The 2009 U.S. Preventive Services Task Force Guidelines Ignore Important Scientific Evidence and Should Be Revised or Withdrawn[1]

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The U.S. Preventive Services Task Force (USPSTF) breast cancer screening guidelines issued in November 2009 (1) ignore fundamental scientific issues and evidence and should be revised or withdrawn. A word limit makes it impossible to cover all of the issues and the details that I would like, but *Radiology* should be complimented for at least allowing both sides of this debate to be provided equally by experts on the topic, unlike some medical journals (*New England Journal of Medicine*, *Journal of the American Medical Association*, and *Annals of Internal Medicine*) that are monitored by the media, which have refused to publish evidence and analysis that dispute the USPSTF conclusions.

Screening Decreases Death Rate

In the United States, the death rate from breast cancer had remained unchanged for 50 years prior to 1990. Mammographic screening began in the mid-1980s, as indicated by a sudden jump in incidence (2). Equally as sudden and as would be expected from periodic screening (length bias sampling), the death rate from breast cancer began to decrease in 1990. As more and more women began to participate in screening, the death rate continued to decrease so that there are now 30% fewer women dying from breast cancer each year (15 000–20 000) than would have been expected had the death rate continued at pre-1990 levels.

By using computer models, some suggested that most of the decrease in deaths is due to improved therapies (3). This is belied by actual population studies that show that the vast majority of the decrease in deaths is owing to screening and not improvements in therapy. In the Netherlands, where municipalities provide health care, the death rate from breast cancer rose despite the introduction of new adjuvant therapies. It was not until mammographic screening was introduced that the death rate decreased in that municipality (4). In multiple studies (5–7) in Sweden, it has been shown that the death rate dropped dramatically when screening was introduced to the general population, while the death rate changed very little for women who either were not offered screening or refused to participate. These latter groups had access to all of the latest therapies, but the vast majority of the decrease in deaths has been owing to screening. The decrease in deaths has been consistently over 40%, including women screened in their 40s.

USPSTF Guidelines

Apparently ignoring these data (they are not even mentioned in the USPSTF report), the USPSTF recommended against mammographic screening for women aged 40–49 years. They also advised mammography every 2 years instead of annually for women aged 50–74 years (1). They advised against teaching women to perform breast self-examination and do not support clinical breast examination. They suggested that women at high risk of developing breast cancer who are under the age of 50 might consider the risks and benefits of mammographic screening. For the vast majority of women in their 40s, the USPSTF leaves nothing, forcing women to return to breast care of the 1950s and 1960s and wait until their cancers can no longer be ignored and then seek attention.

With no apparent concern, the USPSTF also acknowledges, reinforced by Kerlikowske's supporting article (8),

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See also the article by Petitti et al in this issue.

The author earns his living doing breast cancer detection and diagnosis.

that screening every 2 years will mean that women whose lives could have been saved with annual screening will die unnecessarily. Not only were there no experts in mammographic screening on the task force, but there were no medical oncologists on the task force. The USPSTF provides no data to prove that, if screening is curtailed, therapy will maintain the decrease in deaths. I am fairly certain that most experienced medical oncologists will agree that therapy only works when cancers are small and of an early stage. The death rate will almost certainly increase based on the USPSTF guidelines.

Historical Perspective

To understand the present debate, one must go back over many years during which a great volume of misinformation has developed due to poor peer review and the management of information by the medical journals (9,10). These are harsh claims, but they are documented and can be verified.

