

**Fourteenth Edition  
January 2012**

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- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

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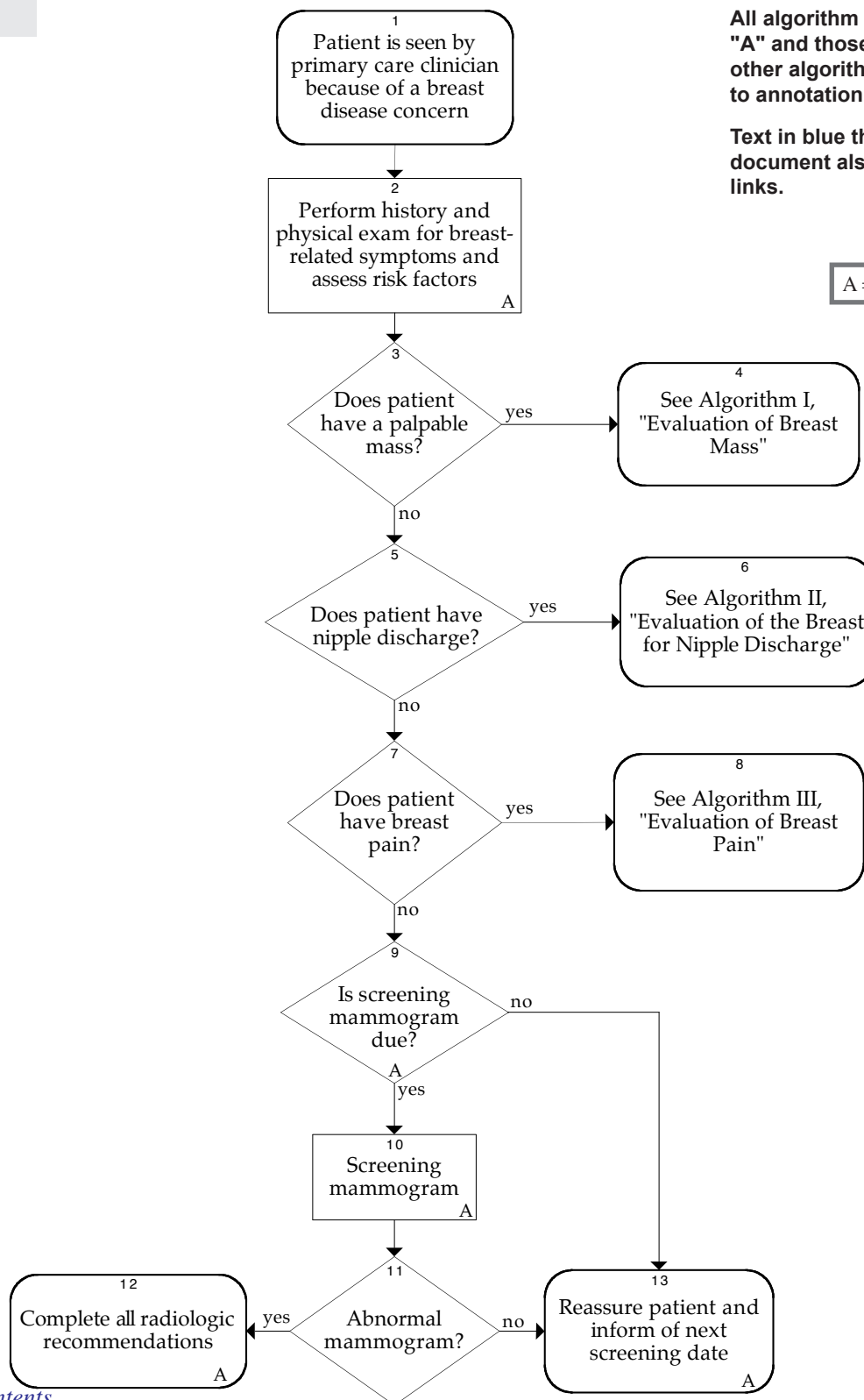
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**Evaluation by Primary Care of Patient with  
Symptoms of Potential Breast Disease**

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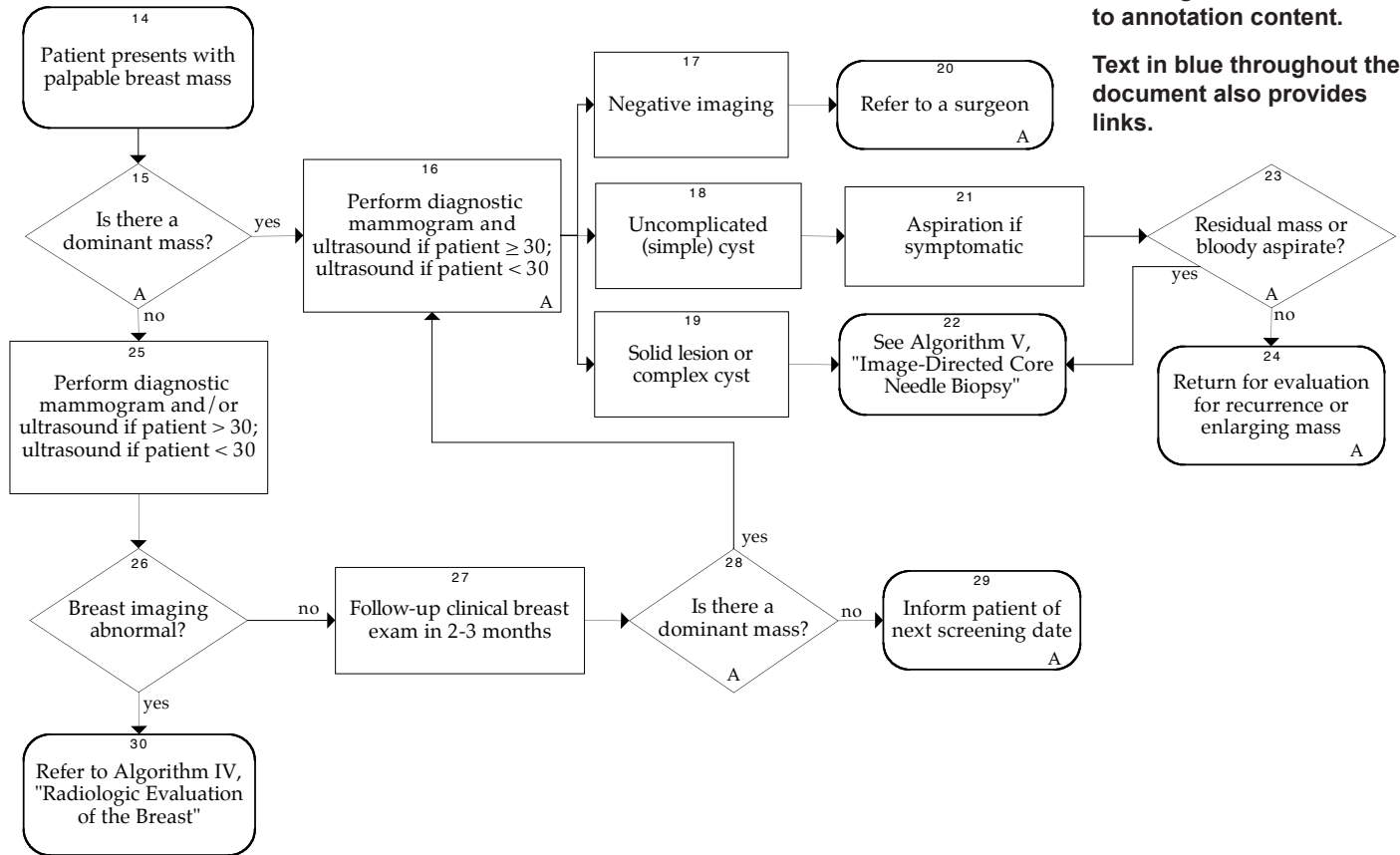
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# I. Evaluation of Breast Mass

