

# US Preventive Services Task Force Recommendations for Screening Mammography: Evidence-Based Medicine or the Death of Science?

The concept of trying to determine the efficacy of medical treatment has its roots in antiquity. The current term used to reference this quest is *evidence-based medicine*. It is relatively new and is variously attributed to a number of medical researchers working in the early 1990s. The concept of evidence-based medicine encompasses the use of the best available evidence developed through scientific medical research for medical decision making. Some observers distinguish between evidence-based guidelines and evidence-based individual decision making, but fundamentally the underlying concept is the same: using the results of scientific medical research to increase the objectivity of medical practice and medical decision making.

The ways the principles of evidence-based medicine have been applied remind me of one of Yogi Berra's great sayings: "In theory, there is no difference between theory and practice. But in practice, there is." The fundamental Achilles' heel in the concept of evidence-based medicine is that the evidence is in the form of statistics that are subject to variable interpretation. As such, evidence-based medicine in many respects looks more like an accounting exercise in which differing assumptions can shape the outcome rather than a scientific pursuit that predictably arrives at the same result whenever and by whom ever the experiment is performed. In theory, all observers with access to the same data should come to the same

"evidence-based" conclusions. In practice, they do not.

In practice, the development of evidence-based guidelines for medical care is heavily dependent on the specific choices observers make in applying the available evidence. Observers must make assumptions and choices about what data should be excluded or included and just how to use the included data. They also must determine what assumptions to make to fill in the blanks when data do not exist. These choices and assumptions can be influenced by underlying biases in outlook.

There are now at least 4 remarkable examples related to medical imaging in which people have promulgated supposedly evidence-based conclusions that on further review hinge on highly selective manipulations of data or assumptions not warranted by available data. Past examples include work from CMS on coronary CT angiography that deliberately left out data from 64-slice scanners and on CT colonography that excluded substantial available clinical trials data and work by others on radiation-induced cancer equating the violent, instantaneous, multisource whole-body exposures sustained by atom bomb victims with the radiation received during CT scanning.

The most recent example of an apparent point of view triumphing over available science is the report of the US Preventive Services Task Force (USPSTF) containing new recommendations for mammo-

graphic screening. The USPSTF no longer supports routine screening for women aged 40 to 49 or >74 years and has modified its recommendations for women aged 50 to 74 years to screening every other year. These new recommendations are startling for the lack of evidence to support them.

The USPSTF acknowledged in its own publication that if the goal of screening was to efficiently maximize the number of life-years gained, the best strategy would be to start screening at 40 years of age. However, the panel concluded in the end that there was limited value in screening between 40 and 49, apparently because of its assumption that false-positive results and anxiety relating to breast care for women in their 40s override the benefit in life-years gained. The task force cites as harms of screening psychological harms; additional medical visits, imaging, and biopsies in women without cancer; inconvenience due to false-positive screening results; and harms of unnecessary treatment and radiation exposure.

In fact, there are no data about whether women are willing to trade years of their lives for the supposed reduced anxiety of not going through the screening process with its inevitable false-positives and risks of over-treatment. The panel made a value judgment, not a scientific judgment.

There are research methods available to help determine to what

extent patients are willing to trade off between short-term inconvenience, pain, and anxiety related to diagnostic tests and their perceptions of the long-term benefits of undergoing the test. Rather than coming to the conclusions it did, the panel could have recommended that the issue of anxiety be studied scientifically to help inform further discussion. Instead, the USPSTF chose to “fill in the blank” about anxiety with its own views.

Another curious aspect of the USPSTF's proceedings relevant to this issue is that none of the members of the task force have any expertise in either imaging or mammographic screening. On one hand, restricting the workings of the task force to people with no professional or personal interest in the topic could be argued as keeping special interests and conflicts of interest out of the analysis. On the other hand, when the task force departed from analysis of statistical evidence to come to the subjective view that the putative anxiety engendered by mammographic screening was sufficient to negate its acknowledged benefits in life-years gained, it clearly entered territory in which there was no expertise or practical experience represented.

