American College of Radiology
ACR Appropriateness Criteria®
Breast Imaging of Pregnant and Lactating Women

Variant 1: **Breast cancer screening during lactation. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
Mammography screening	Usually Appropriate	☢☢
US breast	May Be Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢

Variant 2: **Breast cancer screening during pregnancy. Age younger than 30 at high risk. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
Mammography screening	Usually Appropriate	☢☢
US breast	May Be Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢

Variant 3: **Breast cancer screening during pregnancy. Age 30 to 39 years at elevated risk (intermediate or high risk). Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
Mammography screening	Usually Appropriate	☢☢
US breast	May Be Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢

Variant 4: **Breast cancer screening during pregnancy. Age 40 years or older, any risk level. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
Mammography screening	Usually Appropriate	☢☢
US breast	May Be Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢

Variant 5: **Pregnant women with a palpable breast mass. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Appropriate	O
Digital breast tomosynthesis diagnostic	May Be Appropriate	☢☢
Mammography diagnostic	May Be Appropriate	☢☢
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢
Image-guided core biopsy breast	Usually Not Appropriate	Varies
Image-guided fine-needle aspiration breast	Usually Not Appropriate	Varies

Variant 6: **Clinically suspicious nipple discharge during pregnancy. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Appropriate	O
Digital breast tomosynthesis diagnostic	Usually Appropriate	☢☢
Mammography diagnostic	Usually Appropriate	☢☢
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢

Variant 7: **Locoregional staging of newly diagnosed breast cancer during pregnancy. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
Digital breast tomosynthesis diagnostic	Usually Appropriate	☢☢
Mammography diagnostic	Usually Appropriate	☢☢
US axilla	Usually Appropriate	O
US breast	Usually Not Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
Sestamibi MBI	Usually Not Appropriate	☢☢☢

BREAST IMAGING OF PREGNANT AND LACTATING WOMEN

Expert Panel on Breast Imaging: Roberta M. diFlorio-Alexander, MD, MS[a]; Priscilla J. Slanetz, MD, MPH[b]; Linda Moy, MD[c]; Paul Baron, MD[d]; Aarati D. Didwania, MD[e]; Samantha L. Heller, MD, PhD[f]; Anna I. Holbrook, MD[g]; Alana A. Lewin, MD[h]; Ana P. Lourenco, MD[i]; Tejas S. Mehta, MD, MPH[j]; Bethany L. Niell, MD, PhD[k]; Ashley R. Stuckey, MD[l]; Daymen S. Tuscano, MD[m]; Nina S. Vincoff, MD[n]; Susan P. Weinstein, MD[o]; Mary S. Newell, MD.[p]

Summary of Literature Review

Introduction/Background

Pregnancy-associated breast cancer (PABC) is defined as breast cancer diagnosed during pregnancy, throughout the first postpartum year, or during lactation [1-4]. With a reported incidence of 1 in 3,000 to 10,000 pregnancies, breast cancer is the most common invasive cancer diagnosed during pregnancy [5-10]. Representing up to 3% of all breast cancer diagnoses, PABC is increasing as more women delay child bearing into the fourth decade of life when the incidence of breast cancer is higher [7,10,11]. Breast imaging during pregnancy and lactation is challenging because of the unique physiologic and structural breast changes that increase the difficulty of clinical and radiological evaluation and the need to balance both maternal and fetal well-being.

Throughout pregnancy, there is an increase in the size and number of breast ducts and lobules, an increase in the fluid content of the breast, and involution of stromal adipose tissue [9,12]. After delivery, prolactin stimulates secretory changes and the lobular acini become distended with milk [9,13-15]. These physiologic changes lead to increased breast volume, firmness, and nodularity, thereby making the detection of palpable abnormalities on clinical examination more difficult. As a result, there is often a delay in the diagnosis of PABC, and women typically present with more advanced disease exhibiting larger tumors and a higher likelihood of axillary nodal disease compared to nonpregnant women of the same age [8,16].

There is ongoing controversy as to whether delayed diagnosis and young patient age account for the poor prognosis of PABC, or if there may be additional factors causing increased biologic aggressiveness of gestational breast cancer when matched for age and stage [17-19]. Significant vascular and stromal remodeling is necessary to support the expanded epithelium of pregnancy and lactation, and these changes in the breast microenvironment could potentially be leveraged by breast cancer cells, leading to an increase in biologic aggressiveness [2,18,20]. Despite the long-term decreased risk of breast cancer with pregnancy, there are some data to suggest that there may be a transient increased risk for breast cancer during pregnancy and lactation [6]. Some studies show that women with BRCA gene mutations are overrepresented in PABC, and pregnant and lactating women are more likely to have hormone-negative breast cancer than age-matched controls [7,18,21,22]. Although the underlying cause for these observations is not clear, they support the possibility that the tumor biology of PABC is more aggressive than non-PABC breast cancer in young women with equivalent stage and prognostic factors.

