Complete Summary

GUIDELINE TITLE

Diagnosis of breast disease.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jan. 47 p. [63 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Nov. 51 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- May 23, 2007, Gadolinium-based Contrast Agents: The addition of a boxed warning and new warnings about the risk of nephrogenic systemic fibrosis (NSF) to the full prescribing information for all gadolinium-based contrast agents (GBCAs).

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Breast disease, including breast cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Oncology
Radiology
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To reduce the length of time between first knowledge of a breast abnormality to diagnostic resolution
- To ensure that a bloody tap or a persistent mass following aspiration of a palpable dominant mass is referred to a surgeon regardless of negative imaging
- To ensure that patients with spontaneous bloody or watery discharge have a mammogram (with or without an ultrasound) and are referred to a surgeon or radiologist
- To ensure that needle biopsies demonstrating pathologic findings are followed by performance of an open biopsy
- To ensure that all women with a breast concern that is indeterminate or vague will have short-term follow-up clinical assessment

TARGET POPULATION

All adults who have a breast abnormality

INTERVENTIONS AND PRACTICES CONSIDERED

1. Primary care evaluation of the breast, including history and physical exam, diagnostic mammogram, ultrasound if indicated, aspiration of a dominant palpable mass if needed, and referral to surgery
2. Evaluation of breast for nipple discharge, including discharge appearance and assessment of blood levels of prolactin and thyroid stimulating hormone (TSH)
3. Evaluation and management of breast pain, including history and physical exam; quantitative pain assessment; non-pharmacologic interventions, such as mechanical support and lifestyle changes; and/or pharmacologic interventions, such as evening primrose oil, analgesics, danazol, bromocriptine, and tamoxifen
4. Radiologic evaluation (mammogram, magnetic resonance imaging [MRI] with or without gadolinium contrast, or scintimammography, digital mammography if appropriate, ultrasound)
5. Image-directed core needle biopsy
6. Surgical evaluation
7. Follow-up mammography

MAJOR OUTCOMES CONSIDERED

- Positive predictive value of x-ray mammography and other diagnostic techniques
- Risk for malignancy in patients with biopsy-proven ductal hyperplasia with atypia

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search of clinical trials, meta-analyses, and systematic reviews is performed.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

New Guideline Development Process

A new guideline, order set, and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups or hospitals outside of ICSI.

The work group will meet for 7 to 8 three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

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

Critical Review Process

Every newly developed guideline or a guideline with significant change is sent to Institute for Clinical Systems Improvement (ICSI) members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the

work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the ICSI.

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- Within the knowledge of the reviewer, the scientific recommendations within the document are current.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis, and systematic reviews is performed and reviewed by the work group. The work group will meet for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

Review and Comment Process

ICSI members are asked to review and submit comments for every guideline, order set, and protocol prior to the work group convening to revise the document.

The purpose of the Review and Comment process is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the order set and protocol. Review and Comment also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.

All member organizations are encouraged to provide feedback on order sets and protocol, however responding to Review and Comment is not a criterion for continued membership within ICSI.

After the Review and Comment period, the work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to "Summary of Changes Report – January 2008."

The recommendations for the diagnosis of breast disease are presented in the form of seven algorithms: Evaluation by Primary care of Patient with Symptoms of Potential Breast Disease (Main Algorithm), Evaluation of Breast Mass, Evaluation of the Breast for Spontaneous Nipple Discharge, Evaluation of Breast Pain, Radiologic Evaluation of the Breast, Image-Directed Core Needle Biopsy, and Surgical Evaluation of the Breast for a total of 117 components accompanied by detailed annotations. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Key conclusion grades (I-III, Not Assignable) are provided at the end of the "Major Recommendations" field.

Clinical Highlights

1. It is imperative that communications between the radiologic and surgical consultants and the primary care provider are thorough and consistent. (*Main Algorithm, Annotation #13*)
2. A bloody tap or a persistent mass following aspiration of a palpable dominant mass should be referred to a surgeon regardless of negative imaging. (*Algorithm I, Annotation #23*)

3. Patients with a spontaneous bloody or watery discharge should be referred to a radiologist for imaging studies and a surgeon if appropriate. (*Algorithm II, Annotations #35, 36*)
4. The risk of cancer with a negative evaluation for breast pain is less than 1%. (*Algorithm III, Annotation #52*)
5. Any questionable pathologic finding from image-directed biopsy requires a surgical consultation. (*Algorithm V, Annotation #83*)

Evaluation by Primary Care of Patient with Symptoms of Potential Breast Disease Algorithm Annotations

2. **Perform History and Physical Exam for Breast-Related Symptoms**

   See also Annotations #32, "Patient Presents with Spontaneous Nipple Discharge" and #46, "Patient Presents with Breast Pain" (below) for specific symptom-related history and physical.

   Guidelines for primary care evaluation are initiated with a history aimed at uncovering and characterizing any breast-related symptoms. Likewise, a risk assessment should also be undertaken for identified risk factors: personal history of any breast cancer, personal history of ductal hyperplasia with atypia on previous breast biopsies, or family history of breast cancer in first-degree relatives. A high risk patient would be one with a mother, sister, or daughter who had breast or ovarian cancer before age 50, or a history of prior radiation before age 30, or is a carrier of mutated breast cancer genes. She should be referred for genetic counseling and consider testing.

   A physical examination should include inspection of the breast for any evidence of ulceration or contour changes. This includes examining the nipple for Paget's disease, and the presence of breast nodule(s), nipple disease, evidence of infection and/or spontaneous discharge. Palpation should be performed both in the upright and supine position to determine the presence of a palpable mass. Abnormalities detected during a clinical breast examination – such as masses or nodules, nipple discharge or inflammatory changes – require thorough evaluation and prompt treatment.

