American College of Radiology ACR Appropriateness Criteria® Breast Imaging During Pregnancy

Variant: 1 Pregnant female. Age 40 years or older. Breast cancer screening. Any risk.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| Digital breast tomosynthesis screening | Usually Appropriate | ⊗ ⊗ |
| Mammography screening | Usually Appropriate | |
| US breast | May Be Appropriate | 0 |
| Mammography with IV contrast | Usually Not Appropriate | ⊗ ⊗ |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without and with IV contrast abbreviated | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast abbreviated | Usually Not Appropriate | 0 |
| Sestamibi MBI | Usually Not Appropriate | ♀ • |

<u>Variant: 2</u> Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| US breast | May Be Appropriate | 0 |
| Digital breast tomosynthesis screening | Usually Not Appropriate | ∵ |
| Mammography screening | Usually Not Appropriate | ∵ |
| Mammography with IV contrast | Usually Not Appropriate | ⊗ ⊗ |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without and with IV contrast abbreviated | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast abbreviated | Usually Not Appropriate | 0 |
| Sestamibi MBI | Usually Not Appropriate | ∵ ••• |

<u>Variant: 3</u> Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| Digital breast tomosynthesis screening | Usually Appropriate | ② ③ |
| Mammography screening | Usually Appropriate | ② ③ |
| US breast | May Be Appropriate | 0 |
| Mammography with IV contrast | Usually Not Appropriate | ② ③ |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without and with IV contrast abbreviated | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast abbreviated | Usually Not Appropriate | 0 |
| Sestamibi MBI | Usually Not Appropriate | ∵ |

<u>Variant: 4</u> Pregnant female. Age less than 30 years. Focal pain or palpable breast mass. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| US breast | Usually Appropriate | 0 |
| Digital breast tomosynthesis diagnostic | Usually Not Appropriate | ⊗ ⊗ |
| Mammography diagnostic | Usually Not Appropriate | ⊗ ⊗ |
| Mammography with IV contrast | Usually Not Appropriate | ⊗ ⊗ |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |
| Sestamibi MBI | Usually Not Appropriate | ⊗ ⊗ |

<u>Variant: 5</u> Pregnant female. Age 30 years or older. Focal pain or palpable breast mass. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| US breast | Usually Appropriate | 0 |
| Digital breast tomosynthesis diagnostic | Usually Appropriate | ⊗ ⊗ |
| Mammography diagnostic | Usually Appropriate | ⊗ ⊗ |
| Mammography with IV contrast | Usually Not Appropriate | ⊗ ⊗ |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |
| Sestamibi MBI | Usually Not Appropriate | ** |

<u>Variant: 6</u> Pregnant female. Age less than 30 years. Clinically suspicious nipple discharge. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| US breast | Usually Appropriate | 0 |
| Digital breast tomosynthesis diagnostic | Usually Not Appropriate | ⊗ ⊗ |
| Mammography diagnostic | Usually Not Appropriate | ⊗ ⊗ |
| Mammography with IV contrast | Usually Not Appropriate | ⊗ ⊗ |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |
| Sestamibi MBI | Usually Not Appropriate | ∵ |

<u>Variant: 7</u> Pregnant female. Age 30 years or older. Clinically suspicious nipple discharge. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| US breast | Usually Appropriate | 0 |
| Digital breast tomosynthesis diagnostic | Usually Appropriate | € € |
| Mammography diagnostic | Usually Appropriate | € € |
| Mammography with IV contrast | Usually Not Appropriate | �� |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |
| Sestamibi MBI | Usually Not Appropriate | ⊗ ⊗ |

Variant: 8 Pregnant female. Newly diagnosed breast cancer. Locoregional staging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|-----------|--------------------------|--------------------------|
|-----------|--------------------------|--------------------------|

| US axilla | Usually Appropriate | 0 |
|---|-------------------------|------------|
| US breast | Usually Appropriate | 0 |
| Digital breast tomosynthesis diagnostic | Usually Appropriate | ⊗ ⊗ |
| Mammography diagnostic | Usually Appropriate | ⊗ ⊗ |
| Mammography with IV contrast | Usually Not Appropriate | ⊗ ⊗ |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |
| Sestamibi MBI | Usually Not Appropriate | ★ |

<u>Variant: 9</u> Pregnant female. Breast infection or abscess suspected. Initial imaging.

| Procedure | Appropriateness Category | Relative Radiation Level |
|---|--------------------------|--------------------------|
| US breast | Usually Appropriate | 0 |
| Digital breast tomosynthesis diagnostic | May Be Appropriate | ⊗ ⊗ |
| Mammography diagnostic | May Be Appropriate | ⊗ ⊗ |
| Mammography with IV contrast | Usually Not Appropriate | ⊗ ⊗ |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |
| Sestamibi MBI | Usually Not Appropriate | ⊗ ⊗ ⊗ |

<u>Variant: 10</u> Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

| Procedure | Appropriateness Category | Relative Radiation Level |
|--|--------------------------|--------------------------|
| US breast | Usually Appropriate | 0 |
| US axilla | Usually Not Appropriate | 0 |
| Digital breast tomosynthesis diagnostic | Usually Not Appropriate | ⊗ ⊗ |
| Mammography diagnostic | Usually Not Appropriate | ⊗ ⊗ |
| Mammography with IV contrast | Usually Not Appropriate | ⊗ ⊗ |
| Image-guided core biopsy breast | Usually Not Appropriate | Varies |
| Image-guided fine needle aspiration breast | Usually Not Appropriate | Varies |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |
| MRI breast without IV contrast | Usually Not Appropriate | 0 |
| Sestamibi MBI | Usually Not Appropriate | ∵ • • |

