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A Simple Health-Care Fix Fizzles Out

By [KEITH J. WINSTEIN](#)

It sounds like such a simple concept: Study different medical treatments and figure out which delivers the best results at the cheapest cost, giving patients the most effective care.

Even before Congress took up the now-stalled health-care overhaul, it appropriated \$1.1 billion to fund these studies. Both the Senate and the House included it in their versions of the bill. President Barack Obama backed it.

Yet, an examination of one of the best-known examples of a comparative-effectiveness analysis shows how complicated such a seemingly straightforward idea can get.

The study, known as "Courage" and published in the *New England Journal of Medicine* in 2007, shook the world of cardiology. It found that the most common heart surgery—a \$15,000 procedure that unclogs arteries using a small scaffold or stent—usually yields no additional benefit when used with a cocktail of generic drugs in patients suffering from chronic chest pain.

The Courage trial was led by William Boden, a Buffalo, N.Y., cardiologist, and funded largely by the Department of Veterans Affairs. It tracked 2,287 patients for five years and found that trying drugs first, and adding stents only if chest pain persisted, didn't affect the rate of deaths and heart attacks, although stents did produce quicker pain relief.

Steven Nissen, then chairman of the American College of Cardiology, called the study a "blockbuster." Shares of leading stent maker [Boston Scientific Corp.](#) fell on the day the news broke, as many doctors and investors expected stent usage to fall off.

For a brief while, they were right. U.S. stent implants declined 13% in the month after the study's release. But as the headlines about Courage faded, stentings soon began to rise again, and are now back at peak levels of about one million a year, according to hospital surveyor Millennium Research Group.

"Most [cardiologists] haven't voluntarily incorporated the Courage criteria into their practice," says Dr. Boden. "What's going to continue to drive practice is reimbursement."

Without a way to keep insurers from covering procedures that studies find ineffective, projects like Courage face an uphill climb. The health-care bills passed by the House and Senate have provisions to disseminate study results, but wouldn't require private insurers or Medicare to adjust coverage or payments to doctors in response to findings.

Unlike automobile insurers, which pay for crash-tests themselves, or home insurers, which set up Underwriters Laboratories Inc. to test household products, health insurers rarely conduct controlled studies of medical products. America's Health Insurance Plans, a trade group, says it hopes to see the government establish a standardized way of conducting and interpreting comparative-effectiveness research in order to help insurance companies make decisions.

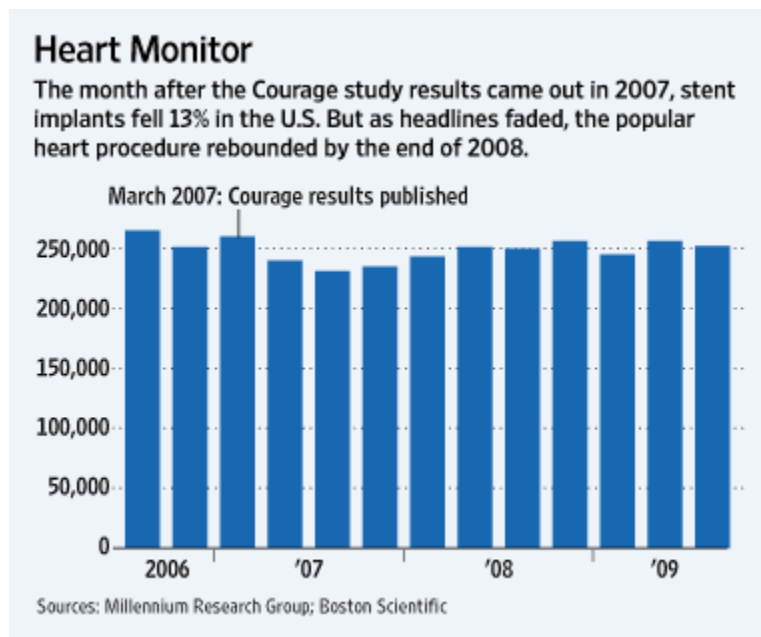
Since the 1970s, the "evidence-based medicine" movement has urged doctors to use studies like Courage as the best way to decide how to treat patients.

Many studies have had a substantial impact, especially those that boost a new therapy and its maker. Examples include studies that found benefits from antidepressants and cholesterol-lowering statins.

Studies that identify dangers have also been influential, including those linking salt to high blood pressure and the government's Women's Health Initiative, which in 2002 warned against overuse of hormone therapy after menopause.

But studies like Courage—that find an already-popular and a lucrative treatment can merely be unnecessary, but not harmful—have rarely altered medical practice to the same degree.

A 2002 government effort comparing treatments for high blood pressure found that generic pills worked better than patented drugs that cost far more, including Pfizer Inc.'s Norvasc. But sales of Norvasc continued to grow, from \$3.8 billion in 2002 to \$4.9 billion in 2006, before the drug lost patent protection.



In a statement, Pfizer said most patients require multiple drugs to control high blood pressure.

"Pfizer medicines are evaluated by health plans and physicians every day when they decide what to offer beneficiaries and patients," a spokeswoman said. "We welcome additional and rigorous research to support those individual decisions."

Sanjay Kaul, a prominent cardiologist and researcher at Cedars-Sinai Heart Institute in Los Angeles, estimates that the U.S. could save \$5 billion of the \$15 billion it spends on stent procedures each year if all doctors followed Courage's

guidance—that is, putting certain heart patients on generic drugs and turning to stents only if the pains persists.

The percentage of stent patients who had been prescribed such drugs at the time of their surgery hasn't changed since Courage, and remains at about 45%, according to data maintained by the American College of Cardiology.

