Breast Cancer Screening and Diagnosis Guidelines

Version: 2.2011

Jordan Breast Cancer Program

البرنامج الأردني لسرطان الثدي

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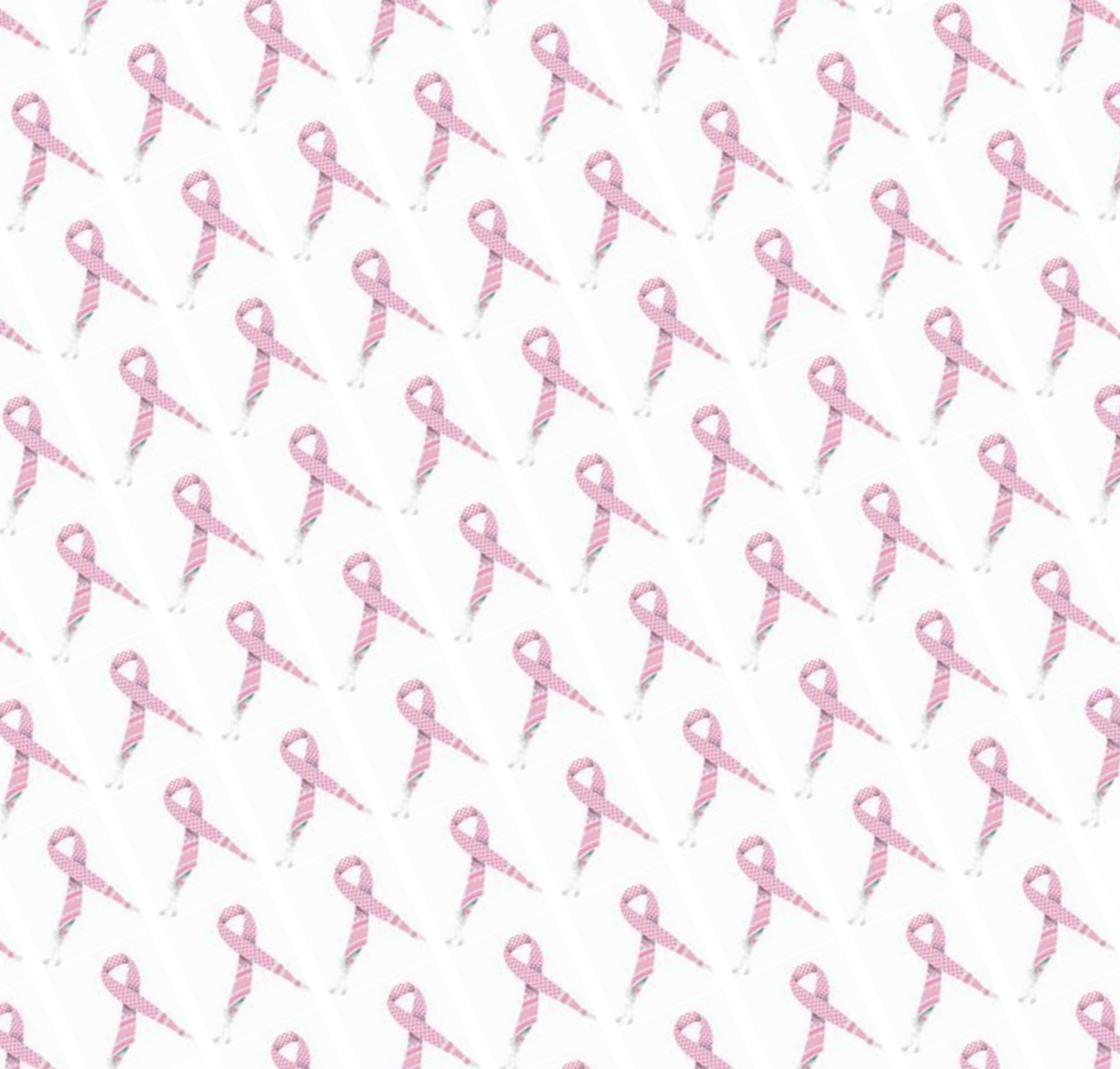

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Minister Foreword

It is my pleasure to introduce to you, for the first time in Jordan, the National Breast Cancer Screening and Diagnosis Guidelines; a long-awaited set of directions to guide us all in the provision of comprehensive and high-quality services for the screening and early detection of breast cancer.

Breast cancer is the most common cancer in Jordan overall, and is the most common malignancy afflicting Jordanian women. Every year, an estimated 700 women in Jordan are diagnosed with breast cancer. However, due to demographic trends, significantly more women will be confronted with this disease in the future. Systematic screening of the female population offers the prospect of detecting breast cancer at earlier stages, thus significantly improving survival rates, and saving lives. This prospect can only be achieved, however, through the coordinated efforts of a multitude of stakeholders, from health providers to policy and decision makers, in establishing a proper nation-wide screening and early detection system.

The Ministry of Health has established a National Steering Committee for Breast Cancer Screening and Early Detection in 2006 and has tasked the King Hussein Cancer Center with its leadership. In order to address identified needs and gaps, the Jordan Breast Cancer Program has been established to orchestrate all required activities, covering accessibility, availability and usability of screening services, awareness and education of females and target population, capacity building of health professionals and quality assurance.

As part of the Ministry of Health's commitment to providing preventive and curative services to the public, and in particular, ensuring that women in Jordan have access to optimal quality breast screening services, it is of utmost importance to establish standardized and dependable guiding principles, and thus, implement these National Guidelines. The Jordan Breast Cancer Program convened representatives from various medical sectors in Jordan in order to work collectively on producing these guidelines specific to the Jordanian context and needs, which are meant to provide relevant healthcare professionals with recommended standards and procedures as well as a framework for screening.

It is my hope that the information presented in this report will guide work on breast cancer screening and diagnosis for years to come, and will move Jordan one step closer towards down-staging breast cancer and implementing universal screening. I extend grateful appreciation to everyone who worked on producing these guidelines, including the Jordan Breast Cancer Program, the Technical Taskforce and the well-thanked Core Reviewers.

Minister of Health

Dr. Salah Mawajdeh

Acknowledgements

The Jordan Breast Cancer Program offers its deepest thanks to the various people who provided their valuable time and helpful feedback and assistance throughout the development of the Guidelines. The Jordan Breast Cancer Program also thanks the National Comprehensive Cancer Network (NCCN) for granting permission to reproduce and adapt the NCCN 2.2008 Breast Cancer Screening and Diagnosis Guidelines.

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± Nursing
Σ Pathology
¥ Pediatrics
Δ Public Health
ϒ Radiology
§ Radiotherapy/Radiation Oncology
¶ Surgery/Surgical Oncology
ð Women's Health

f King Hussein Cancer Center
φ Ministry of Health
π Private Sector
χ Private Sector Project for Women's Health
∝ Royal Medical Services
λ UNRWA

Acronyms

ACR	American College of Radiology
ACS	American Cancer Society
ASCO	American Society of Clinical Oncology
BI-RADS®	Breast Imaging-Reporting and Data System
BRCA 1	Breast Cancer I, early onset gene
BRCA 2	Breast Cancer II, early onset gene
CBE	Clinical Breast Examination
DMIST	Digital Mammographic Imaging Screening Trial
FNA	Fine Needle Aspiration
HBOC	Hereditary Breast and Ovarian Cancer
JBCP	Jordan Breast Cancer Program
JNCR	Jordan National Cancer Registry
LCIS	Lobular Carcinoma In Situ
mo	month(s)
MoH	Ministry of Health
MRI	Magnetic Resonance Imaging
NCCN	National Comprehensive Cancer Network
NCI	National Cancer Institute
RT	Radio Therapy
SBE	Self Breast Examination
UNRWA	United Nations Relief and Works Agency
USAID	United States Agency for International Development
WHO	World Health Organization
y	year(s)

NCCN Categories of Evidence and Consensus

The NCCN Guidelines Steering Committee has devised the following set of Categories of Evidence and Consensus. These annotations contain two dimensions: the strength of the evidence behind the recommendation and the degree of consensus about its inclusion.

Category 1 : Based on high-level evidence and uniform consensus.

Category 2A : Based on lower-level evidence including clinical experience and uniform consensus.

Category 2B : Based on lower-level evidence including clinical experience and nonuniform consensus (but no major disagreement).

Category 3 : Based on any level of evidence but reflects major disagreement.

All recommendations are Category 2A unless otherwise indicated.

Executive Summary

Self Breast Examination

Women should be encouraged to perform self breast examinations (SBE) starting in their adolescent years. By the age of 20, women should have received SBE instruction and perform SBE on a regular monthly basis. Self breast examinations should be performed in combination with clinical breast examinations and mammograms (when appropriate), and not as a substitute for either method. The purpose of SBE is for a woman to gain familiarity with the composition of her breasts and to know how her breasts normally feel, so as to identify and report any new breast changes to a health professional should they occur. Despite the controversy over the usefulness of SBE, this method may detect interval cancers between routine screenings, and therefore, should be required of all women over the age of 20.

Clinical Breast Examination

Clinical breast examination (CBE) is considered an essential part of breast cancer screening for all women. CBE is performed for the purpose of differentiating normal physiologic nodularity from a discrete breast mass. The efficacy of CBE is dependent upon a number of factors including proper positioning of the patient, thoroughness of the search and the area covered, use of a consistent pattern of search, and so on. The age- and risk-specific recommendations for CBE are as follows:

Women at Normal Risk

- Clinical breast examinations every one to three years are recommended for women aged 20 – 39 years.
- Annual clinical breast examinations are recommended for women aged 40 and above

Women at Increased Risk

- Annual clinical breast examinations are recommended for women under the age of 20 years with strong family history or genetic predisposition, or who have received prior thoracic irradiation.
- Clinical breast examinations every 6 to 12 months are recommended for women aged 20 years and older with strong family history or genetic predisposition, or who have received prior thoracic irradiation.
- Clinical breast examinations every 6 to 12 months are recommended for women with Lobular Carcinoma In Situ (LCIS) or atypical hyperplasia.

Summary of CBE Recommendations

Age Group	Normal Risk	Increased Risk		
		Strong Family History or Genetic Predisposition	Prior Thoracic RT	LCIS/Atypical Hyperplasia
Under 20 years	---------	Annually	Annually	Every 6 – 12 months
20 – 39	Once every 1-3 years	Every 6 – 12 months	Every 6 – 12 months	
40 – 52	Annually	Every 6 – 12 months	Every 6 – 12 months	
52 +	Annually	Every 6 – 12 months	Every 6 – 12 months	

Screening Mammography

Mammography is the primary screening tool utilized for the early detection of breast cancer, and is currently the only imaging modality that has been shown to reduce breast cancer mortality. In recent years, digital mammography has started to be used as an alternative to analog (film) mammography. One study suggests the benefit of digital mammography in young women and women with dense breasts.

The mammographic assessment should be reported according to the Breast Imaging Reporting and Data System (BI-RADS®). BI-RADS® assessments are divided into incomplete (category 0) and assessment categories (category 1, 2, 3, 4, 5, and 6).

Category 0 refers to a finding that requires additional evaluation and/or prior mammograms for the radiologist to make a clear diagnosis. The remaining six BI-RADS® categories are used when an abnormality is found. Category 1 is negative; the finding is considered normal. Category 2 is also a normal assessment; but a definite benign finding such as calcified fibroadenomas or oil cysts has been identified in the report. Both Category 1 and Category 2 assessments indicate that there is no mammographic evidence of malignancy, and therefore, only routine screening is recommended. Category 3 suggests a probably benign finding (less than a 2% risk of malignancy) that should be managed with an initial short-term follow-up (6 months). Category 4 describes a suspicious abnormality that has a reasonable probability of being malignant, in which case a biopsy should be considered. Lesions classified as Category 5 have a high probability of being cancer. Biopsy is needed, and appropriate action should be taken. Category 6 refers to lesions proven to be malignant prior to definitive treatment.

<u>Women at Normal Risk</u>

- Screening mammograms every (one - two) years is recommended for women aged 40 – 52 years.
- Once every two years screening mammograms are recommended for women aged 52 years and older.

<u>Women at Increased Risk</u>

- Annual mammograms are recommended for women aged 20 years and older who have received prior thoracic irradiation. Mammography screening is typically initiated 10 years after radiation exposure or after age 40, whichever first.
- Annual mammograms are recommended for women aged 20 years and older with a strong family history or other genetic predisposition for breast cancer, starting 5 to 10 years prior to the youngest breast cancer case in the family.

- Annual mammograms are recommended for women with LCIS or atypical hyperplasia.

Magnetic Resonance Imaging

Over the past decade, MRI of the breast has become a useful diagnostic adjunct to mammography and breast ultrasound for evaluation of breast cancer. Current evidence does not support the routine use of breast MRI as a screening procedure in average risk women.

However, it is recommended to consider MRI as an adjunct to mammogram and clinical breast exam for certain groups of women at increased risk, as summarized below:

- MRI as an adjunct to mammogram and clinical breast exam should be considered for women aged 20 years and older with strong family history or genetic predisposition, or who have received prior thoracic irradiation.
- MRI as an adjunct to mammogram and clinical breast exam should be considered for women with LCIS or atypical hyperplasia.

Summary of Screening Mammography and MRI Recommendations

Age Group	Normal Risk	Increased Risk		
		Strong Family History or Genetic Predisposition	Prior Thoracic RT	LCIS/Atypical Hyperplasia
20 – 39	---------	Annual Mammogram + Consider MRI	Annual Mammogram + Consider MRI	Annual Mammogram + Consider MRI
40 – 52	Mammogram every (1-2) years	Annual Mammogram + Consider MRI	Annual Mammogram + Consider MRI	Annual Mammogram + Consider MRI
52+	Mammogram once every 2 years	Annual Mammogram + Consider MRI	Annual Mammogram + Consider MRI	Annual Mammogram + Consider MRI

Ultrasound

Ultrasound has become a valuable diagnostic adjunct to mammography, and is used to identify and characterize mass or palpable abnormalities noted on physical examination. Its indications also include guidance of interventional procedures. However, there are limited data supporting the use of ultrasound for breast cancer screening as an adjunct to mammography for women with dense breast tissue.

The main indications for breast ultrasound are as follows:

- For women aged 30 years or older, if a dominant mass identified during clinical breast examination is classified as a BI-RADS® category 1, 2, or 3 upon mammographic assessment, further evaluation by ultrasound should then be performed.
- For women under 30 years of age, the preferred option for initial evaluation of a dominant mass is to proceed directly to ultrasound. The other two options are needle sampling and observation for one or two menstrual cycles.

Summary of Main Screening Recommendations for Women at Normal Risk

Screening / Age	20 – 29	30 – 39	40 – 52	52+
Self Breast Exam	Monthly	Monthly	Monthly	Monthly
Clinical Breast Exam	Once every 1-3 years	Once every 1-3 years	Annually	Annually
Mammogram	----------	----------	Every (1-2) years	once every 2 years

Jordan Breast Cancer Program

The Jordan Breast Cancer Program (JBCP) is a nation-wide initiative for the development and provision of comprehensive services for the early detection and screening of breast cancer for all females in Jordan within the age group 40-59 for the purpose of:

1. Reducing morbidity and mortality from breast cancer by screening and early detection; and,
2. Shifting the current state of diagnosis of breast cancer from its late stages (III- IV) to diagnosing breast cancer at its earlier stages (0-II) where the disease is most curable, survival rates are highest, and treatment costs are lowest.

GOALS & OBJECTIVES

JBCP aims to ensure the provision of quality services for screening and increase public awareness and education on the risk factors, symptoms, signs and benefits of early detection and screening of breast cancer. JBCP has a multi-dimensional approach covering the provision of screening services, education of females, capacity building of health professionals and quality assurance.

The overall objectives of JBCP are as follows:

- To improve availability and accessibility of screening services across Jordan, especially to those with low income and those residing in remote areas with little access to healthcare services;
- To increase public knowledge of the benefits of breast cancer prevention and promote attitude and behavioral change in the target population so that they seek early detection services;
- To establish national unified protocols and guidelines that cover all processes of a comprehensive early detection and screening program that include best practice and quality assurance guidelines on training, medical equipment, diagnosis, and referral systems;
- To improve healthcare personnel education and training;
- To evaluate the quality of the program by collecting data for surveillance and epidemiological analysis to record and measure success of early detection.

GOVERNANCE

JBCP has been established under the directive of His Excellency the Minister of Health, and is governed by a National Steering Committee comprising most stakeholders in health including the Ministry of Health, King Hussein Cancer Foundation and Center, USAID's Private Sector Project for Women's Health, World Health Organization (WHO), United Nations Relief and Works Agency (UNRWA), Royal Medical Services, King Abdullah Hospital, Syndicate of Private Hospitals, Jordan University, and Hashemite University.

The King Hussein Cancer Foundation and Center have been tasked with the leadership of JBCP. An executive board led by the King Hussein Cancer Center oversees the operations of JBCP, provides direction, and ensures the implementation of action plans.

Introduction

PURPOSE AND DEVELOPMENT OF THE GUIDELINES

The publication of Jordan's Breast Cancer Screening and Diagnosis Guidelines is a crucial move in the direction of ensuring the provision of high-quality breast cancer screening and diagnostic services to females in Jordan. A variety of guidelines are currently resorted to by practitioners in the medical sector. Thus, these national guidelines have been published to provide healthcare professionals with a unified, standardized and user-friendly document of international standards in application.

Commencing in July 2007, the Jordan Breast Cancer Program undertook the long overdue task of developing breast cancer screening and diagnosis guidelines for Jordan. JBCP convened an expert panel that reviewed several established international guidelines and selected from among them the National Comprehensive Cancer Network (NCCN) Breast Cancer Screening and Diagnosis Guidelines as a baseline that was tailored and modified to suit the Jordanian context and needs. After the technical taskforce delivered their recommendations, a larger group of national experts were invited to review the draft guidelines.

The Breast Cancer Screening and Diagnosis Guidelines are intended to be useful for healthcare professionals and have been designed to provide a practical, consistent framework for screening and evaluating a spectrum of breast lesions. Clinical judgment should always be an important component of the optimal management of the patient. If the physical breast examination, radiologic imaging, and pathologic findings are not concordant, the clinician should carefully reconsider the assessment of the patient's problem. Incorporating the patient into the healthcare team's decision-making empowers the patient to determine the level of breast cancer risk that is personally acceptable in the screening or follow-up recommendations.

