

CLINICAL GUIDELINES

Screening Mammography Guidelines

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The American Cancer Society (ACS) released guidelines for breast cancer screening, which were published in the Oct. 20, 2015 Journal of the American Medical Association. These guidelines have caused confusion because the ACS no longer *specifically* recommends that screening begin at age 40 for all women. **The ACS does strongly reaffirm that mammography screening saves lives. In addition, the ACS guidelines show that if a woman wants to reduce her risk of dying from breast cancer as much as possible, she will choose yearly mammography, starting at age 40. Furthermore, the ACS continues to recommend that women have access to screening mammography from age 40.**

The American Congress of Obstetricians and Gynecologists (ACOG), American College of Surgeons (ACoS), American College of Radiology (ACR), and Society of Breast Imaging (SBI) continue to recommend annual screening mammography from age 40.

The CDI Quality Institute continues to recommend yearly screening mammography, beginning at age 40. We firmly believe the decision whether or not to undergo screening mammography ultimately lies with the patient, who should be informed of the benefits and potential “risks” of mammography. Experts on breast cancer agree that mammography can detect cancer early, when it’s most treatable and can be treated less aggressively; this not only saves lives, but also helps preserve the quality of life.

The attachments to this document provide additional information:

- **Fact Sheet** for patients on the benefits and risks of screening mammography (Attachment A)
- Graph illustrating risk by age (Attachment B)
- Screening Mammography Guidelines for Women at **Average** risk (Attachment C)
- Screening Guidelines for Women at **Higher** than average risk (Attachment D)
- **Laws** pertinent to breast cancer screening (Attachment E)

This is a guideline, not a policy. It is a summary and distillation of relevant literature and subspecialty guidelines. The purpose of the CDI Quality Institute guidelines is to promote quality and continuity, where appropriate for medical practices within the CDI/Insight enterprise, and to provide relevant and up to date background information to support the development of policies within each individual practice. Guidelines should be adjusted for local standards of care, associated hospital or network policies, hospital versus outpatient settings, different patient populations and your own risk tolerance. Guidelines should also be modified to account for new information or publications that become available between revisions.