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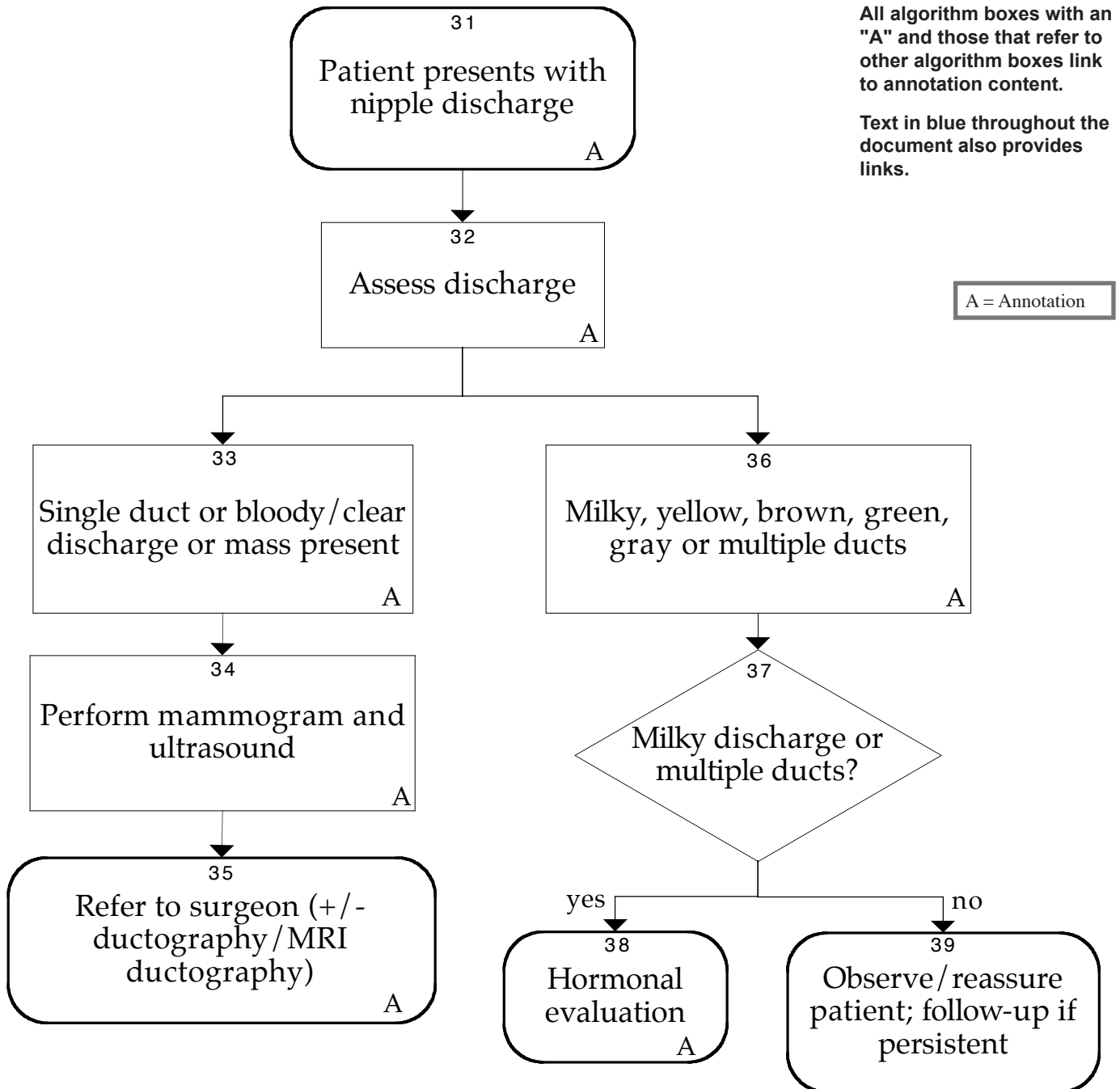
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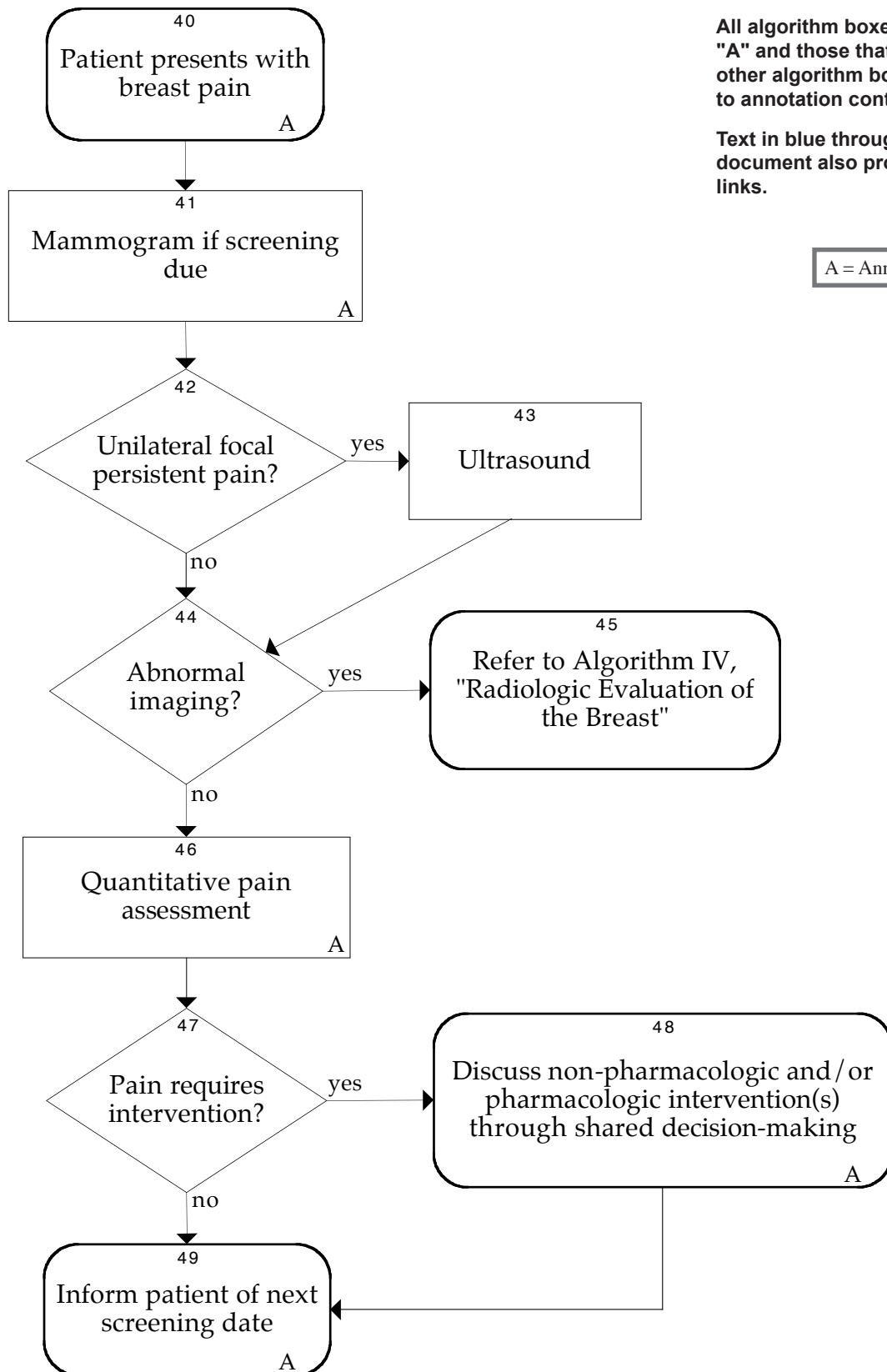
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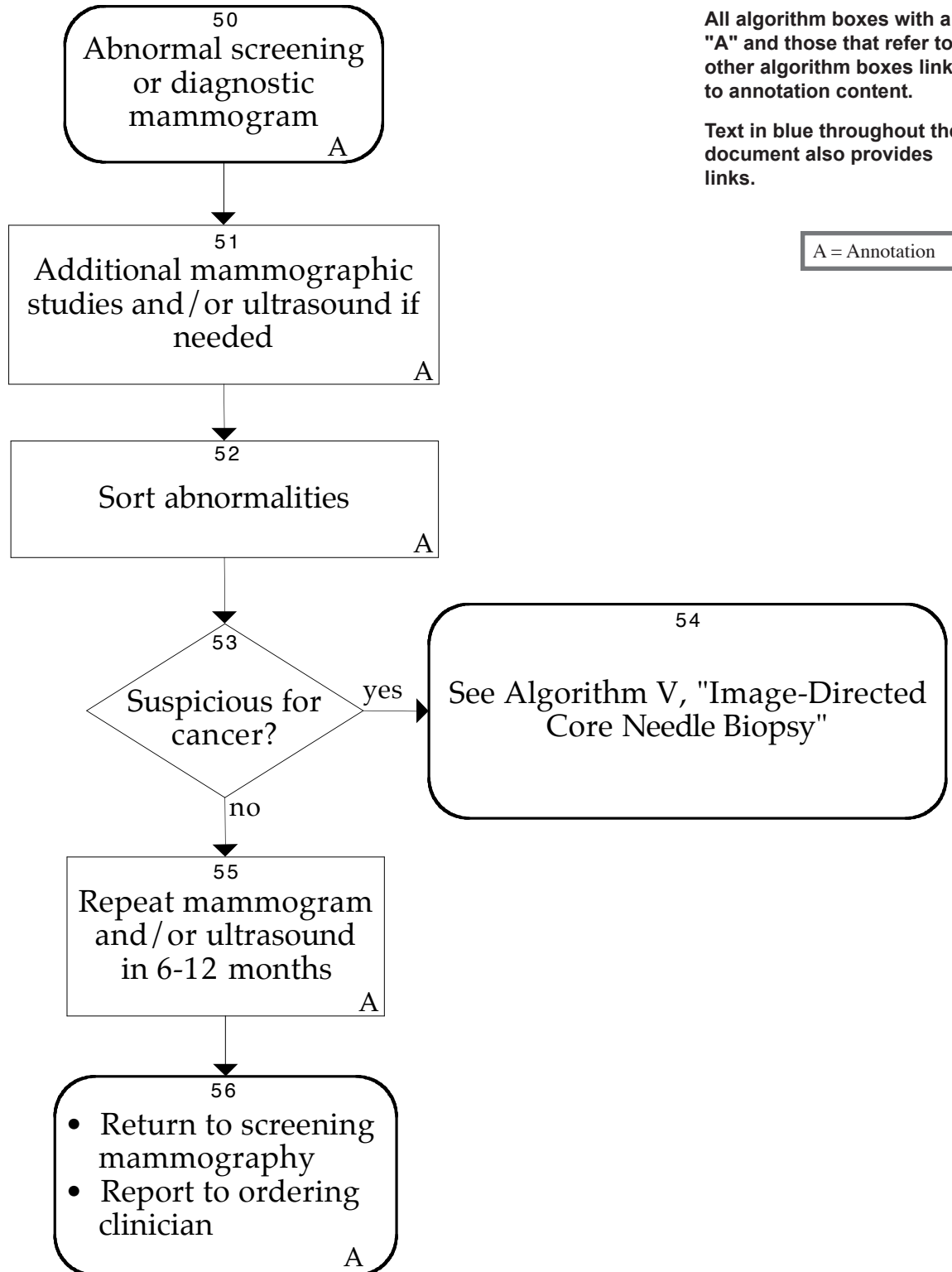