In 1993, the mammographic screening trials, when analyzed as they were designed, showed significant mortality reductions for screening women beginning at 40 years of age (11). However, the National Cancer Institute (NCI) dropped support for screening women in their 40s and advised biennial screening for women 50 years and older by using inappropriate, unplanned, retrospective subgroup analysis of the randomized controlled trials to separate women aged 40–49 years and require that they have a significant mortality reduction within 5 years of the start of screening. Not only was it never explained how such an immediate reduction in deaths could be expected from periodic screening, but the NCI completely ignored the fundamental fact that the trials were not designed or powered to permit this kind of retrospective subgroup analysis of women aged 40–49 years for use in making medical recommendations (12). The NCI ignored the fact that, even after grouping the data from all the trials together, it was mathematically impossible for the trials to fulfill their requirements. The NCI ignored the basic fact that, if retrospective unplanned subgroup analyses that lacked statistical power were scientifically legitimate, then smaller and smaller groups could be analyzed, and trials would only need to involve two women, which is, of course, absurd. However, none of the analysts who opposed screening women in their 40s were ever required to justify the use of these analyses to guide medical recommendations. The NCI decision, which was based on a scientifically unsupportable paper (13), was so egregious that a 1994 congressional review was entitled "Misused Science: The National Cancer Institutes Elimination of Mammography Guidelines for Women in Their Forties" (14).

Other scientifically unsupportable arguments were published to further buttress the NCI decision (15–17). Papers made it appear that screening parameters changed abruptly at the age of 50, when they do not, by grouping data and analyzing it dichotomously. Kerlikowske et al (18) inexplicably combined women aged 30–39 years with those aged 40–49 years (no one was arguing in support of screening women in their 30s) and compared them with all women 50 years and older. This paper made it appear that the cancer detection rate, which actually changes gradually with increasing age, jumped suddenly at the age of 50 years (their ungrouped data showed no jump), and they concluded that we should, therefore, concentrate on older women. Grouping data in this fashion and analyzing women as if changes take place abruptly at the age of 50 years, when there are absolutely no ungrouped data that show that any of the parameters of screening change abruptly at 50 years or any other age (19), has imbued the age of 50 years with scientifically unsupportable importance as a threshold. This use of data grouping to create artificial thresholds is perpetuated by the USPSTF (see below).

With longer follow-up of the randomized controlled trials (increasing the statistical power), the benefit for screening women aged 40–49 years became significant (20). In 1997, a Consensus Development Conference panel was charged with reviewing these new data. For women aged 40–49 years, there was a significant 44% decrease in breast cancer deaths in the Gothenberg trial and a significant 35% decrease in the Malmo trial (20). There was a significant 29% decrease in breast cancer deaths when the five Swedish trials were combined, and a significant 26% decrease when the Edinburgh trial was added (20). Despite having heard the clear proof of benefit for screening women in their 40s, Chairman of the Consensus Development Conference Donald Berry inexplicably ignored the evidence and declared to the media that the panel could find no reason to support screening women in their 40s (21). Editorials in major medical journals also neglected to provide the new data and even labeled radiologists' concerns as driven by greed (22). The NCI director, however, had heard the information and, after listening to the preliminary report, immediately disagreed. He had the National Cancer Advisory Board review the updated trial data and, in 1997, the NCI once again supported screening women aged 40–49 years. The USPSTF also supported screening beginning at age 40 years and reaffirmed this in 2002 (23).

Failure to Understand the Trials

Aside from the continuing decrease in breast cancer deaths in the United States since the last review by the USPSTF, the only new study on the topic was the Age Trial (24) in England. The USPSTF failed to understand that the Age Trial was severely compromised, and they took its results at face value. The Age Trial was designed to evaluate "age creep," a phenomenon that was actually repudiated by its originator (10). An understanding of the actual performance of the trial shows that it was compromised in its ability to show a decrease in deaths from screening. After the prevalence screen, the researchers were forced to use single-view mammography despite knowing that single-view mammography misses as many as 20%–25% of cancers (25). This is why U.S. screening uses two views. Furthermore, the investigators admitted

that they did not biopsy clustered calcifications (26), which are well known to be indicators of early breast cancer. Thus, the trial systematically missed many of the small cancers, the detection of which would have saved more lives. Despite these major failures and the fact that they missed a large number of small cancers that should have been detected at mammography, there was a 17% (nonsignificant) decrease in deaths among the screened women. The USPSTF did not even mention the critical flaws in the Age Trial.

