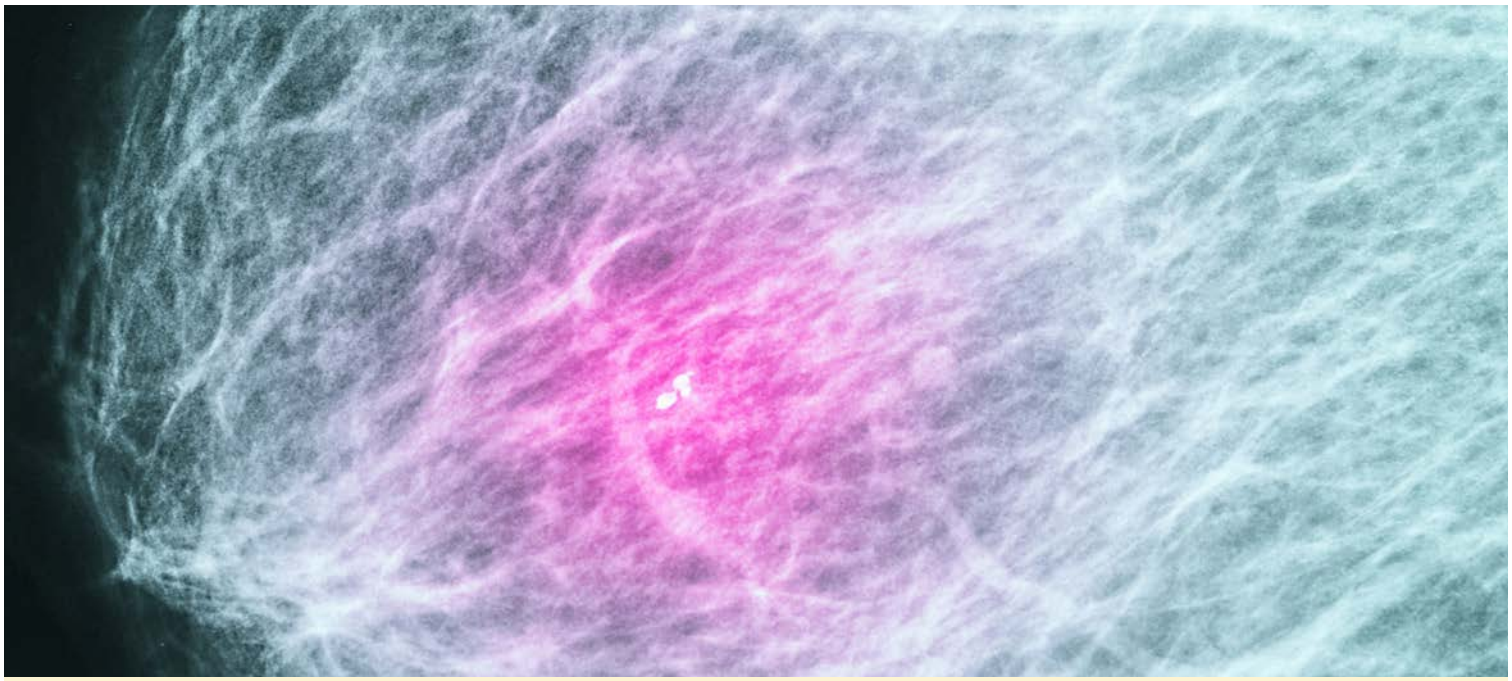


CRICO Breast Care Management Algorithm

A DECISION SUPPORT TOOL

Created: 1998
Revised: 2000, 2003, 2010, 2014
Current: 2019

crico

Improving Breast Patient Safety

Failure to diagnose breast cancer 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 a responsibility for tracking and coordinating their patients' ongoing 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; care plans for individual patients must be based on the provider's professional judgment. 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 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.

Periodic breast cancer risk assessment discussion: Review family history and any other risk factors at least every five years.

Breast Density: For patients with normal or benign findings on mammogram who are identified as having dense breasts, provide access to information explaining the impact of density on their overall breast cancer risk (and on the ability to detect cancer), and the risks and benefits of any follow-up screening options.

Risk factors: Assess—and periodically update—a patient's personal and family history to promote timely age- and risk-stratified breast cancer screening, including appropriate referrals to high-risk counseling.