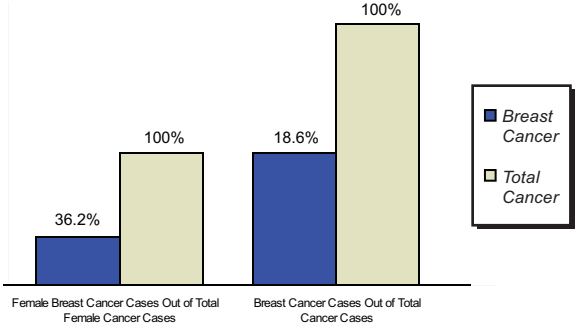
JBCP encourages the medical sector to adopt these Breast Cancer Screening and Diagnosis Guidelines as an important and indispensable resource. However, it is important to note that this document presents guidelines and does not claim to be an all-inclusive resource on breast cancer; clinicians seeking further information on the biology and epidemiology of breast cancer should consult the relevant texts.

These guidelines are a statement of consensus of the authors of the NCCN Breast Cancer Screening and Diagnosis Guidelines regarding their views of currently accepted approaches to screening, and have been modified by specialized reviewers in Jordan (listed in the Acknowledgements Section). They are based on the best evidence available at the time of publication, and will be updated periodically to include new findings and recommendations, in addition to being evaluated to determine their degree of use by practitioners.

BREAST CANCER IN JORDAN

Breast cancer is the most common cancer overall as well as the most common malignancy afflicting women in Jordan. According to the latest statistics from the Jordan National Cancer Registry (JNCR), 674 females and 10 males were diagnosed with breast cancer in 2005, accounting for 18.6 % of the total new cancer cases. Breast cancer ranked first among cancers in females, accounting for 36.2 % of all female cancers.

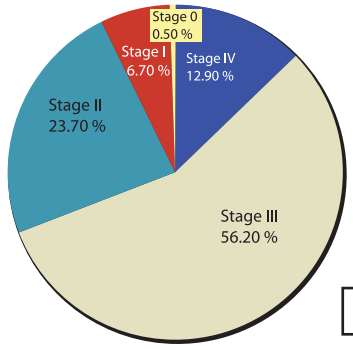
Comparison of Breast Cancer Cases to Total Cancer Cases in 2005



Breast cancer poses an important health issue in Jordan for the following reasons:

- 70 % of breast cancer cases in the country are presented at advanced stages (III-IV) during which survival rates are low and the disease is less curable. This is a reverse statistic in the West. Therefore, even though the incidence of breast cancer in Jordan is lower than incidence in Western countries, the mortality rate is very high due to late presentation of the disease;

Stages of Breast Cancer in Jordan Based on KHCC Experience in 2005/2006



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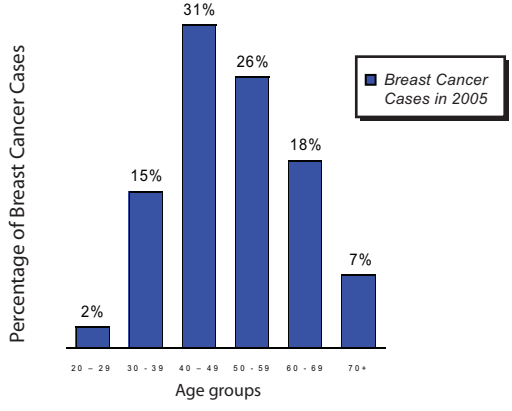
- Jordanian women are afflicted with breast cancer at a much younger age (median age is 49) than women in Western countries (median age is 65), when they are still raising children, caring for their families, and contributing to the growth and development of society;

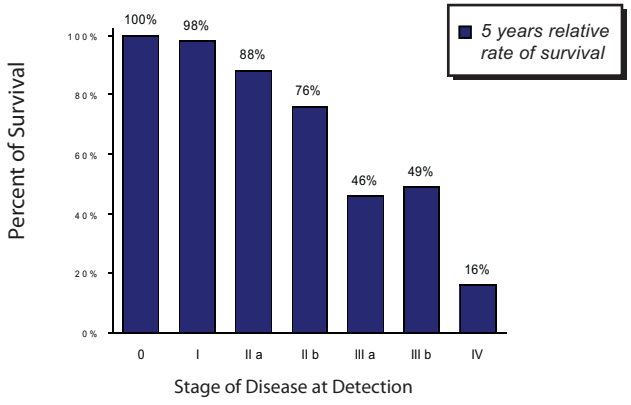
Distribution of Breast Cancer Cases Over Age, JNCR 2005



*Median age in developed countries = 65 years

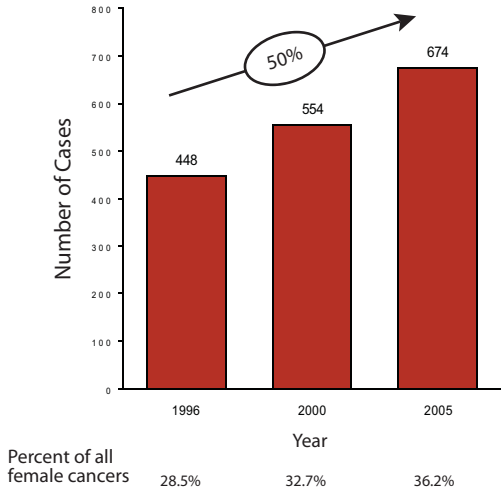
- Survival rates and the early detection of breast cancer are directly connected; yet unfortunately, public awareness in Jordan regarding this fact is minimal and inadequate;
- Treatment of patients when breast cancer is at its earlier stages is generally less expensive and more successful than treatment during later stages of the disease;

Correlation of Survival to Stage of Detection

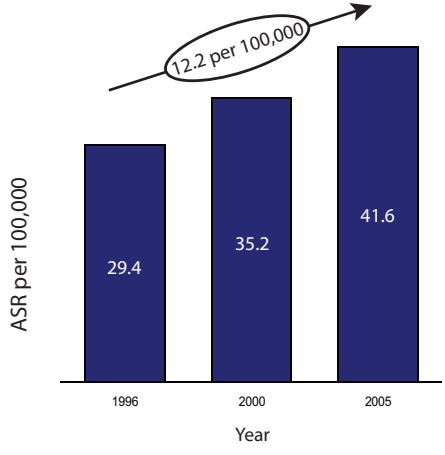


- Incidence rates are steadily increasing, and thus, in a society in which 50% of the population is under the age of 18 years old, the issue of breast cancer awareness needs to be addressed now lest it become uncontainable in the years to come when the population begins to age.

New Cases of Breast Cancer, JNCR



Age Standardized Rates of Breast Cancer Incidence, JNCR



Breast Cancer
Screening and Diagnosis Guidelines

Jordan Breast Cancer Program
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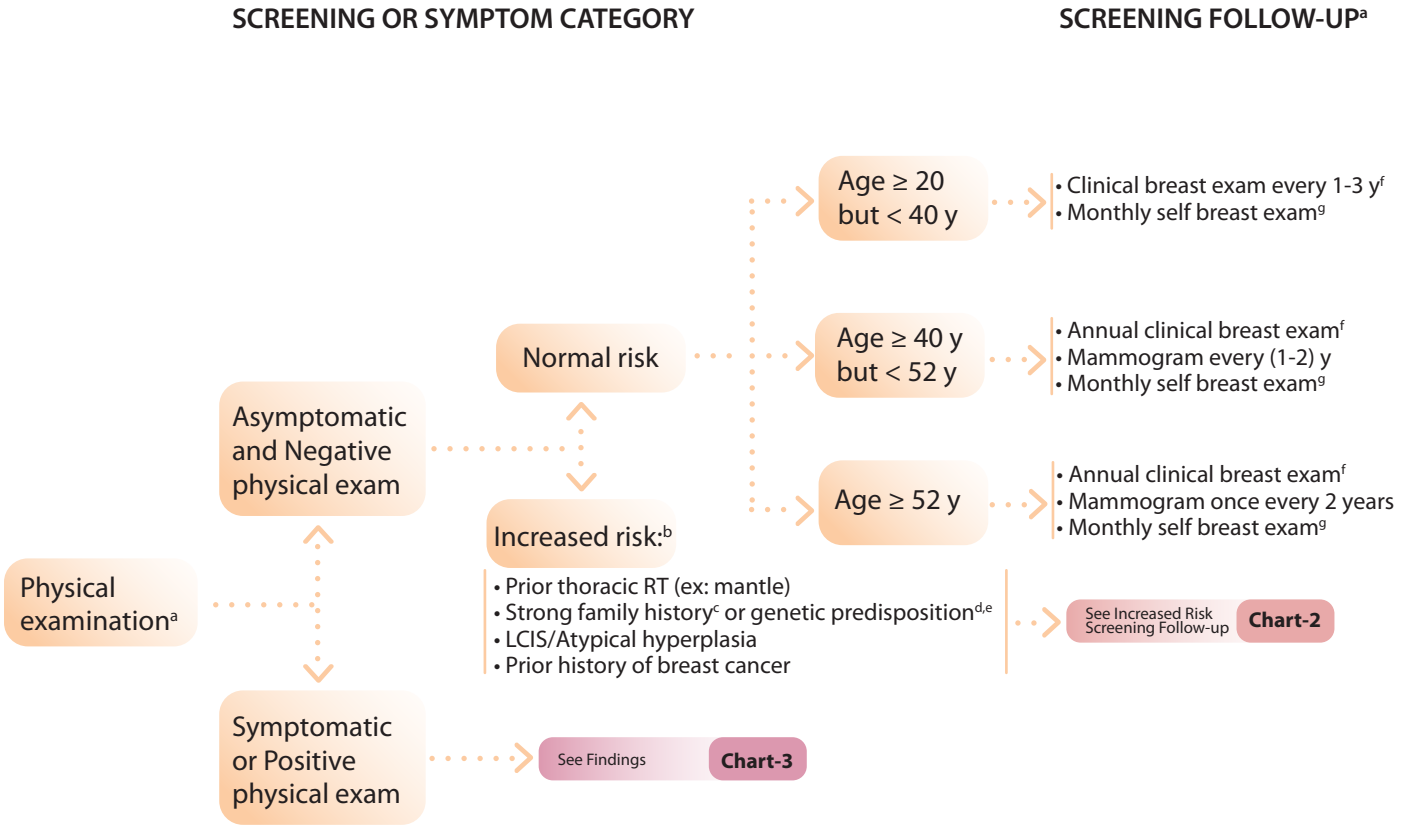
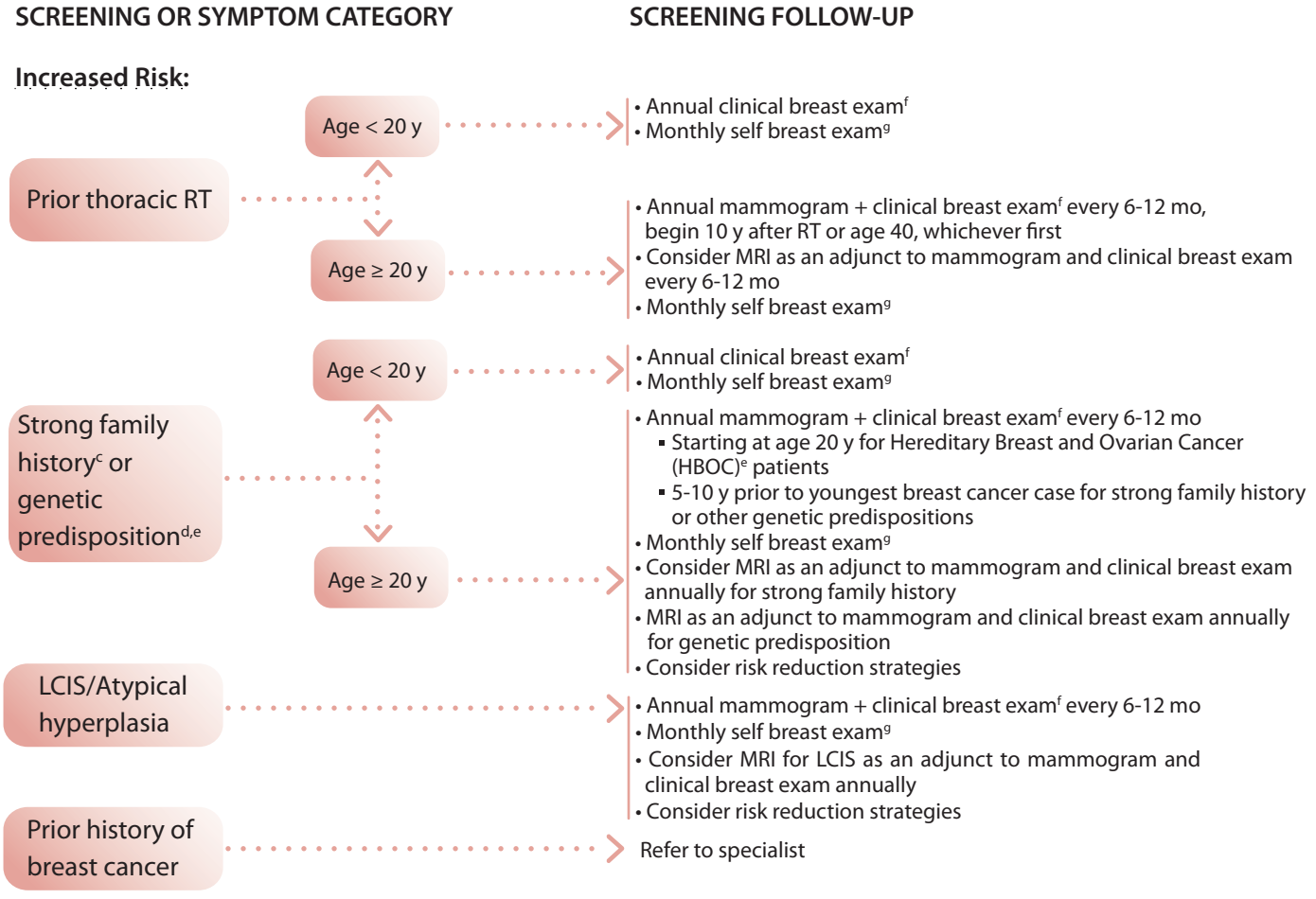


[a] See Breast Screening Considerations. **Annex-A**
[b] Consider Risk Reduction Strategies.
[c] For a definition of strong family history, see Manuscript. **Annex-D**
[d] As currently defined in the American Society of Clinical Oncology Policy Statement Update: Genetic testing for cancer susceptibility. J Clin Oncol 2003, 21:2397-2406.
[e] See Manuscript. **Annex-D**
[f] See Clinical Breast Examination Guidelines. **Annex-B**
[g] Women should be familiar with their breasts and promptly report changes to their healthcare provider. Monthly SBE may facilitate breast self awareness. Premenopausal women may find SBE most informative when performed at the end of menses.

Note: All recommendations are Category 2A unless otherwise indicated.



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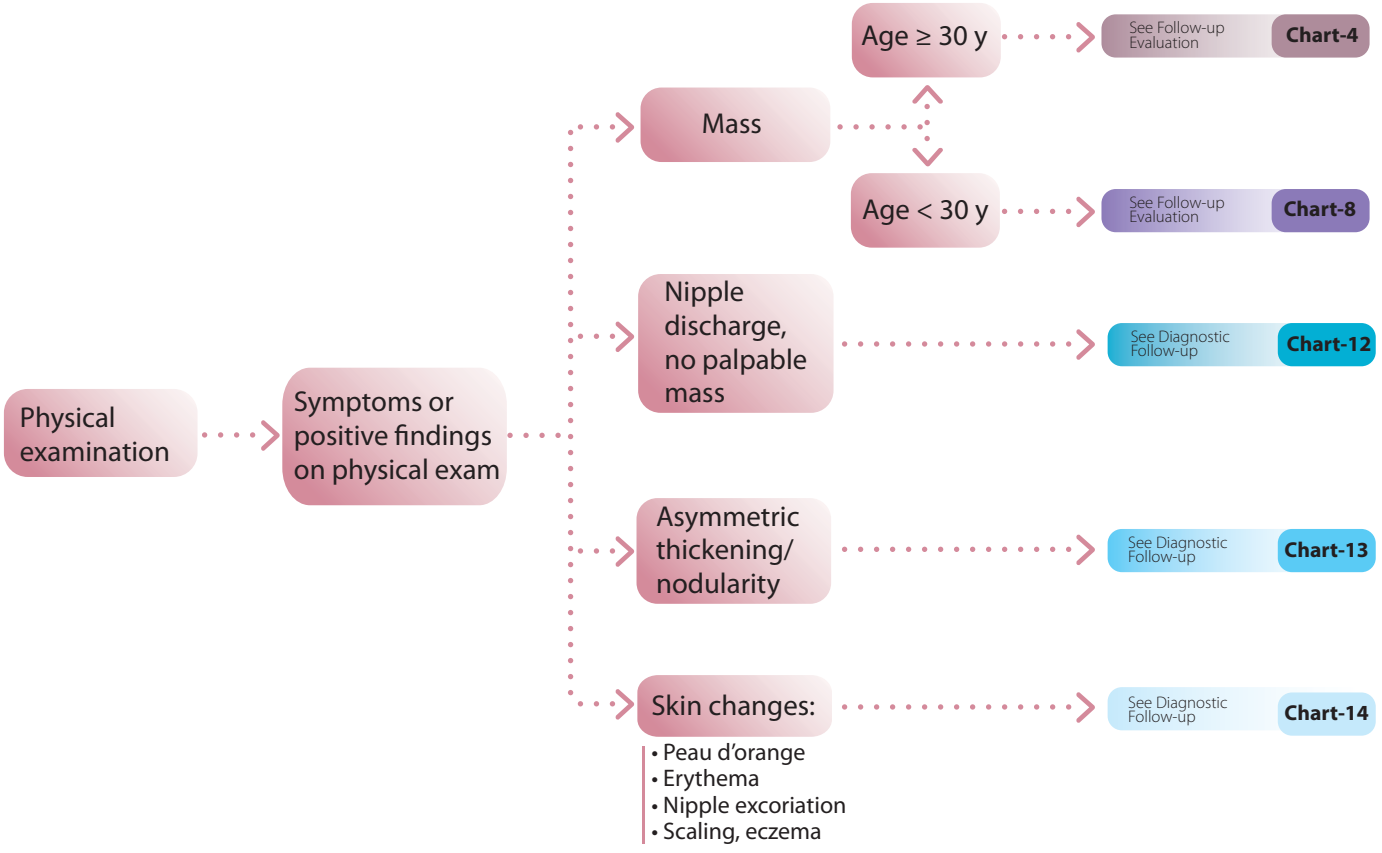
PRESENTING SIGNS/SYMPTOMS