9. **Is Screening Mammogram Due?**

   Following completion of a physical examination in which no palpable mass is identified, a routine screening mammogram should be obtained if one has not been done within the recommended interval.

   Refer to the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guideline Preventive Services in Adults for mammography screening intervals.

12. **Complete All Radiologic Recommendations**

   Should any abnormality be uncovered, it will be the responsibility of the radiologist to complete any additional imaging studies required for the complete radiographic characterization of the lesion. The radiologist should

make certain that all recommendations including additional views, follow-up films, ultrasounds, etc., have been completed prior to referral to surgery. However, it is important that the provider ordering the mammogram review the results of these studies to fully understand the impression of the radiologist, and to insure that all recommendations by the radiologist have been completed within the department of radiology. Should the recommendation be made by radiology that a surgical consultation is warranted, it will be the responsibility of the primary care provider to establish this referral.

See Algorithm IV, Radiologic Evaluation of the Breast.

13. **Inform Patient of Next Screening Date**

Refer to NGC summary of the ICSI guideline Preventive Services in Adults guideline for recommended mammography screening intervals.

I. Evaluation of Breast Mass Algorithm Annotations

15. **Indeterminant or Dominant Mass?**

A dominant mass is a palpable finding that is discrete, solid and clearly different than the surrounding parenchyma. Should a palpable mass be identified, it should be characterized as to whether it represents a dominant (i.e., discrete) mass that requires immediate evaluation. Should physical examination demonstrate a palpable mass that is not clearly discrete and dominant (indeterminant), its size, location, and character should be documented in anticipation of follow-up examination.

16. **Perform Ultrasound and/or Diagnostic Mammogram**

Prior to the referral, a mammogram should be obtained. For women under age 50, digital mammography is preferable for dense breast tissue. Also see Annotation #54, "Abnormal Screening or Diagnostic Mammogram."

21. **Consider Aspiration if Symptomatic or Refer to the Appropriate Consultant**

Aspiration of a pure cyst is only necessary if the cyst is symptomatic and may be performed by the primary care provider or by the appropriate consultant (radiologist, surgeon). A successful aspirate would yield a non-bloody fluid with complete resolution of the dominant mass. The breast skin is prepped with alcohol. Then, with the lesion immobilized by the non-operating hand, an 18 to 25 gauge needle mounted on a 10 cc syringe is directed to the central portion of the mass for a single attempt at aspiration. If the lesion is a simple cyst, the mass should completely resolve.

Cyst fluid should be examined cytologically if it is bloody or unusually tenacious. Typical watery green fluid may be discarded.

For recommendations regarding appropriate further workup and possible biopsy, refer to the following algorithms below and in the original guideline document:

- Algorithm IV. Radiologic Evaluation of the Breast
- Algorithm V. Image-Directed Core Needle Biopsy
- Algorithm VI. Surgical Evaluation of the Breast

The importance of communication between the radiologic and surgical consultants and the primary care provider cannot be overstated. Patients undergoing biopsy should have results reported to both the radiologist or surgeon performing the biopsy and to the primary care provider. More importantly, patients who do not require biopsy following radiologic or surgical consultation should be returned to the routine screening process. This process is under the supervision of the primary care provider. Therefore, it is absolutely necessary for the primary care provider to know when the patient reenters the routine screening population. In the event that new symptoms arise or occur during the screening interval, the patient should be evaluated by the primary care provider using the primary care evaluation process of this guideline.

23. **Residual Mass or Bloody Aspirate?**

    Should the mass remain following the attempt at aspiration or should a bloody aspirate be obtained during the process, the presence of a malignancy cannot be ruled out. Patients with a residual mass or a bloody aspirate should be referred to radiology or surgery for further consultation, work-up, and possible biopsy.

    Surgical excision should be performed for those cysts with bright red bloody aspirate and those that do not completely resolve with aspiration.

    Bloody aspirate should be considered for cytology.

24. **Follow-up Clinical Breast Exam in 4 to 6 Weeks at Discretion of Clinician**

    If no residual mass or blood aspirate remains, a repeat examination should be performed in 4 to 6 weeks at the discretion of clinician. The optimum time for this exam is after one menstrual cycle.

28. **Residual Mass?**

    Persisting palpable masses not resolving in one month and all recurring cystic masses should be referred to radiology for further evaluation. If subsequent ultrasound is unable to confirm the presence of a benign cystic lesion, or if the lesion is worrisome to the patient, surgical consultation is indicated.

29. **Inform Patient of Next Screening Date**

If no mass is apparent at the time of this examination, the patient should be informed of the appropriate date of her next routine screening evaluation.

Refer to NGC summary of the ICSI guideline Preventive Services in Adults for mammography screening intervals.

II. Evaluation of the Breast for Spontaneous Nipple Discharge Algorithm Annotations

32. **Patient Presents with Spontaneous Nipple Discharge**

Guidelines for primary care evaluation of patient presenting with complaint of spontaneous nipple discharge are initiated with a history aimed at uncovering and characterizing any breast-related symptoms, including whether discharge has been spontaneous, persistent, unilateral versus bilateral, single or multiple ducts, its relation to menses, pregnancy, exercise, trauma, medications, and/or thyroid disorders.

The site around nipple should be examined for discharge upon pressure. Hemoccult test for blood may also be administered.

33. **Perform Mammogram/Ultrasound**

A mammogram should be obtained. An ultrasound may be helpful to locate an intraductal nodule or dilated duct.