<u>Variant: 11</u> Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

| <u> </u> | | |
|--|--------------------------|--------------------------|
| Procedure | Appropriateness Category | Relative Radiation Level |
| US axilla | Usually Appropriate | 0 |
| US breast | Usually Appropriate | 0 |
| Digital breast tomosynthesis diagnostic | Usually Appropriate | € € |
| Mammography diagnostic | Usually Appropriate | € € |
| Image-guided core biopsy breast | Usually Appropriate | Varies |
| Image-guided fine needle aspiration breast | May Be Appropriate | Varies |
| Mammography with IV contrast | Usually Not Appropriate | € € |
| MRI breast without and with IV contrast | Usually Not Appropriate | 0 |

| MRI breast without IV contrast | Usually Not Appropriate | 0 |
|--------------------------------|-------------------------|---|
| Sestamibi MBI | Usually Not Appropriate | |

Panel Members

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Summary of Literature Review

Introduction/Background

The physiological and structural changes to the breast during pregnancy pose challenges in the evaluation of the breast. The breasts enlarge and increase in density over a pregnancy. During the first and second trimesters of pregnancy, the lobules, alveoli, and lactiferous ducts of the breast proliferate and differentiate [1-3]. In addition, the alveolar epithelium becomes secretory [1]. In the third trimester, prolactin levels increase. This causes the milk-producing cells to further differentiate, with colostrum filling the alveoli and milk ducts prior to delivery [1,3]. Imaging of the breast is dependent on the patient's age, risk status, and pregnancy status [1].

Most clinical issues that occur during pregnancy are benign (normal breast tissue, cysts, fibroadenomas, abscess, and mastitis). However, it is important to be cognizant of pregnancy-associated breast cancer (PABC). The physiological breast changes that occur during pregnancy can make the detection of palpable abnormalities more difficult. This can contribute to a delay in the diagnosis of PABC, which are often larger more advanced tumors with nodal disease at the time of diagnosis compared with nonpregnant women [4].

PABC refers to breast cancer diagnosed during pregnancy or during the 12 months after delivery [4]. It is uncommon, occurring in 1 per 3,000 to 1 per 10,000 pregnancies [2,4,5], however, it is increasing as more women postpone childbearing [3]. It accounts for <3% of all breast cancers [1]. PABC are biologically aggressive tumors with the majority estrogen and progesterone negative and HER2-neu receptor positive [1,6]. Women diagnosed with PABC are often younger, and the cancers tend to be of a more advanced stage, with lymph node involvement at presentation [6].

The most common presentation of PABC is a palpable mass, but it can present with focal pain, diffuse breast enlargement, nipple discharge, and skin thickening [7]. These clinical findings are nonspecific and can delay the evaluation and diagnosis of PABC.

The majority (>80%) of biopsied palpable masses in pregnancy are benign [1,8,9]. Pre-existing fibroadenomas and other benign masses may enlarge and become palpable during pregnancy. These masses can appear atypical due to enlargement or infarction [2]. They may warrant a biopsy for confirmation.

Infection of the breast is rare during pregnancy. During pregnancy, if there are signs and symptoms (redness, tenderness, fever) of a breast infection, antibiotics should be administered. Any infection that does not respond to antibiotics should be considered suspicious, and the evaluation for inflammatory breast cancer would then be warranted [10].

Spontaneous bloody nipple discharge during pregnancy is nonspecific and may be the result of benign or malignant findings. During pregnancy, ducts undergo physiologic epithelial remodeling, and the associated vascularity is more vulnerable to microtrauma. This is referred to as "rusty pipe syndrome" [2]. It is more common in the third trimester and can occur from multiple ducts. Single-duct bloody nipple discharge warrants clinical and imaging evaluation because such symptoms may be secondary to an intraductal papilloma or ductal carcinoma (including PABC) [2].

There is a limited role for advanced imaging in pregnancy. Intravenous (IV) gadolinium crosses the placenta, and safety in the fetus is unknown [11]. Although the American College of Obstetricians and Gynecologists (ACOG) committee opinion is that gadolinium administration is a relative contraindication during pregnancy, there is no study that has established its safety because it is known to cross the placenta. Therefore, radiologic societies consider it to be contraindicated during pregnancy.

Biopsies can be performed during pregnancy as needed for the evaluation of suspicious imaging findings. Milk fistula and the increased risk of bleeding are 2 potential risks that should be discussed with patients.

Although all patients are at risk for developing breast cancer, this document addresses breast cancer screening in pregnant cisgender women (birth assigned female with a female gender identity). Please refer to the ACR Appropriateness Criteria topic on "Female Breast Cancer Screening" [12]. For breast cancer screening in transgender and gender-diverse patients, please reference the Appropriateness Criteria topic on "Transgender Breast Cancer Screening" [13]. Additional Appropriateness Criteria topics on "Supplemental Breast Cancer Screening Based on Breast Density" [14], "Imaging after Mastectomy and Breast Reconstruction" [15], and "Imaging after Breast Surgery" [16] can be referenced in the appropriate clinical context.

Initial Imaging Definition

Initial imaging is defined as imaging at the beginning of the care episode for the medical condition defined by the variant. More than one procedure can be considered usually appropriate in the initial imaging evaluation when:

• There are procedures that are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care)

• There are complementary procedures (ie, more than one procedure is ordered as a set or simultaneously where each procedure provides unique clinical information to effectively manage the patient's care).

