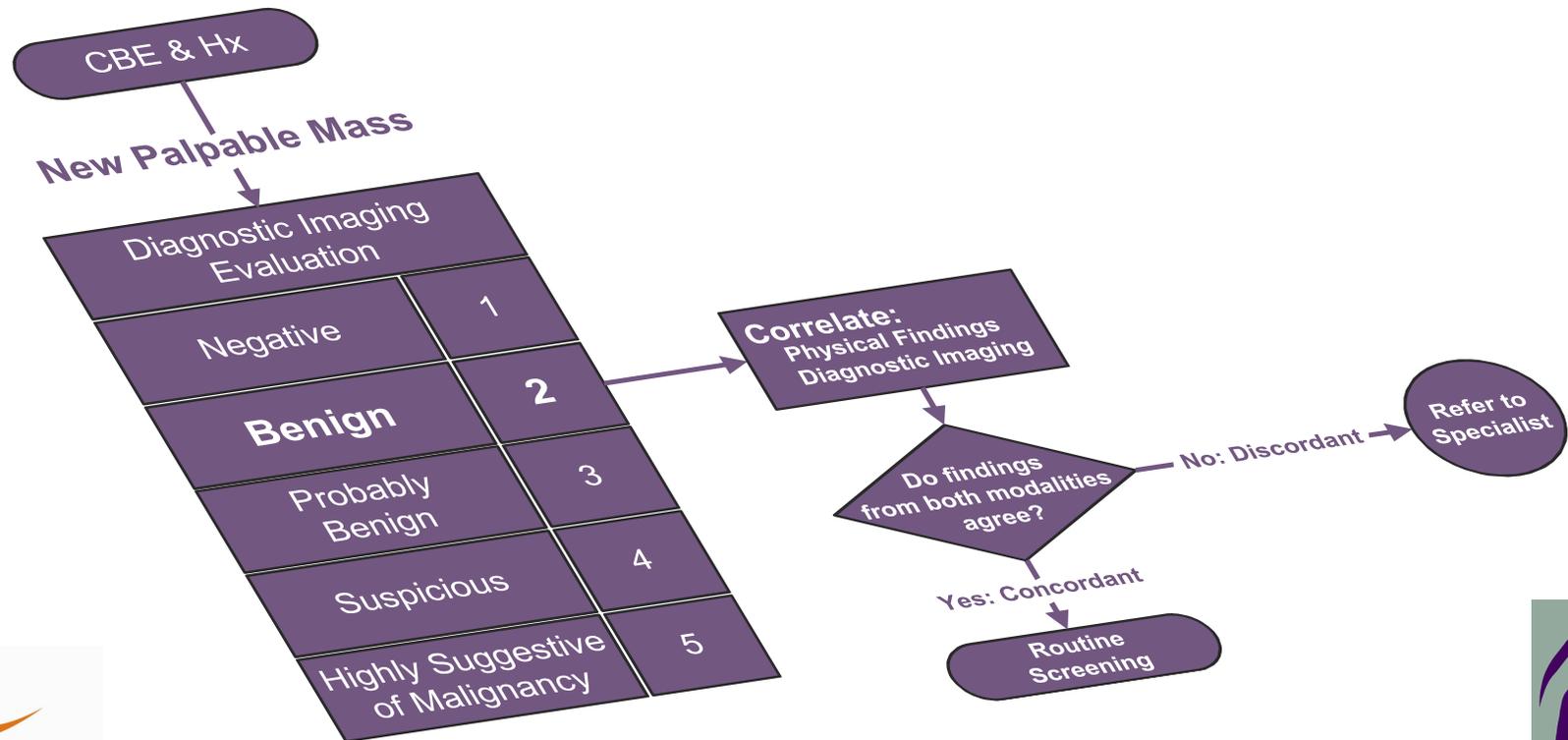


Breast Cancer Diagnostic Algorithms for Primary Care Providers



California Department of Public Health
Cancer Detection Section
Breast Expert Workgroup

online at <http://qap.sdsu.edu>



Cancer Detection Programs:
Every Woman Counts

Created: 1997
Revised: 2000, 2005
Current: 2011

Breast Cancer Diagnostic Algorithms for Primary Care Providers

**California Department of Public Health
Cancer Detection Section
Breast Expert Workgroup**

Fourth Edition, June 2011

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California Department of Public Health

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Preface

The *Breast Cancer Diagnostic Algorithms for Primary Care Providers* was created to facilitate the clinical work-up of patients who present with breast symptoms or an abnormal screening mammogram. Developed for primary care providers enrolled in *Cancer Detection Programs: Every Woman Counts (EWC)*, the algorithms are primarily intended for use with women ages 40 and older. Health care providers are encouraged to use the algorithms as an adjunct to clinical decision-making; they are not intended to replace clinical judgment with regard to individual cases (see also *Clarifications and Disclaimer* below).

Originally published in 1997, this 4th edition incorporates the latest research and guideline updates into a brief, user-friendly format. The algorithms are based on an informal consensus development process with participation by members of the Breast Expert Workgroup, a volunteer panel of California clinicians that provides consultation and leadership to the Cancer Detection Section, California Department of Public Health.

This publication is the product of the Cancer Detection Section (CDS), California Department of Public Health. CDS administers the state and federally funded *EWC*. *EWC* provides free breast and cervical cancer screening and diagnostic services to eligible underserved, low-income women in California. Additionally, CDS provides quality assurance, community outreach and education, professional education, and evaluation and research services.

Clarifications and Disclaimer

These algorithms are intended for informational purposes only. Recommendations in these algorithms do not represent the only medically or legally acceptable approaches to breast cancer screening and follow-up. Rather, they are presented with the recognition that there are other acceptable approaches. Deviations do not necessarily represent a breach of a medical standard of care. New knowledge, new technologies, clinical or research data, individual patient needs, and clinical experiences may provide sound reasons for alternative approaches that may not be described in this document.

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1. Risk Assessment Table

Key Messages: [Go to Table]

- Excluding skin cancer, breast cancer is the most frequently diagnosed cancer in women living in the United States. Gender, aging, and family history are the three most clinically significant risk factors.
- Approximately 77% of women with breast cancer are over the age of 50 at the time of diagnosis (USDHHS, 2008, Aug). For an average risk woman in her 30s, the chance of developing breast cancer is 1 in 233. For a woman in her 60s, it is 1 in 29. If current rates stay the same, a woman born today has about a 1 in 8 chance of developing breast cancer over the course of her lifetime (NCI, 2010, Sep).
- Risk assessment is important for helping to identify women whose chances of developing breast cancer are higher than average and to determine who may benefit from personalized plans for screening and risk reduction. A risk assessment should be performed at each screening visit since risk factors change over time.
- A risk assessment should include a thorough clinical and family history with consideration of genetic factors. Individuals with a history suggestive of an inherited predisposition to breast cancer should be referred for genetic counseling. Reproductive history and other factors, such as alcohol use and obesity, also contribute to a woman's individual risk.
- This Risk Assessment Table yields a qualitative assessment of risk with the outcome of either average or increased risk for breast cancer. It does not include all possible risk factors or provide a quantitative estimate of risk.
- Other risk assessment tools estimate a woman's quantitative breast cancer risk. Four of the most widely used mathematical models are the Gail, Claus, BRCAPRO, and Tyrer-Cuzick (also called IBIS).
 - The Gail Model incorporates a number of established risk factors to estimate a woman's lifetime and 5-year risk for invasive breast cancer. A 5-year risk of 1.67% or higher is considered elevated. This model is not recommended for use with women having a strong family history since it excludes some well-established factors associated with hereditary breast cancer.
 - The Claus Model provides a more accurate estimate of risk for women with a family history of breast cancer by taking into account both maternal and/or paternal histories, including second-degree relatives. The model can also incorporate a family history of ovarian cancer. However, unlike the Gail Model, the Claus Model does not include many of the other risk factors known to increase risk. It may therefore underestimate risk in women with exposure to certain environmental, behavioral or reproductive factors.
 - BRCAPRO can be used to estimate the probability of having a *BRCA1* or *BRCA2* mutation in women whose family histories are suggestive of inherited breast and/or ovarian cancer. It can also be used to estimate breast cancer risk for each individual member of the family. BRCAPRO does not incorporate risk factors that are unrelated to family history.
 - The Tyrer-Cuzick Model is a computer-based model that can be used to estimate the probability of having a *BRCA1* or *BRCA2* mutation as well as individual breast cancer risk for the patient and for family members. In addition to factors related to family history, this model incorporates other well-established risk factors when calculating breast cancer risk estimates.

Notes: [Go to Table]

Note 1A. The Gail Model is accessible through an interactive computer program online. Based on age and other risk factor information provided by the user, the program will estimate a woman's risk of developing invasive breast cancer during the next 5-year period and up to age 90 (lifetime risk). The program, intended primarily for use by health professionals, is available on the website of the National Cancer Institute at <http://www.cancer.gov/bcrisktool/>

Note 1B. Non-proliferative lesions include fibrosis, cysts, mild hyperplasia, non-sclerosing adenosis, simple fibroadenoma, phyllodes tumor (benign), a single papilloma, fat necrosis, mastitis, duct ectasia, and benign lumps or tumors (lipoma, hamartoma, hemangioma, hematoma, neurofibroma).

Note 1C. Proliferative lesions without atypia include usual ductal hyperplasia, complex fibroadenoma, sclerosing adenosis, several papillomas or papillomatosis, and radial scar.

