NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

SCREENING FOR BREAST CANCER

Guidelines

1. **American Cancer Society (ACS)**. (1) ACS guidelines for breast cancer screening: update 2003. (2) American Cancer Society Guideline for breast screening with MRI as an adjunct to mammography (2007). CA Cancer J Clin 2007 Mar-Apr;57(2):75-89. [79 references].
2. **American College of Physicians (ACP)**. Screening mammography for women 40 to 49 years of age: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2007 Apr 3;146(7):511-5. [31 references]
3. **University of Michigan Health System (UMHS)**. Adult preventive health care: cancer screening. Ann Arbor (MI): University of Michigan Health System; 2004 May. 12 p. [4 references]

INTRODUCTION

A direct comparison of American Cancer Society (ACS), American College of Physicians (ACP), and University of Michigan Health System (UMHS) recommendations for screening asymptomatic women for breast cancer is provided in the tables below.

The guidelines differ somewhat in scope. For example, the only screening intervention considered by ACP is mammography and the guideline specifically focuses on women between the ages of 40 to 49 years. The scope of the 2003 ACS guideline differs from the others in that it examines alternative screening modalities for women at increased risk and potential new imaging technologies for women at average risk of breast cancer. The 2007 addendum to the ACS guideline expands on the topic of alternative screening modalities by providing recommendations exclusively for the use of MRI breast cancer screening. The 2003 ACS guideline also gives special focus to the screening of older women and women with comorbid conditions. In addition to breast cancer screening recommendations, UMHS also presents recommendations for cervical, colorectal, and prostate cancer screening. These topics, however, are beyond the scope of this Synthesis.

- Table 1 provides a quick-view glance at the primary interventions considered by each group.
- Table 2 provides a comparison of the overall scope of both guidelines.

- Table 3 provides a more detailed comparison of the specific recommendations offered by each group for the topics under consideration in this synthesis, including:
  - Mammographic Screening
  - Magnetic Resonance Imaging (MRI) Screening
  - Clinical Breast Examination (CBE) and Breast Self Examination (SBE)
- Table 4 lists the potential benefits and harms associated with the implementation of each guideline as stated in the original guidelines.
- Table 5 presents the rating schemes used by the guideline groups to rate the level of evidence and/or the strength of the recommendations.

A summary discussion of the areas of agreement and areas of differences among the guidelines is presented following the content comparison tables.

Listed below are common abbreviations used within the tables and discussions:

- ACP, American College of Physicians
- ACS, American Cancer Society
- BSE, breast self-examination
- CBE, clinical breast examination
- DCIS, Ductal carcinoma in situ
- MRI, magnetic resonance imaging
- RCTs, randomized controlled trials
- UMHS, University of Michigan Health System

TABLE 1: COMPARISON OF INTERVENTIONS AND PRACTICES CONSIDERED
("✓" indicates topic is addressed)

	ACS (2003 & 2007)	ACP (2007)	UMHS (2004)
Mammography	✓	✓	✓
MRI	✓		
BSE	✓		✓
CBE	✓		✓

TABLE 2: SCOPE	
Objective	
ACS (2003 &	**2003 Guideline**

2007)	• To review the existing ACS guidelines for the early detection of breast cancer based on evidence that has accumulated since the last revision in 1997 **2007 Addendum** • To review the existing early detection guideline for women at increased risk and for MRI screening based on evidence that has accumulated since the last revision in 2002 to 2003
ACP (2007)	• To present the available evidence and to increase clinicians' understanding of the benefits and risks of screening mammography
UMHS (2004)	• To implement an evidenced-based strategy for cancer screening in adults
Target Population	
ACS (2003 & 2007)	**2003 Guideline** • United States • Women aged 40 years or older **2007 Addendum** • United States • Women at increased risk of breast cancer based on family history, results of genetic testing, or clinical factors
ACP (2007)	• United States • Women 40 to 49 years of age
UMHS (2004)	• United States • Adult women, 18 years and older
Intended Users	
ACS (2003 & 2007)	Advanced Practice Nurses Allied Health Personnel Health Care Providers Health Plans