Most stent patients never receive a cardiovascular "stress test" to verify that a clogged artery is the cause of their chest pains, despite professional guidelines that urge such a test before stenting.

"It's certainly remarkable that nothing has been done to put some checks and balances," into the stenting decision after Courage, says Eric Topol, the chief academic officer of Scripps Health, a hospital operator in San Diego. "I have a very strong disagreement with cardiologists who see no reason to do the stress test."

Such views aren't universal in the medical community. The late Donald Baim, Boston Scientific's chief medical officer, said Courage didn't change practice because it repeated what several other studies had already found and affirmed that stents reduced pain for patients with stable chest pain.

Dr. Baim, who passed away after the interview, also said that "the patients studied in Courage had very low levels of angina."

Ajay Kirtane, a cardiologist at Columbia University, believes that American expectations about medical "fixes" makes it hard to follow recommendations such as Courage's. If a doctor attempted to persuade a patient to delay stenting in order to see whether drug treatment would work by itself, he says, the patient would likely drop him and see another cardiologist instead.

Courage's findings apply to roughly a third of the people who get stents—those with chronic, stable chest pain. Others who receive the devices have more serious heart disease or heart attacks.

Doctors and health-care watchers point to several reasons Courage didn't move the needle. Patients have little incentive to decline costly care when insurers are paying. Interventional cardiologists, on the other hand, have a financial incentive to use stents—they receive about \$900 per stenting procedure, roughly nine times the amount they get for an office visit.

Insurance companies face their own dilemmas. If they act alone to restrict coverage, private insurers fear employers will switch to insurers that do cover the procedure. And because insurers generally earn a profit by charging a premium on claims they pay, they don't necessarily have an incentive to crack down on excess spending.

Under federal law, Courage's findings about efficacy can't alter the amount Medicare pays doctors for stenting. The government insurance program is legally barred from considering a treatment's benefits when deciding how much to pay doctors for doing a certain procedure. Private insurance carriers, in turn, generally base their rate schedule on Medicare's.

Over the past 10 years, improvements in stents have coincided with an explosion in their use, as the hour-long procedure edged out bypass surgery as the preferred treatment for clogged arteries in all but the sickest patients. The average cardiologist who installs stents made about \$500,000 in 2008, up 22% from 10 years prior, adjusted for inflation, according to the American Medical Group Association.

In 2008, the Courage study faced a key challenge. A Washington state agency called the Health Technology Assessment Program, or HTAP, announced it would consider putting Courage's findings into practice.

The agency, empowered to change coverage decisions for the state's Medicaid program and some public-employee health plans, commissioned a review of the evidence backing stents. That process could have led to

limiting the procedure's use in the state's Medicaid program and health plans for some state employees.

Certain cardiologists, as well as stent manufacturers, rallied to resist the review. In policy papers submitted to the agency, they argued that the Courage study had not included the latest models of stents, which were introduced after the study began, and should not be used to require all patients to attempt drug therapy first.

Other than Leah Hole-Curry, an attorney who heads HTAP, the agency has only one employee. State law requires it to outsource its reviews to private research firms. For the stent review, it hired a Seattle firm, Spectrum Research Inc.

Spectrum decided it needed more medical expertise to tackle the issue, and convened an August 2008 conference call with Ms. Hole-Curry, representatives of stent makers, and a number of interventional cardiologists.

According to an audio recording of the call, Spectrum's researchers asked for assistance paring down the question of comparing stents to drug therapy, such as what kinds of patients should be considered and how to define different kinds of heart disease.

The industry and doctors declined to help. "We don't want to end up being our own willing executioners," said Mitchell Sugarman, the senior director of health economics for [Medtronic Inc.](#), a stent maker, on the call. (Rob Clark, a Medtronic spokesman, later said there was "widespread consensus amongst physician and industry groups that the [agency's] questions were off-base and heavily misguided.")

Steven Goldberg, a cardiologist who directs stenting at the University of Washington, said on the call that the agency's review "borders on the absurd." He and other cardiologists took issue with the agency's choice of terms, and said it was impossible to conduct the review because it was impossible to define "stable" chest pain.

After the conference call, Spectrum concluded that the proposed review wasn't feasible. "There were some sincere and also probably some not-so-sincere questions" about the "definition for stable," says Ms. Hole-Curry. "Even though we wanted to get at the larger question, it didn't seem possible."

The agency eventually settled on a narrower review—one that didn't follow Courage's comparison of stenting versus drugs alone. Instead, the agency compared older bare-metal stents against newer, more expensive models, which are coated with drugs to reduce scar tissue that can relog an artery.

Despite a number of similar trials, performed before and after Courage and that reinforce its findings, few private insurers have shifted procedure.

"There's no incentive on the part of the insurance company to do that," says George Diamond, a Los Angeles cardiologist who used to implant stents. "They would cause an uproar on the part of the physicians saying insurance companies were attempting to interpose themselves on the medical process."

Among the exceptions are Blue Cross-Blue Shield plans in western and northeastern New York state, where Dr. Boden practices.

In July, the plans began requiring a stress test—which verifies that a clogged artery is the cause of a patient's chest pain—before a stent procedure. This year, the Blue Cross plans intend to implement another rule:

Patients having an elective stenting for chronic chest pain must first try drug treatment for 12 weeks.

"Bill Boden has been telling me, we're looking at a potential of \$8 billion in savings," across the country, says Cynthia Ambres, the chief medical officer of HealthNow New York Inc., which operates the two Blue Cross plans in upstate New York.

"If someone needs to go to angioplasty, I'm not saying we don't want to pay for that," Dr. Ambres says. But "these are the things that need to be done first."

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