Discussion of Procedures by Variant Variant 1: Pregnant female. Age 40 years or older. Breast cancer screening. Any risk.

Breast cancer screening during pregnancy is recommended for women assigned female at birth ≥40 years of age who are of average risk of breast cancer as defined in the ACR Appropriateness Criteria[®] topic on "Female Breast Cancer Screening" [12,17].

The goal of screening mammography is to detect cancer at an early stage. Diagnosing breast cancer at an early stage provides the best chance for a cure.

Variant 1: Pregnant female. Age 40 years or older. Breast cancer screening. Any risk. A. Digital breast tomosynthesis screening

Mammography is considered safe for screening for breast cancer for pregnant women ≥40 years of age. Tomosynthesis with mammography may provide added benefit of detection in denser breast tissue of pregnancy [3,8]. Scatter radiation to the fetus is negligible [2].

Variant 1: Pregnant female. Age 40 years or older. Breast cancer screening. Any risk. B. Mammography screening

Mammography is considered safe during pregnancy [2,17]. Scatter radiation to the fetus is negligible [2].

Variant 1: Pregnant female. Age 40 years or older. Breast cancer screening. Any risk. C. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media [11].

Variant 1: Pregnant female. Age 40 years or older. Breast cancer screening. Any risk. D. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 1: Pregnant female. Age 40 years or older. Breast cancer screening. Any risk. E. MRI breast without and with IV contrast abbreviated

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 1: Pregnant female. Age 40 years or older. Breast cancer screening. Any risk.

F. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI for screening of breast cancer in pregnancy.

Variant 1: Pregnant female. Age 40 years or older. Breast cancer screening. Any risk. G. MRI breast without IV contrast abbreviated

There is no evidence to support the use of noncontrast breast MRI for screening of breast cancer in pregnancy.

Variant 1: Pregnant female. Age 40 years or older. Breast cancer screening. Any risk. H. Sestamibi MBI

Molecular breast imaging (MBI) is contraindicated in breast cancer screening in pregnancy. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 1: Pregnant female. Age 40 years or older. Breast cancer screening. Any risk. I. US breast

During pregnancy the breasts undergo considerable physiological changes. No studies to date have evaluated the usefulness of screening whole-breast ultrasound (US) (handheld or automated) during pregnancy [2].

Variant 2: Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

Pregnant women at higher than average risk for breast cancer should be closely followed by their provider for any signs of breast disease (eg, lump, skin changes, or nipple discharge). The criteria and age to begin screening for intermediate- and high-risk women are discussed in the ACR Appropriateness Criteria [®] topic on "Female Breast Cancer Screening" [12].

The goal of screening mammography is to detect cancer at an early stage. Diagnosing breast cancer at an early stage provides the best chance for a cure.

Variant 2: Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

A. Digital breast tomosynthesis screening

Mammography is not advised for screening for breast cancer in women <25 years of age. Digital breast tomosynthesis (DBT) is generally not performed before the age of 30 in high-risk patients.

Variant 2: Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

B. Mammography screening

Mammography is not advised for screening for breast cancer in women <25 years of age. Screening mammography is generally not performed before the age of 30 in high-risk patients.

Variant 2: Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

C. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media [11].

Variant 2: Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

D. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 2: Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

E. MRI breast without and with IV contrast abbreviated

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 2: Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

F. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI for the screening of breast cancer in pregnancy.

Variant 2: Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

G. MRI breast without IV contrast abbreviated

There is no evidence to support the use of noncontrast breast MRI for the screening of breast cancer in pregnancy.

Variant 2: Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

H. Sestamibi MBI

MBI is contraindicated in breast cancer screening in pregnancy. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 2: Pregnant female. Age less than 25 years. Breast cancer screening. Higher-than-average risk.

I. US breast

During pregnancy, the breasts undergo considerable physiological changes. No studies to date have evaluated the usefulness of screening whole-breast US (handheld or automated) during

pregnancy [2]. Screening whole-breast US could be considered supplemental in pregnancy (based on results seen in nonpregnant women) for those at high risk of breast cancer [20,21].

Variant 3: Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

Pregnant women at higher-than-average risk for breast cancer should undergo screening [8,12]. Supplemental screening may be considered for intermediate- and high-risk pregnant women [2]. The criteria and age to begin screening for intermediate- and high-risk women are discussed in the ACR Appropriateness Criteria [®] topic on "Female Breast Cancer Screening" [12].

The goal of screening mammography is to detect cancer at an early stage. Diagnosing breast cancer at an early stage provides the best chance for a cure.

Variant 3: Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

A. Digital breast tomosynthesis screening

Mammography is considered safe in pregnancy. Scatter radiation to the fetus is negligible [2]. For patients who are at higher than average risk, the benefits need to be weighed against the risks. Tomosynthesis with mammography may provide added benefit of detection in denser breast tissue of pregnancy [3,8].

Variant 3: Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

B. Mammography screening

Mammography is considered safe in pregnancy. Scatter radiation to the fetus is negligible [2]. For patients who are at higher than average risk, the benefits need to be weighed against the risks.

Variant 3: Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

C. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media.

Variant 3: Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

D. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 3: Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

E. MRI breast without and with IV contrast abbreviated

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 3: Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

F. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI for the screening of breast cancer in pregnancy.

Variant 3: Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

G. MRI breast without IV contrast abbreviated

There is no evidence to support the use of noncontrast breast MRI for the screening of breast cancer in pregnancy.

Variant 3: Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

H. Sestamibi MBI

MBI is contraindicated in breast cancer screening in pregnancy [18,19]. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 3: Pregnant female. Age 25 years or older. Breast cancer screening. Higher-than-average risk.