Note 1D. Studies suggest that the use of combined (estrogen and progesterone) hormone replacement therapy (HRT) for more than two or three years may increase breast cancer risk. Within five years of stopping combined HRT, a woman's risk appears to return to that of the general population (ACS, 2009a, Sep).

Note 1E. Mutations in several other genes have been associated with hereditary breast and/or ovarian cancer (e.g., *TP53*, *PTEN*, *STK11/LKB1* and *CDH1*). However, the majority of hereditary breast cancers can be accounted for by mutations in the *BRCA1* and *BRCA2* genes.

Note 1F. Other genetic syndromes that predispose to the development of breast cancer include Cowden Syndrome, Li-Fraumeni Syndrome, Peutz-Jeghers Syndrome, ataxia-telangiectasia, and hereditary diffuse gastric cancer.

Note 1G. In patients with one or more of these factors, a thorough genetic cancer risk assessment is warranted. A thorough assessment will determine the patient's level of risk and provide individualized screening recommendations.

Note 1H. There is a lack of consensus among guideline developers regarding the optimal frequency and ages to begin and end mammography screening. For women with average risk for developing breast cancer, the U.S. Preventive Services Task Force recommends biennial mammography screening starting at age 50 and ending at age 74 (USPSTF, 2009), while the American Cancer Society recommends annual mammography screening starting at age 40 and continuing for as long as a woman is in reasonably good health (Smith et al., 2003). The California Department of Public Health recommends that healthcare providers discuss the optimal screening schedule with their patients, based on an individual's breast cancer risk factors, presence of symptoms, and risks and benefits of mammography screening.

Note 1J. Risk assessment models that are largely dependent on family history include the Claus, BRCAPRO, Tyrer-Cuzick (also called IBIS), and others. For a review of these and other breast cancer risk assessment models, see Amir, Freedman, Bostjan and Evans (2010).

Note 1K. Patients may consider bilateral mastectomy and other risk-reducing surgeries for at-risk organs consistent with the diagnosed inherited breast cancer syndrome.

1. Risk Assessment Table

Relative Risk (RR)	Screening Recommendation
<p>Average (RR = 1.0)</p> <ul style="list-style-type: none"> Women without any of the following risk factors (or with a Gail Model Score <1.67%):^{1A} 	<p>Recommendation</p> <p>CBE every 1 - 3 years during 20s and 30s until age 40, then annually Mammogram every 1 - 2 years beginning at age 40 - 50:^{1H}</p>
<p>Slight to Moderate Increase (RR = 1.1 - < 3.0)</p> <p>Clinical History</p> <ul style="list-style-type: none"> Non-proliferative lesions:^{1B} Proliferative lesions without atypia:^{1C} <p>Reproductive Factors</p> <ul style="list-style-type: none"> Menarche < age 12 Menopause > age 55 Combined HRT use for > 2 - 5 years (current or recent use):^{1D} Nulliparity, or first birth > age 30 <p>Family History</p> <ul style="list-style-type: none"> One 1st degree relative with breast cancer ≥ age 50 <p>Other Risk Factors</p> <ul style="list-style-type: none"> Two to five alcoholic drinks per day Obesity, especially after menopause 	<p>Recommendation</p> <p>For patients ≥ age 35 with a combination of slight to moderate risk factors, consider assessment with the Gail Model:^{1A}</p> <p><u>Gail Model Score <1.67%:</u> CBE every 1 - 3 years during 20s and 30s until age 40, then annually Mammogram every 1 - 2 years beginning at age 40 - 50:^{1H}</p> <p><u>Gail Model Score ≥1.67%:</u> CBE at least once a year Consider annual mammogram beginning at an earlier age Offer risk reduction counseling and referral to a breast specialist for further assessment</p>
<p>Strong Increase (RR = ≥ 3.0)</p> <p>Clinical History</p> <ul style="list-style-type: none"> Personal history of breast cancer (invasive or DCIS) Lobular carcinoma in situ (LCIS) Atypical ductal or lobular hyperplasia (ADH or ALH) <p>Other Clinical Factors</p> <ul style="list-style-type: none"> Therapeutic radiation to the chest < age 30 (for Hodgkin's disease, etc.) High breast density (> 75%) as seen on mammogram 	<p>Recommendation</p> <p>CBE at least once a year Annual mammogram after diagnosis Refer to genetic counselor for personal history of breast cancer diagnosed < age 45</p> <p><u>Therapeutic radiation to the chest:</u> CBE at least once a year Annual mammogram beginning 8 - 10 years after radiation but not before age 25 Consider annual breast MRI in addition to mammogram Refer to breast specialist</p> <p><u>High breast density:</u> CBE once a year Consider annual mammogram</p>
<p>Family History</p> <ul style="list-style-type: none"> One 1st or 2nd degree relative with breast cancer < age 50 Two or more relatives in the same lineage with breast cancer 	<p>Recommendation</p> <p>CBE at least once a year Annual mammogram beginning at age 40 or 5 - 10 years younger than earliest affected relative (but not before age 25) Consider annual breast MRI in addition to mammogram for women with a lifetime risk of 20 - 25% or greater, as defined by risk assessment models that are largely dependent on family history:^{1J} Refer to genetic counselor and/or breast specialist</p>
<p>Genetic Factors</p> <ul style="list-style-type: none"> Known carrier or a close relative with an inherited <i>BRCA1</i> or <i>BRCA2</i> mutation:^{1E} Known carrier or a close relative with another hereditary breast cancer syndrome:^{1F} <p>Indications for Genetic Cancer Risk Assessment:^{1G}</p> <ul style="list-style-type: none"> Personal history of breast cancer < age 45 OR breast cancer in one or more close relatives < age 45 Personal history of ovarian cancer or primary peritoneal cancer OR ovarian cancer or primary peritoneal in one or more close relatives at any age Breast cancer in a male relative at any age Breast cancer in two or more close relatives, both diagnosed < age 50 Breast cancer in three or more close relatives at any age Breast and ovarian cancer in the same relative or in two or more close relatives at any age Ashkenazi Jewish heritage with a personal history of breast or ovarian cancer OR one or more close relatives with breast or ovarian cancer at any age Clustering of breast cancer with thyroid cancer, endometrial cancer, bone or soft tissue cancer, sarcoma, adrenocortical carcinoma, brain cancer, diffuse gastric cancer or early onset acute leukemia, all on the same side of the family 	<p>Recommendation</p> <p>CBE every six months Annual mammogram and MRI beginning at age 25 or individualized based on earliest diagnosis in family member Increased surveillance and/or prevention methods for other cancers associated with the syndrome:^{1K} Refer to breast specialist and/or genetic counselor (if the patient has not received formal counseling services)</p>

2. New Palpable Mass

Key Messages: [Go to Algorithm]

- A palpable breast mass is a common clinical finding. While most masses are benign, any suspicious finding should be thoroughly evaluated until cancer is ruled out.
- Depending upon patient age, risk factors, medical history, and exam characteristics, evaluation may include mammography, ultrasound, fine needle aspiration biopsy, core needle biopsy, or surgical biopsy.
- **Diagnostic imaging**, rather than screening, should be ordered by the primary care provider (PCP) for any suspicious palpable mass.
- Clinical breast examination (CBE) can detect breast cancers that are not found with diagnostic imaging. In a study of women with breast cancer who initially presented with palpable breast masses, nearly 4% received normal or benign findings on *both* mammography and ultrasonography (Beyer & Moonka, 2003). Therefore, an abnormal CBE in the presence of a BI-RADS® Category 1 or 2 requires further investigation.
- While surgical biopsy is considered the gold standard, minimally invasive biopsy techniques have become the optimal first step.
- The *Triple Test* is the recommended approach to the evaluation of a palpable breast mass, especially solid lumps. When findings from CBE, breast imaging, and biopsy are concordant (in agreement), diagnostic accuracy approaches 100% (Vetto et al., 1995). If findings from any one test differ from the others, the diagnosis is uncertain and further investigation is required.
- Core needle biopsy (CNB) is the method of choice for obtaining diagnostic tissue for patients with breast lesions where the differential diagnosis includes cancer. Fine needle aspiration biopsy (FNAB) is another technique but due to significant limitations, FNAB is not recommended when CNB is available.

