YSC Response to Changes in American Cancer Society's Mammography and Clinical Breast Exam Guidelines

In October 2015, the American Cancer Society (ACS) revised its guidelines on screening mammography and clinical breast exams (CBEs). These new guidelines state that, in women of average breast cancer risk, annual screening mammography should start at age 45 (instead of 40) and that CBEs should not be performed by physicians on women of any age. For women ages 40-44, the guidelines state that they should have the "opportunity" to begin annual mammography screening. Prior to this October publication, ACS recommended annual mammograms starting at age 40 and CBEs every three years for women in their 20s and 30s, with annual CBEs to begin at age 40.

Screening Mammography Recommendation Changes:

The mammography screening debate is complicated, and a more thorough discussion of the issues and research can be found in the Background & Support section below. Screening mammography for women over 40 or 50 years of age does not directly impact the young breast cancer survivors served by Young Survival Coalition (YSC). YSC interprets the change in ACS guidelines as a public admission that there is no benefit to screening mammography between the ages of 40-44. Not only is there no benefit, the risks outweigh the benefits such that a change in recommendation is warranted.

YSC concurs. It is not YSC's position that screening mammography should be completely eliminated. **We do believe, however, that women should be counseled about the risks and benefits of screening mammography, in consultation with their doctors and make an individual decision that is best for them. It is a long-held YSC belief that better tools are urgently needed to diagnose, detect and monitor for breast cancer in younger women.**

Clinical Breast Exams (CBEs):

YSC has reviewed the ACS recommendation that CBEs no longer be performed. Our review of the data did not find a strong basis for this recommendation. **Therefore, YSC does not support this recommendation.** When clarifying evidence is received, YSC will review and reconsider our recommendation on CBEs. We would welcome further explanation from ACS on its decision, as well as elucidation of the harms that could occur from CBEs and would outweigh the possible benefits. **Especially in populations without access to breast cancer screening or who are too young to receive such screening, we are concerned about the recommendation to eliminate CBEs entirely. In young women with breast cancer, 80% find the breast abnormality themselves[1], suggesting that the cancer was palpable.**

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Background and Support for YSC Response

Mammography Screening Debate

For the past 30 years, women in the United States have been encouraged to get regular mammograms in the hopes that this test, which is an x-ray to look for breast abnormalities, would find breast cancer at an earlier, more treatable stage. Previously, ACS recommended screening mammograms starting at age 40. Its new recommendation is to begin at age 45. The United States Preventative Services Task Force (USPSTF), another entity that makes recommendations for breast cancer screening, currently recommends screening mammograms every other year starting at age 50. It is not clear why ACS's review of the evidence resulted in a recommendation of age 45 while the USPSTF review resulted in a recommendation of age 50.

In general, screening mammography has been shown to be ineffective in women under age 40 because their dense breast tissue impedes accurate results.[2] Screening is testing performed in a healthy population to examine for the presence of disease. The expectation is that detecting a disease, such as breast cancer, at an early stage will lower the number of advanced stage diagnoses and reduce the number of women who die of the disease.

The ACS recommendations address screening mammography only and do not impact the use of diagnostic mammography, a test performed because of a lump or other symptom that may suggest the presence of breast cancer. Diagnostic mammography is a vital tool. Diagnostic mammograms are needed when a woman presents with a symptom that may suggest breast cancer.[3] Throughout the ACS statement, when a mammogram is mentioned, it refers to a screening, not diagnostic, mammogram. Women of any age with signs or symptoms of breast cancer should consult their doctor as soon as possible regarding what screening is best for them. In addition, screening mammography is intended for women at average risk of getting breast cancer in the general population. It is not intended for, and the research quoted in this paper does not address, screening women who are at higher than average risk of being diagnosed with breast cancer, which includes screening residual breast tissue of breast cancer survivors of any age.

