



Effective Health Care

Ultrasound for Breast Cancer Screening

Results of Topic Selection Process & Next Steps

The nominator, Office of the Healthcare Advocate, is interested in a new evidence review on ultrasound for breast cancer screening to share with the legislative body for implementation of change to the insurance criteria.

We identified a review covering the scope of the nomination, therefore, a new review would be duplicative of an existing product. No further activity on this nomination will be undertaken by the Effective Health Care (EHC) Program.

Because of the relevance of this nomination to a preventive service the nominator was invited to nominate this topic to the US Preventive Services Task Force for consideration.

Topic Brief

Topic Name: Ultrasound for Breast Cancer Screening, #826

Nomination Date: 9/24/2018

Topic Brief Date: 9/25/2018

Authors

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Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

Summary

- We found a systematic review that covered the scope of the nomination

Background

- According to the CDC, there were 124.8 new breast cancers per 100,000 women in 2015.¹
- In 2016, The US Preventive Services Task Force recommends screening asymptomatic women 50-74 years old with biennial mammogram.²
- 43.3% of US women 40-74 years old have extremely dense breasts.³
- The performance of mammography for breast cancer screening is impaired in women with dense breasts²
- Based on the available evidence at that time, the USPSTF was unable to conclude whether the balance of benefits outweighed the harms of adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging, DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram (I recommendation).²
- Section 4106 of the Affordable Care Act requires Medicaid to cover preventive services recommended by the USPSTF with a grade of A or B. As a result, breast ultrasound is not a covered benefit.⁴

The key question for this nomination is:

For women with dense breasts, what is the comparative effectiveness of ultrasound with mammogram compared to mammogram alone for breast cancer screening?

To define the inclusion criteria for the key questions we specify the population, interventions, comparators, and outcomes (PICO) of interest (Table 1).

Table 1. Key Questions and PICO

| | |
|----------------------|---|
| Key Questions | |
| Population | Women 50-74 years old with dense breasts eligible for breast cancer screening |
| Interventions | Ultrasound with mammogram |
| Comparators | Mammogram |
| Outcomes | Diagnostic accuracy |

Methods

We assessed nomination for priority for a systematic review or other AHRQ EHC report with a hierarchical process using established selection criteria (Appendix A). Assessment of each criteria determined the need for evaluation of the next one.

1. Determine the *appropriateness* of the nominated topic for inclusion in the EHC program.
2. Establish the overall *importance* of a potential topic as representing a health or healthcare issue in the United States.
3. Determine the *desirability of new evidence review* by examining whether a new systematic review or other AHRQ product would be duplicative.
4. Assess the *potential impact* a new systematic review or other AHRQ product.
5. Assess whether the *current state of the evidence* allows for a systematic review or other AHRQ product (feasibility).
6. Determine the *potential value* of a new systematic review or other AHRQ product.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years on the key questions of the nomination. See Appendix B for sources searched.

Compilation of Findings

We constructed a table with the selection criteria and our assessments (Appendix A).

Results

Appropriateness and Importance

This is an appropriate and important topic.

Desirability of New Review/Duplication

A new evidence review on would be duplicative of an existing product. We identified a 2016 AHRQ systematic review⁵ that informed the US Preventive Services Task Force recommendation on breast cancer screening. This systematic review assessed the evidence for hand-held ultrasound, automated whole breast ultrasound, magnetic resonance imaging, and digital breast tomosynthesis for women with dense breasts and negative mammography.

Summary of Findings

- Appropriateness and importance: The topic is both appropriate and important.
- Duplication: A new review would be duplicative of an existing product. We identified one AHRQ systematic review that addressed the nomination.

References

1. U.S. Cancer Statistics Data Visualizations Tool based on November 2017 submission data (1999-2015). Atlanta, GA: Centers for Disease Control and Prevention and National Cancer Institute; 2018. <https://www.cdc.gov/cancer/breast/statistics/index.htm>. Accessed on 25 September 2018 2018.
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3. Sprague BL, Gangnon RE, Burt V, et al. Prevalence of mammographically dense breasts in the United States. J Natl Cancer Inst. 2014 Oct;106(10). doi: 10.1093/jnci/dju255. PMID: 25217577. <https://www.ncbi.nlm.nih.gov/pubmed/25217577>
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5. Melnikow J, Fenton JJ, Whitlock EP, et al. Supplemental Screening for Breast Cancer in Women With Dense Breasts: A Systematic Review for the U.S. Preventive Service Task Force. Rockville (MD); 2016.
6. Scaranelo A FR, Menezes R, Kulkarni S. Supplemental screening modality in patients with intermediate risk of breast cancer based on breast density with negative mammogram - what is the most effective modality? Systematic review; meta-analysis and cost effectiveness analysis. PROSPERO Database; 2018. http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018080402. Accessed on 25 September 2018 2018.

Appendix A. Selection Criteria Summary

| Selection Criteria | Assessment |
|--|---|
| 1. Appropriateness | |
| 1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.? | Yes |
| 1b. Is the nomination a request for a systematic review? | Yes |
| 1c. Is the focus on effectiveness or comparative effectiveness? | Yes |
| 1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic? | Yes |
| 2. Importance | |
| 2a. Represents a significant disease burden; large proportion of the population | Breast cancer is the most common cancer in women. ¹ |
| 2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population | Yes |
| 2c. Represents important uncertainty for decision makers | Yes. The previous US Preventive Services Task Force recommendation found that the evidence was insufficient to conclude whether or not ultrasound in addition to mammogram would benefit women with dense breasts. ² |
| 2d. Incorporates issues around both clinical benefits and potential clinical harms | Yes, it is unknown whether the benefits outweigh the harms of screening. |
| 2e. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers | Because US is not covered, women who choose to have a breast ultrasound must pay for this service. |
| 3. Desirability of a New Evidence Review/Duplication | |
| 3. Would not be redundant (i.e., the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others) | Yes, this would be duplicative of an existing systematic review. We found a 2016 AHRQ systematic review assessed the evidence for hand-held ultrasound, automated whole breast ultrasound, magnetic resonance imaging, and digital breast tomosynthesis for women with dense breasts and negative mammography. ⁵ We also identified an in-process systematic review that will assess the same interventions against mammography alone. ⁶ This review is expected to be completed in December 2018. |

Abbreviations: AHRQ=Agency for Healthcare Research and Quality

Appendix B. Search for Evidence Reviews (Duplication)

Listed are the sources searched.

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|---|
| Search date: 9/25/2015 to 9/25/2018 |
| AHRQ: Evidence reports and technology assessments, USPSTF recommendations |
| VA Products: PBM, and HSR&D (ESP) publications, and VA/DoD EBCPG Program |
| Cochrane Systematic Reviews and Protocols http://www.cochranelibrary.com/ |
| PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/ |