

SBI Statement on United States Preventive Services Task Force Draft Research Plan for Breast Cancer

November 25, 2013

The Society of Breast Imaging is dedicated to finding breast cancer at its earliest point of development in order to save lives. We have read the Task Force's Draft Plan and we wish to offer the following comments and recommendations regarding the methodology of the process.

1. The USPSTF's stated goal "to improve the health of all Americans" is inconsistent with their current recommendations for breast cancer screening. These recommendations result in unnecessary deaths and morbidity compared to the recommendations of multiple medical societies and organizations which advise annual mammographic screening for women over 40. Therefore, their research plan for a new review of screening mammography requires careful scrutiny.
2. The fundamental question, prior to any new deliberation, is whether the USPSTF metric comparing the value of human life to non-lethal "harms" that are most frequently additional mammographic views or breast ultrasound is appropriate. All other questions are peripheral to this central question since the Task Force's analysis clearly shows that the most lives are saved by annual screening beginning at age 40. Unless this metric reflects the opinion of the American population, there will be further controversy. It should be noted that, because of this controversy, the Department of Health and Human Services reversed their opinion on the 2009 recommendations.
3. Specifically, the USPSTF search dates of 2008-2014 exclude key data from randomized control trials except those which have recently been updated. The search time frame should include all of the randomized control trials. It should be noted that the Edinburgh trial was compromised by economic biases and the Canadian Trial was a non-blinded randomization study that resulted in a bias against mammography. Conversely, the well-run Two County Swedish trial has shown a consistent 30% mortality benefit over a 30 year time frame.
4. Although randomized control trials are the best and only way to prove a benefit, the 2009 Task Force ignored the many observational studies which demonstrated that when screening is introduced into the population, the death rate declines as much, if not more, than the rate which was shown in the randomized control studies. The 2009 USPSTF used observational studies to delineate "harms" but they ignored them with regard to benefit. They also created bias by their incorporation of registry reviews that did not have direct patient data and they used them to determine the "harms" of screening. They also ignored the observational studies that did use direct patient data. In some of the contrary observational studies that claim little

benefit from screening, many women were being screened before the organized programs began, therefore the death rate did not show a sudden decline. This emphasizes the importance of using direct patient data and not registry summaries since many women who die after the onset of a screening program die from cancers diagnosed before screening was initiated.

There are numerous quality observational, population-based service screening studies which should be included for the review process in addition to randomized control trials and CISNET models. Further, the registry-based approaches which were used for the “harms” data should be given less weight because they do not track individual patient outcomes and are subject to bias.

5. The USPSTF Charter prevents it from doing cost/benefit analyses. The 2009 Task Force violated this charter when they performed analyses on numbers needed to screen which is a cost/benefit metric. They should have used Life Years Gained (LYG) as the metric. The Task Force also erred in their use of data from trials that were by “invitation” to screening and not the actual numbers needed to screen. If this process is repeated there should not be an arbitrary threshold for the number needed to be screened.

6. Contemporary USPSTF Colon Cancer Screening guidelines use LYG as a key metric but it was not considered by the Breast Cancer Task Force in 2009 despite the fact that LYG was provided by CISNET. LYG analysis for breast cancer shows greater benefit for younger women compared to mortality reduction in that population.

7. Computer modeling should be based on digital mammography and not on film screen technology. These results would be expected to duplicate recently published digital mammography CISNET values for women 40-49 which demonstrated a benefit.

8. The harms of not screening should be reviewed and quantified in the same manner as harms of screening if a balanced analysis is to be achieved. Specific harms of not screening include quality of life issues such as pain, suffering, and anxiety from living and ultimately dying from metastatic breast cancer. Also, loss of productivity due to metastatic disease and death, unnecessary chemotherapy and its side effects, unnecessary surgery and testing to document metastatic disease as well as loss of support by either a spouse or parent should be included in the methodology.

9. The term “overdiagnosis” has recently received much attention. It has been used to describe malignancies which remain indolent and do not cause death to the patient. In reality, there are three “overs”. One is overdetection which results from physical examination, blood tests, self-awareness and imaging. Second is overdiagnosis which is established by the pathologist. Third

is overtreatment which is instituted by breast cancer disciplines such as surgery, radiation therapy and medical oncology.

Overdetection (and overdiagnosis) may be applicable to some breast malignancies which may not progress to lethal invasive cancers. However, its frequency is overestimated. There are reports in the literature that quantify it at 1-9% of diagnosed breast cancers. The reports which overestimate this metric fail to factor in important variables such as lead time bias and the patient's personal risk for the development of breast cancer. Currently, there are no diagnostic imaging tests which can differentiate these different subtypes of cancers. Much work is being done at the molecular level in order to better understand tumor biology and allow the imager to make these distinctions.

10. "Harms" and benefits should be evaluated not only in the context of intent to screen (providing a societal benefit) but also in the context of actually screened (providing the individual with answers to the question of what can I expect if I decide to be screened). Also, the type and number of harms should be provided. The anxiety a patient may experience from a screening recall should not be equated with the anxiety associated with dying from metastatic disease.

11. Additional benefits of screening should also be reviewed and quantified for factors such as reduced anxiety and reassurance from a true negative test result.

12. The false positive biopsy rate of screening should be compared with the false positive biopsy rate of non-screened women. They should also quantify the number of biopsied lesions which are determined to be high risk or premalignant.

13. The frequency of screening recalls should be compared to the frequency of recalls for diagnostic mammography and ultrasound in matched non-screened women. This frequency of recalls should also be compared to the recall rate from other screening tests such as pap smears for cervical cancer in order to provide women and their health care providers with the proper frame of reference.

14. Data regarding which types of tumors are likely to recur compared to those which are not, as well as new studies which examine tumor biology, should be examined.

15. Most important, the Task Force should be transparent in its methodology. They should state not only the evidence used to make their recommendations but also their rating of the strength of that evidence (SOE) and the criteria used to make the SOE determination. This is the system which the Institute of Medicine employs.

16. Finally, the review process should be completely open and experts should be allowed to participate in the process. If the panel's recommendations are not unanimous then both a majority and minority report should be issued so that the public can judge the validity of the statements.

The Society of Breast Imaging strongly advises that the Task Force and the Evidence-based Practice Centers incorporate the above-mentioned recommendations into their review process. It is critical that all relevant data be included for the subsequent analysis. This is the first step in ensuring that the final recommendations, if they are to be changed, are free from bias.

On behalf of the Board of Directors,

Murray Rebner, MD, FACR, FSBI
President, Society of Breast Imaging