



CRICO Breast Care Management Algorithm

A DECISION SUPPORT TOOL

Created: 1995
Revised: 2000, 2003, 2010
Current: 2014

crico

Improving Breast Patient Safety

Failure to diagnose breast cancer at an early stage affects CRICO-insured providers across a spectrum of specialties. To reduce the likelihood of such events, a task force of breast care specialists and primary care physicians, coordinated by CRICO, identified the key factors contributing to allegations of mismanaged breast care and subsequently developed the CRICO *Breast Care Management Algorithm*. The recommendations within the CRICO *Algorithm* are based on either a) broadly accepted evidence or b) conservative practices which may lack supportive evidence, but represent proven risk management strategies (and pose no risk of patient harm). Our goal is to aid primary care providers at various decision points across three domains of breast health care:

- asymptomatic women eligible for screening,
- individuals seeking an assessment of their risks for developing breast cancer, and
- patients who present with specific breast complaints.

The CRICO *Algorithm* is designed to help providers of primary breast care appropriately use available diagnostic tools. The provider is expected to gather information such as family history, atypia on previous biopsy, thoracic radiation before age 30, and reproductive risk factors to determine if changes to normal screening, or a referral to high-risk counseling, is indicated.

Even after a referral, providers of primary breast care have an ongoing responsibility for tracking and coordinating their patients' routine breast care. In addition to being a tenet of good care, comprehensive provider follow-up is a significant safeguard against allegations of failure to diagnose breast cancer.

The CRICO *Breast Care Management Algorithm* is a suggested guideline and should not be construed as a standard of care. Respected experts endorse differing recommendations, especially for mammographic screening, and physicians may choose to follow alternate recommendations as their standard practice.

RISK MANAGEMENT FOR BREAST CARE

Self-detected mass: The majority of CRICO's failure to diagnose breast cancer cases involve a patient-detected mass, lump, or thickening. Whether or not you can confirm a mass, the patient presenting with a self-detected lump must be followed to conclusion.

Risk factors: Assessment—and periodic updating—of a patient's personal and family history ensures timely age- and risk-stratified breast cancer screening, including appropriate referrals to high risk counseling.

Test results: Primary care providers and radiologists must coordinate the process for communication of all test results to the patient and for confirming receipt of all results by the ordering provider.

Follow up: Document follow-up testing recommendations and communicate the follow-up plan to the patient and all responsible providers.

Referrals: For a patient referred to a specialist, make sure to coordinate the care among providers and clarify for the patient the specific roles and responsibilities.

CRICO's Breast Cancer Diagnosis-related Cases

**29 cases asserted 2008–2012;
\$27.2 million total incurred losses**

(i.e., aggregate of expenses, reserves, and payments on open and closed cases).

PHYSICIAN DEFENDANTS NAMED

52	radiology
10	general medicine
4	ob/gyn
3	pathology
1	general surgery
1	oncology surgery

PATIENT AGE

2	30–39 years old
15	40–49 years old
8	50–59 years old
3	60–69 years old
1	age unknown

BREAKDOWNS IN THE PROCESS OF CARE

STEP	# CASES	TOTAL INCURRED
1. Patient seeks care	0	\$0
2. History/physical/evaluation	8	\$8,144,000
3. Order of diagnostic/lab tests	11	\$12,254,000
4. Performance of tests	4	\$3,786,000
5. Interpretation of tests	23	\$23,250,000
6. Receipt/transmittal of test results	0	\$0
7. Physician follow up with patient	6	\$5,936,000
8. Referral management	5	\$5,255,000
9. Patient compliance with follow-up plan	3	\$1,994,000

A case may involve multiple breakdowns.