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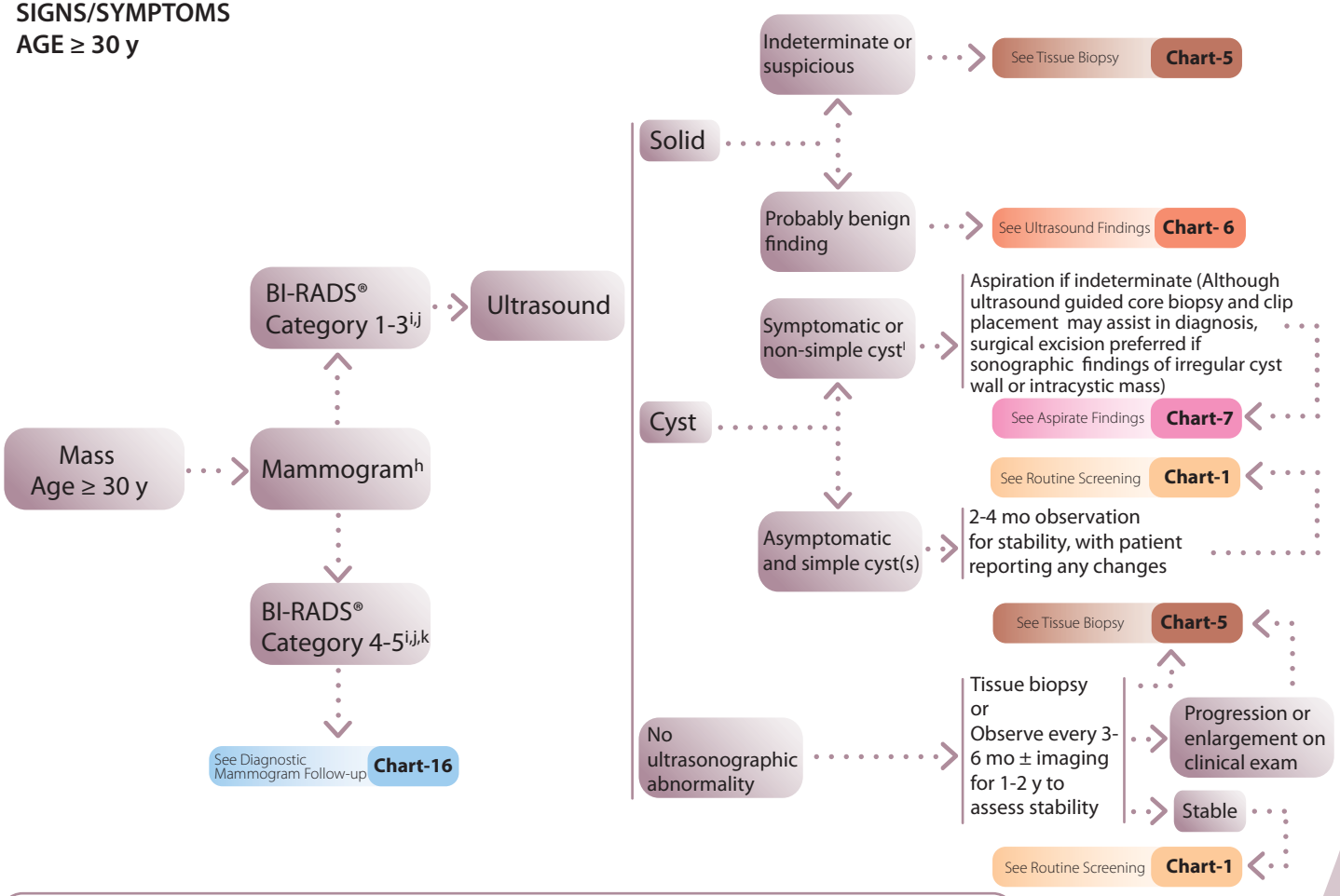
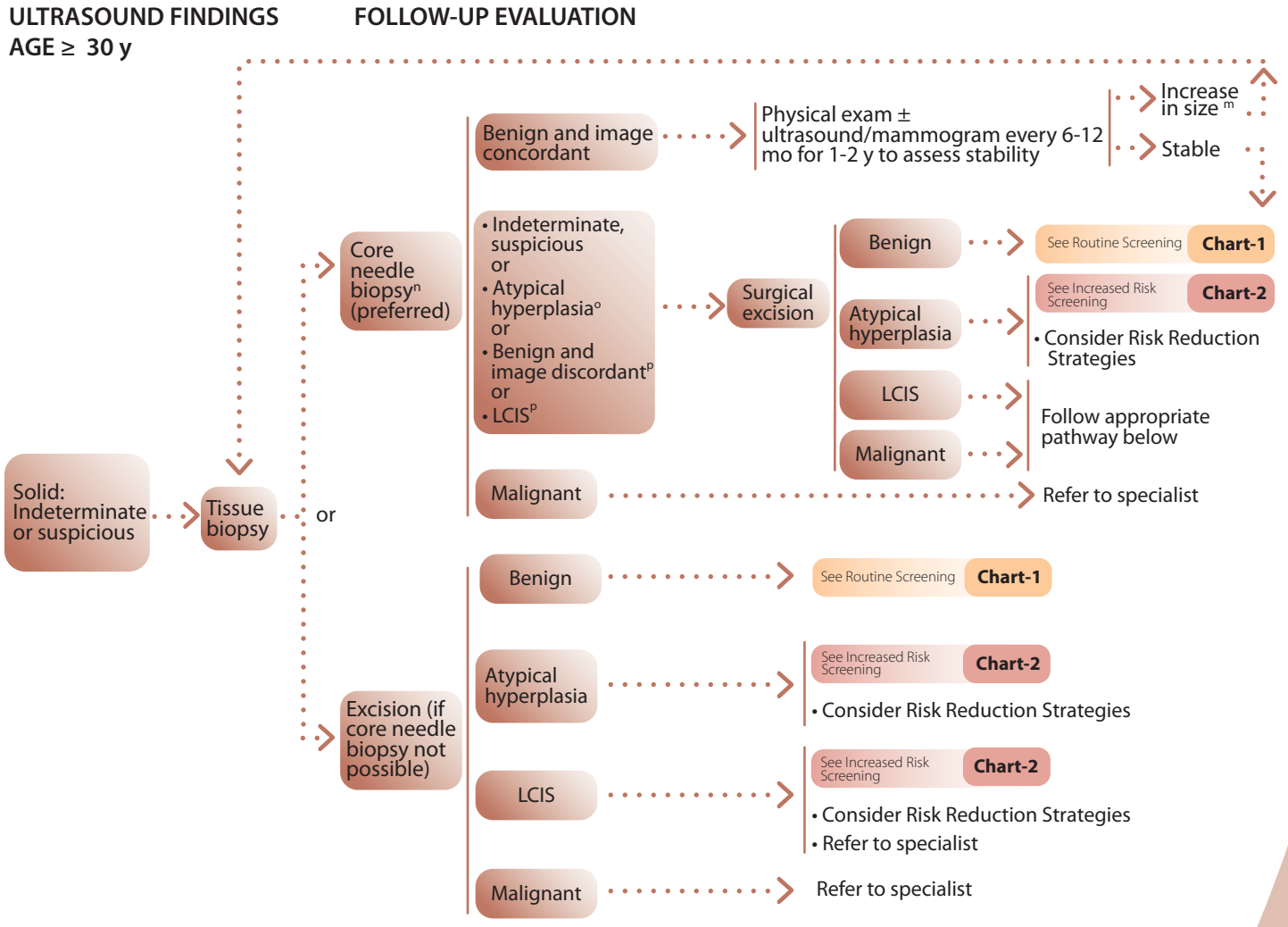


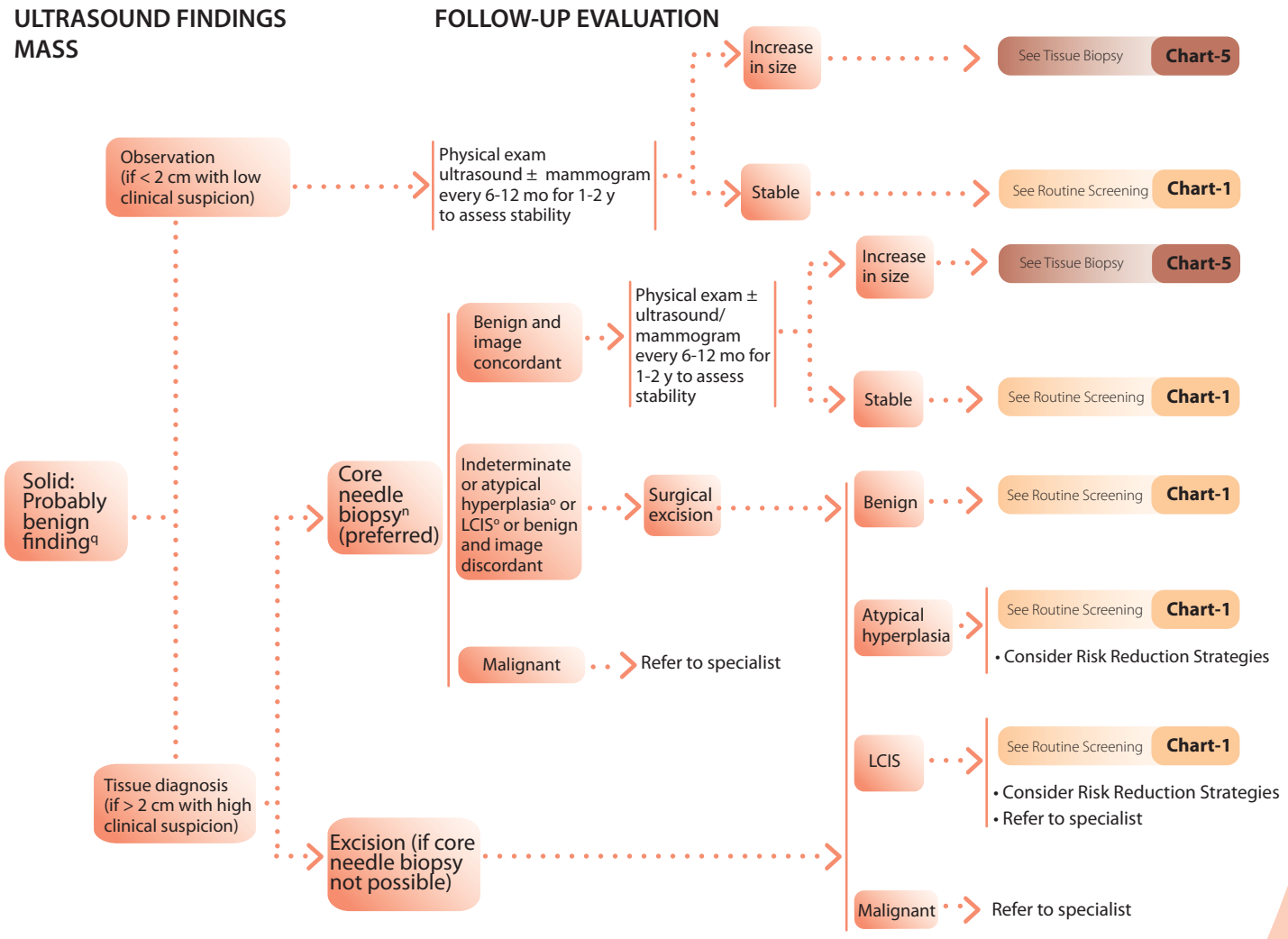
[h] There are a few clinical circumstances in which ultrasound would be preferred (ex: suspected simple cyst).
[i] See Mammographic Assessment Category Definitions. Annex-C
[j] Mammography results are recommended to be reported according to the Breast Imaging Reporting and Data System/ Final Assessment categories. Annex-C
[k] Assess geographic correlation between clinical and imaging findings. If there is a lack of correlation return to Category 1-3 for further work-up of palpable lesion. If imaging findings correlate with the palpable finding, workup of the imaging problem will answer the palpable problem.
[l] Round, circumscribed mass containing low level echoes without vascular flow, fulfilling most but not all criteria for simple cyst.

Note: All recommendations are Category 2A unless otherwise indicated.



[m] For benign and image concordant that increases in size, consider surgical excision.
[n] FNA and core (needle or vacuum-assisted) biopsy are both valuable. FNA requires cytologic expertise.
[o] Other histologies that may require additional tissue: mucin-producing lesions, potential phyllodes tumor, papillary lesions, radial scar or other histologies of concern to pathologist.
[p] Select patients may be suitable for monitoring in lieu of surgical excision (ex., ALH, LCIS , papillomas, fibroepithelial lesions, radial scars, etc).

Note: All recommendations are Category 2A unless otherwise indicated.



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[q] Stavros A, Thickman D, Rapp C et al. Solid breast nodules: use of sonography to distinguish between benign and malignant lesions. Radiology 1995;196:123-124.

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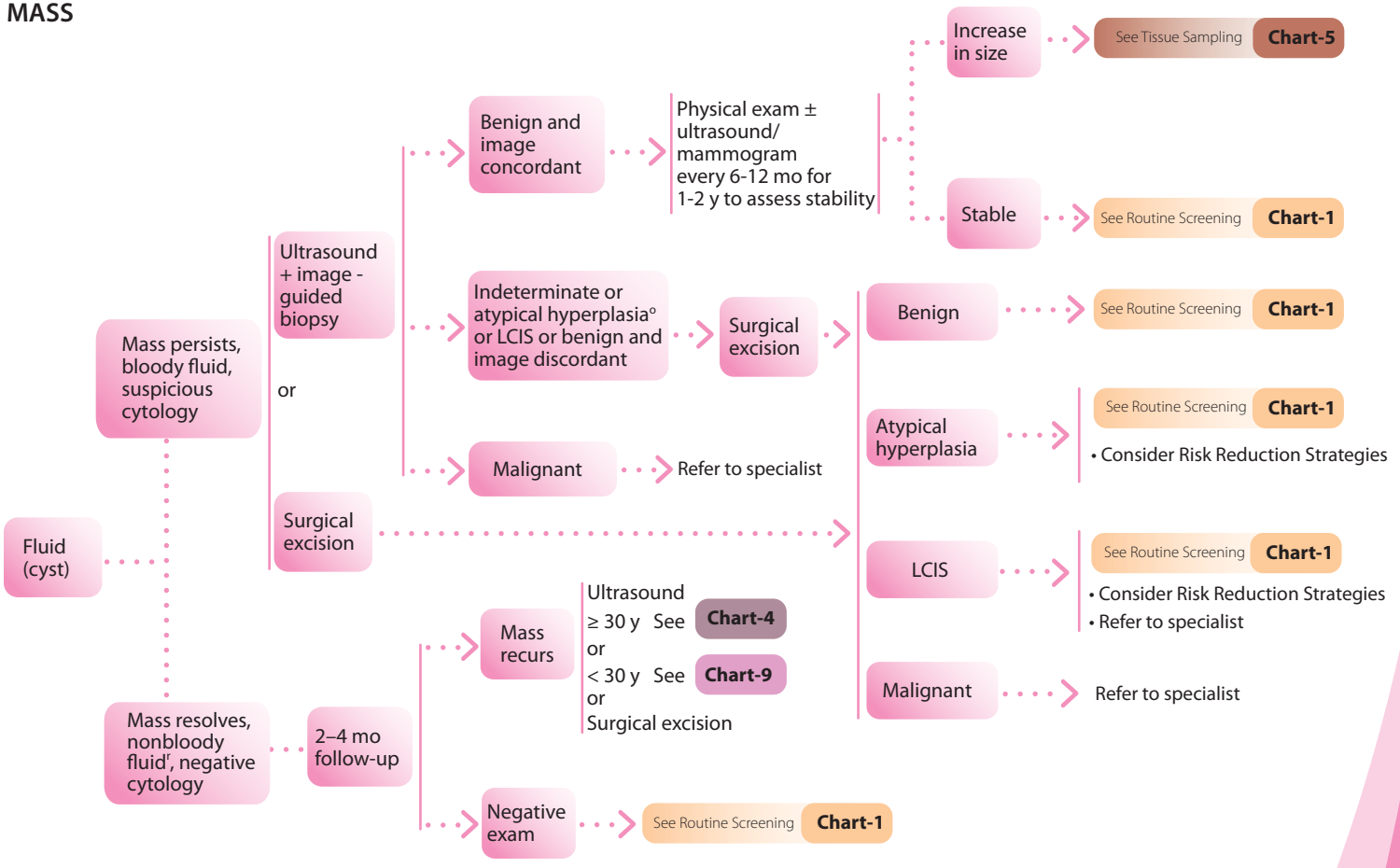
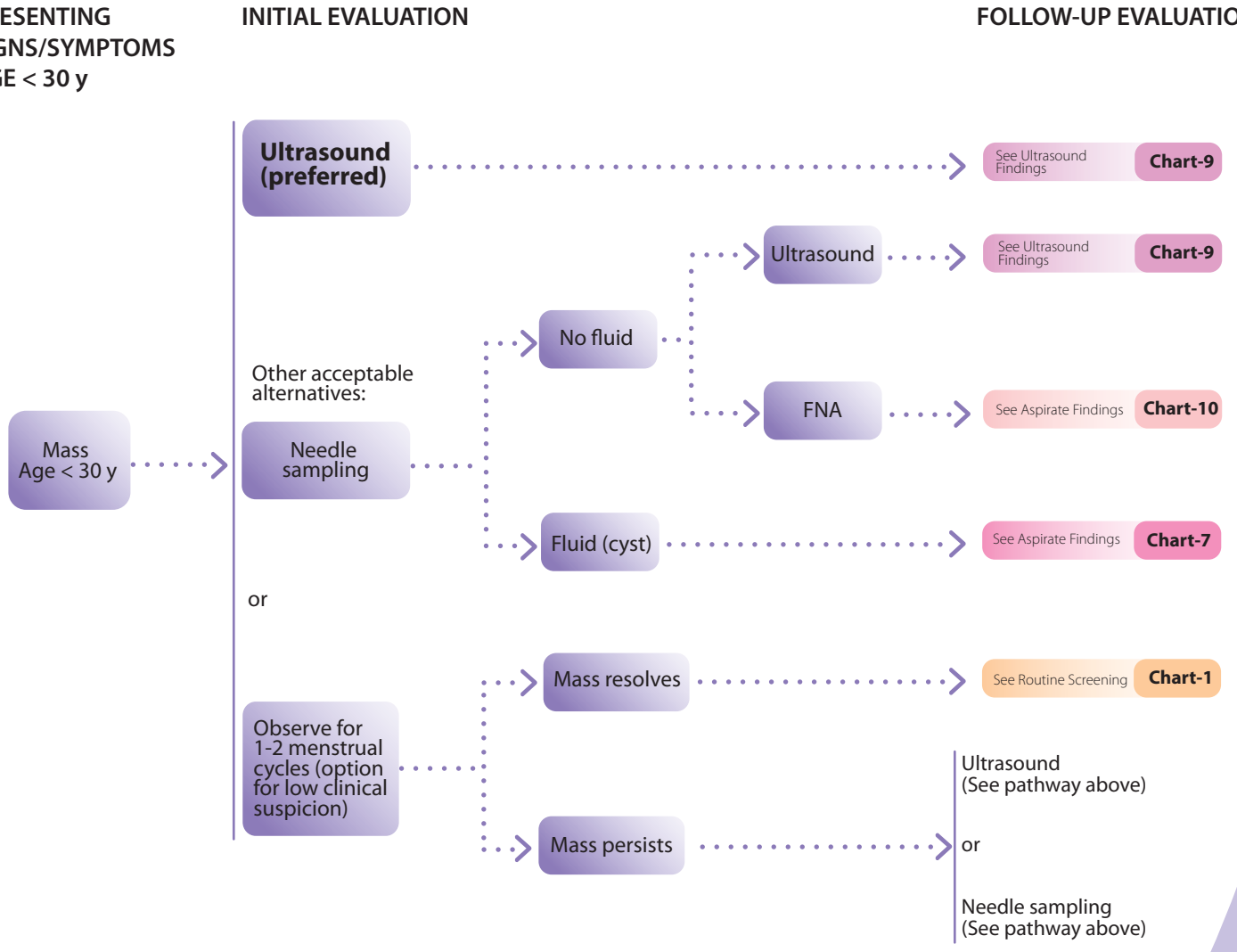