I. US breast

During pregnancy, the breasts undergo considerable physiologic changes. No studies to date have evaluated the usefulness of screening whole-breast US (handheld or automated) during pregnancy [2]. Screening whole-breast US could be considered supplemental in pregnancy (based on results seen in nonpregnant women) for those at high risk of breast cancer [20,21].

Variant 4: Pregnant female. Age less than 30 years. Focal pain or palpable breast mass. Initial imaging.

Patients with a dominant palpable breast mass that persists for ≥2 weeks should be evaluated. Most lumps during pregnancy are benign.

The goal of evaluating focal pain or palpable mass during pregnancy is to determine the cause and if it would require any further imaging or intervention or can be safely observed.

Variant 4: Pregnant female. Age less than 30 years. Focal pain or palpable breast mass. Initial imaging.

A. Digital breast tomosynthesis diagnostic

According to the ACR Appropriateness Criteria [®] for <u>Palpable Breast Masses</u>, DBT should not be the initial imaging modality in this patient population [22]. However, mammography is considered

safe in pregnancy. Scatter radiation to the fetus is negligible [2]. Tomosynthesis with mammography may provide added benefit of detection in denser breast tissue of pregnancy [3,8,23]. It may be a useful adjunct to US findings for focal pain or a palpable mass, especially if US findings are suspicious.

Variant 4: Pregnant female. Age less than 30 years. Focal pain or palpable breast mass. Initial imaging.

B. Mammography diagnostic

According to the ACR Appropriateness Criteria [®] for <u>Palpable Breast Masses</u>, mammography should not be the initial imaging modality in this patient population [22]. However, mammography is considered safe during pregnancy. Scatter radiation to the fetus is negligible [2].

Diagnostic mammography may be a useful adjunct to US findings for focal pain or a palpable mass. Sensitivity of mammography is less than US, 74% to 100% [2,10].

Variant 4: Pregnant female. Age less than 30 years. Focal pain or palpable breast mass. Initial imaging.

C. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media [11]. Mammography with IV contrast would not be expected to be used in pregnancy for the evaluation of focal pain or palpable mass.

Variant 4: Pregnant female. Age less than 30 years. Focal pain or palpable breast mass. Initial imaging.

D. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 4: Pregnant female. Age less than 30 years. Focal pain or palpable breast mass. Initial imaging.

E. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI for the evaluation of pain or palpable breast mass in pregnancy.

Variant 4: Pregnant female. Age less than 30 years. Focal pain or palpable breast mass. Initial imaging.

F. Sestamibi MBI

MBI is contraindicated in pregnant patients [18,19]. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 4: Pregnant female. Age less than 30 years. Focal pain or palpable breast mass. Initial imaging.

G. US breast

US is the first-line imaging in the evaluation of a palpable lump in pregnant patients younger than 30. It can detect both benign and malignant masses. US is reported to have a 100% sensitivity and a 100% negative predictive value for detecting PABC [7,24]. US has a high sensitivity for both benign and malignant abnormalities. It can evaluate for focal pain or palpable finding in pregnancy [2,7]. Due to the changes of the breast during pregnancy, some benign masses can appear suspicious [10].

Variant 5: Pregnant female. Age 30 years or older. Focal pain or palpable breast mass. Initial imaging.

Patients with a dominant palpable breast mass that persists for ≥2 weeks should be evaluated. Most focal pain and palpable findings in pregnancy are benign, however, a change in the clinical examination or symptoms should be evaluated.

The goal of evaluating focal pain or palpable mass during pregnancy is to determine the cause and if it would require any further imaging or intervention or can be safely observed.

Variant 5: Pregnant female. Age 30 years or older. Focal pain or palpable breast mass. Initial imaging.

A. Digital breast tomosynthesis diagnostic

Mammography is considered safe in pregnancy. Scatter radiation to the fetus is negligible [2].

For adult women who are ≥40 years of age, DBT/mammography should be the initial imaging assessment [22].

For adult women 30 to 39 years of age, according to the ACR Appropriateness Criteria[®] for Palpable Breast Masses, diagnostic mammography (DM), DBT, or US may be used as the initial imaging study [22]

Tomosynthesis with mammography may provide added benefit of detection in denser breast tissue of pregnancy [3,8,23].

Variant 5: Pregnant female. Age 30 years or older. Focal pain or palpable breast mass. Initial imaging.

B. Mammography diagnostic

Mammography is considered safe during pregnancy. Scatter radiation to the fetus is negligible [2].

For adult women who are ≥40 years of age, DBT/mammography should be the initial imaging assessment [22].

For adult women 30 to 39 years of age, according to the ACR Appropriateness Criteria $^{\circledR}$ for

Palpable Breast Masses, DM, DBT, or US may be used as the initial imaging study [22].

Variant 5: Pregnant female. Age 30 years or older. Focal pain or palpable breast mass. Initial imaging.

C. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media [11]. Mammography with IV contrast would not be expected to be used in pregnancy for the evaluation of focal pain or palpable mass.

Variant 5: Pregnant female. Age 30 years or older. Focal pain or palpable breast mass. Initial imaging.

D. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 5: Pregnant female. Age 30 years or older. Focal pain or palpable breast mass. Initial imaging.

E. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI for the evaluation of pain or palpable breast mass in pregnancy.

Variant 5: Pregnant female. Age 30 years or older. Focal pain or palpable breast mass. Initial imaging.