	Hospitals Managed Care Organizations Nurses Patients Physician Assistants Physicians Public Health Departments
ACP (2007)	Advanced Practice Nurses Allied Health Personnel Health Care Providers Nurses Physician Assistants Physicians
UMHS (2004)	Physicians

TABLE 3: COMPARISON OF RECOMMENDATIONS FOR BREAST CANCER SCREENING	
Mammographic Screening	
ACS (2003 & 2007)	**2003 Guideline** • **Women age 40 to 69 years**: Women at average risk should begin annual mammography at age 40. Women should have an opportunity to become informed about the benefits, limitations, and potential harms associated with regular screening. • **Older women (over age 69)**: Screening decisions in older women should be individualized by considering the potential benefits and risks of mammography in the context of current health status and estimated life expectancy. As long as a woman is in reasonably good health and would be a candidate for treatment, she should continue to be screened with mammography. However, if an individual has an estimated life expectancy of less than three to five years, severe functional limitations, and/or multiple or severe comorbidities likely to limit life expectancy, it may be appropriate to consider cessation of screening. Chronological age alone should not be the reason for the cessation of regular screening. • **High-risk women**: Women at increased risk of breast cancer might benefit from additional screening strategies beyond those offered to women of average risk, such as earlier initiation of screening, shorter screening intervals, or the addition of screening modalities other than mammography and physical examination, such as ultrasound or MRI. However, the

	evidence currently available is insufficient to justify recommendations for any of these screening approaches. **2007 Addendum** No recommendations offered.
ACP (2007)	**Recommendation 1**: *In women 40 to 49 years of age, clinicians should periodically perform individualized assessment of risk for breast cancer to help guide decisions about screening mammography.* A careful assessment of a woman's risk for breast cancer is important. Risk assessments should be updated periodically, particularly in women whose family history changes (for example, a relative receives a diagnosis of breast or ovarian cancer) and in women who choose not to have regular screening mammography. Although no evidence supports specific intervals, we encourage clinicians to update the woman's risk assessment every 1 to 2 years. Factors that increase the risk for breast cancer include older age, family history of breast cancer, older age at the time of first birth, younger age at menarche, and history of breast biopsy. Women 40 to 49 years of age who have any of the following risk factors have a higher risk for breast cancer than the average 50-year-old woman: two first-degree relatives with breast cancer; two previous breast biopsies; one first-degree relative with breast cancer and one previous breast biopsy; previous diagnosis of breast cancer, ductal carcinoma in situ (DCIS), or atypical hyperplasia; previous chest irradiation; or *BRCA1* or *BRCA2* mutation. **NGC Note**: Refer to the original guideline document for further discussion of risk assessment. **Recommendation 2**: *Clinicians should inform women 40 to 49 years of age about the potential benefits and harms of screening mammography.* Screening mammography for women 40 to 49 years of age is associated with both benefits and potential harms. The most important benefit of screening mammography every 1 to 2 years in women 40 to 49 years of age is a potential decrease in breast cancer mortality. Potential risks of mammography include false-positive results, diagnosis and treatment for cancer that would not have become clinically evident during the patient's lifetime, radiation exposure, false reassurance, and procedure-associated pain. False-positive

mammography can lead to increased anxiety and to feelings of increased susceptibility to breast cancer, but most studies found that anxiety resolved quickly after the evaluation.

Recommendation 3: *For women 40 to 49 years of age, clinicians should base screening mammography decisions on benefits and harms of screening, as well as on a woman's preferences and breast cancer risk profile.*

Because the evidence shows variation in risk for breast cancer and benefits and harms of screening mammography based on an individual woman's risk profile, a personalized screening strategy based on a discussion of the benefits and potential harms of screening and an understanding of a woman's preferences will help identify those who will most benefit from screening mammography. For many women, the potential reduction in breast cancer mortality rate associated with screening mammography will outweigh other considerations. For women who do not wish to discuss the screening decision, screening mammography every 1 to 2 years in women 40 to 49 years of age is reasonable.