The most common presentation of PABC is a palpable mass. Therefore, imaging evaluation of a palpable lesion in a pregnant or lactating woman should not be delayed [7,20,23,24]. Less common presenting complaints include focal pain, diffuse breast enlargement, nipple discharge, and, rarely, unilateral milk rejection in which the infant rejects milk from the breast harboring cancer [7,24]. The imaging appearance of PABC is similar to breast cancer in nonpregnant patients. Because of the young age of these women and higher likelihood of triple negative breast cancer, PABC is more likely to demonstrate areas of necrosis[13,25]. In addition, PABC may have a falsely benign appearance presenting as a mass with relatively circumscribed margins, parallel orientation, and posterior acoustic enhancement [1,7].

[a]Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire. [b]Beth Israel Deaconess Medical Center, Boston, Massachusetts. [c]Panel Vice-Chair, NYU Clinical Cancer Center, New York, New York. [d]Roper St. Francis Physician Partners Breast Surgery, Charleston, South Carolina; American College of Surgeons. [e]Northwestern University Feinberg School of Medicine, Chicago, Illinois; American College of Physicians. [f]New York University School of Medicine, New York, New York. [g]Emory University Hospital, Atlanta, Georgia. [h]New York University School of Medicine, New York, New York. [i]Alpert Medical School of Brown University, Providence, Rhode Island. [j]Beth Israel Deaconess Medical Center, Boston, Massachusetts. [k]H. Lee Moffitt Cancer Center and Research Institute, Tampa, Florida. [l]Women and Infants Hospital, Providence, Rhode Island; American Congress of Obstetricians and Gynecologists. [m]Mecklenburg Radiology Associates, Charlotte, North Carolina. [n]Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Manhasset, New York. [o]Perelman School of Medicine of the University of Pennsylvania, Philadelphia, Pennsylvania. [p]Panel Chair, Emory University Hospital, Atlanta, Georgia.

Although PABC most commonly presents as a palpable mass, greater than 80% of palpable masses that are biopsied in pregnant and breastfeeding women are benign [10,25]. Benign palpable masses may be due to enlargement of pre-existing benign masses, such as fibroadenomas and hamartomas, or they may represent masses unique to pregnancy and lactation, such as lactating adenomas and galactoceles [9,13]. When pre-existing lesions enlarge because of hormonal stimulation, they may appear atypical secondary to infarction or proliferative and lactational changes within the lesion [9,10,13]. These changes may lead to concerning imaging features and warrant further evaluation with biopsy. Some benign palpable masses are definitively benign on imaging evaluation (ie, cysts), whereas other masses may have benign imaging characteristics that allow for close follow-up.

Given the challenge of clinical examination in pregnant and lactating patients, diagnostic breast imaging, particularly breast ultrasound (US), plays a crucial role in characterizing the features of palpable lesions and in determining appropriate management. US has the highest sensitivity for the diagnosis of PABC [24-28]. Furthermore, because of the predominantly young patient age and the decreased sensitivity of mammography in the setting of dense breast tissue, breast US is the first-line imaging examination in pregnant and lactating patients. If breast US is negative, or if there are suspicious sonographic findings, additional imaging with mammography or digital breast tomosynthesis (DBT) may be indicated.

Isolated bloody nipple discharge without associated palpable mass may occur in up to 20% of pregnant women and is most commonly due to benign causes. The proliferative epithelial changes and associated increased breast vascularity of pregnancy may result in unilateral or bilateral bloody nipple discharge that is considered physiologic and sometimes referred to as the "rusty pipe syndrome" [29,30]. This condition may occur during pregnancy or early lactation and is usually self-limited. However, persistent unilateral bloody nipple discharge may be secondary to infection, papilloma, or, less commonly, breast cancer. A review of limited available data from an older report suggests that in nonpregnant patients of similar age, up to 12% of cases of isolated bloody nipple discharge may be due to breast cancer [31,32]. Therefore, diagnostic imaging workup of persistent unilateral bloody nipple discharge is recommended in pregnant and lactating patients.