[o] Other histologies that may require additional tissue: mucin-producing lesions, potential phyllodes tumor, papillary lesion, radial scar or other histologies of concern to pathologist.
[r] Routine cytology not recommended.

Note: All recommendations are Category 2A unless otherwise indicated.



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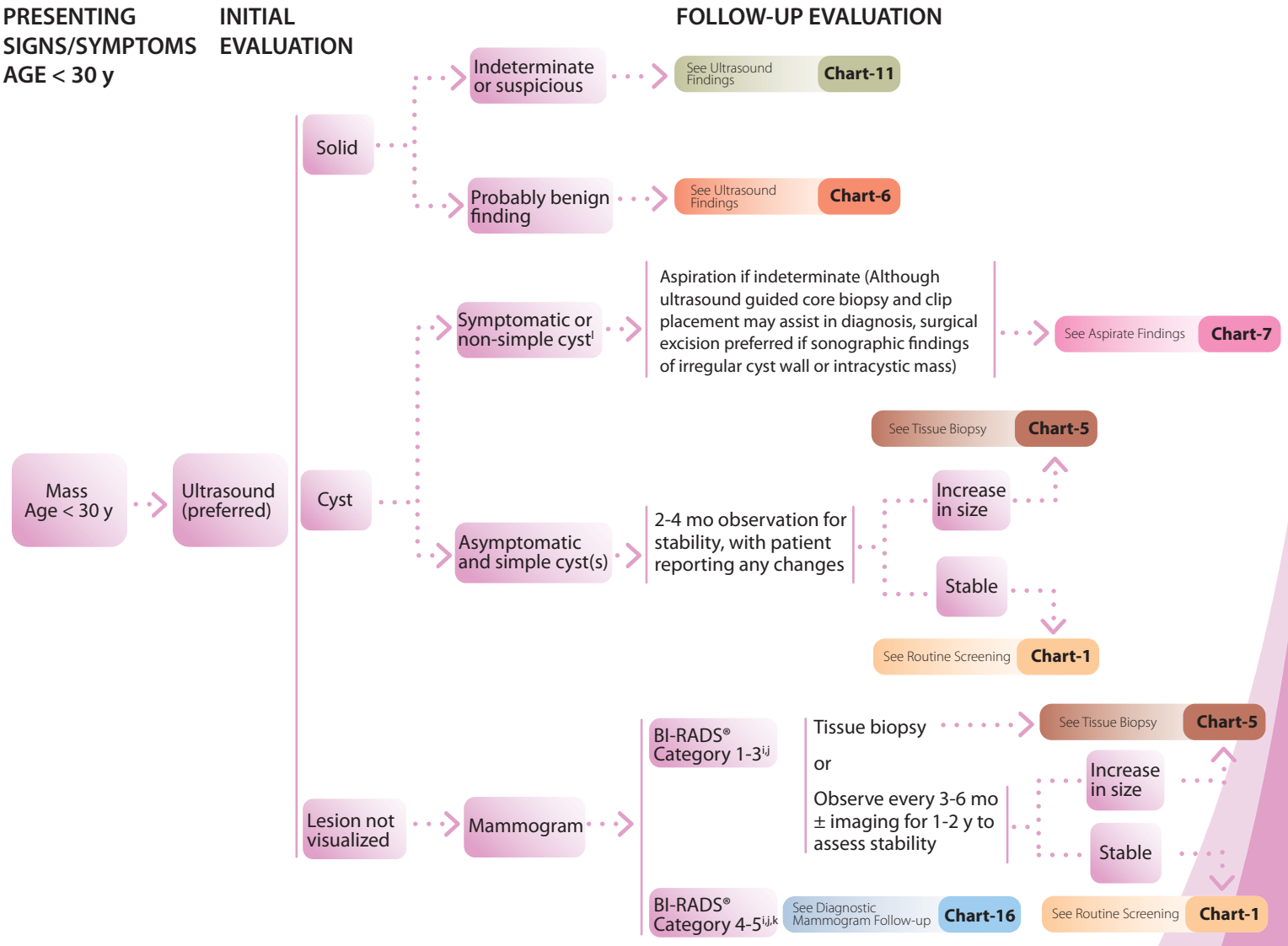
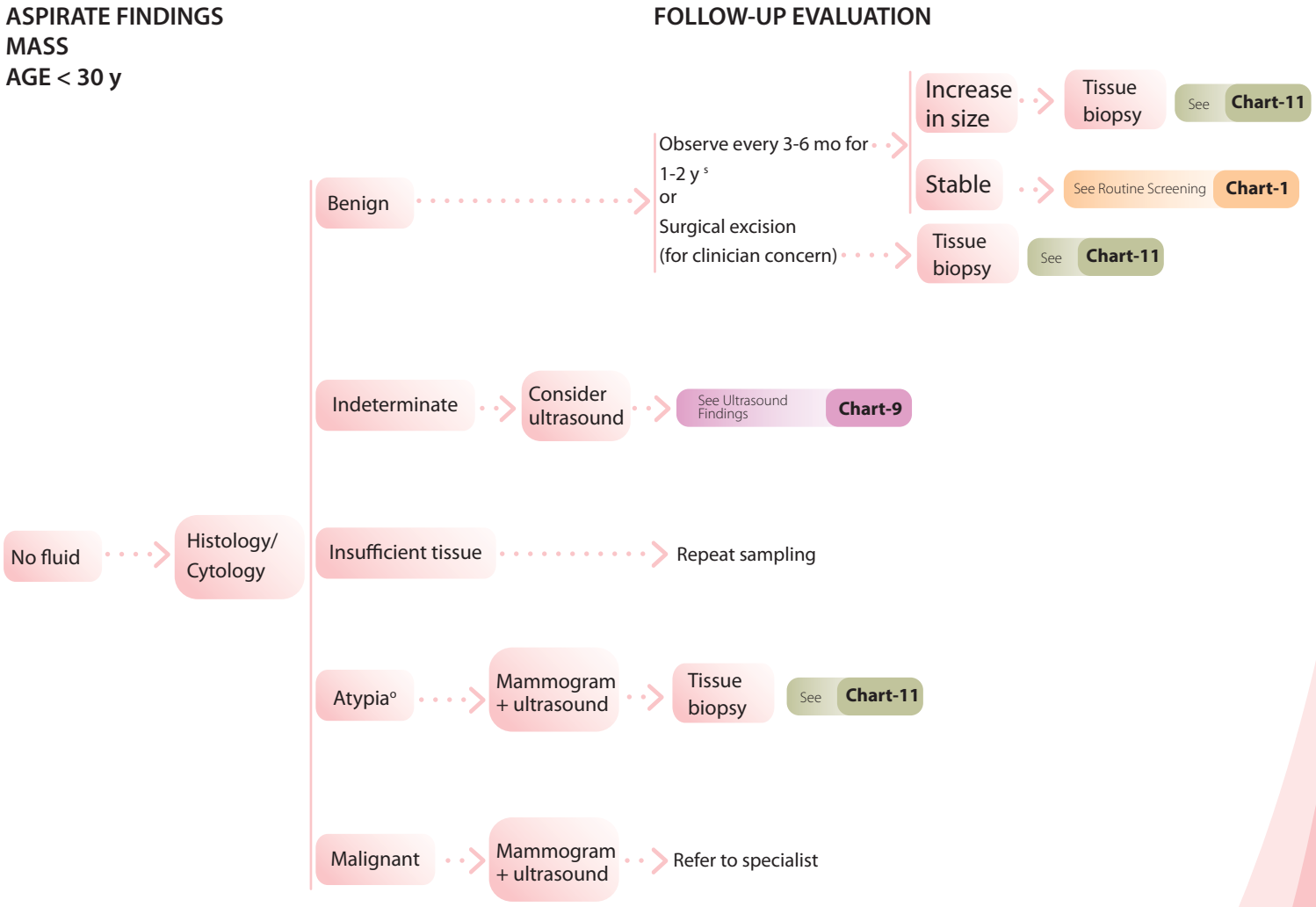


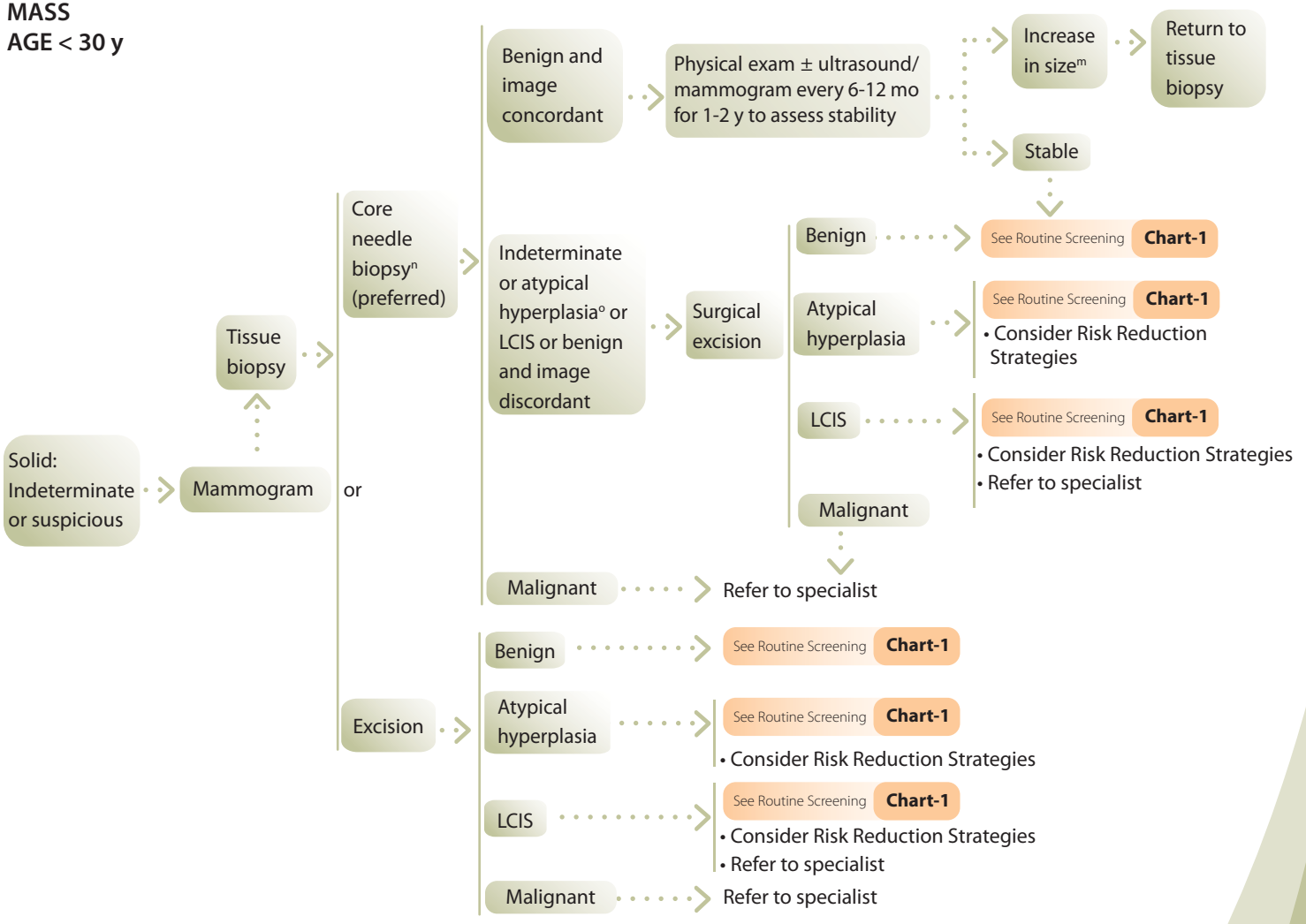
[l] Round, circumscribed mass containing low level echoes without vascular flow, fulfilling most but not all criteria for simple cyst.

Note: All recommendations are Category 2A unless otherwise indicated.



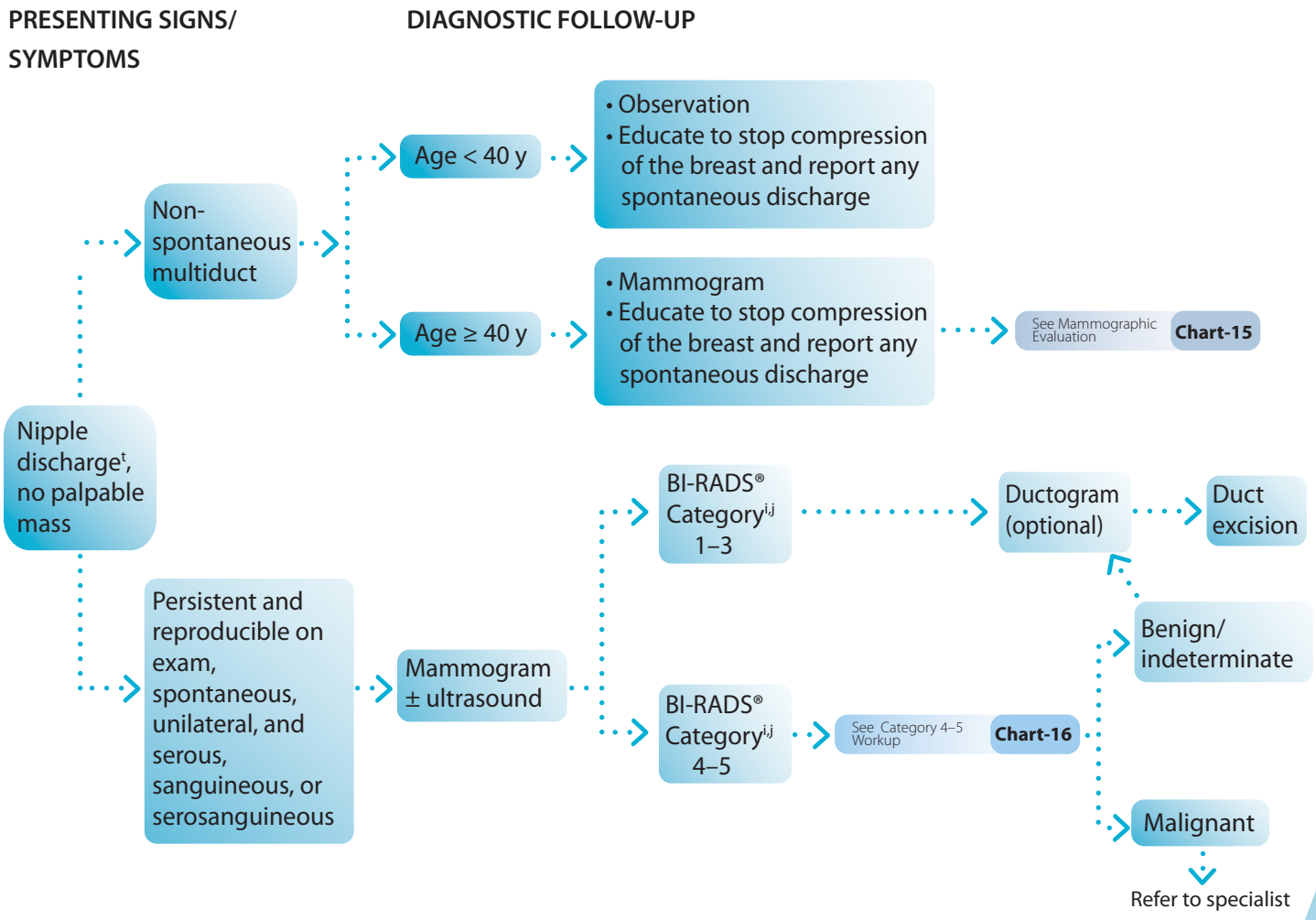
[o] Other histologies that may require additional tissue: mucin-producing lesions, potential phyllodes tumor, papillary lesions, radial scar or other histologies of concern to pathologist.
[s] Consider an ultrasound to obtain size measurement for accurate monitoring of stability.

