Clinical Question: In light of the controversy surrounding the most recent USPSTF recommendation statement regarding screening for breast cancer, how should I screen women for breast cancer in my practice?  
- By what process did the USPSTF arrive at the new clinical guidelines?  
- Are the new recommendations based on valid conclusions?

“BY WHAT PROCESS DID THE USPSTF COME UP WITH THE NEW CLINICAL GUIDELINES?”

STEP 1: Conduct a review of the evidence, including new information since 2002, regarding the benefits, harms and efficacy of breast cancer screening. To focus their review, the USPSTF came up with a series of focused questions outlined in the figure below.

In order to do this, the USPSTF commissioned a systemic review done by Nelson and 5 colleagues at OHSU. The work was funded, overseen, and reviewed by the AHRQ, the Agency for Healthcare Research and Quality, an agency of the federal government. [www.ahrq.gov] The clinical researchers at OHSU performed a literature using the following algorithm:
The OHSU researchers arrived at the following key conclusions:

(Regarding the benefits of screening)
- There is a breast cancer mortality benefit for all age groups from 39 to 69 years. Data for women older than 69 was insufficient to support any conclusions.
- For women age 39-49, the pooled RR for breast cancer mortality for women randomly assigned to screening versus not screening was 0.85. (15% reduction in breast cancer mortality.) This means 1904 women need to be screened to prevent one breast cancer death. For women age 50-59 the RR was 0.86 and the number needed to screen was 1339. Women 60-69 benefited the most with a RR of 0.68 and NNS was 377.

(Regarding the harms of screening)
- Radiation exposure from screening mammography and the corresponding risk of inducing breast cancer is very low.
- 1-77% of women experienced pain and discomfort during mammography. Few of these women would consider this a deterrent from future screening.
- False-positive mammography increased breast-cancer specific anxiety, distress, apprehension and perceived breast cancer risk, but did not effect women's general level of anxiety and depression.
- The probability of a false-positive test of any given exam is 0.9-6.5%. After 10 examinations, the cumulative false positive risk is 21-49% for women in general, and up to 56% in women aged 40 to 49.
- For every case of invasive breast cancer detected by mammography in women 40-49 years, 556 women have mammography, 47 have additional imaging, and 5 have biopsies.
- Overdiagnosis is estimated to be 1-10%
  (regarding CBE Screening)
- There is insufficient evidence to recommend CBE
  (regarding BSE Screening)
- There is insufficient evidence to recommend BSE

STEP 2: The USPSTF reviewed the results of a study by Mandelbratt and colleagues which used 6 different computer models to compare the benefits and harms of various screening intervals. The work was supported by grants from the NCI. The work was reviewed by AHRQ.

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*Model refers to the different computer models used in the study.
### Appendix Table 1. Average Number of Screening Examinations and Percentage of Reduction in Breast Cancer Mortality, by Screening Strategy

<table>
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<tr>
<th>Screening Strategy</th>
<th>Average Screenings per 1000 Women*</th>
<th>Reduction in Breast Cancer Mortality (vs. No Screening), by Model, †</th>
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* Average number of mammograms across models. Not all possible mammograms in the age group are obtained in strategies that continue to the oldest age groups, because many women die of other causes before screening would occur.
† Model group abbreviations: D = Dana-Farber Cancer Institute; E = Emory Medical Center; G = Georgetown University; M = M.D. Anderson Cancer Center; S = Stanford University; W = University of Wisconsin/Madison.
‡ Because of rounding, this strategy seems to be dominated, but the actual result is 29.4.
§ Strategy is dominated ("inefficient") within the specific model. A strategy is classified as dominated if another strategy (from the efficient, borderline, or inefficient/dominated category) results in an equal or higher percentage of mortality reduction with fewer average screening examinations.