Despite 30 years of mammography screening, statistics show that the rate of metastatic (stage IV) disease is unchanged and late stage diagnoses reduced only slightly.[4] Conversely, the number of breast cancer diagnoses as a result of breast cancer screening has significantly increased, especially in the diagnosis of ductal carcinoma in situ (DCIS), a stage 0 cancer.[5] A recent study found an "excess detection of additional early stage cancers that was not matched by a reduction in late stage cancers."[6] To the extent that mortality from breast cancer has declined, analysis suggests that this is due to more effective and targeted treatment of breast cancer.[7] **YSC is greatly concerned about the lack of evidence to show that screening mammography significantly decreases mortality**.

Another concern is whether or not screening mammograms are beneficial for women. Recent studies have suggested that any benefits from screening mammography may be outweighed by harms, such as over-diagnosis and treatment of breast cancers that would not have progressed or otherwise

caused harm. Over-diagnosis refers to a cancer detected through screening that "might not otherwise become clinically apparent during the lifetime of the woman."[8] Some breast cancers will never become life threatening, even without treatment, while other breast cancers are so aggressive that current treatments will not work, no matter how early the cancer is detected. Screening mammograms are increasing the number of breast cancer diagnoses[9], but are not able to distinguish between cancers that will progress and those that will not.

Two recent studies inform this debate. A 2014 publication in the *British Medical Journal*[10] compared the breast cancer incidence and mortality of almost 90,000 Canadian women ages 40-59 who had been randomly assigned to receive (or not receive) annual screening mammography.[11] The Canadian study, with 25 years of follow-up, found that there was no difference in the number of deaths due to breast cancer between the group that received annual mammograms and the group that did not. The study authors concluded that "[a]nnual mammography in women aged 40-59 does not reduce mortality from breast cancer beyond that of physical examination or usual care when adjuvant therapy for breast cancer is freely available." In addition, the authors found that "[o]verall, 22% (106/484) of screen detected invasive breast cancers were over-diagnosed, representing one over-diagnosed breast cancer for every 424 women who received mammography screening in the trial."[12]

A report in the *New England Journal of Medicine* in 2012 presented data showing that the number of cases of early stage breast cancer detected, as a result of widespread use of screening mammography, had substantially increased.[13] The number of women presenting with advanced breast cancer was only marginally reduced, by 8%.[14] The authors estimated that nearly one-third of all newly diagnosed breast cancers were an over-diagnosis and that "screening is having, at best, only a small effect on the rate of death from breast cancer."[15] To the extent that rates of death from breast cancer have declined, the authors attributed this decline largely to improvements in treatment as opposed to screening mammography.

Overall, there have been at least eight studies that examined mammography screening, and they have all concluded that, at best, "mammography screening has a modest effect on breast cancer mortality."[16] To the extent that mammography detects breast cancer, it is thought to be detecting slower growing or low risk breast cancer rather than aggressive disease.[17] Some breast cancers detected by screening may even "spontaneously regress… providing further evidence that screening is detecting 'harmless' cancers."[18] As stated by the National Breast Cancer Coalition (NBCC), of which YSC is a member, "A significant proportion of breast cancers will never spread to other parts of the body. That means that women with a cancer that would have never spread are becoming cancer patients unnecessarily – undergoing surgery, chemotherapy and radiation – and enduring the sometimes life-threatening side effects that come with them."[19] In an era of improved targeting and treatment of breast cancer, screening mammography benefits may be limited.

YSC recommends that all women become familiar with their breasts and aware of the signs and symptoms of breast cancer. If a young woman notices anything suspicious, she should see her primary care or OB/GYN doctor. If a young woman is at high risk, she should speak with a doctor about when she should begin breast screenings. If a young woman does find something suspicious, it is important that she does not accept "You are too young for breast cancer" as an answer from a healthcare provider. YSC published "Breast Health and You: A Young Woman's Guide" as an excellent resource on the facts about breast cancer in young women, including understanding family history and how to be your own best advocate.

ACS Recommendation Changes on Clinical Breast Exams (CBEs)

A Clinical Breast Exam (CBE) is a visual and physical examination of your breasts by a healthcare professional to look and feel for evidence of disease.[20] A CBE is typically performed as part of a regularly scheduled visit or check-up.

