Complete Summary

GUIDELINE TITLE

Screening mammography for women 40 to 49 years of age: a clinical practice guideline from the American College of Physicians.

BIBLIOGRAPHIC SOURCE(S)

Qaseem A, Snow V, Sherif K, Aronson M, Weiss KB, Owens DK, Clinical Efficacy Assessment Subcommittee of the American College of. 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] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
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SCOPE

DISEASE/CONDITION(S)

Breast cancer

GUIDELINE CATEGORY

Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine

Obstetrics and Gynecology
Preventive Medicine
Radiology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To present the available evidence for screening mammography in women 40 to 49 years of age and to increase clinicians' understanding of the benefits and risks of screening mammography

TARGET POPULATION

Women 40 to 49 years of age

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

1. Assessment of risk for breast cancer
2. Informing patient of benefits and harms of screening mammography
3. Screening mammography

MAJOR OUTCOMES CONSIDERED

- Breast cancer mortality rate
- Risks and benefits of mammography screening
- Risk factors for breast cancer

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developers created a framework of the potential risks and benefits of screening mammography to guide the literature search. On the basis of the framework, they searched MEDLINE, Pre-MEDLINE, and the Cochrane Central Register of Controlled Trials for English-language publications. They conducted the

initial searches in spring 2004 and updated them in May 2005. General search strategies included Medical Subject Headings (MeSH) terms *mammography* or *breast neoplasms* and *mass screening*, as well as the keywords *mammography*, *screening*, and *breast cancer*. They conducted additional searches for each individual risk or benefit by using appropriate keywords and MeSH terms. The references of all selected articles were reviewed to identify additional relevant articles.

Study Selection

Although previous systematic reviews have largely focused on randomized, controlled trials of mammography screening to quantify the benefit of screening on breast cancer mortality rates, most evidence about risks and other benefits of mammography is derived from observational studies, primarily prospective cohort studies. Thus, a wide range of study designs were included in our review, with the included studies depending on the question and the available evidence. A meta-analyses was used to assess the effect of mammography screening on breast cancer mortality rates and the risk for a false-positive mammogram at a single screening; randomized, controlled trials and prospective cohort studies to assess the effect of mammography on breast cancer treatment and the cumulative risk for a false-positive mammogram; and both prospective and cross-sectional observational studies to assess the other risks of mammography. The guideline developers excluded case series and ecological designs for all risks except for ductal carcinoma in situ (DCIS) because most published data on DCIS outcomes are derived from these study designs. In addition, they reviewed available publications from the 8 original mammography trials and the published simulation models of the effect of radiation from mammography screening. When possible they focused on evidence from studies of screening mammography in women in their 40s or analyses of this age group within larger cohorts. When this was not possible, the guideline developers used studies of screening mammography in older women. In the case of multiple publications from the same study, only the most recent publication was included in the analysis.

For study selection, a study investigator reviewed abstracts of all primary research articles to determine whether the full-text article should be retrieved.

NUMBER OF SOURCE DOCUMENTS

873 full-text articles were retrieved, and 2 investigators reviewed them. In addition to the publications from the original trials, 117 of these articles met inclusion criteria.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Therapy or Prevention, Etiology or Harm

1a: Systematic review of randomized controlled trials (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"

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction and Quality Assessment

Two investigators abstracted information about the study design, setting, study sample, measures, analysis, and results. When needed, we contacted authors to clarify questions about study design or results. We evaluated study quality by using the approach proposed by the Centre for Evidence-Based Medicine (Appendix Table 1 in the systematic review [see "Availability of Companion Documents" field in this summary]). The lead investigator adjudicated any disagreements between the reviewers about article content and quality.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline was approved by the American College of Physicians (ACP) Board of Regents on July 15, 2006.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

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. The 5-year breast cancer risk can vary from 0.4% for a woman age 40 years with no risk factors to 6.0% for a woman age 49 years with several risk factors. 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: 2 first-degree relatives with breast cancer; 2 previous breast biopsies; 1 first-degree relative with breast cancer and 1 previous breast biopsy; previous diagnosis of breast cancer, ductal carcinoma in situ (DCIS), or atypical hyperplasia; previous chest irradiation; or *BRCA1* or *BRCA2* mutation. A family history can also help identify women who may have *BRCA* mutations that place them at substantially higher risk for breast and other types of cancer (see Table below). These women should be referred for counseling and recommendations specific to this population, as recommended by the U.S. Preventive Services Task Force (USPSTF) (see the National Guideline Clearinghouse summary of the USPSTF guideline Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility: recommendation statement). 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.

