

## Government sets up a tricky balance for heart catheter procedure

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The patient with the bad heart valve will be in his 60s, say, someone who tires easily because of impaired blood flow but is otherwise in pretty good health.

His is an informed consumer and has seen the ads about the new way to fix the problem without having a surgeon crack open his chest. A slender catheter is threaded through the groin, a new [aortic valve](#) implanted, and the patient is home in a few days.

Can he sign up?

For now, Mark B. Anderson has to tell him no.

"Surgery is still the gold standard," said Anderson, chairman of cardiothoracic surgery at Einstein Healthcare Network in Philadelphia.

This kind of discussion is supposed to be happening in more than 350 hospitals nationwide. Einstein does offer the new, less invasive procedure, called a transcatheter aortic valve replacement, as do 11 other hospitals in the area. But the government has set up a tricky balancing act.

On the one hand, those who undergo the catheter procedure have a 4 percent chance of stroke, so the option is approved only for high-risk patients - those who would have a hard time withstanding the rigors of [traditional surgery](#).

As the technology improves, ongoing studies may eventually prompt the Food and Drug Administration to approve the procedure for intermediate-risk patients. But at the moment, younger, fitter people such as Anderson's hypothetical patient still have to have surgery. Instead.

Yet to maintain Medicare coverage for the procedure, hospital heart teams have to perform at least 20 of them a year, or 40 in two years, to stay sharp.

Translation: Do enough of them to be good at it, but only on the right people.

In the Philadelphia area, hotbed of so many other medical arms races, the concentration of programs offering transcatheter aortic valve replacement is so dense, some worry there are not enough patients to go around.

All 12 programs in the eight-county region said they performed at least 20 of the catheter valve procedures in 2014, meeting Medicare's requirement. But half of those programs did 25 such procedures or fewer.

That concerns Michael J. Mack, who helped devise recommendations on program criteria for the FDA and the Center for Medicare and Medicaid Services.

"Doing one of anything every two weeks is probably not a good idea," said Mack, chief of cardiovascular disease for Baylor Scott & White Health in Dallas, the largest nonprofit health system in Texas.

The Dallas-Fort Worth area has one catheter-valve program per million people, said Mack, past president of the Society of Thoracic Surgeons.

With a population of 5.3 million, Philadelphia and its suburbs have more than two transcatheter aortic [valve replacement](#) programs per million residents.

Still, the 12 hospitals say they are getting good outcomes, with few strokes and 30-day mortality rates generally well below the national average of 7.6 percent

Nationally, experts have raised concerns that competition for patients has led some hospitals to oversell the procedure, at least on the Internet.

Among 262 hospitals with websites describing transcatheter [aortic valve replacement](#) programs, just 69 mentioned one or more risks of the procedure, according to a University of Pennsylvania study in January's JAMA Internal Medicine.

A further wrinkle: With every one of the \$32,000 valves it implants, a hospital at best breaks even, and, depending on the patient, may even lose a bit of money.

Why offer it? Hospitals want to show customers that they have full menus of cardiac services.

"Unfortunately in health care, if there's a technique out there, every hospital has to be doing it, or they are for some reason viewed as being less than their competitors," said Temple University School of Medicine executive dean Arthur M. Feldman, co-author of a July 2014 analysis in the *Journal of the American Medical Association*.

In addition to open surgery and the catheter procedure, there is a middle ground: minimally invasive surgery that involves a small incision above the right breast. But many patients are too sick even for that.

Brenda Cramer, 75, of Mullica Township, was happy to have the catheter option.

She found herself tiring easily, so much that she cut back on her favorite exercise, swimming.

Tests revealed her aortic valve was failing. Cramer was a veteran of two open-heart surgeries, and Cooper University Health Care physicians deemed her too risky for a third.

The 90-minute catheter procedure took place in December, and Cramer said she felt better almost immediately.

"I was feeling like, OK, I could get up and dance," she said.

For now, patients are eligible for the catheter procedure if their predicted risk of death from traditional surgery exceeds 8 percent. Patients with other issues, such as frailty, may also be eligible even with a surgery risk below 8 percent.

Meanwhile, the catheter-implanted valves continue to improve, said Penn cardiologist Howard C. Herrmann, a co-author of the study that led to their FDA approval.

More flexible catheters. Better-fitting valves with fewer leaks. Fewer strokes and other complications. Eventually, that will mean more people can avoid surgery, and doctors will have more patients to help maintain their skills.

Patients who undergo traditional surgery spend more than a week in the hospital, often followed by weeks of recovery at home.

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