The new ACS guideline states: "Given the lack of benefit concurrent with the increase in false positive rates, we do not recommend CBE as a method of breast cancer screening among women at any age with an average risk of breast cancer. Recognizing the time constraints in a typical clinic visit, we encourage clinicians to use this time instead for counseling women regarding the potential benefits, limitations and harms of screening mammography."

This portion of the ACS guidelines cites three articles to support its decision.[21] The Bobo article it cites concluded that "CBEs performed in community-based screening programs can detect breast cancers as effectively as CBEs performed in clinical trials and may modestly improve early-detection campaigns." The second article by McDonald concluded that physicians are not confident in their CBE skills and would welcome training. In addition, there was a need for optimization and standardization of CBE procedure. Finally, the ACS recommendation cited an article by Bancej, which looked at the additional benefit of CBE in conjunction with mammography and concluded that "Inclusion of CBE in an organised [sic] programme [sic] contributes minimally to early detection."

None of these articles, in our opinion, supports the ACS decision on CBEs.

The most recent version of the USPSTF guidelines conclude that current evidence is insufficient to assess the additional benefits and harms of CBE beyond screening mammography. "The evidence for CBE, although indirect, suggests that CBE may detect a substantial proportion of cases of cancer if it is the only screening test available."[22] It did not, however, recommend that CBEs no longer be performed. In parts of the world where mammography is infeasible or unavailable (such as India), CBE is being investigated in this way…. The potential harms of CBE are thought to be small but include false-positive test results, which lead to anxiety and breast cancer worry, as well as repeated visits and unwarranted imaging and biopsies…. The principal cost of CBE is the opportunity cost incurred by clinicians in the patient encounter."[23]

There is currently no effective screening tool for breast cancer in young women. Nearly 80% of young women[24] find their lump or other symptom of breast cancer themselves, suggesting that their symptoms were palpable or visible. It is not clear why ACS recommends that CBEs, a physical exam to detect visible and palpable breast cancer by a medical professional, should be entirely eliminated, especially in young women for whom there is no effective breast cancer screening. **In populations without access to mammography or who are too young for mammography, YSC is especially concerned about the recommendation to not perform CBEs. Until data supporting ACS's decision is presented, YSC will remain opposed to this new recommendation.**

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[1] Ruddy, K. et al., "Presentation of breast cancer in young women," Journal of Clinical Oncology 27:15S (2009).
[2] Checka CM, Chun JE, Schnabel FR, Lee J, Toth H. The relationship of mammographic density and age: implications for breast cancer screening. *AJR Am J Roentgenol.* 2012; 198(3): W292-95. Doi:10.2214/AJR.10.6049.
[3] Screening and diagnostic mammograms are performed on the same machine. A screening mammogram typically takes only two x-ray pictures of each breast and is an overall picture of your breasts. A diagnostic mammogram will focus on the area of concern with spot or magnification views in order to look more closely. A radiologist will also likely view a diagnostic mammogram at the time of your appointment so that additional photos can be taken if needed. What's the difference between a screening mammogram and a diagnostic mammogram? American Cancer Society Web site. http://www.cancer.org/treatment/understandingyourdiagnosis/examsandtestdescriptions/mammogramsandotherbreastimagingprocedures/mammograms-and-other-breast-imaging-procedures-types-of-mammograms. Updated April 9, 2015. Accessed June 25, 2015.
[4] Bleyer and Welch, n.3.
[5] Id.
[6] Id.
[7] As evidence of this, Bleyer and Welch found that the decrease in death from breast cancer had actually increased in women under age 40 who are not screened for breast cancer. Again, suggesting that any mortality benefit was not due to screening mammography.
[8] Miller AB, et al. Twenty five year follow-up for breast cancer incidence and mortality of the Canadian national breast screening study: randomised screening trial. *BMJ*. 2014; 348:g366.
[9] Bleyer and Welch, n.3. See also Kalager, M, Adami HO, Bretthauer M, Tamimi RM. Overdiagnosis of invasive breast cancer due to mammography screening: results from the Norwegian screening program. *Ann Intern Med.* 2012; 156 (7): 491-499.
[10] Miller, n.14.
[11] At time of enrollment, the women in both groups, mammogram and no mammogram, were given a clinical breast exam and taught how to perform breast self-exam. Thereafter, all women ages 50-59 and women in the mammography group ages 40-49 received annual physical breast exams. The women in the 40-49 year old control group (no mammograms) were given usual care in the community but did not receive annual physical breast exams.
[12] There was a survival difference between the arms for those who were diagnosed with breast cancer. The 25-year survival rate for breast cancer was 70.6% in the mammography arm versus 62.8% in the arm that did not receive annual mammograms. Although acknowledging that this was a significant difference, the authors stated that this was "due to lead time, length time bias and over-diagnosis."
[13] Bleyer and Welch n.3. See also Kalager, M, Adami HO, Bretthauer M, Tamimi RM. Overdiagnosis of invasive breast cancer due to mammography screening: results from the Norwegian screening program. *Ann Intern Med.* 2012; 156 (7): 491-499.
[14] Id.
[15] In terms of absolute numbers, screening mammography more than doubled the number of breast cancer diagnoses. The number of diagnoses increased from 112 cases per 100,000 to 234 cases per 100,000 women.

