General

Guideline Title

ACR Appropriateness Criteria® palpable breast masses.

Bibliographic Source(s)

Harvey JA, Mahoney MC, Newell MS, Bailey L, Barke LD, D'Orsi C, Hayes MK, Jokich PM, Lee S, Lehman CD, Mainiero MB, Mankoff DA, Patel SB, Reynolds HE, Sutherland ML, Haffty BG, Expert Panel on Breast Imaging. ACR Appropriateness CriteriaÂ® palpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 16 p. [45 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Parikh JR, Bassett LW, Mahoney MC, Bailey L, Birdwell RL, Burnside ES, D'Orsi CJ, Harvey JA, Kaplan SS, Newell MS, Rabinovitch R, Rosen EL, Sutherland ML, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® palpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 10 p.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Palpable Breast Masses

Variant 1: Woman 40 years of age or older, initial evaluation. (See Appendices 1A-1B in the original guideline document for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	9		☢☢
US breast	4	If she had recent mammogram (i.e., past 6 months), US may be appropriate.	O
MRI breast without and with contrast	2		O
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢

Radiologic Procedure	Rating	Comments	RRL*
Image-guided fine needle aspiration breast	1		Varies
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 2: Woman 40 years of age or older, mammography findings suspicious for malignancy. Next examination to perform. (See Appendix 1A in the original guideline document for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
US breast	9		O
MRI breast without and with contrast	2		O
Image-guided core biopsy breast	2		Varies
Mammography short interval follow-up	1		☢☢
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢
Image-guided fine needle aspiration breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 3: Woman 40 years of age or older, mammography findings probably benign. Next examination to perform. (See Appendix 1A in the original guideline document for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
Mammography short interval follow-up	8		☢☢
US breast	8	US is frequently performed to confirm correlation of imaging and clinical findings, as well as lesion characterization.	O
MRI breast without and with contrast	2		O
Image-guided core breast biopsy	2		Varies
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢
Image-guided fine needle aspiration breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 4: Woman 40 years of age or older, mammography findings benign (like lipoma) at site of palpable mass. Next examination to perform.

Radiologic Procedure	Rating	Comments	RRL*
Mammography short interval follow-up	2		☢☢
US breast	2	US may be done if correlation between the clinical examination and mammography is not clear.	O
Image-guided fine needle aspiration breast	2		Varies
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 5: Woman 40 years of age of older, mammography findings negative. Next examination to perform. (See Appendix 1B in the original guideline document for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
US breast	9		O
Mammography short interval follow-up	1		☢☢
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢
Image-guided fine needle aspiration breast	1		Varies
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 6: Woman younger than 30 years of age, initial evaluation. (See Appendices 2A-2B in the original guideline document for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
US breast	9		O
Mammography diagnostic	3		☢☢
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢

Radiologic Procedure	Rating	Comments	RRL*
Image-guided fine needle aspiration breast			
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 7: Woman younger than 30 years of age, US findings suspicious for malignancy. Next examination to perform. (See Appendix 2A in the original guideline document for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
Image-guided core biopsy breast	9	Either mammography or biopsy is appropriate. It depends on the history and findings.	Varies
Mammography diagnostic	8	Either mammography or biopsy is appropriate. It depends on the history and findings.	☢☢
US breast short interval follow-up	1		O
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢
Image-guided fine needle aspiration breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 8: Woman younger than 30 years of age, US findings probably benign. Next examination to perform. (See Appendix 2B in the original guideline document for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
US breast short interval follow-up	9		O
Mammography diagnostic	3		☢☢
Image-guided core biopsy breast	3		Varies
MRI breast without and with contrast	2		O
Image-guided fine needle aspiration breast	2		Varies
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 9: Woman younger than 30 years of age, US findings benign (like simple cyst). Next examination to perform.

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	2		☢☢
US breast short interval follow-up	2		O
Image-guided fine needle aspiration breast	2		Varies
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 10: Woman younger than 30 years of age, US findings negative. Next examination to perform.

