



**Ontario  
Health**

# Supplemental Screening as an Adjunct to Mammography for Breast Cancer Screening in People With Dense Breasts: Recommendation

## Final Recommendation

Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding supplemental screening as an adjunct to mammography for people with extremely dense breasts.

## Rationale for the Recommendation

The Ontario Health Technology Advisory Committee reviewed the findings of the health technology assessment.<sup>1</sup>

The Ontario Health Technology Advisory Committee made the above recommendation after considering the clinical, economic, patient preferences and values, and ethical evidence for people with dense breasts, which included people with heterogeneously dense breasts and people with extremely dense breasts.

The committee acknowledged that the evidence showed that supplemental screening for people with dense breasts detects more cases of breast cancer and leads to fewer interval cancers (breast cancer detected after negative screening mammography and before the next scheduled screening appointment). However, there was no evidence describing the impact of supplemental screening on mortality. The committee recommended publicly funding supplemental screening for people with extremely dense breasts, a focused portion of people with the densest breasts, because the highest quality of clinical evidence was in this population. As well, the cost-effectiveness and budget impact of supplemental screening with ultrasound, digital breast tomosynthesis (DBT), or magnetic resonance imaging (MRI) were more favourable (i.e., a lower cost per benefit of screening) for people with extremely dense breasts compared to all people with dense breasts. The committee recognized that the main harms of supplemental screening for dense breasts are false-positives and overdiagnosis, both of which may lead to unnecessary and burdensome health care treatments, with implications for both individuals and health systems. The committee also acknowledged the greater feasibility of expanding screening resources to only those with extremely dense breasts. The available evidence for people with heterogeneously dense breasts alone was insufficient for the committee to recommend supplemental screening in this population.

The Ontario Health Technology Advisory Committee elected not to specify a preferred imaging modality, acknowledging the lack of comparative evidence across modalities to determine which is best. This decision facilitates flexibility in the implementation of supplemental screening by recognizing variations across the province in terms of access to and availability of imaging modalities and necessary health human resources. The committee also reflected on the continued importance of improving equitable access to first-line mammography-based breast screening.

# Decision Determinants for Supplemental Screening as an Adjunct to Mammography for Breast Cancer Screening in People With Dense Breasts

## Overall Clinical Benefit

### **Effectiveness**

*How effective is the health technology/intervention likely to be (taking into account any variability)?*

Among people with heterogeneously and extremely dense breasts, the body of evidence from both randomized controlled trials and nonrandomized studies (Grading of Recommendations, Assessment, Development and Evaluations [GRADE]: Very low to Moderate) suggests that mammography plus ultrasound was more sensitive and less specific, and detected more cancers compared to mammography alone. Fewer interval cancers occurred after mammography plus ultrasound (GRADE: Very low to Low), but recall rates were nearly double that of mammography alone (GRADE: Very low to Moderate). No studies compared screening mammography plus DBT with mammography alone; however, evidence of Low to Very low quality suggested that compared to DBT, supplemental ultrasound after negative mammography was more sensitive, detected more cancers, and led to more recalls. Among people with extremely dense breasts, notably fewer interval cancers occurred after mammography plus supplemental MRI compared to mammography alone (GRADE: High). Supplemental MRI after negative mammography was highly accurate in people with extremely dense breasts and heterogeneously dense breasts in randomized and nonrandomized studies (GRADE: Moderate and Very low, respectively). In people with extremely dense breasts, MRI after negative mammography detected 16.5 cancers per 1,000 screens (GRADE: Moderate), and 3% to 9.5% of all people screened were recalled (GRADE: Moderate). No study reported psychological impacts, breast cancer–specific mortality, or overall mortality.

### **Safety**

*How safe is the health technology/intervention likely to be?*

Contrast-related adverse events with supplemental MRI were infrequent (GRADE: Moderate). Any x-ray–based imaging modality—including mammography and DBT—involves exposure to ionizing radiation. Although the projected incidence of radiation-induced cancers from cumulative breast screening is low, minimizing unnecessary exposure to radiation-sensitive breast tissue is prudent. Not everyone who may be eligible can have MRI or contrast-enhanced mammography because of contraindications.

No test is perfect; all supplemental screening modalities have the potential to yield inaccurate (false) test results—both false-positives and false-negatives. Other potential risks in breast cancer screening include overdiagnosis and overtreatment.

## **Burden of Illness**

*What is the likely size of the burden of illness pertaining to this health technology/intervention?*

Higher breast tissue density is both normal and common; about 50% of people aged 40 to 74 years are classified as having dense breasts (approximately 10% extremely dense breasts and 40% heterogeneously dense breasts). In the general population, about 13% of women will develop breast cancer in their lifetime.

## **Need**

*How large is the need for this health technology/intervention?*

High breast density alone does not confer high risk of breast cancer, but it may confer higher-than-average risk. Dense breast tissue attenuates x-rays (i.e., reduces their intensity as they pass through) to a greater extent than fatty tissue, potentially masking lesions. In dense breast tissue, mammography is limited—with sensitivities as low as 50% to 60% in the most dense tissue—and it may not be as accurate in detecting abnormalities.

## **Patient Preferences and Privacy**

### ***Patient Preferences and Values***

*Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment?*

Participants from the literature included in the qualitative review and our direct patient engagement described similar preferences and values. Participants who had a diagnosis of breast cancer expressed a feeling of “peace of mind” as a result of supplemental screening for people with dense breasts, and they perceived that it would protect them from feeling as vulnerable to breast cancer. There was also an expressed interest in supplemental screening among those who had or may have had dense breasts, despite the risks of false-positive test results and overtreatment. Participants said that knowing the risks of dense breast tissue might allow people to make informed decisions about supplemental screening in the context of individual risks and vulnerabilities.