F. Sestamibi MBI

MBI is contraindicated in pregnant patients [18,19]. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 5: Pregnant female. Age 30 years or older. Focal pain or palpable breast mass. Initial imaging.

G. US breast

As per the ACR Appropriateness Criteria [®] for <u>Palpable Breast Masses</u>, breast US may be used in conjunction with DBT/mammography [22]. US has a high sensitivity for both benign and malignant abnormalities. It can evaluate for focal pain or palpable finding in pregnancy regardless of patient age [2,7]. US can distinguish between cystic and solid masses. Because of the changes of the breast during pregnancy, some benign masses can appear suspicious [10].

Variant 6: Pregnant female. Age less than 30 years. Clinically suspicious nipple discharge. Initial imaging.

Single-duct bloody nipple discharge is more worrisome than multiple ducts, which are more likely due to physiological changes. Both entities warrant evaluation.

The goal of evaluating suspicious nipple discharge during pregnancy is to determine the cause and if it would require any further imaging or intervention or if it can be safely observed.

Variant 6: Pregnant female. Age less than 30 years. Clinically suspicious nipple discharge. Initial imaging.

A. Digital breast tomosynthesis diagnostic

Mammography is considered safe in pregnancy. Scatter radiation to the fetus is negligible [2]. DBT should not be the initial imaging modality in this patient population [22]. Tomosynthesis with mammography may provide added benefit of detection in denser breast tissue of pregnancy [3,8,23]. It may be a useful adjunct to US findings for suspicious nipple discharge, especially if US findings are suspicious. Mammography may reveal suspicious calcifications.

Variant 6: Pregnant female. Age less than 30 years. Clinically suspicious nipple discharge. Initial imaging.

B. Mammography diagnostic

Mammography is considered safe during pregnancy. Scatter radiation to the fetus is negligible [2]. Mammography should not be the initial imaging modality in this patient population [22]. It may be a useful adjunct to US findings for suspicious nipple discharge, especially if the US findings are suspicious. Sensitivity of mammography is less than US, 74% to 100% [2,10]. Mammography may reveal suspicious calcifications.

Variant 6: Pregnant female. Age less than 30 years. Clinically suspicious nipple discharge. Initial imaging.

C. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media [11]. Mammography with IV contrast would not be expected to be used in pregnancy for the evaluation of suspicious nipple discharge.

Variant 6: Pregnant female. Age less than 30 years. Clinically suspicious nipple discharge. Initial imaging.

D. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 6: Pregnant female. Age less than 30 years. Clinically suspicious nipple discharge. Initial imaging.

E. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI for evaluation of nipple discharge in pregnancy.

Variant 6: Pregnant female. Age less than 30 years. Clinically suspicious nipple discharge. Initial imaging.

F. Sestamibi MBI

MBI is contraindicated in pregnant patients [18,19]. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 6: Pregnant female. Age less than 30 years. Clinically suspicious nipple discharge. Initial imaging.

G. US breast

US can evaluate suspicious nipple discharge finding in pregnancy [2,7]. US of the subareolar region can be used to identify duct ectasia or intraductal filling defects. Suspicious US findings can aid in any further intervention [2].

Variant 7: Pregnant female. Age 30 years or older. Clinically suspicious nipple discharge. Initial imaging.

Single-duct bloody nipple discharge is more worrisome than multiple ducts, which are more likely due to physiological changes. Both entities warrant evaluation.

The goal of evaluating suspicious nipple discharge during pregnancy is to determine the cause and if it would require any further imaging or intervention or if it can be safely observed.

Variant 7: Pregnant female. Age 30 years or older. Clinically suspicious nipple discharge. Initial imaging.

A. Digital breast tomosynthesis diagnostic

Mammography is considered safe in pregnancy. Scatter radiation to the fetus is negligible [2].

For adult women who are ≥40 years of age, DBT/mammography should be the initial imaging assessment in the evaluation of suspicious nipple discharge (see the ACR Appropriateness Criteria [®] topic on "Evaluation of Nipple Discharge" [25]).

For adult women 30 to 39 years of age, according to the ACR Appropriateness Criteria[®] topic on "Evaluation of Nipple Discharge," DM, DBT, or US may be used as the initial imaging study [25].

Tomosynthesis with mammography may provide added benefit of detection in denser breast tissue of pregnancy [3,8,23]. Mammography may reveal suspicious calcifications.

Variant 7: Pregnant female. Age 30 years or older. Clinically suspicious nipple discharge. Initial imaging.

B. Mammography diagnostic

Mammography is considered safe during pregnancy. Scatter radiation to the fetus is negligible [2].

For adult women who are ≥40 years of age, DBT/mammography should be the initial imaging assessment in the evaluation of suspicious nipple discharge (see the ACR Appropriateness Criteria [®] topic on "Evaluation of Nipple Discharge" [25]).

For adult women 30 to 39 years of age, according to the ACR Appropriateness Criteria [®] topic on "Evaluation of Nipple Discharge," DM, DBT, or US may be used as the initial imaging study [25]. Mammography may reveal suspicious calcifications.

Variant 7: Pregnant female. Age 30 years or older. Clinically suspicious nipple discharge. Initial imaging.

C. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media [11]. Mammography with IV contrast would not be expected to be used in pregnancy for the evaluation of suspicious nipple discharge.

Variant 7: Pregnant female. Age 30 years or older. Clinically suspicious nipple discharge. Initial imaging.

D. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for use of gadolinium in pregnancy.

Variant 7: Pregnant female. Age 30 years or older. Clinically suspicious nipple discharge. Initial imaging.

E. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI for evaluation of nipple discharge in pregnancy.

Variant 7: Pregnant female. Age 30 years or older. Clinically suspicious nipple discharge. Initial imaging.

F. Sestamibi MBI

MBI is contraindicated in pregnant patients [18,19]. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 7: Pregnant female. Age 30 years or older. Clinically suspicious nipple discharge. Initial imaging.

G. US breast

US can evaluate suspicious nipple discharge finding in pregnancy [2,7]. Breast US may serve as a useful adjunct to DBT/mammography. US of the subareolar region can be used to identify duct ectasia or intraductal filling defects. Suspicious US findings can aid in any further intervention [2].

Variant 8: Pregnant female. Newly diagnosed breast cancer. Locoregional staging.

The goal of imaging for locoregional staging of newly diagnosed breast cancer is to provide information about the local tumor extent and regional lymph nodes. This can provide the surgeons and oncologists important information related to treatment options or need for additional imaging/intervention. Locoregional staging involves evaluation of the primary tumor size and

determining if the disease is unifocal, multifocal (≥2 foci of cancer in the same quadrant) or multicentric (2 or more quadrants of the breast involved with cancer) [9]. Assessing regional nodal status is also evaluated.

Variant 8: Pregnant female. Newly diagnosed breast cancer. Locoregional staging. A. Digital breast tomosynthesis diagnostic

Mammography is considered safe in pregnancy. Scatter radiation to the fetus is negligible [2]. Tomosynthesis with mammography may provide added benefit of detection in denser breast tissue of pregnancy [3,8,23]. After the detection of a new breast cancer, it can be used to evaluate the rest of the breast for any additional masses or suspicious calcifications.

Variant 8: Pregnant female. Newly diagnosed breast cancer. Locoregional staging. B. Mammography diagnostic

Mammography is considered safe during pregnancy. Scatter radiation to the fetus is negligible [2]. After the detection of a new breast cancer, it can be used to evaluate the rest of the breast for any additional masses or suspicious calcifications.

Variant 8: Pregnant female. Newly diagnosed breast cancer. Locoregional staging. C. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media [11].

Variant 8: Pregnant female. Newly diagnosed breast cancer. Locoregional staging. D. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 8: Pregnant female. Newly diagnosed breast cancer. Locoregional staging. E. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI in the evaluation of breast cancer in pregnancy.

Variant 8: Pregnant female. Newly diagnosed breast cancer. Locoregional staging. F. Sestamibi MBI

MBI is contraindicated in pregnant patients [18,19]. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 8: Pregnant female. Newly diagnosed breast cancer. Locoregional staging. G. US axilla

US of the ipsilateral axilla may be performed to evaluate the morphology of the lymph nodes [26,27]. Level I lymph nodes are lateral to the pectoral is minor muscle, level II lymph nodes are

posterior to the pectoralis minor muscle, and level III lymph nodes are medial to the pectoralis minor muscle. Identification of abnormal lymph nodes may facilitate clinical management.

Variant 8: Pregnant female. Newly diagnosed breast cancer. Locoregional staging. H. US breast

Breast US may be a useful adjunct to DBT/mammography. US can be used to evaluate a palpable mass [2,7], additional lesions seen on mammography, and aid in the management of any further intervention [2]. There is a lack of evidence to support whole-breast US during locoregional staging of newly diagnosed breast cancer in pregnant patients [3,8].

Variant 9: Pregnant female. Breast infection or abscess suspected. Initial imaging.

Infectious issues of the breast are rare during pregnancy and more common during lactation. Clinically, they can present as a sudden onset of erythema and/or a painful lump with or without fever. Inflammation of the breast that does not respond to antibiotics should be considered for tissue sampling [10].

The goal of imaging the breast in suspected infection is to determine the presence or extent of the infection. These findings will guide treatment options and/or intervention needed.

Variant 9: Pregnant female. Breast infection or abscess suspected. Initial imaging. A. Digital breast tomosynthesis diagnostic

Mammography is considered safe in pregnancy. Scatter radiation to the fetus is negligible [2]. Tomosynthesis with mammography may provide added benefit as an adjunct to US imaging.

Variant 9: Pregnant female. Breast infection or abscess suspected. Initial imaging. B. Mammography diagnostic

Mammography is considered safe in pregnancy. Scatter radiation to the fetus is negligible [2]. Mammography may provide added benefit as an adjunct to US imaging.

Variant 9: Pregnant female. Breast infection or abscess suspected. Initial imaging. C. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media [11]. Mammography with IV contrast would not be expected to be used in pregnancy for the evaluation of a possible breast infection.

Variant 9: Pregnant female. Breast infection or abscess suspected. Initial imaging. D. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 9: Pregnant female. Breast infection or abscess suspected. Initial imaging.

E. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI for the evaluation of infection of the breast cancer in pregnancy.

Variant 9: Pregnant female. Breast infection or abscess suspected. Initial imaging. F. Sestamibi MBI

MBI is contraindicated in pregnant patients [18,19]. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 9: Pregnant female. Breast infection or abscess suspected. Initial imaging. G. US breast

US can evaluate a palpable mass or possible infection [2,7]. If warranted, it can guide intervention or future surveillance.

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

Most masses in pregnancy are benign [7,28]. During pregnancy, benign masses can enlarge due to hormonal fluctuations. If the lesion's appearance becomes worrisome, then biopsy is necessary to rule out malignancy. However, there are no clinical trials published on the management of pregnant women with lesions classified as BI-RADS 3.