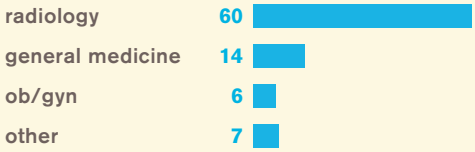
Follow up: Document follow-up testing recommendations (including for tests reported as not completed) and communicate the follow-up plan to the patient and all responsible providers.

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

47 cases asserted 2008–2017

PHYSICIAN DEFENDANTS NAMED



PATIENT AGE

BREAKDOWNS IN THE PROCESS OF CARE

	STEP	% CASES
1.	Patient seeks care	0%
2.	History / physical / evaluation	9%
3.	Patient assessment / evaluation of symptoms	28%
4.	Diagnostic processing	14%
5.	Order of diagnostic / lab tests	40%
6.	Performance of tests	9%
7.	Interpretation of tests	74%
8.	Receipt / transmittal of test results	0%
9.	Physician follow up with patient	28%
10.	Referral management	9%
11.	Provider-provider communication	7%
12.	Patient compliance with follow-up plan	12%

A case may involve multiple breakdowns.

Breast Cancer Assessment

Suggested Guidelines for Asymptomatic Patients

1

Update the patient's personal and family history for cancers (especially breast and ovarian).

FAMILY HISTORY

- Note the relationship (i.e., parent, sibling, aunt, uncle) and the age at onset for each relative
- First degree relative = parent, sibling, child
- Second degree relative = other blood relatives excluding great-grandparents and cousins

2

Review the criteria for recommending genetic testing (for patients without a known genetic predisposition to breast cancer) and advise patients accordingly.

CLINICAL BREAST EXAMS

- 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. For patients at elevated risk, annual CBEs should be considered as part of the comprehensive assessment.

MAMMOGRAMS

- Screening recommendations for patients at usual risk vary among experts. The *CRICO Breast Care Management Algorithm* recommendations are based on the 2016 United States Preventive Services Task Force (USPSTF) and the National Comprehensive Cancer Network recommendations.
- 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)

3

Assess the patient's risk status, including increased risk for patients:

1. **with a known genetic predisposition to breast cancer,**
2. **who underwent therapeutic radiation before age 30,**
3. **with a history of atypical hyperplasia, or**
4. **with reproductive risk factors (see page 3).**

RISK PREDICTION MODELS

- For women ≥ age 35, prediction models establish their 5- or 10-year risk. Commonly used tools include:
  - **The Gail Model**, which calculates actuarial estimates of future breast cancer risk based on race, age, reproductive risk factors, maternal family history, and previous biopsy status. The Gail Model calculates the risk of developing cancer over the next five years. Note that the Gail Model may underestimate the risk for patients with a strong family history of breast or ovarian cancer. [bcrisktool.cancer.gov]
  - **The Breast Cancer Surveillance Consortium Risk Calculator** calculates 5- and 10-year breast cancer risk estimates based on age, race/ethnicity, family history, history of a breast biopsy, and breast density. [tools.bcsc-scc.org]
- For patients with a significant family history of breast cancer, consider models such as Claus or Tyler-Cusick, or a referral for genetic testing.

Breast Cancer Screening
Considerations and Recommendations

...for patients with a known genetic predisposition to breast cancer

KNOWN CARRIER OF A BRCA1 OR BRCA2 MUTATION (HIGH PENETRANCE BREAST CANCER PREDISPOSING GENES)

- Untested individual with known close relative with BRCA1 or BRCA2 mutation
- Known carrier or untested individual with known close relative with another hereditary breast cancer syndrome gene (Li-Fraumeni syndrome, Cowden's disease, Peutz-Jeghers syndrome, hereditary diffuse gastric cancer, other)

RECOMMENDATIONS

- Beginning at age 25, CBE at least once per year
- 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.
- If close relative, consider genetic testing