35. **Complete All Radiologic Recommendations**

A patient with an abnormal mammogram or ultrasound should be further evaluated within the department of radiology to best characterize the lesion, and then be referred to surgery if appropriate. Make certain that all recommendations for additional views, ultrasound examinations, and follow-up studies have been obtained prior to referral to surgery. A ductogram may be completed as part of the radiologic workup.

38. **Clear or Bloody Discharge**

Bloody or, less commonly, clear watery discharge raises the possibility of cancer, although the most common causes of hemoccult-positive discharges are benign. The most common causes of bloody nipple discharge are intraductal papilloma (45%), duct ectasia (36%), carcinoma (8% to 15%), and infection and other causes (5% to 10%).

Bloody discharge needs further evaluation to determine the etiology.

39. **Refer to Surgeon (+/- Ductography)**

Most pathologic nipple discharges should be treated with duct excision. The use of ductography is controversial, and depends on the decision of the surgeon and radiologist.

43. **Hormonal Evaluation**

Prolactin and thyroid stimulating hormone (TSH) levels are obtained to determine an endocrinologic basis for the nipple discharge. A prolactinoma typically causes a milky or clear discharge bilaterally. (See the original guideline document for a discussion of discharge appearance.)

Assay should be performed for prolactin and TSH as both of these pituitary hormones may induce galactorrhea, may have a reversible cause, and may likewise reflect further underlying pathology (e.g., pituitary adenoma, hypothyroidism, etc.).

45. **Follow-Up Visit Scheduled at the Discretion of the Treating Clinician**

If the mammogram and the endocrinologic screening studies are normal, the patient should schedule a follow-up visit at the discretion of the responsible clinician.

If the evaluation at the time of that follow-up visit fails to reveal any palpable or visible abnormalities, the patient should be returned to the routine screening process.

III. Evaluation of Breast Pain Algorithm Annotations

46. **Patient Presents with Breast Pain**

Key Points:

- The information gathered should include location and severity of pain, relationship to menstrual cycle or physical activities, and hormonal influences.
- As appropriate, an exam directed at the cervical and thoracic spine, chest wall, and upper extremities may be helpful in assessing other causes of pain.

Breast pain is one of the most common symptoms evaluated in primary care, surgery or specialty breast clinics. Approximately 41% to 69% of women report having experienced breast pain. Breast pain may interfere with daily activities, relationships and quality of life.

History and Physical Exam

The symptom of breast pain prompts many patients to make an appointment for a medical examination out of concern for the possible presence of breast cancer. A patient history is directed toward identifying and characterizing breast-related symptoms. The information gathered should include location and severity of pain, relationship to physical activities or the menstrual cycle, and interference with routine activities. Hormonal influences, such as pregnancy, use of contraceptives, and hormone therapy, should also be reviewed. Obtaining a history may also provide information identifying non-breast sources of pain. The patient should also be asked about any new

medications, or those that can be associated with breast pain should be noted. Risk assessment for breast cancer should include the appropriate reproductive, medical, and family history.

A clinical examination of the breast should be performed with careful inspection and palpation of each breast, nipple-areolar complex, and regional lymph nodes. Localized, generalized, or bilateral breast tenderness should be noted. In addition to palpating the breasts while the patient is supine, examining the breasts while the patient is sitting or lying on her side may allow breast and chest wall tenderness to be distinguished.

Laboratory studies are generally not useful. A pregnancy test, however, should be considered in women of reproductive age if the history or examination suggests pregnancy. Other hormone levels (e.g., estrogen, progesterone, and prolactin) are typically normal in patients with breast pain.

Breast pain may occur as a result of pregnancy, mastitis, trauma, thrombophlebitis, macrocysts, benign tumors, or cancer; however, only a minority of breast pain is explained by these conditions. Most breast pain is of unknown cause. A variety of conditions can result in pain perceived in the breast. A variety of conditions can be revealed as a result of a directed history and physical. As appropriate, an exam directed at the cervical and thoracic spine, chest wall, shoulders and upper extremities, sternum, heart, lungs, and abdomen may be helpful in assessing other potential causes of the pain.

Breast pain is commonly categorized into three classifications:

- **Cyclic mastalgia** occurs in premenopausal women and is clearly related to the menstrual cycle. The pain is typically bilateral and diffuse, often located in the upper outer quadrants of the breasts with frequent radiation to the axilla and the ipsilateral arm. Occasionally, breast pain may be unilateral or more intense in one breast.
- **Non-cyclic mastalgia** may involve continuous or intermittent pain that does not concur with the menstrual cycle. The pain is more often unilateral and localized with the pain in the lower inner portions of the breast. Non-cyclic breast pain generally occurs in older women, with symptoms often occurring in postmenopausal women.
- **Non-mammary pain** may present with the symptom of breast pain. Following the history and physical exam, differentiating breast pain and pain radiating from the chest wall or another site is usually straightforward. Occasionally the origin of pain is not evident, or there are multiple origins of pain, making evaluation more challenging.

47. **Mammogram and/or Ultrasound at the Discretion of the Clinician**

Imaging studies are frequently utilized in the evaluation of the breast. A mammogram should be considered especially in women with a family history of early breast cancer. Ultrasound may be useful for focal breast pain in both younger and older women. Subclinical breast cancer has been reported to occur in 2% to 7% of women who have pain as the only symptom. It is unclear whether the pain is related to the cancer or whether this symptom initiates a breast evaluation in which an asymptomatic cancer is identified.

Breast pain secondary to malignancy is typically unilateral and persistent. In these cases, imaging with directed ultrasound may be a more valuable assessment tool.