ADHERENCE ACROSS CRICO WITH THE BREAST CARE MANAGEMENT ALGORITHM

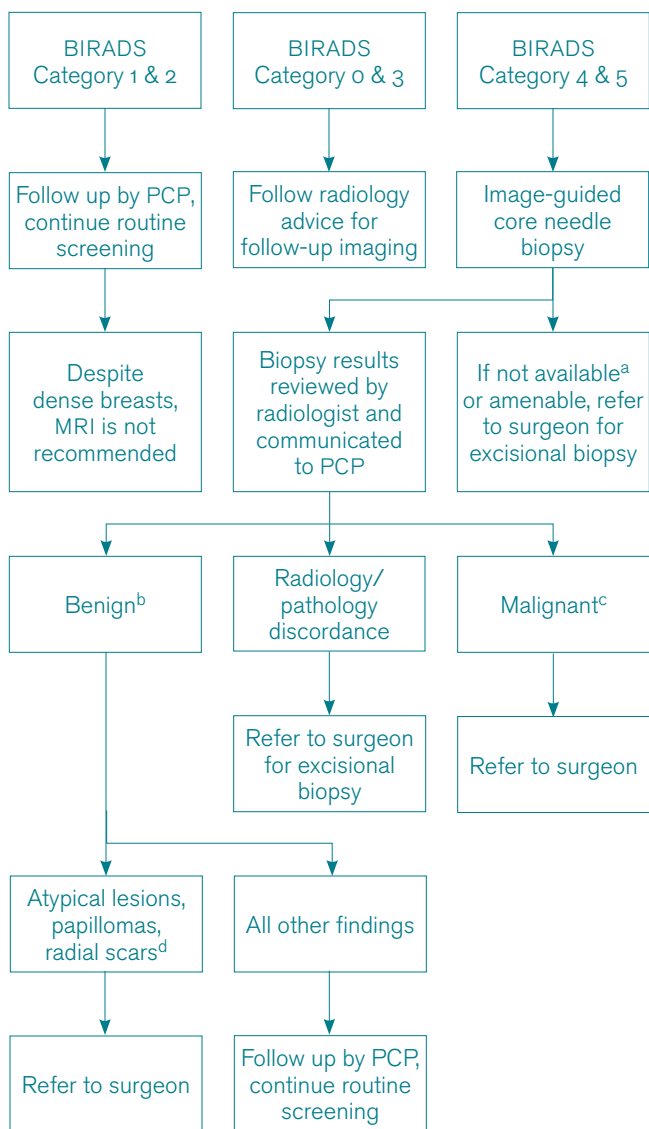
A review of medical records for patients who sought care by a CRICO-insured provider for a complaint of breast lump, mass, or thickening indicates the following rates of adherence with the recommendations embedded in this guideline (N=1,305 records reviewed 2007–2011)

GUIDELINE	RECORDS SHOWING ADHERENCE
Capture personal history of predisposing breast conditions	83%
Capture family history of breast cancer	62%
Clinical breast exam at time of discovery	95%
Review of diagnostic tests at the time of the breast complaint	91%
Recommendations for women age <30	54%
Recommendations for women age ≥30	77%

Risk Assessment and Recommendations (based on NCCN Guidelines)