The USPSTF claims to have used the highest quality scientific studies to guide their review, yet they continued to incorporate data from the Canadian National Breast Screening Study-1 (CNBSS-1) (27) despite the fact that it violated the fundamental requirements of randomized controlled trials and was so corrupted that its results are very much in doubt.

1. CNBSS-1 was greatly underpowered. It could not show anything less than a 40% decrease in deaths (28). Noncompliance and contamination further weakened its power.

2. CNBSS-1 was a trial of mammographic screening, yet the quality of the mammography was poor (29,30). Their own reference physicist stated that the quality of the mammography was not only not state of the art, but that it was even below the quality of mammography being practiced in Canada at the same time (31).

3. These problems are overshadowed by the design and execution of the CNBSS-1. Random assignment is paramount in randomized controlled trials. To avoid possible bias, those performing the random allocations can have no information about the participants. Disregarding this fundamental requirement, a clinical breast examination was performed on all CNBSS-1 participants prior to allocation. Those who were assigning women to be in the mammographic screening group or the unscreened control group knew, prior to allocation, which of the women had clinically evident breast lumps (cancers), as well as which women had palpable axillary lymph nodes signifying advanced incurable cancer. Since the assignment was on open lists (another major trial violation), they only needed to skip a line to insure that a woman with advanced breast cancer would be assigned to the mammography group. It is likely that this occurred, since there was an excess of advanced cancers allocated, at the start of the trial, to the mammography group (32). Thus, it is not surprising that for almost 10 years there were more deaths among women in the screened group.

It was argued that the demographics of the two groups were similar, suggesting random assignment, but tens, if not hundreds, of women could have been shifted in a trial of 50 000 women without altering the demographic distribution. The fact is that there were significantly more women with four or more positive nodes (incurable cancer) who were allocated to the mammography group (33). The survival rate for women in their 40s with breast cancer was 75% in Canada at the time. In the CNBSS-1, the control group, which was supposed to represent Canadian women, had a 5-year survival of over 90%. With such an exceptional 5-year survival among the control group, to show a benefit, almost none of the women in the screened group could have died. This major paucity of deaths among the unscreened women, and the apparent excess of cancer deaths among the screened women clearly suggests that women with incurable cancers were allocated to the screened group, imbalancing the trial from the start. Given the fact that strict blinded allocation is mandatory in randomized controlled trials, the major failures in the CNBSS-1 should invalidate its results, yet it is given equal weight with the other randomized controlled trials in the analysis used by the USPSTF (34).

Nine Fundamental USPSTF Errors

The USPSTF recommendations are not based on the scientific evidence.

1. No Scientific Basis for Threshold at 50

The most fundamental and scientifically unsupportable concept that has been developed and now perpetuated by the USPSTF is that the age of 50 years has any scientific basis as a threshold for determining at what age screening should begin. Grouping the data makes it appear that the age of 50 years is a biologically legitimate threshold when there are absolutely no ungrouped data that support 50 years as being anything but an arbitrary threshold. None of the parameters of screening (recall rates, biopsy recommendation rates, and cancer detection rates) change abruptly at the age of 50, or at any other age (19,35). The USPSTF, without any justification, continues to promulgate this mythology. Opponents of screening women aged 40–49 have routinely ignored the scientific issues (12) and, through data manipulation (18,36), have convinced the world that the age of 50 is a scientifically valid cutoff with some real basis in biology, when this is simply false. The age of 50 was initially chosen as a surrogate for menopause, yet menopause has no demonstrable effect on mammographic screening. Some will no doubt say that arbitrary thresholds are set all the time. However, the USPSTF did not say that their threshold was arbitrary, and their arguments try to suggest that women under the age of 50 years are actually different, as a group, when this is not supported by any data.

