

Understanding Breast Cancer Screening Recommendations

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Who knew that setting up a breast cancer screening program for corrections could be such a big deal? Fortunately, I don't have to deal with screening mammograms much in my jails. But we have been wrestling with this subject for some time in the prison systems I am affiliated with. And for prisons, setting up an appropriate breast cancer screening program is indeed a "Big Deal" with both medical and legal implications.

It doesn't help that this is quite a controversial subject. In fact, in the 30 years that I have been practicing medicine, the fight over the appropriate intervals for breast cancer screening has been the most strident medical controversy that I remember. This controversy was born in 2009 when the US Preventative Services Task Force (USPSTF) released its recommendations for mammogram breast

cancer screening.

Prior to this, the established standard for screening mammograms was that mammograms began when a woman reached age 40 and then occurred every year for the rest of her life. But after examining the evidence for the effectiveness of mammograms, the USPSTF made the following recommendations:

1. Routine mammograms for asymptomatic women should not begin until they reach age 50.
2. Routine mammograms should be done every other year, instead of yearly.
3. Screening mammograms should stop when a woman reaches the age of 75.

To the chagrin of the USPSTF (who naively did not see this coming), these recommendations generated tremendous controversy and even outrage. The former head of the federal government's National Institutes of Health, Dr. Bernadine Healy, heatedly said on national TV that women should out-and-out ignore the USPSTF recommendations. "Unequivocally" she said, "this will increase the number of women dying of breast cancer." The American College of Radiology said "These new recommendations seem to reflect a conscious decision to ration care." Politicians opined that the guidelines were the first steps toward health care rationing and even that the USPSTF had become a death panel.

But if all of that is true, how could the USPSTF have gotten it so wrong? The USPSTF consists of independent, supposedly smart, medical professionals who are tasked with evaluating evidence dispassionately. They are not political. They have no agenda. Their work in other areas is well-respected and uncontroversial. What were they thinking in this case? Was this a great big, forehead slapping "Duh?"

To answer that question, of course, it is necessary to understand the evidence that the USPSTF reviewed. Only then can we decide if they were right, wrong or some of each. And only then can we come to a well-thought out and rational policy for screening mammography in our prisons.

What evidence did the USPSTF review?

It turns out that there have been many well-designed studies looking into the effectiveness of mammograms. The best

medical studies have this in common:

- They randomize patients to different treatments.
- They study a large number of patients (the larger, the better).
- They follow these patients for a long time.

Several mammography studies have met all of these criteria. As one example, the Swedish Mammography Trial initially enrolled 42,000 women but ended up years later having studied almost 250,000. Half of these women were screened yearly with breast exams and mammography. The other half had no breast screening done at all. The Swedes reported their initial results in 1988 after twelve years of follow-up but have published several updates since, the last in 2009. Similar national trials have been done in Canada, Scotland and elsewhere. The total number of women enrolled in seven of these large, randomized trials has been a staggering 600,000.

Large randomized trials such as these are the grade “A” studies that provide the best evidence about whatever was studied—including the effectiveness of screening mammography. However, none of these “A” list studies were done in the United States and we Americans tend to be suspicious of foreign medical studies. Besides these seven big national studies, many, many other smaller studies have been done using less stringent (or no) randomization, fewer patients and for shorter periods of time. These are the “B” and “C” (and “D” and “F”) quality studies. Lots of these have been done in the US. The USPSTF reviewed literally hundreds of these lesser studies but tended not to weigh their conclusions as heavily as the “A” studies.

Have any other respected bodies besides USPSTF come to similar conclusions after reviewing the evidence?

The answer to this is yes. Probably the most respected organization to also review the data on mammography is the Cochrane Collaboration. The Cochrane Collaboration is an independent, nonprofit, multi-national organization that exists solely for the purpose of reviewing medical evidence within a framework of Evidence-Based Medicine. Their conclusions regarding screening mammography are similar to the USPSTF and can be found [here](#). The main difference is that the Cochrane Collaboration only included the data from the “A” list studies and discounted all of the grade “B” and “C” studies.

Other prestigious organizations which have come to the similar conclusions as the USPSTF (or simply back the USPSTF recommendations), are the American Academy of Family Physicians, the American College of Physicians, Britain’s National Health Service, The Advisory Committee on Cancer Prevention and the Canadian Task Force on Preventative Health Care.

Arrayed against these organizations is another big-hitter list that does not accept (or actively opposes) the USPSTF recommendations. This includes the American College of Obstetricians and Gynecologists, the American College of Radiology, the American Cancer Society and the American Medical Association.

But this disparity of opinion has resulted in two separate and different clinical guidelines. These groups disagree about the relative risks and benefits of screening mammography. Why? What is the benefit of mammography? Does mammography have harms? What are they? What other factors are at play here?