PATIENTS WITH A GENETIC PREDISPOSITION TO BREAST CANCER	RECOMMENDATIONS
<ul style="list-style-type: none"> Known carrier of a BRCA1 or BRCA2 mutation, or close relative with known mutation Known carrier or close relative with another hereditary breast cancer syndrome gene^b 	<p>Beginning at age 25, clinical breast exam (CBE) at least once per year.^a</p> <p>Annual mammogram and MRI beginning at age 25 or individualized based on earliest age onset in family. Preliminary data suggest that alternating MRI and mammography every six months may be helpful.</p>
PATIENTS WITHOUT A KNOWN GENETIC PREDISPOSITION TO BREAST CANCER	RECOMMENDATIONS
<p>Personal history: genetic testing criteria</p> <ul style="list-style-type: none"> Breast cancer diagnosed at age ≤ 40, or Ovarian cancer at any age <p>Family history: genetic testing criteria</p> <ul style="list-style-type: none"> Breast cancer (or DCIS) at age ≤ 40 or ovarian cancer (any age) in 1st degree relative, or in paternal 2nd degree relative Breast cancer (or DCIS) and ovarian cancer in one 1st or 2nd degree relative, or in close relatives in the same lineage Male relative(s) with breast cancer Any 1st or 2nd degree relative with breast cancer age < 50 Two relatives in the same lineage with early onset breast cancer Women of Ashkenazi Jewish ancestry may be included despite fewer affected relatives or later age onset 	<p>These criteria should prompt consideration of genetic testing.</p> <ul style="list-style-type: none"> Women who test positive should follow the recommendations above. Women in a family with a known mutation who test negative are true negative and should follow the recommendations for patients at usual risk (below). Women without a known mutation in the family who test negative should be referred to a genetics center. If possible, genetic testing should be performed with a genetic counselor or genetics expert.
<p>Therapeutic thoracic radiation (e.g. Hodgkins) before age 30^c</p>	<p>In women over age 25, annual mammogram starting 8–10 years after completion of radiation, or by age 40.</p> <p>Consider CBE at least once per year beginning at age 25.</p> <p>Consider annual MRI in addition to annual mammogram.</p>
<p>Histology</p> <ul style="list-style-type: none"> Lobular carcinoma in situ (LCIS) History of ductal carcinoma in situ (DCIS) History of invasive breast cancer Atypical ductal or lobular hyperplasia (ADH or ALH) (consider using the Gail Model for risk assessment) 	<p>Annual mammogram after diagnosis</p> <p>CBE at least once per year</p> <p>Consider referral to high-risk counseling or risk reducing medication.</p>
<p>Reproductive and other risk factors</p> <ul style="list-style-type: none"> Menarche before age 12 Nulliparity First birth after age 30 Prior breast biopsy > 5 years of combined estrogen/progesterone hormone replacement therapy 	<p>For a patient age ≥ 35 with a constellation of these risk factors, consider assessment via the Gail Model to determine her level of risk for breast cancer.</p> <p>For patients with Gail Model five-year risk ≥ 1.67: CBE at least once per year, annual mammogram, consider high-risk counseling or risk reducing medication.^d</p>
PATIENTS AT USUAL RISK	RECOMMENDATIONS
<p>None of the above risk factors, or a Gail Model value < 1.67</p>	<p>Annual mammogram, beginning at age 40.^{e,f}</p> <p>Consider CBE every 1–3 years until age 40, then annually.</p>
<p>Gail Model (for women age ≥ 35)</p> <p>The Gail Model calculates actuarial estimates of future breast cancer risk based on race, age, reproductive risk factors, maternal family history, and previous biopsy status. The computerized version of the Gail Model is available at: www.cancer.gov/bcrisktool.</p> <p>The Gail Model calculates the risk of developing cancer over the next five years. The Gail Model may underestimate the risk for patients with a strong family history of breast or ovarian cancer.</p>	<p>Notes</p> <ol style="list-style-type: none"> The efficacy of clinical breast exams (CBEs) has not been evaluated independent of mammography. Clinicians might, however, consider a periodic CBE as an opportunity to engage their patients in discussion about overall breast evaluation. Li-Fraumeni syndrome, Cowden's disease, Peutz-Jeghers syndrome, hereditary diffuse gastric cancer, other. Risk from therapeutic radiation is much greater than risk from diagnostic radiation. The risk from internal thymus radiation, fluoroscopy for TB, or multiple X-rays for scoliosis is not well quantified. Patient may also be eligible for risk reducing clinical trials. Screening recommendations for patients at usual risk vary among experts. The CRICO Breast Care Management Algorithm recommendations are based on the 2013 NCCN Guidelines. The decision to start regular, biennial screening mammography before age 50 should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms. (USPSTF)

SCREENING MAMMOGRAM
(not appropriate for women with breast complaints)



Screening by Age

Screening recommendations for patients at usual risk vary among experts. The following recommendations are based on the 2013 NCCN Guidelines.