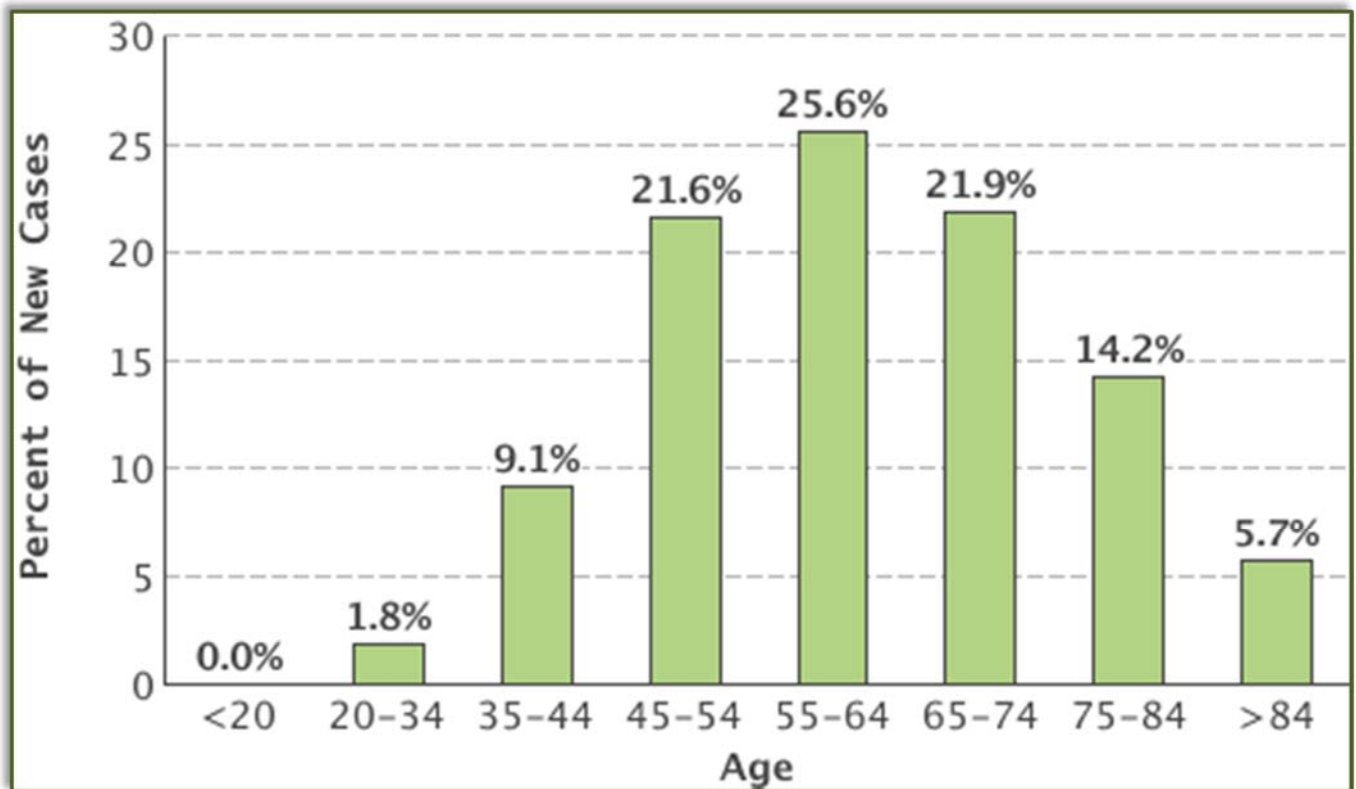
ATTACHMENT A

Facts: Benefits and Risks of Screening Mammography

- Mammograms are not perfect and do not find all breast cancers. However, when used by women beginning at age 40, screening has been shown to significantly reduce the number of women who die from breast cancer. A mammogram can find breast cancer years before physical symptoms develop.
- Multiple studies, involving millions of women have demonstrated a reduction in the death rate from breast cancer by 35% since the 1990s, largely attributed to screening mammography.
- Women who undergo regular mammograms are more likely to have breast cancer found early, are less likely to need aggressive treatment, such as surgery to remove the entire breast (mastectomy) and chemotherapy, and are more likely to be cured.
- There is a small possibility of being diagnosed with a cancer that would have never caused any problems had it not been found during screening. However, it is not possible to determine which cancers will never threaten women and which ones will become lethal.
- 75% of women diagnosed with breast cancer have no family history of the disease and were not considered to have an elevated risk of developing breast cancer prior to their diagnosis.
- 20% of breast cancer is seen in women younger than age 50, and 1 in 6 breast cancers are seen in women in their 40s. **40%** of patient years of life saved by mammography are in women aged 40-49.
- For women 50 years of age or greater, skipping mammography every other year would result in missing up to 30% of the cancers.
- The amount of radiation from a mammogram is very small; it is about the same as 2 months of natural background radiation from the soil or atmosphere.
- 7 to 10% of women undergoing standard 2D screening mammography will be recalled for additional tests, such as an ultrasound or diagnostic mammography to find out if something found on a screening mammogram is or is not a cancer.
 - 1) The vast majority of callbacks / false positives are resolved with only additional imaging. A small percentage of women will be asked to return for a short-term follow up examination.
 - 2) Fewer than 2% of women undergoing screening mammography will have a recommendation for a minimally invasive needle biopsy. Three out of four of those that undergo biopsy will not have cancer, and the majority of these patients can then return to yearly screening.
 - 3) Research shows that nearly all women who have experienced a false-positive exam still support screening.
- The callback rate with 3D / tomosynthesis **decreases** by 25-40%, so 5-8% of women will be recalled from a screening exam. Tomosynthesis also **increases** the cancer detection rate of mammography by up to 40% and it is especially beneficial in women with dense breast tissue or with a personal or family history of breast cancer.