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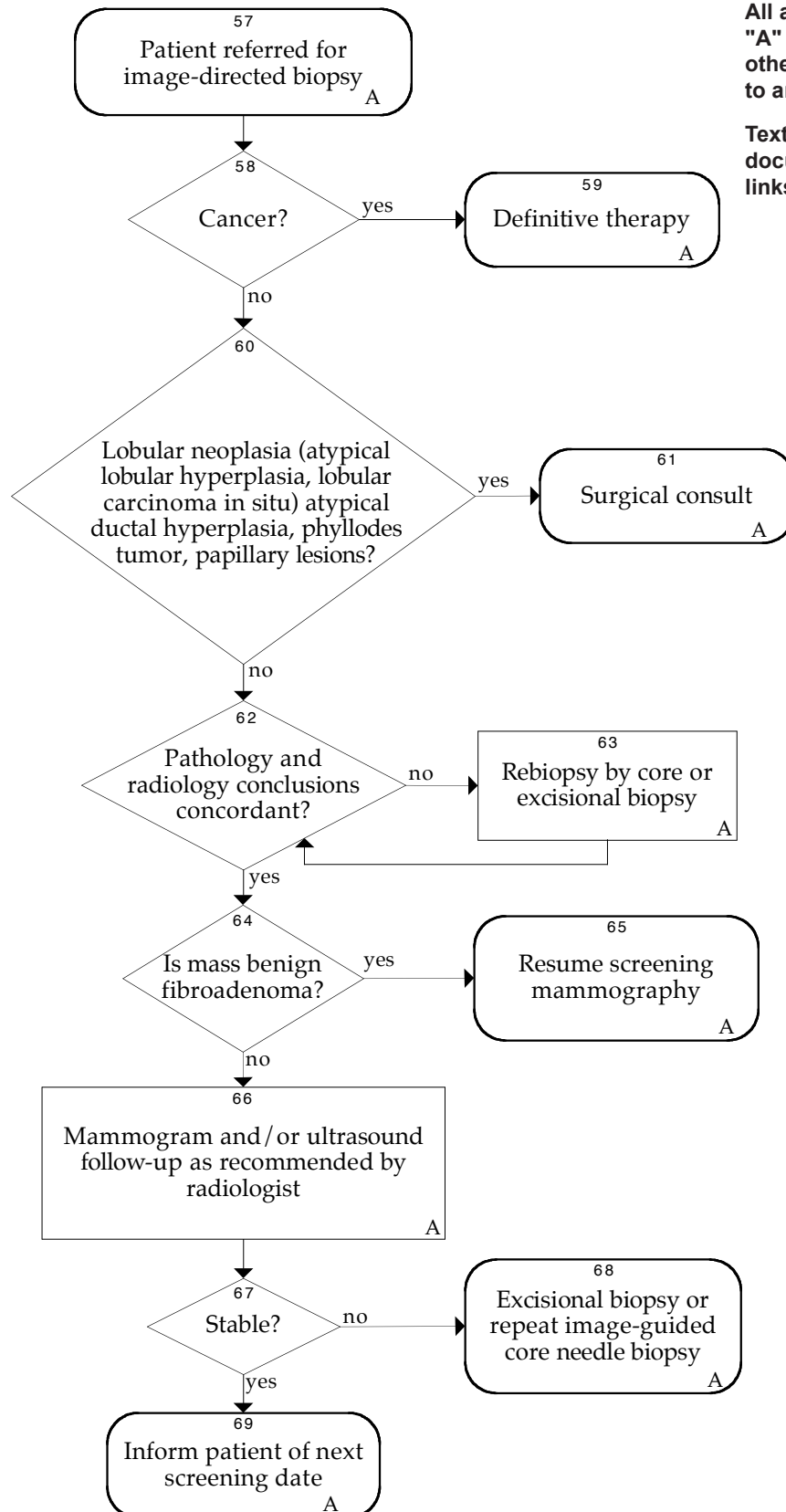
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## Disclosure of Potential Conflict of Interest

In the interest of full disclosure, 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. It is not assumed that these financial interests will have an adverse impact on content. They are simply noted here to fully inform users of the guideline.

Mary Lechner, MD, had received speaker's fees from Dilon Technologies in 2009.

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

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## Evidence Grading

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. Literature search terms for the current revision of this document include diagnosis of breast disease, MRI, mammography, breast pain and breast discharge from August 2009 through August 2011.

In 2011, ICSI began its transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system as a method of assessing the quality of evidence and writing recommendations.

GRADE has many advantages over other systems including these:

- Developed by a widely representative group of international guideline developers
- Explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings
- Clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations
- Clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy makers
- Explicit acknowledgement of values and preferences
- Explicit evaluation of the importance of outcomes of alternative management strategies

In the GRADE process, evidence is gathered related to a specific question. Systematic reviews are utilized first. Further literature is incorporated including randomized control trials, observational studies, etc. The evidence addresses the same population, intervention, comparisons and outcomes. The overall body of evidence for each topic is reviewed and then given a quality rating.

Once the quality of the evidence has been determined, recommendations are formulated to reflect their strength. The strength of a recommendation is either strong or weak. Only outcomes considered critical are the primary factors influencing a recommendation and are used to determine the overall quality of evidence supporting this recommendation. Each recommendation answers a focused health care question.

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**Description of Evidence**

<b>Category</b>	<b>Quality Definitions</b>	<b>Strong Recommendation</b>	<b>Weak Recommendation</b>
<b>High Quality Evidence</b>	Further research is very unlikely to change our confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
<b>Moderate Quality Evidence</b>	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
<b>Low Quality Evidence</b>	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

**Supporting Literature**

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader on other topics of interest. This literature is not given an evidence grade and is instead used as a reference for the associated topic and is found in the References section of this document.

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**Description of Evidence**

**Evidence-Based Recommendations Table**

The following table is a list of evidence-based recommendations for the diagnosis of breast disease. **Note: other recommendation language may appear throughout the document as a result of work group consensus or expert opinion, but it is not included in this evidence-based recommendations table.**

<b>Topic</b>	<b>Quality of Evidence</b>	<b>Recommendation(s)</b>	<b>Strength of Recommendation</b>	<b>Annotation Number</b>	<b>Relevant References</b>
Breast exam	Low	A clinical breast exam should be performed in the presence of breast-related symptoms.	Strong	2	<i>Barton, Smith</i>
Mammograms, screening	Moderate	Screening mammograms must be recommended every one to two years for women ages 50-75 years.	Strong	9	<i>Armstrong, Badgwell, Gøtzsche, Humphrey, Jonsson, Norman, Qaseem, Tabar</i>
	Moderate	Screening mammograms could be recommended to women ages 40-49 and over the age of 75.	Weak		
Mammograms, breast mass	Low	A mammogram and ultrasound should be obtained for patients with a breast mass. Patients under the age of 30 should receive an ultrasound.	Weak	16	<i>Pisano</i>
Image directed core biopsy	Low	Patients with a residual mass or a bloody aspirate should have an image-directed core biopsy or surgical consult.	Strong	28	<i>Ciatto, Hamed, Parker, Verkooijen</i>

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# Foreword

## Scope and Target Population

This guideline applies to all average risk patients who have a breast concern or abnormality.

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## Aims

1. Reduce the length of time between first knowledge of a breast abnormality and diagnostic resolution.
2. Ensure that patients with bloody or clear discharge have a mammogram (with or without an ultrasound) and are referred to a surgeon or radiologist.
3. Ensure that needle biopsies demonstrating abnormal findings are followed by performance of an excisional biopsy.
4. Ensure that all women with a breast concern that is indeterminate will have a follow-up clinical assessment within 6 to 12 months.

