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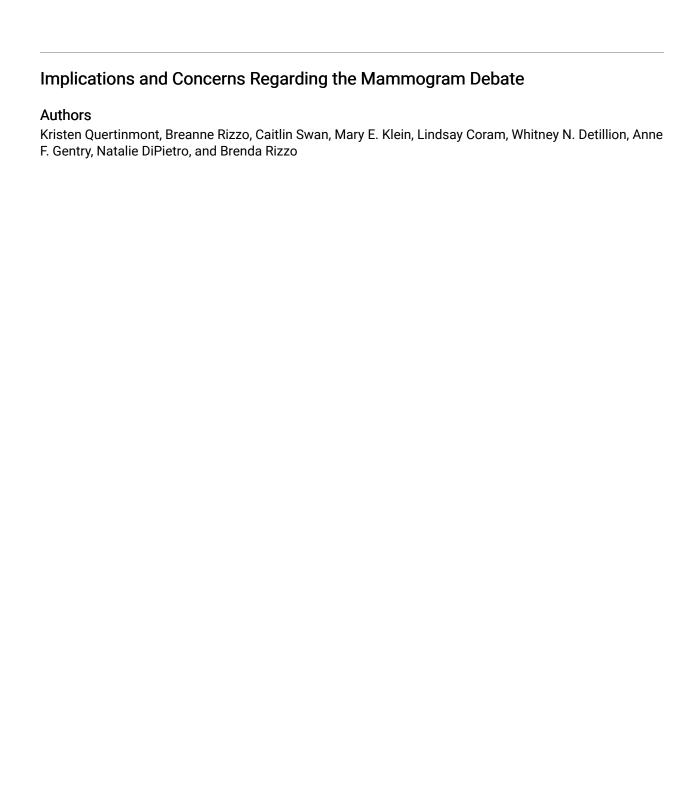
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# Implications and Concerns Regarding the Mammogram Debate

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### Abstract

Screening procedures that detect breast cancer in its early stages are an important element of preventative health care for all women. When official guidelines and recommendations for screening are modified, their changes impact health care at both the population and individual patient levels. Recently, the United States Preventive Service Task Force (USPSTF) has developed new recommendations regarding when to start mammogram screening for breast cancer in women of average risk for the development of breast cancer. This article discusses the rationale behind the updated USPSTF recommendations and also presents the current American Cancer Society (ACS) guidelines.

#### Introduction

Breast cancer is the second most common type of cancer among women in the U.S.¹ Screening procedures that detect breast cancer in its early stages are an important element of preventative health care for women. Official guidelines and recommendations for screening have been developed to assist women and health care providers in optimizing these procedures. As these guidelines are modified, their changes impact health care at both the population and individual patient levels. Recently, the United States Preventive Service Task Force (USPSTF) has developed new recommendations regarding when to start mammogram screening for breast cancer as well as new recommendations regarding clinical and self breast exams (Table 1).² These new recommendations not only have sparked debate, but also have left many women and health care professionals confused.

The American Cancer Society (ACS) has chosen to adhere to their current recommendations (Table 1).<sup>2</sup> The difference in recommendations has prompted various reactions from other advocacy and professional organization as well as health care professionals, not to mention increased patient concerns over the risks and benefits of screening. Adding to this unease are the financial implications due to possible modifications in insurance coverage and costs.

## USPSTF guidelines

The USPSTF is an independent panel of primary care physicians that assesses the net effectiveness of preventative services by reviewing the benefits and harms of services. The controversy began when the group updated its breast-screening mammogram guidelines for the general population (i.e., women of average risk for the development of breast cancer) in November 2009.3 Previously, the 2002 recommendations stated that women 40 years and older should be screened for breast cancer via mammogram every one to two years. The new 2009 guidelines recommend that women 40 to 49 years old of average risk should not have regular mammograms unless determined on an individual basis with their health care provider following a discussion on the benefits and harms of the screening. These guidelines state that regular mammograms should begin when a woman of average risk is 50 years old and occur biennially up until the age of 74. The USPSTF claims the net benefit of screening women in both the 40-49 age group and the 50-59 age group is small. However, the USPSTF recognizes increasing age as the greatest risk factor for breast cancer and, therefore, recommends beginning screening at 50 years old to accommodate for greater risk. The USPSTF's recommendations are based on the results of several clinical trials that examine the efficacy as well as benefits and harms of screening in different age groups.2