Important factors in the decision to undergo screening mammography are women's preferences for screening and the associated outcomes. Concerns about risks for breast cancer or its effect on quality of life will vary greatly among women. Some women may also be particularly concerned about the potential harms of screening mammography, such as false-positive mammograms and the resulting diagnostic work-up. When feasible, clinicians should explore women's concerns about breast cancer and screening mammography to help guide decision making about mammography.

The relative balance of benefits and harms depends on women's concerns and preferences and on their risk for breast cancer. Clinicians should help women to judge the balance of benefits and harms from screening mammography. Women who are at greater-than-average absolute risk for breast cancer and who are concerned that breast cancer would have a severely adverse effect on quality of life may derive a greater-than-average benefit from screening mammography. Women who are at substantially lower-than-average risk for breast cancer or who are concerned about potential risks of mammography may derive a less-than-average benefit from screening mammography.

If a woman decides to forgo mammography, clinicians should readdress the decision to have screening every 1 to 2 years.

Recommendation 4: *ACP recommends further research on the net benefits and harms of breast cancer screening modalities for*

	women 40 to 49 years of age. Methodological issues associated with existing breast cancer screening trials, such as compliance with screening, lack of statistical power, and inadequate information about inclusion or exclusion criteria and study population, heighten the need for high-quality trials to confirm the effectiveness of screening mammography in women in this age group. Furthermore, harms of screening in this age group, such as pain, radiation exposure, and adverse outcomes related to false-positive results, should also be studied.
UMHS (2004)	• **Average risk**. Recommend screening mammography for women age 40 and older. Evidence for mortality reduction is strongest for women aged 50 and older **[A]**. Evidence is weaker and absolute benefit of mammography is smaller for women age 40 to 49. • **High risk**. Women at increased risk of breast cancer (see Table 1 in the original guideline document) may benefit from earlier screening and discussion of risk reduction strategies **[D]**. • **Frequency.** Little evidence is available regarding frequency of screening. Most experts recommend mammography either annually or every 1 to 2 years **[D]**. • **Terminate**. Consider screening depending on life expectancy (even for women over 69) **[D]**.
Magnetic Resonance Imaging (MRI) Screening	
ACS (2003 & 2007)	**<u>2003 Guideline</u>** • **High-risk women**: Women at increased risk of breast cancer might benefit from additional screening strategies beyond those offered to women of average risk, such as earlier initiation of screening, shorter screening intervals, or the addition of screening modalities other than mammography and physical examination, such as ultrasound or MRI. However, the evidence currently available is insufficient to justify recommendations for any of these screening approaches. **<u>2007 Addendum</u>** **Recommendations for Breast MRI Screening as an Adjunct to Mammography** *Recommend Annual MRI Screening (Based on Evidence*)* • *BRCA* mutation • First-degree relative of *BRCA* carrier, but untested

	• Lifetime risk ~20% to 25% or greater, as defined by BRCAPRO or other models that are largely dependent on family history *Recommend Annual MRI Screening (Based on Expert Consensus Opinion**)* • Radiation to chest between age 10 and 30 years • Li-Fraumeni syndrome and first-degree relatives • Cowden and Bannayan-Riley-Ruvalcaba syndromes and first-degree relatives *(Insufficient Evidence to Recommend for or Against MRI Screening***)* • Lifetime risk 15% to 20%, as defined by BRCAPRO or other models that are largely dependent on family history • Lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALH) • Atypical ductal hyperplasia (ADH) • Heterogeneously or extremely dense breast on mammography • Women with a personal history of breast cancer, including ductal carcinoma in situ (DCIS) *Recommend Against MRI Screening (Based on Expert Consensus Opinion)* • Women at <15% lifetime risk *Evidence from nonrandomized screening trials and observational studies. **Based on evidence of lifetime risk for breast cancer. ***Payment should not be a barrier. Screening decisions should be made on a case-by-case basis, as there may be particular factors to support MRI. More data on these groups is expected to be published soon.
ACP (2007)	No recommendations offered.
UMHS (2004)	No recommendations offered.
Clinical Breast Examination (CBE) and Breast Self-Examination (BSE)	
ACS (2003 & 2007)	**2003 Guideline**

