

1825 Marion Street
Denver, CO 80218
303-318-3414
www.SaintJosephCancerCenter.org

Screening Mammography Guidelines

In the week of November 16th, 2009, the United States Preventative Service Task Force (USPSTF) issued guidelines changing the widely accepted recommendations for screening mammography by eliminating the recommendation completely for women in their 40s and changing the recommendation for screening in women over the age of 50 to every other year. Although the USPSTF is an 'independent panel of private-sector experts in prevention and primary care,' no breast screening experts were a part of the panel that devised these guideline changes.

Even though the USPSTF '...recognizes that the benefit of screening seems equivalent for women aged 40 to 49 years and 50 to 59 years...' (their website), they have chosen to drop all recommendations for screening women in their 40s, mostly due to the number of women needed to be screened (1904 women in their 40s invited to be screened compared to 1339 women in their 50s and 337 women in their 60s) in order to save one life and their concerns over 'psychological harms' and 'inconvenience due to false-positive screening results.'

The USPSTF also raises concerns about 'over diagnosis' and treating cancers that wouldn't otherwise kill the patient. They further state that 'a large proportion of the benefit of screening mammography is maintained by biennial screening' thereby justifying their recommendation for every-other-year screening in women over age 50.

These new guidelines are contradictory to the recommendations of the American Cancer Society, the American College of Radiology, the Susan G. Komen for the Cure Foundation, the American College of Obstetrics and Gynecology, the Society of Breast Imaging and the National Cancer Institute all of which recommend at least biennial mammography beginning at age 40, with most recommending annual mammography.

Breast cancer is the most common non-skin cancer in women with nearly 230,000 new cases of invasive or non-invasive cancer in American women annually, or one case diagnosed every 2-3 minutes. It is second in cancer deaths to lung cancer, killing over 41,000 American women annually. This is about the same number of deaths from annual motor vehicle accidents, with one death every 13 minutes on average.

Since the establishment of regular screening mammograms in the US in the mid 1980s, there has been a precipitous decrease in the death rate from breast cancer, dropping over 2% per year since 1990, after remaining completely unchanged for the previous 50 years. Since the treatment of breast cancer has improved only minimally in that same time, the main reason for the drop in the death rate is screening mammography.

Part of the controversy over whom and when to screen with mammography stems from the various analyses of 9 'original' Randomly Controlled Trials (RCTs), which established the utility of mammography screening, the newest of which was completed in the early 1980s with the oldest ones from the 1960s. We are indebted to these ground-breaking studies as they were the first to firmly establish a death rate decrease among women invited to screening with mammography. These studies showed a significant decrease in breast cancer death rate in the group invited to screening compared to the age-matched not-invited control group, with individual trials showing up to a 31%

decrease. The RCTs naturally underestimate the benefit of screening on the individual level, since they estimate the “intention-to-treat” benefit (i.e. mortality among screen-detected cases plus cases among non-attendees and compare it with the mortality among control cases). When evaluating “service screening” and adjusting for potential biases, one can see that the benefit for women regularly attending screening is a 43% decrease in risk of dying from breast cancer.

Dr. Daniel Kopans, professor of Radiology at Harvard and senior radiologist in the Breast Imaging Division at Massachusetts General Hospital points out that the USPSTF used computer models over direct data to reach their conclusions and ignored other models which contradicted their results and even ignored their own data proving a significant death benefit for women screened in their 40s. He also reminds us that the National Cancer Institute issued guidelines similar to the USPSTF in 1993, reversing them (back to annual or biennial screening beginning at age 40) in 1997 when it became ‘clear that they had misinterpreted the data.’

Kopans also illustrates that, while the death rate overall has dropped by 2.3% per year in screening populations since 1990, the drop in death rate has averaged 3.3% per year in women in their forties. Furthermore, nearly 41% of life years lost to breast cancer occur in women diagnosed in their forties, despite accounting for only 15% of breast cancer cases overall.