2. Lowest Possible Mortality Benefit Used

The USPSTF based its recommendations on a 15% mortality reduction in the randomized controlled trials. The fact is that the randomized controlled trials underestimate the benefit from screening owing to contamination and noncompliance. Women cannot be forced to be screened. In the trials they are "invited to be screened." Many refused the invitation (noncompliance). If these unscreened women died of breast cancer, they were still counted as deaths in the screened group. Similarly, many women who were allocated to the unscreened control group went outside the trials and had mammograms on their own (contamination). They are still counted with the unscreened controls even if the mammograms saved

their lives. Thus, the randomized controlled trials underestimate the true benefit from screening. The 15%, which is diluted by the corrupted CNBSS-1 results, is an underestimate. They ignored the data that show that screening women in their 40s can significantly reduce deaths by as much as 44%.

3. Computer Models Favored over Direct Data

The USPSTF claims to adhere to strict guidelines in their review of the data and to grade the quality of the material that they use in their deliberations, yet they ignored large published studies with direct data that show that, when mammographic screening is offered to the general population, the death rate from breast cancer decreases by 30%–40% (5–7). Instead, they used computer models to speculate on what would happen in the general population. There are numerous computer models that have been developed for breast cancer. There is no justification given as to why these particular models were selected. There is no magic in computer models. Their results are determined by the assumptions built into their algorithms, which predetermine the outcome. Evidence of the fact that the models used by the USPSTF are no substitute for direct data is seen in the fact that, in a study noted previously (3), these same computer models produced widely divergent results. Computer modeling is used when direct data are not available. Some computer models predicted that Hurricane Katrina would miss New Orleans. Does this mean that the destruction in that city never happened? For a supposedly evidence-based review, it is unclear why such models were used instead of the direct data that were available but not even mentioned by the USPSTF. There is no justification for using models when direct measurements are available.

Despite the fact that models should not have been substituted for direct data, the models all show that the maximum decrease in deaths occurs when women begin annual screening at the age of 40 years (37). The USPSTF even ignored their own models.

4. Decrease in Deaths Mostly Due to Screening, Not Therapy

The USPSTF ignored the large amount of published data that show that the decrease in breast cancer deaths that has occurred among the general public is due, primarily, to mammographic screening and not to improvements in therapy (see above).

5. Breast Cancer Not Trivial in Women in Their 40s

The USPSTF trivialized the importance of breast cancer among women in their 40s, apparently unaware that over 40% of the years of life lost to breast cancer are among women diagnosed in their 40s (38).

6. No Data Support Only Screening High-Risk Women

With no scientific justification, the USPSTF advised that only high-risk women in their 40s should participate in mammographic screening, ignoring the fact that the randomized controlled trials (which they agree are the only way to prove a benefit) did not stratify by risk so that there are no data that prove that screening high-risk women will save any lives. They were also apparently unaware that the vast majority (75%–90%) of women who are diagnosed with breast cancer each year are not at high risk (39). The USPSTF guidelines will deny access to mammographic screening for the majority of women in their 40s who develop breast cancer each year.

7. Annual Screening from Age 40 Saves the Most Lives

In a previous study (40), annual mammographic screening beginning at the age of 40 was shown to be cost-effective. Although analysis of cost-effectiveness is apparently not part of the USPSTF charter, they circumvented this proscription by substituting the "number of women needed to be screened" to save one life (NNTS). This is clearly a surrogate for cost-effectiveness, since the NNTS is of little importance to the individual woman who is only screened once a year, regardless of the NNTS.

In addition to relying on the NNTS, the USPSTF failed to alert the reader that their figures were derived by grouping women by decades. In fact, the NNTS for a woman aged 49 years is not significantly different from that for a woman aged 51 years, yet by grouping the data, the USPSTF made it appear that the NNTS jumps at 50 years and again at 60 years.

The USPSTF calculated their NNTS by using a 15% mortality reduction. They estimated that approximately 1900 women in their 40s needed to be screened to save one life, while this dropped to approximately 1300 for women in their 50s. They arbitrarily decided that the former was too many, but that the latter was low enough to justify screening. Even using this method, had they made their calculations with a realistic 30% reduction in deaths and not the 15% that they used, the NNTS for women aged 40–49 years would be 950, which is within their threshold, and we would not be having this discussion.