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	3		☢☢
MRI breast without and with contrast	2		O
US breast short interval follow-up	1		O
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢
Image-guided fine needle aspiration breast	1		Varies
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 11: Woman age 30-39 years of age, initial evaluation. (See Appendix 3 in the original guideline document for additional steps in the workup of these patients.)

Radiologic Procedure	Rating	Comments	RRL*
US breast	8	If imaged initially with US, see variants 7-10 for additional imaging.	O
Mammography diagnostic	8	If imaged initially with mammography, see variants 2-5.	☢☢
MRI breast without and with contrast	2		O
MRI breast without contrast	1		O
FDG-PEM	1		☢☢☢☢
Tc-99m sestamibi BSGI	1		☢☢☢☢

Radiologic Procedure	Rating	Comments	RRL*
Image-guided fine needle aspiration breast	1		Varies
Image-guided core biopsy breast	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

Breast cancer is the most common female malignancy and the second leading cause of female cancer deaths in the United States. The American Cancer Society estimates that 226,870 new cases of invasive breast cancer and 63,300 new cases of in situ breast cancer will be diagnosed in 2012. A breast mass is one of the most frequent presenting features of breast carcinoma. A palpable breast mass may become evident during breast self-examination (BSE) or clinical breast examination (CBE). Breast cancer may present as a palpable mass in women not undergoing regular screening mammography due to young or advanced age or personal choice, or within 1-2 years of a normal screening mammogram (interval cancer).

Determining if a mass is present by physical examination can be difficult, as all breasts have variable combinations of glandular tissue, fibrosis, and fat. True masses are generally asymmetrical in relation to the other breast, distinct from the surrounding tissues, and three-dimensional. A typical cancer may be firm, have indistinct borders, and have attachments to the skin or deep fascia with dimpling or nipple retraction. Palpable breast thickening, defined as greater firmness of an area of the breast compared with the contralateral breast or other quadrants of the ipsilateral breast, may also be associated with breast cancer in about 5% of women. Benign masses typically have discrete, well-defined margins, a soft or rubbery texture, and are mobile. Cysts cannot reliably be distinguished from solid breast masses by palpation. In one study, only 58% of 66 palpable cysts were correctly identified by physical examination. Significant disagreement among experienced examiners may occur. In another study, four surgeons performed physical examination independently and agreed on the need for biopsy of only 73% of 15 masses subsequently proven malignant.

Because many breast masses may not exhibit distinctive physical findings, an imaging evaluation is necessary in almost all cases to characterize the palpable lesion and screen the remainder of each breast for additional lesions if the patient is age 40 years or older. It is preferable for imaging to occur before biopsy, as changes related to the biopsy may confuse, alter, obscure, and/or limit image interpretation. The negative predictive value of mammography with ultrasound (US) ranges from 97.4% to 100%. Nevertheless, negative imaging evaluation should never overrule a strongly suspicious finding on physical examination or vice versa. Any highly suspicious breast mass detected by imaging or palpation should undergo biopsy unless there are exceptional clinical circumstances such as the patient having significant comorbid factors.

Mammography

Several imaging techniques are commonly used in evaluating palpable breast masses. Diagnostic mammography may be used to evaluate a palpable finding. It is typically performed under the direct supervision of a radiologist and usually consists of craniocaudal and mediolateral oblique views of each breast. The mammogram need only include the ipsilateral breast if the patient has had a recent bilateral mammogram (within the last 6 months). A small radio-opaque marker is placed on the skin over the palpable finding to identify its location. Spot compression views obtained with or without magnification or tangential views are typically obtained to specifically evaluate the clinical finding. Supplemental mammographic views may also be needed to clarify the features, location, or reality of a mammographic lesion, including craniocaudal exaggerated to the lateral, cleavage, step-oblique, and 90-degree lateral views. Any creative nonstandard view may be used to image a palpable lesion or move it closer to the image receptor. These supplemental views improve visualization of palpable and nonpalpable masses and are predictive of whether they are benign or malignant.