### Appendix Table 4. Average Number of Screening Examinations and Life-Years Gained, by Screening Strategy

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<th>Screening Strategy</th>
<th>Average Screenings per 1000 Women*</th>
<th>Life-Years Gained per 1000 Women (vs. No Screening), by Model †</th>
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<th>M</th>
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* Average number of mammograms across models. Not all possible mammograms in the age group are obtained in strategies that continue to the oldest age groups, because many women die of other causes before screening would occur.
† Model group abbreviations: D = Dana-Farber Cancer Institute; E = Emory Medical Center; G = Georgetown University; M = M.D. Anderson Cancer Center; S = Stanford University; W = University of Wisconsin/Madison.
‡ Strategy is dominated within a specific model. A strategy is classified as dominated if another strategy (from the efficient, borderline, or inefficient/dominated category) results in an equal or higher percentage of mortality reduction with fewer average screening examinations.
Mandelbratt and colleagues arrived at the following key conclusions:

- (EFFICIENCY is defined as the ratio of benefits to number of screening exams.) [note that this is not the same thing as ratio of benefits: harms]
- All 6 models conclude that the most EFFICIENT screening strategies are those that include a biennial screening interval.
- If the goal of a national screening program is to reduce mortality in the most efficient manner, then programs that screen biennially from 50-69, 74, or 79 years are the most efficient.
- If the goal of a national screening program is to maximize the number of life-years gained in the most efficient manner then the preferred strategy is to start screening biennially at age 40.
- All models showed reduction in breast cancer mortality by screening strategies that started at age 40 versus age 50.

**STEP 3:** The 15 USPSTF Committee Members discussed the results of the above systemic review combined with the Cancer Intervention and Surveillance Modeling Network (CISNET) modeling studies to arrive at the current recommendations, which are as follows:

**Summary of Recommendations**

- The USPSTF recommends against routine screening mammography in women aged 40 to 49 years. The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient’s values regarding specific benefits and harms. Grade: C recommendation.*
- The USPSTF recommends biennial screening mammography for women aged 50 to 74 years. Grade: B recommendation.*
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older. Grade: I Statement.*
- The USPSTF recommends against teaching breast self-examination (BSE). Grade: D recommendation.*
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years or older. Grade: I Statement.*

The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer. Grade: I Statement.*

*A,B= Offer or provide this service. C=offer/provide this service only if other considerations support offering or providing the service in an individual patient. D=Discourage the use of this service. I: the balance of benefits and harms are uncertain.

The recommendations apply to: Women 40 and older who are not at increased risk for breast cancer by virtue of a known underlying genetic mutation or a history of chest radiation.

[Recall...
…the Old Recommendations: Screening every 1-2 y for women over 40 with or without CBE.]

Q1. How did the USPSTF decide to recommend biannual over annual screening?
The USPSTF states that biannual screening retains between 77 and 90% of annual screening with a significant reduction in the number of mammograms required and therefore a decreased risk for harms.

**Q2. How did the USPSTF decide to recommend against routinely screening women age 39-49?**

Screening between ages 50-69 produced a projected 17% reduction in mortality compared with no screening. Extending the age range to 40-69 produced only an additional 3% of mortality reduction and extending the age range from 50-79 produced only an additional 7% reduction.

***The USPSTF reached the conclusion that the benefits of increased screening in these scenarios did not outweigh the harms, although Nelsen and colleagues state in their paper that the harms are difficult to quantify and that the ages at which this tradeoff becomes acceptable to individuals and society are not clearly resolved by the available evidence.***

“ARE THE NEW GUIDELINES BASED ON VALID CONCLUSIONS?”

**Some of My Concerns:**

- The work of the USPSTF panel was funded, overseen and reviewed exclusively by the AHRQ, an agency of the federal government. In the current political climate, it is in the interest of the federal government to limit health care expenditure.
- USPSTF recommendations, which are at least partially a value judgment, may be used by insurance companies and various levels of government to limit access to preventative services, even though the recommendations state that the decision to screen outside the ages of 50-74 should be a value judgment left up to each individual patient.
- The harms:benefits ratio, while influenced by evidence, is not a calculable mathematical ratio, but a heuristic of 15 individuals which may or may not match the heuristic of society, the heuristic of medical professionals in general or the heuristic of individual patients.
- The guidelines are a blanket recommendation based off European, European Canadian and European-American women and may not be in the best interest of non-caucasians. For example, African American women may benefit from earlier screening as they have lower breast density, more aggressive cancer, and a higher overall mortality risk.
- The guidelines were released at the same time as the two supporting studies, allowing no time for objective review and criticism by experts outside the USPSTF of the methodology or validity of the studies.