	Clinical Breast Examination • For average-risk asymptomatic women in their 20s and 30s, it is recommended that CBE be part of a periodic health examination, preferably at least every three years. The exam should include BSE instruction for the purpose of gaining familiarity with breast composition. Information should be provided about the benefits and limitations of CBE and BSE, and it should be emphasized that breast cancer risk is very low for women in their 20s and gradually increases with age. The importance of prompt reporting of any new symptoms to a health professional should also be emphasized. • Asymptomatic women aged 40 and over should continue to receive a CBE as part of a periodic health examination, preferably annually. Beginning at age 40, discussion during CBE should include information about screening mammography. There may be some benefit to performing the CBE shortly before the mammogram. At the time of CBE, the benefits and limitations of physical examination and mammography should be discussed with the patient. *Breast Self Examination* • Beginning in their 20s, women should be told about the benefits and limitations of BSE. The importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination. It is acceptable for women to choose not to do BSE or to do BSE irregularly. **2007 Addendum** No recommendations offered.
ACP (2007)	No recommendations offered.
UMHS (2004)	• Evidence is insufficient to recommend for or against CBE and BSE. **CBE**. There is insufficient evidence to recommend for or against CBE. Clinical breast examination may augment mammography, but cannot be used alone as a screening tool. **BSE**. There is no randomized controlled trial in American women on the efficacy of breast self-examination (BSE). A large Chinese and a Russian randomized controlled trial on BSE revealed no decrease in mortality from breast cancer and a lack of stage shift. A substantial increase in the number of benign breast lesions were

	detected in women randomized to BSE.

TABLE 4: BENEFITS AND HARMS	
Benefits	
ACS (2003 & 2007)	**2003 Guideline** • Decreased breast cancer morbidity and mortality due to early detection. • A meta-analysis of seven RCTs showed a 24% mortality reduction associated with an invitation to screening. • Evidence from service screening (i.e., screening in the community setting) demonstrates that modern, organized screening programs with high rates of attendance can achieve breast cancer mortality reductions equal to or greater than those observed in RCTs. Evaluation of service screening is an important new development because it measures the value of modern mammography in the community and it measures the benefit of mammography screening to women who actually get screened. **2007 Addendum** • Several studies have demonstrated the ability of MRI screening to detect cancer with early-stage tumors that are associated with better outcomes. While survival or mortality data are not available, MRI has higher sensitivity and finds smaller tumors, compared with mammography, and the types of cancers found with MRI are the types that contribute to reduced mortality. It is reasonable to extrapolate that detection of noninvasive (DCIS) and small invasive cancers will lead to mortality benefit.
ACP (2007)	Screening mammography likely reduces breast cancer mortality in women 40 to 49 years of age modestly. However, compared to women over 50, the reduction in mortality is smaller and subject to greater uncertainty about the exact reduction in risk and comes with the risk of potential harms.
UMHS (2004)	Early detection and treatment may avert future cancer-related illness. From prospective randomized clinical trials, the evidence for screening is strongest in women age 50 to 69 with a relative risk of

