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CLINICAL COMMENTARY

Understanding the Controversy Behind the U.S. Preventative Services Task Force Recommendations for Breast Cancer Screening

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Background

Breast cancer is the most common diagnosed cancer in women in the United States, not including skin cancer, and is second only to lung cancer in cancer death. In 2008, over 250,000 in situ and invasive breast cancers were diagnosed and over 40,000 breast cancer deaths occurred¹. According to the Surveillance Epidemiology and End Result data² (SEER), the lifetime risk for a woman to develop breast cancer is approximately 12%. Furthermore, the risk for breast cancer increases with age. It is estimated that the 10-year risk for breast cancer is 1 in 69 for a woman at age 40 years, 1 in 42 at age 50 years, and 1 in 29 at age 60 years³.

In November 2009, the United States Preventative Services Task Force (USPSTF) released an update to their breast cancer screening recommendation to much controversy and media attention. In order to come to these recommendations, the USPSTF commissioned 2 studies: 1) a targeted systematic evidence review of 6 selected questions relating to the benefits and harms of screening, and 2) a decision analysis that used population modeling techniques to compare the expected health outcomes and resource requirements of starting and ending mammography screening at different ages and using annual versus biennial screening intervals⁴. A comparison of the most recent and 2002 guidelines are the following:

New USPSTF Guidelines for Breast Cancer Screening

- 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.*

<http://www.ahrq.gov/CLINIC/uspstf/uspstf/rca.htm>

2002 USPSTF Guidelines

- The U.S. Preventive Services Task Force (USPSTF) recommends screening mammography, with or without clinical breast examination (CBE), every 1-2 years for women aged 40 and older. *Grade: B Recommendation.*
- The USPSTF concludes that the evidence is insufficient to recommend for or against routine CBE alone to screen for breast cancer. *Grade: I Statement.*
- The USPSTF concludes that the evidence is insufficient to recommend for or against teaching or performing routine breast self-examination (BSE). *Grade: I Statement.*

<http://www.ahrq.gov/dinic/pocketgd09/gcp09s2.htm#BreastScreening>

Discussion

The most controversial recommendation of the Task Force is to delay the onset of routine screening mammography from 40 to 50 years of age. The controversy stems partly from an interpretation of what constitutes an effective screening test. In order to detect a disease in early stages, the disease must have a period of detectability before clinical symptoms start. Even if the cancer is screenable, it must also be prevalent enough in society to be worth screening. The screening test must also have desirable sensitivity (i.e., a low false negative rate) and specificity (a low false positive rate). The test must also be cheap, easy, reliable, and as painless as possible. Even if you can detect the disease, the ultimate purpose is to treat it. If a disease can be screened but its treatment shows no benefit, then screening is less acceptable. In other words, if a group that is screened and treated lives longer than another group that is not screened, then the screening test may be successful. If the 2 groups have the same survival rate, there is little evidence to support screening for the disease.

With this in mind, from strictly a statistical point of view, the USPSTF concluded that among women between 39 and 49 years of age, screening mammography results in a 15% reduction in the risk of death from breast cancer in addition to breast cancer mortality benefit for all age groups from 39 to 69 years. The task force also concluded that you would need to screen 1339 women in their 50s to save one life. Similarly, screening 1,904 women between ages 40 and 49 is needed to save one life⁵.

Prominent groups, including the American Cancer Society, feel that the USPSTF is placing an arbitrary line as to what makes a screening test cost-effective as well as making a similar dogmatic judgment on just actual number of lives saved is not enough to recommend population screening. The data show that approximately 17% of breast cancer deaths occurred in women who were diagnosed in their 40s, and 22% occurred in women diagnosed² in their 50s. The argument is, if the disease is prevalent, and mammography reduces mortality, how can one mandate that screening approximately 600 more women per saved life is not justified? Furthermore, statistics show that breast cancer mortality has been decreasing since 1990 at a rate of 2.3% per year⁶. Women ages 40 to 50 years have seen an even higher decline in mortality of 3.3% per year. One study evaluating mortality trends from 1990 through 2000 attributed 28% to 65% of the decline to mammographic screening⁷.

The counterargument is that an arbitrary line has to be made at some level with regards to any cancer screening program. Furthermore, younger women have higher rates of additional imaging and lower rates of biopsy than older women. The downstream harms involved with this process include additional cost, pain and potential complications from invasive procedures, not to mention the psychological and emotional burdens involved. On a population basis, the net gain from adding 10 years of mammography in all women ages 40 to 49 is relatively small in comparison to the risks of over-diagnosis, over treatment, unnecessary biopsies, and anxiety. A 15% reduction in risk of death in ages 40 to 49 would equate to approximately 1000 lives saved per year. Is that worth having 20 million women get an annual test that over 10 years will result in many of them having an unnecessary procedure? A recent cost-benefit analysis showed that adherence to the current guidelines from the American Cancer Society costs more than \$680,000 per quality-adjusted life-year (QALY) gained⁸.

The USPSTF is composed mainly of people who represent the breadth of primary care - mostly family physicians, general internists, obstetricians and gynecologists, pediatricians, and nurse practitioners. What are primary doctors supposed to recommend to their patients when The American Cancer Society (ACS), the American College of Obstetricians and Gynecologists, and the American College of Radiology continue to recommend routine mammogram screening every 1 to 2 years starting at age 40?

The definition of screening is a test that gets applied to members of a population who are asymptomatic or who are not at particularly high risk. People with risk factors such as strong family history are no longer members of the general population. Recommendations for screening do not apply to them because they are already placed into a different risk category. Thus, screening recommendations issued by the USPSTF are meant for the general population and deal with screening to detect early disease in which treatment or intervention will make a difference in ultimate health outcomes. Therefore, a woman in her 40s with a strong family history of breast cancer or someone with history of atypical ductal hyperplasia would not be in this category. Similarly, a 77-year-old woman with no medical conditions may still benefit from screening, as her anticipated lifespan is longer than that of the general population.

In addition, like any other practice in medicine, the patient needs to be counseled to the downsides of any tests. Namely, the inevitable path of more tests to investigate false positives. There are also many tools available to better assess a patient's risk profile. For instance, the National Cancer Institute has a breast cancer risk assessment guide taking into account age, family history, previous breast biopsies, race, age at first menses, and other factors (<http://www.cancer.gov/bcrisktool/>). Such tools can better guide patients and primary care doctors to determine whether regular screening before the age of 50 is justified. One must, however, always keep in mind potential liability of not recommending a screening test that prominent societies such as the ACS have recommended.

Thus far, despite the controversy, most health plans including Kaiser Permanente, Aetna, Cigna, Geisinger Health Plan, Group Health Cooperative and WellPoint have not proposed changing their coverage. Also, the Secretary of Health and Human Services, Kathleen Sebelius, tried to ease fears by announcing her support for mammography and noting that government policy won't change. However, questions still linger regarding how much of the USPSTF guidelines may be incorporated into future health care bills.

Conclusions

With the new guidelines proposed by the USPSTF for breast cancer screening, primary care doctors are now faced with the challenge of having a more detailed, balanced discussion with younger women regarding the pros and cons of early mammographic screening. With proper risk profiling, the doctor now has a choice of discussing it as an option rather than an absolute recommendation for low-risk, young patients. Additional research on the effects of mammography screening with regards to quality-of-life, as well as morbidity and mortality outcomes, would provide further insight into the implications of routine screening.

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