Health Quality Ontario

The provincial advisor on the quality of health care in Ontario

Ultrasound as an Adjunct to Mammography for Breast Cancer Screening: OHTAC Recommendation

ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE RECOMMENDATIONS

- The Ontario Health Technology Advisory Committee recommends publicly funding screening breast ultrasound as an adjunct to screening mammography for high-risk women in whom magnetic resonance imaging (MRI) is contraindicated.
- The Ontario Health Technology Advisory Committee recommends against publicly funding screening breast ultrasound as an adjunct to screening mammography in women at average risk for breast cancer.

RATIONALE FOR THE RECOMMENDATION DECISION

Given the absence of evidence demonstrating benefit,[1] there was consensus among members of the Ontario Health Technology Advisory Committee (OHTAC) that adjunct screening breast ultrasound not be publicly funded for women at average risk of breast cancer.

After a review of the evidence in high-risk women,[1] OHTAC recognized that the number needed to screen with adjunct ultrasound to detect one additional breast cancer is large, and the ratio of false-positive tests to true-positive tests is high. However, OHTAC also considered other factors: the evidence of test sensitivity, the evidence on patients' perspectives and experiences with breast cancer screening,[2] and the low budget impact. OHTAC also recognized that the population of high-risk women is very small, with a high burden of disease, and that this technology may be particularly helpful in women who have a contraindication to MRI, the current standard of care.

Decision Determinants for Ultrasound as an Adjunct to Mammography for Breast Cancer Screening

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	**Effectiveness** How effective is the health technology/intervention likely to be (taking into account any variability)?	**Average-Risk Women** No comparative primary studies evaluating the effectiveness or diagnostic accuracy of ultrasound as an adjunct to mammography in comparison to mammography screening alone were identified. **High-Risk Women** No studies evaluating the effectiveness of screening breast ultrasound as an adjunct to mammography, as measured by patient survival, were identified. Among high-risk women, screening breast ultrasound as an adjunct to mammography improves the sensitivity of screening relative to mammography alone, while resulting in an increase in false-positive tests. Assuming a prevalence of 2.5% in the population (out of 1,000 screens there would be 25 cancers), ultrasound would capture 3 additional cancer cases, compared to mammography, with 19 additional false-positive tests. It would require 308 screenings with ultrasound to identify 1 additional cancer, at a cost of 6 additional false-positive tests.
	Safety How safe is the health technology/intervention likely to be?	Ultrasound screening is a safe procedure that does not emit radiation. Downstream harms associated with false-positive tests include unnecessary diagnostic testing and biopsy and potentially unnecessary treatment. It is unknown if screening with ultrasound results in overdiagnosis or overtreatment of breast cancer.
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	An estimated 1 in 9 Canadian women are expected to develop breast cancer in their lifetimes. In Ontario, approximately 9,500 women will be diagnosed and 1,950 will die of the disease annually. Women at average risk of breast cancer have a less than 15% lifetime risk of developing the disease, and women at high risk have a greater than 25% risk of the disease.
	Need How large is the need for this health technology/intervention?	Women at average risk for developing breast cancer currently only receive mammography screening for breast cancer. Mammography screening is not perfect, and therefore a number of these women may have their cancers missed by mammography due to factors such as dense breasts and younger age. Currently, 1.15 million women in Ontario aged 50 to 74 years are screened with mammography annually. Women at high risk for breast cancer are eligible to receive both mammography and MRI screening because mammography alone is particularly poor for this population. A number of women are contraindicated to MRI and therefore receive mammography and ultrasound, which may improve the accuracy and cancer-detection rate. In 2014, approximately 180 of the women participating in the Ontario Breast Screening Program were considered high risk and contraindicated for MRI.
Consistency with expected societal and	**Societal values** How likely is the adoption of the	The experience of a false-positive test causes immediate and reoccurring anxiety for women, particularly for those

Decision Criteria	Subcriteria	Decision Determinants Considerations
ethical values[a] How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	health technology/intervention to be congruent with expected societal values? **Ethical values** How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	at high risk for breast cancer. Despite the anxiety associated with a false-positive test, women are generally supportive of screening practices for breast cancer.
Value for money How efficient is the health technology likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	For high-risk women, who are contraindicated with MRI, the budget required to add ultrasound as an adjunct to screening mammography in the next 5 years would range from $15,473 in year 1 to $37,058 in year 5.
Feasibility of adoption into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	**Economic feasibility** How economically feasible is the health technology/intervention?	For high-risk women, both mammography and ultrasound are currently funded and provided to women who are contraindicated for MRI.
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	For average-risk women, the economic and organizational feasibility are unknown. Implementation of screening breast ultrasound would require additional professional resources and potentially an increased number of ultrasound devices.

Abbreviations: MRI, magnetic resonance imaging.

[a]The anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

REFERENCES

(1) Health Quality Ontario. Ultrasound as an Adjunct to Mammography for Breast Cancer Screening: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2016 July;16(15):1-71. Available from: http://www.hqontario.ca/evidence-to-improve-care/journal-ontario-health-technology-assessment-series.

(2) Health Quality Ontario. Women's experiences of inaccurate breast cancer screening results: a systematic review and qualitative meta-synthesis. Ont Health Technol Assess Ser [Internet]. 2016 July;16(16):1-22. Available from: http://www.hqontario.ca/evidence-to-improve-care/journal-ontario-health-technology-assessment-series.

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Health Quality Ontario
130 Bloor Street West, 10th Floor
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M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

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