



# Effective Health Care

## Comparative Effectiveness of Emerging Breast Imaging for Screening, Diagnosis, and Treatment Planning Nomination Summary Document

### Results of Topic Selection Process & Next Steps

- The topic area, *Comparative Effectiveness of Emerging Breast Imaging for Screening*, was found to be addressed by an in-process US Preventive Services Task Force (USPSTF) review and seven guidelines.
  - USPSTF In-Process Topics: U.S. Preventive Services Task Force. Screening for breast cancer. Accessed July 30, 2014. <http://www.uspreventiveservicestaskforce.org/uspstf/topicsprog.htm>.
  - National Comprehensive Cancer Network. Breast Cancer Screening and Diagnosis. Fort Washington, PA: National Comprehensive Cancer Network, 2013. [http://www.nccn.org/professionals/physician\\_gls/pdf/breast-screening.pdf](http://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf)
  - Mainiero MB, Lourenco A, Mahoney MC, Newell MS, et al. ACR Appropriateness Criteria® breast cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2012.
  - University of Michigan Health System. Cancer screening. Ann Arbor (MI): University of Michigan Health System; 2012.
  - Canadian Task Force on Preventive Health Care, Tonelli M, Gorber SC, Joffres M, Dickinson J, Singh H, Lewin G, Birtwhistle R. Recommendations on screening for breast cancer in average-risk women aged 40-74 years. CMAJ. 2011 Nov 22;183(17):1991-2001.
  - American College of Obstetricians and Gynecologists (ACOG). Breast cancer screening. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2011.
  - Singapore Ministry of Health. Cancer screening. Singapore: Singapore Ministry of Health; 2010.
  - Kaiser Permanente Care Management Institute. Breast cancer screening clinical practice guideline. Oakland (CA): Kaiser Permanente Care Management Institute; 2010.
- The topic area, *Comparative Effectiveness of Emerging Breast Imaging for Treatment Planning* was also found to be addressed by a recently completed EPC Program technical brief.
  - Evidence-based Practice Center Technical Brief Protocol. Imaging Techniques for Treatment Evaluation for Metastatic Breast Cancer
- The topic areas, *Comparative Effectiveness of Emerging Breast Imaging for Diagnosis of Breast Cancer, for Treatment Planning, and for Evaluating Treatment Response to a Breast Cancer Chemotherapy Regimen*, are not feasible for a full systematic review due to the limited data available for a review at this time.
- Given the existing guidance identified no further activity will be undertaken on these topic areas.

### Topic Description

**Nominator(s):** Organization

**Nomination  
Summary:**

This nomination aims to compare the effectiveness of new modalities or approaches to breast imaging, to standard approaches, to screen for, diagnose, plan treatment or follow up patients with breast cancer. New modalities include digital tomosynthesis, positron emission mammography (PEM), molecular breast imaging (MBI), and computed tomography of the breast (breast CT; still in development and not yet approved for marketing). Other new approaches use existing technology and include contrast-enhanced, full field digital mammography and diffusion-weighted imaging with magnetic resonance imaging (DWI-MRI).

**Staff-Generated PICO:**

**Screening:**

**Population(s):** General population of women eligible for breast cancer screening (i.e., women 40 and over or 50 and over, depending on the guidelines used); women at elevated risk for breast cancer (e.g., with BRCA1 or BRCA2 mutations or high familial risk); women with dense breasts

**Intervention(s):** Digital tomosynthesis, MBI. At this point, it is not clear whether PEM, MBI, and dedicated breast CT, when approved, would be suggested for use in general screening, depending on the radiation dose associated with these tests

**Comparator(s):** Film or digital mammography, breast MRI

**Outcome(s):** Earlier identification of cancer, recall rates, negative biopsies, risks for repeated radiation exposure, stage at diagnosis, survival

**Setting:** Screening

**Diagnosis :**

**Population(s):** General population of women eligible for breast cancer screening (i.e., women 40 and over or 50 and over, depending on the guidelines used); women with dense breasts

**Intervention(s):** Digital tomosynthesis, PEM, MBI, breast CT

**Comparator(s):** Diagnostic film or digital mammography, breast MRI, ultrasonography, scintimammography

**Outcome(s):** Earlier identification of cancer, negative biopsies, risks for repeated radiation exposure, stage at diagnosis, recurrence rates, survival

**Setting:** Diagnosis

**Treatment planning among breast cancer patients eligible for breast-conserving surgery:**

**Population(s):** Breast cancer patients eligible for breast-conserving therapy

**Intervention(s):** PEM, MBI, breast CT

**Comparator(s):** Breast MRI, ultrasonography, scintimammography

**Outcome(s):** Identification of multifocal or multicentric disease, recurrence rates, survival

**Setting:** Treatment planning

**Evaluating tumor response to a chemotherapy regimen:**

**Population(s):** Breast cancer patients undergoing neoadjuvant chemotherapy

**Intervention(s):** PEM, MBI, breast CT

**Comparator(s):** Breast MRI, scintimammography

**Outcome(s):** Tumor response, change in treatment, recurrence rates, survival  
**Setting:** Monitoring response to neoadjuvant chemotherapy

**Key Questions from Nominator:** What is the comparative effectiveness of new modalities or approaches to breast imaging, compared to standard approaches, to screen for, diagnose, plan treatment or follow up patients with breast cancer?

## Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- Breast cancer ranks first in cancers among women, and second in cancer-related deaths among women. Imaging can be used for screening, diagnosis, treatment planning, treatment monitoring, and monitoring for recurrence. The interest in new imaging modalities stems from the limitations of the current options. However, there is limited evidence of the harms and benefits these new modalities. Decisionmakers must consider the accuracy, effectiveness, and potential harms of any imaging modality. Use of various modalities could potentially result in overtreatment, with the administration of treatment that may not be necessary; or undertreatment, when the full extent of disease is not identified.
- For the topic area, *Comparative Effectiveness of Emerging Breast Imaging for Screening*, we identified an in-process USPSTF review and seven guidelines that address the topic.
  - The SRC identified an in-process USPSTF review on breast cancer screening that will address the following key questions related to the topic nomination that are evaluating several interventions, including breast tomosynthesis, breast MRI, hand-held ultrasonography, and whole breast ultrasonography.
    - What are the test performance characteristics of tomosynthesis (3-D mammography) as a primary screening modality for breast cancer, performed either alone or simultaneously with 2-D digital mammography? How do these performance characteristics differ by age and risk factor?
    - What are the test performance characteristics of newer technologies for breast cancer screening when used as adjunctive screening after a negative screening mammogram in women found to have dense breasts? How do these performance characteristics differ by age and risk factor?
    - What is the effectiveness of adjunctive screening for breast cancer with newer technologies on intermediate breast cancer outcomes (e.g., ductal carcinoma in situ [DCIS] detection rates, stage at diagnosis, and interval cancer rates) when performed after a negative screening mammogram in women found to have dense breasts?
  - Seven guidelines on imaging for breast cancer screening were identified. However, only the American College of Radiology (ACR) guideline addresses the use of 18F-fluorodeoxyglucose positron emission mammography (FDG PEM) for screening. The guideline states that there is insufficient evidence to recommend imaging modalities other than mammography, MRI and ultrasound, including FDG PEM as a radiologic procedure for breast cancer screening.

- For the topic area, *Comparative Effectiveness of Emerging Breast Imaging for Diagnosis of Breast Cancer*, we identified an updated EPC Program systematic review on noninvasive diagnostic tests for breast cancer, *Non-Invasive Diagnostic Tests for Breast Abnormalities: Update of a 2006 Review*. However the review focuses on diagnosis with more established technologies, such as mammography, magnetic resonance imaging (MRI), and ultrasound. We also identified seven primary research studies. The studies compared digital breast tomosynthesis to full-field digital mammography, mammography breast ultrasound, and conventional diagnostic mammography; and one-view breast tomosynthesis to two-view mammography.
  - Kalles V, Zografos GC, Provatopoulou X, et al. The current status of positron emission mammography in breast cancer diagnosis. *Breast Cancer*. 2013 Apr;20(2):123-30.
  - Mun HS, Kim HH, Shin HJ, et al. Assessment of extent of breast cancer: comparison between digital breast tomosynthesis and full-field digital mammography. *Clin Radiol*. 2013;68(12):1254-9.
  - Thibault F(1), Dromain C, Breucq C, et al. Digital breast tomosynthesis versus mammography and breast ultrasound: a multireader performance study. *Eur Radiol*. 2013;23(9):2441-9.
  - Brandt KR, Craig DA, Hoskins TL, et al. Can digital breast tomosynthesis replace conventional diagnostic mammography views for screening recalls without calcifications? A comparison study in a simulated clinical setting. *AJR Am J Roentgenol*. 2013;200(2):291-8.
  - Waldherr C, Cerny P, Altermatt HJ, et al. Value of one-view breast tomosynthesis versus two-view mammography in diagnostic workup of women with clinical signs and symptoms and in women recalled from screening. *AJR Am J Roentgenol*. 2013;200(1):226-31.
  - Takamoto Y, Tsunoda H, Kikuchi M, et al. Role of breast tomosynthesis in diagnosis of breast cancer for Japanese women. *Asian Pac J Cancer Prev*. 2013;14(5):3037-40.
  - Stijven S, Gielen E, Bevernage C, et al. Magnetic resonance imaging: value of diffusion-weighted imaging in differentiating benign from malignant breast lesions. *Eur J Obstet Gynecol Reprod Biol*. 2013;166(2):215-20.
  
- For the topic area, *Comparative Effectiveness of Emerging Breast Imaging for Treatment Planning*, we identified a recently completed EPC Program technical brief that addresses the topic.
  - The SRC identified one recently completed EPC Program technical brief, *Imaging Techniques for Treatment Evaluation for Metastatic Breast Cancer*. This brief investigates current utilization patterns of metastatic breast imaging modalities in the US, emerging technologies, research in progress, patient values, and study design issues.
  
- The topic area, *Comparative Effectiveness of Emerging Breast Imaging for Evaluating Treatment Response to a Breast Cancer Chemotherapy Regimen*, is not feasible for a full systematic review due to the limited data available for a review at this time, which consists of one primary study comparing diffusion-weighted imaging (DWI) to 18F-fluorodeoxyglucose positron emission tomography/computed tomography (FDG PET/CT). The authors concluded that DWI and FDG PET/CT showed similar diagnostic accuracy for predicting polymerase chain reaction (PCR) to neoadjuvant chemotherapy in breast cancer patients.
  - Park SH, Moon WK, Cho N, Chang JM, et al. Comparison of diffusion-weighted MR imaging and FDG PET/CT to predict pathological complete response to neoadjuvant chemotherapy in patients with breast cancer. *Eur Radiol* 2012; 22(1): 18-25.