...for patients without a known genetic predisposition to breast cancer

PATIENTS WHO SHOULD CONSIDER GENETIC TESTING

- Personal history of breast cancer diagnosed at age ≤ 50
- Personal history of ovarian cancer at any age
- Male relative with breast cancer
- 1st- or 2nd-degree relative diagnosed with breast cancer at < age 50
- 1st-degree relative, or (paternal) 2nd-degree relative diagnosed with DCIS at age ≤ 40 or ovarian cancer (any age)
- A diagnosis of breast cancer (or DCIS) and ovarian cancer in a single 1st- or 2nd-degree relative—or two close relatives in the same lineage
- 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

RECOMMENDATIONS

- For women whose genetic test results are positive, follow the recommendations above
- For women whose genetic test results are negative:
  - 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 in a family without a known mutation who test negative should be referred to a genetics center. If possible, genetic testing should be performed with a genetic counselor or genetics expert.
  - Consider breast MRI for patients with a lifetime risk of breast cancer > 20% as defined by BRACPRO or other models that are largely dependent on family history.

...for patients with a higher than usual risk for breast cancer

THERAPEUTIC THORACIC RADIATION (E.G. HODGKINS) AGE < 30

- Risk from therapeutic radiation is much greater than risk from diagnostic radiation. The risk from infant thymus radiation, fluoroscopy for TB, or multiple X-rays for scoliosis is not well quantified.

RECOMMENDATIONS

- Annual mammogram beginning 8–10 years after radiation or at age 25
- Consider CBE at least once per year beginning at age 25
- Annual MRI in addition to annual mammogram

HISTOLOGY

- 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

RECOMMENDATIONS

- Annual mammogram after diagnosis
- CBE at least once per year
- Consider referral to high-risk counseling or risk reducing medication

REPRODUCTIVE AND OTHER RISK FACTORS

- Menarche before age 12
- Nulliparity
- First birth after age 30
- Prior breast biopsy
- >5 years of combined estrogen/progesterone hormone replacement therapy

RECOMMENDATIONS

- 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.
- 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. (USPSTF recommends starting medication at ≥ 3.0. Patient may also be eligible for risk reducing clinical trials.)

...for patients at usual risk for breast cancer

PATIENTS WHO HAVE NONE OF THE RISK FACTORS LISTED ABOVE

RECOMMENDATIONS

- Age ≥ 50: Begin bi-annual mammograms, consider annual CBE
- Age 40-49: Annual breast cancer risk discussion with risk factor review and CBE, consider bi-annual mammogram
- Age < 40: Consider CBE every 1–3 years