What is the Benefit of Screening Mammography in women aged 40-49?

First let’s be clear what benefit we are talking about here. The overall goal of screening mammography is to prevent deaths from breast cancer. We want to discover cancer earlier, so it can be treated earlier and thereby save the woman’s life. This is the scenario we envision happening:

Without mammography, a woman finds a cancer in her breast, gets treatment, but it is too late, so despite lots of treatment (surgery, radiation, chemotherapy) she dies. With mammography, that very cancer is found earlier, treated earlier, and so the woman survives.

That is the effect we want to see! If, by finding the cancer earlier, we have to do less surgery, less radiation therapy and less chemotherapy, that would be a bonus. But the ultimate goal is to save lives.

So what effect does mammography have on the death rate in women aged 40-49? Well, unfortunately, the answer seems to be “not much.” The USPSTF data says that for women in their 40s, you would have to do mammograms on over 1900

women for 10 years to prevent one death due to breast cancer. S. Mukherjee, in his Pulitzer Prize winning book *The Emperor of All Maladies: A History of Cancer*, equates this degree of risk as being equivalent to riding a bicycle without a helmet for 15 hours. And this is important: though the USPSTF does not mention this, the Cochrane Collaboration notes that the overall death rate for 40ish year old women did not change in these studies.

What are the harms of mammography?

This is the aspect of mammography that tends to be totally glossed over. When I ask, no one has ever mentioned any “risks” of mammography to my mother or my wife. But it turns out that mammography does have substantial harms that should not be ignored.

Mammography harms come in two main types: False Positives and Overdiagnosis.

False Positives occur when the mammogram is positive or “suspicious” and yet follow-up testing such as ultrasound or biopsy is normal. This very thing occurred in one of my incarcerated patients just last month! How often do False Positives happen? The answer is: For every 1000 women screened yearly for ten years, between 500 and 600 will have at least one false positive result. So what is the harm in that? At least we caught our mistake! The harms of False Positives are

1. The expense of the extra work up, which, in the end, was unnecessary.
2. The unnecessary worry and anxiety that a positive mammogram induces. Judging by my patient who had a false positive last month, this can be considerable. (She did not take the news that she had a suspicious lesion well).
3. Finally, for every 1000 women screened annually for ten years, 200 or so will have an unnecessary needle or open biopsy. Nobody is going to argue that biopsies are no big deal!

Overdiagnosis, however, is a bigger problem than False Positives. Unfortunately, it is also a more difficult concept to wrap one’s head around. The problem is that many people, even doctors, believe (consciously or unconsciously) that cancer, if untreated, is inevitably a death sentence. With regard to the microscopic breast cancer lesions found by mammography, for example, the mistaken belief is that if these cancers are not found and treated, they would all inevitably grow, metastasize, and kill, every single one.

However, this is simply not the case. Breast cancers are not all the same. Some breast cancers are aggressive and fast growing. More, though, are slow-growing and indolent and can be dealt with by the body’s own immune system.

This is quite comparable to bacterial infections. Some infections overwhelm the body’s defenses and cause death quickly, despite antibiotics. We call this septicemia or septic shock. Other infections, like the one I recently had on the end of my finger, are nuisances that certainly do not need to be treated with antibiotics. Finally, there are the infections, like a bad pneumonia, where appropriate antibiotics will save the patient’s life. Three kinds of infection: one so severe that the patient dies despite antibiotics. One so mild that the body’s immune system will clear the infection without need of antibiotics. And one where antibiotics save the patient’s life.

Breast cancers fall into the same three categories. Aggressive breast cancers grow fast, and metastasize early. Aggressive cancers like these often are going to result in the death of the patient whether or not they were caught “early” by mammography. On the other hand, many other breast cancers are slow-growing and indolent and even if they had never been discovered by mammography, would have been cleared by immune system itself. In fact, without mammography, these women would never have known that they had these cancer cells because they would never have grown, or caused any symptoms, and definitely would not have shortened their lives. Finally, there is the third category of breast cancers. These are the ones that would kill except for being found early enough to treat successfully with surgery, radiation and chemotherapy. This is the category where mammography potentially saves lives.

So note the three categories of women with actual breast cancer who would not be helped by mammography.

1. The women with super-aggressive breast cancers who are going to die no matter what.
2. The women with minor indolent cancers which would never have been a problem even if they had not been discovered.
3. The women with breast cancers that would be successfully treated even if they are not discovered until they are a palpable lump.

And consider the group of women with the minor indolent cancers that would never have caused them a problem in their

lifetime. This is overdiagnosis. Every single one of these women will be harmed by mammography because all of their biopsies, surgeries, chemotherapy, and radiation are unnecessary.

So how much overdiagnosis is there with yearly mammography in the 40-49 age group? From the USPSTF data, for every 1000 women who have mammograms done every year for ten years, 15 will be diagnosed with cancer. Of those 15, one had her life saved because of the mammogram (though again, the overall death rate did not change). 8 would have been cured regardless of whether the mammogram had been done or not. 3 would die despite having had the mammogram done. And 3 will be diagnosed and treated for a cancer that, if it had never been discovered, would never have caused them a problem in their lifetime.

The biggest problem are those 3 last women, who were overdiagnosed. They would have been better off medically without any mammograms at all! Remember when I said that if our mammography program reduced biopsy, surgery, radiation therapy and chemotherapy, that would be a bonus? Note that because of overtreatment of those women who were overdiagnosed, mammography in women in their 40s substantially increases all of these!

Putting it all together—Comparing Benefit to Harm: The USPSTF Data

Women aged 40-49:

- 1,900 women need to be screened yearly for ten years to prevent one death from breast cancer.
- The overall death rate does not change.
- 1000 or so of these 1,900 women will have at least one false positive mammogram.
- 350 or so will have an unnecessary biopsy.
- 15 will be diagnosed correctly with cancer. Of these:
 - 1 will have her life saved
 - 3 will be harmed (the cancer would never have been a problem)
 - For 11, the mammogram made no difference.

Finally, in the words of the USPSTF: “(Overdiagnosis) leads women to overestimate the likelihood that their life has been saved by mammography (which is actually only about 10% of women diagnosed with breast cancer).”

Women aged 50-59:

- 1,339 women need to be screened yearly for ten years to prevent one death from breast cancer.
- For every 1000 women screened, the overall death rate drops by one.
- 625 or so will have an unnecessary biopsy.
- 28 will be diagnosed correctly with cancer. Of these:
 - 1-2 will have her life saved
 - 7 will be harmed (the cancer would never have been a problem)
 - For 19, the mammogram made no difference.

Women aged 60-69:

- 377 women need to be screened yearly for ten years to prevent one death from breast cancer.
- For every 1000 women screened, the overall death rate drops by six.
- 3360 or so will have an unnecessary biopsy.
- 37 will be diagnosed correctly with cancer. Of these:
 - 36 will have her life saved
 - 37 will be harmed (the cancer would never have been a problem)
 - For 24, the mammogram made no difference.

Why every other year instead of every year?

According to the USPSTF, the reason to do screening mammograms every other year instead of every year is to decrease the harms of overdiagnosis and overtreatment. After crunching the numbers, the USPSTF believes that biennial mammograms will reduce the harms of overdiagnosis by 50% but will preserve 80% of the benefits. This is a statistical analysis and so is not based on direct research. Other entities looking at the same numbers recommend reducing the interval between

screening mammograms to 3 years! The USPSTF actually was conservative (IMO) in this recommendation.

So what is the correct age to begin routine screening mammograms?

The answer to this question depends on the individual. Some 40-year-old women will look at this data and decline routine mammograms until they are 50. Some may even decline mammograms until they are 60! Looking at this data, that actually would not be unreasonable. Others are going to want the mammogram, despite the risk of harm. And actually, it is incorrect to say that the USPSTF said not to do screening mammography at all in women aged 40-49. What they actually said was that individual women should be presented with this data and allowed to make their own decision:

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.

Just as is the case for individual women, policy makers for US prisons should take into account the harms as well as the benefits of screening mammography.

So why is this so controversial?

Well, the short answer is that Elizabeth Healy and the contrary organizations simply don't believe this data. They think that the USPSTF and the data they relied on exaggerate the harms and underestimate the benefit of mammography and, in the end, simply got it wrong. Some have questioned the validity of the studies used by the USPSTF by, for example, suggesting that the women in these studies simply weren't followed long enough or pointing out methodology errors that, they say, invalidate all of the data that the USPSTF relied on. Others are opposed because of the financial or political implications of the recommendations. Still others are opposed because they don't understand what the recommendations are saying. Finally, this is an emotionally charged issue—highly so. When someone says to you “My (mother, wife, sister, friend) would be dead if a mammogram had not caught her cancer early!” and then fold their arms to wait for a reply, it is hard then to have a conversation about overdiagnosis and the statistic cited by the USPSTF that says only 1 in 10 women who say this are right.

The issue of screening mammograms is a complex one. It is easier to believe that mammograms are always good than to wrestle with the concepts of false positives, overdiagnosis, age related benefits and the lot. And yet wrestle we must! What are you going to do when 45-year-old woman in your correctional facility wants her yearly mammogram? Are you going to order the mammogram without question? Deny the request until she turns 50? Discuss the potential harms of the procedure as well as the potential for benefit with the patient and let her decide? You have to pick one of the three!

What breast cancer screening program do you have at your facility? Has your facility discussed the USPSTF recommendations? Did it lead to a change in your program? Please comment!

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