

HIGH RISK SCREENING

Women aged 30-69 at high risk for breast cancer are eligible to receive annual MRI and mammogram screening through the OBSP.

In the March 2011 Ontario Budget, the Government announced funding to expand the Ontario Breast Screening Program (OBSP) to screen women at high risk for breast cancer. There is evidence that annual screening with breast magnetic resonance imaging (MRI) in addition to mammography (MM) benefits women at high risk.

The introduction of combined MM/MRI screening into the OBSP for women aged 30-69 who are at high risk for breast cancer will improve their quality of care, ensuring that they receive the benefits of screening and promoting the early detection of breast cancer.

Women are deemed eligible for OBSP high risk screening if they:

- Are Ontario residents and have a valid OHIP number;
- Have no acute breast symptoms;
- Are 30 to 69 years of age;

AND meet one of the following four **HIGH RISK CRITERIA**¹:

- Are known to be carriers of a deleterious gene mutation (e.g., BRCA1, BRCA2);
- Are the first degree relative of a mutation carrier (e.g., BRCA1, BRCA2) and have declined genetic testing;
- Have been determined to be at $\geq 25\%$ lifetime risk of breast cancer – must have been assessed using either the IBIS or BOADICEA risk assessment tools, preferably by a genetics or breast cancer clinic;
- Have received chest radiation (not x-ray) before age 30 and at least 8 years previously.

IBIS and BOADICEA

These breast risk assessment tools are used to assess the probability of carrying the BRCA gene mutation and the probability of developing breast cancer.² Carriers of the BRCA gene mutation have been identified as being at high risk for breast cancer. The IBIS and BOADICEA breast risk assessment tools have been chosen as the standard assessment tools to determine eligibility for high risk screening through the OBSP.

Mammography

Screening mammography (either film-screen or digital) refers to two-view x-rays of the breast used to identify abnormalities in asymptomatic women. Digital mammography has been found to be better than film screen mammography for screening women under the age of 50. The OBSP high risk screening program recommends women at high risk receive digital mammography examinations.

Breast magnetic resonance imaging (MRI)

MRI uses magnetic fields to produce detailed cross-sectional images of the breasts. A gadolinium-based contrast agent is injected intravenously during the MRI exam to provide reliable detection of cancers and other lesions.³

The Ontario Breast Screening Program (OBSP)

The OBSP is a province-wide organized breast screening program, managed by Cancer Care Ontario (CCO), which ensures that eligible Ontario women receive the benefits of regular screening. The program is designed to increase the number of women who have regular breast cancer screening so that cancers are diagnosed early. Early detection means that most women have more treatment options, a reduced chance of cancer recurrence, and an improved chance of survival.

The OBSP assists primary care providers by:

- Arranging genetic counselling and testing, if appropriate.
- Booking mammography and MRI examinations.
- Arranging follow-up breast assessment services after abnormal screens.
- Informing patients of screening results.
- Providing automatic recall of patients.



Centre for Effective Practice



Ontario
Cancer Care Ontario
Action Cancer Ontario

Clinical practice guideline for screening women at high risk for breast cancer

Women who are at high risk for breast cancer should be screened annually with breast MRI and mammography starting at age 30.

In 2007, Cancer Care Ontario's Program in Evidence-Based Care (PEBC) issued clinical practice guidelines recommending annual MRI, in addition to mammography, for women at high risk for breast cancer aged 30-69.⁴ Other jurisdictions have also issued clinical guidelines recommending annual MRI screening for women at high risk.⁵

What the OBSP can do for you and your patients

The OBSP offers a comprehensive breast screening process which:

- Navigates the patient through the screening process.
- Arranges genetic counselling/testing, if appropriate.
- Provides high quality two-view screening digital mammography.
- Provides high quality breast magnetic resonance imaging.
- Reports findings to healthcare providers.
- Notifies patients of normal and abnormal screening results.
- Arranges diagnostic tests recommended by the screening radiologist, if authorized by the primary care provider.
- Facilitates access to multi-disciplinary approach to breast assessment.
- Provides automatic recall of patients at high risk at annual intervals.
- Monitors and evaluates screening outcomes for patients at high risk.
- Sets and maintains high quality assurance standards for all components of the program.

How the OBSP navigator supports healthcare providers

The OBSP navigator will support healthcare providers in screening women at high risk for breast cancer by arranging genetic assessment/testing (if appropriate), screening breast MRI, screening mammography, and diagnostic tests to follow-up on abnormal screening results. The OBSP keep healthcare providers informed of all test results along the screening pathway.

Navigators working at OBSP High Risk Screening Centres are specially trained healthcare professionals who work one-on-one with patients, helping them to make informed decisions as they deal with testing and/or a new diagnosis.

Enrolling patients in the OBSP for high risk screening

To enroll a patient in the OBSP, simply complete a Requisition for High Risk Screening and send by fax to the OBSP High Risk Screening Centre in your area. Fax numbers are listed on the reverse side of the form. Forms are available at www.cancercare.on.ca/obsresources

What to expect if your patient has an abnormal screening result

Automatic booking of diagnostic tests recommended by the screening radiologist may be arranged by the OBSP if authorized by the healthcare provider. Results are sent directly to the healthcare provider.