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## Clinical Highlights

- It is imperative that communications between the radiologic and surgical consultants and the primary care clinician are thorough and consistent. (*Annotation #20*)
- Patients with a bloody or clear discharge should be referred to a radiologist and/or surgeon for further evaluation. (*Annotation #35; Aim #2*)
- A persistent mass with negative imaging does not rule out malignancy and requires a referral to a surgeon. (*Annotations #20, 23*)
- Abnormal pathologic findings from image-directed biopsy requires a surgical consultation and possible excisional biopsy. (*Annotations #63, 66; Aim #4*)

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## Implementation Recommendation Highlights

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.

1. Primary Care, Radiology and Surgery:

Establish a communication plan to include all clinicians 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 clinician.

2. Primary Care:

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

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

3. 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.

4. Surgery:

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

5. Documentation:

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

- Telephone call documentation

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## Related ICSI Scientific Documents

### Guidelines

- [Assessment and Management of Chronic Pain](#)
- [Preventive Services for Adults](#)

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## Algorithm Annotations

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

#### 2. Perform History and Physical Exam for Breast-Related Symptoms and Assess Risk Factors

##### Recommendation:

- A clinical breast exam should be performed in the presence of breast-related symptoms. (*strong recommendation, low quality evidence*)

See also [Annotations #31, "Patient Presents with Nipple Discharge,"](#) and [#40, "Patient Presents with Breast Pain,"](#) 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 (*Smith, 2003*). 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 (*Barton, 1999*). Abnormalities detected during a clinical breast examination – such as masses or nodules, nipple discharge or inflammatory changes – require thorough evaluation and prompt treatment.

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#### 9. Is Screening Mammogram Due?

##### Recommendations:

- Screening mammogram must be recommended every one-two years for women ages 50-75 years (*strong recommendation, moderate quality evidence*).
- Screening mammograms could be recommended to women ages 40-49 and over the age of 75 (*weak recommendation, moderate quality evidence*).

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.

Regular mammographic screening has been shown to reduce mortality in breast cancer. The results of the mammogram are provided to the primary care physician for reporting to the patient (*Fletcher, 2003; Tabar, 2001; Jonsson, 2000*). Screening mammogram must be recommended every one-two years for women ages 50-75 years. Screening mammograms could be recommended to women ages 40-49 and over the age of 75. All women over age 40 should routinely be given the opportunity to receive information about breast cancer screening and informed decision-making (*Gøtzsche, 2011; Badgwell, 2008; Armstrong, 2007; Norman, 2007; Qaseem, 2007; Humphrey, 2002*).

See [Appendix A, "Breast MRI,"](#) for information on screening high-risk patients.

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## 10. Screening Mammogram

Regular mammographic screening has been shown to reduce mortality in breast cancer. The results of the mammogram are provided to the primary care physician for reporting to the patient (*Fletcher, 2003; Tabar, 2001; Jonsson, 2000*).

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## 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 clinician ordering the mammogram review the results of these studies to fully understand the impression of the radiologist, and to assure 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."](#)

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## 13. Reassure Patient and Inform of Next Screening Date

Refer to [Annotation #9, "Is Screening Mammogram Due?"](#) for recommended mammography screening intervals.

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# I. Evaluation of Breast Mass Algorithm Annotations

## 15. Is there a 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 (*Pruthi, 2001*).

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## 16. Perform Diagnostic Mammogram and Ultrasound If Patient $\geq 30$ ; Ultrasound If Patient $< 30$

### Recommendation:

- A mammogram and ultrasound should be obtained for patients with a breast mass. Patients under the age of 30 should receive an ultrasound (*strong recommendation, low quality evidence*).

Prior to the referral, a mammogram should be obtained. Patients under the age of 30 should receive an ultrasound. For women under age 50, digital mammography is preferable for dense breast tissue (*Pisano, 2005*). Also see [Annotation #50, "Abnormal Screening or Diagnostic Mammogram."](#)

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## 20. Refer to a Surgeon

Patients referred to the department of surgery for evaluation of breast disease will have undergone previous mammography that has demonstrated an abnormality that has been worked up and requires further surgical intervention, or the patient may be referred on the basis of a physical finding uncovered in the primary care clinician'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 coexist 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 clinician cannot be overstated. Patients undergoing biopsy should have results reported both to the surgeon and the primary care clinician. More importantly, patients who do not require biopsy following surgical consultation should be returned to the routine screening process only after the surgeon has completed full evaluation, including any interval follow-up exams, and is satisfied that the symptom does not represent malignancy. For example, if the surgeon feels that the symptom should be followed up in six months to document stability, this follow-up visit should take place with the surgeon. Once the surgeon is satisfied that no further follow-up is needed, the patient may return to routine screening. This process is under the supervision of the primary care clinician. Therefore, it is absolutely necessary for the primary care clinician 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."](#)

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## 23. Residual Mass or Bloody Aspirate?

### Recommendation:

- Patients with a residual mass or a bloody aspirate should have an image-directed core biopsy or surgical consult (*strong recommendation, low quality evidence*).

A simple cyst is one that resolves with aspiration of non-bloody fluid. If fluid is clear and non-spontaneous (e.g., as in compression mammogram), a workup is not always necessary, as this is benign. Surgical excision should be performed for those cysts with 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 (*Ciatto, 1987*).

Among 401 patients with cystic masses, only four had cancer and all had either bloody fluid or a residual mass. This would be demonstrated by palpation or imaging (*Hamed, 1989*).

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 proceed to image-directed core biopsy or surgical consult.

Bloody aspirate should be considered for cytology.

(*Silverstein, 2009; Schnitt, 1996*)

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## **24. Return for Evaluation for Recurrence or Enlarging Mass**

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

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## **28. Is There a Dominant Mass?**

Refer to [Annotation #15](#) for further information.

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

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

Refer to the [ICSI Preventive Services for Adults](#) guideline for mammography screening intervals.

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# **II. Evaluation of the Breast for Nipple Discharge Algorithm Annotations**

## **31. Patient Presents with 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, pathologic, persistent, unilateral vs. bilateral, single or multiple ducts, and its relation to menses, pregnancy, exercise, trauma, medications and/or thyroid disorders.

The site around the nipple should be examined for discharge upon pressure and for a mass. Hemocult test for blood may also be administered.

*(Schnitt, 1996; Winchester, 1996; Leis Jr, 1989; Urban, 1978)*

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## **32. Assess Discharge**

*Pathologic* discharges are spontaneous, may be associated with a mass, and are usually bloody, blood-containing or sometimes watery (clear). They are usually unilateral, involve a single duct, and are more worrisome in patients greater than 50 years old.

*Physiologic* discharges usually are bilateral, involve multiple ducts, are multicolored or milky, sticky and those that are stimulated rather than spontaneous.

*(Harris, 2009)*

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## **33. Single Duct or Bloody/Clear Discharge or Mass Present**

Bloody or, less commonly, clear watery discharge raises the possibility of cancer, although the most common causes of hemocult-positive discharges are benign.

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Secretory production of fluids other than milk may be due to a pathological process in the breast. The discharge is usually unilateral and localized to a single duct, persistent and spontaneous. It can be serous, sanguinous, or serosanguinous. The most common cause of pathologic nipple discharge is a papilloma (52 to 57%). A papilloma is a papillary tumor growing from the lining of the breast duct. The discharge associated with a papilloma can be clear or grossly bloody. Solitary papillomas can harbor areas of atypia or ductal carcinoma in situ (DCIS). Although there is some debate in the literature, the standard recommendation for management of papillomas is that they be excised whenever they are diagnosed (by core needle biopsy). The remainder of cases are caused by ductal ectasia or fibrocystic changes (14 to 32%). Malignancy is found in 5 to 15% of cases of pathologic nipple discharge. The most common malignancy associated with nipple discharge in the absence of other findings is DCIS. Age is predictive of the risk of cancer in women with nipple discharge. In one series of women with isolated nipple discharge, malignancy was present in 3% of those < 40 years of age, 10% of those 40 to 60 years of age, and 32% of those over 60 (*Goldshan, 2009*).

Bloody or clear discharge needs further evaluation to determine the etiology.

(*Bauer, 1998; Schnitt, 1996; Winchester, 1996*)

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### **34. Perform Mammogram and Ultrasound**

A mammogram and ultrasound should be obtained with presence of bloody or clear discharge to rule out malignancy. An ultrasound may be helpful to locate an intraductal nodule or duct ectasia 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.

Malignancy is found in 5 to 15% of cases of pathologic nipple discharge. The most common malignancy associated with nipple discharge in the absence of other findings is DCIS. Age is predictive of the risk of cancer in women with nipple discharge.

(*Goldshan, 2009; Winchester, 1996*)

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### **35. Refer to Surgeon (+/- Ductography/MRI Ductography)**

Most pathologic nipple discharges should be treated with duct excision. The use of ductography and/or MRI ductography is dependent on the decision of the surgeon and radiologist.