50. **Quantitative Pain Assessment**

Breast pain may be difficult to assess as the symptoms may appear and subside without provocation, with certain activities, or with the menstrual cycle. An attempt must be made to measure the amount and severity of the patient's breast pain over time, which is difficult as there is no standard unit of pain. Prospective assessment of breast pain may be a valuable tool when considering an intervention. Possible tools to document an individual's pain include pain rating instruments, a daily breast pain chart or a diary to document the occurrence and severity of pain, use of medications, and interferences with lifestyle. These tools are particularly important in making an initial diagnosis of cyclic mastalgia and response to therapy. For more information on pain assessment see the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guidelines Assessment and Management of Acute Pain and Assessment and Management of Chronic Pain.

52. **Initiate Non-Pharmacologic and/or Pharmacologic Intervention(s)**
    - The first line of treatment for breast pain is to reassure the patient that she does not have breast cancer. The risk of malignancy following a negative examination has been estimated to be only 0.5%, so reassurance following a negative evaluation is appropriate. Approximately 15% of women choose a treatment intervention to reduce the symptom of pain. During encounters for breast pain, the patient's description of the pain, quantitative assessment of the pain, and decisions regarding reassurance, follow-up, or therapeutic intervention should be documented.
    - Few women will require treatment with more than reassurance and well-tolerated medications such as evening primrose oil. For those with severe, refractory breast pain, the significant side effects of some of these medications must be balanced against the potential benefit in ameliorating breast discomfort and pain.
    - Non-pharmacologic interventions for breast pain are appropriate for women with breast pain. Although there has been little scientific investigation into the effectiveness of these non-pharmacologic approaches, they are frequently found to improve breast pain symptoms in clinical practice and are of low risk and expense to the patient.

Potential non-pharmacologic therapies include:

Mechanical Support

A professionally fitted support bra, irrespective of age, cup size, or underlying breast disease, has been shown to relieve breast pain even in patients who have not responded to hormonal treatments. Support bras are recommended for exercise. A soft supportive bra during sleep may also improve symptoms.

Lifestyle Changes

Lifestyle changes such as smoking cessation, stress reduction, and improving coping skills may be possible low-risk interventions. Hot packs, cold packs and massage may also relieve symptoms.

The effectiveness of dietary measures is unclear. Studies have demonstrated improvement in breast pain symptoms following dietary reduction of saturated fat. Caffeine reduction or elimination has been found to be helpful by some patients, particularly those who consume large quantities of caffeine. Clinical studies have not shown this to be a consistent outcome.

Pharmacologic Interventions

The decision whether to treat breast pain along with the selection of a particular agent to utilize requires balancing the need for symptom relief against the likelihood of medication side effects. If considering a pharmacologic therapy, consult with a specialist should be considered.

Pharmacologic interventions may include the adjustment of medications that may be contributing to breast pain, such as oral contraceptives, hormone therapy, spironolactone, and others. Eliminating or decreasing the dose of estrogen in an oral contraceptive or hormone regimen is often effective.

Possible pharmacologic therapies include:

Evening Primrose Oil

Evening primrose oil is often used as an initial treatment for breast pain because of its low incidence of side effects and positive response rates for cyclic and non-cyclic pain. It is rich in gamma-linolenic acid and is believed to alter the saturated/polyunsaturated fat balance and decrease sensitivity to hormonal influences. The average dose is 2 x 500 mg soft-gel capsules three times a day for a minimum of three to four months.

Analgesics

Analgesics, such as ibuprofen, 400 mg every 4 to 6 hours, may reduce breast pain.

Danazol

Danazol is the only medication that is labeled by the United States Food and Drug Administration for treatment of breast pain. Danazol is an antigonadotropin with some androgenic activity.

Danazol relieves breast pain in 75% to 92% of women. A typical initial dose of 200 mg per day is recommended with gradual tapering to an alternate day or luteal phase dosing; doses from 100 to 400 mg per day have also been described. Reported side effects are common and include hair loss, acne,

decrease in voice pitch, weight gain, irregular menses, and depression. There may also be a possible increase in venous thromboembolic events. Barrier contraception must be utilized. Danazol administered in the luteal phase only has been found to relieve premenstrual breast pain in women with premenstrual syndrome with minimal side effect. It was not effective for other premenstrual syndrome symptoms.

Bromocriptine

One of the few hormonal abnormalities detected in breast pain has been an increase in thyrotropin induced prolactin secretion. Bromocriptine has been shown to decrease serum prolactin levels in normal and hyperprolactinemic women and may decrease dynamic secretion of prolactin in cyclic mastalgia patients. In several European studies, bromocriptine has shown significant decreases in breast pain (approximately 54%), as well as heaviness and tenderness in the breasts. Prolactin levels decline during therapy while estrogen, progesterone, testosterone, and gonadotropin releasing hormones do not significantly change. Side effects are common and dose related, including nausea, vomiting, headache, dizziness, and fatigue. An incremental dosing regimen is used beginning with 1.25 mg at bedtime, gradually increasing until a dose of 2.5 mg twice daily is reached. The beneficial effects lasted three to six months after bromocriptine was discontinued.

Tamoxifen

Tamoxifen is a selective estrogen receptor modulator (SERM) utilized for the prevention and treatment of breast cancer. Response rates have demonstrated tamoxifen to be effective in reducing pain in 75% to 90% women with cyclic and 56% of women with non-cyclic mastalgia in controlled trials. Tamoxifen has significant side effects, with the principle concerns being from thromboembolic disease and endometrial cancer. Additional side effects include hot flashes, nausea, menstrual irregularity, and vaginal dryness or discharge. The 10 mg daily dose of tamoxifen appeared to be as effective as the 20 mg daily dose, with fewer side effects. Tamoxifen, like other hormonal interventions, should be reserved for women with severe mastalgia. Contraception must be utilized.