Notes: [Go to Algorithm]

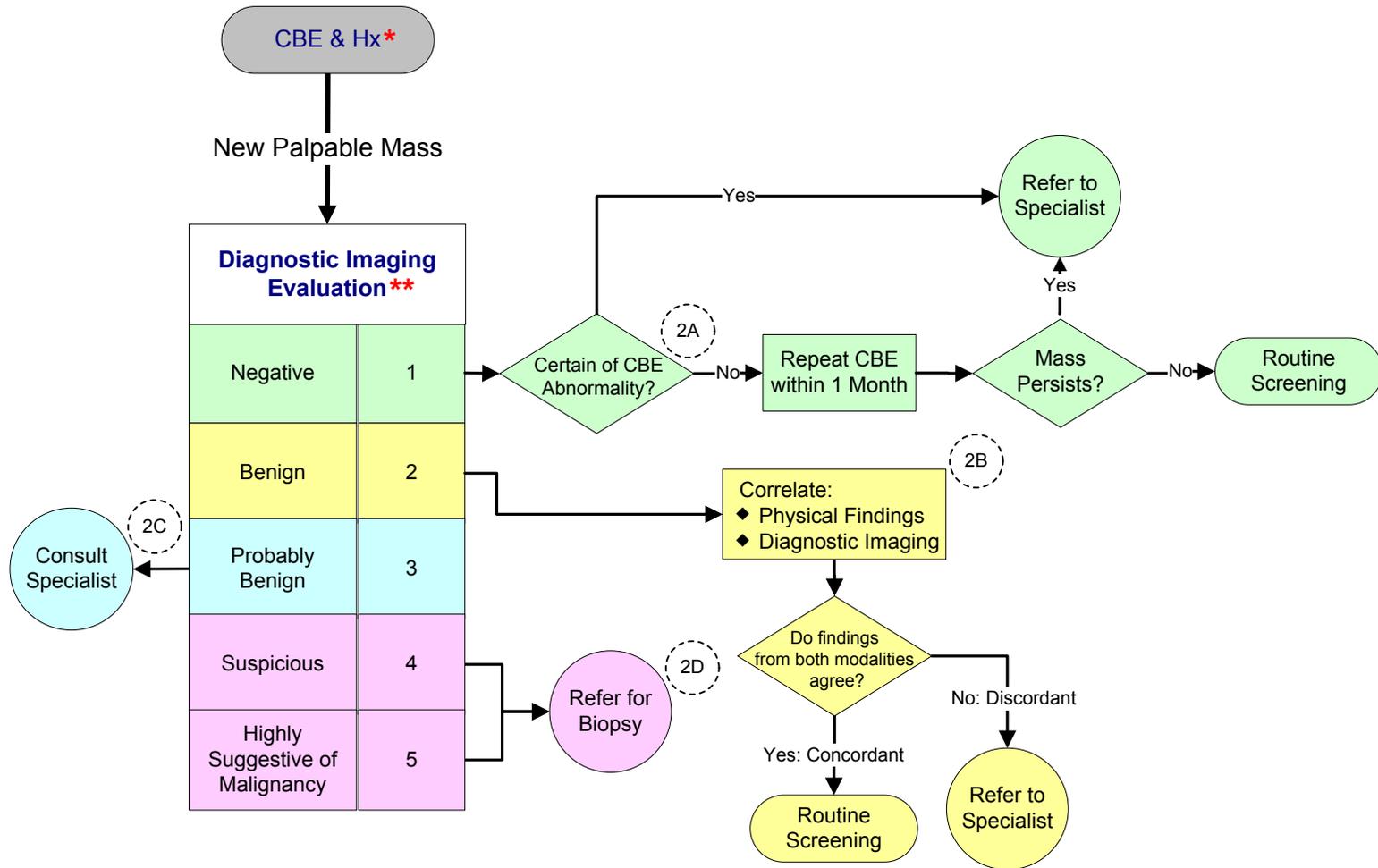
Note 2A. A Negative finding (BI-RADS® Category 1) on mammogram and/or ultrasound does not preclude the existence of a non-radiographically evident lesion. If the PCP is certain that a palpable abnormality exists, the patient should be referred to a breast specialist for further evaluation. In cases where certainty is lacking, the CBE should be repeated within 30 days. At that time, if the mass is no longer felt, the patient can return to routine screening intervals. A patient with a persistent mass at the follow-up CBE should be referred to a breast specialist for decisions regarding further follow-up and the need for biopsy.

Note 2B. A Benign finding (BI-RADS® Category 2) on mammogram and/or ultrasound should be correlated with the physical findings to assure concordance. If the location and characteristics of the palpable abnormality match, the patient can return to routine screening. If the physical and imaging findings are discordant, further follow-up is required.

Note 2C. The American College of Radiology (ACR) does not recommend the use of Probably Benign (BI-RADS® Category 3) as the final diagnostic imaging evaluation for a patient with a palpable mass. Per ACR (2003), "all the published studies exclude palpable lesions, so the use of a probably benign assessment for a palpable lesion is not supported by scientific data." If the results of the CBE screening indicate a palpable mass and a BI-RADS® Category 3 is assigned as the final diagnostic imaging evaluation, contact the radiologist for further consultation. The radiologist may be unaware of the CBE findings.

Note 2D. The particular method of biopsy is based on a combination of factors that include the characteristics of the abnormality as well as the available resources at a given medical facility. For brief descriptions of the various types of biopsy, see *Algorithm 7, Breast Biopsy*.

2. New Palpable Mass



*Copies of standardized clinical tools for performing and documenting CBE can be found in the appendix. Current tools can be downloaded at no cost and tailored to meet your needs at <http://qap.sdsu.edu/>

****Diagnostic Imaging Evaluation** usually includes a diagnostic mammogram and breast ultrasound. Additional radiographic procedures may be recommended. A final BI-RADS® category will be assigned to the case based on the results of all diagnostic imaging procedures. Women should return to routine screening once the diagnostic and/or treatment cycle is completed.

3. Abnormal Screening Mammogram with Normal CBE

Key Messages: [Go to Algorithm]

- There are two types of mammograms: screening and diagnostic. Screening mammograms are used for women who have no clinical signs or breast complaints. Diagnostic mammograms are used to evaluate an abnormal clinical finding or an area of concern from an abnormal screening mammogram. The ordering of a screening mammogram when a diagnostic mammogram is required can cause a delayed diagnosis of breast cancer.
- Mammograms should only be performed in facilities certified under the Mammography Quality Standards Act (MQSA) with FDA accreditation. As an MQSA certified facility, all mammographic imaging results are required to be reported using the Breast Imaging Reporting and Data System (BI-RADS®).
- BI-RADS® was developed by the American College of Radiology (ACR) to standardize mammography reports. It is also used for breast ultrasound and MRI.
- BI-RADS® categories provide a characterization of the imaging results and have implications for follow-up and management. In total, there are seven BI-RADS® assessment categories. Categories 1 - 6 are used for complete assessments (ACR, 2003).
 - BI-RADS® Category 0 (Assessment is Incomplete) – Used for indicating that further tests and/or records are needed before a final assessment category can be assigned.
 - BI-RADS® Category 1 (Negative) – Continue routine interval screening.
 - BI-RADS® Category 2 (Benign Findings) – Continue routine interval screening.
 - BI-RADS® Category 3 (Probably Benign) – Initial short-interval follow-up examination, usually in 6 months, followed by another examination in 6 months, then annually until stability is demonstrated for a minimum of 2 to 3 years. Women at increased risk should be referred to a breast specialist. Category 3 is not recommended for screening mammograms; it is intended for use with diagnostic mammograms only.
 - BI-RADS® Category 4 (Suspicious Abnormality) – Requires an intervention, usually biopsy.
 - BI-RADS® Category 5 (Highly Suggestive of Malignancy) – Requires biopsy.
 - BI-RADS® Category 6 (Proven Malignancy) – Used for biopsy-proven cancer. (Not applicable to this algorithm.)
- Evaluations that use multiple imaging procedures (mammography plus breast ultrasound and/or MRI) may be assigned a separate BI-RADS® category for each procedure. In such cases, appropriate management is based on the BI-RADS® category that reflects the highest level of suspicion for cancer (ACR, 2003).
- Primary care clinicians are encouraged to discuss with patients their BI-RADS® assessment category and its meaning with regard to appropriate follow-up and likelihood of breast cancer.

Notes: [Go to Algorithm]

Note 3A. Screening mammogram results of Negative (BI-RADS® Category 1) or Benign (BI-RADS® Category 2) prompt routine interval screening for women with normal clinical breast examinations.

Note 3B. A BI-RADS® Category 0 (Assessment is Incomplete) may be used temporarily for a screening mammogram when the final assessment requires additional views and/or tests, or a review of previous imaging results. Category 0 should never be used as a final assessment category.

