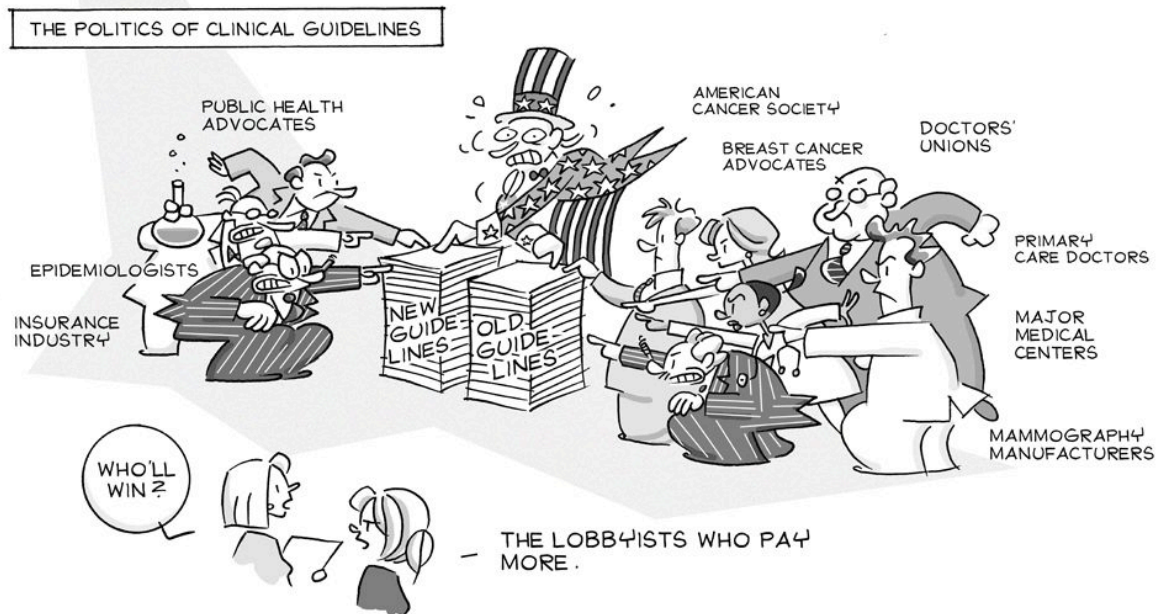


The Mammo Controversy-- So Much for Evidence-Based Medicine

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“No good deed goes unpunished” is a dictum that applies to the ongoing controversy surrounding recommendations of the U.S. Preventive Services Task Force (USPSTF), an independent group of 16 private sector clinicians and scientists appointed by the federal Department of Health and Human Services (DHHS), which rigorously assesses ever changing evidence on medical care, and makes recommendations based on explicit criteria. Their recommendations, which do not apply to a small group at high risk for breast cancer, now suggest women in their 40s should stop routinely having annual mammograms, that women aged 50-74 should have them less frequently (every two years rather than every year) and that breast self-examinations produce no significant medical benefit. Just 7 years earlier (2002) the same group, but with different members looking at earlier evidence, recommended annual mammograms for women starting at age 40. The task force also reversed its previous guidance that encouraged doctors to teach women how to do breast self-exams.

The heated controversy surrounding the panel’s recommendations may benefit from the balm of statistical context. According to data from the National Cancer Institute (NCI) approximately 192,000 women in the U.S will be diagnosed with breast cancer and over 40,000 will die of the disease in 2009. Over her entire lifetime, a woman’s risk of breast cancer is 2.86 per cent. The risk that a woman aged 40 will be diagnosed with invasive breast cancer before her 50th birthday is 1.44 per cent. The risk that a 40-year old woman will die of breast cancer before her 50th birthday is small-just 0.19 per cent according to

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the NCI. About 39 million women undergo mammograms each year in the U.S, costing the health care system an estimated \$5 billion annually.