*Abbreviated Response from the American Cancer Society:*
“The USPSTF says that screening 1339 women in their 50s to save one life makes screening worthwhile in that age group. Yet USPSTF also says screening 1904 women ages 40-49 in order to save one life is not worthwhile. The ACS feels that in both cases, the lifesaving benefits of screening outweigh any potential harms. Survey’s of women show that they are aware of these limitations and also place a high value on detecting breast cancer early. With its new recommendations, the USPSTF is essentially telling women that mammography at age 40 to 49 saves lives, just not enough of them.”

Conclusion: the ACS continues to recommend annual screening with mammography and CBE for women starting at age 40.

Response from the American College of Radiology:

Detailed ACR Statement on Ill Advised and Dangerous USPSTF Mammography Recommendations

Mammography screening for women ages 40 and above is one of the major health care advances of the past 40 years. With the onset of mammography screening, the death rate from advanced breast cancer, that had been unchanged for the preceding 50 years, has decreased by 30 percent since 1990. Moreover, early mammography screening means cancers can be caught sooner, often allowing women to choose less invasive treatments that help to preserve the quality of women’s lives as well.

Newly revised U.S. Preventive Services Task Force (USPSTF) recommendations could reverse this decline in breast cancer morbidity and mortality, causing undue suffering to women facing breast cancer and their families. In a decision that dismisses thousands of scientific studies and data analysis, ignores the physical and psychological harms of the more aggressive treatment required for advance cancers, and prioritizes dollars saved over lives saved the AHRQ-supported taskforce rescinds recommendations for regular mammography screening for women 40-49 years of age and those over 74, and reduces the frequency of screening from annually to every other year for women between 50 and 74.

The Federally Supported U.S. Preventative Services now recommends:

AGAINST routine screening mammography in women age 40-49

AGAINST teaching breast self examinations

AGAINST clinical breast examinations

AGAINST previously recommended routine screening for women 75 years or older

AGAINST annual screening mammograms for women age 50-74 (Recommended screening every OTHER year versus the currently recommended annual screening)

In other words, USPSTF is recommending against ALL commonly accepted routine breast cancer screening methods for women in their forties despite their statement that the ten year risk for
breast cancer in a 40 year old woman is 1 in 69. They also rescind their previous recommendation providing for screening beyond 74 because “the shortened life among woman 75 and older” makes it more likely that she could die from another cause before the cancer kills her. Finally, even for those for whom they do recommend screening, delays in treatment resulting from less frequent screening will cost lives and result in more aggressive and debilitating treatment.

The recommendations make unconscionable decisions about the value of human life

The purported basis of the recommendation not to screen women in their 40s is one of risk-benefit analysis.