There is a limited role for advanced breast imaging techniques in pregnant women. The ACR does not recommend the intravenous (IV) administration of gadolinium during pregnancy [33]. The physiologic increased breast vascularity of pregnancy and lactation may limit the sensitivity of dynamic contrast-enhanced (DCE) breast MRI [12,33-35]. Biopsy should be recommended for any suspicious imaging findings, and patients should be informed regarding the possibility of milk fistula and increased risk of bleeding.

Breast cancer screening in lactating women has several important considerations, as outlined below. However, diagnostic breast imaging during lactation is the same as for nonlactating women. See the ACR Appropriateness Criteria® for "Palpable Breast Masses" [36], "Evaluation of Nipple Discharge" [32], and "Breast Cancer Screening" [37].

Discussion of Procedures by Variant

Variant 1: Breast cancer screening during lactation. Initial imaging.

There is limited evidence on breast cancer screening in lactating women. Because of the potential increased risk of breast cancer in this population, consider continued screening during lactation dependent upon the level of underlying risk and the expected duration of lactation.

Mammography and DBT

With the onset of lactation, mammographic density increases to variable degrees among patients because of the distention of lobules with milk. Sonographic evaluation of the distribution of glandular and adipose tissue during lactation has shown that up to half of the breast volume continues to consist of adipose tissue [14]. Nursing or pumping before mammography may decrease parenchymal density and thereby improve sensitivity of mammography in lactating patients [9,10,13,38]. There is no contraindication to performing mammography during lactation. There are limited data available concerning screen-detected PABC. In one recent study, 9 of 117 (7.7%) cancers in patients with PABC were subclinical, and 5 of these cases were detected only with screening mammography in high-risk women [7]. In another small study, 2 of 22 cases of PABC were detected on screening mammography [24]. Therefore, screening mammography may be of benefit in lactating women, in accordance with ACR Appropriateness Criteria® for "Breast Cancer Screening" [37], and breastfeeding or pumping should be encouraged prior to the examination to minimize breast density and optimize the sensitivity of screening mammography.

There are no studies specifically evaluating DBT in this patient population. The increased breast density seen in younger women and in the hormonally altered breasts of lactating women is more likely to mask small lesions. Therefore, this population may benefit from the ability of 3-D mammography to decrease the masking effect of dense breast tissue.

US Breast

There are no studies specifically evaluating hand-held or automated whole-breast US screening in women who are breastfeeding. Given the increased mammographic density during lactation, screening US could be considered as a supplemental screening option in lactating women at intermediate and high risk for breast cancer. It is, however, important to keep in mind that screening US may increase the false-positive rate and prompt additional biopsies with small additional risk of milk fistula in lactating women [39,40].

MRI Breast

The physiologic increased vascularity of lactation causes a marked increase in background parenchymal enhancement on breast DCE-MRI. Although this may limit the sensitivity for detecting small enhancing masses and nonmass enhancement, studies have shown that breast DCE-MRI can differentiate enhancing breast cancer from background parenchymal enhancement based on kinetics and morphology [19,34,35,38,41]. A study of 53 patients with known PABC demonstrated moderate or marked background parenchymal enhancement in 58% of patients. Despite increased background parenchymal enhancement, there was 98% sensitivity for detection of known PABC; however, it is unknown how many women were lactating at the time of the MRI [19]. There are scant data on MRI screening in lactating women. In one study, 4 breast cancers in 3 patients were detected on high-risk screening MRI [7]. It may be helpful to wait until 3 months after cessation of breastfeeding. However, if a woman plans to nurse for a long period, or is at very high risk for breast cancer, screening breast MRI during lactation may be considered [10]. The amount of gadolinium excreted in human breast milk over the first 24 hours after IV contrast administration is <1% of the permitted dose for neonates [42]. Up-to-date recommendations with regard to breastfeeding following IV administration of gadolinium are outlined in detail in the ACR Manual on Contrast Media [33]. Therefore, although not the initial imaging tool of choice, screening breast MRI is not contraindicated during lactation and may be considered in lactating women with a high lifetime risk of breast cancer. An informed decision should be made by the mother regarding continuation of breastfeeding after the examination [3,33,42].

Sestamibi MBI

There is no role for molecular breast imaging (MBI) in breast cancer screening during lactation.

Variant 2: Breast cancer screening during pregnancy. Age younger than 30 at high risk. Initial imaging.