Coming in the midst of an already overheated national debate over health care reform the new breast cancer guidelines quickly sparked intense controversy—they were released on Monday, November 16th, and the following evening discussed on Fox News as presaging rationing. The controversy centers on a classic medical tradeoff—whether the risks of screening many healthy people are outweighed by the benefits to those whose illnesses will be detected early enough to be treated effectively. Every interest group entered the fray to advance some position for or against the USPSTF screening guidelines. Patient advocacy groups (like the National Breast Cancer Coalition, Breast Cancer Action and the National Women’s Health Network) and some breast cancer experts and scientists welcomed the new guidelines, noting that mammograms produce false-positive results in about 10 per cent of cases, causing anxiety and prompting many women to undergo follow-up testing, sometimes disfiguring biopsies, unnecessary surgery, harmful radiation and chemotherapy.

Other powerful interests viewed the guidelines differently. The American Cancer Society (ACS) vigorously defended the old guidelines (more mammograms) saying they have reduced mastectomies and save thousands of lives annually. Raising the specter of Sarah Palin’s “death panels”, one ACS spokesperson asked “How many mothers, sisters, aunts, grandmothers, daughters and friends are we willing to lose while the debate goes on about the limitations of mammography?” Doctors’ unions, like the American College of Radiology, the American College of Obstetricians and Gynecologists and the Society for Breast Imaging, reflexively denounced the new guidelines, urging their members to stick with the old guidelines advising annual mammograms starting at age 40. Prestigious medical centers like Memorial Sloan Kettering in New York, the Mayo Clinic in Rochester, Minnesota, the University of Pittsburgh Medical Center, the Johns Hopkins Breast Cancer Center in Baltimore and the M.D. Anderson cancer Center in Texas supported use of the old guidelines. Primary care physicians opposed the new guidelines arguing they were the ones “working in the trenches” and declaring they would continue existing practice. Cancer survivors and their families presented personal moving accounts of how mammography has saved lives. Manufacturers of mammography machines were understandably opposed because the new guidelines could adversely affect profitability— shares of Hologic, which produces a breast cancer detection product (Selenia), dropped 6.6 per cent following release of the USPSTF recommendations. The combined power of these interest groups is depicted in the accompanying illustration. Representatives of the imaging industry and some patient groups alleged the Obama administration was pursuing a “federal plot against medical imaging”.

Shooting the messenger became the sport du jour. The USPSTF was denounced as an agent of the Obama administration, prompting House Speaker Nancy Pelosi (D., California) to quickly circulate talking points reminding the media that the members of the panel were chosen during the previous Bush administration. Because there were no breast surgeons or oncologists on the panel they were dismissed as unqualified and inexperienced. The panel was characterized as “a far away group of pinheads” who deal in “statistical abstractions.” Despite repeated assurances from its Vice Chairman, Dr. Diana Petitti, that their deliberations were in no way influenced by the health care reform debate or cost issues, the guidelines were still viewed as motivated by an attempt to save billions of dollars in health care costs. Some objected that the new guidelines were based on an analysis of older data and did not take into account new digital mammography, which was able to detect more cancers in the denser breast tissue of younger women. Ethnocentric criticism was directed at overseas data, especially from China and Russia concerning the effectiveness of breast self-exams. Others complained the USPSTF recommendations were just too stark, and that they failed to offer “something to replace it with that has an advantage over

mammograms.” One professor of radiology at Harvard Medical School stated the panel’s recommendations “will condemn women ages 40-49 to unnecessary deaths from breast cancer” and “It’s crazy-unethical really.”