SCREENING MAMMOGRAM

Not Appropriate for Women with Breast Complaints

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

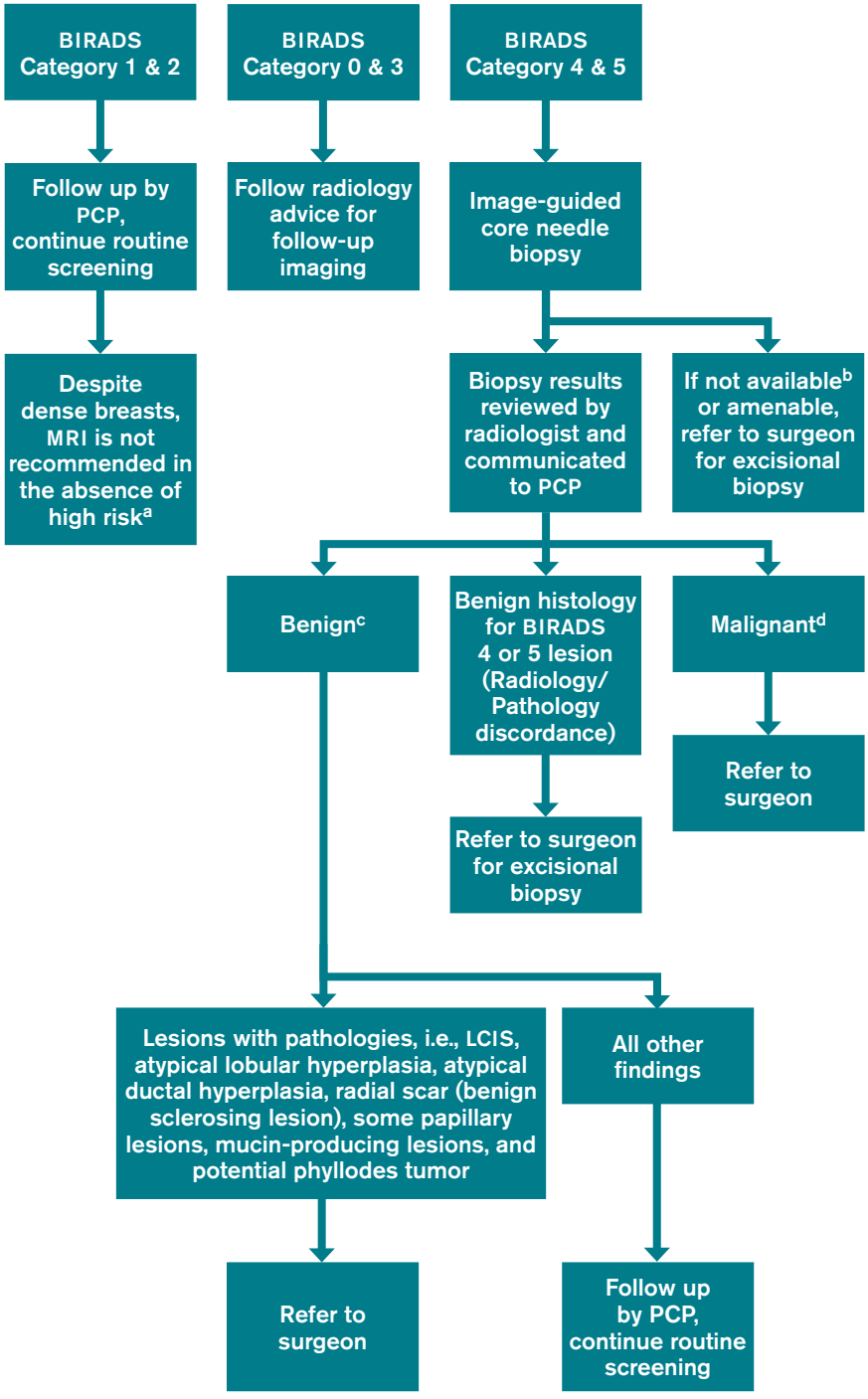
Screening by Age

Screening recommendations for patients at usual risk vary among experts. The following guidance is based on the 2016 USPSTF Recommendations.

- Women 40–49 years old should be engaged in discussions regarding the screening options and recommendations related to their breast cancer risk status.
- Women 50–74 years old should be screened bi-annually.
- Women age 75 or older should be engaged in shared decision making regarding the continuation of screening, with consideration for overall quality of life.