Screening is not recommended for pregnant women at average or intermediate risk for breast cancer if younger than age 30. However, consider screening before age 30 for pregnant women at high risk for breast cancer. Criteria for high risk, and the age at which to begin screening in women at high risk, are discussed in the ACR Appropriateness Criteria® for "Breast Cancer Screening" [37].

Mammography and DBT

Screening mammography can be performed in pregnant women at high risk. Mammography is not contraindicated during pregnancy, and the dose to the fetus is negligible. The fetal radiation dose from a 4-view mammogram is <0.03 mGy. No teratogenic effects have been demonstrated below 50 mGy [43]. Screening mammography is not recommended for pregnant women who are at average or intermediate risk for breast cancer. However, in women who have a high risk of breast cancer, mammographic screening should be considered.

There are no studies specifically evaluating DBT in this patient population. The increased breast density seen in younger women and in the hormonally altered breast of pregnant women is more likely to conceal small lesions. Therefore, this population may benefit from the ability of 3-D mammography to decrease the masking effect of dense breast tissue.

Ductal and lobular hyperplasia, combined with increased water content and decreased stromal fat, may increase mammographic density throughout pregnancy. A small study has shown that the anticipated changes in breast density are less pronounced during pregnancy than during lactation, and that most pregnant patients had scattered or heterogeneously dense fibroglandular tissue [44]. Many studies have shown that mammograms may be diagnostic in 74% to 100% of gravid pregnant women [7,24-28]. With current digital techniques and increased

use of DBT, the ability to detect breast cancer with mammography in pregnant patients may improve. There are several studies that report screen-detected PABC in a small number of patients [7,24].

US Breast
Throughout pregnancy, there is progressive ductal and lobular hyperplasia as well as increased duct ectasia. These changes lead to prominent hypoechoic ducts and lobules with diffuse decreased breast echogenicity [9,10]. There are no studies available at this time evaluating the use of screening whole-breast US during pregnancy. Despite the physiologic changes that alter the sonographic appearance of the breasts during pregnancy, screening whole-breast US may be used as a supplemental screening modality in pregnant women younger than 30 at high risk for breast cancer. It is, however, important to keep in mind that screening US may increase the false-positive rate and prompt additional biopsies.

MRI Breast
It is well-established that IV gadolinium chelates cross the placenta and enter the fetal circulation. Although there are no reported adverse fetal effects due to IV gadolinium in the pregnant mother, there is the potential for the dissociation of free toxic gadolinium ion with limited data in this patient population. Guidelines regarding gadolinium administration during pregnancy are outlined in detail in the ACR Manual on Contrast Media [33]. Because of the concerns regarding gadolinium crossing the placenta and limited data regarding its safety in this setting, screening breast DCE-MRI is not recommended in pregnant women with any breast cancer risk profile.

Sestamibi MBI
There is no role for MBI in breast cancer screening during pregnancy.

Variant 3: Breast cancer screening during pregnancy. Age 30 to 39 years at elevated risk (intermediate or high risk). Initial imaging.

Screening is not recommended for pregnant women who are at average risk for breast cancer if age 30 to 39 years. However, in pregnant women at high risk for breast cancer, breast cancer screening between the ages of 30 to 39 years may be appropriate. Pregnant women who are at intermediate risk for breast cancer may also benefit from screening before age 40. Criteria for intermediate and high risk, and the age at which to begin screening women at intermediate and high risk, are discussed in the ACR Appropriateness Criteria® for "Breast Cancer Screening" [37].

Mammography and DBT
Mammography is not contraindicated during pregnancy. The fetal radiation dose from a 4-view mammogram is <0.03 mGy. No teratogenic effects have been demonstrated below 50 mGy [43]. There are no studies specifically evaluating DBT in this patient population. The increased breast density seen in younger women and in the hormonally altered breast of pregnant women is more likely to conceal small lesions. Therefore, this population may benefit from the ability of 3-D mammography to decrease the masking effect of dense breast tissue.

Ductal and lobular hyperplasia, combined with increased water content and decreased stromal fat, may increase mammographic density throughout pregnancy. A small study has shown that the anticipated changes in breast density are less pronounced during pregnancy than during lactation, and that most pregnant patients had scattered or heterogeneously dense fibroglandular tissue [44]. Many studies have shown that mammograms may be diagnostic in 74% to 100% of pregnant women [7,24-28]. With current digital techniques and increased use of DBT, the ability to detect breast cancer with mammography in pregnant patients may improve. There are several studies that report screen-detected PABC in a small number of patients [7,24].