Disturbingly, there have been claims that these new guidelines have been released during the Health Care Debate in order to offer a way to ‘decrease’ the costs of breast cancer screening. Certainly, costs have to be weighed before recommending any screening test. Arguably, in terms of lives saved per dollar spent, a better benefit would be to shift health care funds towards programs like immunizations, which have a much larger ‘bang for the buck.’ However, our society has determined that spending money to diagnose curable breast cancers is a worthwhile endeavor, considering the breadth and reach of this disease. Furthermore, if the USPSTF used its own data and logic, they would stop recommending screening for all women under age 60 as it still takes over 1300 women in their 50s invited to be screened to save one life. They seem to imply that it is worth spending the money to save a woman in her 50s but not to save a woman in her 40s, as both groups have a similar screening benefit. Although no insurance company has, as yet, publicly changed its annual mammogram benefits, in states like Utah, the only state that does not require insurance companies to provide annual mammograms, these recommendations may have deadly results.

Since the inception of regular screening mammograms, the percentage of non-invasive cancer (DCIS) diagnosed has gone from a rarity to up to 40% of cancers diagnosed in some settings. It is theoretical that a certain percentage of these cancers, and even some low-grade invasive cancers, will never pose a lethal threat to the woman diagnosed. Currently, however, there is no reliable method of determining which of these cancers needs to be treated and which can be left alone, with no threat to the patient. We are, however, beginning to understand the biology and genetics of individual breast cancers and this knowledge is already influencing our treatment of certain cancers, obviating the need for chemotherapy in cases which previously would have been treated with aggressive and often debilitating and toxic agents. This is where I feel the debate about breast cancer should be heading. Instead of forming recommendations that may have political, financial or even personal biases, we should be working harder to understand the biology and science of this disease in order to develop more intelligent screening and treatment methods. This may mean performing breast MRI in addition to or instead of mammography in some patient populations. Newer, faster MRI imaging protocols may soon bring the costs of performing an MRI and the time it takes to do an MRI down to the currently accepted time and costs of doing a mammogram. Knowing who is performing and interpreting mammograms and ensuring high quality outcomes is another way of maximizing the usefulness of screening mammography.

Using ‘anxiety’ over callback imaging and/or biopsies and citing the ‘inconvenience’ of having to undergo additional tests to justify screening recommendation changes is demeaning to women and their ability to withstand periods of uncertainty. In fact, many studies have indicated only minimal and fleeting anxiety in women having to undergo additional tests with most women stating that the anxiety was ‘worth it’ to be certain of a negative final result with virtually none stating that their experience would prevent them from returning for annual screening. In my own practice,

I've experienced nearly universal cooperation with recommended additional imaging and biopsies, with an overwhelming percentage of women grateful for the 'thoroughness' of their care and their relief of having a negative final result.

In the end, whether or not to have an annual screening mammogram is and should be the decision of the individual patient after she has weighed the risks and benefits and has applied it to her own personal situation. The benefits of annual screening mammography for all women over 40 are clear and far outweigh the risks. The Breast Care Center at Exempla St. Joseph Hospital continues to strongly recommend annual mammography for all average-risk women from age 40 on and more aggressive screening for women determined to be at higher-than-average risk.

Statements of support for annual mammography from age 40:

- **American Cancer Society:** http://www.cancer.org/docroot/MED/content/MED_2_1x_American_Cancer_Society_Responds_to_Changes_to_USPSTF_Mammography_Guidelines.asp
- **American College of Obstetrics and Gynecology:** http://www.acog.org/from_home/Misc/uspstfResponse.cfm
- **Society of Breast Imaging:** <http://www.sbi-online.org>
- **American College of Radiology:** http://acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/breast/Screening_Diagnostic.aspx
- **Susan G. Komen for the Cure:** <http://ww5.komen.org/BreastCancer/GeneralRecommendations.html>

References

The Randomized Controlled Trials of Screening

- Duffy SW, Tabar L, Smith RA. The Mammographic Screening Trials: Commentary on the Recent Work by Olsen and Gotzsche. *CA A Cancer J Clin.* 2002;52:68-71.
- Kopans DB. The Most Recent Breast Cancer Screening Controversy About Whether mammographic Screening benefits Women at Any Age: Nonsense and Nonsense. *AJR* 2003;180:21-26