(*Dennis, 2000; Kenney, 2003; Klein, 2002 [R]*)

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### **36. Milky, Yellow, Brown, Green, Gray Discharge or Multiple Ducts**

The appearance of the fluid generally correlates with the cause. Yellow, brown, green or gray fluid is associated with fibrocystic change in most patients. Purulent discharge can result from duct ectasia or partial duct obstruction.

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### **38. Hormonal Evaluation**

Obtain prolactin and TSH levels to determine an endocrinologic basis for the nipple discharge. A prolactinoma typically causes a milky or clear discharge bilaterally (*Schnitt, 1996; Winchester, 1996*).

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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.) (*Schnitt, 1996; Winchester, 1996*).

If the mammogram and the endocrinology screening studies are normal, the patient should schedule a follow-up visit at the discretion of the responsible clinician. If the hormonal evaluation shows abnormal findings, patient should be referred to an endocrinologist for further evaluation.

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### **III. Evaluation of Breast Pain Algorithm Annotations**

#### **40. Patient Presents with Breast Pain**

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 (*Ader, 1997*). 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, association with redness or warmth of overlying skin 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 all medications and 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.

(*Ader, 2001; Dixon, 1999; Ader, 1997*)

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Breast pain is commonly categorized into three classifications (*Smith, 2004*):

- **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.

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## **41. Mammogram If Screening Due**

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. The risk of malignancy after normal findings on mammographic evaluation for breast pain is about only 0.5%. 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 (*Smith, 2004; Duijm, 1998*). Also see [Annotation #9, "Is Screening Mammogram Due?"](#) for further information.

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## **46. 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 (*Smith, 2004; Ader, 2001; Dixon, 1999*). For more information on pain assessment, see [ICSI Assessment and Management of Chronic Pain](#) guideline.

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## **48. Discuss Non-Pharmacologic and/or Pharmacologic Intervention(s) Through Shared Decision-Making**

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 (*Smith, 2004*). 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.

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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**

#### **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.

### **Complimentary and Alternative Medicine**

#### **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.

#### **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.

#### **Analgesics**

Analgesics, such as ibuprofen, may reduce breast pain.

#### **Danazol**

Danazol is approved by the United States Food and Drug Administration for fibrocystic conditions, which often cause breast pain.

Danazol relieves breast pain in 75-92% of women. 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 (*O'Brien, 1999*).

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According to the package labeling, thromboembolism, thrombotic and thrombophlebitic events have been reported including life-threatening or fatal strokes. Peliosis hepatitis and benign hepatic adenoma have also been reported with long-term use. Danazol may cause benign intracranial hypertension. Pregnancy must be ruled out prior to treatment.

### **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. The beneficial effects lasted three to six months after bromocriptine was discontinued (*Mansel, 1990*).

### **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 75-90% 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. Tamoxifen, like other hormonal interventions, should be reserved for women with severe mastalgia. Contraception must be utilized (*Fentimen, 1988*). In 2002, the Food and Drug Administration added a boxed warning stating that serious and life-threatening events (including stroke, pulmonary emboli and uterine malignancy) have occurred at an incidence greater than placebo during use for cancer risk reduction.

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm154510.htm>

### **Other medications**

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. Gestrinone, buserelin and quinagolide are not readily available within the United States. 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 (*Ader, 2001; BeLieu, 1994*).

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## **49. Inform Patient of Next Screening Date**

Refer to *Annotation #9, "Is Screening Mammogram Due?"* for recommended mammography screening intervals.

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# **IV. Radiologic Evaluation of the Breast Algorithm Annotations**

## **50. Abnormal Screening or Diagnostic Mammogram**

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

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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 clinician.

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## **51. 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. Additional projections, spot compression, magnification and/or ultrasound may be necessary to obtain further characterization of indeterminate lesions of the breast. In the event that a soft tissue mass is identified on the mammogram, further studies with ultrasound are required to determine its relative risk for malignancy. 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 and to allow for ultrasound directed intervention such as cyst aspiration if indicated (*Kolb, 2002; Kolb, 2000*).

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## **52. 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. In the event that a soft tissue mass is identified in the mammogram, further studies are required to determine its relative risk for malignancy. Should the mass not be immediately suspicious for cancer, an ultrasound should be performed (if not already done) to determine whether or not the lesion is solid.

In certain circumstances where diagnosis is difficult, a functional exam, either breast MRI or nuclear (molecular) imaging may be suggested by the radiologist or surgeon to sort out inconclusive cases. These cases may include:

- those with mammographic or ultrasound findings of uncertain significance (such as scar vs. tumor)
- multiple lesions
- metastatic lymph nodes with no known primary
- suspicious clinical findings without imaging abnormality
- the presence of silicone injections/implants or other problematic issues

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## **55. Repeat Mammogram and/or Ultrasound in 6-12 Months**

If further mammographic studies or sonography demonstrate findings that are felt to be Probably Benign, a repeat image of the breast at six months is warranted to document stability of low-risk, probably benign lesions. The term Probably Benign is an assessment category from the Breast Imaging and Reporting Data

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System (BI-RADS). If the six-month mammogram is felt to be benign, return in six months for yearly screening mammography.

**BI-RADS descriptors**

- BIRADS 0: Incomplete. Needs additional imaging.
- BIRADS 1: Negative.
- BIRADS 2: Benign findings.
- BIRADS 3: Probably benign. Short-interval follow-up.
- BIRADS 4: Suspicious finding. Consider biopsy.
- BIRADS 5: Highly suspicious for malignancy. Take appropriate action.

If BI-RADS descriptors are used appropriately, lesions placed in the BI-RADS 3 -Probably Benign category have a rate of malignancy lower than 2% (0.5-1.7%). Short-term imaging follow-up (six-month intervals for two years) will identify by interval progression almost all of the few lesions that actually are malignant. These cancers still have a very favorable prognosis at the time of diagnosis being early-stage cancers. The recommendation for surveillance should be given to the patient in person, immediately after completion of the full imaging workup, while the patient is still in the radiology department and should be done by the radiologist or radiology technologist who is sufficiently knowledgeable to provide a competent explanation of the rationale behind surveillance. Direct discussion with the patient should help to alleviate anxiety and also further ensure compliance.

*(Eberl, 2005; Varas, 2002)*

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## **56. Return to Screening Mammography/Report to Ordering Clinician**

If the lesion is of benign findings, the patient should be referred back to the screening process and completion of this evaluation should be reported to the ordering clinician. Refer to [Annotation #9, "Is Screening Mammogram Due?"](#) for mammography screening intervals.

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## **V. Image-Directed Core Needle Biopsy Algorithm Annotations**

### **57. Patient Referred for Image-Directed Biopsy**

**Recommendation:**

- Large core image-guided breast biopsy should be performed for biopsy of non-palpable breast masses and abnormal calcifications.

Patients referred for biopsy based on the presence of a mammographic and/or sonographic MRI nuclear molecular imaging finding that is suspicious for or highly suggestive of malignancy will undergo either conventional open excisional biopsy or large core needle biopsy (*Silverstein, 2009; Parker, 1996*).

Large core imaging-guided breast biopsy is now the technique of choice in most institutions in the United States for biopsy of non-palpable breast masses and abnormal calcifications based on decreased cost and less invasiveness. 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.

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Large core image-guided needle breast biopsy is recommended for tissue diagnosis in cases of obvious cancer, as it is less invasive and saves the patient an additional surgical procedure, is more cost effective and expedites the diagnostic process.

*(Verkooijen, 2000; Parker, 1996; Parker, 1994; Parker 1990)*

### **Current changes in breast disease diagnosis**

Over the past 20 years, advances in mammographic and sonographic technology have established a new subspecialty in radiology. Image-guided, vacuum-assisted breast biopsy, and core needle biopsy under image guidance have changed diagnostic breast biopsy from a surgical open biopsy to image-guided needle biopsy (*Silverstein, 2009*).

The following percutaneous techniques have been developed over the past 15 years:

- **Fine-needle aspiration (FNA):**  
A 22- to 24-gauge needle is used for cytology. This is best used with a cytopathology department. It is also used in abnormal cyst aspiration (where fluid is obviously benign). FNA has limited use in most community hospitals because of inadequate specimens (in 30-40% of FNA biopsies). Therefore, large core image-directed breast biopsy has replaced most FNA biopsies (*Liao, 2004; Norton, 1988; Pisano, 1998; National Cancer Institute Sponsored Conference, 1997; Mitnick, 1996*).
- **Core needle biopsy (CNB):**  
Spring-loaded devices are used for image-guided biopsies more than any other percutaneous needle. They may be used with solid lesions of any size, under ultrasound guidance (*Silverstein, 2009; Philpotts, 2003; Smith, 2001; Liberman, 1998b; Nguyen, 1996; Israel, 1995*).
- **Vacuum-assisted large core image-guided biopsy under stereotactic guidance:**  
Vacuum-assisted needles, 8, 9-, 11- or 12-gauge are used for microcalcifications, small masses or architectural distortion. Larger, vacuum-assisted electro-cautery devices may be used. These larger needles may help with avoiding undersampling and atypia diagnostic problems (*Dennis, 2000; Liberman, 1998a; Burbank, 1997; Meyer, 1997*).