US Breast
Throughout pregnancy, there is progressive ductal and lobular hyperplasia as well as increased duct ectasia. These changes lead to prominent hypoechoic ducts and lobules with diffuse decreased breast echogenicity [9,10]. There are no studies available at this time evaluating the use of screening whole-breast US during pregnancy. Despite the physiologic changes that alter the sonographic appearance of the breasts during pregnancy, screening whole-breast US may be used as a supplemental screening modality in pregnant women between 30 and 39 years of age with a high risk of breast cancer. It is, however, important to keep in mind that screening US may increase the false-positive rate and prompt additional biopsies.

MRI Breast
It is well established that IV gadolinium chelates cross the placenta and enter the fetal circulation. Although there are no reported adverse fetal effects due to IV gadolinium in the pregnant mother, there is the potential for the

dissociation of free toxic gadolinium ion with limited data in this patient population. Guidelines regarding gadolinium administration during pregnancy are outlined in detail in the ACR Manual on Contrast Media [33]. Because of the concerns regarding gadolinium crossing the placenta and limited data regarding its safety in this setting, screening breast DCE-MRI is not recommended in pregnant women with any breast cancer risk profile.

Sestamibi MBI
There is no role for MBI in breast cancer screening during pregnancy.

Variant 4: Breast cancer screening during pregnancy. Age 40 years or older, any risk level. Initial imaging examination.

Breast cancer screening during pregnancy is recommended for pregnant women age 40 or older who are at average risk of breast cancer as defined in the ACR Appropriateness Criteria® for "Breast Cancer Screening" [37].

Mammography and DBT
Mammography is not contraindicated during pregnancy. The fetal radiation dose from a 4-view mammogram is <0.03 mGy. No teratogenic effects have been demonstrated below 50 mGy [43]. There are no studies specifically evaluating DBT in this patient population. The increased breast density seen in younger women and in the hormonally altered breast of pregnant women is more likely to conceal small lesions. Therefore, this population may benefit from the ability of 3-D mammography to decrease the masking effect of dense breast tissue.

Ductal and lobular hyperplasia, combined with increased water content and decreased stromal fat, may increase mammographic density throughout pregnancy. A small study has shown that the anticipated changes in breast density are less pronounced during pregnancy than during lactation, and that most pregnant patients had scattered or heterogeneously dense fibroglandular tissue [44]. Many studies have shown that mammograms may be diagnostic in 74% to 100% of pregnant women [7,24-28]. With current digital techniques and increased use of DBT, the ability to detect breast cancer with mammography in pregnant patients may improve. There are several studies that report screen-detected PABC in a small number of patients [7,24].

US Breast
Throughout pregnancy, there is progressive ductal and lobular hyperplasia as well as increased duct ectasia. These changes lead to prominent hypoechoic ducts and lobules with diffuse decreased breast echogenicity [9,10]. There are no studies available at this time evaluating the use of screening whole-breast US during pregnancy. Despite physiologic changes that alter the sonographic appearance of the breasts during pregnancy, screening whole-breast US may be used as a supplemental screening modality in pregnant women 40 and older, especially those at elevated risk. It is, however, important to keep in mind that screening US may increase the false-positive rate and prompt additional biopsies.

MRI Breast
It is well established that IV gadolinium chelates cross the placenta and enter the fetal circulation. Although there are no reported adverse fetal effects due to IV gadolinium in the pregnant mother, there is the potential for the dissociation of free toxic gadolinium ion with limited data in this patient population. Guidelines regarding gadolinium administration during pregnancy are outlined in detail in the ACR Manual on Contrast Media [33]. Because of the concerns regarding gadolinium crossing the placenta and limited data regarding its safety in this setting, screening breast DCE-MRI is not recommended in pregnant women with any breast cancer risk profile.

Sestamibi MBI
There is no role for MBI in breast cancer screening during pregnancy.

Variant 5: Pregnant women with a palpable breast mass. Initial imaging.

The most common presentation of PABC is a palpable mass. Therefore imaging evaluation of a palpable lesion in a pregnant or lactating woman should not be delayed [7,20,23,24]. Given the challenge of clinical examination in pregnant and lactating patients, diagnostic breast imaging, particularly breast US, plays a crucial role in characterizing the features of palpable lesions and in determining appropriate management. US has the highest sensitivity for the diagnosis of PABC [24-28]. Furthermore, due to the predominantly young patient age and the decreased sensitivity of mammography in the setting of dense breast tissue, breast US is the first-line imaging examination in pregnant and lactating patients. If breast US is negative, or if there are suspicious sonographic findings, additional imaging with mammography or DBT may be indicated.