Ultrasound

Breast US should be performed using a high-resolution, real-time, linear array scanner with an adjustable focal zone, and a transducer with a minimum center frequency of 10 MHz. US is preferably targeted specifically to the palpable finding. A major advantage of US is the ability to directly correlate the clinical and imaging findings. Many palpable masses that are not visualized on mammography can be characterized as benign using US. These may include simple cysts, clustered microcysts, or sebaceous cysts.

Due to its lack of ionizing radiation, US is the modality of choice for evaluating a palpable mass in pregnant women. However, mammography

when performed preoperatively in pregnant patients has a sensitivity of around 90%. US is also the modality of choice for evaluating palpable masses in lactating women because tissue density limits mammographic evaluation. However, mammography is not contraindicated during pregnancy or lactation and should be performed if malignancy is suspected, because it is particularly effective in detecting microcalcifications and subtle architectural distortion, features often not as well seen on US.

Multiple Modalities

The use of multiple modalities in diagnosing palpable masses has been advocated as a measure to increase the true positive rate. In two series evaluating palpable breast abnormalities, the sensitivity of mammography was 86% to 91%. The addition of US detects 93% to 100% of cancers that are occult on mammography. The addition of US to mammography may also improve detection of a benign etiology for a palpable finding. In one series, 40% of benign palpable masses were identified only on US.

When the mammogram shows a definite benign mass (e.g., lymph node, hamartoma, oil cyst), US is not necessary as long as the benign mass identified on mammography is a definite correlate of the clinical finding. When the mammogram shows a probably benign mass (e.g., round or oval circumscribed mass), US is usually indicated to further characterize the finding. The addition of US in these cases will often yield a benign result (e.g., simple cyst) and may identify features that are suspicious, appropriately prompting biopsy in other cases.

Solid palpable breast lesions with benign morphology as visualized on US have been studied in seven series. These studies include 1,438 patients with solid masses that have benign features by US; nine cancers were diagnosed for an overall incidence of 0.6%. Cancer incidence for six of the seven series ranges from 0% to 0.6%. One series had a higher cancer incidence of 3.2%. Given the large number of women studied to date, short-interval follow-up is a reasonable alternative to biopsy for solid masses with benign features identified by US, if the mammogram and clinical examination also suggest a benign etiology. Benign US features of a solid mass include oval or round shape, abrupt well-defined margin, homogeneous echogenicity, and orientation parallel to the chest wall with no posterior acoustic shadowing. The vast majority of these lesions represent benign fibroadenomas.

When both mammography and US are negative or benign in the evaluation of a palpable breast mass, the negative predictive value is also very high, over 97%. Together, these imaging modalities can be reassuring when the physical examination is not highly suspicious and follow-up is planned. However, a highly suspicious physical examination should prompt biopsy regardless of the imaging findings.

Magnetic Resonance Imaging

With respect to a palpable breast mass, other imaging techniques remain investigational. Magnetic resonance imaging (MRI) has emerged as a promising modality for detecting occult breast cancer in high-risk women and for evaluating disease extent in women diagnosed with breast cancer. Although palpable masses can be imaged with MRI, it is generally more cost effective to use mammography and US as the initial imaging examinations. The use of MRI to evaluate women with a clinically suspicious clinical examination and negative imaging is not well documented. In one series, 112 women were referred for breast MRI with the indication of a clinical finding; MRI resulted in no true-positive findings and one false-negative finding. In patients with palpable biopsy-proven breast malignancy in nonfatty tissue, MRI appears to be more sensitive than mammography or US for evaluating the extent of disease.

Nuclear Medicine

The use of nuclear techniques using whole-body scanners has shown limited detection of small breast cancers. The use of small, high-resolution cameras specifically designed for imaging of the breast have improved detection of small and noninvasive carcinomas. However, research specific to evaluation of women with palpable findings is lacking. Initial imaging with mammography and US is preferable.