8. Screening Anxiety is Not Equal to Death from Breast Cancer

The USPSTF argued against annual screening by trading deaths from breast cancer for reduced anxiety from being called back from screening. The USPSTF acknowledges, and Kerlikowske agrees (8), that going to biennial screening will mean that as many as 30% or more of the lives that could have been saved with annual screening will be lost, but they are willing to sacrifice those lives because it lowers the false-positive rate.

9. All Women Should Be Informed of Risks and Benefits

The stated fundamental reason that the USPSTF is not recommending screening to women in their 40s and is recommending only biennial screening for women aged 50–74 years is that they do not feel that women, particularly those in their 40s, can tolerate false-positive studies. They have decided to protect women from false-positive findings by denying them access to screening. Although the USPSTF now claims that their guidelines were really only a recommendation for women in their 40s to discuss the risks and benefits with their physicians, there is no doubt

that physicians and insurers will use the guidelines to deny women access to screening. It is also unclear why they would suggest that only women in their 40s need to discuss the risks and benefits of screening with their physicians. All women, regardless of age, should be informed of the risks and benefits of any intervention. Nothing happens at the age of 50 to change this.

The majority of false-positive studies are easily resolved with a few extra mammographic views and ultrasonography (US). A small number of women will be asked to return in 6 months for a follow-up study as a precaution (just like the short-interval clinical follow-up that is used for areas on clinical examination that the surgeon would like to reevalaute over time). Approximately 1%–1.5% of women who are screened will be advised to have a biopsy (41). The majority of these are now needle biopsies with local anesthesia. Between 20% and 30% of biopsies prove to be cancerous. Since there were no breast surgeons on the USPSTF, it is likely that they are unaware that if we return to a time when only palpable lumps are biopsied, cancers will be diagnosed at a larger size and later stage, and the yield of cancers will be lower than for those detected with mammography since there is a lower positive predictive value for biopsies performed on the basis of clinical findings (42) than for those based on mammograms.

Conclusion

The USPSTF comprised individuals who had no direct expertise in mammographic screening. The members chosen to review mammographic screening are, by charter, "internists, pediatricians, family physicians, gynecologists/obstetricians, and nurses" (43). Based on the oversights listed above, it seems to me that they did not understand the fundamentals of the randomized controlled trials of screening. They ignored direct data from screened populations in favor of computer models that were selected for them and decided to deprive women of access to screening because the task force decided that the anxiety caused by a recall from screening (most of which are easily resolved by extra mammographic views or US) was too much for women to tolerate.

Since the controversy originally developed, the USPSTF has now begun to backtrack and suggest that they only meant that women should consult their physicians about screening. Not only is this not what is said in their documents, but it is even more hypocritical. Based on my experience with many primary care physicians over the years, I have little doubt that most do not have the time to rigorously review the mammographic screening data. Instead, they rely on groups such as the USPSTF for guidance. A recent poll by the *Annals of Internal Medicine* revealed that 67% of their physician readers plan to follow the USPSTF guidelines (44). It is difficult for the USPSTF to argue that they only wanted patients to discuss the harms and benefits when they directly state in the guidelines that they "recommend against…." The USPSTF knows full well, or should know, that their written guidelines, and not revisionist statements, will be used to dissuade, if not prevent, women from participating in mammographic screening. The USPSTF is a group that claims to champion informed decision making. Since many physicians follow the USPSTF guidelines and insurance companies also use the guidelines to determine coverage, women will be denied access to screening, making the new guidelines the height of hypocrisy by removing the choice. Mammographic screening has been shown in the most rigorous scientific studies to significantly decrease breast cancer deaths for women aged 40–74 years. When introduced into the general population, the death rate has been dramatically decreased for U.S. women, and direct data show that most of the decrease in deaths is due to mammographic screening. The USPSTF guidelines ignore many of the scientific facts. Their implementation will severely reduce the benefit that has been achieved over the past 20 years, will increase the death rate in the United States, and will set back women's breast health to the 1950s. The USPSTF should revise or withdraw its scientifically unsupportable guidelines.

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