should be done in areas that have been under-researched.
- New innovations should be encouraged, but they should not be adopted until CER proves them superior to current treatments.

Support for decision-making

The recently passed Patient Protection and Affordable Care Act reform law does little to bend the cost curve of U.S. medicine, and the current post-reform system is not sustainable. Comparative effectiveness research is certainly not intended to be the final answer. Still, physicians can't possibly keep up to date with all the research in their specialty fields. In that regard, CER can support them in making good decisions for/with their patients, and that should improve the quality and lower the cost of health care they receive.

Besides CER, some contend that a major part of the solution is to change from the current fee-for-service payment system to a global or comprehensive payment system that would encourage providers to deliver more efficient care consistent with evidence-based medicine. Others are looking to Health 2.0 technologies to transform how we deliver care to patients in their homes and wherever they carry their smart phones.

Federal and state reform efforts emphasize value-based purchasing, bundled payments, and accountable care organizations. Forward-thinking providers will make sure their information technology systems measure quality and outcomes metrics, their networks are compatible with the accountable care organization, and their physician culture supports total cost of care instead of paying for service volume.

Kent Bottles, MD, *is president of the Institute for Clinical Systems Improvment, an independent, non-profit organization that helps its members provide evidence-based health care services to people in Minnesota and surrounding states.*