Note: All recommendations are Category 2A unless otherwise indicated.



[m] For benign and image concordant that increases in size, consider surgical excision.
[n] FNA and core (needle or vacuum-assisted) biopsy are both valuable. FNA requires cytologic expertise.
[o] Other histologies that may require additional tissue: mucin-producing lesions, potential phyllodes tumor, papillary lesions, radial scar or other histologies of concern to pathologist.

Note: All recommendations are Category 2A unless otherwise indicated.

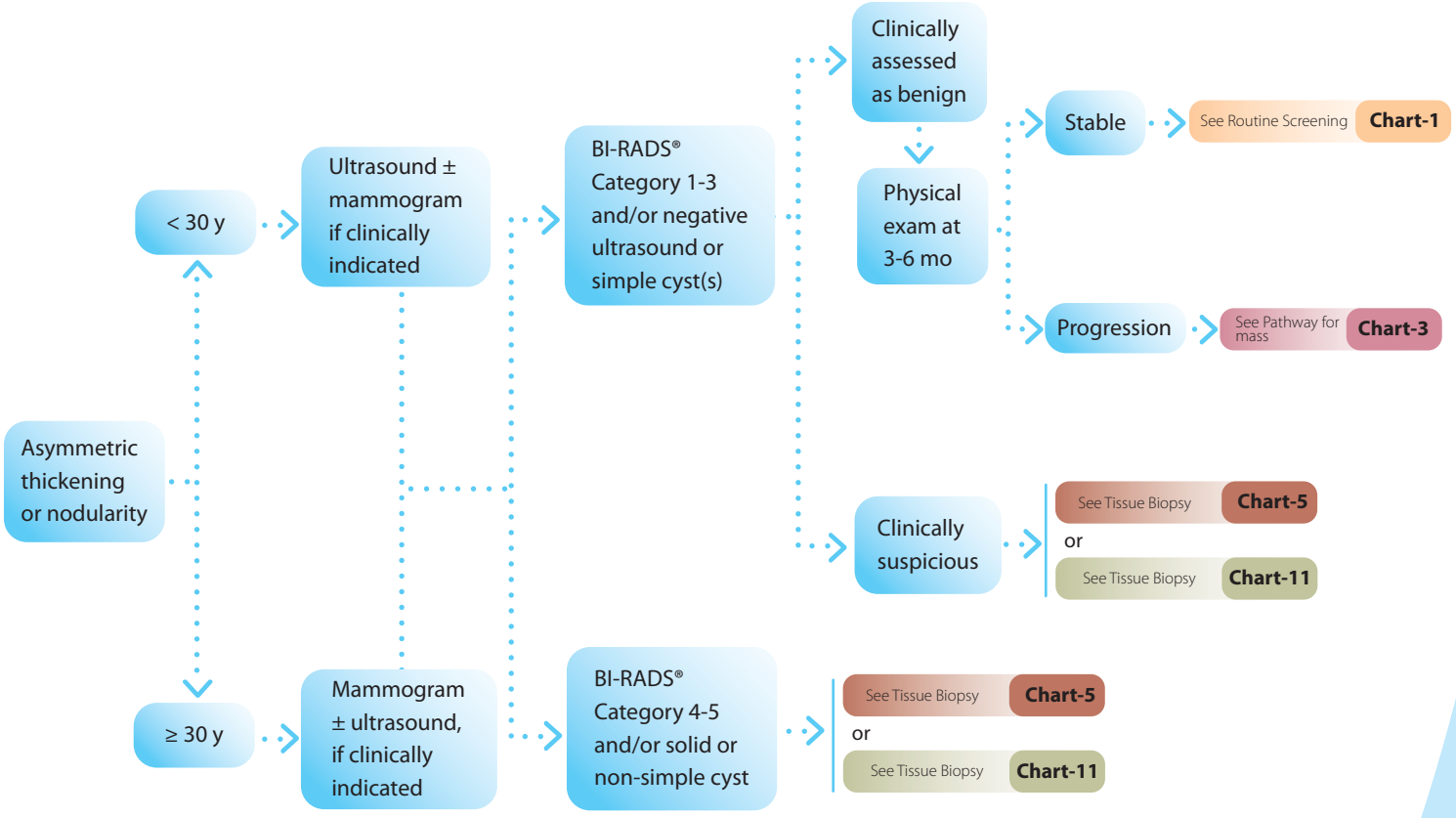


[i] See Mammographic Assessment Category Definitions. **Annex-C**
[j] Mammography results are recommended to be reported according to the Breast Imaging Reporting and Data System/ Final Assessment categories. **Annex-C**
[t] A list of drugs that can cause nipple discharge (not all inclusive): Psychoactive drugs, antihypertensive medications, opiates, oral contraceptives, and estrogen.

Note: All recommendations are Category 2A unless otherwise indicated.

PRESENTING SIGNS/ SYMPTOMS

DIAGNOSTIC FOLLOW-UP



Note: All recommendations are Category 2A unless otherwise indicated.

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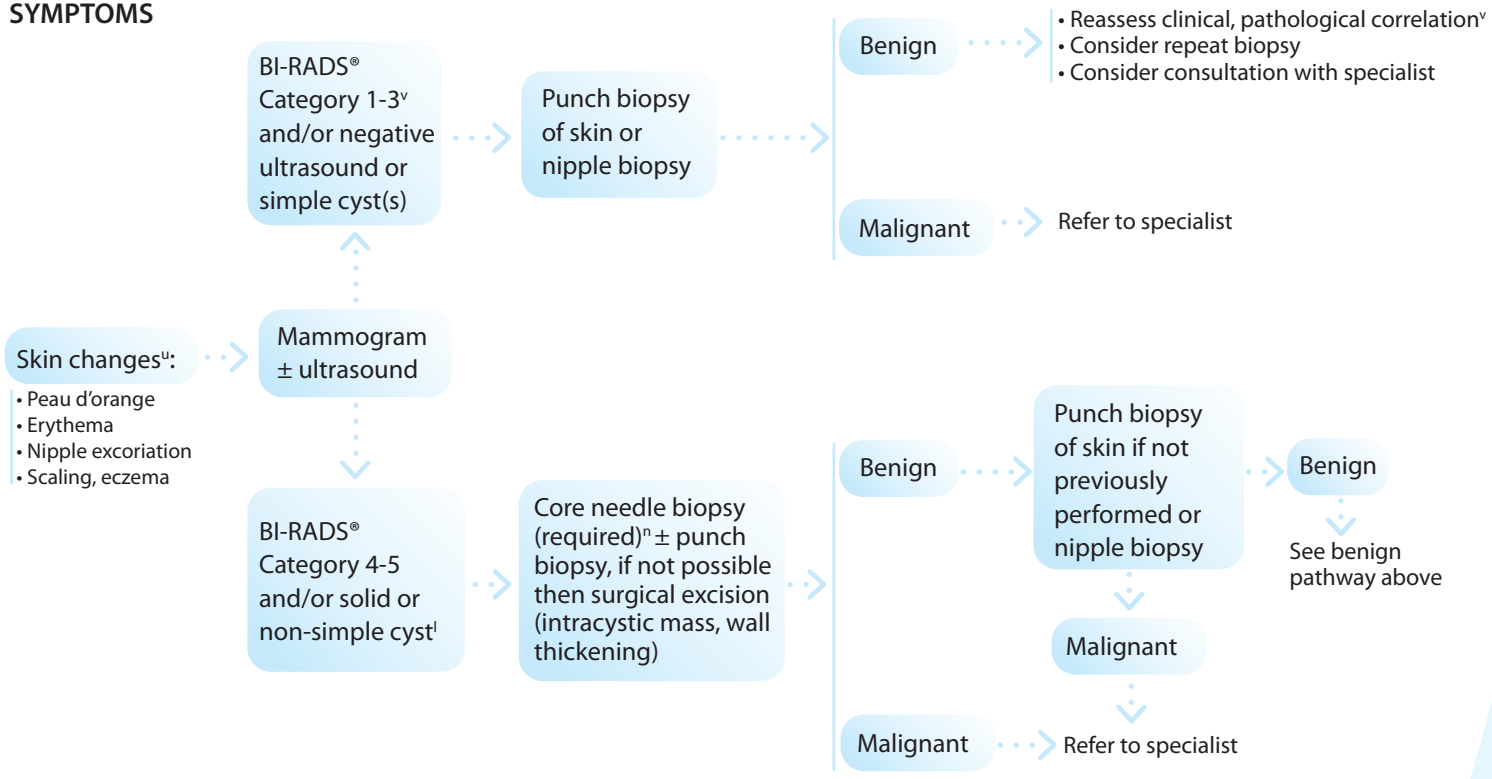
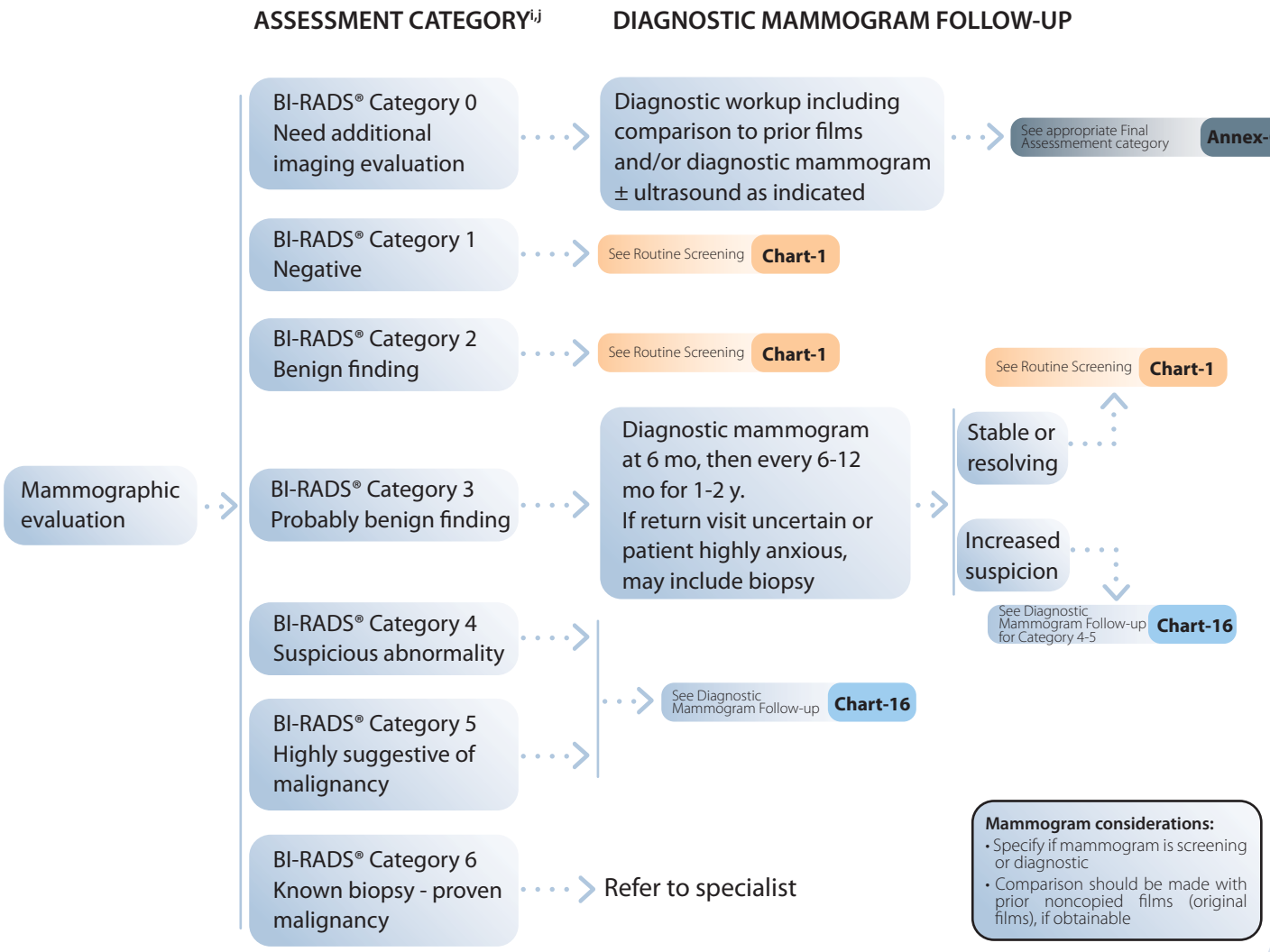
PRESENTING SIGNS/ SYMPTOMS

DIAGNOSTIC FOLLOW-UP



[l] Round, circumscribed mass containing low level echoes without vascular flow, fulfilling most but not all criteria for simple cyst.
[n] FNA and core (needle or vacuum-assisted) biopsy are both valuable. FNA requires cytologic expertise.
[u] This may represent serious disease of the breast and needs evaluation.
[v] If clinically of low suspicion, a short trial (7-10 days) of antibiotics for mastitis may be indicated.

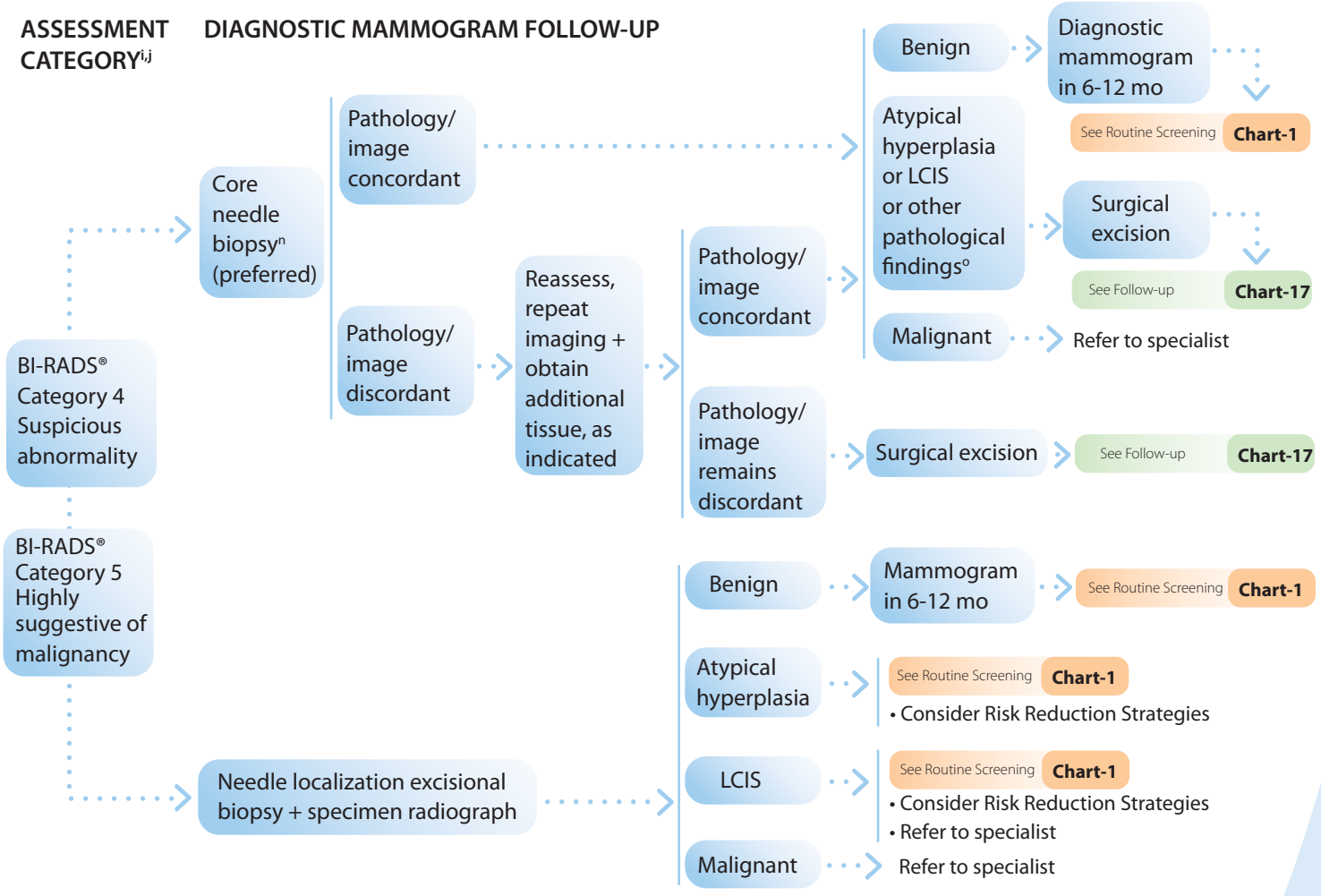
Note: All recommendations are Category 2A unless otherwise indicated.



[i] See Mammographic Assessment Category Definitions. **Annex-C**

[j] Mammography results are recommended to be reported according to the Breast Imaging Reporting and Data System/ Final Assessment categories. **Annex-C**

Note: All recommendations are Category 2A unless otherwise indicated.



[i] See Mammographic Assessment Category Definitions. **Annex-C**

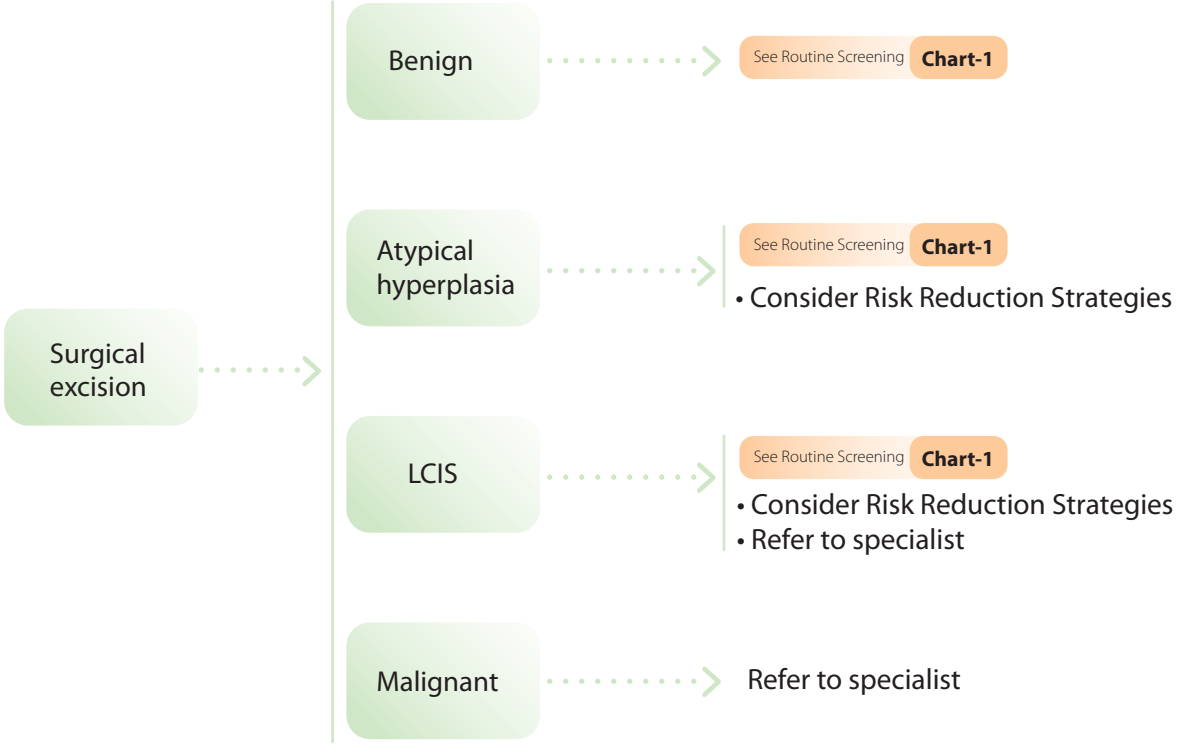
[j] Mammography results are recommended to be reported according to the Breast Imaging Reporting and Data System/ Final Assessment categories. **Annex-C**

[n] FNA and core (needle or vacuum-assisted) biopsy are both valuable. FNA requires cytologic expertise.

[o] Other histologies that may require additional tissue: mucin-producing lesions, potential phyllodes tumor, papillary lesions, radial scar or other histologies of concern to pathologist.

Note: All recommendations are Category 2A unless otherwise indicated.

FOLLOW-UP EVALUATION



Note: All recommendations are Category 2A unless otherwise indicated.

BREAST SCREENING CONSIDERATIONS

- Consider severe comorbid conditions limiting life expectancy and whether therapeutic interventions are planned.
- Upper age limit for screening is not yet established.
- Current evidence does not support the routine use of breast scintigraphy (ex: sestamibi scan), or ductal lavage as screening procedures.
- Current evidence does not support the routine use of breast MRI as a screening procedure, in average risk women.
- Criteria for the use of breast MRI screening as an adjunct to mammography for high risk women include[1]:
  - Have a BRCA 1 or 2 mutation
  - Have a first-degree relative with a BRCA 1 or 2 mutation and are untested
  - Recieved radiation treatment to the chest between ages 10 and 30, such as for Hogkin's Disease
  - Carry or have a first-degree relative who carries a genetic mutation in the TP53 or PTEN genes (Li-Fraumeni syndrome and Cowden and Bannayan-Riley-Ruvalcaba syndromes).
- There are limited data supporting the use of ultrasound for breast cancer screening as an adjunct to mammography for high risk women or women with dense breast tissue.
- A single study (DMIST) suggested benefit of digital mammography in young women and women with dense breasts.[2]

[1] Saslow D, Boetes C, Burke W, et al. American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography. CA Cancer J Clin 2007; 57: 75-89.
[2] Pisano ED, Gatsonis C, Hendrick E et al for the Digital Mammographic Imaging Screening Trial (DMIST) Investigators. Diagnostic performance of digital versus film mammography for breast cancer screening. N Engl J Med 2005;353:1773-1783.

Note: All recommendations are Category 2A unless otherwise indicated.

Clinical Breast Examination Guidelines
Summary Chart

	Medical History	Patient Preparation	Visual Inspection Step 1	Visual Inspection Step 2	Palpation of Lymph Nodes (Axillary Examination) Step 3	Palpation of Breast Supine position (30-45 degrees)
Position			Sitting up right with arms on hips	Sitting up right with arms over head	Patient seated or standing	Patient lying flat with ipsilateral arm behind head
Tips	Use sample form provided	• Ensure privacy • Undress patient till waist • Explain steps of CBE • Explain area to be covered			• Hold patient's right arm just before elbow while patient's forearm rests on examiner's left forearm. • Palpate lymph nodes and other axilla the other way around using the fingers of left hand.	• Follow a consistent pattern of search (vertical strip, radial spoke or concentric circle) • Use finger pads of middle three fingers to palpate one breast at a time, with overlapping dime-sized-circular motions • Palpate using variable levels of pressure (light, medium, and deep)
Look for	• Screening Practices (SBE, CBE, mammograms) • Breast Changes • Risk Factors		• Asymmetry in breast shape or contour • Dimpling, puckering or bulging of the skin • Tethering in the breast and nipple retraction • Rash or swelling • Scaling of the nipple or breast skin • Change in the breast/nipple skin or color (erythema), nodules or edema, or thickening of the breast skin (Peau d'orange) • Nipple discharge, crusting, or ulceration			
Perimeter			Entire breast area from mid-sternum to the posterior axillary line, and from the costal margin to the supraclavicular area.		Starting at apex, against chest wall palpating apical & medial groups, then anterior group, then rotating towards the posterior axillary fold, then humeral group against upper part of inner arm.	Down midaxillary line, across inframammary ridge at fifth/sixth rib, up lateral edge of sternum, across clavicle, and back to midaxilla.

Manuscript of Physical Examination (Clinical Breast Examination)[1]

Despite the advances in breast imaging, there are clear indications for the need of Clinical Breast Examination (CBE) as part of breast cancer screening for all women. The main goal of the clinical breast examination is to differentiate normal physiologic nodularity from a discrete breast mass. If a discrete mass is identified, follow the evaluation guidelines starting with **Chart-1** in this manual.

The Clinical Breast Examination consists of two main parts; (1) visual inspection to identify physical signs of breast cancer and (2) palpation which involves using the finger pads to physically examine all areas of breast tissue and axillary lymph nodes to identify lumps.

A STEP-BY-STEP GUIDE FOR CLINICAL BREAST EXAMINATION

A) Conduct a complete medical history to: *(Refer to sample form at the end of this section)*

a. Identify screening practices of women covering monthly Self Breast Examination, prior CBE and mammograms: when they were performed and what were the results.

Screening Recommendations:
- Mammogram every (1-2) yrs starting at age 40, and every 2 years starting at age 52.
- CBE every 1-3 yrs starting at age 20, and every year starting at age 40.
- SBE every month starting by age 20.

b. Ask about any breast changes and how they were identified including changes in appearance of skin or nipples, presence of lump(s), pain (focal vs. general, constant vs. cyclic), itching, nipple discharge, or staining of clothes or bed sheets indicative of nipple discharge.

TIP: These questions help assess risk factors and allow the female to express symptoms with the breast which she may not say voluntarily. This medical history will provide important context to interpret findings.

c. Assess risk by asking about age, age at menarche and menopause, personal history including benign breast disease, previous breast biopsy, cancer, cosmetic or other breast surgery, history of hormonal therapy, obstetric history, family history of cancer, and health promotion habits such as exercise and nutrition.

[1]This section has been compiled from several sources all listed at the end under "References for CBE Section".

B) Prepare Your Patient:

- The examination should be done in a private comfortable atmosphere with good light and in the presence of a chaperone.
- The woman should be undressed till the waist and start in a sitting position.
- The optimal time for a clinical breast examination in a premenopausal woman is 5-10 days after the onset of menses, avoiding the week before the period is preferable. Women who are postmenopausal may have CBE performed at any time.
- The examiner should prepare the patient for CBE and take time to explain the steps to be carried out.
  a. Explain that breast tissue covers a large area that extends from the clavicle to the bra line and from the sternum to the middle of the underarm.
  b. Explain that you will examine the breast visually first then each breast, underarms, and clavicle in the sitting and supine positions using the flat of your fingers to palpate all breast tissue.

C) Sitting Position:

In this position, the visual inspection of the breast (Steps 1 & 2) will take place followed by thorough examination of the lymph nodes (Step 3).

Step 1: The patient should be sitting up right with her arms on her hips. The examiner should look for changes/abnormalities in color, shape, and size of the breast or the detection of any obvious lumps, any nipple discharge or change in the direction of the nipple or inversion of the nipple. No visible distortion or swelling should be detected. Attention should be given to the entire breast area from mid-sternum to the posterior axillary line, and from the costal margin to the supraclavicular area. (See Figure 1)

Figure 1

TIP: Physical signs associated with advanced breast cancer have been summarized by the acronym BREAST signifying: Breast mass, Retraction, Edema, Axillary mass, Scaly nipple and Tender breast.

Step 2: The same inspection should be repeated with the patient's arms raised over the head (See Figure 2). If the breast is pendulous elevate the breast (infra-mammary area/undersurface of the breast). Notice any changes in the breast skin such as dimpling, puckering, or asymmetry.


Figure 2

In both steps, LOOK FOR:

- Asymmetry in breast shape or contour
- Dimpling, puckering or bulging of the skin
- Tethering in the breast and nipple retraction*
- Rash or swelling
- Scaling of the nipple or breast skin
- Change in the breast/nipple skin or color (erythema), nodules or edema, or thickening of the breast skin (Peau d'orange)
- Nipple discharge, crusting, or ulceration

* Some women have inverted nipples (nipples point inwards instead of outwards). This is not abnormal as long as this appearance does not change over time.

Step 3: Still in the sitting position, the examiner should move to the Axillary Examination (See Figure 3). The examiner should hold the patient's right arm just before the elbow while the patient's forearm rests on the examiner's left forearm. The examiner should palpate the lymph nodes and the other axilla the other way around using the fingers of the left hand. The examiner should start from the apex, and then slide down firmly against the chest wall palpating the apical & medial groups, then the anterior group, then rotate towards the posterior axillary fold to examine the post group, then examine the humeral group against the upper part of the inner arm.


Figure 3

REPEAT SAME EXAMINATION FOR THE OTHER SIDE

D) Supine Position: (30-45 degrees)

Step 1 – Position the Patient: Patients should be lying down for breast palpation, with their ipsilateral hand overhead to flatten the breast tissue on the chest wall, thereby reducing the thickness of the breast tissue being palpated (See Figure 4). If this maneuver does not result in a relatively even distribution of breast tissue, the breast should be further centralized by placing a small pillow under the shoulder/ lower back on the side of the breast being examined. The tissue being examined needs to be as thin as possible over the chest wall. The examiner must be able to see the full palpation area.

Figure 4

Step 2 – Identify the Perimeter: All breast tissue falls within a pentagon shape (as opposed to the traditional perception of the breast as a conical structure). The examiner should use the following landmarks to cover all of this area: down the midaxillary line, across the inframammary ridge at the fifth/sixth rib, up the lateral edge of the sternum, across the clavicle, and back to the midaxilla (See Figure 5).

Figure 5

TIP: The examination should include the axillary tail of breast tissue and the axilla to search for palpable lymphadenopathy. One should be aware that the breast tissue is not evenly distributed across the chest. Rather, 50% of the breast tissue is located in the upper outer quadrant, and 20% is located under the nipple areolar complex. See Figure 6 for the percentage of breast cancers found in each clinical quadrant.

Clinical quadrants of the breast with the percentage of all cancers of the breast found in each.

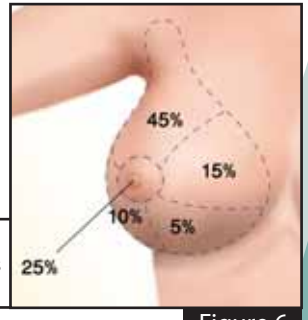


Figure 6

Step 3 – Search with Palpation:

- Select a consistent pattern of search (vertical strip, radial spoke or concentric circle – described in detail under the "Clinical Breast Examination Technique Highlights" section on page 25. Initiate the search at the axilla. (See Figure 7)
- Use the finger pads of the middle three fingers to palpate one breast at a time. Palpate with overlapping dime-sized-circular motions. (See Figure 8)
- Palpate gently but firmly using variable pressure with rolling and dipping of the fingers. Apply in sequence three levels of pressure (light, medium, and deep – See Figure 9) to each area of tissue examined and adapt palpation and pressure to the size, shape and consistency of tissue.
- Cover the entire breast. Search using, for example, the vertical strip pattern (See Figure 10).

⚠ **REPEAT SAME EXAMINATION FOR THE OTHER SIDE**

Figure 7

Figure 8

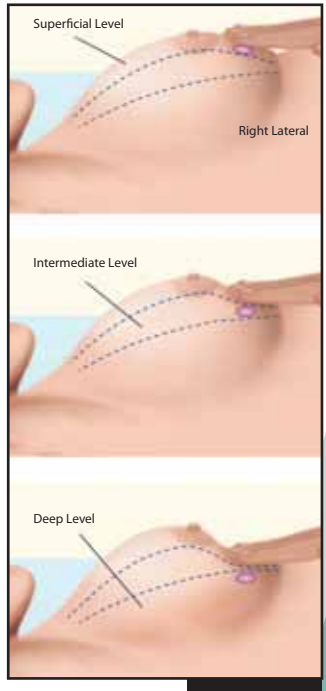


Figure 9

Figure 10

CLINICAL BREAST EXAMINATION TECHNIQUE HIGHLIGHTS

There are three specific components of the clinical breast examination that have been systematically evaluated and found to influence the accuracy of the examination. These are: (1) the amount of time spent on the examination, (2) the search pattern utilized, and (3) the finger technique in palpation.

1. **Time spent on clinical breast examination** is one of the best predictors of sensitivity. Although the increased time spent on examining the breast area improves sensitivity; time should be assessed versus the potential distress caused to the patient. Sometimes, even two minutes can seem like a long time for examination. Additionally, no studies have provided evidence supporting an optimal palpation timeframe, but most studies insist on the importance of the duration of breast palpation which appears to reflect a balance between enhancing sensitivity and reducing specificity. Coleman and colleagues recommend about one second per circular motion at each of three depths for each point along a vertical strip search pattern. Pennypacker and Pilgrim recommend eight or nine vertical strips to fully cover a teaching breast model, assumed to reflect an average size breast. Based on these parameters, the time required to examine both breasts of an average patient would range from about 6 to 8 minutes (See Figure 11).

Figure 11

2. The second critical aspect of the clinical breast examination technique is the **search pattern** used to detect abnormalities. Studies have documented that a systematic search pattern that ensures that all breast tissue is examined is essential for increasing the sensitivity of the clinical breast examination. Three search patterns are commonly described:

a. **The first is the radial spoke method** -- wedges of tissue are examined beginning at the periphery toward the nipple in a radial pattern.

b. **The second is the concentric circle method** -- the breast is examined in larger or smaller concentric circles.

c. **A third search pattern, often called the vertical strip pattern**, has shown to increase sensitivity of the examination in comparison to the above two patterns. This pattern examines the breast tissue in overlapping vertical strips across the chest wall. The vertical strip method is probably superior for

TIP: The radial and concentric methods share similar limitations.

- Often the tissue under the nipple-areolar complex is omitted, thus as much as 20% of breast tissue goes unexamined.
- These two patterns are more likely to skip areas of tissue during the examination.

ensuring that all breast tissue is examined, because the examiner is better able to track which areas have been examined, and the entire nipple-areolar complex is included.

3. The third critical aspect of the clinical breast examination is the **finger technique**. Again, systematic studies have shown that the superior technique entails the use of the pads of the 2nd, 3rd, and 4th fingers held together, making dime-sized circles. The finger pads begin in each circle using light pressure, then repeat in the same area with medium and deep pressure before moving to the next area for examination. (See Figure 8)

INTERPRETATION AND REPORTING

At present, no standardized system exists for interpreting and reporting the results of CBE. No standardized terminology exists for describing findings such as degree of nodularity; thickening versus a mass; dimpling of skin; or the size, mobility, shape, or consistency of an abnormality.

It is highly recommended that findings should be recorded on a simple breast diagram included in the patient's notes and to document glandular tissue distribution in the medical record of the patient. (See Figure 12)

The information recorded should include "general comments regarding breast size, consistency, scars... details of any lumps, including size, shape, consistency, mobility, tenderness, and fixation to skin or muscle... and the exact position should be described in terms of the clock face and distance from the nipple." [2]

Recording Tips:

When conducting the clinical examination, first describe the overall texture of the breast tissue and specific areas of increased density or nodularity. Then question whether there is an area that would be described as discrete or dominant within the underlying nodularity.

The discrete mass should be carefully described in terms of location, size, mobility, and texture. Follow flow of next steps as per Chart-4.

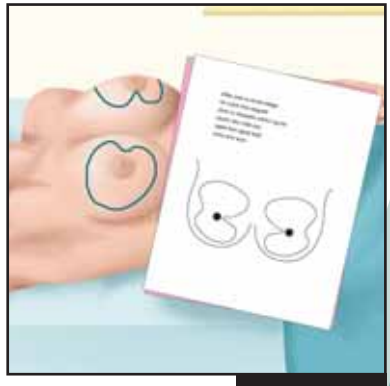


Figure 12

Interpretation

Interpretation involves three elements:

1. Identification of visual and palpable characteristics of the breasts and lymph nodes;
2. Accurate assignment of specific, common, descriptive terminology to each characteristic; and,
3. Determination of appropriate follow-up actions for identified findings.

[2] Sharon McDonald, Debbie Saslow, and Marianne H. Alciati. "Performance and Reporting of Clinical Breast Examination: A Review of the Literature." CA Cancer J Clin 2004; 54; 351.

The interpretation and reporting elements described below provide a general framework for identifying all relevant features of a proficient CBE, describing visual and physical findings, and reporting these findings and follow-up recommendations. Describing and interpreting findings can be challenging, as when women have highly nodular breasts, for example. The role of CBE, however, is to identify and appropriately describe visual and palpable findings; not to determine benign or malignant status. Clinicians are encouraged to adopt and begin implementing this suggested general framework for CBE interpretation and reporting.

In the most general form, the results of CBE can be interpreted in two ways:

- **Normal/Negative:** No abnormalities on visual inspection or palpation.
- **Abnormal:** Asymmetrical finding on either visual inspection or palpation that warrants further evaluation and possible referral. Findings will reflect a continuum of possible outcomes, from probably benign to highly suspicious of cancer. Determination of benign or malignant status, however, can be established only through further evaluation. Refer to **Chart-3** for next steps.

Interpretation Tips :

Interpreting the visual and tactile observations of CBE is complex as a variety of patient characteristics can influence interpretation, including age, parity, tissue density and nodularity, menopausal status, phase of the ovarian cycle, and health history.

- Bloody nipple discharge during the last trimester of pregnancy or the first three months of lactation may be considered a normal physiologic change but not so in non-pregnant/non-lactating women.
- Grossly bloody nipple discharge simply means that a lesion in the duct is bleeding. One-third of these cases are due to an intraductal carcinoma (in-situ or invasive), one-third are due to bleeding papillomata, and one-third are from fibrocystic changes with an active intraductal component (ex. plasma cell mastitis, ductal ectasia, intraductal hyperplasia, or papillomatosis). All require surgical evaluation and treatment.
- Skin erythema or lymphedema would not necessarily require further evaluation in a woman having recently undergone radiation therapy of the breast but would certainly require follow up in a woman without such a history.
- Increased nodularity might be normal during the luteal phase of the menstrual cycle, but at other times it might be cause for further examination.

Reporting

Reporting should include a description of all findings in specific and precise language, regardless of interpretation. In the case of a negative interpretation, description of findings provides a baseline for interpreting future results from visual inspection and palpation. In the case of an abnormal interpretation, a description provides an important guide for follow-up examination. Reporting should follow the same sequence as the examination itself. The sample form on the following page directs providers' attention to those aspects of the examination that represent unique patient characteristics or abnormalities.

Name:	Date:
Age:	Filled by:

CLINICAL HISTORY

Breast Screening Practices	☐ Mammogram	Date of last mammogram:
	☐ CBE	Starting at age:
	☐ SBE	Starting at age:

				Remarks (ex: N/A* or indicate details):
Breast Changes	• Changes in appearance of skin	No ☐	Yes ☐	
	• Changes in nipples	No ☐	Yes ☐	
	• Presence of lump(s)	No ☐	Yes ☐	
	• Pain (focal vs. general, constant vs. cyclic)	No ☐	Yes ☐	
	• Itching	No ☐	Yes ☐	
	• Nipple discharge	No ☐	Yes ☐	
	• Staining of clothes or bed sheets indicative of nipple discharge	No ☐	Yes ☐	
Risk Factors	• Family history of cancer (breast, ovarian or prostate)	No ☐	Yes ☐	
	• Any personal history of cancer (breast, ovarian, uterine, colon)	No ☐	Yes ☐	
	• Any personal history of benign breast disease	No ☐	Yes ☐	
	• Previous breast biopsy	No ☐	Yes ☐	
	• Previous cosmetic or other breast surgery	No ☐	Yes ☐	
	• Exposure to large amounts of radiation, such as frequent X-rays in youth	No ☐	Yes ☐	
	• Early onset of menarche (before age 12)	No ☐	Yes ☐	
	• Late onset of menopause (after age 55)	No ☐	Yes ☐	
	• Number of pregnancies/Obstetric history			
	◦ Age at first pregnancy			
	◦ Breast feeding of children	No ☐	Yes ☐	
	• Use of hormone replacement therapy (HRT)	No ☐	Yes ☐	
	• Atypical hyperplasia or LCIS	No ☐	Yes ☐	

*N/A: Not Applicable

Risk Factors (continued)	• Lack of exercise	No ☐ Yes ☐	
	• Smoking	No ☐ Yes ☐	
	• Alcohol consumption	No ☐ Yes ☐	
	• Obesity	No ☐ Yes ☐	
Hormonal Factors (at time of examination)	• Time in menstrual cycle		
	• Pregnancy		
	• Breast feeding		
	• Hormonal contraceptive		
	• Hormone therapy		

VISUAL INSPECTION		Description/Remarks:	
• Scarring	No ☐ Yes ☐		
• Symmetry of breast shape and appearance of skin and nipple-areolar complex	No ☐ Yes ☐		
• Contour (skin retraction, dimpling)	No ☐ Yes ☐		
• Color (erythema)	No ☐ Yes ☐		
• Texture (skin thickening or lymphedema)	No ☐ Yes ☐		
• Skin retraction or dimpling	No ☐ Yes ☐		
• Nipple scaling or retraction	No ☐ Yes ☐		
• Nipple inversion (age at onset during adulthood)	No ☐ Yes ☐		
• Nipple discharge if spontaneous	No ☐ Yes ☐		
• Abnormal findings or mass	No ☐ Yes ☐	Location of abnormal findings or mass according to a clock face as the examiner faces the patient, clearly indicating whether the abnormality is in the right or left breast	
		Size/extent of abnormal finding or mass	

PALPATION OF LYMPH NODES	Description/Remarks	
	Right	Left
• Infra- and supraclavicular nodes		
• Axillary nodes		

PALPATION OF BREAST		Description/Remarks	
		Right	Left
Nodularity*			
Symmetry			
Tenderness (focal versus generalized and constant versus intermittent)			
Nipple discharge	• Spontaneous or self-induced		
	• Color (white, clear viscous, yellow, green, blue, brown, or red)		
	• Number of involved orifices (one or more nipple openings)		

*Normal nodularity should not be described as a fibrocystic condition
*Normal cyclic breast tenderness should not be described as a pathologic condition

PALPABLE ABNORMALITY*			Description/Remarks
Right	☐ Three-dimensional dominant mass ☐ Two-dimensional thickening	• Location in three diamensions (subcutaneous, midlevel, next to chest wall, and according to a clock face as the examiner faces the patient)	
		• Size	
		• Shape (round, oblong, irregular, lobular [having one to four rounded or curved extensions from a central mass])	
		• Mobility (mobile, fixed to skin or chest wall)	
		• Consistency (soft, similar to surrounding breast tissue, hard)	
		• External texture (smooth, irregular surface [having bumps distributed over the external surface of the mass])	
		• Well-defined or not	
Left	☐ Three-dimensional dominant mass ☐ Two-dimensional thickening	• Location in three diamensions (subcutaneous, midlevel, next to chest wall, and according to a clock face as the examiner faces the patient)	
		• Size	
		• Shape (round, oblong, irregular, lobular [having one to four rounded or curved extensions from a central mass])	
		• Mobility (mobile, fixed to skin or chest wall)	
		• Consistency (soft, similar to surrounding breast tissue, hard)	
		• External texture (smooth, irregular surface [having bumps distributed over the external surface of the mass])	
		• Well-defined or not	

*To be filled for each palpable abnormality including breast tissue and infraclavicular, supraclavicular, and axillary lymph nodes.

References for Clinical Breast Examination Section

1. Debbie Saslow, Judy Hannan, et al. "Clinical Breast Examination: Practical Recommendations for Optimizing Performance and Reporting." CA Cancer J Clin 2004; 54; 327-344.

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MAMMOGRAPHIC ASSESSMENT CATEGORY DEFINITIONS[1,2]

A. Assessment Is Incomplete:

Category 0- Need Additional Imaging Evaluation and/or Prior Mammograms For Comparison:

Finding for which additional evaluation is needed. This is almost always used in a screening situation. Under certain circumstances this category may be used after a full mammographic workup. A recommendation for additional imaging evaluation may include, but is not limited to spot compression, magnification, special mammographic views and ultrasound. Whenever possible, if the study is not negative and does not contain a typically benign finding, the current examination should be compared to previous studies. The radiologist should use judgment on how vigorously to attempt obtaining previous studies. Category 0 should only be used for old film comparison when such comparison is required to make a final assessment.

B. Assessment Is Complete - Final Assessment Categories:

Category 1: Negative:

There is nothing to comment on. The breasts are symmetric and no masses, architectural distortion, or suspicious calcifications are present.

Category 2: Benign Finding(s):

Like Category 1, this is a "normal" assessment, but here, the interpreter chooses to describe a benign finding in the mammography report. Involuting, calcified fibroadenomas, multiple secretory calcifications, fat-containing lesions such as oil cysts, lipomas, galactoceles, and mixed-density hamartomas all have characteristically benign appearances, and may be labeled with confidence. The interpreter may also choose to describe intramammary lymph nodes, vascular calcifications, implants or architectural distortion clearly related to prior surgery while still concluding that there is no mammographic evidence of malignancy.

Note that both Category 1 and Category 2 assessments indicate that there is no mammographic evidence of malignancy. The difference is that Category 2 should be used when describing one or more specific benign mammographic findings in the report, whereas Category 1 should be used when no such findings are described.

MAMMOGRAPHIC ASSESSMENT CATEGORY DEFINITIONS[1,2] (continued)

Category 3: Probably Benign Finding - Short Interval Follow-Up Suggested:

A finding placed in this category should have less than a 2% risk of malignancy. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability.

There are several prospective clinical studies demonstrating the safety and efficacy of initial short-term follow-up for specific mammographic findings.

Three specific findings are described as being probably benign (the noncalcified mass, the focal asymmetry and the cluster of round [punctate] calcifications; the latter is anecdotally considered by some radiologists to be an absolutely benign feature). All the published studies emphasize the need to conduct a complete diagnostic imaging evaluation before making a probably benign (Category 3) assessment; hence it is inadvisable to render such an assessment when interpreting a screening examination. Also, 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. Finally, evidence from all published studies indicate the need for biopsy rather than continued follow-up when most probably benign findings increase in size or extent.

While the vast majority of findings in this category will be managed with an initial short-term follow-up (6 mo) examination followed by additional examinations until longer-term (2 y or longer) stability is demonstrated, there may be occasions where biopsy is done (patient anxiety, wishes or clinical concerns).

Category 4: Suspicious Abnormality - Biopsy Should Be Considered:

This category is reserved for findings that do not have the classic appearance of malignancy but have a wide range of probability of malignancy that is greater than those in Category 3. Thus, most recommendations of breast interventional procedures will be placed within this category. It is encouraged that the relevant probabilities be indicated so the patient and her physician can make an informed decision on the ultimate course of action.

MAMMOGRAPHIC ASSESSMENT CATEGORY DEFINITIONS[1,2] (continued)

Category 5: Highly Suggestive of Malignancy - Appropriate Action Should Be Taken:

These lesions have a high probability (≥95%) of being cancer, nevertheless, biopsy is still needed. In addition, oncologic management requires percutaneous tissue sampling for histological identification of the lesion. For example, this is applicable when sentinel node imaging is included in surgical treatment or when neoadjuvant chemotherapy is administered at the outset.

Category 6: Known Biopsy - Proven Malignancy - Appropriate Action Should Be Taken:

This category is reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.

BI-RADS® SUMMARY

Category	Diagnosis	Number of Criteria
0	Incomplete	Mammogram or ultrasound did not give radiologist enough information to make a clear diagnosis; follow-up imaging is necessary.
1	Negative	There is nothing to comment on; routine screening recommended.
2	Benign Finding(s)	A definite benign finding; routine screening recommended.
3	Probably Benign Finding	Findings that have a high probability of being benign (>98%); six-month short term follow-up.
4	Suspicious Abnormality	Not characteristic of breast cancer, but reasonable probability of being malignant (3-94%); biopsy should be considered.
5	Highly Suggestive of Malignancy	Lesion that has a high probability of being malignant (≥ 95%); take appropriate action.
6	Known Biopsy Proven Malignancy	Lesions known to be malignant that are being imaged prior to definitive treatment; assure that treatment is completed.

[1] Mammography results are recommended to be reported according to the Breast Imaging Reporting and Data System/Final Assessment categories.
[2] Terminology in this table is reflective of the American College of Radiology (ACR). ACR-BI-RADS® - Mammography. 4th Edition. In: ACR Breast Imaging Reporting and Data System , Breast Imaging Atlas. Reston VA. American College of Radiology, 2003. For more information, see www.acr.org.
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Manuscript

This manuscript highlights the most important considerations and pathways recommended within the guidelines flow charts. Some recommendations herein have also been further clarified by examples of studies and research that resulted in verification of the pathway.

Physical Examination

The starting point of these guidelines for screening and evaluating breast abnormalities is physical examination. The general public and healthcare providers need to be aware that mammography is not a stand-alone procedure. Neither the current technology of mammography nor its subsequent interpretation is foolproof. Clinical judgment is needed to ensure appropriate management. The patient's concerns and physical findings must be considered along with the radiographic and histologic assessment.

I. Asymptomatic Women with Negative Physical Findings

If the physical examination is negative in an asymptomatic woman, the next decision point is based on risk stratification. Women can be stratified into two basic categories for the purpose of screening recommendations: those at normal risk and those at increased risk. The increased risk category consists of four groups:

(1) Women who have previously received therapeutic thoracic irradiation or mantle irradiation;
(2) Women with a strong family history or genetic predisposition;
(3) Women with lobular carcinoma in situ (LCIS) or atypical hyperplasia; and,
(4) Women with a prior history of breast cancer.

Strictly speaking, monthly self breast examination (SBE) is considered optional in all risk groups because data from a large, randomized trial of SBE screening in Shanghai, China, has shown that instruction in SBE has no effect on reducing breast cancer mortality. In this study, 266,064 women were randomly assigned to either receive instruction in SBE or not. Compliance was encouraged through feedback and reinforcement sessions. After 10 to 11 years of follow-up, 135 breast cancer deaths in the instruction group and 131 in the control group were observed and the cumulative breast cancer mortality rates were not significantly different between the two arms. The number of benign breast lesions detected in the SBE instruction group was higher than that detected in the control group.[1] However, SBE may detect interval cancers between routine screenings and, therefore, should be required. Monthly, consistent SBE may facilitate breast self-awareness. Premenopausal women may find SBE most informative when performed at the end of menses.

A- Women at Normal Risk

For women ages 20-39 years, a clinical breast examination every 1 to 3 years is recommended, with monthly SBE required. For women ages 40-52, an annual clinical breast examination and screening mammogram once every (1-2) yrs

is recommended, with monthly SBE required. For women ages 52 and older, an annual clinical b reast examination and a mammogram once every 2 years are recommended, with monthly SBE. Although controversies persist regarding cost-effectiveness of screening in certain age categories and the diagnostic work-up required of false positives, most medical experts reaffirmed current recommendations supporting screening mammography.

This recommendation that women begin mammography screening every (1-2) years at age 40 is based on a conseneus between JBCP's international advisory board, the ministry of health, & other specialists in Jordan. in addition, the American Cancer Society and the National Cancer Institute in the United States agree that annual screening starting at age 40 decreases mortality from breast cancer. [2]Recent studies have reported a survival benefit in younger women that is equivalent to that seen in women over age 50.[3]

B- Women at Increased Risk

(1) Women Who Have Received Prior Thoracic Irradiation: For women aged 20 years and older who have received prior thoracic irradiation, annual mammograms and a clinical breast examination every 6 to 12 months are recommended. Monthly SBE is required. For these patients mammogram screening is usually initiated 10 years after radiation exposure or after age 40. MRI as an adjunct to mammogram and clinical breast exam every 6-12 mo should also be considered. For women younger than 20, an annual clinical breast examination is recommended and monthly SBE is required.

Results from the Late Effects Study Group[4] indicate that women who received thoracic irradiation in their second or third decade of life have a 35% risk of developing breast cancer by the age of 40. The overall risk associated with prior thoracic irradiation at a young age is 75 times greater than the risk of breast cancer in the general population. Although there is a concern that the cumulative radiation exposure from mammography in a young woman may itself pose a risk for cancer, the benefit of early detection of breast cancer in this high-risk group would outweigh the potential side effect.[5]

(2) Women with a Strong Family History or Genetic Predisposition: Genetic predisposition is defined by the family history one would use to refer a patient for genetic testing. Women in smaller families with an unusually early onset of breast cancer, particularly those families with male breast cancer, should also be considered at genetic risk.

The criteria for genetic predisposition (BRCA 1 mutations) developed by the American Society of Clinical Oncology (ASCO)[6] are as follows:

- A family has more than two breast cancer cases and one or more cases of ovarian cancer diagnosed at any age.
- A family has more than three breast cancer cases diagnosed before the age of 50.
- A family has sister pair in which one of the following combinations was diagnosed before the age of 50: two breast cancers, two ovarian cancers, or a breast and an ovarian cancer.

ASCO endorsed the following indications for genetic testing in the 2003 updated statement on Genetic Testing for Cancer Susceptibility[7]:

(i) personal or family history suggesting genetic cancer susceptibility;

(ii) the test can be adequately interpreted; and,

(iii) the results will aid in the diagnosis or influence the medical or surgical management of the patient or family members at hereditary risk of cancer.

Women with a genetic predisposition for Hereditary Breast and Ovarian Cancer (HBOC) should have clinical breast exams every 6 to 12 months and annual mammograms beginning at age 20. Women 20 years or older with a strong family history or other genetic predisposition for breast cancer should have clinical breast exams every 6 to 12 months and annual mammograms starting 5-10 years prior to the youngest breast cancer case in the family. Monthly SBE is required. Annual MRI is also recommended as an adjunct to mammogram and clinical breast exam for strong family history and genetic predisposition. Women younger than age 20 with strong family history or genetic predisposition should have an annual clinical breast exam and be required to perform monthly SBE. Women in this group should be afforded the opportunity to consider risk reduction strategies.

The risk from radiation exposure due to mammography in young women with an inherited cancer predisposition is unknown, and there is concern about whether this genetic factor may increase sensitivity to irradiation.

The cumulative risk of breast cancer, however, may be as high as 19% by the age of 40 in women with BRCA1 mutations.[8] Because the overall risk of breast cancer in BRCA1 or BRCA2 mutation carriers is estimated to be 20-fold greater than in the general population, the benefit of screening may justify the radiation exposure.

(3) Women with LCIS or Atypical Hyperplasia: LCIS, although not in itself considered to be a site of origin for cancer, is associated with an eight- to ten-fold increase in the relative risk of subsequent development of cancer in either breast. A pathologic diagnosis of atypical hyperplasia confers a four- to five-fold increased relative risk of developing breast cancer. For women with LCIS or atypical hyperplasia, an annual mammogram and clinical breast examination every 6 to 12 months are recommended. Monthly self breast exam is required. Annual MRI for LCIS as an adjunct to mammogram and clinical breast exam should be considered. These women should also be asked to consider risk reduction strategies.

(4) Women with prior history of breast cancer should be referred to a specialist for follow-up, surveillance, and/or treatment options.

Breast Screening Considerations:

There are limited data regarding screening of elderly women because most clinical trials for breast screening have used a cutoff age of 65 or 70 years. With the high incidence of breast cancer in the elderly population, the same screening guidelines used for women who are age

50 or older are recommended. Clinicians should always use judgment when applying screening guidelines. If a patient has severe comorbid conditions limiting her life expectancy and no intervention would occur based on the screening findings, then the patient should not undergo screening.

A second consideration is the time interval of screening in women aged 40 to 52 years. Even though there is agreement between the American Cancer Society and the National Cancer Institute on the benefit of annual breast cancer screening in this group, the interval of screening remains controversial as to whether or not mammograms should be performed every year or every 1 to 2 years. JBCP recommends a mammogram every (1-2) years for women ages 40-52, and once every 2 years for women ages 52 and above.

As mentioned earlier, a survival benefit for SBE has not yet been demonstrated. SBE should be required, however, because it may detect interval cancers between screenings. Women should be familiar with their breasts and promptly report any change to their health care provider.[1] Current evidence does not support the use of breast scintigraphy (ex: sestamibi scan), ductal lavage, or MRI in average risk women as routine screening procedures. Criteria for the use of breast MRI screening as an adjunct to mammography for high risk women include:

- Have a BRCA 1 or 2 mutation
- Have a first-degree relative with a BRCA 1 or 2 mutation and are untested
- Recieved radiation treatment to the chest between ages 10 and 30, such as for Hogkin's Disease
- Carry or have a first-degree relative who carries a genetic mutation in the TP53 or PTEN genes (Li-Fraumeni syndrome and Cowden and Bannayan-Riley-Ruvalcaba syndromes).

There are limited data available supporting the use of ultrasound for breast cancer screening as an adjunct to mammography for high risk women or women with dense breast tissue. A single study (DMIST) suggested benefit of digital mammography in young women and women with dense breasts.

Mammographic Evaluation

If the results of a screening mammography are normal, the follow-up is routine screening. When screening mammography reveals an abnormal finding, the radiologist should attempt to obtain any prior mammograms. This is most important for lesions that are of low suspicion mammographically. If, after a comparison of films, there is still a questionable area that is not clearly benign, then a diagnostic mammogram, with or without sonography, should be performed.

The decision tree is then based on the Breast Imaging Reporting and Data System (BI-RADS®) developed by the American College of Radiology.[9] The purpose of BI-RADS® now referred to as Assessment Category Definitions, is to create a uniform system of reporting mammography results with a recommendation associated with each category. The forth edition of BI-RADS® is adopted in this guideline.

BI-RADS® assessments are divided into incomplete (category 0) and assessment categories (category 1, 2, 3, 4, 5, and 6). An "incomplete assessment" refers to a finding for which additional evaluation is necessary. This category is almost always used in the context of a screening situation. Under certain circumstances this category may be used after a full mammographic workup. A recommendation for additional imaging evaluation may include, but is not limited to, spot compression, magnification, special mammographic views and ultrasound. Whenever possible, if the study is not negative and does not contain a typical benign finding, the current examination should be compared to previous studies. The radiologist should use judgment on how vigorously to obtain previous studies.

After the mammographic assessment is completed, the abnormality is placed in one of the following six BI-RADS® categories:

1. ***Negative:*** This is a negative mammogram. The breasts are symmetric, and there are no masses, architectural distortion or suspicious calcification. For example, the screening mammogram shows a small area of questionable abnormality but, after the spot compression views are performed, the finding is considered completely normal and of no clinical concern.
2. ***Benign Finding(s):*** This is also a negative mammogram, but there may be an actual finding that is benign. The typical case scenarios include benign-appearing calcifications, such as a calcifying fibroadenoma, an oil cyst, or a lipoma. The interpreter may also choose to describe intramammary lymph nodes, vascular calcification, implants or architectural distortion clearly related to prior surgery while still concluding that there is no mammographic evidence of malignancy.
3. ***Probably Benign Finding(s) -*** *Short-Interval Follow-up*

   Suggested: This is a mammogram that is usually benign. Close monitoring of the finding is recommended to ensure its stability. The risk of malignancy is estimated to be less than 2%.
4. ***Suspicious Abnormality -*** *Core Needle Biopsy Should Be Considered:* These lesions fall into the category of having a wide range of probability of being malignant but are not obviously malignant mammographically. The risk of malignancy is widely variable and is greater than that for category 3 but less than that for category 5.
5. ***Highly Suggestive of Malignancy:*** These lesions have a high probability (95%) of being a cancer. They include spiculated mass or malignant-appearing pleomorphic calcifications, etc.
6. ***Known Biopsy*** - *Proven Malignancy:* This category has been added for breast lesions identified on the imaging study with biopsy proof of malignancy but prior to definitive therapies.

For categories 1 and 2, in which the mammogram is completely normal or the finding is benign mammographically, the recommendation is routine screening mammography in 1 year.

For category 3 (probably benign), diagnostic mammograms at 6 months, then every 6 to 12 months for 1 to 2 years are appropriate. At the first 6-month follow-up, a unilateral mammogram of the index breast is performed. The 12-month study would be bilateral in women aged 40 years and older so that the contralateral breast is imaged at the appropriate yearly interval. Depending on the level of concern, the patient is then followed, either annually with bilateral mammograms or every 6 months for the breast in question, for a total of 2 years.

If the lesion remains stable or resolves mammographically, the patient resumes routine screening intervals for mammography. If, in any of the interval mammograms, the lesion increases in size or changes its benign characteristics, a biopsy is then performed. The exception to this approach of short-term follow-up is when a return visit is uncertain or the patient is highly anxious or has a strong family history of breast cancer. In those cases, initial biopsy with histologic sampling may be a reasonable option.

For categories 4 and 5, tissue diagnosis using core needle biopsy or needle localization excisional biopsy with specimen radiograph is necessary. When a needle biopsy is used (aspiration or core needle biopsy), concordance between the pathology report and the imaging finding must be obtained.[10,11] For example, a negative fine-needle aspiration associated with a spiculated category 5 mass is discordant and clearly would not be an acceptable diagnosis. When the pathology and the imaging are discordant, the breast imaging should be repeated and additional tissue sampled or excised.

For category 6 (proven malignancy), the patient should be managed according to the recommendations of a specialist. If the pathology is benign and concordant with the mammogram risk of suspicion, the patient is followed mammographically and a new baseline mammogram is performed in 6 to 12 months, depending on institutional preferences, or the patient returns to routine screening. However, certain benign histologies diagnosed using core needle biopsy, such as atypical hyperplasia, LCIS or other pathological findings require excisional biopsy because these lesions may have an associated malignant process and the benign diagnosis may represent a sampling error.[12,13]

II. Positive Findings on Physical Examination

A- Dominant Mass in Breast

A dominant mass is a discrete lesion that can be readily identified during a clinical breast examination. The guidelines separate the evaluation of the dominant mass into two age groups:

(1) Women aged 30 years or older; and,

(2) Women under 30 years of age.

(1) Women aged 30 years or older:

The main difference in the guidelines for evaluating a dominant mass in women age 30 or older is the increased degree of suspicion of breast cancer. The initial evaluation begins with a bilateral diagnostic mammogram. Observation without further evaluation is not an option. After the mammographic assessment, the abnormality is placed in one of the six BI-RADS® categories.

For BI-RADS® categories 1, 2, and 3, the next step is to obtain an ultrasound and the findings are discussed below.

For BI-RADS® categories 4 and 5, assessment of the geographic correlation between clinical and imaging findings is indicated. If there is a lack of correlation, further evaluation is as for BI-RADS® categories 1, 2 or 3. If the imaging findings correlate with the palpable findings, workup of the imaging problem answers the palpable problem. Tissue diagnosis through core needle biopsy (preferred), or needle localization excisional biopsy with specimen radiograph is necessary. When a core needle biopsy is utilized, concordance between the pathology report and imaging finding must be obtained as described in the Mammographic Evaluation section of this manuscript.

Ultrasound Findings

If ultrasound indicates a solid lesion that is suspicious or indeterminate, tissue biopsy should be obtained using core needle biopsy (preferred) or surgical excision (if core needle biopsy not available). If the pathology is benign and image concordant with the ultrasound, physical examination with or without ultrasound or mammogram, is recommended every 6 to 12 months for 1 to 2 years to assess stability. Follow-up may be considered at earlier time intervals if clinically indicated. If the solid lesion increases in size, repeat tissue biopsy. For benign and image concordant that increases in size, consider surgical excision. Routine breast screening is followed for stable lesions. If the findings are indeterminate, atypical hyperplasia, or benign and image discordant, surgical excision should be performed. Routine breast screening is followed for the confirmed benign lesion. If the lesion is classified as atypical hyperplasia or LCIS, the physician should consider risk reduction therapy, and the patient should be counseled to maintain regular breast screening. If the lesion is malignant, the patient is treated according to the recommendations of a specialist.

If the solid lesion on ultrasound is probably benign, several options are available: surgical excision, core needle biopsy (preferred), or observation. If the lesion has been surgically excised and proven to be benign, the patient undergoes routine screening. If the lesion is classified as atypical hyperplasia or LCIS, the physician should consider risk reduction therapy, and the patient should be counseled to maintain regular breast screening. Malignant lesions are treated according to the recommendations of a specialist. If the option of core needle biopsy is elected, and the result is benign and image concordant, a physical examination with or without ultrasound or mammogram, is recommended every 6 to 12 months for 1 to 2 years to ensure that the lesion is stable. Follow-up may be considered at earlier time intervals if clinically indicated. If the solid lesion increases in size, repeat tissue biopsy. Routine breast screening is followed for stable lesion. If the lesion is indeterminate or atypical hyperplasia, LCIS or benign and image discordant, surgical excision is recommended and the patient is followed as mentioned previously. Observation may be elected only if the lesion is less than 2 cm and there is low clinical suspicion, in which case a physical examination with or without ultrasound or mammogram is recommended every 6 months for 1-2 years to assess stability.

If the ultrasound evaluation reveals the mass to be consistent with an asymptomatic simple cyst, observation for 2-4 months for stability with patient reporting any changes would be appropriate, unless the patient is symptomatic or desires intervention because of anxiety. If a symptomatic or non-simple cyst is found, aspiration should be considered. With an irregular cyst wall or intracystic mass, surgical excision is preferred although ultrasound guided core biopsy and clip placement may assist in diagnosis. If blood-free fluid is obtained on aspiration and the mass resolves, the patient should be reexamined in 2 to 4 months. If the physical examination remains negative, the patient returns to routine screening. If the mass recurs, further evaluation can be done by ultrasound following age recommendations, or surgical excision can be considered. If a bloody fluid is obtained on initial aspiration or if the mass persists after aspiration, then ultrasound with image-guided biopsy or surgical excision is warranted. If the ultrasound with image-guided biopsy findings are benign and image concordant, physical exam with or without ultrasound or mammogram every 6-12 months for 1-2 years is recommended. Follow-up may be considered at earlier time intervals if clinically indicated. If the mass increases in size, tissue sampling has to be repeated, whereas routine breast screening is recommended if the mass remains stable. If the ultrasound and image-guided biopsy findings turn out to be benign and image discordant or intermediate or atypical hyperplasia or LCIS, surgical excision is recommended. If the mass has been surgically excised and proven to be benign, the patient undergoes routine screening. If the mass is classified as atypical hyperplasia or LCIS, routine breast screening along with risk reduction therapy is recommended. For LCIS findings, in addition to the above two options, the patient should be treated according to the recommendations of a specialist. Malignant findings either on ultrasound with image-guided biopsy or surgical excision should also be treated according to the recommendations of a specialist.

If there is no ultrasonographic abnormality, tissue biopsy (core needle biopsy or excision) or observation at 3-6 months intervals with or without imaging should be considered for 1-2 years to assess stability. If progression or enlargement on clinical exam, tissue sampling has to be repeated, whereas routine breast screening is recommended if the lesion remains stable.

(2) Women under 30 years of age:

The preferred option for initial evaluation of a dominant mass is to proceed directly to ultrasound. From this point, the decision tree for women under 30 years of age is almost identical to the pathway for older women. The only difference is the need for a diagnostic mammogram, in some situations for the younger women. The other two options are needle sampling and observation. Because the degree of suspicion in women who are under the age of 30 is low, observation of the mass for one or two menstrual cycles is an option. If observation is elected and the mass resolves after one or two menstrual cycles, the patient may return to routine screening. If the mass persists, then needle sampling or ultrasound should be performed. The threshold for needle sampling will be lower for women at increased risk based on prior thoracic irradiation exposure,

previous biopsy findings, or a family history of breast cancer, with or without genetic test results.

The two outcomes of needle sampling are fluid or no fluid. If no fluid is obtained, ultrasound or fine needle aspiration (FNA) should be performed. The ultrasound findings are managed as previously discussed. If a FNA is performed, a pathologist should evaluate the cellular aspirate. If the cytology is benign, the indications for surgical excision are the patient's level of anxiety, immediate plans for pregnancy, or a history of the mass increasing in size, with the possible differential diagnosis of a phyllodes tumor. Excision is also recommended for larger masses. The benign lump must be observed for 1-2 years with a recommended observation interval of 3-6 months. In addition, ultrasound may be considered to obtain size measurement each time and accurately monitor the mass stability. If there is an increase in size, tissue sampling has to be repeated, whereas routine breast screening is recommended if the lesion remains stable.

If the aspirate is nondiagnostic or indeterminate, ultrasound should be considered. If ultrasound indicates a solid lesion that is indeterminate or suspicious, a diagnostic mammogram should be obtained and further histologic tissue sampling should be performed by core needle or surgical biopsy. The evaluation then proceeds as described under ultrasound findings section for women aged 30 years or older. If the cytology study reveals insufficient tissue, then sampling must be repeated. If the cytology study reveals atypical hyperplasia, mammogram with ultrasound should be obtained prior to tissue biopsy. If the histologic evaluation reveals malignancy, the patient should be treated according to the recommendations of a specialist.

If nontraumatic bloody fluid is obtained on initial aspiration or if the mass persists after aspiration, then ultrasound with image-guided biopsy or surgical excision is warranted. Further management is as for a woman 30 years or older. If blood-free fluid is obtained on aspiration and the mass resolves, the patient should be reexamined in 2 to 4 months. If the physical examination remains negative, the patient returns to routine screening. If the mass persists or recurs, further evaluation is required by ultrasound or surgical excision.

B- Nipple Discharge without a Palpable Mass

In patients with a nipple discharge but no palpable mass, an evaluation of the character of the nipple discharge is the first step. The appropriate follow-up of a nonspontaneous, multiple-duct discharge in women under age 40 is observation, coupled with education of the patient to stop compression of the breast and to report any spontaneous discharge, if appropriate. In women aged 40 years or older, screening mammography and a further workup based upon the BI-RADS® category along with education similar to that for younger women is recommended.

The most worrisome nipple discharge is one that is persistent and reproducible on exam, spontaneous, unilateral, serous, sanguinous, or serosanguinous. A guaiac test and cytology of the nipple discharge are

optional, as a negative result should not stop further evaluation. Evaluation of this type of nipple discharge is based on the BI-RADS® category of the diagnostic mammogram. If the diagnostic mammogram is BI-RADS® category 1, 2, or 3, then a ductogram is optional to guide the surgical excision. Ductal excision is indicated for diagnosis of an abnormal nipple discharge, even if the ductogram is negative. However, the ductogram is useful to exclude multiple lesions and to localize the lesions prior to surgery. If the patient has a mammogram that is a BI-RADS® category 4 or 5, then the workup should proceed based on the diagnostic mammogram findings. If the findings are benign or intermediate, a ductogram is optional, but surgical duct excision would still be necessary. If the category 4 or 5 mammogram indicates malignancy, the patient should be treated according to the recommendations of a specialist.

C- Asymmetric Thickening or Nodularity

Thickening, nodularity, or asymmetry is distinct from a dominant mass in that the finding is ill defined and often vague on physical breast examination. If the patient is under the age of 30 and has no high risk factors, ultrasound evaluation is appropriate. A mammogram would be performed only if the physical finding were clinically suspicious. Diagnostic mammograms for this age group are fairly low in yield because of the density of the breast and low risk of breast cancer.

In women over the age of 30, bilateral diagnostic mammograms, with or without an ultrasound evaluation should be obtained. If the breast imaging results are abnormal, assessment of the thickening, nodularity, or asymmetry should be performed as previously outlined for a mammographic abnormality. If the mammogram and ultrasound findings are normal, the patient should be reexamined in 3 to 6 months. If the finding is stable, annual screening can be resumed. If a progressive or clinically suspicious change is noted, however, workup should proceed as for a dominant mass.

D- Skin Changes

Any type of unusual skin changes around the breast may represent serious disease and needs evaluation. The initial evaluation begins with a bilateral diagnostic mammogram with or without ultrasound examination. If the mammogram is abnormal, the evaluation proceeds based on the mammogram findings. If the breast imaging results are normal, further workup is still needed. Punch biopsy of skin or nipple biopsy should be performed for BI-RADS® category 1-3. Core needle biopsy (required) with or without punch biopsy should be performed of the mammographic lesion or BI-RADS® category 4-5, if not possible, then surgical excision (intracystic mass, wall thickening) is another option. If the skin biopsy is malignant, the patient should be treated according to the recommendations of a specialist.

However, if the skin biopsy is benign, a repeat biopsy or punch biopsy of the skin or nipple biopsy (if not previously done) should be performed. Consideration should be given to consultation with a specialist.

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