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## **59. Definitive Therapy**

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

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## **61. Surgical Consult**

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 (*Jackman, 1997*).

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## **63. Rebiopsy by Core or Excisional 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, excisional 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.

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## **65. Resume Screening Mammography**

If the mass is a fibroadenoma, then follow up with mammogram or ultrasound in 6 to 12 months. However, if the patient is experiencing extreme pain and/or extreme tenderness, the fibroadenoma may be surgically removed or undergo cryotherapy (*Kaufman, 2005; Littrup, 2005*).

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## **66. Mammogram and/or Ultrasound Follow-Up as Recommended by Radiologist**

Patients who have benign results from stereotactic or image-guided biopsy may have a repeat mammogram and/or ultrasound. The radiologist should correlate the pathology results with the mammographic/sonographic abnormalities for all patients. If they do not correlate, rebiopsy with image-directed core needle or excisional biopsy is necessary.

*(National Comprehensive Cancer Network, 2009)*

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## **68. Excisional Biopsy or Repeat Image-Guided Core Needle Biopsy**

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

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## **69. Inform Patient of Next Screening Date**

Refer to [Annotation #9, "Is Screening Mammogram Due?"](#) for mammography screening intervals.

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This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Aims and Measures
  - Measurement Specifications
- Implementation Recommendations
- Resources
- Resources Table

## **Aims and Measures**

1. Reduce the length of time between first knowledge of a breast abnormality and diagnostic resolution.

Measures for accomplishing this aim:

- a. Average number of days between patient phone call about breast abnormality and RN or MD visit.
- b. Average number of days between a breast abnormality noted by RN or MD and a diagnostic workup to be maximum of 7-10.
- c. Percentage of BI-RADS category 4 or BI-RADS category 5 mammograms that are followed by a biopsy within 7-10 days.
- d. Average number of days between pathology report and documentation that patient was informed of results.

The ultimate goal is to decrease the time from identification of a breast abnormality to notification of the patient of biopsy results.

2. Ensure that patients with bloody or clear discharge have a mammogram (with or without an ultrasound) and are referred to a surgeon or radiologist.

Measure for accomplishing this aim:

- a. Percentage of patients with bloody or clear discharge who have a mammogram (with or without an ultrasound) and are referred to a surgeon or radiologist.

3. Ensure that needle biopsies demonstrating abnormal findings (any questionable or pathologic findings that do not correlate with imaging pathologic findings) are followed by performance of an excisional biopsy.

Measure for accomplishing this aim:

- a. Percentage of patients with a diagnosis of abnormal pathologic findings (lobular neoplasia, ductal hyperplasia with atypia, phylloides tumor, lobular carcinoma insitu [LCIS] or papillary lesions) on needle biopsy who subsequently have an excisional biopsy performed.

4. Ensure that all women with breast concern that is indeterminate will have a follow-up clinical assessment in two or three months.

Measure for accomplishing this aim:

- a. Percentage of women with an indeterminate breast concern who have a follow-up clinical exam within three months.

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## **Measurement Specifications**

### **Measurement #1c**

Percentage of BI-RADS category 4 or BI-RADS category 5 mammograms that are followed by a biopsy within 7-10 days.

### **Population Definition**

Women through age 74 with biopsy for possible diagnosis of breast cancer.

### **Data of Interest**

Percentage of BI-RADS category 4 or BI-RADS category 5 abnormal mammograms that are followed by a biopsy within 7-10 days.

### **Numerator/Denominator Definitions**

Numerator: Total # of patients with less than 10 days between the first documentation of a mammogram abnormality and a completed biopsy for all records reviewed.

Denominator: Total # of patients with an abnormal mammogram undergoing biopsy.

### **Method/Source of Data Collection**

A list of all patients with breast biopsies for mammogram abnormalities during the previous target period. The medical records can be reviewed to determine the number of days between first documentation of an abnormal mammogram and completion of a biopsy.

### **Time Frame Pertaining to Data Collection**

Data may be collected semiannually.

### **Notes**

The intent of this measure is to determine the time interval involved and provide a sense of the extent of "sleepless nights" for the patient.

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## Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization

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.

1. Primary Care, Radiology and Surgery:

Establish a communication plan to include all clinicians 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 clinician.

2. Primary Care:

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

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

3. 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.

4. Surgery:

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

5. Documentation:

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

- Telephone call documentation

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## Resources

### Criteria for Selecting Resources

The following resources were selected by the guideline work group as additional resources for clinicians and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

### Resources Available to ICSI Members Only

ICSI has knowledge resources that are *only* available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on Continuous Quality Improvement processes and Rapid Cycling that can be helpful. To obtain copies of these or other Resources, go to [Education and Quality Improvement](#) on the ICSI Web site. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge unless otherwise indicated.

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## Resources Table

Author/Organization	Title/Description	Web Sites/Order Information
Agency for Health Care Policy & Research (AHRQ)	Things to Know About Quality Mammograms	<a href="http://www.ahrq.gov">http://www.ahrq.gov</a> 800-358-9295
American Academy of Family Physicians	Web site includes recent articles about breast disease published in the journal of the academy.	<a href="http://www.aafp.org">http://www.aafp.org</a> 1-800-274-2237
American Cancer Society	Web site is rich in information about breast cancer risk factors, screening and treatment. Diagrams assist with understanding of breast anatomy and surgery. By calling organization, this educational information can be ordered: <ul style="list-style-type: none"> <li>- <i>For Women Facing Breast Cancer</i> (booklet, #4652.00)</li> <li>- <i>For Women Facing a Breast Biopsy</i> (English or Spanish)</li> <li>- <i>ABCs of Breast Health-A Personal Plan of Action</i> (#3416.01)</li> <li>- <i>The Older You Get, the More You Need a Mammogram</i> (#5020.00)</li> <li>- <i>Guidelines for the Early Detection of Cancer</i> (#2070.00)</li> <li>- <i>Breast Health</i> (#2048.00, available in multiple languages)</li> <li>- <i>Cancer Facts for Women</i> (#2007.00, Spanish available)</li> <li>- <i>After Diagnosis: A Guide for Patients and Families</i> (#9440.00)</li> </ul>	<a href="http://www.cancer.org/">http://www.cancer.org/</a>  Phone#: 800-ACS-2345
American College OB/GYN	Detecting and Treating Breast Lumps Early	<a href="http://www.acog.org">http://www.acog.org</a>
HealthEast Care System	Information from health library index includes topics related to breast disease, cancer and breast self-exam.	<a href="http://www.healtheast.org">http://www.healtheast.org</a>
Krames Experts in Patient Education	This educational literature can be ordered from Web site: <ul style="list-style-type: none"> <li>- <i>Breast Biopsy</i></li> <li>- <i>Stereotactic Breast Biopsy</i></li> </ul>	<a href="http://www.krames.com">http://www.krames.com</a>
Mayo Clinic	The Condition Center on Breast Cancer Web site provides information on frequently asked questions. A search on breast disease yields multiple topics. Women may e-mail questions to Mayo physicians.	<a href="http://www.mayoclinic.com">http://www.mayoclinic.com</a>
National Alliance of Breast Cancer Organizations (NABCO)	Calendar of conferences, as well as data from clinical trials. Information on choosing support groups. E-mail reminders of breast exam available.	<a href="http://www.nabco.org">http://www.nabco.org</a>

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**Resources Table**

<b>Author/Organization</b>	<b>Title/Description</b>	<b>Web Sites/Order Information</b>
National Cancer Institute	The latest information on cancer treatment at both the professional and lay public level, the latest cancer research news, and clinical trial information. Cancer information hotline and ability to search cancer scientific literature. All NCI publications are available online. Additionally, calling NCI can obtain: <ul style="list-style-type: none"> <li>• <i>What You Need to Know About Breast Cancer</i> (booklet)</li> <li>• <i>Mammograms: Not Just Once but for a Lifetime</i> (booklet)</li> </ul>	<a href="http://www.cancer.gov">http://www.cancer.gov</a> 1-800-4-CANCER
National Cancer Institute	Gail clinical risk assessment tool	<a href="http://www.cancer.gov/bcrisk-tool/">http://www.cancer.gov/bcrisk-tool/</a>
Park Nicollet Health Services	Mammography and Breast Cancer Screening (brochure)	<a href="http://www.icsi.org">http://www.icsi.org</a> Search: mammography
Susan G. Komen Breast Cancer Foundation	Advocacy and support information for special populations with breast cancer. Glossary of terms. Recent relevant breast cancer news items. Educational literature available to order through Web site includes: <ul style="list-style-type: none"> <li>- <i>Breast Health – Learn the Facts</i></li> </ul> By calling organization can order: <ul style="list-style-type: none"> <li>- <i>Breast Self-Exam Shower Card</i> (English &amp; Spanish)</li> </ul>	<a href="http://www.komen.org">http://www.komen.org</a> 1-800-462-9273
Y-Me National Breast Cancer Organization	Access available in English or Spanish. 24-hour toll-free hotline. Information on male breast cancer and advocacy. Information for partners supporting women with breast cancer. Men's match program to support male partners of women with breast cancer through trained phone volunteers.	<a href="http://www.y-me.org">http://www.y-me.org</a>

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The subdivisions of this section are:

- References
- Appendices

## References

Links are provided for those new references added to this edition (author name is highlighted in blue).