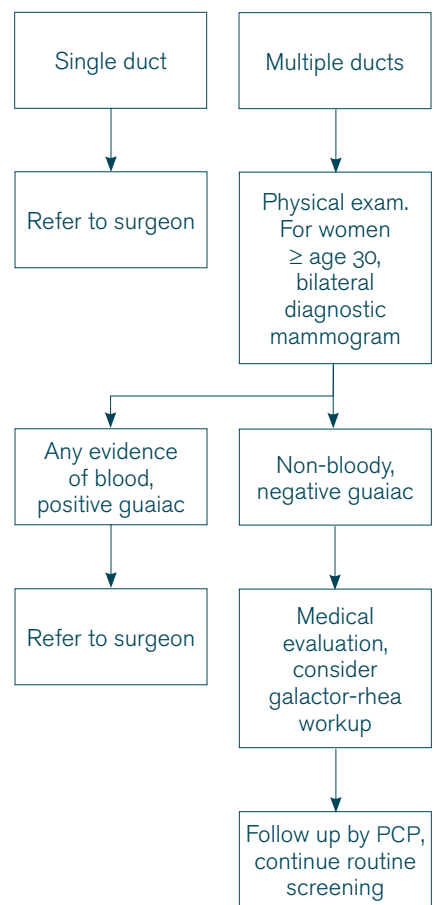
- Women 40–69 years old should be screened annually.
- Women more than 70 years old should be screened at least biennially, with consideration for overall quality of life.

Screening Technology

- Overall, digital mammography is of equivalent sensitivity to film/screen mammography.
- Digital mammography has slightly better sensitivity than film/screen mammography for women less than age 50, with dense breasts, and/or pre-menopausal.
- Data do not support the use of whole breast ultrasound or MRI as screening tools for women at usual risk with or without dense tissue or numerous calcifications.

a. Patients should be informed about their options for image-guided core needle biopsy.
 b. Consider referral to surgeon for excision of mass > 2cm.
 c. Ductal carcinoma in situ or invasive cancer.

SPONTANEOUS NIPPLE DISCHARGE
with no palpable mass (non-lactating)

