In the Spotlight: Comparative Effectiveness Research

Medical costs are soaring nationwide at rates far above those of inflation. As part of an overall effort to contain these costs and keep medical care more affordable, health care reform promotes the use of research that compares drugs, devices, surgeries, and other treatment options so that health care providers can make decisions based on clinical evidence. The research can help providers weigh the effectiveness, benefits, costs and potential harms of different treatment options. In other words, comparative effectiveness research can help determine the degree to which alternative treatments produce the same or better results for similar conditions.

Two major laws passed since 2009 have provided funding, structure, and guidance for comparative effectiveness research: the American Reinvestment and Recovery Act of 2009 (ARRA) and the Affordable Care Act of 2010 (ACA). ARRA contributed over $1 billion to expand comparative effectiveness research at the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ). ACA establishes a Patient-Centered Outcomes Research Institute (PCORI) that is charged with identifying research priorities and funding comparative effectiveness research. Most recently, President Obama’s proposed budget for 2011 added an additional $286 million in funding for comparative effectiveness.

Benefits of Comparative Effectiveness Research

Patients and providers both stand to benefit a great deal from comparative effectiveness research. The first and most obvious benefit of comparative effectiveness research is better clinical decisions. Equipped with the most current and consistent information about treatments and therapies, doctors can make the best treatment decisions for their patients. As a result of better information, it is also likely that certain adverse events will be avoided, as providers will be able to more easily identify the risks associated with different treatment options. As an example, in the 1990s, providers were using autologous bone marrow transplants as a treatment method for breast cancer. Without sufficient clinical evidence supporting this as an effective treatment, many insurers were reluctant cover the procedure. In 2000, the New England Journal of Medicine published the results from a major randomized clinical trial that determined autologous bone marrow transplants did not increase the survival rate for breast cancer patients. The conclusion drawn was that “to a reasonable degree of probability, this form of treatment for women with metastatic breast cancer has been proved to be ineffective and should be abandoned in favor of well-justified alternative approaches.” Comparative effectiveness research would encourage more clinical trials and more dissemination of information on the effectiveness of treatments for certain conditions and the value of a treatment to improve safety and affordability for everyone.

Additionally, providers and patients can gauge treatment options that produce similar results that are less expensive, lowering overall medical costs. Though studies are unclear on how much, if any, money comparative effectiveness research will save, there is widespread agreement that, at minimum, comparative effectiveness research will result in better value per dollar spent if the information is used as it is intended.

Currently, providers have different levels of information and understanding of treatment effectiveness. This can result in different quality of care as well as different costs for the same quality of care.

Consider the Piedmont Health Services (PHS) example right here in North Carolina. With 50% uninsured, 30% Medicaid beneficiaries, and 10% Medicare beneficiaries, the vast majority of patients at the Piedmont Health centers have very limited resources. In order to help keep costs reasonable and care effective, primary care physicians at PHS have been using comparative effectiveness research for years. By staying abreast of current research, doctors are often able to determine the most effective and affordable treatment. For example, an older, less expensive medication or treatment can be more effective than the newest edition. As some examples of comparative research performed and used in North Carolina, PHS cites a recent Duke study that determined that 1 in 4 patients who received cardiac
defibrillators did not need them. Additionally, after years of research, a UNC study found that psychiatric patients are having more success using older, less expensive drugs than the newer ones.

Comparative effectiveness research has the potential to aid providers and patients alike in making health care decisions that are both affordable and effective.

**Obstacles to Comparative Effectiveness Research**

Despite its many purported benefits, some obstacles and up-front costs are certainly associated with comparative effectiveness research. In order that this information is useful, there must be mechanism in place to distribute what has been learned by the research about effective treatments. The efficacy of comparative effectiveness research relies exclusively on providers having access to and using the information produced. This makes disseminating the information of paramount importance.

Several issues remain about how comparative effectiveness research will work:

- It still must be determined which treatments will be compared.
- Private insurers and the government have different negotiated rates for many treatments. Based on the payer, costs may vary, which make costs difficult to compare.
- Providers are anxious to retain total control of treatment decisions, meaning that they want to retain the right to choose a course that is deemed less cost effective. There is some concern that coverage decisions will be based solely on comparative effectiveness research.
- Different results may also be attributed to different skill levels of physicians, depending on the type of procedures compared. Providers argue that it is difficult to expect the same results from a newly licensed doctor as an experienced surgeon.

Compiling the information necessary to make comparative effectiveness useful will take years. Testing, refining, and expanding models will take time and, in the near term, this could prove to be an important barrier to comparative effectiveness.

Even with all the information collected and distributed, there are limits to how comparative effectiveness research can be applied to coverage. The ACA allows the use of comparative effectiveness in Medicare:

Communicating the information to health care providers and the public and providing incentives for providers to use the research will be a critical step in realizing the potential benefits of comparative effectiveness research.

**Insurer Fees**

Under Section 6301 of the ACA, health insurance issuers and sponsors (usually employers) of self-funded group health plans will be assessed an annual fee to fund comparative effectiveness research. The fee is imposed for a limited number of years, beginning in 2012 and ending in 2019.

The amount of the assessment is $1 times the average number of covered lives under the plan for policy years or plan years ending on or after September 30, 2012 (i.e. beginning on or after October 2, 2011). The fee increases to $2 per participant in 2013, then to an amount indexed to national health expenditures thereafter. The comparative effectiveness fee phases out by 2019. Revenue from this fee will fund research to determine the effectiveness of various forms of medical treatment.

**IRS Request for Comments**

The Internal Revenue Service (IRS) has issued a request for comments on the funding mechanism for the ACA’s PCORI, regarding how these fees should be calculated and paid, including several possible rules and safe harbors. Comments on the notice will be accepted until September 6, 2011.
BCBSNC Views

At Blue Cross and Blue Shield of North Carolina, all of our medical policies are based on the best available evidence. Comparative effectiveness research has the potential to provide even more much-needed information by simultaneously promoting appropriateness, affordability, and evidence-based practice on which treatments and care delivery approaches work best and helping translate them into practice. BCBSNC believes that, for patients to receive the best care, doctors need to be equipped with the best information about treatments and procedures from a trusted and up-to-date source and applauds the establishment of the Patient-Centered Outcomes Research Institute. To ensure that the ACA-created PCORI is useful, there should be a mechanism to produce rigorous and consistent standards to evaluate the clinical effectiveness of a service or technology as well as costs. BCBSNC is strongly committed to advancing an evidence-based health care system in which information generated through rigorous analysis and research is quickly and effectively translated into everyday medical practice. In fact, over twenty-five years ago, the Blue Cross and Blue Shield Association created a Technology Evaluation Center which sought to progress along just such goals. Comparative effectiveness research can make information available about safety, effectiveness, and the value of health care for patients and providers – an outcome fully supported by BCBSNC.

For More Information

Medicare Physician Compare Website: http://www.medicare.gov/find-a-doctor/provider-search.aspx
BCBSA TEC: http://www.bcbs.com/blueresources/tec/

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