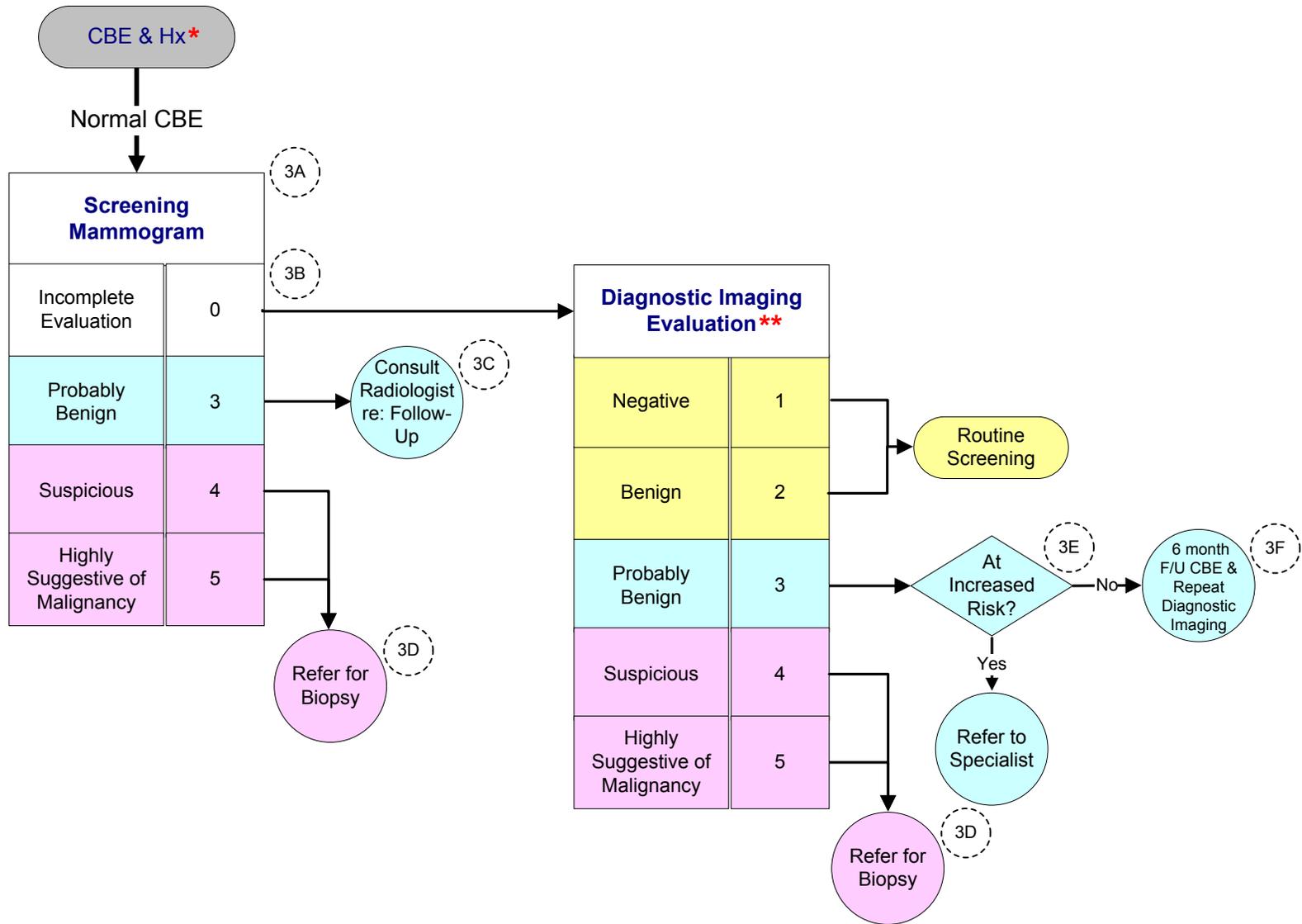
Note 3C. The American College of Radiology (ACR) advises against the use of Probably Benign (BI-RADS® Category 3) for screening mammograms. Per ACR (2003), “such findings are generally identified on baseline screening or on screening for which previous examinations are unavailable for comparison. Immediate evaluation with additional mammographic views and/or ultrasound is required to render a Category 3, probably benign assessment.”

Note 3D. A BI-RADS® Category 4 (Suspicious Abnormality) requires an intervention, usually biopsy. (The use of three subdivisions are optional for this category, with 4a reflecting the lowest level of suspicion for cancer and 4c reflecting the highest.) Category 5 (Highly Suggestive of Malignancy) always requires biopsy. The particular method of biopsy is based on a combination of factors that include the characteristics of the abnormality as well as the available resources at a given medical facility. For brief descriptions of the various types of biopsy, see *Algorithm 7, Breast Biopsy*.

Note 3E. A BI-RADS® Category 3 requires a differential assessment of risk. (See the *Risk Assessment Table, page 3*, to determine if the patient is at increased risk for breast cancer.) A woman with a diagnostic imaging result of Category 3 who is at increased risk for breast cancer should be referred to a breast specialist (i.e., a health professional with special education and/or experience in breast cancer). A referral can also be offered to any woman who is concerned about her results and desires further information.

Note 3F. For BI-RADS® Category 3, the vast majority of findings are managed with an initial short-interval examination, usually in 6 months, followed by another examination in 6 months, then annually until stability is demonstrated for a minimum of 2 to 3 years. There may also be occasions when a biopsy is done as a result of patient and/or clinician concerns.

3. Abnormal Screening Mammogram with Normal CBE



*Copies of standardized clinical tools for performing and documenting CBE can be found in the appendix. Current tools can be downloaded at no cost and tailored to meet your needs at <http://qap.sdsu.edu/>

****Diagnostic Imaging Evaluation** usually includes a diagnostic mammogram and breast ultrasound. Additional radiographic procedures may be recommended. A final BI-RADS® category will be assigned to the case based on the results of all diagnostic imaging procedures. Women should return to routine screening once the diagnostic and/or treatment cycle is completed.

4. Spontaneous Unilateral Nipple Discharge (Non-Lactating)

Key Messages: [Go to Algorithm]

- Nipple discharge is the third most frequently reported breast complaint, after breast pain and breast mass (Hussain, Policarpio & Vincent, 2006). The vast majority of nipple discharges are normal (related to lactation) or otherwise benign.
- A detailed history and careful physical examination are the important first steps in the evaluation of nipple discharge. A discharge that is spontaneous (occurs without stimulation), unilateral, and uniductal is more concerning than a discharge without these characteristics. Bloody or guaiac-positive discharge raises the possibility of cancer, although the character of the fluid is generally unreliable for differentiating among the various possible causes.
- A nipple discharge related to lactation is considered normal. It is typically bilateral and the fluid is milky. Normal milk secretion can continue for up to one year after the cessation of breastfeeding.
- Galactorrhea describes a nipple discharge that has the appearance of milk but is unrelated to lactation. Most often, the discharge is spontaneous, multiductal, and bilateral. Galactorrhea occurs in approximately 20% - 25% of women (Pena & Rosenfeld, 2001) and is rarely associated with cancer. Possible causes are many, including certain medications, hypothyroidism, pituitary adenomas, breast stimulation, chest wall irritation, and numerous other origins.
- Pathologic nipple discharge is also characterized as spontaneous but is typically unilateral and uniductal. Fluid that contains blood, or less frequently, fluid that is clear, raises concern. However, even with these features, most cases of pathologic nipple discharge are due to benign causes.
- The most common causes of a pathologic nipple discharge are benign intraductal papilloma, duct ectasia, and fibrocystic changes. An estimated 5% - 15% are due to an underlying malignancy (Golshan & Iglehart, 2010b). The risk of cancer is greater for women ages 40 and older.
- Every patient with pathologic nipple discharge should be referred for diagnostic imaging evaluation. While imaging may detect an underlying abnormality, negative results should not deter further evaluation. In women with this symptom, imaging studies are not sufficiently reliable for identifying all cancers or high risk lesions (Golshan & Iglehart, 2010b).
- Cytologic examination of nipple discharge is considered useful in some cases; however, as with imaging, a negative result should not stop further evaluation. In the majority of cases, a histological diagnosis by surgical procedure is needed.

Notes: [Go to Algorithm]

Note 4A. Spontaneous nipple discharge occurs unprovoked and without stimulation. Nipple discharge that occurs only with stimulation is rarely associated with cancer.

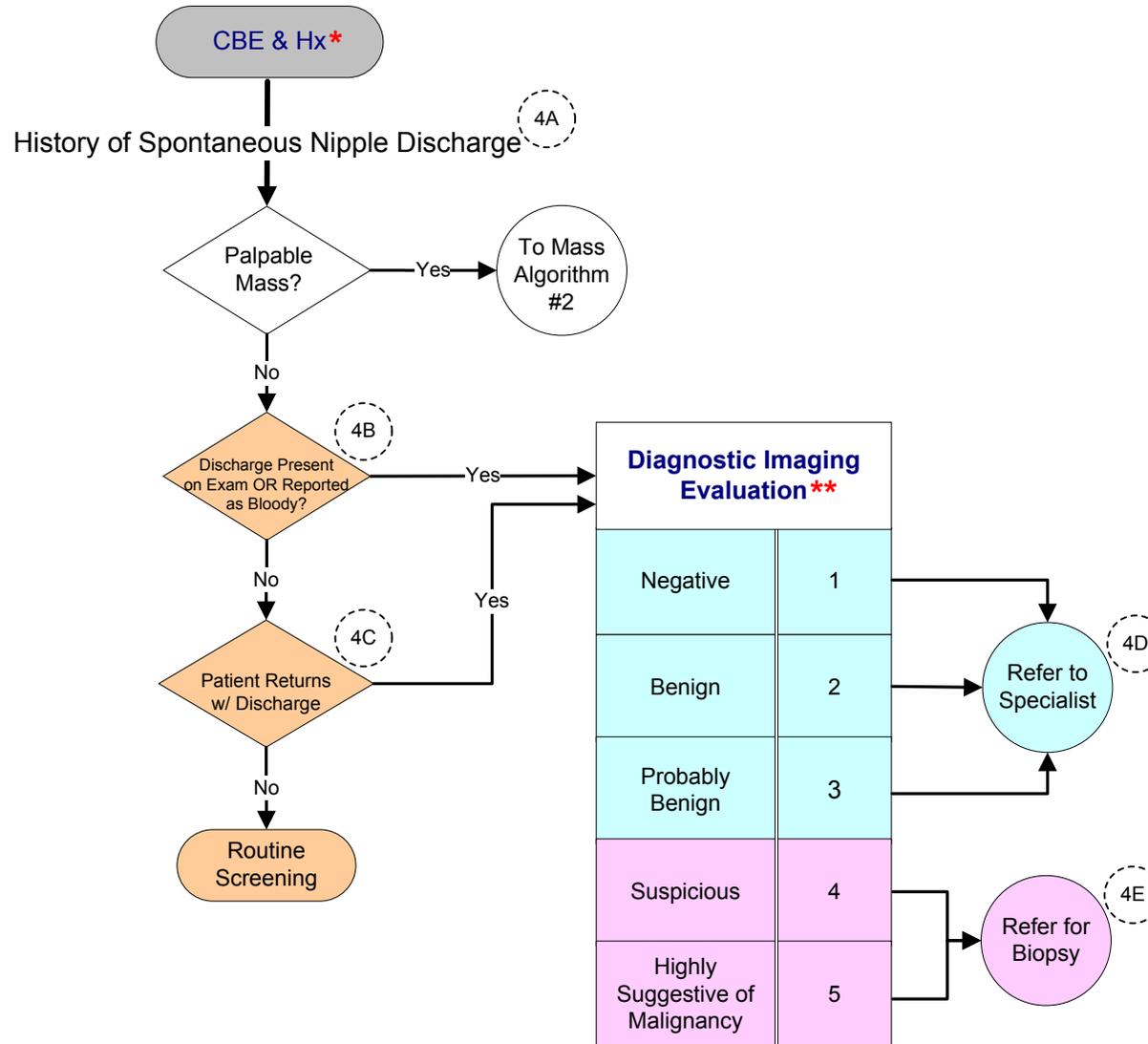
Note 4B. The physical examination should attempt to obtain fluid from the nipple by using a warm compress and gentle pressure at the base of the areola. If discharge is present on exam, diagnostic imaging evaluation is indicated. Diagnostic imaging is also indicated for a patient who reports a history of bloody discharge (including the report of finding stains of blood on her bra or underclothing), even if bilateral. Fluid that is clear and watery can also be associated with cancer. For bilateral and milky nipple discharge (including yellow, green, or grey), consider causes related to breast stimulation, medications, or endocrine abnormalities.