- As acknowledged in the research of the taskforce, if regular mammography screening does not begin until age 50, more women will die of breast cancer.
- Likewise, the research cited by the taskforce acknowledges that lives will be lost if screening becomes biennial versus annual.
- The taskforce recommendations are based on the implausible presumption that the “harms” of screening (the discomfort of squeezing the breast, the anxiety associated with an abnormal result, the chance of a false positive result requiring additional exams [e.g., additional mammography views, ultrasound, etc.], or biopsy, and the chance for over-diagnosis – detecting a cancer that would never have become life threatening) outweigh the benefit of lives saved.
- The taskforce did not examine the benefit of less invasive and less disfiguring therapy that can be achieved with early diagnosis through screening mammography. The morbidity, personal grief AND financial costs of breast cancers diagnosed in late stages is tremendous. For example, treatment that might have consisted of a lumpectomy if caught early might instead require a mastectomy and chemotherapy. The USPSTF did not acknowledge, evaluate or account for this.
- Although USPSTF states that their recommendations were not motivated by cost savings, based on the above, we cannot help but draw the conclusion that the taskforce recommendations amount to rationing on the basis of financial costs. The USPSTF’s analysis evaluates the number of lives lost under a variety of screening scenarios and then blatantly recommend the most “efficient” (i.e. less expensive) screening interval, not the one that saves more lives. Not only are these numbers based on the lowest estimate of benefit, but they have no meaning for the women being screened. Each woman has a single screening study each year regardless of the yield of cancers. Numbers only suggest the relative “cost” of curing a cancer by early detection and the USPSTF has, arbitrarily, decided that the cost of saving women ages 40-49 is too high.

USPSTF Selectively Reviewed the Literature, Ignoring Hundreds of Well-Regarded Studies on the Subject
The taskforce commissioned its own computer models that had never been subject to critical peer review, ignoring previously published computer modeling studies and direct scientific evidence from large clinical trials that contradict their conclusion. The recommendations also ignored peer reviewed journal articles that critiqued studies on which their recommendations rely. They did not consider literature that didn’t evaluate mortality as an endpoint.

Notably, the USPSTF does not even mention the actual published data from Sweden and the Netherlands that directly show what happens when new therapies and mammography are introduced into the population. These studies demonstrate that it is mammography screening and not new therapies or practices that are responsible for most of the decrease in deaths over the past 20 years.

The fact that hundreds of respected journal articles were ignored while another trial was translated from Russian to English for consideration by the taskforce makes the entire literature review suspect.

The elaborate academic exercise that the taskforce conducted is obviated by one important truth – almost universally, clinicians will agree that breast cancer therapy is far more successful when the cancer is found at a smaller size and earlier stage by mammography. In Sweden mammography screening has decreased breast cancer deaths among women in their 40’s by over 40 percent.

The taskforce makes assumptions that are contrary to the evidence. For example, the presumption that loss of life can be minimized if “high risk” women opt to be screened earlier or more frequently than recommended, overlooks the fact that about 75 percent of all breast cancers occur in women who are not at high risk.

The taskforce ignored literature describing survey results that women prefer to experience false-positives if the overall result is finding additional cancers in the screened population.

The development of the recommendations violated the Administration’s Commitment to Transparency

The taskforce made their recommendations without allowing for public input or involving anyone with expertise in breast cancer detection and diagnosis. Rejecting both randomized, controlled trials and already-existing modeling studies, they instead commissioned their own modeling study, and made recommendations in reliance on this study before the study had ever been published, made public or held to critical peer review.

The USPSTF is a Government-Sponsored Body Making Recommendations that will be Published and Recognized by the Federal Government

Notwithstanding disclaimers disassociating AHRQ with the recommendations of the taskforce, the Agency for Healthcare Research and Quality (AHRQ) funded the project, selected the USPSTF members, provided staff support to the taskforce, provided project oversight, developed key
questions in conjunction with the taskforce, assisted with internal and external review of the draft manuscript, and will be posting the recommendations on their website. The bibliography even cites journal articles written by AHRQ staff.

On December 9th 2009, the members of the USPSTF unanimously voted to amend the wording of the recommendations to the following:

Summary of Recommendations

- The USPSTF recommends biennial screening mammography for women aged 50 to 74 years.
  Grade: B recommendation.

- The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.
  Grade: C recommendation.

- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older.
  Grade: I Statement.

- The USPSTF recommends against teaching breast self-examination (BSE).
  Grade: D recommendation.

- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years or older.
  Grade: I Statement.

- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer.
  Grade: I Statement.

Members of the USPSTF are listed below and include internist, pediatricians, nurses, family physicians, and ob/gyn specialists.

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References:


DISCUSSION: WHAT DO YOU THINK?