Mammography and DBT
Mammography has slightly decreased sensitivity compared to breast sonography in this clinical setting, ranging from 74% to 90% [7,24-27] in most studies. One recent study has reported 100% sensitivity of mammography that may in part be explained by use of full-field digital technique rather than film screen mammography [28]. The advanced stage of PABC may also contribute to the moderate sensitivity of diagnostic mammography given the physiologic increased breast density in these patients that may compromise mammography. Therefore, although diagnostic mammography is not recommended as the initial examination in patients with a palpable mass, there is a role for diagnostic mammography as an adjunct to US. If US does not show an etiology for the palpable mass, diagnostic mammography should be done to look for malignant calcifications or architectural distortion. If a suspicious finding is seen by US, mammography is also recommended to evaluate for additional suspicious findings, particularly microcalcifications that may be occult by US.

Mammography is not contraindicated during pregnancy, and the dose to the fetus is negligible. The fetal radiation dose from a 4-view mammogram is <0.03 mGy, and no teratogenic effects have been demonstrated below 50 mGy [43].

There are no studies specifically evaluating DBT in this patient population. DBT may improve visualization of breast masses in pregnant women. The increased breast density seen in younger women and in the hormonally altered breast of pregnant women is more likely to conceal small lesions; therefore, this population may benefit from the ability of 3-D mammography to decrease the masking effect of dense breast tissue.

US Breast
PABC most commonly presents as a palpable mass, and breast US is recommended as the first-line imaging modality in pregnant and lactating women regardless of age [9,10,23,25,26,36]. Breast US can define benign etiologies for palpable masses that require no further evaluation, such as simple cysts or galactoceles. Breast US has the highest sensitivity for diagnosis of PABC in the setting of a palpable mass with 100% sensitivity reported in many studies [24-28,45,46]. Several authors have cautioned that PABC may have benign features, including parallel orientation, circumscribed margins, and posterior acoustic enhancement [7,24,26].

MRI Breast
It is well established that IV gadolinium chelates cross the placenta and enter the fetal circulation. Although there are no reported adverse fetal effects due to IV gadolinium in the pregnant mother, there is the potential for the dissociation of free toxic gadolinium ion with limited data in this patient population. Guidelines regarding gadolinium administration during pregnancy are outlined in detail in the ACR Manual on Contrast Media [33]. There is no role for MRI as the initial imaging evaluation in the diagnostic workup of palpable lumps in pregnant patients.

Sestamibi MBI
There is no role for MBI as the initial imaging evaluation in the diagnostic workup of palpable lumps in pregnant patients.

Image-Guided Core Biopsy
Image-guided core biopsy should not be the initial evaluation of a palpable mass as postbiopsy changes may obscure lesion visualization or negatively impact image interpretation. If initial diagnostic imaging evaluation demonstrates a suspicious mass, image-guided core biopsy should be obtained. Consent for low risk of milk fistula and increased risk of bleeding is recommended for pregnant and lactating women. If a palpable mass is clinically suspicious and initial imaging does not demonstrate etiology for a clinically suspicious mass, non–image-guided biopsy should be performed via palpation.

Image-Guided Fine-Needle Aspiration
Fine-needle aspiration should not be the initial evaluation of a palpable mass as postaspiration changes may obscure lesion visualization or negatively impact image interpretation. If initial diagnostic imaging evaluation demonstrates a suspicious mass, image-guided core biopsy should be obtained. If initial imaging does not demonstrate etiology for a clinically suspicious mass, non–image-guided biopsy or fine-needle aspiration should be performed via palpation.

Variant 6: Clinically suspicious nipple discharge during pregnancy. Initial imaging.

Isolated bloody nipple discharge without associated palpable mass may occur in up to 20% of pregnant women and is most commonly due to benign causes. The proliferative epithelial changes and associated increased breast

vascularity of pregnancy may result in unilateral or bilateral bloody nipple discharge that is considered physiologic and sometimes referred to as the "rusty pipe syndrome" [29,30]. This condition may occur during pregnancy or early lactation and is usually self-limited. However, persistent unilateral bloody nipple discharge may be secondary to infection, papilloma, or, less commonly, breast cancer. A review of limited available data from an older report suggests that in nongestational patients of similar age, up to 12% of cases of isolated bloody nipple discharge may be due to breast cancer [31,32]. The risk of malignancy in women younger than age 40 with isolated pathologic nipple discharge is approximately 3%. Therefore, although there are very little data on pathologic nipple discharge in pregnant women, diagnostic imaging workup of pathologic bloody nipple discharge is recommended in pregnant patients [31,32].