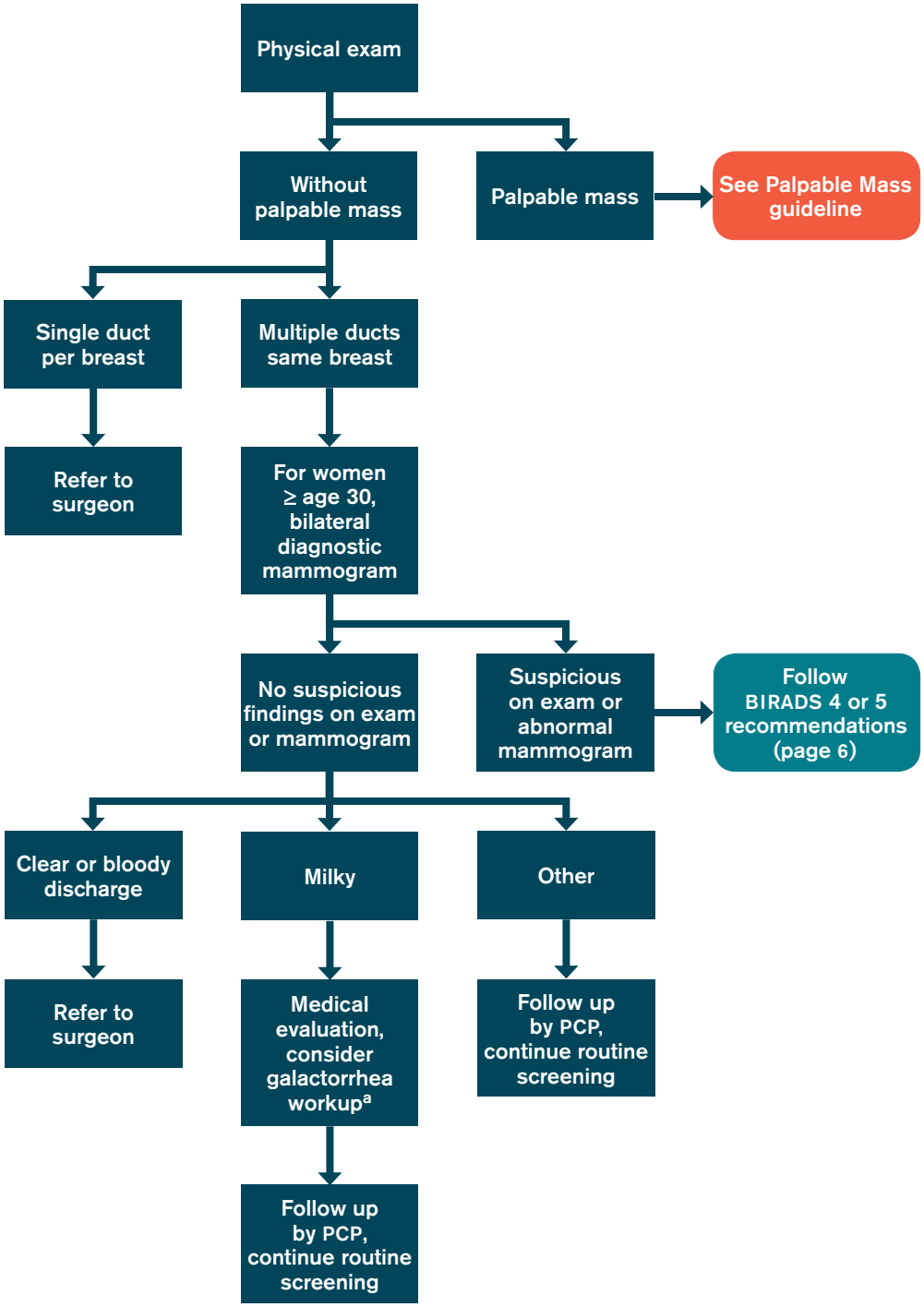
Dense Breast Tissue

- Women with normal or benign findings on mammogram who are identified as having dense breasts should have access to information explaining the impact of density on their overall breast cancer risk (and on the ability to detect cancer), and the risks and benefits of any follow-up screening options.
- Breast tomosynthesis has slightly better sensitivity than digital mammography and fewer callbacks/false positives for women with dense breasts.
- Current data do not support the use of whole breast ultrasound or MRI as screening tools for women at usual risk for breast cancer with or without dense tissue or numerous calcifications.



a. MRI is not required for all dense breasts.
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.

