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ESSAYS ON TRENDS, INNOVATIVE IDEAS AND CUTTING-EDGE RESEARCH IN HEALTH CARE

Getting Better Value For Our Health Spending

A Value Deficit In U.S. Health Care

Peter J. Neumann, ScD, Director, Center for the Evaluation of Value and Risk in Health, Tufts-New England Medical Center

Two well-known springs of health data point to a persistent gap – a “value deficit” – between the outcomes actually produced by the American health care system and the outcomes that would appear attainable with some judicious reallocations. One source shows large and unexplained regional variations in U.S. health spending. The other demonstrates that compared to other developed nations, the U.S. spends much more per capita on health care but performs worse on measures such as life expectancy and infant mortality.

Estimating the amount of waste and inefficiency in the health system has been a favorite parlor game among health policy analysts, with estimates in the range of 10-25%. Whatever the numbers, the geographic variations and cross-national comparisons underscore the notion that as a society we could be doing much better in terms of total health we receive for the dollars we spend.

One promising strategy for addressing the value deficit involves producing more and better information on the effectiveness and cost-effectiveness of medical procedures, diagnostics,

drugs, devices, and other health interventions. Policy makers have debated this idea for some time, but lately momentum has gathered to substantially expand U.S. capability in this area.

Cost-Effectiveness and Comparative Effectiveness Analysis

Cost-effectiveness analysis (CEA). By providing a structured analytic framework for quantifying the costs and health benefits associated with alternative health strategies, cost-effectiveness analysis can help decision makers make better choices about which health strategies to pay for. Strategies that provide poor value – that cost a great deal and deliver little or no marginal gains in health received would not be covered or would receive lower priority – while those offering better value would receive higher priority.

Researchers have published a large number of cost-effectiveness analyses over the years, many of which use a common metric, such as cost per life years gained or cost per quality-adjusted life years gained.¹ The amount

and quality of this evidence base continues to improve. Many countries now use cost-effectiveness analysis as an important input into reimbursement decisions. Some, like Australia, require that drug manufacturers submit cost-effectiveness analyses for reimbursement consideration, while others, like the United Kingdom, conduct their own analyses on classes of drugs and other technologies.

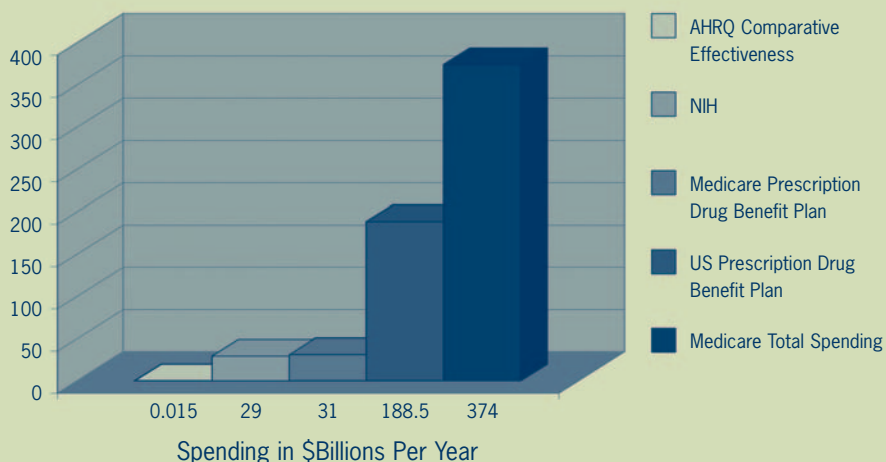
In contrast, U.S. policy makers have tended to resist using formal CEA. Notably, the U.S. Medicare program's policy does not consider costs and cost-effectiveness when deciding whether to cover a new technology. Other payers have a similar policy: they consider new technologies on the basis of clinical evidence not economic evidence. Lately, some public and private payers have begun incorporating cost-effectiveness analysis into their policies, however, including the Department of Defense, the State of Washington, and WellPoint.²

Comparative effectiveness analysis. More recently, U.S. policy makers have used the term *comparative effectiveness* rather than cost-effectiveness analysis when discussing information about the value of health services. The Medicare Modernization Act, for example, provides resources for the Agency for Healthcare Research and Quality (AHRQ) to conduct comparative effectiveness analysis and does not use the term cost-effectiveness analysis.

Comparative effectiveness generally means an analysis based on clinical not economic grounds. That is, it addresses whether drug A offers more clinical benefit than drug B not whether its extra health benefits are worth its extra costs. At its heart, it is still about obtaining better value: not paying for care that does not work. However, it says nothing about whether drug A's added clinical benefits are worthwhile.

The push by policy makers to increase U.S. spending on comparative effectiveness research

Comparative Effectiveness Research in Perspective



responds to a public good and public policy problem: that left to their own devices, the marketplace and existing public institutions – including AHRQ, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) – under-supply information on the relative effectiveness of health services. Private plans do not possess the resources to supply the research themselves. NIH and AHRQ conduct clinical research but traditionally have provided minimal funding for “head-to-head” clinical trials, which compare alternative viable strategies for treating an illness or condition, rather than comparing one strategy to placebo. The FDA, for its part, approves drugs based on safety and efficacy, but generally requires placebo-controlled clinical trials, rather than studies comparing a new drug to the next best alternative.