Mammography and DBT

There is wide variation in degree of mammographic density during pregnancy, and many studies have shown that mammograms have a sensitivity of 74% to 100% in the diagnostic setting [25,28]. This is particularly true for the detection of suspicious calcifications that may be detected despite mammographically dense breast tissue and that may be sonographically occult [7,24]. Mammography is not contraindicated during pregnancy, and the dose to the fetus is negligible. The fetal radiation dose from a 4-view mammogram is <0.03 mGy, and no teratogenic effects have been demonstrated below 50 mGy [43]. Diagnostic mammograms with retroareolar magnification views may be of benefit as the initial examination in pregnant women with persistent nipple discharge or as an adjunct to diagnostic breast US.

US Breast

Although there are no studies specifically evaluating diagnostic US for nipple discharge in pregnant women, retroareolar sonographic evaluation should be the first-line imaging examination to look for papilloma or other breast masses as the cause of pathologic nipple discharge regardless of patient age. The peripheral compression technique, 2-handed compression technique, and the rolled nipple technique described by Stavros may increase the ability of breast US to detect the cause for bloody nipple discharge [47].

MRI Breast

It is well established that IV gadolinium chelates cross the placenta and enter the fetal circulation. Although there are no reported adverse fetal effects due to IV gadolinium in the pregnant mother, there is the potential for the dissociation of free toxic gadolinium ion with limited data in this patient population. Guidelines regarding gadolinium administration during pregnancy are outlined in detail in the ACR Manual on Contrast Media [33]. There is no role for MRI as the initial imaging evaluation in nipple discharge during pregnancy.

Sestamibi MBI

There is no role for MBI as the initial imaging evaluation in nipple discharge during pregnancy.

Variant 7: Locoregional staging of newly diagnosed breast cancer during pregnancy. Initial imaging.

Chemotherapy may be used to treat breast cancer after the first trimester of pregnancy [21,48]. Accurate staging is therefore important in order to determine optimal therapy while limiting harm to the fetus. The risk-to-benefit ratio will vary from patient to patient depending on many factors, including gestational age at the time of diagnosis and personal perspectives regarding pregnancy interruption. Locoregional staging is obtained to identify primary tumor size, regional node status, extent of disease, and additional foci of malignancy in the ipsilateral or contralateral breast. This information optimizes definitive local treatment and is used to determine the need for systemic staging to evaluate for distant metastases. Locoregional staging in pregnant patients is discussed below. However, decisions regarding systemic breast cancer staging in pregnant women are best addressed via patient-centered multidisciplinary tumor boards in order to provide specialized care in this complex clinical scenario [11,49].

Mammography and DBT

Mammography is not contraindicated during pregnancy, and the dose to the fetus is negligible. The fetal radiation dose from a 4-view mammogram is <0.03 mGy, and no teratogenic effects have been demonstrated below 50 mGy [43]. Complete mammographic evaluation is recommended as a component of locoregional staging in pregnant women with newly diagnosed breast cancer. Microcalcifications due to ductal carcinoma in situ adjacent to the index cancer may not be seen by US. Therefore, mammography is recommended for evaluating extent of disease. Multifocal or multicentric disease presenting as microcalcifications due to sonographically occult ductal carcinoma in situ may similarly be identified with adjunctive mammographic breast cancer staging. These findings would affect surgical management and aid in obtaining clear margins and improved patient outcomes.

There are no studies specifically evaluating DBT during pregnancy. DBT may improve visualization of breast masses in pregnant women. The increased breast density seen in younger women and in the hormonally altered breast of pregnant women is more likely to conceal small masses because of the masking effect of dense breast tissue.