In day-to-day practice, radiologists and their patients deal with the issue of anxiety very commonly and for the most part very well. In a real sense, it is an insult to women in America that “Big Brother” should determine that their inability to deal with the anxieties of mammographic screening justifies giving up years of life.

What impact has mammographic screening had? Data indicate that the death rate from breast cancer, after remaining unchanged for 50 years, has decreased progressively since 1990 by 30%. The trend started about 5 years after the

promulgation of screening guidelines by a number of organizations, including the American Cancer Society and the ACR. The guidelines resulted in a substantial increase in women seeking screening and led to insurance reimbursement. The 30% decrease in the death rate from breast cancer is dramatic but is actually less than those seen in some other countries, where screening rates are higher than the 65% or so experienced in the United States.

The USPSTF asked 6 different groups to create computer models to determine what percentage of the decrease in deaths is due to mammographic screening vs improved therapies. These models varied among one another by a factor of 3—in itself a cautionary tale—and the USPSTF simply decided to conclude that only half of the decrease in the breast cancer mortality rate was due to screening vs the effects of newer therapies, another conclusion subject to choice vs science. However, direct data obtained in other medically developed countries from clinical trials that compared screened and unscreened populations both having access to the same therapies clearly indicate that the vast majority of the improvement in death rate is due to screening. The USPSTF ignored these direct data in favor of modeling.

If one assumes that only half of the observed decrease in death rate from breast cancer is due to screening, then the cost-benefit equation changes by the same ratio, and the projected cost per life-year saved doubles, making mammographic screening look less efficient and less attractive for the health system to invest in. Getting this number right should be a high priority and not turned over to theoretical models. Direct data exist from clinical trials. We should use them.

In the aftermath of the USPSTF's report, numerous professional societies and advocacy groups joined the ACR in raising concerns. The secretary of the US Department of Health and Human Services, Kathleen Sebelius, distanced her agency and the Obama administration from the report, noting that the task force does not set federal policy.

It is disheartening that some members of the fourth estate immediately labeled the raising of concerns as political or motivated by consumerism while accepting the task force's report as scientific. Demonizing those with differing points of view and differing interpretations of available data, including scientific experts, will not lead to a better health system; that requires open and honest inquiry and discussion. The ACR would welcome more than anything a truly inclusive process whereby all of the available science is considered and people with expertise on the subject at hand are included in the discussion.

Members of the USPSTF have expressed surprise at the intensity of the negative response to their work. This would seem to be another strong argument for including people who have some knowledge of a subject in the proceedings of the task force. Anyone who has followed the subject of mammographic screening could have helped with insight about the intensity of feelings on the matter.

The number of centers offering mammographic screening has been steadily decreasing because of poor reimbursement, high malpractice exposure, and the inordinate pressures on radiologists who perform the procedures. This hardly argues that blatant self-interest is motivating radiologists in their defense of screening mammography but does raise serious concerns about future access to these lifesaving studies.

Beyond other issues, the timing of the USPSTF report was unfortunate, coming in the middle of the debate on health care reform. Whatever the scientific merits of the task force's recommendations, they were immediately swept up into the debate and fueled concerns that health reform could simply be a disguised way of introducing rationing into the health care system. By choosing to come forward in the middle of the debate

on health care reform with a subject that has such important psychological and emotional overtones as breast cancer, the task force effectively added to an already highly polarized situation, making it even more difficult for lawmakers on both sides of the aisle to come together beneficially to craft legislation in the interests of the American public.

The US health system has been criticized because life expectancy

is lower here than in many other first-world countries. However, only 25% of middle-aged Americans follow screening recommendations known to add years of life to the population, and 1 of 6 people has historically been without health insurance. If we do not improve on this dismal performance while abandoning what we know works, no one should be surprised if we fall further behind.

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