The efficacy of mammograms was examined in a standard randomized, controlled trial of 160,921 women who were 39-41 years old at the beginning of the study.4 The women in the intervention group were offered mammograms yearly until they reached 48 years old, and the control group received no mammograms during the same period. No statistical significance was shown between the groups for reducing mortality. The total reduction of breast cancer mortality was 0.4 per 1,000 women assigned to the intervention group.

Six models were evaluated to estimate the relative benefits and harms of mammogram screening strategies, which varied by interval (annual and biennial) as well as by starting and stopping ages.5 Mortality was reduced by 8 percent and 7 percent through extending the age of mammograms to 79 years old for annual and biennial screenings, respectively. There was a smaller increase in mortality reduction of 3 percent when screening began at age 40. The 40-49 age group had almost a doubling of false positives when screening annually versus those receiving biennial screenings. Overdiagnosis was shown to rise with age but was lowered with biennial screening. Results found that biennial screening achieves 81 percent of the benefits attained by annual screening. The increases in false positives and overdiagnosis rates, combined with the lower cancer risk for those 40-49 years old, did not support screening in this age group, according to USPSTF. These findings suggest a greater benefit by increasing the starting age to 50 years old and the stopping age to 74 years old.

Table 1: ACS and USPSTF Screening Guidelines<sup>2</sup> women *not* at increased risk for breast cancer

	ACS	USPSTF
Breast self- exam (BSE)	Regularly for women starting in their 20s	Recommend against teaching BSE
Clinical breast exam (CBE)	Periodically (about every three years) for women in their 20s and 30s Periodically (every year) for women 40 and over	Insufficient evidence for CBE beyond screening mammography in women 40 years or older
Mammograms	Yearly starting at age 40 and continuing for as long as a woman is in good health.	Recommend biennial screening mam- mography for women 50-74 Biennial screening before 50 should be individual and take patient context into account, including the patient's values regarding specific benefits and harms

## ACS guidelines

Despite the USPSTF's change in recommendations, the ACS stands by its current recommendations. In 1997, the ACS held a workshop to assess data regarding breast cancer screening and re-evaluated the existing ACS guidelines for early detection of breast cancer. The ACS determined that sufficient data suggested potentially positive implications for yearly mammograms in women ages 40-49. Therefore, the 1997 revised recommendations included annual mammograms for women beginning at age 40.6

The recommendations of the ACS that were published in 1997 were determined from eight randomized, controlled trials of mammogram screening. According to the ACS, a meta-analysis of all eight studies published by the National Institute of Health in 1997 demonstrated an 18 percent mortality

reduction within the 40-49 age group. Two studies conducted in Sweden, the Gothenburg trial and the Malmo trial, also revealed a statistically significant reduction in mortality among women in the 40-49 age group.6 The Gothenburg trial was a randomized, controlled trial that included 51,611 women, with 21,650 randomized to receive mammograms at 18-month intervals. The 39-49 age group showed a 31-44 percent reduction in mortality after a 14year follow-up.7 According to the ACS, the Malmo trial showed a 36 percent reduction in mortality after 12 years of follow-up.6 A guideline review was conducted with a panel of experts from the ACS in 2003 to review literature published since the guidelines were established. A meta-analysis conducted in 2002 revealed a 24 percent decrease in mortality of those invited to screening in each trial, many of which included the 40-49 age group. As a result, the 2003 guidelines remained unchanged in regards to the starting age and the frequency of annual mammography.8