Table. Family History Patterns Associated with an Increased Risk for BRCA1 or BRCA2 Gene Mutations*

Both maternal and paternal family histories are important
Women not of Ashkenazi Jewish heritage

- Two first-degree relatives with breast cancer, 1 of whom received the diagnosis at age ≤50 years
- A combination of ≥3 first- or second-degree relatives with breast cancer regardless of age at diagnosis
- A combination both breast and ovarian cancer among first- and second-degree relatives
- A first-degree relative with bilateral breast cancer
- A combination of ≥2 first- or second-degree relatives with ovarian cancer regardless of age at diagnosis
- A first- or second-degree relative with breast and ovarian cancer at any age
- A history of breast cancer in a male relative

Women of Ashkenazi Jewish heritage

Any first-degree relative (or 2 second-degree relatives on the same side of the family) with breast or ovarian cancer

*Adapted from data from the U.S. Preventive Task Force (Genetic risk assessment and *BRCA* mutation testing for breast and ovarian cancer susceptibility: recommendation statement. Ann Intern Med. 2005;143: 355-61).

The risk for invasive breast cancer can be estimated quantitatively by using the Web site calculator provided by the National Institutes of Health (http://bcra.nci.nih.gov/brc/q1.htm). This calculator is based on the Gail model, which takes into account many of the risk factors previously mentioned. However, clinicians who use the Gail model should be aware of its limitations. Although the model accurately predicts the risk for cancer for groups of women, its ability to discriminate between higher and lower risk for an individual woman is limited. This limitation occurs because many women have similar, relatively low absolute risks for invasive breast cancer over 5 years, which makes discrimination among levels of risk difficult for an individual woman.

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. A recent meta-analysis estimated the relative reduction in the breast cancer mortality rate to be 15% after 14 years of follow-up (relative risk, 0.85 [95% credible interval, 0.73 to 0.99]). An additional large randomized clinical trial of screening mammography in women 40 to 49 years of age found a similar decrease in the risk for death due to breast cancer, although the decrease did not reach statistical significance (relative risk, 0.83 [95% confidence interval, 0.66 to 1.04]). 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: *We recommend 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.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

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

POTENTIAL HARMS

- 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.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Clinical practice guidelines are guides only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians' judgment. All American College of Physicians' clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Qaseem A, Snow V, Sherif K, Aronson M, Weiss KB, Owens DK, Clinical Efficacy Assessment Subcommittee of the American College of. 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] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Apr 3

GUIDELINE DEVELOPER(S)

American College of Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Physicians

GUIDELINE COMMITTEE

Clinical Efficacy and Assessment Subcommittee (CEAS)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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Clinical Efficacy Subcommittee Members: Douglas K. Owens, MD, MS (*Chair*); Mark Aronson, MD; Patricia Barry, MD, MPH; Donald E. Casey Jr., MD, MPH, MBA;

J. Thomas Cross Jr., MD, MPH; Nick Fitterman, MD; E. Rodney Hornbake, MD; Katherine D. Sherif, MD; Kevin B. Weiss, MD, MPH (*Immediate Past Chair*)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Grants received: V. Snow (Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Atlantic Philanthropies)

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Annals of Internal Medicine Web site.

Print copies: Available from Amir Qaseem, MD, PhD, MHA, American College of Physicians, 190 N. Independence Mall West, Philadelphia, PA 19106; E-mail, aqaseem@acponline.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Armstrong K, Moye E, Williams S, Berlin JA, Reynolds EE. Screening mammography in women 40 to 49 years of age: a systematic review for the American College of Physicians. Ann Int Med 2007 Apr 3;146(7):516-526. Electronic copies: Available from the Annals of Internal Medicine Web site.
- CME questions from the American College of Physician's (ACP's) Medical Knowledge Self-Assessment Program (MKSAP). Available from the Annals of Internal Medicine Web site.

Print copies: Available from Katrina Armstrong, MD, MSCE, University of Pennsylvania, 1204 Blockley Hall, 423 Guardian Drive, Philadelphia, PA 19104.

PATIENT RESOURCES

The following is available:

- Screening mammography in women age 40 to 49 years. Ann Int Med 2007 Apr 3;146(7):I-20. Electronic copies: Available from the Annals of Internal Medicine Web site.

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

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NGC STATUS

This NGC summary was completed by ECRI Institute on May 9, 2007. The information was verified by the guideline developer on May 24, 2007.

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