Moving Forward

Who will conduct comparative effectiveness research? Exactly who should produce comparative effectiveness information is a longstanding question. As the lead federal agency for health services research, AHRQ is the most natural candidate. Other options exist such as assigning the role to the National Institutes of Health, which has sponsored selected research in the area. Another possibility is to create a new government or quasi-public agency. Presumably, the organization would either conduct its own studies or award contracts and grants to academic or private organizations to carry out the research.

How much funding will it require? The big question on policy makers’ minds is how much money will be required. The subtext: are we talking millions or billions?

Current public resources for comparative effectiveness research seem scant by almost any accounting. In 2006 the federal government earmarked only \$15 million for AHRQ to conduct comparative effectiveness research, which represents only 0.052% of the NIH budget; 0.008% of the nation’s prescription drug bill; 0.004% of Medicare spending; and 0.00086% of total health spending (Figure 1). Increasing funding for comparative effectiveness research to 5% of the NIH budget would mean \$1.45 billion; raising it to 1% of Medicare spending would translate to \$3.74 billion.

A more important issue is not the absolute amount of spending but what would policy makers do with the funding and what kind of payback could society expect for the investment? The answers to those questions will largely depend on whether one is talking about synthesizing existing evidence – as is the case with much

existing comparative effectiveness research – or about conducting new clinical trials. For evidence syntheses, which involve systematically reviewing existing data and sometimes databases, the estimate would probably be in the tens of millions. The budget of the United Kingdom’s National Institute for Clinical Health and Excellence (NICE), for example, whose researchers and contractors synthesize evidence and construct models to project future consequences, is roughly \$35 million per year. Funding requirements for new clinical trials would undoubtedly be much higher.

Will it save the system money? Promised savings of 10-25% from uncovering and cutting “waste” in the system are probably wild overstatements. Attempting to find and remove pure waste in the system is always a fool’s errand, in part because comparative effectiveness research will uncover interventions that cost money but offer good value as well as those that do not work. Moreover, strong pressure from patients and physicians will remain to pay for care that offers uncertain benefit or questionable value. Comparative effectiveness research is still well worth doing but should not be oversold. At its best it will help modulate expenditure growth and will help deliver better value for the spending.

Will it fly politically? Policy discussions over comparative effectiveness embody ideological struggles about the appropriate role and problem-solving abilities of government. To some extent, comparative effectiveness transcends this traditional chasm: the notion of investigating through experimentation and analyzing the effectiveness of health interventions holds bipartisan appeal. As others have noted, even Republican programs to foster market-based competition tend to favor more information for the marketplace.³ However, there are also concerns about adding another layer of bureaucracy and yet another obstacle to innovation. The opposition is not so much to the information but to a single, central evaluator doing the analysis.

While momentum for comparative effectiveness builds, the current fiscal climate makes it hard to imagine Congress earmarking billions per year for the effort. History suggests that incrementalism will prevail: this will likely translate into tens or perhaps hundreds of millions, rather than billions more for comparative effectiveness research. Nevertheless, even if tens of millions more were forthcoming, it would pay for a great deal of evidence reviews with some left over for key clinical trials.

Is the U.S. ready for cost-effectiveness analysis? Conventional wisdom says that the

U.S. is not ready for cost-effectiveness analysis, and that the American people will never tolerate explicit rationing. This framing mischaracterizes the issue. For one thing, it is not clear that the premise has ever really been tested. For another, the key question is not whether the people are “ready” in some abstract sense, but under what circumstances and conditions will decisions be made. A Congressional or CMS dictate for Medicare to begin using cost-effectiveness analysis will likely not work in the current climate. However, a policy that grows out of discussions with all stakeholders, that is bundled with risk sharing for plans and beneficiaries, and that is developed alongside an ever-worsening fiscal outlook for the programs, could translate into a more welcoming environment.

Some Concluding Thoughts

Comparative effectiveness won’t remove the hard choices. Comparative effectiveness and cost-effectiveness analysis can illuminate choices and tradeoffs inherent in many health care decisions, but they do not remove them. New technologies will continue to emerge that offer positive health benefits and increased costs, forcing patients, their families, physicians, and payers, to confront difficult decisions.

Comparative effectiveness will raise additional questions. Comparative effectiveness research rarely “solves” a clinical question under investigation. Even the best randomized trials include selected populations and comparator treatments. Questions about whether a drug works in other population groups or compared to different alternatives remain. Moreover, drugs typically work better in some subgroups than others – often for reasons that are difficult to predict beforehand or explain afterward. The point is not that comparative effectiveness is not worth pursuing but that expectations should be tempered.

Don’t forget incentives. Inserting comparative effectiveness research into a system plagued by perverse incentives will only go so far. The information can help deliver better value, but only alongside intelligently designed systems and benefit packages that involve sharing risk at multiple levels. ■

1 Neumann et al. *Growth and quality of the cost-utility literature, 1976-2001. Value in Health.* 2005;8(1):3-9.

2 Neumann, PJ, et al. *Integrating cost-effectiveness into the U.S. health care system. Report for AHRQ.* March 28, 2007.

3 Wilensky GR. *Developing a center for comparative effectiveness information. Health Aff (Millwood)* 2006; 25(6):w572-w585.