Because MRI is less specific than mammography, there will be a higher recall rate and biopsy rate due to MRI as compared to mammography.

- Recall rates for additional imaging ranged from 8% to 17% in the MRI screening studies, and biopsy rates ranged from 3% to 15%.³ However, several researchers have reported that recall rates decreased in subsequent rounds of screening: prevalence screens had the highest false-positive rates, which subsequently dropped to less than 10%.³
- Most recalls can be resolved without biopsy.³
- The estimated proportion of biopsies that are cancerous (the positive predictive value) is 20%-40%.³

Evidence for the benefits of screening women at high risk

- A meta-analysis found MRI to have superior discriminatory power overall compared to mammography in determining the true breast cancer status of women at high risk.¹
- The recommendations for MRI screening are according to indirect evidence and certain assumptions, according to the following rationale:
 - Screening mammography, which downstages cancers (relative to no screening) in the general population, has demonstrated a mortality decrease of 20% to 30% in RCTs.¹
 - Since MRI screening downstages cancers (relative to mammography) in a particular high risk population in prospective comparative studies, it likely decreases mortality in that high risk population.

- c. Screening women at high risk with MRI in addition to mammography significantly increases sensitivity, with a moderate but acceptable decrease in specificity.

The advantages of an organized screening program such as the OBSP include:

- Increased appropriate use of MRI breast screening;
- Surveillance and data acquisition;
- Quality assurance, setting standards and evaluation.

These elements minimize the harms of screening.

Potential harms of screening women at high risk

- a. Although the sensitivity of MRI is excellent, it is less than 100%. Therefore, women who opt for screening should strongly consider other risk-reducing measures (e.g., chemoprevention and/or oophorectomy) and must be able to accept some risk.¹
- b. The benefits of MRI screening for women at high risk for breast cancer come with a higher false positive rate and biopsy rate compared to mammography. For every 1,000 high risk women screened with MRI and mammography, it is expected that 17 cancers would be detected, with 57 women falsely screened positive.¹
- c. Women with abnormal results have significantly higher breast cancer-related anxiety than women not recalled.¹
- d. Not all women can tolerate a breast MRI examination. Contraindications include having metallic implants (e.g., pacemakers or aneurysm clips) and claustrophobia. Obese women, particularly those with broad shoulders, may not fit into the magnet.¹ Women for whom a screening MRI is contraindicated will be scheduled to receive an ultrasound in addition to their mammogram.
- e. Although there has been some theoretical concern about the possible risk of mammography inducing breast cancer in young women in general and in women with BRCA mutations in particular (these genes have a role in repairing DNA damage), studies to date have found that the benefit of finding early cancers far outweighs any possible risk of developing breast cancer from mammography exposure.⁶
- f. A contrast agent, gadolinium, is injected into the patient prior to the breast MRI examination. Some patients have adverse reactions to gadolinium. Women for whom a screening MRI is contraindicated will be scheduled to receive an ultrasound in addition to their mammogram.

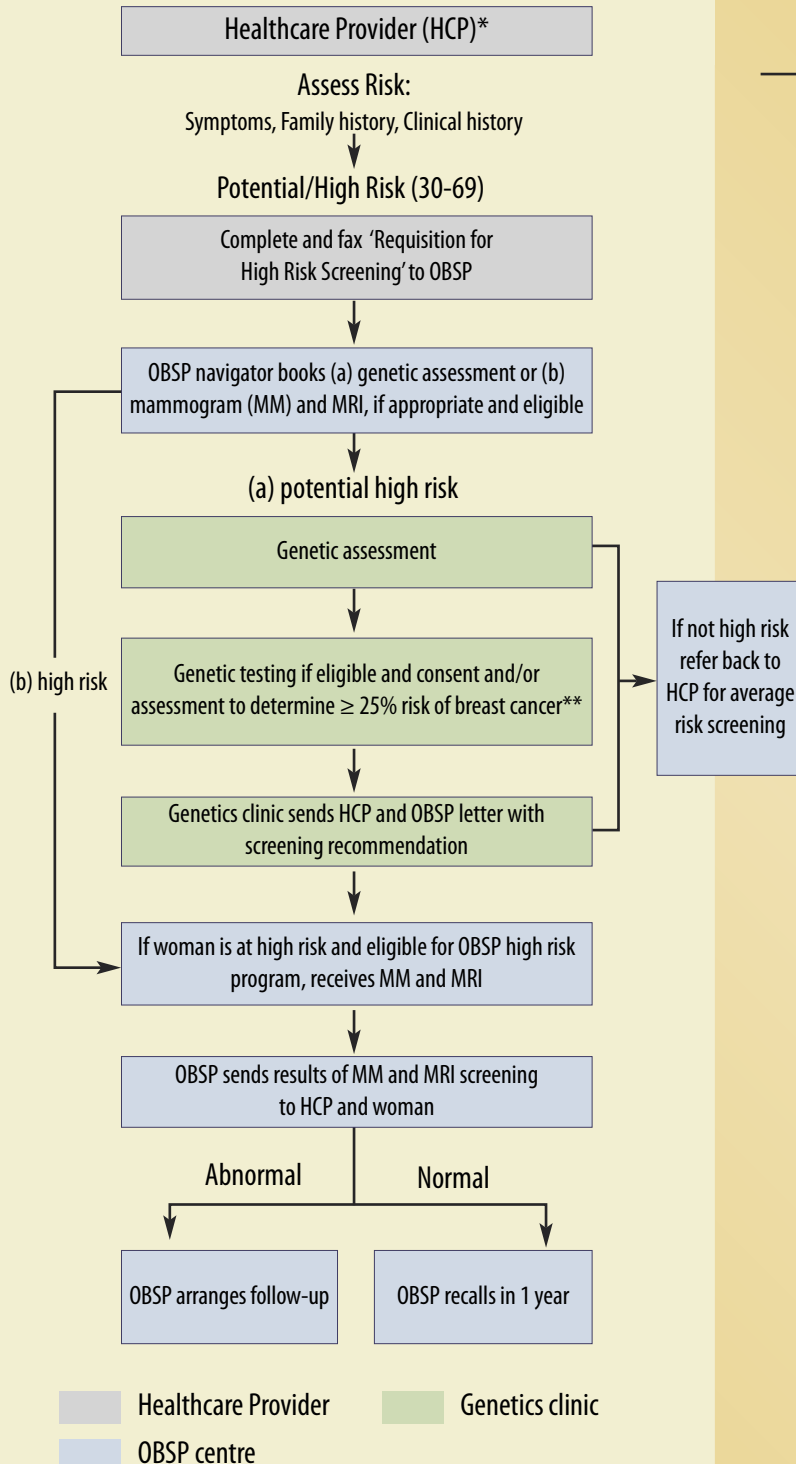
Why women with a family history suggestive of hereditary breast cancer syndrome are being encouraged to attend a genetics assessment