#### Patient concerns

One of the greatest concerns for the patient is the availability of mammograms for women under 50. The guidelines do not say that women under 50 should not receive mammograms; they state that women under 50 should not automatically receive mammograms without first speaking with their physician to weigh their personal risks and benefits. It is also important for women to realize that the new guidelines pertain only to women without any risk factors for breast cancer and, therefore, do not include patients with any increased risk for the disease. Another concern to health care providers with the new USPSTF guidelines is whether the cost of mammograms was factored into the studies and that recommendations were based primarily on fiscal considerations. However, the USPSTF denied that finances were considered and indicated that only the risks and benefits of receiving mammograms at certain ages from an epidemiological perspective were used to make their new recommendations.9

### Benefits and harms of screening

The benefits and risks of breast cancer screening are at the forefront of the debate. Benefits of mammograms include mortality and morbidity reduction as well as patient reassurance.9

Risks of breast cancer screening include radiation-induced cancer, false-positive results, overdiagnosis, false reassurance, and pain or discomfort during the procedure. Although high-dose radiation exposure, such as radiation treatment or diagnostic radiography, significantly increases the risk for breast cancer,10 the amount of radiation a woman receives during a mammogram usually occurs at much lower doses.2 In addition, a false-positive result remains a key risk of screening, which may result in unnecessary additional procedures and costs. A systematic review for the American College of Physicians included 117 randomized, controlled trials involving women age 40-49 and found the probability of obtaining a false-positive was 2-4 percent for each mammogram. 10 Also, a meta-analysis of six models conducted to estimate the benefits and harms of breast cancer screening found that annual screening resulted in almost twice the number of false-positive test results than biennially screening, which caused twice the number of women to undergo unnecessary biopsies.5 These false-positive results could lead to anxiety, depression, and increased screenings and health care visits, both related and unrelated to the test result.10

Overdiagnosis is another risk of screening, which can cause unnecessary early treatment of a cancer that may have never been clinically detected due to its slow-growing nature.2 The Advisory Committee on Breast Cancer Screening in England estimated that one in eight women would not have had their breast cancer diagnosed had they not had a mammogram.11 Overdiagnosis could be reduced by biennial screening,2 and there is an increased risk of overdiagnosis with increasing age. 5 Conversely, beginning screening at an earlier age may enable the patient to avoid less aggressive therapies and allow the patient to receive more breast-conserving surgery, such as lumpectomy instead of a mastectomy, thus reducing the morbidity rate.10

False reassurance and pain and/or discomfort during the procedure are other minor risks of mammograms. False reassurance is the concern that a negative test result would deter women from seeking medical advice if a breast abnormality was observed or found with a self-breast exam. Few women claimed that pain was a deterrent for routine mammograms, and if a lump were found, a Dutch survey of 516 women found 99 percent of the women would still seek medical advice. 10

## Financial implications

There are financial implications with the new task force recommendations regarding whether or not third-party payers will continue to cover annual mammograms for women under 50 years old. Currently, the U.S. government will continue to recommend annual mammograms and cover the payment of any mammogram that is recommended by a health care provider. 12 Of yet, many private third-party payers have not changed their policies and have indicated that they will continue to evaluate the recommendations before making any changes to their coverage on mammograms. While many private third-party payers look to the USPSTF when making their coverage plans, recommendations of other associations, such as the ACS and the American College of Obstetrics and Gynecology (ACOG), also are considered.

### Discussion

The differences in the USPSTF and ACS recommendations show that further research needs to be conducted regarding mammogram screening in women age 40-50. Although harms of screening may be more common with younger age groups, health care professionals should consider the benefits of beginning screening at an earlier age and understand that mammograms have been primarily responsible for a number of breast cancers being identified and treated earlier. It is always important for women to discuss these concerns and controversies with their primary health care provider before making any decisions regarding mammograms on their own. Although the media intensified the focus on the changes of the new recommendations, the decision about when to obtain a mammogram should be based on individual risk factors.

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