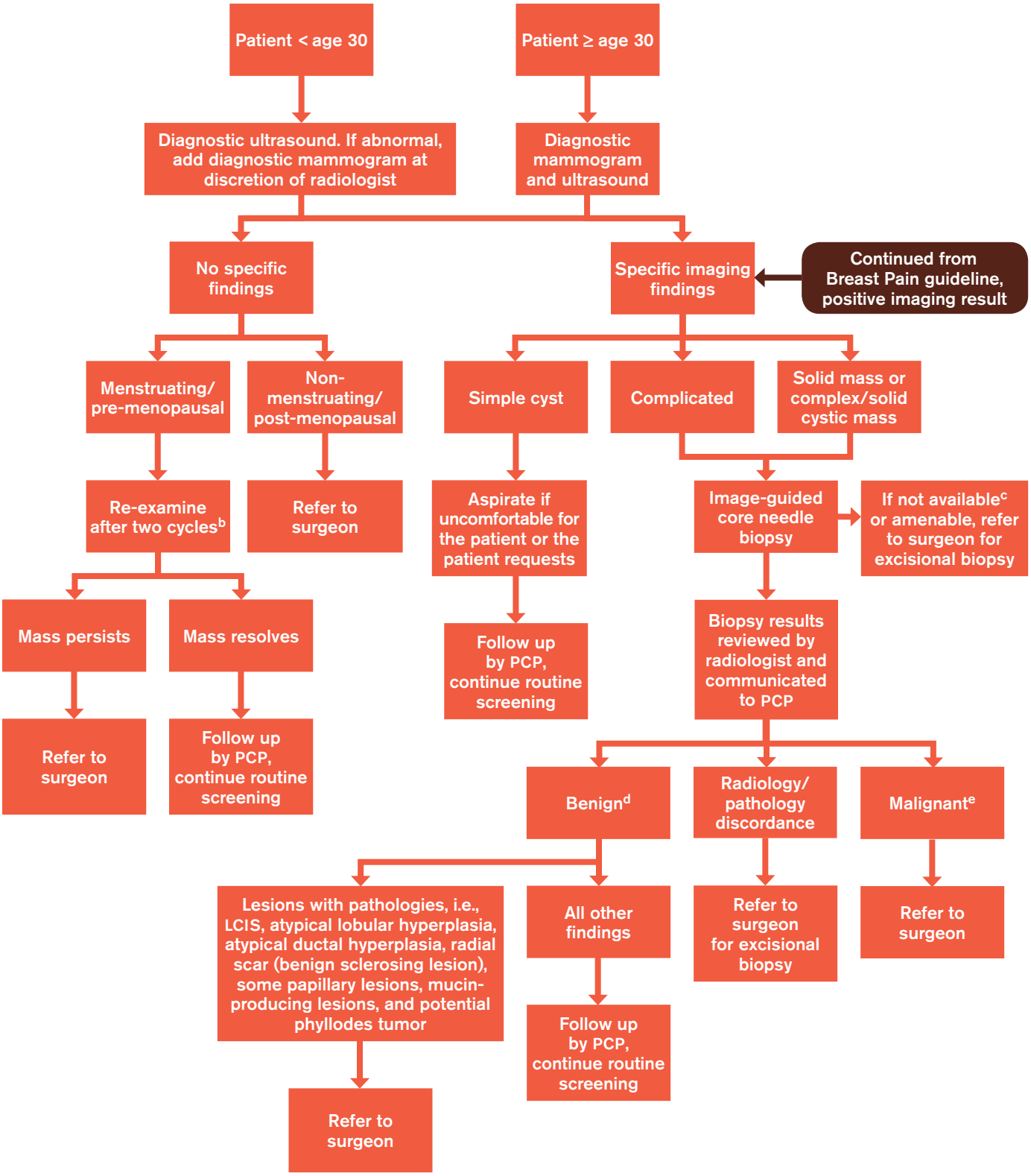
SPONTANEOUS NIPPLE DISCHARGE (NON-LACTATING)



a. For medications that cause galactorrhea see *Medication Causes of Hyperprolactinemia* at www.fpnotebook.com

