

**Washington State Health Care Authority, HTA Program
FINAL Key Questions and Background
Breast MRI in Diagnosis and Treatment of Cancer**

Introduction

HTA has selected using magnetic resonance imaging (MRI) of the breast used in diagnosis and treatment of cancer to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input on all available evidence. Key questions guide the development of the draft evidence report.

Breast cancer is the second most common malignancy affecting women, and is an important public health concern. Accurate diagnosis and appropriate treatment are critical. Patients identified as having a possible abnormality on screening mammography or physical examination or who are at high risk may undergo additional tests, including imaging, and physical examination. An ideal diagnostic test to evaluate risk/breast abnormalities would provide accurate information appropriate to guide patient-management decisions. Such test would accurately distinguish patients who need to have a biopsy from those who can safely avoid one as well as accurately identify extent or location of malignancy (e.g. detection of contra lateral disease) for optimizing treatment. In order to appropriately guide decisions, a person who has a negative test result should be very confident that the result is correct. There are concerns about the safety, cost, and efficacy of MRI to diagnose and stage women at high risk or with breast cancer.

Key Questions

For women at risk of breast cancer based on presentation of with an abnormal mammogram; palpable breast abnormality; or relevant demographic and clinical risk factors:

1. What is the evidence that Breast MRI has the ability to diagnose or exclude breast cancer compared to current tests including mammography?
 - a. Describe sensitivity, specificity, and other key test characteristics
2. What is the evidence that breast MRI improves health outcomes for patients with suspected or diagnosed breast cancer? Including consideration of:
 - a. reduced need for other tests
 - b. more accurate diagnosis
 - c. change in treatment plan
 - d. reduced mortality and morbidity
3. What is the evidence of the safety of breast MRI?
4. What is the evidence that breast MRI has differential efficacy or safety issues in sub populations? Including consideration of:
 - a. Age, breast tissue characteristics; breast implants
 - b. Other patient characteristics or evidence of appropriate patient selection criteria
 - c. Type of scanning machine and software, reader training, and other operational factors
 - d. Provider type, setting or other provider characteristics
 - e. Health care system type, including worker's compensation, Medicaid, state employees

5. What is the evidence about the cost implications and cost effectiveness of breast MRI?

Technology Background

Technology: Breast MRI is being investigated as an adjunct to mammography for screening of high-risk women since its accuracy is not affected by breast density, it does not use radiation, and it has high sensitivity. The goal of providing early, accurate diagnosis and reducing the mortality rate associated with breast cancer is an important public health goal. Important questions include the how accurate breast MRI is in detecting breast cancer compared with conventional techniques; does imaging with a breast MRI as a supplement to mammography reduce biopsy, use of other tests, produce appropriate changes in treatment, and reduce morbidity or mortality? Further, have definitive patient selection criteria for the use of breast MRI in screening and staging been established?