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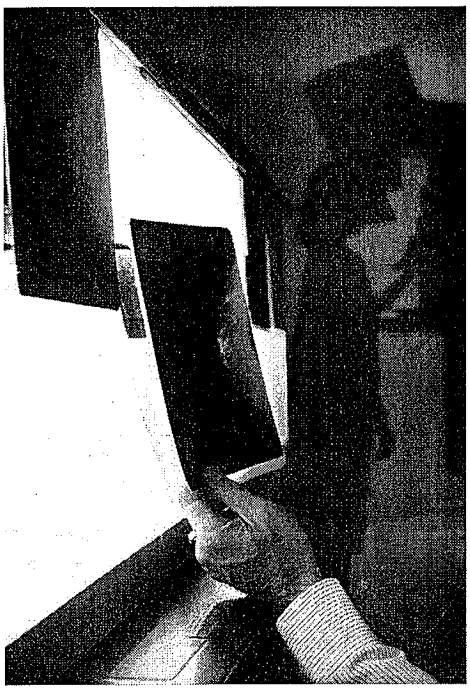

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Evidence and Fear: Navigating the Politics of Evidence-Based Medicine

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[F]or the purposes of this Act, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009. (Section 2713 of the Patient Protection and Affordable Care Act)

Section 2713 of the Patient Protection and Affordable Care Act that President Obama signed into law on March 23 contains lessons for those who believe in evidence-based policy and practice. The passage above tells potential users to ignore a recent evidence-based practice recommendation. This curious legislative language was, of course, the outcome of a public controversy that began with the publication in November 2009 of the Preventive Service Task Force's updated recommendations on the use of screening mammograms.

For a professional society whose members are engaged in the enterprise of generating evidence that might inform policy, it is worth considering why research can stimulate powerful objections.

The Mammography Screening Recommendations

In November 2009, the U.S. Preventive Services Task Force (USPSTF) published new recommendations about routine breast cancer screening mammography."[1] If followed, the new recommendations would reduce substantially the use of the procedure among women ages 40 to 49.[2]

The 2009 recommendations, which replaced guidance issued in 2002, were based on a detailed review and analysis of the relevant research. They called for the continuation of routine screening mammography among women age 50 and older, but not for younger women who had no specific risk factors. The Task Force explained that "for biennial screening mammography in women aged 40 to 49 years, there is moderate certainty that the net benefit is small"[3] and that the harms associated with breast cancer screening outweighed the benefits. These harms include "psychological harms, unnecessary imaging tests, biopsies in women without cancer, and inconvenience due to false-positive screening results." They also include "harms associated with treatment of cancer that would not have become clinically apparent during a woman's lifetime (overdiagnosis), as well as the harms of unnecessary earlier treatment of breast cancer that would have become clinically apparent but would not have shortened a woman's life."[4]

The Task Force enjoys a reputation for independence and quality, and some responses to its mammography recommendations were positive. Groups such as Breast Cancer Action, the National Women's Health Network, the National Breast Cancer Coalition, and Our Bodies Ourselves, embraced the recommendations. The recommendations were touted by some leading health policy researchers as "rational"[5] and "objective."[6]

Yet, the positive evaluations were overwhelmed by an avalanche of negative reactions from professional associations, patient advocates, and elected officials from both political parties.[7] Some of the opposition came from organizations with obvious economic interests, but strong objections also came from advocacy organizations like the American Cancer

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Society. Susan G. Komen for the Cure® stated that, "There is enough uncertainty about the age at which mammography should begin and the frequency of screening that we would not want to see a change in policy for screening mammography at this time."[8] Objections also came from within the medical profession. Former NIH Director Bernadine Healy, M.D., said on Fox News, "I'm saying very powerfully [to] ignore [the recommendations], because unequivocally ... this will increase the number of women dying of breast cancer."