The new mammography guidelines provided fuel for broader partisan political interests. Because they were published in the midst of heated debate surrounding health care reform, they provided an opportunity to raise the specter of rationing. Representative Marsha Blackburn (R., Tenn) argued “This is how rationing begins. This is the little toe in the edge of the water. This is where we start getting a bureaucrat between you and your doctor.” Another representative, Cathy McMorris Rodgers (R., Washington), expressed concern “that these recommendations mirror policies in single-payer nations like England”. Congressional Democrats said privately that they would distance themselves from the new guidelines--which they viewed as politically problematic—while attacking Republicans as seeking to politicize the new guidelines. Perhaps because they had bigger health care reform fish to fry the Obama administration also quickly distanced itself from its own federally supported USPSTF recommendations. Correctly acknowledging they had “caused a great deal of confusion and worry”, Kathleen Sebelius, Secretary of Health and Human Services devalued the contributions of the task force by describing it as only “an outside independent panel of doctors and scientists who make recommendations,” who neither “set federal policy” nor “determine what services are covered by the federal government.” Appearing as a deer in the headlights, Secretary Sebelius lamely advised women to “keep doing what you’ve been doing for years—talk to your doctor about your individual history, ask questions, and make the decision that is right for you.” The American College of Radiology called on Secretary Sebelius to order the task force to rescind its recommendations and to make sure any future panel included “experts from the areas on which they will be advising lawmakers and submit their recommendations for comment and review to outside stakeholders.”

Can the ongoing controversy surrounding mammography screening serve as an instructive case study, to provide useful lessons for the future? **First**, it is important to remember that this is not the first such controversy, especially concerning screening. Similar eruptions have surrounded the release of updated guidelines for prostate cancer—like mammograms, PSA tests can also trigger false alarms and identify precancerous growths and tiny tumors that would never become life-threatening, but nonetheless prompt a range of costly treatments. Widespread confusion and anxiety followed the release of results of the Women’s Health Initiative showing hormone replacement therapy (HRT) actually increased the risk of strokes and breast cancer. Scarce public resources continue to be invested in large well-designed multi-year clinical trials, the often unsettling results of which are simply dismissed by physicians, their professional unions and the public. The lesson here is the NIH and other federal agencies need to immediately introduce and adequately fund an effective mechanism for disseminating the results of major studies to the full range of interests – health professions, policy makers and the general public.

Second and as depicted in the accompanying illustration, the acceptability of new guidelines depends more on the preservation of stakeholder interests and political considerations than on the quality of scientific evidence. If new guidelines threaten the status quo and established interests then they will be disparaged and dismissed and their implementation obstructed. Future task force members should understand that they are essentially on their own if their evidence-based recommendations threaten dominant professional and political interests. Given what has occurred repeatedly, this observation should surprise no one. The lesson here is while lip service is given to the sanctity of evidence-based medicine, the best new evidence will be disparaged and dismissed if it runs counter to established interests.

Third, unlike every interest group either opposed to or in support of the new mammography guidelines, the USPSTF has no dog in the hunt. The task force is independent, nonpartisan and comprises well-intentioned respected scientists who are prepared to undertake public service for minimal reward, often at considerable personal and professional cost. Their good deed in helping develop guidelines does not go unpunished. And anyone who has served on federal committees or review panels knows that the pay is below minimum wage. The USPSTF point person, Dr Petitti, is an internationally respected epidemiologist with outstanding expertise in breast cancer.

While the guidelines developed by the USPSTF are based on a disinterested analysis of the latest available data, this is not the case for many other clinical guidelines which are heavily influenced by the pharmaceutical industry and special interest groups and unquestioningly adopted as standard practice. As examples, sixteen of the 28 members of an American Psychiatric Association task force overseeing revision of its diagnostic manual, the profession's so-called "diagnostic bible," disclosed financial ties to drug or medical device companies. One survey revealed 87 per cent of guideline authors for diseases such as diabetes, hypertension and asthma had some relationship with companies producing drugs for these conditions. These results may actually underestimate the magnitude of the problem since only 52 per cent of the authors contacted for the survey responded, reportedly because they did not wish to disclose their industry relationships. In May 2003, an NIH panel recommended broader use of hypertension drugs at lower blood pressures. Nine of the 11 authors of these guidelines had ties to the drug companies. Again, in 2004 new cholesterol guidelines were presented by the federal government (NHLBI) in lockstep with the American Heart Association. They were written by 9 of the top cholesterol experts in the U.S. At least 6 of these had financial ties to manufacturers of the most widely used anti-cholesterol drugs. Assuming them to be appropriately developed, many groups unquestioningly adopted these new guidelines. And not surprisingly, as well-intentioned physicians follow the new guidelines and treated hypertension and hypercholesterolemia at ever lower levels—sales of the newer drugs increased. Even the Institute of Medicine (IOM) has called for an end to the cozy relationship between clinicians, medical researchers and drug and device manufacturers, and has suggested ways to curb it. The Physician Payment Sunshine Act, recently sponsored by Senators Charles Grassley (R., Iowa) and Herb Kohl (D., Wisconsin), would require drug and medical device companies to disclose any payments of \$100 or more.