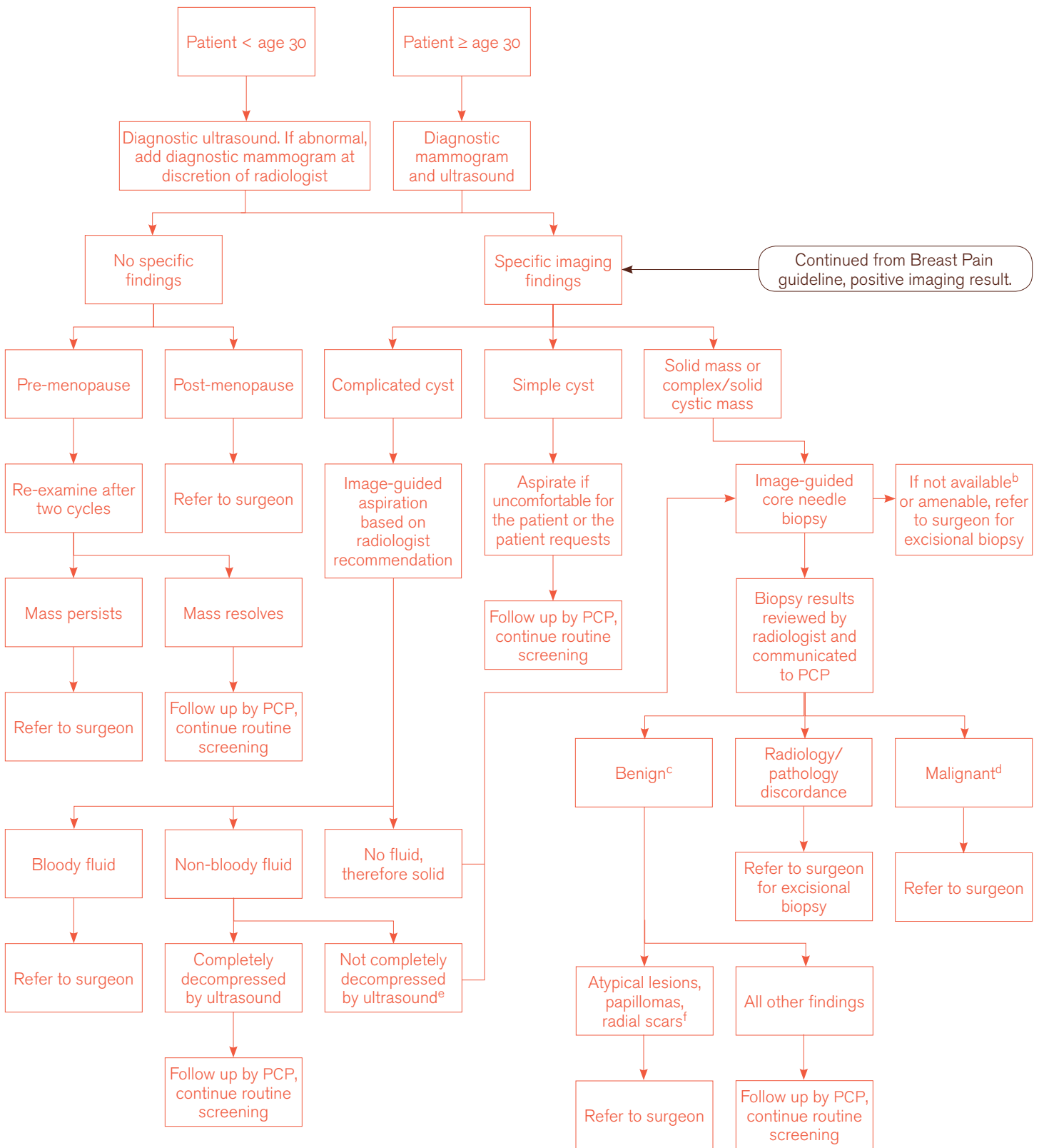


American College of Radiology Breast Imaging Reporting and Data System (BIRADS)

- 0 Assessment is incomplete; additional imaging needed
- 1 Negative
- 2 Benign finding
- 3 Probably benign finding—short interval follow-up suggested. Probable risk of breast cancer 2%.
- 4 Suspicious abnormality—biopsy should be considered. Probable risk of breast cancer:
 - a) low suspicion (<15%)
 - b) intermediate suspicion (15–60%)
 - c) high suspicion (60–95%)
- 5 Highly suspicious of malignancy—do biopsy. Probable risk of breast cancer is greater than 95%.
- 6 Known biopsy-proven malignancy—appropriate action should be taken.

d. Lesions that may fit this category include LCIS, atypical lobular hyperplasia, atypical ductal hyperplasia, radial scar (benign sclerosing lesion), some papillary lesions, mucin-producing lesions, and potential phyllodes tumor.