	0.76 in breast cancer mortality after 10 or more years of regular screening. Regular screening of 10,000 50 year-old women for 10 years saves about 37 lives. Based on the incidence rates and effectiveness of screening, screening 10,000 40 year-old women every year for 10 years, results in about 4 lives being saved. However, women in their 40s have more years of life saved than older women.
Harms	
ACS (2003 & 2007)	**2003 Guideline** Limitations and harms of breast cancer screening include false negatives, false positives, over-treatment, and radiation. **False Negatives/False Positives** False negatives can be attributed to inherent technological limitations of mammography, quality assurance failures, and human error; false positives also can be attributed to these factors as well as to heightened medical-legal concerns over the consequence of missed cancers. Further, in some instances, a patient's desire for definitive findings in the presence of a low-suspicion lesion also contributes to false positives. The consequences of these errors include missed cancers, with potentially worse prognosis, as well as anxiety and harms associated with interventions for benign or nonobligate precursor lesions. The evidence suggests that some women experience anxiety related to screening and a greater percentage experience anxiety related to false-positive results, but for most women psychological distress is short-lived and does not have lasting consequences on either stress levels or likelihood of subsequent screening. **Overtreatment** Since some ductal carcinoma in situ (DCIS) is not progressive, diagnostic evaluation and treatment of DCIS lesions that would not progress to invasive disease is a harm associated with screening, although the extent of harm is uncertain, as is how it might be avoided. Overtreatment of a progressive DCIS lesion that could be cured with less aggressive treatment also represents a harm, although it should not be attributed to screening. **Radiation** Several studies have provided evidence for an increased risk of breast cancer after therapeutic radiation exposure or multiple exposures to diagnostic radiation. Overall risk from single and

cumulative diagnostic exposures is small, but risk increases with the amount of exposure and with younger age at exposure. Thus, it is theoretically possible that cumulative radiation exposure associated with screening mammography increases the risk of breast cancer. It has also been hypothesized that some women at increased inherited risk for breast cancer may also have increased radiation sensitivity, which could increase their risk for radiation-induced breast cancer.

Women whose regular screening begins at an early age (e.g., age 30) may have a higher potential for radiation-induced cancers.

2007 Addendum

Although the efficacy of breast MRI has been demonstrated, it does not achieve perfect sensitivity or specificity in women undergoing screening, and as such, the issue of adverse consequences for women who do, but especially those who do not, have breast cancer is important to address. As with mammography and other screening tests, false negatives after MRI screening can be attributed to inherent technological limitations of MRI, patient characteristics, quality assurance failures, and human error; false positives also can be attributed to these factors, as well as heightened medical-legal concerns over the consequence of missed cancers. A patient's desire for definitive findings in the presence of a low-suspicion lesion may also contribute to a higher rate of benign biopsies. The consequences of all these factors include missed cancers, with potentially worse prognosis, as well as anxiety and potential harms associated with interventions for benign lesions.

The specificity of MRI is significantly lower than that of mammography in all studies to date, resulting in more recalls and biopsies. Call-back rates for additional imaging ranged from 8% to 17% in the MRI screening studies, and biopsy rates ranged from 3% to 15%. However, several researchers have reported that recall rates decreased in subsequent rounds of screening: prevalence screens had the highest false-positive rates, which subsequently dropped to less than 10%. Most call backs can be resolved without biopsy. The call-back and biopsy rates of MRI are higher than for mammography in high-risk populations; while the increased sensitivity of MRI leads to a higher call-back rate, it also leads to a higher number of cancers detected. The proportion of biopsies that are cancerous (positive predictive value) is 20% to 40%. Since false-positive results appear to be common, more data are needed on factors associated with lower specificity rates.

See the original addendum document for more information about technological limitations and potential harms associated with MRI screening, including psychological concerns, costs, and limited access.