The goal of evaluating a palpable mass during pregnancy is to determine the cause and if it would require any further imaging (mammography) or intervention or can be safely observed.

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

A. Digital breast tomosynthesis diagnostic

Mammography is considered safe in pregnancy. Scatter radiation to the fetus is negligible [2]. Tomosynthesis with mammography may provide added benefit of detection in denser breast tissue of pregnancy [3,8,23]. It may be a useful adjunct to US findings, especially if US findings are suspicious.

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

B. Image-guided core biopsy breast

Probably benign breast lesions are safe to observe and follow during pregnancy. Core needle biopsies can be safely performed during pregnancy if indicated. They have increased risks of bleeding due to the breast vascularization and ductal dilatation [2]. During pregnancy, the risk of developing a milk fistula is low, except it increases the closer to delivery.

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

C. Image-guided fine needle aspiration breast

It is safe to perform fine needle aspirations, however, because of the histologic features between neoplasia and cellular changes of the breast during pregnancy, it may lead to false-positive diagnosis for malignancy [3]. Probably benign breast lesions are safe to observe and follow during pregnancy.

Mammography Diagnostic

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

D. Mammography diagnostic

Mammography is considered safe during pregnancy. Scatter radiation to the fetus is negligible [2]. It may be a useful adjunct to US findings.

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

E. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media [11].

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

F. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

G. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI for evaluating probably benign lesions in pregnancy.

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

H. Sestamibi MBI

MBI is contraindicated in pregnant patients [18,19]. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

I. US axilla

Imaging of the axilla for probably benign lesions has little or no value.

Variant 10: Pregnant female. Palpable breast mass. US findings are probably benign. Next imaging study.

J. US breast

US can evaluate a palpable mass [2,7]. It may be used in continued surveillance of probably benign masses. Masses (fibroadenomas) that are assessed as probably benign (BI-RADS 3) warrant US follow-up to assess for progression [28].

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

During pregnancy, some lesions may be difficult to distinguish between benign and malignant.

The goal of evaluating a palpable mass during pregnancy is to determine the cause and if it would require any further imaging (mammography) prior to intervention (biopsy). US-guided procedures of the breast can be safely performed during pregnancy.

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

A. Digital breast tomosynthesis diagnostic

Mammography is considered safe in pregnancy. Scatter radiation to the fetus is negligible [2]. Tomosynthesis with mammography may provide added benefit of detection in denser breast tissue of pregnancy [3,8,23]. It may be a useful adjunct to US findings, especially if US findings are suspicious. Mammography may reveal suspicious calcifications.

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

B. Image-guided core biopsy breast

Core needle biopsies can be safely performed during pregnancy. They have increased risks of bleeding due to the breast vascularization and ductal dilatation [2]. There is also a risk of a milk fistula, but this risk is greater during lactation.

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

C. Image-guided fine needle aspiration breast

It is safe to perform fine needle aspirations, however, due to the difficulty in evaluating the histologic features between neoplasia and cellular changes of the breast during pregnancy, it is less advised and may lead to a false-positive diagnosis for malignancy [3].

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

D. Mammography diagnostic

Mammography is considered safe during pregnancy. Scatter radiation to the fetus is negligible [2]. It may be a useful adjunct to US findings.

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly

suggestive of malignancy. Next imaging study.

E. Mammography with IV contrast

Diagnostic iodinated contrast media crosses the placenta and enters the fetus. There are no available data regarding potential harm to the fetus exposed to maternal iodinated contrast media [11].

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

F. MRI breast without and with IV contrast

Contrast-enhanced MRI is not recommended during pregnancy because IV gadolinium crosses the placenta and enters fetal circulation [3,7]. Within the amniotic fluid, the gadolinium may dissociate into toxic free gadolinium ions [7]. The <u>ACR Manual on Contrast Media</u> [11] outlines the guidelines for the use of gadolinium in pregnancy.

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

G. MRI breast without IV contrast

There is no evidence to support the use of noncontrast breast MRI for evaluating breast cancer in pregnancy.

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

H. Sestamibi MBI

MBI is contraindicated in pregnant patients [18,19]. Tc-99m sestamibi crosses the placenta and thus exposes the fetus to unnecessary radiation [18,19].

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

I. US axilla

If a suspicious mass is identified, evaluation of the ipsilateral axilla for nodal pathology could assist with clinical management.

Variant 11: Pregnant female. Palpable breast mass. US findings are suspicious or highly suggestive of malignancy. Next imaging study.

J. US breast

US can evaluate a palpable mass [2,7] and provide information on the morphology, size, and characterize the mass and its need for intervention. Suspicious US findings should prompt consideration of a US-guided biopsy.

Summary of Highlights

This is a summary of the key recommendations from the variant tables. Refer to the complete narrative document for more information.