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## Appendix A – Breast MRI

The following women SHOULD undergo yearly breast MRI screening\* beginning at or around 30 years of age and consider continuing as long as the woman is in good health (however, there is no data about screening with MRI beyond 69 years of age).

- Known carriers of BRCA 1 or BRCA 2 mutations
- Patients with therapeutic radiation to the chest between ages 10 and 30
- First-degree relatives with known BRCA 1 or BRCA 2 mutations
- Clinical risk estimated at greater than 20% using clinical risk estimator (Claus or BRCAPRO models are some of the tools currently available). The work group also recommends the Gail screening assessment tool; however, there are some limitations with this as it is a population-based model. Refer to the Resources Tables for further information.
- Known Cowden's, Li-Fraumeni or Bannayan-Riley-Ruvalcaba Syndrome or first-degree affected relative

\* Recommended at six-month offset interval from yearly mammogram, as recommended by a radiologist  
(*Saslow, 2007*)

In women with increased lifetime risk due to strong family history or genetics, MRI has high sensitivity (up to 100%) for the detection of breast cancer when used as an adjunct to mammography. There is also evidence to support the use of MRI screening in women who were exposed to chest radiation as children or young adults. Because of the high rate of false positives, MRI screening should be recommended only to women at high risk of breast cancer. There is insufficient evidence to make recommendations for other groups of women (*Saslow, 2007; Lehman, 2005; MARIBS, 2005; Kriege, 2004; Warner, 2004; Stoutjesdijk, 2001*).

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

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

(*Saslow, 2007*)

### **Gadolinium warning**

In patients who receive gadolinium contrast media used in MRI, there is the potential for renal toxicity and the rare complication (3-5% 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. <http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM154532.pdf>

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## Appendix B – ICSI Shared Decision-Making Model

The technical aspects of Shared Decision-Making are widely discussed and understood. **Decisional conflict** occurs when a patient is presented with options where no single option satisfies all the patient's objectives, where there is an inherent difficulty in making a decision, or where external influencers act to make the choice more difficult. **Decision support** clarifies the decision that needs to be made, clarifies the patient's values and preferences, provides facts and probabilities, guides the deliberation and communication, and monitors the progress. **Decision aids** are evidence-based tools that outline the benefits, harms, probabilities and scientific uncertainties of specific health care options available to the patient.

However, before decision support and decision aids can be most advantageously utilized, a Collaborative Conversation™ should be undertaken between the provider and the patient to provide a supportive framework for Shared Decision-Making.

### Collaborative Conversation™

A collaborative approach toward decision-making is a fundamental tenet of Shared Decision-Making (SDM). The Collaborative Conversation™ is an inter-professional approach that nurtures relationships, enhances a patient's knowledge, skills and confidence as vital participants in his/her health, and encourages him/her to manage his/her health care. Within a Collaborative Conversation™, the perspective is that both the patient and the provider play key roles in the decision-making process. The patient knows which course of action is most consistent with his/her values and preferences, and the provider contributes knowledge of medical evidence and best practices. Use of Collaborative Conversation™ elements and tools is even more necessary to support patient, care provider and team relationships when patients and families are dealing with high stakes or highly charged issues. A diagnosis of a life-limiting illness presents such a circumstance.

The overall framework for the Collaborative Conversation™ approach is to create an environment in which the patient, family and care team work collaboratively to reach and carry out a decision that is consistent with the patient's values and preferences. A rote script or a completed form or checklist does not constitute this approach. Rather it is a set of skills employed appropriately for the specific situation. These skills need to be used artfully to address all aspects involved in making a decision: cognitive, affective, social and spiritual.

**Key communication skills** help build the Collaborative Conversation™ approach. These skills include many elements, but in this appendix only the questioning skills will be described. (For complete instruction, see O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007], and Bunn H, O'Connor AM, Jacobsen MJ "Analyzing decision support and related communication" [1998, 2003].)

#### 1. Listening skills:

**Encourage** patient to talk by providing prompts to continue such as *go on, and then?, uh huh*, or by repeating the last thing a person said, *It's confusing*.

**Paraphrase content of messages shared by patient** to promote exploration, clarify content and to communicate that the person's unique perspective has been heard. The provider should use his/her own words rather than just parroting what he/she heard.

**Reflection of feelings** usually can be done effectively once trust has been established. Until the provider feels that trust has been established, short reflections at the same level of intensity expressed by the patient without omitting any of the message's meaning is appropriate. Reflection in this manner communicates that the provider understands the patient's feelings and may work as a catalyst for further problem solving. For example, the provider identifies what the person is feeling and responds back in his/her own words like this: *"So, you're unsure which choice is the best for you."*

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**Summarize the person's key comments** and reflect them back to the patient. The provider should condense several key comments made by the patient and provide a summary of the situation. This assists the patient in gaining a broader understanding of the situations rather than getting mired down in the details. The most effective times to do this are midway through and at the end of the conversation. An example of this is "*You and your family have read the information together, discussed the pros and cons, but are having a hard time making a decision because of the risks.*"

**Perception checks** ensure that the provider accurately understands a patient or family member, and may be used as a summary or reflection. They are used to verify that the provider is interpreting the message correctly. The provider can say, "*So you are saying that you're not ready to make a decision at this time. Am I understanding you correctly?*"

## 2. Questioning Skills

**Open and closed questions** are both used, with the emphasis on open questions. Open questions ask for clarification or elaboration and cannot have a yes or no answer. An example would be "*What else would influence you to choose this?*" Closed questions are appropriate if specific information is required such as "*Does your daughter support your decision?*"

Other skills such as summarizing, paraphrasing and reflection of feeling can be used in the questioning process so that the patient doesn't feel pressured by questions.

Verbal tracking, referring back to a topic the patient mentioned earlier, is an important foundational skill (Ivey & Bradford-Ivey). An example of this is the provider saying, "*You mentioned earlier...*"

## 3. Information-Giving Skills

**Providing information** and **providing feedback** are two methods of information giving. The distinction between providing information and giving advice is important. Information giving allows a provider to supplement the patient's knowledge and helps to keep the conversation patient centered. Giving advice, on the other hand, takes the attention away from the patient's unique goals and values, and places it on those of the provider.

**Providing information** can be sharing facts or responding to questions. An example is "*If we look at the evidence, the risk is...*" **Providing feedback** gives the patient the provider's view of the patient's reaction. For instance, the provider can say, "*You seem to understand the facts and value your daughter's advice.*"

## Additional Communication Components

Other elements that can impact the effectiveness of a Collaborative Conversation™ include:

- Eye contact
- Body language consistent with message
- Respect
- Empathy
- Partnerships

Self-examination by the provider involved in the Collaborative Conversation™ can be instructive. Some questions to ask oneself include:

- Do I have a clear understanding of the likely outcomes?
- Do I fully understand the patient's values?

- Have I framed the options in comprehensible ways?
- Have I helped the decision-makers recognize that preferences may change over time?
- Am I willing and able to assist the patient in reaching a decision based on his/her values, even when his/her values and ultimate decision may differ from my values and decisions in similar circumstances?

### **When to Initiate a Collaborative Conversation™**

A Collaborative Conversation™ can support decisions that vary widely in complexity. It can range from a straightforward discussion concerning routine immunizations to the morass of navigating care for a life-limiting illness. Table 1 represents one health care event. This event can be simple like a 12 year old coming to the clinic for routine immunizations, or something much more complex like an individual receiving a diagnosis of congestive heart failure. In either case, entering the clinic or receiving a diagnosis of a life-limiting illness is the catalyst that starts the process represented in this table. There are cues for providers and patient needs that exert influence on this process. They are described below. The heart of the process is the Collaborative Conversation™. The time the patient spends within this health care event will vary according to the decision complexity and the patient's readiness to make a decision.

Regardless of the decision complexity, there are cues applicable to all situations that indicate an opportune time for a Collaborative Conversation™. These cues can occur singularly or in conjunction with other cues.

### **Cues for the Care Team to Initiate a Collaborative Conversation™**

- **Life goal changes:** Patient's priorities change related to things the patient values such as activities, relationships, possessions, goals and hopes, or things that contribute to the patient's emotional and spiritual well-being.
- **Diagnosis/prognosis changes:** Additional diagnoses, improved or worsening prognosis.
- **Change or decline in health status:** Improving or worsening symptoms, change in performance status or psychological distress.
- **Change or lack of support:** Increase or decrease in caregiver support, change in caregiver, change in caregiver status, change in financial standing, difference between patient and family wishes.
- **Change in medical evidence or interpretation of medical evidence:** Providers can clarify the change and help the patient understand its impact.
- **Provider/caregiver contact:** Each contact between the provider/caregiver and the patient presents an opportunity to reaffirm with the patient that his/her care plan and the care the patient is receiving and consistent with his/her values.