Participants perceived that supplemental screening provided accurate cancer detection for patients with dense breasts. Patients valued the potential medical benefits of early detection, such as access to information for decision-making and eligibility for less invasive treatment options.

### ***Autonomy, Privacy, Confidentiality, and/or Other Relevant Ethical Principles as Applicable***

*Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment?*

The impact of supplemental screening for dense breasts on mortality is unclear. The main harms of supplemental screening for dense breasts are false-positives and overdiagnosis, both of which may lead to unnecessary and burdensome health care treatments, with implications for individuals and health systems. Discussions with patients about the benefits and risks of supplemental screening will support patient autonomy with respect to decision-making.

## Equity and Patient Care

### ***Equity of Access or Outcomes***

*Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?*

There are several types of equity considerations relevant to supplemental screening for people with dense breasts:

- Equity of disease risk: people with dense breasts have a higher-than-average risk for breast cancer
- Equity of screening effectiveness: people with dense breasts are more likely to have lesions missed with conventional mammography screening
- Equity of access: there are inequities in access to regular breast cancer screening. Marginalized groups tend to have lower participation rates in current mammography-based breast screening. Furthermore, in the absence of publicly funded supplemental screening for dense breasts, access to supplemental screening depends on an individual's ability to pay for private screening, advocate for themselves, or access a health care provider who is willing to order such screening
- Equity of outcome: people from higher socioeconomic groups have higher breast cancer survival rates compared to other groups
- Equitable distribution of health benefits: offering supplemental screening for people with dense breasts may create opportunity costs. This redistribution of resources could result in an inequitable allocation of goods, including the benefits of access to these resources by other disease groups and populations (e.g., use of MRI for non-breast indications)

Offering supplemental screening for people with dense breasts may address inequities in disease risk and screening effectiveness. However, it is not clear whether supplemental screening for people with dense breasts would result in greater equity in positive outcomes for people with dense breasts.

Inequities persist in access to breast screening and treatment, and in breast cancer outcomes. Offering supplemental screening for people with dense breasts could amplify these inequities if the barriers to screening or treatment faced by marginalized groups remain unaddressed.

The redistribution of resources to support supplemental screening for dense breasts may entail a loss of health benefits for others, which could be inequitable.

### ***Patient Care***

*Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?*

In the context of publicly funded supplemental screening, many people with dense breasts and their health care providers may not have enough of an awareness or understanding of breast density to make

informed decisions about whether to engage with or offer such screening. People who experience barriers to accessing routine mammography, receive health care in their nonpreferred language, or are perceived to have lower economic status or health literacy levels may be especially likely to lack such awareness and understanding.

Initiatives aimed at enhancing people's awareness and understanding of breast density and supplemental screening may be helpful complements to supplemental screening programs. People with dense breasts and their health care providers recommended revising notification letters to contain clear, simple, specific language; delivering these letters alongside informational pamphlets with visual aids; and producing practice guidelines on breast density.

## **Cost-Effectiveness**

### ***Economic Evaluation***

*How efficient is the health technology/intervention likely to be?*

Our cost-effectiveness analyses showed that over a lifetime horizon, compared to mammography alone, supplemental screening with ultrasound, MRI, or DBT as an adjunct to mammography increased the number of screen-detected cancers, decreased the number of interval cancers, led to small gains in life years- or quality-adjusted life-years (QALYs) and was associated with lower cancer management costs. However, supplemental screening also increased imaging costs and the number of false-positive cases. Also compared to mammography alone, supplemental screening with handheld ultrasound, MRI, or DBT resulted in incremental cost-effectiveness ratios of \$119,943, \$314,170, or \$212,707 per QALY gained for people with dense breasts, and \$83,529, \$101,813, or \$142,730 per QALY gained for people with extremely dense breasts.

## **Feasibility of Adoption Into Health System**

### ***Economic Feasibility***

*How economically feasible is the health technology/intervention?*

Over the next 5 years, publicly funding supplemental screening with handheld ultrasound, MRI or DBT for people with dense breasts would require an additional \$15 million, \$41 million, or \$33 million, respectively. For people with extremely dense breasts, publicly funding supplemental screening with handheld ultrasound, MRI or DBT would require an additional \$4 million, \$10 million, or \$9 million, respectively. Uptake of supplemental screening would depend on the capacity and availability of the imaging modalities in Ontario, and of the human resources required to conduct such screening.

### ***Organizational Feasibility***

*How organizationally feasible is it to implement the health technology/intervention?*

Ontario has an existing organized screening program, which may help with the implementation of supplemental screening as an adjunct to mammography for people with extremely dense breasts. However, the feasibility of supplemental screening may have to be evaluated for each screening site (e.g., independent health facility, hospital-based facility), given that the capacity and availability of imaging modalities vary across sites across Ontario.

## Reference

1. Ontario Health. Supplemental screening as an adjunct to mammography for breast cancer screening in people with dense breasts: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2023 Dec;23(9):1–293. Available from: [hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/supplemental-screening-as-an-adjunct-to-mammography-for-breast-cancer-screening-in-people-with-dense-breasts](https://hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/supplemental-screening-as-an-adjunct-to-mammography-for-breast-cancer-screening-in-people-with-dense-breasts)

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