- Variants 1 and 3: For pregnant women 40 years of age or older of any risk for breast cancer, and higher than average risk pregnant women 25 years of age or older, screening mammography and screening DBT are usually appropriate. Breast US may be appropriate in selective cases. Mammography with IV contrast, MRI breast without and with IV contrast, MRI breast without and with IV contrast abbreviated, MRI breast without IV contrast, MRI breast without IV contrast abbreviated, and sestamibi MBI are usually not appropriate in evaluating the breast during pregnancy.
- **Variant 2**: For screening in pregnant women <25 years of age who are higher than average risk for breast cancer, breast US may be appropriate to evaluate the breast. However, screening mammography, screening DBT, mammography with IV contrast, MRI breast without and with IV contrast, MRI breast without and with IV contrast abbreviated, MRI breast without IV contrast abbreviated, and sestamibi MBI are usually not appropriate in evaluating the breast during pregnancy in these individuals.
- Variants 4 and 5: Breast US is usually appropriate to evaluate focal pain or palpable breast
 mass in all pregnant women regardless of age. In pregnant women >30 years of age or older,
 it is usually appropriate to also evaluate with diagnostic DBT or mammography. If <30 years
 of age, it is usually not appropriate to perform diagnostic DBT or mammography. It is usually
 not appropriate to perform mammography with IV contrast, MRI breast without and with IV
 contrast, MRI breast without IV contrast, or sestamibi MBI during pregnancy in these
 individuals.
- Variants 6 and 7: Breast US is usually appropriate to evaluate clinically suspicious nipple discharge as the initial imaging examination in all pregnant females regardless of age. In pregnant females >30 years of age or older, it is usually appropriate to also evaluate with diagnostic DBT or mammography. If <30 years of age, it is usually not appropriate to perform diagnostic DBT or mammography. It is usually not appropriate to perform mammography with IV contrast, MRI breast without and with IV contrast, MRI breast without IV contrast, or sestamibi MBI during pregnancy in these individuals.
- Variant 8: Breast cancers newly diagnosed during pregnancy can be aggressive, and there
 may be a need to evaluate locoregional staging. It is usually appropriate to image
 locoregional extent with US of the axilla and breast. In addition, a diagnostic mammogram or
 DBT would be appropriate to evaluate both breasts. It is usually not appropriate to perform
 mammography with IV contrast, MRI breast without and with IV contrast, MRI breast without
 IV contrast, or sestamibi MBI during pregnancy in these individuals.
- **Variant 9**: If there is a suspected breast infection or abscess during pregnancy, then it is usually appropriate to perform a breast US. It may be appropriate to evaluate the breast with a diagnostic mammogram or DBT. It is usually not appropriate to perform mammography with IV contrast, MRI breast without and with IV contrast, MRI breast without IV contrast, or sestamibi MBI during pregnancy in these individuals.
- Variant 10: After a probably benign palpable mass (a mass that is considered safe to follow) is identified in the breast during pregnancy, it is usually appropriate to perform breast US for these palpable masses. It is usually not appropriate to perform axillary US, diagnostic DBT or mammogram, mammography with IV contrast, image-guided core biopsy, image-guided fine needle aspiration, MRI breast without and with IV contrast, MRI breast without IV contrast, or sestamibi MBI during pregnancy to follow these probably benign masses.
- **Variant 11**: A palpable mass in a pregnant woman that is determined to be suspicious or highly suggestive of malignancy on an US examination usually warrants additional

evaluation. It is usually appropriate in these cases to perform an axillary US, breast US (for other lesions), diagnostic DBT, mammogram with IV contrast, and image-guided core biopsy of the breast mass. In certain instances, it may be appropriate to perform an image-guided fine needle aspiration of the breast mass. It is usually not appropriate to perform a diagnostic mammogram, MRI breast without and with IV contrast, MRI breast without IV contrast, or sestamibi MBI during pregnancy to evaluate a mass that is suspicious of malignancy.

Supporting Documents

The evidence table, literature search, and appendix for this topic are available at https://acsearch.acr.org/list. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents, please go to the ACR website at https://www.acr.org/Clinical-Resources/Clinical-Tools-and-Reference/Appropriateness-Criteria.

Safety Considerations in Pregnant Patients

Imaging of the pregnant patient can be challenging, particularly with respect to minimizing radiation exposure and risk. For further information and guidance, see the following ACR documents:

- ACR-SPR Practice Parameter for the Safe and Optimal Performance of Fetal Magnetic Resonance Imaging (MRI) [29]
- ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [30]
- ACR-ACOG-AIUM-SRU Practice Parameter for the Performance of Obstetrical Ultrasound [31]
- ACR Manual on Contrast Media [11]
- ACR Manual on MR Safety [32]

Gender Equality and Inclusivity Clause

The ACR acknowledges the limitations in applying inclusive language when citing research studies that predates the use of the current understanding of language inclusive of diversity in sex, intersex, gender, and gender-diverse people. The data variables regarding sex and gender used in the cited literature will not be changed. However, this guideline will use the terminology and definitions as proposed by the National Institutes of Health.

Appropriateness Category Names and Definitions

| Appropriateness A Category Name | Appropriateness Rating | Appropriateness Category Definition |
|------------------------------------|---------------------------|-------------------------------------|
|------------------------------------|---------------------------|-------------------------------------|

| Usually Appropriate | 7, 8, or 9 | The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable riskbenefit ratio for patients. |
|--------------------------------------|------------|--|
| May Be Appropriate | 4, 5, or 6 | The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal. |
| May Be Appropriate (Disagreement) | 5 | The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned. |
| Usually Not Appropriate | 1, 2, or 3 | The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable. |

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, because of both organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared with those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria Radiation Dose Assessment Introduction document.

Relative Radiation Level Designations

| Relative Radiation Level* | Adult Effective Dose Estimate Range | Pediatric Effective Dose Estimate Range |
|---------------------------|--|--|
| 0 | 0 mSv | 0 mSv |

| | <0.1 mSv | <0.03 mSv |
|------------|------------|--------------|
| ※ ※ | 0.1-1 mSv | 0.03-0.3 mSv |
| | 1-10 mSv | 0.3-3 mSv |
| | 10-30 mSv | 3-10 mSv |
| *** | 30-100 mSv | 10-30 mSv |

^{*}RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination