

Use of unproven mammography tool soars with Medicare coverage

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In a study illustrating the potentially powerful influence of political pressure on medical practice, a UC Davis physician-researcher has found that use of a largely unproven mammography screening device has surged since Medicare began covering its cost.

Joshua Fenton, assistant professor in the UC Davis Department of Family and Community Medicine, with colleagues from the University of Washington and University of Minnesota, examined use of computer-aided detection (CAD), a medical device designed to help radiologists interpret mammograms, since Congress mandated that Medicare pay for it 10 years ago.

He found that the prevalence of CAD jumped from 5 percent in 2001 when Medicare began covering it, to 27 percent in 2003, the most recent year for which data was available. Extra mammography fees for CAD use cost Medicare an estimated \$19.5 million in 2003 alone. But actual costs are probably greater because the device has been associated with higher recall rates and greater use of diagnostic tests such as breast biopsy.

The increase in computer-aided detection use occurred even though "systemic reviews point to uncertainty regarding whether CAD has a clinically important impact on key breast cancer outcomes," Fenton writes in today's issue of the [Archives of Internal Medicine](#).

The authors explain that [Medicare coverage](#) of the device was key to

marketing the device to hospitals and health-care facilities, which resulted in intense lobbying of Congress for approval of CAD as a covered benefit.

"This illustrates how industry and government interact to determine the course of health-care practice, and it's not really guided by science," Fenton said. "This is a case in which expensive technology gets widely adopted in clinical practice before it is proven effective."

Computer-aided detection software analyzes the mammogram image and marks suspicious areas for radiologists to review. In a previous study of more than 200,000 women who had [mammograms](#), published in the New England Journal of Medicine in 2007, Fenton and colleagues found that CAD produced excessive false-positive results. His research demonstrated that when it was used, 32 percent more women were recalled for additional tests and 20 percent more women had a breast biopsy, yet use of the software had no clear impact on the early detection of breast cancer.

"This argues that we need a way of evaluating technologies before we put them into practice," Fenton said. "The government has a huge stake in this. And once the train leaves the station, it's difficult to call it back."

In the current review, Fenton suggests that intense lobbying by manufacturers of the technology, combined with the politically volatile issue of [breast cancer](#) screening, resulted in fast-track approval by the government of [Medicare](#) coverage of the device. He also argues that industry representatives were better able to market the device, which require a large capital investment of over \$100,000, after providers were assured their costs would be reimbursed by the government insurance program.

In an accompanying commentary in the same issue of the Archives,

Karla Kerlikowske, professor of medicine, epidemiology and biostatistics at UC San Francisco, says health-care providers and others cannot presume that newer technologies are better than existing ones.

"Health-care providers should not adopt new technologies without first demanding scientific evidence beyond that required for FDA approval," she writes, adding that such evidence should include not just clinical benefits, but also important associated harms and whether benefits outweigh those harms.

Provided by University of California - Davis

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