Screening Reduces Death Rate in the General Population

- Kopans DB. Beyond Randomized, Controlled Trials: Organized Mammographic Screening Substantially Reduces Breast Cancer Mortality. *Cancer* 2002;94: 580-581.
- Tabar L, Vitak B, Tony HH, Yen MF, Duffy SW, Smith RA. Beyond randomized controlled trials: organized mammographic screening substantially reduces breast carcinoma mortality. *Cancer* 2001;91:1724-31
- Duffy SW, Tabar L, Chen H, Holmqvist M, Yen M, Abdsalah S, Epstein B, Frodis Ewa, Ljungberg E, Hedborg-Melander C, Sundbom A, Tholin M, Wiege M, Akerlund A, Wu H, Tung T, Chiu Y, Chiu Chen, Huang C, Smith RA, Rosen M, Stenbeck M, Holmberg L. The Impact of Organized Mammography Service Screening on Breast Carcinoma Mortality in Seven Swedish Counties. *Cancer* 2002;95:458-469.
- Otto SJ, Fracheboud J, Looman CWN, Broeders MJM, Boer R, Hendriks JNHCL, Verbeek ALM, de Koning HJ, and the National Evaluation Team for Breast Cancer Screening* Initiation of population-based mammography screening in Dutch municipalities and effect on breast-cancer mortality: a systematic review *Lancet* 2003;361:411-417.
- Feig S. Estimation of Currently Attainable Benefit from Mammographic Screening of Women Aged 40-49 Years. *Cancer* 1995;75:2412-2419.
- Swedish Organised Service Screening Evaluation Group. Reduction in breast cancer mortality from organized service screening with mammography: 1. Further confirmation with extended data. *Cancer Epidemiol Biomarkers Prev.* 2006;15:45-51.

Screening Women Ages 40-49

- Kopans DB. The Breast Cancer Screening Controversy and the National Institutes of Health Consensus Development Conference on Breast Cancer Screening for Women ages 40-49. *Radiology* 1999;210:4-9.
- Kopans DB, Halpern E, Hulka CA. Statistical Power in Breast Cancer Screening Trials and Mortality Reduction Among Women 40-49 with Particular Emphasis on The National Breast Screening Study of Canada. *Cancer* 1994;74:1196-1203.
- Shapiro S. Evidence on Screening for Breast Cancer from a Randomized Trial. *Cancer*. 1977;39:2772-278
- Hendrick RE, Smith RA, Rutledge JH, Smart CR. Benefit of Screening Mammography in Women Ages 40-49: A New Meta-analysis of Randomized Controlled Trials. *Monogr Natl Cancer Inst* 1997;22:87-92.
- Kopans DB, Moore RH, McCarthy KA, Hall DA, Hulka C, Whitman GJ, Slanetz PJ, Halpern EF. Biasing the Interpretation of Mammography Screening Data By Age Grouping: Nothing Changes Abruptly at Age 50. *The Breast Journal* 1998;4:139-145
- Kopans DB. Bias in the Medical Journals: A Commentary. *Am. J. Roentgenol* 2005; 185: 176 - 182.
- Kopans DB. Informed decision making: age of 50 is arbitrary and has no demonstrated influence on breast cancer screening in women. *Am J Roentgenology* 2005;185:177-82
- Kopans DB. The Canadian Screening Program: A Different Perspective. *AJR* 1990;155:748-749
- Yaffe MJ. Correction: Canada Study. *Letter to the Editor JNCI* 1993;85:94
- Tarone RE. The Excess of Patients with Advanced Breast Cancers in Young Women Screened with Mammography in the Canadian National Breast Screening Study. *Cancer* 1995;75:997-1003.

Screening Interval

- Michaelson JS, Halpern E, Kopans DB. Breast Cancer: Computer Simulation Method for Estimating Optimal Intervals for Screening. *Radiology* 1999;21:551-560.