Note 4C. A spontaneous nipple discharge that persists should be referred to diagnostic imaging.

Note 4D. Regardless of negative imaging results, a persistent and spontaneous discharge requires follow-up with a breast specialist. It remains necessary to determine and treat the cause. A guaiac-positive (evidence of blood) or uniductal discharge should be referred to a surgical clinician experienced in breast disorders.

Note 4E. Biopsy should be performed by terminal duct excision. The goal is to excise the duct from which the discharge occurs along with as little additional tissue as possible.

4. Spontaneous Unilateral Nipple Discharge (Non-Lactating)



*Copies of standardized clinical tools for performing and documenting CBE can be found in the appendix. Current tools can be downloaded at no cost and tailored to meet your needs at <http://qap.sdsu.edu/>

****Diagnostic Imaging Evaluation** usually includes a diagnostic mammogram and breast ultrasound. Additional radiographic procedures may be recommended. A final BI-RADS® category will be assigned to the case based on the results of all diagnostic imaging procedures. Women should return to routine screening once the diagnostic and/or treatment cycle is completed.

5. Breast Skin Changes/Nipple Retraction

Key Messages: [Go to Algorithm]

- A thorough history and clinical breast examination (CBE) are the first steps to the assessment of the patient who presents with skin changes or nipple retraction. Important questions to consider include:
 - How long has the change been present?
 - Is there an associated palpable mass or mammographic abnormality?
 - Is it a unilateral finding?
- Diagnostic imaging is the next line of investigation for suspicious skin or nipple changes (even if no mass is palpable on CBE). However, a negative or benign imaging result must not preclude referral to a breast specialist. A clinical abnormality of the breast requires further evaluation.
- Eczema must be distinguished from Paget's disease of the nipple, an uncommon but very serious form of breast cancer. Despite clinical differences, Paget's disease should be considered until proven otherwise.
- Patients with a unilateral nipple retraction of recent onset, even if slight, require a thorough diagnostic evaluation. Unilateral nipple retraction is more suspicious than bilateral nipple inversion. Congenital nipple inversion is insignificant.
- Skin redness associated with breast pain and swelling is seen with mastitis or infected skin lesions. These symptoms can also be signs of inflammatory breast cancer (IBC). If the suspicion for IBC is low, a 7-10 day course of antibiotics may be indicated. If symptoms are not completely (100%) resolved, IBC should be suspected and diagnostic imaging is required.
- IBC may be confused with certain inflammatory noninfectious diseases, such as atopic dermatitis, psoriasis, eczema, systemic lupus erythematosus, and vasculitis. Treatment with steroids is not recommended when diagnosis is in doubt since the clinical signs of IBC may be temporarily improved by steroids.
- IBC is characterized by rapid onset of erythema (occupying at least one-third of the breast), edema, fine dimpling (peau d'orange), and/or a warm breast. IBC may or may not be accompanied by a distinct palpable mass. IBC is an aggressive disease and usually progresses rapidly. The incidence of IBC in U.S. women ranges from 1% - 5% (Dawood et al, 2010).
- Mammographic characteristics of IBC are often diffuse and subtle; skin and trabecular thickening are the most common but are nonspecific (i.e., can also be associated with mastitis). It is critical that a proper clinical history be included in the request for diagnostic imaging and/or any other follow-up for ensuring a prompt and accurate diagnosis.

Eczema	Paget's disease of the nipple
Usually bilateral	Unilateral
Intermittent history with rapid evolution	Continuous history with slow progression
Moist	Moist or dry
Indefinite edge	Irregular but definite edge
Nipple may be spared	Nipple always involved and disappears in advanced cases
Itching common	Itching common

Adapted from Hughes, L.E., Mansel, R.E. & Webster, D.J.T. (1989). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Ballière Tindall.

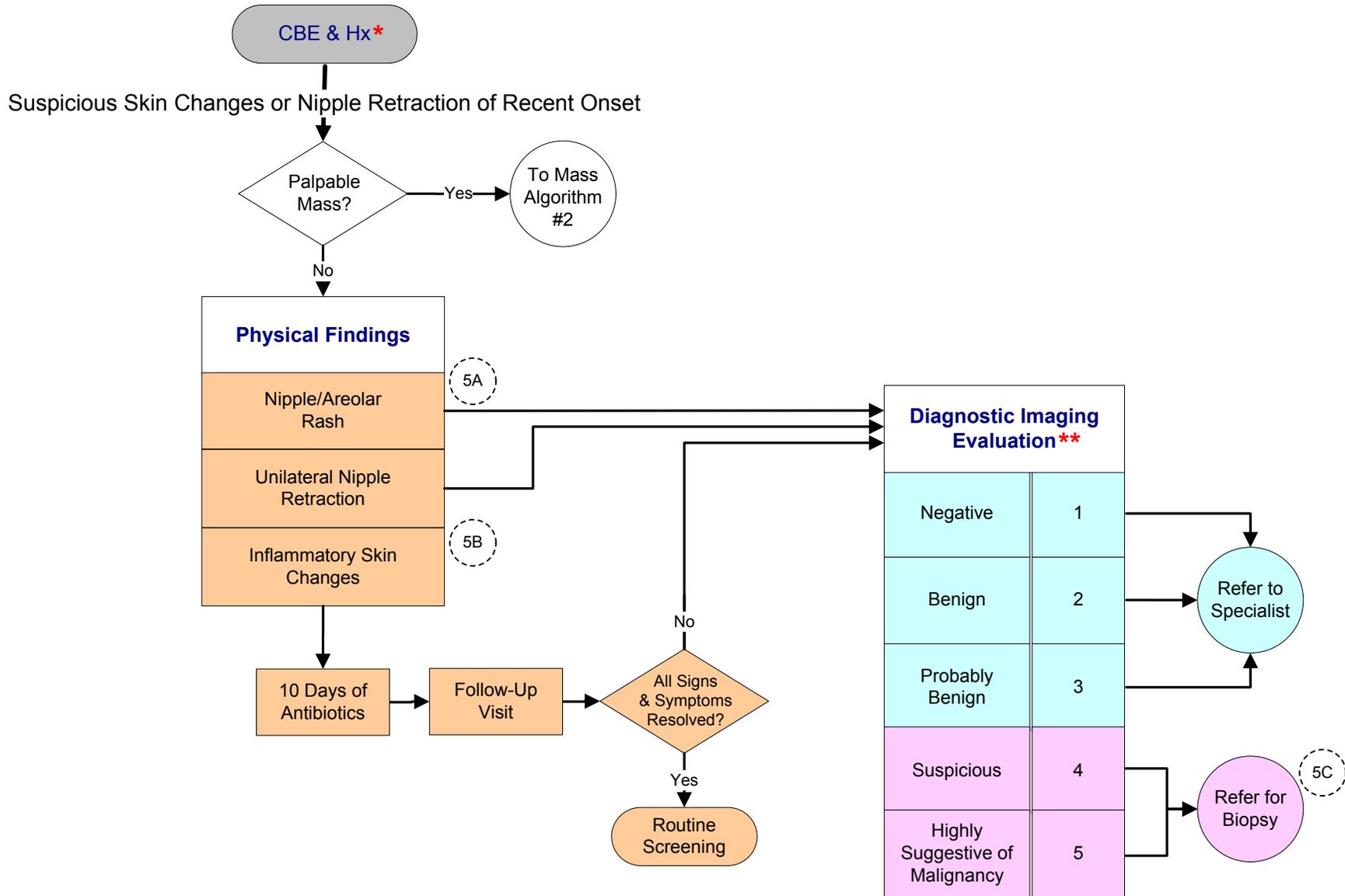
Notes: [Go to Algorithm]

Note 5A. Treatment with topical steroid cream for nipple/areolar rash is not recommended prior to diagnostic evaluation. Steroids can temporarily improve symptoms and mask the clinical signs of an underlying malignancy (i.e., Paget's disease of the nipple).