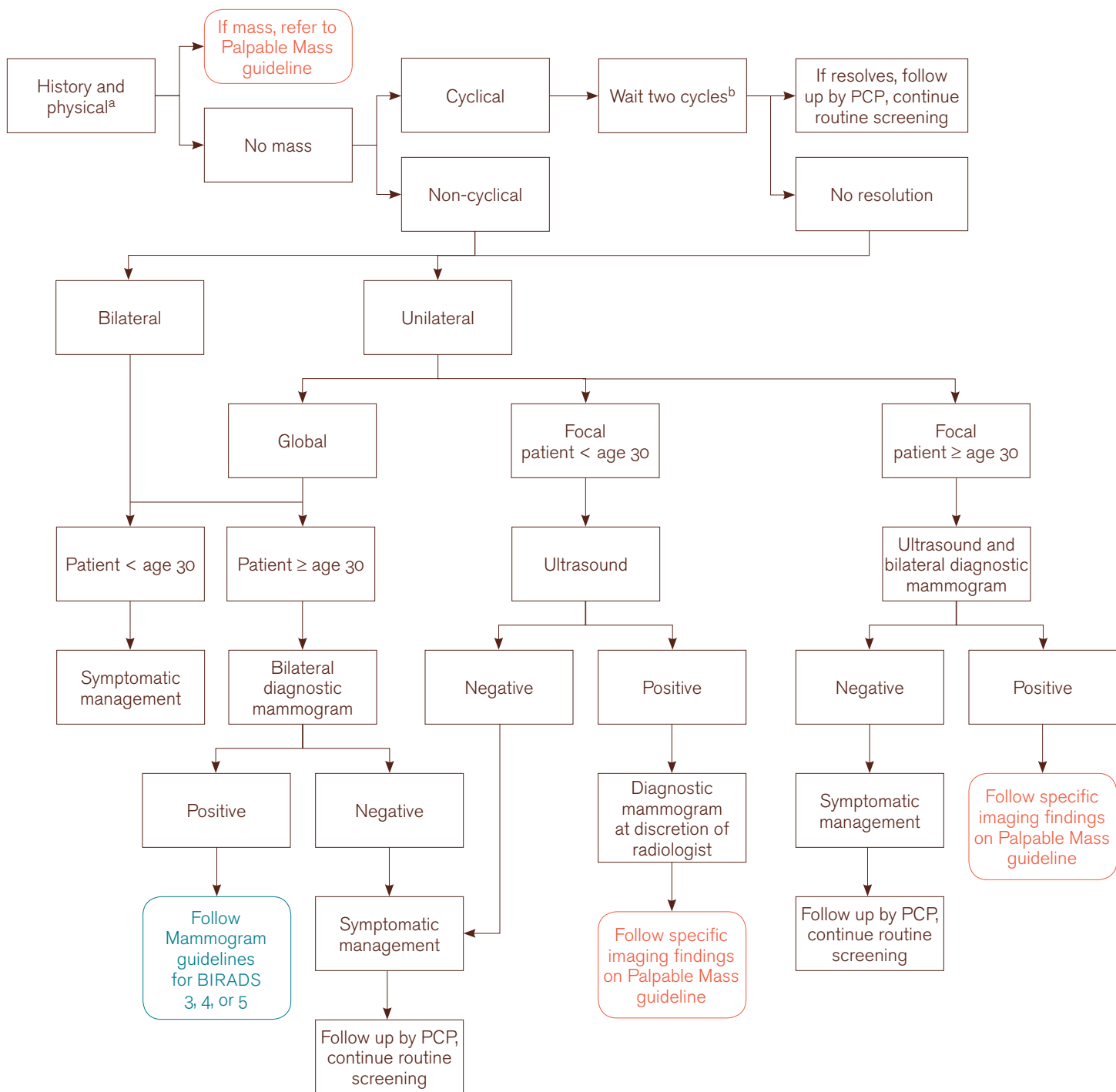
PALPABLE MASS DETECTED OR CONFIRMED BY CLINICIAN^a



a. If the physician does not concur with the patient regarding the presence of a mass, confirm that routine screening is up to date. Advise the patient to return if her concern or symptoms persist or change.
 b. Patients should be informed about their options for image-guided core needle biopsy.
 c. Consider referral to surgeon for excision of mass >2cm.

d. Ductal carcinoma in situ or invasive cancer.
 e. Image-guided core needle biopsy or ultrasound after two cycles at discretion of radiologist.
 f. Lesions that may fit this category include LCIS, atypical lobular hyperplasia, atypical ductal hyperplasia, radial scar (benign sclerosing lesion), some papillary lesions, mucin-producing lesions, and potential phyllodes tumor.

BREAST PAIN



a. Differential diagnosis includes: chest wall pain, costochondritis, cervical radiculopathy, MI, lung disease, hiatal hernia, cholelithiasis, thoracic aortic dissection, aortic aneurysm, post partum mastitis.

b. Cycles if premenopausal; months if postmenopausal.

The CRICO *Breast Care Management Algorithm* is a decision support tool for the evaluation of breast health and the care of a patient with a breast complaint. It is intended for use by clinicians providing primary breast care. It should not be construed as a standard of care.

REFERENCE ARTICLES

Berg WA, Blume JD, Adams AM, et al. Reasons women at elevated risk of breast cancer refuse breast MR imaging screening: ACRIN 6666. *Radiology*. 2010;254:79–87

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Screening for Breast Cancer, Topic Page. November 2009. U.S. Preventive Services Task Force. Rockville, MD. <http://www.ahrq.gov/clinic/uspstf/uspstfbrca.htm>.