The lesson here is the development of clinical guidelines needs to be completely overhauled: with federal sponsorship they should be, and be seen to be, developed by independent scientists with no evident interest in a particular outcome. The independent National Institute for Health and Clinical Excellence (NICE) in the U.K provides a model for how things could be done in the U.S. Complete disclosure of any type of tie with private industry should be a minimal requirement. Professional medical associations should neither accept corporate money to underwrite the development of guidelines, nor allow members with financial ties to industry to serve on committees that develop guidelines, most of which are usually adopted as standard medical practice. Rather than being considered a weakness, the validity and integrity of the recent USPSTF mammography guidelines may have been enhanced by the absence of breast surgeons and radiation oncologists on the panel. Federal sponsors of clinical guidelines obviously need to stand behind them and not throw panel members under a political bus as has occurred, especially when panel members were hauled before a congressional committee and regaled with the personal stories of breast cancer survival.

In stark contrast to many of the guidelines shaped by interested parties, the USPSTF did an exceedingly careful job. They laboriously combed through the most recent published literature, systematically combining and analyzing the latest studies. The resulting report was then sent to 15 outside scientists for independent review. They included overseas data, including an update of a Swedish study

involving about 70,000 women, recent results from a British trial involving more than 160,000 women and data from the Breast Cancer Surveillance Consortium involving over 600,000 women. Moreover, they commissioned an initiative, supported by the NCI, involving 6 independent teams of researchers who undertook separate mathematical modeling studies of the risks and benefits of 20 screening strategies. All of that is not enough however and the often tragic story of a breast cancer survivor, especially if a member of the U.S Congress, trumps the mountain of objective scientific data. That the 2009 recommendations of the USPSTF differed from those previously issued in 2002 based on earlier data is considered a weakness—one commentator observing “science routinely second-guesses itself and women have often been caught in the middle.” Of course the knowledge base in medicine is always in a continuous state of flux. That is the nature of the scientific enterprise. New results frequently suggest earlier widely accepted findings, presented by well-intentioned scientists, may be limited and perhaps even wrong. The history of medicine is littered with discarded therapies once considered standard practice.

In due course, after the mammo controversy has been supplanted by some other political issue, the USPSTF recommendations are likely to be viewed as the gold standard and followed--Medicare generally adopts panel recommendations when it makes coverage decisions for seniors, and private insurers usually follow suit. The new guidelines are expected to alter the grading system for private health plans. The National Committee for Quality Assurance has already announced the way in which it grades private insurers will change as a result of the new guidelines.

It is important to understand the basic purpose of clinical guidelines—they are developed, most appropriately by independent well-qualified clinicians and scientists, to provide an up-to-date evidence base for the everyday practice of medicine. They are designed to be used to improve the quality of medical care and to reduce worrisome disparities by standardizing everyday practice. However, the way in which they are currently developed (with heavy influence of various interests) or in many cases disparaged (if challenging the status quo and prevailing interests) makes a mockery of the laudable goal of evidence-based medicine. The lesson here is the success or failure of clinical guidelines is presently determined by political processes, not by the quality of the science dispassionately analyzed by qualified independent experts, And appropriate support from federal sponsors is a sine quo non.

As a timely postscript – on the same day USPSTF members were being interrogated by a congressional committee, the results of a new study by Dutch researchers reliably quantified what has been reported over several decades. Mammographic screening actually doubles the risk of breast cancer among high-risk women and the researchers urge avoidance of repeated exposure, especially at younger ages. If the USPSTF had included these latest data from the Netherlands, would it have made any difference?