Patients and families have a role to play as decision-making partners, as well. The needs and influencers brought to the process by patients and families impact the decision-making process. These are described below.

### **Patient and Family Needs within a Collaborative Conversation™**

- **Request for support and information:** Decisional conflict is indicated by, among other things, the patient verbalizing uncertainty or concern about undesired outcomes, expressing concern about choice consistency with personal values, exhibiting behavior such as wavering, delay, preoccupation, distress or tension. Generational and cultural influencers may act to inhibit the patient from actively participating in care discussions, Often patients need to be given "permission" to participate as partners in making decisions about his/her care.

Support resources may include health care professionals, family, friends, support groups, clergy and social workers. When the patient expresses a need for information regarding options and his/her potential outcomes, the patient should understand the key facts about options, risks and benefits, and have realistic expectations. The method and pace with which this information is provided to the patient should be appropriate for the patient's capacity at that moment.

- **Advance Care Planning:** With the diagnosis of a life-limiting illness, conversations around advance care planning open up. This is an opportune time to expand the scope of the conversation to other types of decisions that will need to be made as a consequence of the diagnosis of a life-limiting illness.
- **Consideration of Values:** The personal importance a patient assigns potential outcomes must be respected. If the patient is unclear how to prioritize the preferences, value clarification can be achieved through a Collaborative Conversation™ and by the use of decision aids that detail the benefits and harms of potential outcomes in terms the patient can understand.
- **Trust:** The patient must feel confident that his/her preferences will be communicated and respected by all caregivers.
- **Care Coordination:** Should the patient require care coordination, this is an opportune time to discuss the other types of care-related decisions that need to be made. These decisions will most likely need to be revisited often. Further, the care delivery system must be capable of delivering coordinated care throughout the continuum of care.
- **Responsive Care System:** The care system needs to support the components of patient- and family-centered care so the patient's values and preferences are incorporated into the care he/she receives throughout the care continuum.

The Collaborative Conversation™ Map is the heart of this process. The Collaborative Conversation™ Map can be used as a stand-alone tool that is equally applicable to providers and patients as shown in Table 2. Providers use the map as a clinical workflow. It helps get the Shared Decision-Making process initiated, and once on its way, provides navigation for the process. Care teams can use the Collaborative Conversation™ to document team best practices and to formalize a common lexicon. Organizations can build fields from the Collaborative Conversation™ Map in his/her electronic medical records to encourage process normalization. Patients use the Map to prepare for decision-making, to help guide them through the process and to share critical information with his/her loved ones.

### **Evaluating the Decision Quality**

Adapted from O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007].

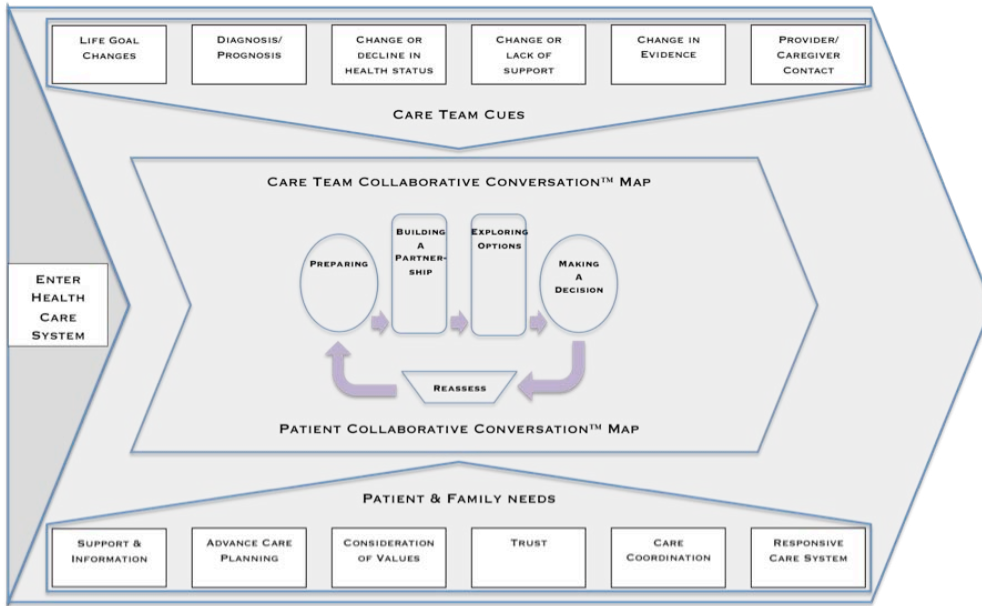
When the patient and family understand the key facts about the condition and his/her options, a good decision can be made. Additionally, the patient should have realistic expectations about the probable benefits and harms. A good indicator of the decision quality is whether or not the patient follows through with his/her chosen option. There may be implications of the decision on patient's emotional state such as regret or blame, and there may be utilization consequences.

Decision quality can be determined by the extent to which the patient's chosen option best matches his/her values and preferences as revealed through the Collaborative Conversation™ process.

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Appendix B – ICSI Shared Decision-Making Model

Table One

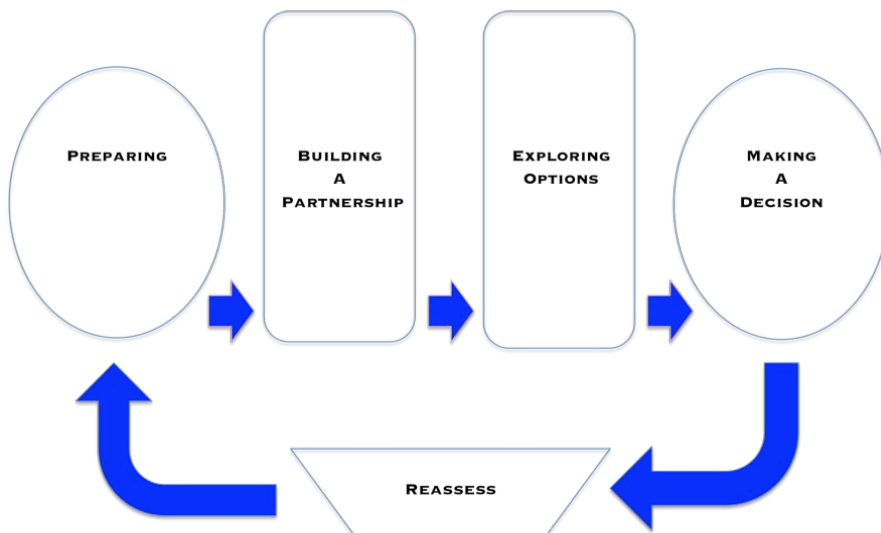


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Table Two

SDM COLLABORATIVE CONVERSATION™ MAP



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### Document History

- In 2000 the Breast Cancer Diagnosis guideline became the Diagnosis of Breast Disease guideline. In 2003 the Breast Cancer Treatment guideline was merged into the Diagnosis of Breast Disease guideline.
- In 2011 the document utilized GRADE methodology in evaluating evidence and making recommendations.

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*The next scheduled revision will occur within 24 months.*

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## **ICSI Document Development and Revision Process**

### **Overview**

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

### **Document Development and Revision Process**

The development process is based on a number of long-proven approaches. ICSI staff first conducts a literature search to identify pertinent clinical trials, meta-analysis, systematic reviews, regulatory statements and other professional guidelines. The literature is reviewed and graded based on the ICSI Evidence Grading System.

ICSI facilitators identify gaps between current and optimal practices. The work group uses this information to develop or revise the clinical flow and algorithm, drafting of annotations and identification of the literature citations. ICSI staff reviews existing regulatory and standard measures and drafts outcome and process measures for work group consideration. The work group gives consideration to the importance of changing systems and physician behavior so that outcomes such as health status, patient and provider satisfaction, and cost/utilization are maximized.

Medical groups that are members of ICSI, review each guideline as part of the revision process. The medical groups provide feedback on new literature, identify areas needing clarification, offer recommended changes, outline successful implementation strategies and list barriers to implementation. A summary of the feedback from all medical groups is provided to the guideline work group for use in the revision of the guideline.

### **Implementation Recommendations and Measures**

Each guideline includes implementation strategies related to key clinical recommendations. In addition, ICSI offers guideline-derived measures. Assisted by measurement consultants on the guideline development work group, ICSI's measures flow from each guideline's clinical recommendations and implementation strategies. Most regulatory and publicly reported measures are included but, more importantly, measures are recommended to assist medical groups with implementation; thus, both process and outcomes measures are offered.

### **Document Revision Cycle**

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. Each ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group mid-cycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

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