ACP (2007)	• Risks of mammography include false-positive results, diagnosis of cancer that would not have become clinically evident during the patient's lifetime, radiation exposure, false reassurance, and procedure-associated pain. • Women 40 to 49 years of age may have a higher risk for a false-positive result, and false-positive rates vary widely among several studies.
UMHS (2004)	**False negatives**. Younger women are more likely to have false negative results as the sensitivity of screening mammography is lower in pre-menopausal women who have dense, nodular breasts. As women age, breast tissue becomes more fatty and breast cancers are more easily detected by screening mammography. **False positives**. Younger women are also more likely to have false positive mammogram results. False positive results necessitate further evaluation and have been shown to increase anxiety. About 97% of women aged 40 to 49 who have abnormal mammograms do not have cancer, compared to 86% of women age 50 and older. **Radiation-induced breast cancer**. It is estimated that annual mammography of 100,000 women for 10 consecutive years beginning at age 40 would result in up to 8 radiation-induced breast cancer deaths.

TABLE 5: EVIDENCE RATING SCHEMES AND REFERENCES	
ACS (2003 & 2007)	**2003 Guideline** The primary evidence supporting the recommendation for periodic screening for breast cancer with mammography derives from seven randomized controlled trials (RCTs). **2007 Addendum** Recommendations for breast MRI screening as an adjunct to mammography are based on nonrandomized screening trials, observational studies, and expert consensus opinion based on lifetime risk for breast cancer.
ACP (2007)	**Levels of Evidence** **Therapy or Prevention, Etiology or Harm**

	1a: Systematic review of RCTs 1b: Individual RCT (with narrow confidence interval) 1c: All or none 2a: Systematic review of cohort studies 2b: Individual cohort study (including low quality RCT; e.g., <80% follow-up) 2c: "Outcomes" research; ecological studies 3a: Systematic review of case-control studies 3b: Individual case-control study 4: Case-series (and poor quality cohort and case-control studies) 5: Expert opinion without explicit critical appraisal or based on physiology, bench research or "first principles" **Prognosis** 1a: Systematic review of inception cohort studies 1b: Individual inception cohort study with >80% follow-up 1c: All or no case-series 2a: Systematic review of either retrospective cohort studies or untreated control groups in RCTs 2b: Retrospective cohort study or follow-up of untreated control patients in an RCT 2c: "Outcomes" research 4: Case-series (and poor quality prognostic cohort studies) 5: Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" **Symptom Prevalence Study** 1a: Systematic review of prospective cohort studies

	1b: Prospective cohort study with > 80% follow-up 1c: All or no case-series 2a: Systematic review of 2b and better studies 2b: Retrospective cohort study or poor follow-up 2c: Ecological studies 3a Systematic review of 3b and better studies 3b: Non-consecutive cohort study, or very limited study population 4: Case-series or superseded reference standards 5: Expert opinion without explicit critical appraisal or based on physiology, bench research or "first principles"
UMHS (2004)	**Levels of evidence reflect the best available literature in support of an intervention or test:** A. Randomized controlled trials B. Controlled trials, no randomization C. Observational trials D. Opinion of expert panel

GUIDELINE CONTENT COMPARISON

The American Cancer Society (ACS), the American College of Physicians (ACP), and the University of Michigan Health System (UMHS) present recommendations for screening mammography for breast cancer based on evidence available at the time of each report and provide explicit reasoning behind their judgments. With the exception of ACP, the guidelines also evaluate screening interventions other than mammography for breast cancer, such as teaching breast self-examination in the periodic health examination and clinical breast examination. The 2003 ACS guideline, while primarily focused on breast cancer screening using traditional methods, also examines new screening technologies as well as issues pertinent to screening older women and high-risk women. The 2007 addendum to the ACS guideline continues this theme, providing recommendations exclusively for the use of MRI breast cancer screening. UMHS addresses cancer screening in general, providing recommendations for breast as well as cervical, colorectal, and prostate cancer screening. Mammography is the only screening intervention considered by ACP.

Areas of Agreement

Mammographic Screening for Women Aged 50 to 69 Years

Among the two guidelines that address this age group (ACS [2003] and UMHS), the groups agree that routine screening mammography is indicated in women aged 50 to 69. ACS endorses annual screening, while UMHS recommends either annual or biennial screening.