ATTACHMENT B

**Percent of New Cases by Age Group:
Female Breast Cancer – 2009-2012 Data**



ATTACHMENT C

AMERICAN CANCER SOCIETY (ACS) Recommendations for Breast Cancer Screening in: Women at AVERAGE Risk

- **Women ages 40 to 44** should have the choice to start annual breast cancer screening with mammograms if they wish to do so. The risks of screening as well as the potential benefits should be considered.
- **Women age 45 to 54** should get mammograms every year.
- **Women age 55 and older** should switch to mammograms every 2 years, **or** have the choice to continue yearly screening.
- Screening should continue as long as a woman is in good health and is expected to live 10 years or longer.
- **All women** should be familiar with the known benefits, limitations, and potential harms associated with breast cancer screening. They should also be familiar with how their breasts normally look and feel and report any changes to a health care provider right away.

These above guidelines are for women at average risk for breast cancer. Women with a personal history of breast cancer, a family history of breast cancer, a genetic mutation known to increase risk of breast cancer (such as BRCA), and women who had radiation therapy to the chest before the age of 30 are at higher risk for breast cancer, not average-risk. (See below for guidelines for women at higher than average risk).

ATTACHMENT D

AMERICAN CANCER SOCIETY (ACS) Recommendations for Breast Cancer Screening in: Women at HIGHER than Average Risk

Women who are at high risk ($\geq 20\%$ lifetime risk) for breast cancer based on certain factors should get an MRI **and a mammogram every year. This includes women who:**

- Have a lifetime risk of breast cancer of about 20% to 25% or greater, according to risk assessment tools that are based mainly on family history (such as the Claus model)
- Have a known *BRCA1* or *BRCA2* gene mutation
- Have a first-degree relative (parent, brother, sister, or child) with a *BRCA1* or *BRCA2* gene mutation, and have not had genetic testing themselves
- Had radiation therapy to the chest when they were between the ages of 10 and 30 years
- Have Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, or have first-degree relatives with one of these syndromes.

There is not enough evidence to make a recommendation for or against yearly MRI screening for women who have a moderately increased risk of breast cancer (a lifetime risk of 15% to 20% according to risk assessment tools that are based mainly on family history) or who may be at increased risk of breast cancer based on certain factors, such as:

- **Having a personal history of breast cancer, ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), atypical ductal hyperplasia (ADH), or atypical lobular hyperplasia (ALH)**
- **Having dense breasts (“extremely” or “heterogeneously” dense) as seen on a mammogram**

If MRI is used, it should be in addition to, not instead of, a screening mammogram. This is because although an MRI is a more sensitive test (it’s more likely to detect cancer than a mammogram), it may still miss some cancers that a mammogram would detect.

For most women at high risk, **screening with MRI and mammograms** should begin at age 30 years and continue for as long as a woman is in good health. But, because the evidence is limited regarding the best age to start screening, this decision should be based on shared decision-making between patients and their health care providers, taking into account personal circumstances and preferences.

Additional CDI Quality Institute Guidelines: Supplemental breast screening using whole breast ultrasound is also beneficial in women with dense breast tissue, especially in women with a personal or family history of breast cancer. Women can speak with their health care provider regarding breast ultrasound.

ATTACHMENT E

Laws Requiring Coverage for Breast Cancer Screening

Coverage of mammograms for breast cancer screening is mandated by the **Affordable Care Act**, which provides that these be given without a co-pay or deductible in plans that started after August 1, 2012. This doesn't apply to health plans that were in place before the law was passed (called *grandfathered* plans). A woman can find out the date her insurance plan started by contacting the health insurance plan administrator. Even grandfathered plans may still have coverage requirements based on state laws, which vary, and other federal laws.

In order to continue to protect a woman's access to screening mammography, Senators, Kelly Ayotte (R-NH) and Barbara Mikulski (D-MD) introduced the Protect Access to Lifesaving Screenings (PALS) Act (S. 1926) in the U. S. Senate. Congresswomen Renee Ellmers (R-NC) and Debbie Wasserman Schultz (D-FL) introduced similar legislation in the House of Representatives. This legislation placed a two-year moratorium on payers using the United States Preventative Services Task Force (USPSTF) draft breast cancer screening recommendations to deny coverage or require co-pays from patients undergoing screening mammography. This legislation was added to the "omnibus" spending bill and passed at the end of 2015. This law protects access to annual screening mammography for women ages 40 to 74 through January 1, 2018.