Other medications that have been found to be effective for the treatment of breast pain include goserelin, gestrinone, buserelin, leuprolide, quinagolide, cabergoline, thyroxine, and topical nonsteroidal anti-inflammatory agents. Medroxyprogesterone has shown variable results in the treatment of breast pain. In general, antibiotics, diuretics, and most vitamins have not been effective in the treatment of breast pain.

IV. Radiologic Evaluation of the Breast Algorithm Annotations

54. **Abnormal Screening or Diagnostic Mammogram**

Key Points:

- It is recommended that an abnormal finding on routine mammography be evaluated under the direction of a radiologist.

Patients referred to the department of radiology most commonly enter for screening mammography. However, patients will occasionally be referred for diagnostic mammography based on the presence of symptoms or findings on examination. In the event of an abnormal finding on mammography, it is recommended that a complete evaluation be undertaken within the department of radiology under the direction of a radiologist in order that a full characterization of the lesion will be provided back to the primary care physician ordering the original study. It will be the responsibility of the radiologist to complete the radiologic assessment of the patient within the department of radiology so that the best possible characterization of the abnormality may be provided to the primary care physician in an expeditious fashion. Any recommendations for referral to the department of surgery for possible biopsy should be made directly to the primary care physician. However, the ultimate responsibility to make the referral will rest with the primary care provider.

Refer to the original guideline document for information on nuclear medicine breast imaging, sentinel lymph node, and continued research in breast disease imaging.

55. **Presence of: Solid Mass? Abnormal Microcalcifications? Architectural Distortion?**

For patients referred with an abnormal mammogram, the surgeon or radiologist should determine whether the above suspicious changes are present. If not, the patient should report to ordering provider for follow-up and clinical exam. Recommend repeat mammogram in six to twelve months.

57. **Increased Risk?**

Patients considered at increased risk may have one or more of the following:

- Previous breast biopsy demonstrating ductal hyperplasia with atypia
- Family history of breast or ovarian cancer in patient's mother, sister, or daughter under age 50, or breast cancer in male family member
- Past personal history of breast cancer
- A breast cancer gene
- Previous radiation to the chest (i.e., Hodgkin's Disease)

Consider genetic counseling for possible genetic testing and lifetime risk analyses.

58. **Consider Magnetic Resonance Imaging (MRI)**

The use of MRI in the evaluation of breast disease has progressed rapidly over the last several years. MRI has previously been proven extremely useful in the evaluation, staging and monitoring of breast cancer and other breast problems. Recently, however, several studies have also demonstrated its

ability to detect early breast cancer in high-risk women (screening). This has prompted the American Cancer Society to issue formal guidelines for Breast MRI screening of high risk women IN ADDITION to the recommended yearly mammogram. Below is a synopsis of the new guidelines.

The following women **SHOULD** undergo yearly breast MRI screening* beginning at or around 30 years of age:

- Known carriers of BRCA 1 or BRCA 2 mutations
- First-degree relatives with known BRCA 1 or BRCA 2 mutations
- Clinical lifetime risk estimated at greater than 20% using clinical risk estimator (the Gail, Claus or BRCAPRO models are among the tools suggested)
- Known Cowden's, Li-Fraumeni or Bannayan-Riley-Ruvalcaba syndrome or first-degree affected relative

*Recommended at six-month offset interval from yearly mammogram

In women at high genetic or familial risk of breast cancer, MRI has high sensitivity (up to 94%) for the detection of breast cancer when used as an adjunct to mammography. This increase in sensitivity may lead to an earlier diagnosis of malignant breast lesions. However, MRI and mammography combined may lead to an increase in false positives, resulting in higher rate of benign biopsies. At this time there are no studies on the differential effect of screening modalities on mortality or long-term outcomes. *[Conclusion Grade II: See Conclusion Grading Worksheet A-- -- Annotation #58 (Magnetic Resonance Imaging) in the original guideline document]*.

Gadolinium Warning

In patients who receive gadolinium contrast media used in MRI, there is the potential for renal toxicity and the rare complication (3% to 5% risk in patients with moderate to end-stage renal disease) of life-threatening nephrogenic systemic fibrosis.

It is recommended that gadolinium use be avoided when possible in patients with advanced renal disease.

Evidence is inconclusive regarding the following situations and **DOES NOT YET SUPPORT** routine breast MRI screening:

- Clinical lifetime risk estimated at 15% to 20% using clinical risk estimator
- Previous lobular carcinoma in situ (LCIS), atypical lobular hyperplasia (ALH), atypical ductal hyperplasia (ADH) biopsy results
- Previous history of breast cancer including ductal carcinoma in situ (DCIS)
- Extremely dense mammogram (density 4)

The following Web address provides access to the Gail clinical risk assessment: http://www.cancer.gov/bcrisktool/.

See ICSI Magnetic Resonance Imaging for the Detection of Breast Cancer Abnormalities, TA #81.

59. **Additional Mammographic Studies and/or Ultrasound if Needed**

Upon obtaining an abnormal finding on a mammogram, the radiologist will determine whether further mammographic images or ultrasound are required for completion of the evaluation process. Alternatively, spot compression, magnification and/or ultrasound may be necessary to obtain further characterization of indeterminate lesions of the breast. These additional studies should be done with the radiologist present, to reduce the risk of patient recall for further studies necessary to evaluate the same lesion.

61. **Repeat Mammogram at 6-Month Intervals x 2**

If further mammographic studies or sonography demonstrate findings which are felt to be Probably Benign (an assessment category from the Breast Imaging and Reporting Data System [BI-RADS]), a repeat image of the breast at six months to document stability of low-risk, probably benign lesions. Perform mammograph again in another six months.

63. **Sort Abnormalities**

Upon completion of these views, each and every abnormality uncovered for each independent lesion of the breast studied should be sorted according to the nature of the abnormality. The radiologist should classify the lesion as representing either suspicious microcalcifications, architectural distortion or a soft tissue mass.

64. **Mass**

In the event that a soft tissue mass is identified in the mammogram, further studies are required to determine its relative risk for malignancy.

69. **Ultrasound (if Not Already Performed)**

Should the mass not be immediately suspicious for cancer, an ultrasound should be performed (if not already) to determine whether or not the lesion is solid. (See Annotation #59 "Additional Mammographic Studies and/or Ultrasound if Needed," above.)

71. **Fits Benign Criteria?**

A solid mass should be further characterized for its risk of malignancy according to three criteria. Lesions may be observed and followed with studies repeated in six months **if they fit all 3 of the following criteria**:

- Size less than 15 mm
- Three or fewer lobulations
- More than 50% of the lesion margin appears well-circumscribed in any view

Any lesion not fitting **all three of the above criteria** should be considered indeterminate and the patient should be referred for surgical evaluation regarding open biopsy or large-core image-guided core biopsy.

75. **Indications for Aspiration?**

    If the ultrasound of the soft tissue mass demonstrates that this is a cystic lesion, the cyst should be further categorized according to the following criteria:

    - Internal echoes
    - Palpability within the region of the ultrasound-proven cyst
    - Complex septated appearance

    All cysts do not have to be aspirated if they meet benign criteria with an ultrasound exam.

    If one or more of the preceding criteria are present, ultrasound-directed aspiration of the cyst is indicated. Likewise, aspiration should be offered if the patient so requests.

76. **Aspirate and Single View Mammogram**

    Following cyst aspiration, a single view mammogram may be performed to demonstrate complete resolution of the mammographic lesion. However, if the cyst completely disappears with ultrasound, a mammogram may not be necessary. If sufficiently complex, a pneumocystogram with post-mammogram view may be completed by radiology.

78. **Return to Screening Mammography/Report to Ordering Provider**

    If the lesion represents a simple cyst not fitting any of the criteria mentioned in Annotation #75 "Indications for Aspiration?" above, the patient should be referred back to the screening process and completion of this evaluation should be reported to the ordering provider. Refer to the NGC summary of the (ICSI) guideline Preventive Services in Adults for mammography screening intervals.

V. Image-Directed Core Needle Biopsy Algorithm Annotations

79. **Patient Referred for Image-Directed Biopsy**

    Patients referred for biopsy based on the presence of a mammographic and/or sonographic finding that is suspicious for or highly suggestive of malignancy will undergo either conventional open excisional biopsy (see Algorithm IV, Surgical Evaluation of the Breast, below) or large core needle biopsy.

    Large core imaging-guided breast biopsy is now the technique of choice in many institutions in the United States for biopsy of non-palpable breast masses and abnormal calcifications. Either stereotactic or ultrasound-guided

breast biopsy may be used for reliable diagnosis of breast cancer. Stereotactic guidance is preferable for biopsy of calcifications. Most solid breast masses are amenable to large core needle biopsy with either stereotactic or ultrasound guidance. The location of the lesion, its visibility at ultrasound, equipment availability and the radiologist's expertise will determine the approach selected.

In some institutions, large core imaging-guided needle breast biopsy is performed for tissue diagnosis in cases of obvious cancer, as it saves the patient an additional surgical procedure, as well as expediting the diagnostic process.

See the original guideline document for information on current changes in breast disease diagnosis.

81. **Definitive Therapy**

If cancer is diagnosed, definitive therapy may be performed on the basis of stereotactic or image-guided needle biopsy alone.

83. **Surgical Consult for Open Biopsy**

Any questionable pathologic findings or pathologic findings that do not correlate with the imaging are indications for repeat biopsy by excision to rule out the presence of occult malignancy in the region of the mammographic abnormality.

85. **Are Calcifications Present on Specimen Radiograph?**

To assure that an adequate core biopsy sample has been obtained for patients with suspicious microcalcifications, evidence of microcalcifications must be present on the specimen micrographs following stereotactic biopsy (if calcifications were present on mammogram).

86. **Rebiopsy by Core or Open Biopsy**

The original specimen (pathology block) can be reexamined and recut for pathology exam if calcifications were noted. If calcifications cannot be demonstrated mammographically in the specimen, repeat biopsy, open or stereotactic, is necessary to assure that the abnormal mammographic lesion has been sampled. Biopsy must be repeated until the calcifications can be confirmed in the specimen.

88. **Yearly Screening Mammogram or Refer to Surgeon**

If the mass is a fibroadenoma, then only yearly screening mammogram is necessary for follow-up. Benign fibroadenomas should be followed at routine screening intervals. However, if the patient is experiencing extreme pain and/or extreme tenderness, the fibroadenoma may be surgically removed or undergo cryotherapy.

89. **Mammogram in 6-12 Months, Then Annually for 3 Years**

For all patients who have benign results from stereotactic or image-guided biopsy, a repeat mammogram of the involved breast in 6 to 12 months, then annually for three years, is necessary to document stability of the lesion. The radiologist should correlate the pathology results with the mammographic abnormalities for all patients. If they do not correlate, rebiopsy with image-directed core needle or open biopsy is necessary.

91. **Open Biopsy or Repeat Image-Guided Core Needle Biopsy**

Any lesion which has grown or has become more dense on mammography, despite a previous benign core biopsy, must be rebiopsied or excised to rule out cancer.

VI. Surgical Evaluation of the Breast Algorithm Annotations

93. **Patient Referral to Surgeon for Evaluation**

Patients referred to the department of surgery for the evaluation of breast disease will have undergone previous mammography that has demonstrated an abnormality warranting biopsy or may be referred on the basis of a physical finding uncovered in the primary care provider's office. It is the role of the surgeon to evaluate each and every abnormality uncovered in each patient. It is important for the surgeon to recognize that mammographically depicted lesions and palpable abnormalities may co-exist as separate entities within the breast. It is therefore important that each lesion be evaluated for its own merit, using this algorithm.

The importance of communication between the surgical consultant and the primary care provider cannot be overstated. Patients undergoing biopsy should have results reported both to the surgeon and the primary care provider. More importantly, patients who do not require biopsy following surgical consultation should be returned to the routine screening process. This process is under the supervision of the primary care provider. Therefore, it is absolutely necessary for the primary care provider to know when the patient reenters the routine screening population. In the event that new symptoms arise or occur during the screening interval, the patient should be evaluated by the primary care physician using the primary care evaluation process stated in Algorithm I, Evaluation of Breast Mass in this guideline.

94. **Palpable Mass**

Patients with palpable masses referred to surgery should first be evaluated to determine the presence of a dominant and discrete mass.

95. **Consider Imaging Prior to Aspiration**

Consider an ultrasound and determine if the mass is solid or cystic.

96. **Aspirate Mass if Symptomatic**

If a palpable and discrete mass is present and symptomatic, an attempt should be made by the surgeon to aspirate the mass to rule out the presence of a simple cyst. An 18 to 25 gauge needle mounted on a syringe is inserted into an alcohol-prepped dominant breast mass for attempted aspiration.

97. **Residual Mass or Bloody Aspirate?**

A simple cyst is one that resolves with aspiration of non-bloody fluid. If fluid is clear and non-spontaneous (i.e., as in compression mammogram) a work-up is not always necessary as this is benign. Surgical excision should be performed for those cysts with bright red bloody aspirates and those that do not completely resolve with aspiration. A cyst that recurs may be re-aspirated, but the number of times this procedure can be repeated without surgical excision will depend upon the surgeon and patient's level of confidence that the lesion is benign.

Non-bloody fluids should be discarded based on a study where no cancers were detected among 6,747 non-bloody specimens.

Among 401 patients with cystic masses, only 4 had cancer and all had either bloody fluid or a residual mass. This would be demonstrated by palpation or imaging.

101. **Spontaneous Nipple Discharge**

Patients who present with nipple discharge or morphologic abnormality should be evaluated to determine the presence of bloody or unilateral discharge or palpable abnormality. Paget's disease of the nipple must be excluded. Open biopsy is recommended if any of these symptoms are present.

See Algorithm II, Evaluation of the Breast for Spontaneous Nipple Discharge.

103. **Breast Pain**

Patients with breast pain referred to the surgical department should be evaluated for any focal findings identified on physical examination or on mammography. Any abnormalities uncovered warrant biopsy before consideration of symptomatic treatment of the process.

See Algorithm III, Evaluation of Breast Pain.

106. **Suspicious Solid Mass? Abnormal Microcalcifications? Progressive Changes? Architectural Distortion?**

For patients referred with an abnormal mammogram, the surgeon should determine whether the above suspicious changes are present. If not, the patient should undergo a repeat mammogram in six months, at a minimum, to document stability of the lesion.

107. **Image-Directed Biopsy?**

Patients referred for biopsy based on the presence of a mammographic and/or sonographic finding highly suspicious for cancer will undergo either conventional open excisional biopsy or image-directed needle core biopsy. (See Algorithm V, Image-Directed Core Needle Biopsy.) Indications for biopsy are establishing a definitive diagnosis, finding multicentric lesions or associated intraductal pathology which may influence the choice to perform either mastectomy or breast conserving surgery for definitive treatment of the malignancy.

Image-directed core biopsy is the method of choice if sentinel lymph node study will be completed.

See the following algorithms in this guideline for other indications for open excisional breast biopsy:

- Radiologic Evaluation of the Breast
- Image-Directed Core Needle Biopsy
- Evaluation of the Breast for Spontaneous Nipple Discharge

110. **Open Biopsy**

Any questionable pathologic findings are indications for repeat biopsy by excision to rule out the presence of occult malignancy in the region of the mammographic abnormality.

112. **Definitive Therapy**

If cancer is diagnosed, definitive therapy may be performed on the basis of stereotactic core biopsy alone.

113. **Benign**

Benign fibroadenomas should be followed at routine screening intervals. However, if the patient is experiencing extreme pain and/or extreme tenderness, the fibroadenoma may be surgically removed or undergo cryotherapy.

114. **Return in 6 Months for Breast Examination**

If no focal findings are uncovered, a repeat examination within six months is warranted to rule out the presence of occult neoplastic process.

116. **Progression**

If the lesion is progressing in size and density or is otherwise worrisome, open biopsy is recommended.