Note 5B. A 7-10 day course of antibiotics with follow-up may be initiated for skin changes that appear consistent with infection. If symptoms are not completely (100%) resolved, prompt diagnostic imaging evaluation is required. A negative or benign imaging result must not preclude referral to a breast specialist.

Note 5C. The particular method of biopsy is based on a combination of factors that include the characteristics of the abnormality as well as the available resources at a given medical facility. For brief descriptions of the various types of biopsy, see *Algorithm 7, Breast Biopsy*.

5. Breast Skin Changes/Nipple Retraction



*Copies of standardized clinical tools for performing and documenting CBE can be found in the appendix. Current tools can be downloaded at no cost and tailored to meet your needs at <http://qap.sdsu.edu/>

****Diagnostic Imaging Evaluation** usually includes a diagnostic mammogram and breast ultrasound. Additional radiographic procedures may be recommended. A final BI-RADS® category will be assigned to the case based on the results of all diagnostic imaging procedures. Women should return to routine screening once the diagnostic and/or treatment cycle is completed.

6. Breast Pain in a Non-Lactating Woman

Key Messages: [Go to Algorithm]

- Breast pain affects 60% - 70% of women at some point during their lives. In rare instances, pain is a sign of breast cancer.
- The most common causes of breast pain are fibrocystic changes and hormonal changes related to menstruation, pregnancy, and menopause. Pain is also common with breast cysts and infection (mastitis). Physical activities or trauma and certain types of medications can also cause breast pain.
- The differential diagnosis of breast pain requires a clinical breast examination (CBE) and careful history. Important considerations include:
 - Onset, location and severity
 - Relationship to the menstrual cycle
 - Related physical activities
 - History of trauma
 - Hormonal influences (contraceptives, HRT, pregnancy, etc.)
 - Medications associated with breast pain (hormonal, antidepressant, antipsychotic, anxiolytic, antihypertensive and cardiac, antimicrobial agents, and others)
- Breast pain is generally classified as cyclic, noncyclic or extramammary. Cyclic pain is most common.
- Cyclic pain is related to the timing of the menstrual cycle and often accompanied by swelling. It is usually bilateral and frequently located in the upper, outer quadrants of the breast, sometimes radiating to the underarm. It is often described as diffuse, dull, full, aching, and heavy.
- Noncyclic pain can be either constant or intermittent. It is most often unilateral and localized to one area of the breast, but it may also radiate outward. The pain may be described as sharp, burning, throbbing, or sore.
- Extramammary breast pain is experienced as originating from the breast, but the actual origin is elsewhere (most frequently, the chest wall).
- Distinguishing the source of the pain is usually straightforward; inconsistent or multiple sources may present more of a challenge. Cardiac, pulmonary, and gastrointestinal causes need to be excluded.
- Breast cancer must be considered in patients with well-localized, non-cyclic pain. In studies of women presenting with focal pain as the primary (or only) symptom, a diagnosis of breast cancer has been reported for 1.2% - 6.7% of cases (Smith, Pruthi & Fitzpatrick, 2004).
- For most women, treatment of breast pain consists of symptom relief and reassurance. When both CBE and diagnostic imaging studies are normal, the probability of breast cancer is estimated at only 0.5% (Smith et al., 2004).

Notes: [Go to Algorithm]

Note 6A. Distinguish between cyclic and non-cyclic breast pain. Cyclic pain is typically bilateral and described as diffuse, dull, full, aching, and heavy. Non-cyclic pain tends to be unilateral and well-localized. It may be described as sharp, burning, throbbing, or sore.

Note 6B. First-line treatments, such as oral or topical nonsteroidal anti-inflammatory agents, may be offered for pain relief while awaiting the results from diagnostic imaging procedures.

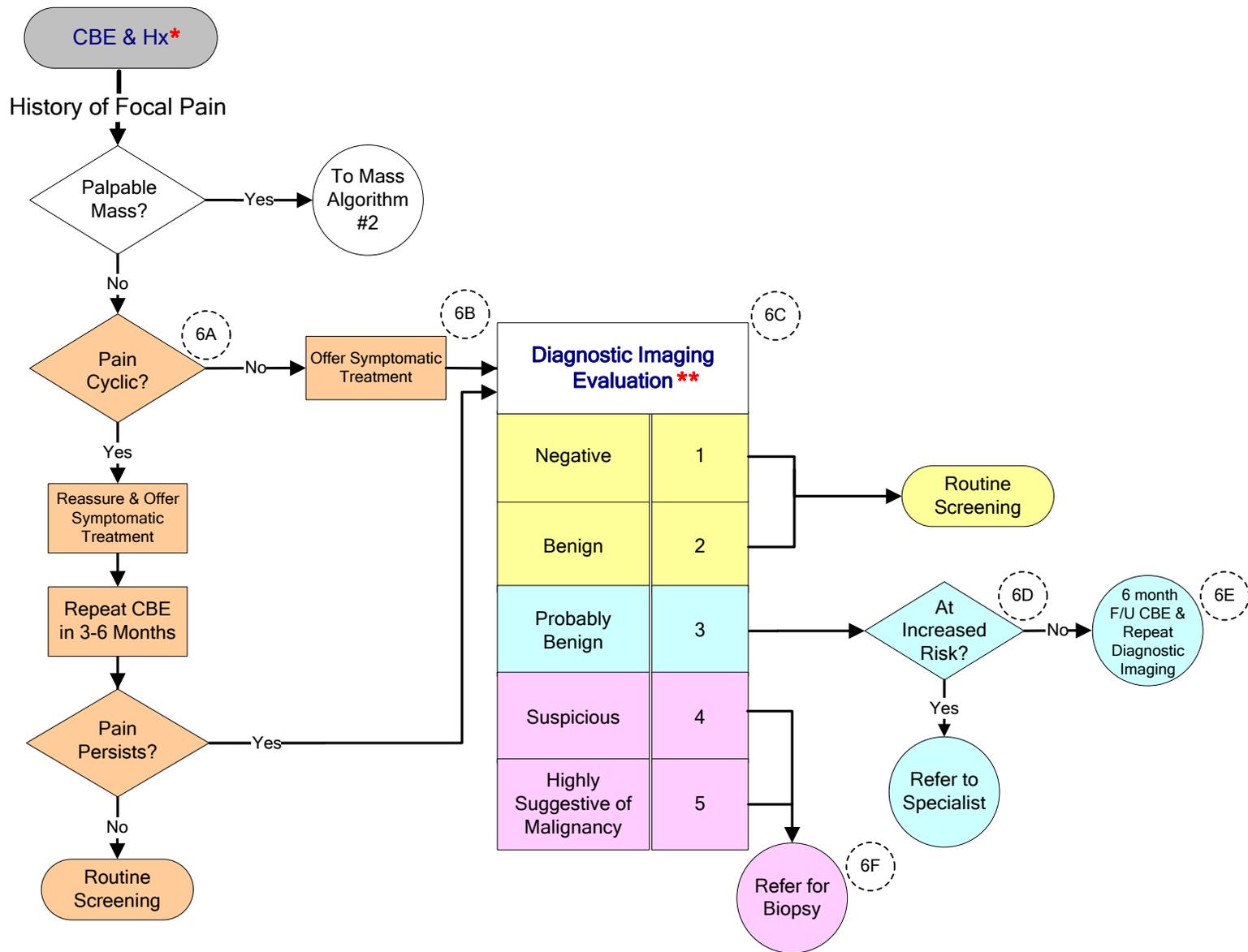
Note 6C. Although there are no radiologic features associated with breast pain, diagnostic imaging studies are used to exclude the rare presence of a subclinical breast cancer.

Note 6D. A BI-RADS[®] Category 3 result (Probably Benign) requires a differential assessment of risk. (See the *Risk Assessment Table, page 3*, to determine if the patient is at increased risk for breast cancer.) A patient with a diagnostic imaging result of Probably Benign, who is also at increased risk for breast cancer, should be referred to a breast specialist. A referral can also be offered to any woman who is concerned about her results and desires further information from a breast specialist.

Note 6E. For BI-RADS[®] Category 3, the vast majority of findings will be managed with an initial short-term follow-up examination in 3 to 6 months, followed by additional examinations until stability is demonstrated (for a minimum of 2 years). There may be occasions when a biopsy is done (e.g., patient request or clinical concerns). Evidence from published studies indicates the need for biopsy if the lesion increases in size or undergoes morphologic change (ACR, 2003).

Note 6F. The particular method of biopsy is based on a combination of factors that include the characteristics of the abnormality as well as the available resources at a given medical facility. For brief descriptions of the various types of biopsy, see *Algorithm 7, Breast Biopsy*.

6. Breast Pain in a Non-Lactating Woman



*Copies of standardized clinical tools for performing and documenting CBE can be found in the appendix. Current tools can be downloaded at no cost and tailored to meet your needs at <http://qap.sdsu.edu/>

****Diagnostic Imaging Evaluation** usually includes a diagnostic mammogram and breast ultrasound. Additional radiographic procedures may be recommended. A final BI-RADS® category will be assigned to the case based on the results of all diagnostic imaging procedures. Women should return to routine screening once the diagnostic and/or treatment cycle is completed.