Conversely, the rate at which women presented with late stage breast cancer declined by only 8%. Specifically, the number of late stage diagnoses went from 102 per 100,000 to 94 per 100,000. Therefore, of the 122 additional early stage breast cancer diagnoses expected, only 8 of them would be expected to progress to advanced disease. See Bleyer and Welch, n.3.

[16] NBCC Statement on USPSTF Mammography Screening Recommendations, April 2015, available at http://www.breastcancerdeadline2020.org/about-nbcc/newsroom/2015-press-releases/nbcc-statement-on-u.html. See also Nelson HD, Cantor A, Humphrey L, Fu R, Pappas M, Daeges M, Griffin J. Screening for Breast Cancer: A Systematic Review to Update the 2009 U.S. Preventive Services Task Force Recommendation. Rockville, MD: Agency for Healthcare Research and Quality; 2015.

[17] Barratt A. Overdiagnosis in mammography screening: a 45 year journey from shadowy idea to acknowledged reality. *BMJ*. 2015; 350: h867.

[18] Id.

[19] NBCC Statement on USPSTF Mammography Screening Recommendations, April 2015, available at http://www.breastcancerdeadline2020.org/about-nbcc/newsroom/2015-press-releases/nbcc-statement-on-u.html.

[20] Clinical Breast Exam. American Cancer Society Web site. http://www.cancer.org/cancer/breastcancer/moreinformation/breastcancerearlydetection/breast-cancer-early-detection-acs-recs-clinical-breast-exam. Updated August 19, 2015. Accessed October 5, 2015.

[21] Bobo JK, Lee NC, Thames SF. Findings from 752,081 clinical breast examinations reported to a national screening program from 1995 through 1998. *J Natl Cancer Inst.* Jun 21 2000;92(12):971-976, available at http://jnci.oxfordjournals.org/content/92/12/971.abstract?ijkey=85a82662e9502c74dbe59d4be360215b673a010b&keytype2=tf_ipsecsha. McDonald S, Saslow D, Alciati MH. Performance and reporting of clinical breast examination: a review of the literature. *CA Cancer J Clin.* Nov-Dec 2004;54(6):345-361 available at http://www.ncbi.nlm.nih.gov/pubmed/15537577. Bancej C, Decker K, Chiarelli A, Harrison M, Turner D, Brisson J. Contribution of clinical breast examination to mammography screening in the early detection of breast cancer. *J Med Screen.* 2003;10(1):16-21, available at http://www.ncbi.nlm.nih.gov/pubmed/12790311

[22] Final Recommendation Statement Breast Cancer: Screening November 2009. USPSTF Web site. http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening. Updated December, 2009. Accessed October 5, 2015.

[23] See n.1.

[24] Ruddy, n.26.