Some political leaders also responded with strong criticism. Within two weeks of their release, Secretary Sebelius decried the "confusion and worry" the recommendations had stimulated and noted that the Task Force does not "set federal policy and [doesn't] determine what services are covered by the federal government." She advised the public, "Keep doing what you have been doing for years: talk to your doctor about your individual history, ask questions, and make the decision that is right for you."[9] Within a month, the Senate agreed by voice vote to an amendment that effectively required the federal government to ignore the Task Force's recommendations.[10] In altered form, but not changed substance, the amendment found its way into the health reform legislation.

Lessons from the Mammography Controversy

It is not unprecedented for new practice guidelines to generate powerful opposition, as when the very funding of the Agency for Health Care Policy and Research was successfully attacked in 1996 in part because of political objections to practice guidelines regarding back surgery.[11] Similarly, recommendations from MedPAC, particularly those that call for payment reductions, are also criticized regularly by stakeholders.[12] Even so, an important point about such controversies regarding practice guidelines is they have been unusual. Several hundred new or revised practice guidelines are added every year to AHRQ's National Guideline Clearinghouse which now catalogues about 2,400 guidelines, few of which have attracted any public concern.

So, why the controversy in this case? Comparative effectiveness research (CER) and evidence-based medicine (EBM) seem most likely to face challenges when findings call for some degree of "disinvestment"[13]—reducing use of an established technology. The mammogram recommendations, like the back surgery guidelines 15 years earlier, involved replacing some uses of a technology with a more conservative approach. Health care providers and the public at large have an appetite for the new. Calls for doing less can be more difficult to accept. Even so, recommendations to do less do not necessarily generate controversy. For example, there was little public debate in 1996 when the USPSTF recommended against the use of screening asymptomatic persons for lung cancer with either low dose computerized tomography or chest X-ray.

The mammography guidelines had important economic implications for providers of the service in question—and indeed, there were some allegations that this was the primary source of the objections to the new guidelines[14]—but several additional factors were also involved in the mammography case. One is the special nature of breast cancer, a disease that has generated a highly active advocacy community, many of whose members have long promoted screening mammography among women ages 40 to 49 based on the presumption that early detection saves lives. The research community has gone back and forth on the issue of screening for years,[15] but this ambivalence had not always been reflected in the messages from the advocacy community. As one commentator put it, "Breast cancer is viewed as a plague. A 'war' on breast cancer is viewed as a crusade. Screening mammography is Excalibur."[16] The USPSTF recommendations differed from the long standing public health message advanced by several prominent advocacy groups, and they responded accordingly.

The response of the breast cancer community may also have been affected by the way the recommendations were developed and released. The Task Force is a private, non-governmental entity, and its meetings are not open. The release of the recommendations took place in a peer-reviewed journal that has rules against prior release of content. There was little awareness that the Task Force was seriously considering this particular revision of its breast cancer guidelines. Had there been, the Task Force might have received information that would have helped it to anticipate the shock the recommendations would produce and it could have worked more in advance to address possible misinterpretations, as it in fact did after the controversy blew up. (As the controversy raged, the Task Force reconsidered the matter and decided to stick with its recommendations, but with modified language.)

Another factor was that the Task Force's recommendation was based on a particular weighing of the evidence. That is, it was possible to consider the evidence that the Task Force cited and come to a different conclusion. Deciding how much weight should be given to false positives and to the possibility that screening might detect some cancers that would never become life-threatening are matters of judgment, not fact. The Task Force decided that the risks of breast cancer screening of women younger than age 50 who carried no known special risk factors (e.g., genetic) outweigh the benefits of screening. Some advocates of screening, reviewing the same evidence, reached the opposite conclusion. Evidence that is less subject to conflicting interpretations may not produce the same defense of the status quo.[17] But judgment about incommensurate factors will often be needed when evidence is evaluated.

Perhaps most important factor in this particular instance was the highly charged political environment into which the Task Force released its recommendations. Attacking the USPSTF and the mammography recommendations gave politicians an attractive way to advocate for women's health.