7. Breast Biopsy

Key Messages: [Go to Algorithm]

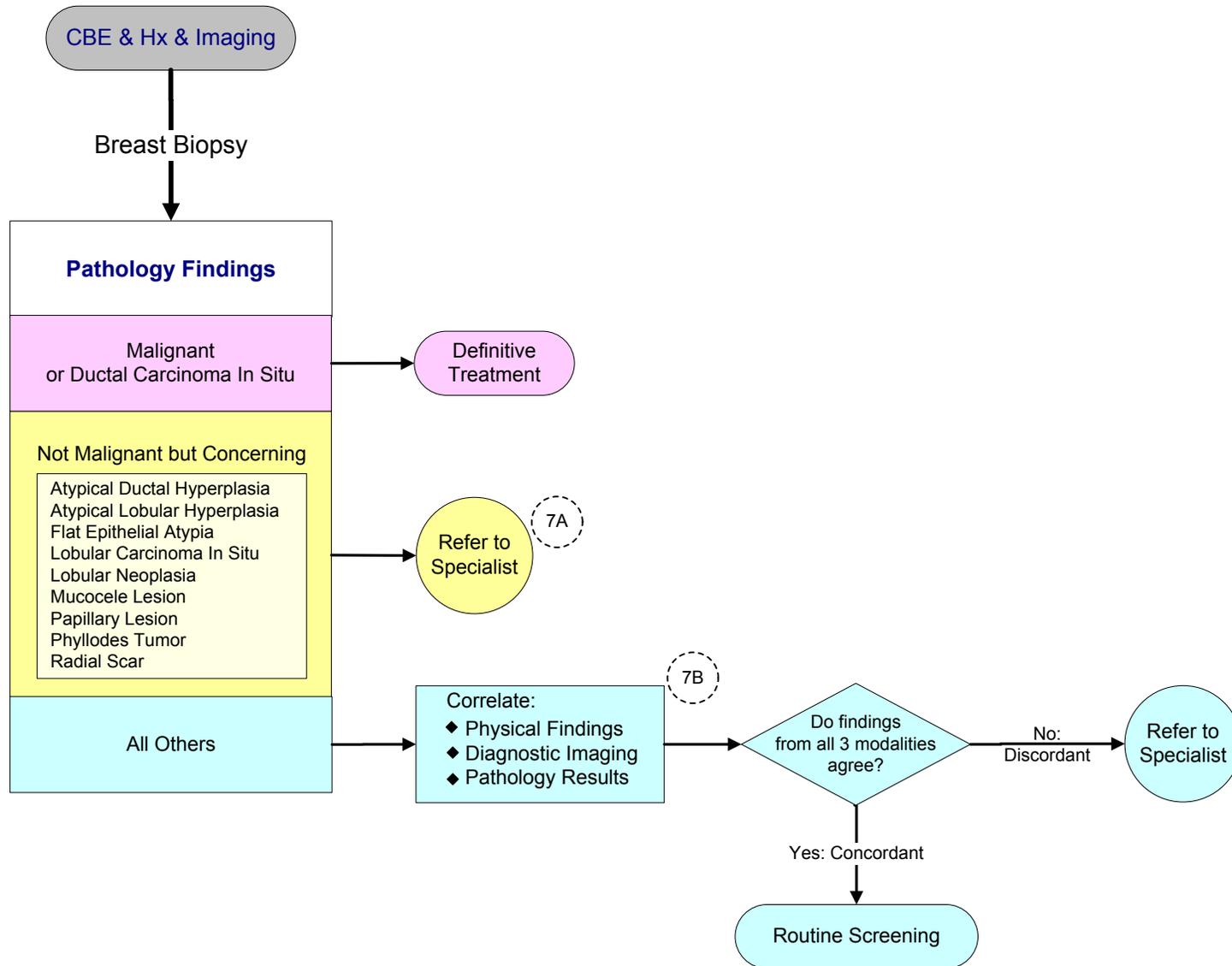
- Biopsy is the only definitive method for diagnosing breast cancer.
- The type of biopsy is determined by the clinical and radiographic features of the abnormality as well as the availability of resources and expertise within a given medical setting.
- Skin punch biopsy uses a hand-held circular tool for removing a small core of skin and tissue. Typically used for sampling skin rashes, it is also used for suspected cases of inflammatory breast cancer (IBC) and Paget's disease. This method of biopsy is not appropriate for sampling deeper subcutaneous lesions or nodules.
- Fine needle aspiration biopsy (FNAB) uses a thin, hollow needle to obtain a small sample of cellular tissue from the area of concern. Accuracy relies upon the specialized training and experience of the pathologist as well as the clinician obtaining the sample.
- Core needle biopsy (CNB) is similar to FNAB but uses a wider needle to remove larger, multiple samples of tissue. CNB is generally considered more accurate than FNAB and is the preferred method of biopsy for determining whether a breast abnormality is breast cancer.
- Image guidance with mammography, ultrasound, or MRI is often used to facilitate the sampling of cells or tissue from nonpalpable breast masses. Image guidance is also useful for sampling palpable lesions that are small, deep, mobile, vaguely palpable, or multiple.
- Stereotactic-guided (mammography) needle biopsy is most often used when the lesion of concern has microcalcifications. Ultrasound-guided needle biopsy is well suited for solid masses. MRI-guided needle biopsy is recommended for lesions that are not well defined by either mammography or ultrasound.
- Vacuum assisted breast biopsy is an alternative to traditional CNB, allowing approximately twice the amount of breast tissue removal while still offering a minimally invasive biopsy procedure.
- When FNAB or CNB yields a result that is in disagreement with findings from clinical breast examination or breast imaging, it is essential that the provider pursue the situation with repeat biopsy (either CNB or surgical biopsy).
- Surgical biopsy is generally used for an abnormality that is not accessible by needle biopsy. There are two types. Incisional biopsy removes a small portion of the lesion. Excisional biopsy removes the entire lesion along with a surrounding margin of normal appearing tissue.
- Surgical biopsy of a nonpalpable lesion or a lesion that is difficult to locate is most frequently facilitated by a preoperative wire localization technique (inserted by the radiologist) that guides the surgeon to the direct location.

Notes: [Go to Algorithm]

Note 7A. When biopsy finds that an abnormality is not malignant but concerning, the patient should be referred to a breast specialist for further evaluation. Such abnormalities are sometimes associated with a malignancy.

Note 7B. If physical findings and/or diagnostic imaging results are suspicious for a malignancy, then a negative biopsy finding must be considered discordant. It may represent a false negative result.

7. Breast Biopsy



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Appendix - Clinical Tools

The American Cancer Society and Centers for Disease Control and Prevention sponsored a national workgroup comprised of breast cancer screening experts with the goal of reaching consensus on standardized core competencies for the practice and reporting of clinical breast examination (CBE). The following clinical tools are based on the workgroup's recommendations as published in the article, *Clinical Breast Examination: Practical Recommendations for Optimizing Performance and Reporting*, CA: A Cancer Journal for Clinicians, November/ December 2004.

Core Competencies of Clinical Breast Examination

This form highlights the nine core competencies considered essential to a comprehensive clinical breast examination. It can be printed and used as a guide by clinicians who perform CBE.

CBE Results Documentation Form

This form standardizes the documentation of CBE results. When completed with care and accuracy, it is a valuable tool for both assisting providers with the communication of key findings within and across specialties and for clinical risk management. A copy of this form should accompany referrals to mammography and/or other follow-up procedures.

Breast Cancer History and Risk Assessment Form

This form offers a systematic approach for gathering and recording key information needed for determining a patient's breast cancer risk and plan of action. It is intended to be completed by the patient and reviewed by the clinician with the patient.

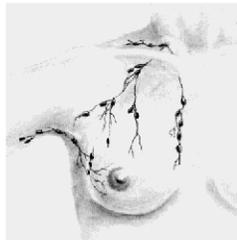
Core Competencies of Clinical Breast Examination

HISTORY



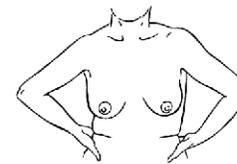
- ⌘ Health history questions regarding age, family history, personal history, reproductive history
- ⌘ Review patient's concerns or symptoms
- ⌘ Assess actual and perceived risk

LYMPH NODE EXAM



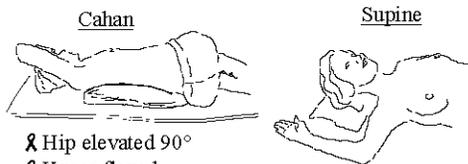
- Clavicular
Palpate deep above & below the clavicle
- Axillary
Palpate in a diamond pattern
 - ⌘ Deep at the apex
 - ⌘ Medially along pectoralis muscle
 - ⌘ Laterally along subscapular muscle
 - ⌘ High under humeral head

VISUAL INSPECTION



- In sitting position check for:
- ⌘ Symmetry
 - ⌘ Skin changes
 - ⌘ Nipple changes
 - ⌘ Dimpling
 - ⌘ Venous Pattern

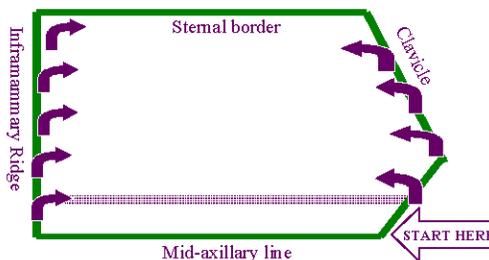
PATIENT POSITIONING



- Cahan**
- ⌘ Hip elevated 90°
 - ⌘ Knees flexed
 - ⌘ Support lower back or shoulder
 - ⌘ Elbow - 90° angle, back of hand on forehead