Age-related Issues

The probability of a woman developing breast cancer over the next decade increases with age; the risk is one in 1,681 at age 20, one in 232 at age 30, and one in 69 at age 40. Diagnostic mammography is indicated as the initial examination in the evaluation of a palpable breast finding for women age 40 and older. Because of the theoretical increased radiation risk of mammography and the low incidence of breast cancer (less than 1%) in younger women, their imaging evaluation differs from that performed for older patients, according to most investigators. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

Most benign lesions in young women are not visualized on mammography, and US is therefore used as the initial imaging modality in younger women. The criteria for "young" have historically been considered as younger than age 30. However, the risk of breast cancer remains relatively low for women in their fourth decade. The sensitivity of US may be higher than mammography for women younger than age 40. A recent study of 1,208 women age 30 to 39 presenting with focal breast symptoms found higher sensitivity for US compared with mammography (95.7% versus 60.9%) with similar specificity (89.2% and 94.4% respectively). It is therefore reasonable to use US as the initial imaging modality for women younger than age 40, with a low threshold for using mammography if the clinical examination or other risk factors are concerning.

If US demonstrates a suspicious finding in a younger woman, bilateral mammography is recommended to evaluate for additional ipsilateral and contralateral lesions. If US demonstrates a probably benign lesion such as a fibroadenoma in this age group, sonographic surveillance may be an acceptable alternative to traditional biopsy. In one study only one of 357 patients (0.3%) younger than age 25 with such features were subsequently diagnosed with malignancy. If US demonstrates a classic benign lesion such a simple cyst correlating to the palpable abnormality, clinical follow-up without imaging surveillance is indicated. If the US finding is negative, mammography is still recommended as a prebiopsy assessment in cases where cancer is strongly suspected clinically. As with women age 40 and older, if physical examination is highly suspicious and mammography and US are negative, tissue sampling with fine-needle aspiration/biopsy (FNAB), core biopsy, or surgical biopsy is warranted.

Biopsy/Aspiration

Imaging is preferably performed prior to intervention since biopsy changes may obscure or complicate a finding. FNAB is used to remove fluid from a cyst and cellular material from a solid mass. Some practices demonstrate very good results using FNAB as the first means of diagnostic evaluation of a palpable breast masses. However, larger series demonstrate that core biopsy is superior to FNAB in terms of sensitivity, specificity, and correct histological grading of palpable masses. Stereotactic (x-ray) or US guidance may be used for FNAB or core biopsy, especially if the mass is vaguely palpable, small, deep, mobile, or multiple, or if attempts using palpation to biopsy the mass have been unsuccessful. The decision to perform excisional versus percutaneous biopsy should involve the patient and her health care provider. About 20% of women prefer to have the palpable lesion removed surgically despite benign imaging features or even benign core biopsy results.

Summary

- Because of inconsistencies in clinical examination, a thorough imaging workup of a palpable mass should be completed prior to biopsy.
- Diagnostic mammography is the initial imaging modality of choice for evaluating a clinically detected palpable breast mass in a woman age 40 or older.
- Breast US is the initial imaging modality of choice for evaluating a clinically detected palpable breast mass in a woman younger than age 30.
- For women age 30 to 39, either US or diagnostic mammography may be used for initial evaluation.
- Correlation between imaging and the palpable area of concern is essential.
- Any highly suspicious breast mass detected by imaging should be biopsied, irrespective of palpable findings.
- Any highly suspicious breast mass detected by palpation should be biopsied, irrespective of imaging findings.

Abbreviations

- BSGI, breast specific gamma imaging
- FDG-PEM, fluorodeoxyglucose positron emission mammography
- MRI, magnetic resonance imaging
- Tc, technetium
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢☢	0.1-1 mSv	0.03-0.3 mSv
☢☢☢	1-10 mSv	0.3-3 mSv
☢☢☢☢	10-30 mSv	3-10 mSv
☢☢☢☢☢	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."		

Clinical Algorithm(s)

Algorithms are provided in Appendices 1A, 1B, 2A, 2B, and 3 of the original guideline document for:

- Evaluation of palpable breast lesions in women age 40 years or older with probably benign or suspicious findings on mammography
- Evaluation of palpable breast lesions in women age 40 years or older with mammogram that is negative or shows benign findings
- Evaluation of palpable breast lesions in women less than 30 years old with probably benign or suspicious findings on US
- Evaluation of palpable breast lesions in women less than 30 years old with benign or negative findings on US
- Management of palpable findings in women age 30-39 years of age

Scope

Disease/Condition(s)

- Palpable breast mass
- Breast cancer

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Family Practice

Internal Medicine

Nuclear Medicine

Obstetrics and Gynecology

Oncology

Radiology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of initial radiologic examinations for patients with palpable breast masses

Target Population

Women with palpable breast masses

Interventions and Practices Considered

1. Mammography
    - Diagnostic
    - Short interval follow-up
2. Ultrasound breast
    - Short interval follow-up
3. Image-guided fine needle aspiration, breast
4. Magnetic resonance imaging (MRI) breast
    - Without and with contrast
    - Without contrast
5. Fluorodeoxyglucose-positron emission mammography (FDG-PEM)
6. Technetium (Tc)-99m sestamibi breast-specific gamma imaging (BSGI)
7. Image-guided core biopsy breast

Major Outcomes Considered

Utility of radiologic examinations in the evaluation and diagnosis of a palpable breast mass

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

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

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis, and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not

reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

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

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for the evaluation of palpable breast masses

Potential Harms

- In one series of 112 women were referred for breast magnetic resonance imaging (MRI) with the indication of a clinical finding; MRI resulted in no true-positive findings and one false-negative finding.
- Because of the theoretical increased radiation risk of mammography and the low incidence of breast cancer (less than 1%) in women younger than age 30, the imaging evaluation for these patients differs from that performed for older patients, according to most investigators. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional

information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

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

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Harvey JA, Mahoney MC, Newell MS, Bailey L, Barke LD, D'Orsi C, Hayes MK, Jokich PM, Lee S, Lehman CD, Mainiero MB, Mankoff DA, Patel SB, Reynolds HE, Sutherland ML, Haffty BG, Expert Panel on Breast Imaging. ACR Appropriateness CriteriaÂ® palpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 16 p. [45 references]

Adaptation

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

Date Released

1996 Sep (revised 2012)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Breast Imaging

Composition of Group That Authored the Guideline

Panel Members: Jennifer A. Harvey, MD (*Principal Author*); Mary C. Mahoney, MD (*Panel Chair*); Mary S. Newell, MD (*Panel C-Chair*); Lisa Bailey, MD; Lora D. Barke, DO; Carl D'Orsi, MD; Mary K. Hayes, MD; Peter M. Jokich, MD; Su-Ju Lee, MD; Constance D. Lehman, MD, PhD; Martha B. Mainiero, MD; David A. Mankoff, MD, PhD; Samir B. Patel, MD; Handel E. Reynolds, MD; M. Linda Sutherland, MD; Bruce G. Haffty, MD

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Parikh JR, Bassett LW, Mahoney MC, Bailey L, Birdwell RL, Burnside ES, D'Orsi CJ, Harvey JA, Kaplan SS, Newell MS, Rabinovitch R, Rosen EL, Sutherland ML, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® palpable breast masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 10 p.

Guideline Availability

Electronic copies: Available from the American College of Radiology (ACR) Web site .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the ACR Web site.
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site.
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in PDF from the ACR Web site.
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the ACR Web site.
- ACR Appropriateness Criteria® palpable breast masses. Evidence table. Reston (VA): American College of Radiology; 2012. 21 p. Electronic copies: Available from the ACR Web site.

Patient Resources

None available

NGC Status

This summary was completed by ECRI on March 25, 1999. The information was verified by the guideline developer on September 9, 1999. The NGC summary was updated on November 12, 2004. The information was verified by the guideline developer on December 21, 2004. This NGC summary was updated by ECRI Institute on May 17, 2007, May 12, 2010, and April 17, 2013.

Copyright Statement

Disclaimer

NGC Disclaimer