Screening of Women with Selected Risk Factors for Breast Cancer

UMHS and ACS generally agree that there is value in adjusting the screening recommendations for women with risk factors for breast cancer. UMHS suggests that women at increased risk may benefit from earlier screening and discussion of risk strategies. Regarding frequency of testing, UMHS further adds that individuals with breast conditions or specific risk profiles may require adjustments to this screening interval, although no definitive mammography screening interval has been determined. The ACP guideline, which applies to women 40 to 49 years of age, recommends that clinicians should periodically perform individualized assessment of risk for breast cancer to help guide decisions about screening mammography.

While ACS (2003) recommends annual screening of all women beginning at age 40, it also states that high-risk women might benefit from additional screening strategies. These strategies could include initiation of screening at age 30 years or younger, shorter mammographic screening intervals (e.g., every six months), and the addition of MRI or ultrasound screening. (Refer to the MRI Screening section below for information regarding the 2007 ACS addendum "American Cancer Society Guideline for breast screening with MRI as an adjunct to mammography.")

Magnetic Resonance Imaging (MRI) Screening

ACS (2007) is the only group to provide recommendations for breast cancer screening with MRI as an adjunct to mammography. These recommendations were published in 2007 as an addendum to the 2003 ACS breast cancer screening guideline. ACS provides two sets of recommendations for annual MRI screening, those based on evidence from nonrandomized screening trials and observational studies, and those based on expert consensus opinion. They also describe women for whom insufficient evidence is available to recommend for or against MRI screening. ACS further recommends against MRI screening for women at less than 15% lifetime risk (based on expert consensus opinion).

Mammographic Screening of Older Women (≥70 years)

Among the two guidelines that address this age group (ACS [2003] and UMHS), the groups generally agree that there is no clear age at which mammographic screening should be discontinued. Rather, the decision to screen should be made on an individual basis, taking into account personal preferences and weighing individual risks and benefits.

Areas of Differences

Mammographic Screening of Women Aged 40 to 49 Years at Average Risk of Breast Cancer

The value of routine screening of women aged 40 to 49 years at average risk of breast cancer is an area of controversy among the guideline groups. Much of the controversy is due to the quality and interpretation of clinical trial data regarding mortality benefits of mammographic screening. The groups acknowledge that the evidence for absolute benefit from screening of women younger than 50 years is weaker than the evidence for older women; however, a mortality benefit for women aged 40 to 49 has still been shown in some clinical trials.

ACS (2003) recommends routine annual mammographic screening, while UMHS recommends annual **or** biennial screening in this age group.

ACS (2003) cites updates in the evidence from a number of individual RCTs of breast cancer screening and meta-analyses of these data, including a 2002 meta-analysis performed by the U.S. Preventive Services Task Force (USPSTF) to justify their recommendation for annual screening in women beginning at age 40 years. In addition, ACS (2003) presents evidence from service screening (i.e., screening in the community setting), which appears to show mortality reductions similar to those seen in randomized controlled trials.

ACP differs from ACS (2003) and UMHS in that it does not present recommendations regarding the frequency with which women in this age group should undergo screening mammography. Rather, they recommend that clinicians inform women 40 to 49 years of age about the potential benefits and harms of screening mammography, and that the decision to screen should be a joint decision between the physician and the patient based on assessment of benefits and harms of screening, as well as on the woman's preferences and breast cancer risk profile. They therefore recommend a case-by -case screening method for determining how often a particular woman should have mammography, based on the woman's breast cancer risk profile and her preferences.

They do, however, address screening intervals in the context of women in this age group with certain circumstances. They note that for women who do not wish to discuss the screening decision, screening mammography every 1 to 2 years is reasonable. They also note that if a woman decides to forgo mammography, clinicians should readdress the decision to have screening every 1 to 2 years.

