

In Focus Ending the Practice of Medicine

They Said It

"Comparative effectiveness research" is probably not the first key-word string you would choose to Google if you were diving into the Patient Protection and Affordable Care Act. How about an even less like entry? Try "Patient-Centered Outcomes Research Institute". While these are terms perhaps only their authors could love, we need to get used to them. Why? Because taken together, they are backed by more than \$1.6 billion dollars in federal funding from both last year's economic stimulus bill and this year's healthcare reform legislation *and* because many commentators, ruefully or otherwise, believe they amount to just about the only visible national efforts that are aimed at improving the practice of medicine and slowing the pace of rising healthcare costs.

"Doctors want to do what their colleagues are doing," says Elliott Fischer of Dartmouth Medical School. "Identifying what works and what doesn't is only secondarily about saving money and primarily about proper care, he says." It's an absurd mischaracterization of effectiveness research to equate it with cost-benefit analysis. Instead, it's the only way to protect ourselves from practices that are not beneficial and even dangerous, which so many treatments now in use are."

Comparative effectiveness research (CER) is intended to rely on evidence-based studies to show which medical treatments, drugs and medical devices work the best; and which don't. The goal is to apply a much greater amount of scientific rigor to healthcare decision making, using facts, (rather than practice traditions or pharmaceutical and medical device marketing) to influence and perhaps even to standardize and unify medical decision making.

Dr. John Wennberg and his colleagues at The Dartmouth Institute for Health Policy and Clinical Practice have spent over 40 years documenting sometimes dramatic geographic variations in healthcare that patients in the U.S. receive - a phenomenon called practice pattern variation. The Dartmouth researchers have concluded that if unwarranted variation were eliminated, the quality of care would increase and health care savings of up to 30% would be possible - a statistic that has been often repeated in the case for CER.

While benefits managers can root for the quick and widespread application of CER, not everyone is cheering. For example, Senator Tom Coburn, Republican of Oklahoma (who also is a doctor) has warned of "a Soviet-style Federal Health Board that will put bureaucrats and politicians in charge of our nation's health-care system." And then there are the physicians and medical device makers who stand to lose revenue if the unique effectiveness of procedures like angioplasties cannot be established by CER. Comparative effectiveness research could be "a headwind for the healthcare industry", says John Sullivan of investment bank Leerink Swann. "If research shows that less complex and maybe less expensive products and therapies work just as well, that is not good news for many companies."

By law, the Patient-Centered Outcomes Research Institute will be run by a 19-member board of governors that must include three representatives of the drug, medical device and medical testing industries. The Institute must focus its studies on effectiveness and not cost. Nevertheless, substantial cost savings could be uncovered "if you're drawing a clinical study conclusion that a generic drug works as well as a branded drug, says Leerink Swann's Sullivan. He predicts that Pfizer's Lipitor along with J & J's Remicade are two drugs whose sales are likely to be affected as well as heart stents made by Medtronic and Boston Scientific.

Even so, Big Pharma and the medical device industry have had only kind words for CER. Drug makers support the effort as "an important solution for better quality and ultimately better value in health care, says Randy Burkholder, spokesman for the drug industry's trade group, PhRMA. The medical device industry supports it (so far) because "it focuses on clinical effectiveness rather than cost, according to David Nexon at the medical device-maker trade group, AdvaMed.

CER actually has been around for a long time, operating under the now-familiar label of "evidence-based medicine". But after nearly 40 years, why haven't we seen science-based treatment protocols and consequent health insurance coverage rules flourish? Simply put, many providers have a vested interest in perpetuating the status quo. As for insurance companies, "There's no incentive on the part of the insurance company to do that," says George Diamond, a Los Angeles based cardiologist in a recent Wall Street Journal article. "That would cause an uproar on the part of the physicians saying insurance companies were attempting to interpose themselves on the medical process."

The key to wide-spread application of evidence-based medicine is, not surprisingly, money. "Most cardiologists haven't voluntarily incorporated the [evidence-based] criteria into their practice," says Br. William Boden, a Buffalo, N.Y., cardiologist who led a 2007 ground-

breaking study for the Veterans Administration on the effectiveness of angioplasties. "What's going to continue to drive practice is reimbursement."


That brings us to benefits managers of self-insured medical and drug plans. These are the people who can tell their TPAs and PBMs what procedures and drugs to cover (reimburse) with or without some form of pre-certification or step therapy.

So let's assume that forthcoming CER studies establish that there is scant evidence supporting the effectiveness of getting an MRI for lower back pain, or undergoing most angioplasties supplemented by a stent insertion or that Nexium has next to no therapeutic benefits over Prilosec OTC and that nearly all men with elevated PSA scores will die with prostate cancer and not because of it. Will benefits managers "follow the science" and instruct their TPAs and PBMs to cover such treatments and drugs only after the patient has established the efficacy of the procedure or drug in question? Or instead, will benefits managers yield to the pressure of emotional employees (and probably their doctors, too) who hurl charges of interrupting the doctor-patient relationship, "rationing" of healthcare and demand the plan cover what it used to in the way it used to?

The last issue of In Focus urged benefits managers to be more assertive in helping their employees resist Big Pharma's heavy-handed marketing of expensive brand name drugs when so many sound and less expensive alternatives exist. We are putting that same encouragement out there again, only this time extending it to medical treatments and devices that cannot withstand the scrutiny of dispassionate, objective, comparative effectiveness research.

It may take a little while but soon enough the benefits manager's seat is going to get hotter. The right thing to do may not be the popular thing, but it's still the right thing to do.

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