Nelson HD, Zakher B, Cantor A, et al. Risk factors for breast cancer for women aged 40 to 49 years: a systematic review and meta-analysis. *Annals of Internal Medicine*. 2012 May;156(9):635–48.



The entire CRICO *Breast Care Management Algorithm*, along with related information and links, is available at www.rmfm.harvard.edu/guidesbreasts

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Physician-Patient Discussion and Take-home Points Related to Breast Patient Safety

PATIENT-DETECTED LUMP/MASS

A self-discovered lump should be followed to resolution even if there is provider-patient discordance on the presence of the lump. Follow every mass to conclusion.

PATIENT UNSATISFIED WITH A NEGATIVE FINDING

Engage the patient in a discussion about her breast care management subsequent to negative test/imaging results. Develop a clear and effective plan, and ensure the patient's understanding and agreement of that plan.

Document all interactions as they occur to support future care and to clarify any disputes that may arise later. This includes:

- in the history and physicals section of the record, include the findings of the breast examination (note—in quotes—what the patient said, as well as your own findings);
- for a confirmed lump or lesion, use a diagram to record the exact location; and
- for an unconfirmed mass, record—in the patient's words—the location and nature of the complaint.

SIGNIFICANCE OF EARLY DETECTION OF BREAST CANCER

Without reliable evidence that early detection of breast cancer can significantly reduce the risk of mortality, health care providers cannot guarantee a cure based on the timing of the diagnosis. Patients may need to be educated as to the rigors and subtleties of research data, and discrepancies in findings among various studies.

RISK OF BREAST CANCER FOR WOMEN YOUNGER THAN AGE 30

Although the level of risk for women under 30 is much lower than for older women, it is not non-existent (an approximately 1

in 2,000 chance of being diagnosed with breast cancer at an early age).¹ Women with multiple risk factors—especially those that indicate a high level of risk and possible BRCA1/BRCA2 gene mutation—should be concerned about the possibility of early breast cancer.

COMMUNICATION

- Communicate all abnormal findings to the patient and document that act.
- Avoid sending the wrong message to a patient by just telling her that a palpable lump is probably benign. Stress that additional studies may be needed to rule out malignancy.
- Share any uncertainty on your part in a way that helps your patient appreciate the importance of adherence to follow-up.
- Confirm and document with other providers which of you will be the clinician of record and responsible for ordering tests and following up with the patient.

TEST RESULTS

- Explain to the patient how test results will be communicated to her and (if appropriate) other clinicians.
- Document any telephone conversations with patients regarding the reported results.
- To ensure notification of test results, employ a system to track ordered tests through the receipt and communication to the patient.

FOLLOW UP

- Make follow-up or test appointments before the patient leaves your office.
- Physicians and patients share responsibility for follow up; explain to your patients your tracking and compliance system (contacting patients a day or two before their follow-up appointments can reduce non-adherence).

- Track all surgical referrals to ensure that you are receiving a timely report from the surgeon.
- Ask the Radiology department, breast care center, or specialist to notify your office of patients who do not keep scheduled appointments. Document all patient no-shows or cancellations.
- If a patient refuses follow up, explain the risks of not having a recommended diagnostic test or procedure. Note the patient's refusal for follow up in the record; consider using an informed refusal form signed by the patient.

DOCUMENTATION

- Document a thorough breast examination in the history and physical examination; enter, in quotes, the patient's breast complaints and what she says.
- Use a diagram to record the exact location of all confirmed lumps or lesions.
- For an unconfirmed mass, record—in the patient's words—the location and nature of the complaint.
- In the event that a patient's breast care is being managed by another clinician, document the date of the patient's last exam to ensure that subsequent exams are performed when appropriate.
- During each visit, update the patient's risk factor assessment and your recommendations for screening based on that patient's current risk for developing breast cancer.
- Consider using a problem list to highlight patients with a positive family history of breast cancer.

Reference

- ¹ Siegal R, Naishadham D, Jemal A. Cancer statistics, 2012. *CA: A Cancer Journal for Clinicians*. 2012;62:10–29.