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

CLINICAL ALGORITHM(S)

Seven detailed and annotated clinical algorithms are provided for diagnosis of breast disease:

- Evaluation by Primary Care of Patient with Symptoms of Potential Breast Disease (Main Algorithm)
- Evaluation of Breast Mass
- Evaluation of the Breast for Spontaneous Nipple Discharge
- Evaluation of Breast Pain
- Radiologic Evaluation of the Breast
- Image-Directed Core Needle Biopsy
- Surgical Evaluation of the Breast

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate and timely identification and diagnosis of breast abnormalities
- Earlier detection of breast disease
- Reduced morbidity and mortality associated with breast cancer

POTENTIAL HARMS

Side Effects of Medications

- *Danazol* may cause hair loss, acne, decrease in voice pitch, weight gain, irregular menses, and depression. There may also be a possible increase in venous thromboembolic events.
- Side effects of *bromocriptine* are dose related and include nausea, vomiting, headache, dizziness, and fatigue.
- *Tamoxifen* has significant side effects with the principle concerns being from thromboembolic disease and endometrial cancer. Additional side effects include hot flashes, nausea, menstrual irregularity, and vaginal dryness or discharge.
- In patients who receive *gadolinium contrast media* used in magnetic resonance imaging (MRI), there is the potential for renal toxicity and the rare complication (3% to 5% risk in patients with moderate to end-stage renal disease) of life-threatening nephrogenic systemic fibrosis. It is recommended that gadolinium use be avoided when possible in patients with advanced renal disease.

Disadvantages of Diagnostic Procedures

Magnetic resonance imaging and mammography combined may lead to an increase in false positives, resulting in higher rate of benign biopsies.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This Institute for Clinical Systems Improvement (ICSI) Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. If you are not one of the expert audiences, you are urged to consult a health care professional regarding your own situation and any specific medical questions you may have. In addition, you should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in your individual case.
- This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. An ICSI Health Care Guideline rarely will establish the only approach to a problem.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

Primary Care, Radiology, and Surgery

Establish a communication plan to include all providers involved in the patient's treatment plan:

- Patients undergoing biopsy should have results reported to the radiologist and/or surgeon performing the procedure as well as the primary care provider.

Primary Care

Establish a system for education of all female patients regarding self breast examination and age-appropriate mammographic screening intervals.

Develop a system for timely assessment of palpable breast masses including necessary imaging studies, follow-up, and referral to radiology or surgery for biopsy.

Radiology

Establish a process that ensures that abnormalities of the breast are accurately identified and sorted, and that all appropriate radiologic imaging studies necessary to the evaluation process are efficiently completed.

Surgery

Establish a process for timely completion of evaluation of breast lesions and provide additional surgical breast consultation as needed.

Documentation

Develop a system to document time frame from receipt of pathology to patient information.

- Telephone call documentation

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Pocket Guide/Reference Cards
Quality Measures

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

RELATED NQMC MEASURES

- Diagnosis of breast disease: percentage of class 4 or class 5 abnormal mammograms that are followed by a biopsy within 7 to 10 days.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jan. 47 p. [63 references]

ADAPTATION

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

DATE RELEASED

1994 Jan (revised 2008 Jan)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: icsi.info@icsi.org; Web site: www.icsi.org.

SOURCE(S) OF FUNDING

The following Minnesota health plans provide direct financial support: Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, Metropolitan Health Plan, PreferredOne, and UCare Minnesota. In-kind support is provided by the Institute for Clinical Systems Improvement's (ICSI) members.

GUIDELINE COMMITTEE

Committee on Evidence-Based Practice

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Michael Nelson, MD (Work Group Leader) (University of MN Physicians) (Radiology); Charles McCoy, MD (Park Nicollet Health Services) (Family Practice); Jay Gutenkauf, MD (HealthPartners Medical Group) (Family Practice); Ruth Johnson, MD (Mayo Clinic) (Internal Medicine); Joseph Tashjian, MD (St. Paul Radiology) (Radiology); Clive Grant, MD (Mayo Clinic) (Surgery); Omer Sanan, MD (Aspen Medical Group) (Surgery); Barbara Maclin, RN, OC (HealthPartners Medical Group) (Nursing); Sylvia Robinson, BSN, MBA (Institute for Clinical Systems Improvement) (Measurement and Implementation Advisor); Brent Metfessel, MD, MPH (Institute for Clinical Systems Improvement) (Evidence Analyst); Linda Setterlund, MA (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, the Institute for Clinical Systems Improvement (ICSI) has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic, but they are noted to fully inform readers. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline. Readers of the guideline may assume that only work group members listed below have potential conflict of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Nov. 51 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Diagnosis of breast disease. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2005 Nov. 1 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- ICSI pocket guidelines. May 2007 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2007.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

The following is available:

- Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement, 2006 May. 22 p.

Electronic copies: Available in Portable Document Format (PDF) from the Institute for Clinical Systems Improvement (ICSI) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on July 10, 2000. The information was verified by the guideline developer on April 25, 2001. This summary updated on March 15, 2002. The updated information was reviewed by the guideline developer as of April 25, 2002. This summary was updated again on September 3, 2003. The information was verified by the guideline developer on November 26, 2003. This summary was updated by ECRI on May 26, 2004, and most recently on January 11, 2006. This summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This summary was most recently updated by ECRI Institute on March 19, 2008.

COPYRIGHT STATEMENT

The abstracted ICSI Guidelines contained in this Web site may be downloaded by any individual or organization. If the abstracted ICSI Guidelines are downloaded by an individual, the individual may not distribute copies to third parties.

If the abstracted ICSI Guidelines are downloaded by an organization, copies may be distributed to the organization's employees but may not be distributed outside of the organization without the prior written consent of the Institute for Clinical Systems Improvement, Inc.

All other copyright rights in the abstracted ICSI Guidelines are reserved by the Institute for Clinical Systems Improvement, Inc. The Institute for Clinical Systems Improvement, Inc. assumes no liability for any adaptations or revisions or modifications made to the abstracts of the ICSI Guidelines.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 9/29/2008


DEPARTMENT OF HEALTH & HUMAN SERVICES • USA