For decades, clinicians have been bombarded with the results of clinical trials and meta-analyses that purport to show differences—or lack thereof—between therapeutic agents. Sorting through the evidence can be daunting, especially for someone not well versed in statistics and study design. If new funding has its intended impact, this situation may soon change. The following news item, which appeared in the New York Times on February 15, 2009, provides the background for this impending shift in the way drugs and other therapies are evaluated and compared:

WASHINGTON — The $787 billion economic stimulus bill approved by Congress will, for the first time, provide substantial amounts of money for the federal government to compare the effectiveness of different treatments for the same illness.

Under the legislation, researchers will receive $1.1 billion to compare drugs, medical devices, surgery and other ways of treating specific conditions. The bill creates a council of up to 15 federal employees to coordinate the research and to advise President Obama and Congress on how to spend the money.

The program responds to a growing concern that doctors have little or no solid evidence of the value of many treatments. Supporters of the research hope it will eventually save money by discouraging the use of costly, ineffective treatments...

The stimulus bill, which creates the Federal Coordinating Council for Comparative Effectiveness Research, is a top priority for President Obama’s administration in its mission to provide more care and better quality care, and to make health care more cost effective. Predictably, reactions to passage of the bill have been mixed.

Those who prescribe psychotropic medications recognize that prediction of treatment response is virtually impossible. Among the most widely used types of these medications, the antidepressants and antipsychotics, the overall likelihood of a patient being helped by any drug in a therapeutic class is about the same. No one can predict which drug is best for a patient until they have actually been tried on medication. One size does not fit all, so having many options is helpful. Currently, the option of finding the right drug for the right patient is taken for granted. However, this may change under the new system.

As would be expected, pharmaceutical companies and device makers are concerned about the impact of a comparative effectiveness board. Although not mandated, one goal of the new board will be cost control. The government could theoretically establish price controls through Medicare and Medicaid programs. A widely expressed concern is that the government, which foots the bill for most medication, might wind up being more concerned with cost than with minor differences in treatment effects.

At the moment, the pharmaceutical and device industries find themselves in an awkward position. Almost daily disclosures of buried studies and manipulation of physicians has engendered mistrust among clinicians and the public. These practices have made many physicians question the validity of any data that show an advantage for one psychotropic treatment over another. In that respect, one of the best aspects of the funding for this program is that it will not only facilitate analysis of the existing evidence but will also result in sponsorship of trials that industry will not support.

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There is a British National Health Service version of the comparative effectiveness board. The National Institute for Health and Clinical Excellence (NICE) controls the available choice of treatment availability, just as a formulary committee would. NICE is a national organization that evaluates data on how well treatments work and what they cost. There has been considerable controversy when NICE has declined to pay for experimental treatments for life-threatening diseases. The same has occurred in the United States when insurance companies refuse to cover a treatment or procedure.

Overall, if it is done correctly, a comparative effectiveness board could provide accurate guidance for clinicians making treatment decisions. There are several pitfalls that will need to be addressed. One has to do with the fact that there are marked differences between individuals in terms of how they respond to the therapeutic effects of a treatment and how they absorb and metabolize medication. These differences may be gender based or based on ethnic factors. What probably will get worse is the paperwork needed to override a denial of treatment that cites the board’s findings as justification for that rejection. However, if there is just one national policy on which drugs can be prescribed—at least as initial therapy—it might mean that clinicians do not have to deal with the multiple pharmacy benefit managers that currently send their “prior approval” letters.

On balance, I wish the current system worked better. I wish there were no constraints when I make a treatment decision. Nevertheless, it is obvious that we all could benefit from objective evidence about the benefits, risks, and costs of these treatments. Unless an alternative strategy is devised, the intervention of the federal government may represent the only option we have. It is important that there be complete transparency, as well as policing of potential conflicts of interest. If comparative effectiveness research facilitates improved treatment decisions, it should be welcomed. PP

REFERENCE