- Supine**
- ⌘ Elbow - 90° angle

PERIMETER & PATTERN (VERTICAL STRIP)



PALPATION



Pads of three middle fingers



Dime size circles

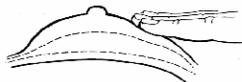
JAMA, Vol. 282, No 13, Oct. 1999



Slide or walk between palpations without lifting fingers

PRESSURE

Light



Medium



Deep



JAMA, Vol. 282, No 13, Oct. 1999

PLAN OF ACTION & PATIENT ED



- ⌘ Determine next steps for abnormal results
- ⌘ Stress importance of adherence to f/u
- ⌘ Emphasize rescreening
- ⌘ Impart cultural sensitivity
- ⌘ Discuss/teach B SE

DOCUMENTATION

- ⌘ Patient concerns
- ⌘ Exam findings
- ⌘ Plan of action
- ⌘ Referrals made
- ⌘ Patient education
- ⌘ Results notification (tests/procedures)



Discreet Mass

- ✓ Location
- ✓ Size
- ✓ Shape
- ✓ Margins
- ✓ Mobility
- ✓ Consistency
- ✓ Tenderness



Cancer Detection Programs
Every Woman Counts

CBE RESULTS DOCUMENTATION FORM

Pt Name: _____
ID #: _____
DOB: _____

Breast Health History	Purpose of Visit <input type="checkbox"/> Annual screening <input type="checkbox"/> New problem <input type="checkbox"/> Recall <input type="checkbox"/> Short-term F/U ___ mos. <input type="checkbox"/> Other: _____	Date of Last CBE _____ <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown	Breast Cancer History Patient: Age at Dx _____ <input type="checkbox"/> N/A Mother: Age at Dx _____ <input type="checkbox"/> N/A Sister(s): Age(s) at Dx _____ <input type="checkbox"/> N/A Daughter(s): Age(s) at Dx _____ <input type="checkbox"/> N/A Aunt(s): Age(s) at Dx _____ <input type="checkbox"/> N/A Male Relative(s): _____ <input type="checkbox"/> N/A <i>specify relationship</i>																											
	Patient Concerns <input type="checkbox"/> None <input type="checkbox"/> Lump <input type="checkbox"/> Nipple discharge <input type="checkbox"/> Nipple skin retraction <input type="checkbox"/> Erythema / swelling <input type="checkbox"/> Rash / scaling <input type="checkbox"/> Breast pain <input type="checkbox"/> Other: _____	<table border="0"> <tr> <td>R</td><td>L</td><td>Cyclic</td><td>Date Pt Found</td></tr> <tr> <td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>_____</td></tr> </table>	R	L	Cyclic	Date Pt Found	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
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Physical Exam	Breast Findings None <input type="checkbox"/> Fine nodularity <input type="checkbox"/> <input type="checkbox"/> Dense nodularity <input type="checkbox"/> <input type="checkbox"/> Skin edema <input type="checkbox"/> <input type="checkbox"/> Nipple/areolar change <input type="checkbox"/> <input type="checkbox"/> Tenderness <input type="checkbox"/> <input type="checkbox"/> Nipple discharge <input type="checkbox"/> <input type="checkbox"/> Mass <input type="checkbox"/> <input type="checkbox"/> Symmetry <input type="checkbox"/> <input type="checkbox"/>	<table border="0"> <tr> <td>R</td><td>L</td><td>Depth of Pressure</td><td>O'Clock</td><td>Distance from Nipple</td></tr> <tr> <td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>_____</td><td>_____</td><td>_____</td></tr> </table>	R	L	Depth of Pressure	O'Clock	Distance from Nipple	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	Discrete Mass <table border="0"> <tr> <td>Shape</td><td>Margins</td><td>Size</td><td>Texture</td><td>Mobility</td><td>Other</td></tr> <tr> <td><input type="checkbox"/> round</td><td><input type="checkbox"/> well-defined</td><td><input type="checkbox"/> <5 mm</td><td><input type="checkbox"/> soft</td><td><input type="checkbox"/> fixed</td><td><input type="checkbox"/> _____</td></tr> <tr> <td><input type="checkbox"/> oval</td><td><input type="checkbox"/> ill-defined</td><td><input type="checkbox"/> 5-9 mm</td><td><input type="checkbox"/> firm</td><td><input type="checkbox"/> mobile</td><td><input type="checkbox"/> _____</td></tr> <tr> <td><input type="checkbox"/> irregular</td><td></td><td><input type="checkbox"/> 1-2 cm</td><td><input type="checkbox"/> rubbery</td><td></td><td></td></tr> <tr> <td></td><td></td><td><input type="checkbox"/> 3-4 cm</td><td><input type="checkbox"/> hard</td><td></td><td></td></tr> <tr> <td></td><td></td><td><input type="checkbox"/> >4 cm</td><td></td><td></td><td></td></tr> </table>	Shape	Margins	Size	Texture	Mobility	Other	<input type="checkbox"/> round	<input type="checkbox"/> well-defined	<input type="checkbox"/> <5 mm	<input type="checkbox"/> soft	<input type="checkbox"/> fixed	<input type="checkbox"/> _____	<input type="checkbox"/> oval	<input type="checkbox"/> ill-defined	<input type="checkbox"/> 5-9 mm	<input type="checkbox"/> firm	<input type="checkbox"/> mobile	<input type="checkbox"/> _____	<input type="checkbox"/> irregular		<input type="checkbox"/> 1-2 cm	<input type="checkbox"/> rubbery					<input type="checkbox"/> 3-4 cm	<input type="checkbox"/> hard					<input type="checkbox"/> >4 cm				<p>+++ = scar • = palpable mass /// = dimpling Δ = uncertain thickening</p>
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Results	CBE Result Date _____ <input type="checkbox"/> Normal <input type="checkbox"/> Benign finding <input type="checkbox"/> Abnormality: suspicious for cancer	Imaging Referral Date _____ <input type="checkbox"/> Screening imaging <input type="checkbox"/> Diagnostic imaging <input type="checkbox"/> Ultrasound (only) <input type="checkbox"/> Other	Patient Education <input type="checkbox"/> Importance of annual screen <input type="checkbox"/> Referral follow-up <input type="checkbox"/> Breast self-examination <input type="checkbox"/> Other
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Overall Summary

Clinician Signature for CBE: _____ **Date:** _____

Case Management	Date _____ CBE & imaging results concordant _____ CBE & imaging discordant _____ Patient notified of mammogram results _____ Patient informed and referred _____ Referral for risk assessment counseling	Date _____ Radiology/imaging workup _____ Surgical consult _____ Return for CBE in 1 2 3 mos. _____ Return for CBE in 6 mos. _____ Return in one year for annual CBE Other _____
	Final Diagnosis Date _____ Diagnosis _____	
	Clinician Signature: _____ Date: _____	

14. Have you ever had radiation treatment to your chest (not mammography)?

No Not sure Yes Reason _____

15. Have any of your mammograms shown dense breast tissue?

No Not sure Yes How dense? _____ % Not sure

16. Please indicate whether you or your family members have had any of the cancers listed in the top row of the table by circling yes (Y) or no (N). Provide information about your biological (blood) relatives only, both living and deceased.

	<i>Breast cancer at or before age 50</i>		<i>Breast cancer after age 50</i>		<i>Breast cancer in a male relative</i>		<i>Ovarian cancer</i>		<i>Other related cancers* (please specify)</i>
<i>Yourself (personal history)</i>	Y	N	Y	N	-----	Y	N		
<i>Your parents</i>	Y	N	Y	N	Y	N	Y	N	_____
<i>Your brothers & sisters</i>	Y	N	Y	N	Y	N	Y	N	_____
<i>Your children</i>	Y	N	Y	N	Y	N	Y	N	_____
<i>Your father's parents</i>	Y	N	Y	N	Y	N	Y	N	_____
<i>Your mother's parents</i>	Y	N	Y	N	Y	N	Y	N	_____
<i>Your father's brothers & sisters</i>	Y	N	Y	N	Y	N	Y	N	_____
<i>Your mother's brothers & sisters</i>	Y	N	Y	N	Y	N	Y	N	_____

*Other related cancers include thyroid cancer, endometrial cancer, bone or soft tissue cancer, sarcoma, adrenocortical carcinoma, brain cancer, diffuse gastric cancer, and early onset acute leukemia.

17. If you answered yes to having a personal history of breast cancer, what treatments did you have? (If you have not had breast cancer, skip to 18)

Surgery: Lumpectomy Mastectomy Circle one: Lt Breast Rt Breast Both Breasts
 Radiation
 Chemotherapy
 Hormones
 Other: _____

18. Have you ever had breast surgery for reasons other than breast cancer (implants, reduction, other)?

No Not sure Yes Circle all that apply: Implants Breast Reduction Other

19. Have you or a family member tested positive for a mutation in a breast cancer susceptibility gene?

No Not sure Yes What gene(s)? _____ Not sure

20. Do you have Ashkenazi Jewish ancestry?

No Not sure Yes



Cancer Detection Programs:
Every Woman Counts

To obtain a copy of this document in an alternate format, please contact:

California Department of Public Health
Cancer Detection Section
MS 7203
P.O. Box 997377
Sacramento, CA 95899-7377
916 449-5300 (Phone)
916 449-5310 (FAX)

Please allow at least 10 working days to coordinate alternate format services.