US Breast

Whole-breast US, including US of the nodal basins, is a staging modality with no known adverse effects on the fetus. In a single study by Yang et al [50], preoperative breast US was performed in 23 pregnant patients for the purpose of evaluating response to neoadjuvant chemotherapy during pregnancy. In this small study, 15 of 18 axillary metastases were correctly diagnosed with sonographic staging of the axilla, and all breast masses were identified by breast US. Whole-breast US staging has been evaluated in nonpregnant patients with reported incremental cancer detection rates similar to those of staging breast MRI [51]. Several additional studies in nonpregnant women support the use of whole-breast US staging [25,52,53]. However, these studies were performed by breast radiologists with extensive experience in sonographic locoregional staging of breast cancer, and it is not clear to what degree these results would be reproducible in other centers. Therefore, although staging of the axilla via US is recommended, there is no evidence to support whole-breast US for locoregional staging in pregnant patients at this time.

US Axilla

Sonographic evaluation of the axilla is often performed to stage pregnant patients who are diagnosed with breast cancer. In a study of 23 pregnant patients undergoing neoadjuvant chemotherapy for newly diagnosed breast cancer, 15 of 18 axillary metastases were correctly diagnosed by sonographic evaluation of the axilla [50].

MRI Breast

It is well established that IV gadolinium chelates cross the placenta and enter the fetal circulation. Although there are no reported adverse fetal effects due to IV gadolinium in the pregnant mother, there is the potential for the dissociation of free toxic gadolinium ion with limited data in this patient population. Guidelines regarding gadolinium administration during pregnancy are outlined in detail in the ACR Manual on Contrast Media [33]. Because of the concerns regarding gadolinium crossing the placenta and limited data regarding its safety in this setting, breast DCE-MRI is therefore not recommended in pregnant women. However, immediately following delivery or pregnancy termination, breast MRI is recommended for locoregional staging. A small series evaluating PABC on breast MRI showed that 23% of patients had pathologically proven greater extent of disease than was identified with mammography and breast US. This study showed variable background parenchymal enhancement with 58% of patients demonstrating moderate or marked enhancement. Despite increased background parenchymal enhancement, this study showed 98% sensitivity for PABC [19].

Sestamibi MBI

There is no role for MBI as the initial imaging evaluation in locoregional breast cancer staging during pregnancy.

Summary of Recommendations

- **Variant 1:** For lactating women, DBT or mammography is indicated with minor modifications to address increased mammographic density, increased breast vascularity, and duration of lactation.
- **Variant 2:** Breast cancer screening is not contraindicated during pregnancy. For women younger than age 30 at high risk for breast cancer, DBT or mammography is appropriate.
- **Variant 3:** Breast cancer screening is not contraindicated during pregnancy. For women between 30 and 39 years of age at elevated risk for breast cancer (intermediate or high risk), DBT or mammography is appropriate.
- **Variant 4:** Breast cancer screening is not contraindicated during pregnancy. For women age 40 and older, screening DBT or mammography is appropriate.
- **Variant 5:** Pregnant women with a palpable mass should be evaluated initially by US. If US is suspicious for malignancy or does not show the etiology for the lump, diagnostic mammography is recommended.
- **Variant 6:** Pregnant women with pathologic nipple discharge should be initially evaluated by US. DBT or diagnostic mammography with retroareolar magnification views may be obtained as a complementary initial imaging examination to look for calcifications that may be sonographically occult or may be obtained if US does not show the etiology for nipple discharge.

- **Variant 7:** Pregnant women with newly diagnosed breast cancer should undergo locoregional staging via both diagnostic mammography and US of the axilla.

Summary of Evidence

Of the 59 references cited in the *ACR Appropriateness Criteria® Breast Imaging of Pregnant and Lactating Women* document, 1 is categorized as a therapeutic reference that may have design limitations. Additionally, 56 references are categorized as diagnostic references including 4 good-quality studies and 12 quality studies that may have design limitations. There are 40 references that may not be useful as primary evidence. There is 1 reference that is a meta-analysis study.

The 59 references cited in the *ACR Appropriateness Criteria® Breast Imaging of Pregnant and Lactating Women* document were published from 1990-2017.

Although there are references that report on studies with design limitations, 4 good-quality studies provide good evidence.

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) [54]
- ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [55]
- ACR-ACOG-AIUM-SRU Practice Parameter for the Performance of Obstetrical Ultrasound [56]
- ACR Manual on Contrast Media [33]
- ACR guidance document on MR safe practices: 2013 [57]

Appropriateness Category Names and Definitions

Appropriateness 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 risk-benefit 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, both because of 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 to 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 [58].

Relative Radiation Level Designations		
Relative Radiation Level*	**Adult Effective Dose Estimate Range**	**Pediatric Effective Dose Estimate Range**
O	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 (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies".		

Supporting Documents

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

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