- a. Women with first-degree relatives with proven gene mutations that increase risk of breast cancer have a 50% risk of having one of these mutations themselves. Genetic assessment will help these women decide if they want genetic testing. Testing may tell them they are not at increased risk and can return to average risk breast screening, or may indicate they are at increased risk and should consider breast and ovarian cancer risk reducing options, as well as annual MRI and mammography screening.
- b. For women with a family history that may be suggestive of a hereditary cancer syndrome, genetic assessment will clarify their risk, by confirming family history, possibly offering genetic testing and/or assessing risk with the IBIS or BOADICEA breast cancer risk assessment tools.
- c. If women decline genetic testing after genetic assessment and have been found to be at $\geq 25\%$ high risk via IBIS or BOADICEA they are still eligible for MRI and mammography screening through the OBSP.

How women at high risk can reduce their risk of developing breast cancer

- a. Some women choose mastectomy, oophorectomy or tamoxifen to reduce their risk of developing breast and ovarian cancer.¹ Risk reduction surgery is generally only offered to women who have had positive genetic tests for deleterious gene mutations shown to cause breast or ovarian cancer.
 - i. Prophylactic bilateral mastectomies remove nearly all of the breast tissue and greatly reduce the risk of breast cancer in women at high risk.⁷
 - ii. Research has shown that premenopausal women who have BRCA gene mutations and have had their ovaries removed reduce their risk of breast cancer (by 50%-60%) as well as their risk of ovarian cancer (by 85%-95%).⁸
 - iii. Tamoxifen blocks estrogen by binding to estrogen receptors, causing cancer cells that need estrogen to divide to stop growing and die.⁹
- b. Most women at high risk (75%-90%) decline these risk reduction options.^{10, 1}
- c. Ideally, breast cancer screening for women at high risk should be combined with risk reduction strategies.¹ Women at high risk for breast cancer can be referred to high risk breast cancer clinics for assessment on risk reduction options.

Ontario Breast Screening Program (OBSP): Program Details



Notes:

* Any MD (e.g., Family Physician, GP oncologist, oncologist) can assess risk and make a referral. Nurse Practitioners can assess risk and complete the referral form, however, an MD colleague needs to sign off on the referral form.

** Using a risk assessment tool (IBIS or BOADICEA)

Cancer Care Ontario gratefully acknowledges the contributions of members of the Expert Panel in guiding the expansion of the OBSP to include women at high risk and in authoring the supporting clinical guidelines, tools and education materials.

Expert Panel Members

Dr. Linda Rabeneck, MD, MPH, FRCPC

Dr. Ellen Warner, MD, FRCPC, FACP, MSc

Dr. Andrea Eisen, MD, FRCPC

Dr. June Carroll, MD, CCFP, FCFP

Dr. Wendy Meschino, MD, FRCPC, FCCMG

Dr. Donald Plewes, PhD

Dr. Rene Shumak, MD, FRCPC

Dr. Anna M. Chiarelli, PhD

For further information or patient education materials, please contact us at:

1 800 668-9304

To view OBSP High Risk Screening Referral Contacts, go to:
www.cancercare.on.ca/obsphighrisk

To view provider tools and references, go to:
www.cancercare.on.ca/obsresources

We welcome your feedback and comments about this material at:

breastscreen@cancercare.on.ca