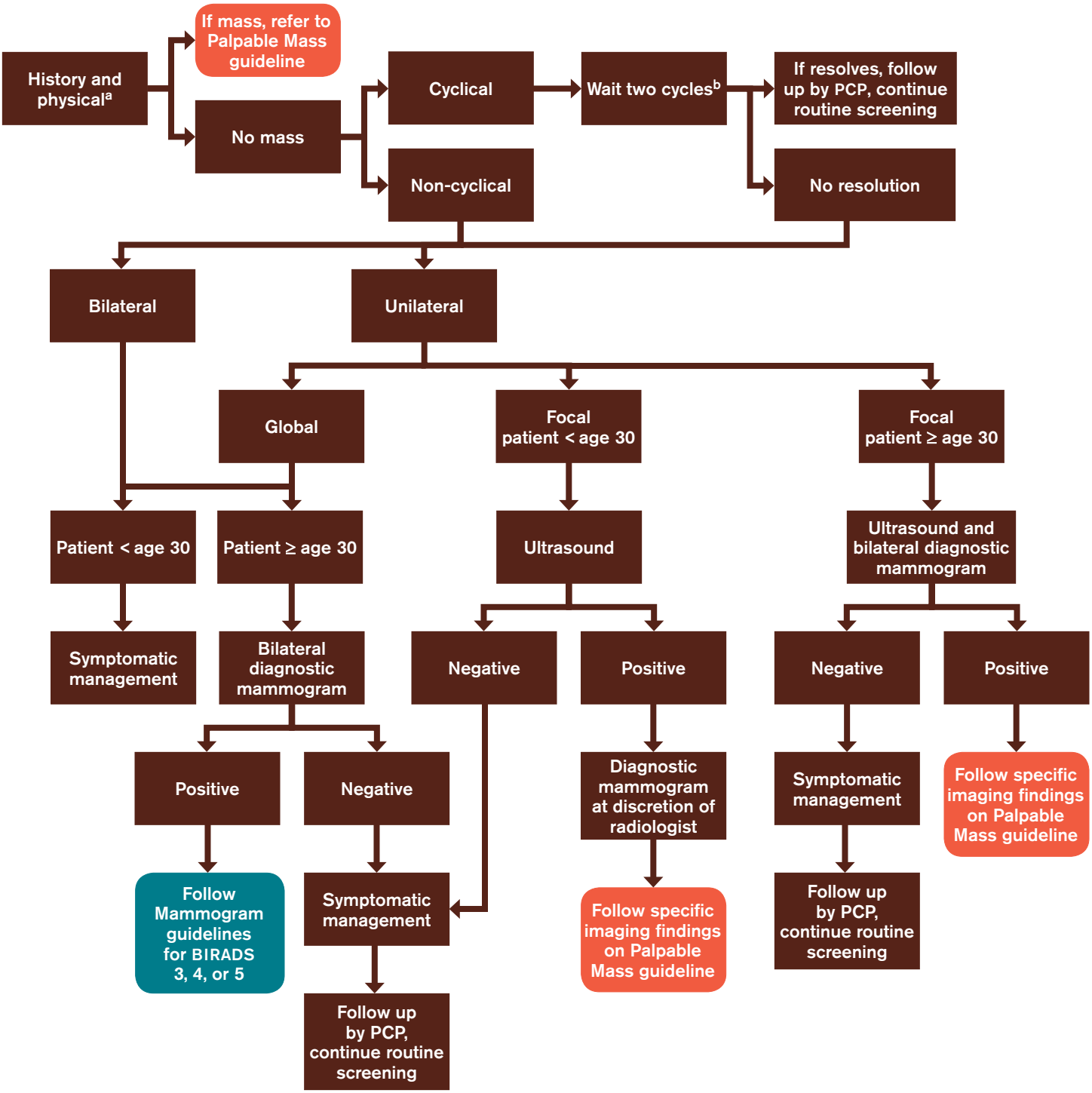
PALPABLE MASS

Detected and 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. If pregnant or not cycling monthly—but not later than two months—refer to a breast specialist.
c. Patients should be informed about their options for image-guided core needle biopsy.
d. Consider referral to surgeon for excision of mass >2cm.
e. Ductal carcinoma in situ or invasive cancer.

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.

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 or description to record the exact location and size (if known); 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

Be careful not to dismiss patients under age 30, who have 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, such as BRCA1/BRCA2 gene mutation in a family member under age 40—should be concerned about the possibility of early breast cancer.

PATIENTS IDENTIFIED AS HAVING DENSE BREASTS

Offer patients access to information explaining the impact of breast density on their overall breast cancer risk (and on the ability to detect cancer), and the risks and benefits of any follow-up screening options.

- Provide all patients the opportunity for a follow-up discussion (with you or a designee) to ensure that they comprehend their overall breast cancer risk, and the risks and benefits of any follow-up screening options. For some patients, printed/online information may be sufficient.
- Document any decisions reached regarding additional cancer screening due to breast density.

COMMUNICATION

- Communicate all abnormal findings to the patient and document that act.
- Avoid sending the wrong message to a patient by only telling her that a palpable lump is probably benign. Stress that additional studies may be needed to look for evidence of malignancy.
- Share any uncertainty on your part in a way that helps your patient appreciate the importance of 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 breast specialist or 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 including for time-sensitive testing.
- 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 or description to record the exact location and size (if known) 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 any available information from those visits needed to ensure that subsequent exams are performed when appropriate.
- Update any known changes to 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

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

Reference Articles

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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 review by clinicians providing primary breast care and application in line with the risk assessment processes in place where they practice. Care plans for individual patients must be based on the providers' professional judgment; this document should not be construed as conveying a universal standard of care.

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