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EXPLAINING HEALTH REFORM: What is Comparative Effectiveness Research?

Comparative effectiveness research is being discussed as part of the national health reform debate as a mechanism for improving the quality of health care and for decreasing health care spending. The aim of comparative effectiveness research is to improve health outcomes by developing and disseminating evidence-based information to patients, providers, and health care decision-makers about the effectiveness of treatments relative to other options. Identifying the most effective and efficient interventions has the potential to reduce unnecessary treatments, which in turn, may help lower costs.

Traditional clinical research typically examines the effectiveness of one method, product, or service at a time. Comparative effectiveness research compares two or more different methods for preventing, diagnosing, and treating health conditions. Such research is performed using methods such as practical clinical trials, analyses of claims records, computer modeling, and systematic reviews of existing literature. For example, one comparative effectiveness study conducted a randomized trial for treatments of osteoarthritis of the knee and found that patients receiving surgery did not have better outcomes than those treated with medicine and physical therapy. Another study, known as ALLHAT, compared diuretics to three newer and more costly blood-pressure lowering drugs, and found that diuretics worked best to lower blood pressure and prevent heart problems and strokes.

Recent Federal Action

Over the past decade, there has been some federal funding for comparative effectiveness research, primarily through the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ), but the funding was relatively meager before the American Recovery and Reinvestment Act of 2009 (ARRA). ARRA allocated \$1.1 billion over two years to expand comparative effectiveness research at AHRQ and NIH. It also established a Federal Coordinating Council to recommend research priorities and create a strategic framework for research activities. The Institute of Medicine (IOM), as mandated by ARRA, recommended 100 research areas to be given priority for funding from ARRA. Both sets of recommendations, from the Federal Coordinating Council and from the IOM, were released on June 30, 2009. ARRA requires the Secretary of the U.S. Department of Health and Human Services (HHS) to consider both sets of recommendations in directing research funds.

Provisions in Health Reform Legislation

The major Congressional health reform proposals build on ARRA by creating comparative effectiveness research centers. The Senate Committee on Health, Education, Labor, & Pensions' health reform bill entitled "Affordable Health Choices Act" (S. 1679) proposes to create a Center for Health Outcomes Research and Evaluation. The House Tri-Committee bill, "America's Affordable Health Choices Act" (H.R. 3200), would establish a Center for Comparative Effectiveness Research. Both research centers would be established within AHRQ and would be overseen by an independent commission. The Chairman's Mark, "America's Healthy Future Act," from the Senate Finance Committee would create a non-profit institute, governed by a multi-stakeholder board, to conduct comparative effectiveness research.

Ongoing Comparative Effectiveness Research

AHRQ and the NIH currently administer some federal funding for comparative effectiveness research, and make the research results available to the public. The Veterans Health Administration (VHA) and the Department of Defense (DOD) conduct comparative effectiveness assessments to support formulary and pricing decisions. The private sector also funds and conducts research on the comparative effectiveness of treatments, some of which is publicly available. Such private sector organizations include the Technology Evaluation Center (TEC) of the BlueCross BlueShield (BCBS) Association, the Drug Effectiveness Review Project (DERP) at Oregon Health Sciences University, and the ECRI Institute, as well as other consulting firms, private insurers, and

pharmaceutical manufacturers. Some of the funding for these private sector initiatives comes from the public sector. For example, the BCBS TEC receives funding from AHRQ, and DERP is funded through participating Medicaid programs.

KEY QUESTIONS

1) What kinds of treatments will comparative effectiveness research compare?

While there is general agreement that comparative effectiveness research should compare the effectiveness of two or more health care services or treatments, there is disagreement on precisely what types of treatments should be compared. Some believe that all types should be compared, including medical and surgical procedures, medical devices, pharmaceuticals, screening and diagnostics, behavioral health care, and other medical interventions. Others believe that comparing treatments in which the effectiveness can vary depending on the training and experience of the health care provider, such as health counseling, to those in which the effectiveness does not vary across providers, such as pharmaceuticals, is not a fair comparison. Current research primarily focuses on the effectiveness of one type of treatment, and although some efforts are underway to compare multiple treatments, companies often do not have a financial incentive or the resources to compare their product to other types of treatments.

2) Should comparative effectiveness research include measures of cost?