The recommendations also became part of the broader argument about the dangers of government control of health care. When the Obama administration had included $1.1 billion for CER in the stimulus package in early 2009, opponents warned that such research would be used by government to ration care and deny life saving treatments.[18] Although USPSTF is independent, the recommendations by the Task Force are often adopted by public and private purchasers. In the context of the health reform debate, the recommendations were painted as a move toward government rationing of care and framed as "a glaring example of the dangers of increasing the federal government's control of health care."[19] An online editorial published by *The Wall Street Journal* argued that this was an example of the "political rationing of care" that we can expect under "ObamaCare."[20]

Indeed, both the Senate bill (Patient Protection and Affordable Care Act - H.R. 3590) and the final reconciliation act adopted by both houses of Congress, "require qualified health plans to provide at a minimum coverage without cost-sharing for preventive services rated A or B by the U.S. Preventive Services Task Force."[21] Screening mammography for women ages 40 to 49 had received a rating from the USPSTF of "C," so the charge that this recommendation could affect coverage was understandable.[22] That helps to explain why Secretary Sebelius made her statement about the recommendations and why Congress included a provision in the health reform bill to disregard them.

Summary and Lessons

Professional and advocacy opposition, along with financial interests and ideological concerns about government "rationing," may create barriers to the implementation of CER and EBM, particularly when existing practices are challenged. This seems more likely when health policy issues are highly salient to industry, professional, and consumer organizations.

With the adoption of U.S. health care reform and the future expansion of government-funded health insurance, health care costs will continue to be a major concern for policymakers. Both governmental and private purchasers of care will continue to have to make decisions about what services to pay for. Although analysts disagree about the potential for CER to reduce health care spending,[23] the *idea* of using evidence to improve health care policy decisions enjoys support from a broad range of actors.[24] Nevertheless, the strong negative reaction to the 2009 mammography recommendations from the USPSTF is a powerful signal that the *implementation* of CER and EMB can encounter great resistance, particularly when this research suggests that broadly accepted health care technologies that have been promoted by the health care community and patient advocates may not be worth the cost. Although, to date, controversies regarding practice guidelines have been unusual, the conditions that produced the objections in the mammography case could become more important, and more common, as the use of CER and EMB are extended.

The USPSTF did not base its mammography recommendations on possible cost savings, but proponents of CER and EMB often claim that this research will reduce spending by eliminating unnecessary care.[25] The *reactions* to the mammography recommendations suggest that the health services research community needs to understand better what the public believes about evidence and ways that health care costs might be constrained. Greater focus on likely public reactions may encourage the research community and entities like USPSTF to work with the media, anticipate possible misinterpretations, and reduce public anxiety. Leaders at AHRQ and USPSTF appear to be moving in that direction already by providing additional opportunities for public comment on forthcoming recommendations, which will be posted on http://www.preventiveservices.ahrq.gov.[26]

Providing such opportunities for public comment may help the health services research community build support for basing policy decisions and practice guidelines on a strong evidence base and perhaps increase understanding of and confidence in the research base for such decisions. The new health reform legislation calls for establishment of a Methodology Committee to advise the Patient-Centered Outcomes Research Institute, which is charged with conducting CER. The Methodology Committee is required to "develop and improve the science and methods of comparative clinical effectiveness research."[27] Establishing the credibility of its methods among a broad array of stakeholders will not insulate the new Institute, or health services researchers more generally, from controversy. Nevertheless, establishing broader support for the value of health services research, coupled with sustained efforts to communicate more effectively with the public, is crucial as the United States grapples with how best to improve the quality and efficiency of its health system.

Endnotes

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18 During a December 1, 2009 statement on the floor of the U. S. Senate, Senator Coburn claimed that seniors "are going to die sooner" as a result of health reform

19 "Majority's Health Bill Empowers Government Task Force at Center of Mammogram Controversy." From Website of Senator Tom Coburn (R-OK).

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21 Patient Protection and Affordable Care Act (P.L. 111-148) with amendments included in the Health Care and Education Reconciliation Act of 2010 (H.R. 4872); Patient Protection and Affordable Care Act (H.R. 3590).

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