Clinical Breast Examination (CBE)

Among the two guidelines that address CBE as a breast cancer screening measure (ACS [2003] and UMHS), there are some differences in the recommendations offered. The differences stem chiefly from the lack of firm evidence that CBE alone reduces breast cancer mortality and from the perceived value of CBE in detecting palpable tumors.

UMHS states that there is insufficient evidence to recommend for or against routine CBE alone to screen for breast cancer. They note that only 4% of women with abnormal CBE are subsequently diagnosed with cancer. They further note that CBE may augment mammography, but cannot be used alone as a screening tool.

ACS on the other hand, recommends CBE in all women over age 20. ACS recommends that CBE be performed at least every three years for women in their 20s and 30s and annually beginning at age 40. ACS presents a detailed discussion of available data. ACS concludes (based on weak and indirect evidence) that the contribution of CBE to breast cancer detection in asymptomatic women is small, especially in view of the high-quality mammography available today. They note, however, that when done prior to mammography, CBE may identify an area of suspicion and/or help guide subsequent imaging exams. They further note that as the proportion of women receiving regular mammograms increases, the relative contribution of CBE to early breast cancer detection and its cost-effectiveness warrant renewed attention. ACS still recommends periodic CBE, however, in part because the exam may provide the opportunity for clinicians to educate patients on breast cancer-related topics, including screening mammography. ACS also notes that its expert panel was divided in continuing to recommend periodic CBE, with some members believing that the evidence against the benefit of CBE was not strong enough to abandon the recommendation and others advocating elimination of the recommendation because it was not evidence-based.

Breast Self-examination (BSE)

Although the two guidelines that address BSE (ACS [2003] and UMHS) have reservations about its value, they differ somewhat in their final recommendations to patients and health care providers.

There is general agreement on the lack of a clear benefit for BSE as a screening measure for breast cancer. UMHS acknowledges that there is no RCT in American women on the efficacy of breast self-examination, but does refer to other RCTs in China and Russia that revealed no decrease in mortality for breast cancer despite a substantial increase in the number of breast lesions detected.

Among the guideline groups, ACS makes the strongest recommendation in favor of BSE, even though they acknowledge the absence of definitive randomized clinical trial data from which to draw conclusions. Their recommendation is derived from expert opinion, which in turn is based on population-based studies showing that many breast cancers are self-detected. Earlier detection of palpable masses, they reason, can lead to earlier treatment in average-risk women under age 40. ACS also emphasizes that BSE heightens awareness of women to normal breast tissue, which makes it more likely for them to detect changes from normal. Thus, ACS advocates BSE instruction for women beginning in their 20s, with the dual provisos that women are told of both its benefits and limitations, and that it is acceptable for women not to perform BSE. Women should be advised to report any new breast symptoms promptly to their health care provider. Finally, as with CBE, the ACS guideline panel was divided on whether to abandon the recommendation for BSE because of the lack of sufficient evidence.

This Guideline Synthesis was prepared by ECRI on December 28, 1998. It was reviewed and verified by the guideline developers as of February 19, 1999. This Synthesis was subsequently modified by ECRI in 2001, 2002, 2003, 2004, and 2005. The most current version of this Synthesis incorporates the 2004 UMHS recommendations. This synthesis was verified by UMHS on November 3, 2005.

This Synthesis was updated by ECRI on August 8, 2006 and on December 14, 2006 following the withdrawal of the Kaiser Permanente Southern California guideline, and the Brigham and Women's and Canadian Task Force guidelines respectively from the NGC Web site. This synthesis was revised on November 27, 2007 to remove recommendations from USPSTF. This synthesis was revised on January 28, 2008 to add ACP recommendations. The information was verified by ACP on February 4, 2008. This synthesis was revised on May 2, 2008 to incorporate the 2007 ACS addendum. This Synthesis was revised in October 2008 to remove outdated ACOG recommendations.

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