There is debate as to whether evaluations should address not only the clinical effectiveness of treatments, but also the costs. The inclusion of costs in research tends to be less controversial when the results are not directly linked to medical and health policy decision-making. However, concern arises when the results may be used to make decisions regarding pricing, coverage, insurance reimbursement, or affect patient and provider treatment choices in other ways. Part of the controversy is that costs can be defined and measured in different ways. Treatment costs may differ, sometimes dramatically, depending upon which perspective (e.g. patient, government payer, private insurer, and society) is considered in the analysis, and which costs are included. For example, some factors, such as the time required to receive the treatment and patient side effects, may be an

important part of patients' decisions, but would not be included in an analysis of treatment costs from the payer's perspective. Yet, some policymakers and researchers believe that not including the cost of treatments provides an incomplete comparison of treatments, and does not address the problem of rising health care costs. In part to address these concerns, current health reform legislation in the Senate Finance Committee would restrict the research institute from using a measure (such as dollars per quality adjusted life year) that would discount the value of a life because of a person's disability in order to establish whether a particular health care service or treatment is cost-effective.

3) How will comparative effectiveness research results be disseminated?

Dissemination of research is important if the aim is to change health care practice patterns and decision-making. In particular, the manner in which new information about the safety or effectiveness of treatments is disseminated may affect whether the research findings lead to changes in physicians' clinical practice. Simple dissemination of educational materials has often been found to be ineffective in changing physicians' habits. More active (and costly) methods, such as one-to-one education and incorporating research findings into clinical guideline development tend to be more effective. Even the wording of a study's results may influence whether physicians change their practice behavior. Regardless of the effectiveness of dissemination strategies, other factors, which can be more difficult to change, such as the management structure of private insurers and the hospitals that employ the physicians, also influence physicians' clinical practice.

Another important target for the dissemination of research findings is the public. By making research results available to the public, some patients may be able to use the information to inform their health care decision-making, though the extent to which they rely on this information depends on how it is disseminated as well as other factors.

KEY QUESTIONS (continued)

The current health reform proposals call for the dissemination of research results to health care providers, patients, private and public health plans, vendors of health information technology, professional associations, and other relevant stakeholders. Some proposals also require that relevant comparative effectiveness reports be available to the public after a defined period of time, and require the development of protocols and strategies to effectively disseminate the research.

4) Will comparative effectiveness research be used to make coverage decisions and recommendations?

One of the main controversies surrounding comparative effectiveness research is whether research findings will be used to make coverage decisions. Some are concerned that if the research is used to make coverage decisions, it will limit the autonomy of physicians and restrict patients' access to different treatments. Currently, both the private and public sectors use comparative effectiveness research in limited ways to inform coverage decisions. Government health care programs have incorporated comparative effectiveness research into coverage decisions to varying degrees. The Veterans Health Administration has been incorporating research findings into its coverage decisions for years. Some Medicaid programs have used comparative effectiveness research from DERP to develop their preferred drug lists (PDLs). The Centers for Medicare and Medicaid Services (CMS) was precluded by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) from incorporating results from the comparative effectiveness research authorized under MMA into its coverage decisions for Medicare. Current health reform proposals in the House and Senate include

restrictions on how CMS could use comparative effectiveness research in Medicare coverage decisions, such as prohibiting the use of comparative effectiveness research to deny or ration care, or prohibiting coverage decisions based solely on one comparative effectiveness study.

5) Will comparative effectiveness research save money for the health care system?

As with any research, comparative effectiveness research requires upfront funding and time to determine the clinical effectiveness, and potentially the cost-effectiveness, of treatment options for different populations and subpopulations. However, any savings will occur over the longer term as research findings promote changes in clinical practice that drive greater efficiency in the health care system. Comparative effectiveness research has the potential to save money if the findings conclude that less expensive treatments are at least as effective as more costly treatments some of the time.

Ultimately, however, conducting research and gaining knowledge about what is clinically effective is only valuable if the findings are used by the health care system. Once the research is performed, it takes time to disseminate the findings throughout the system and encourage health care providers to utilize treatment options that are determined to be clinically effective and cost-effective. In 2007, the Congressional Budget Office (CBO) estimated that the comparative effectiveness research provision in The Children's Health and Medical Protection Act of 2007 (CHAMP) would reduce total spending by public and private purchasers by \$0.5 billion over five years and \$6 billion over 10 years, with the majority of the savings realized as a result of private purchasers using the information to make coverage decisions.

Conclusion

Improving the quality of health care services and reducing health care costs are key components of the national health reform debate. Comparative effectiveness research may be an important mechanism in achieving these goals, but its value will depend on how it is implemented and how several key challenges are handled. Providing adequate funding for the research will be important and may require upfront investments. The research must be credible and able to keep pace with new treatment options and procedures. Once the research is performed, communicating the information to health care providers and the public and providing incentives for providers to use the research will be a crucial step in realizing the potential benefits of comparative effectiveness research.

Resources

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Ways and Means Committee: [<http://waysandmeans.house.gov/MoreInfo.asp?section=52>]

Energy and Commerce Committee: [http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1687&catid=156&Itemid=55]

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