Disclaimer
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Target Population

Women who meet criteria for the Ontario Breast Screening Program (OBSP) or who present with symptoms of breast cancer. The OBSP is intended for individuals who do not demonstrate any symptoms or previously diagnosed breast cancer.

Pathway Map Considerations

- The OBSP requires that a set of minimum standards for breast screening be adhered to: Ultrasound Standards and MRI Standards.
- It is presumed that the patient is assessed clinically throughout the entire pathway map.
- It is presumed that at each step along the pathway map, the risks and benefits of screening are discussed with the patient.
- Primary care providers play an important role in the cancer journey and should be informed of relevant tests and consultations. Ongoing care with a primary care provider is assumed to be part of the pathway map. For patients who do not have a primary care provider, Health Care Connect, is a government resource that helps patients find a family doctor or nurse practitioner.
- Throughout the pathway map, a shared decision-making model should be implemented to enable and encourage patients to play an active role in the management of their care. For more information see Person-Centered Care Guideline and EBS #19-2 Provider-Patient Communication.
- Hyperlinks are used throughout the pathway map to provide information about relevant CCO tools, resources and guidance documents.
- The term ‘health care provider’, used throughout the pathway map, includes primary care providers and specialists, nurse practitioners, and emergency physicians.

* Note. EBS #19-2 is older than 3 years and is currently listed as ‘For Education and Information Purposes’. This means that the recommendations will no longer be maintained but may still be useful for academic or other information purposes.
Pathway Map Glossary

IBIS – an evaluation tool that uses a woman’s family history to calculate the likelihood of her carrying a deleterious mutation in BRCA 1/2 and calculates the risk of developing breast cancer. For more information visit http://www.ems-trials.org/riskevaluator/

BOADICEA (Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm) – an evaluation tool used to calculate the risk of breast and ovarian cancer in a woman based on her family history. For more information visit http://ccge.medschl.cam.ac.uk/boadicea/

BI-RADS (Breast Imaging Reporting and Data System) – a reporting system developed by the American College of Radiology to report the results of ultrasounds, mammograms and MRIs. BI-RADS assessment categories include:

<table>
<thead>
<tr>
<th>Assessment Categories</th>
<th>Management Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For Mammography</strong></td>
<td><strong>For MRI</strong></td>
</tr>
<tr>
<td>Category 0 - Incomplete</td>
<td>Additional imaging evaluation and/or comparison with no previous examinations</td>
</tr>
<tr>
<td>Category 1 - Negative</td>
<td>Routine mammography screening</td>
</tr>
<tr>
<td>Category 2 - Benign</td>
<td>Routine mammography screening</td>
</tr>
<tr>
<td>Category 3 – Probably benign</td>
<td>Short-interval (6-month) follow-up or continued surveillance mammography</td>
</tr>
<tr>
<td>Category 4 – Suspicious 4A - Low suspicion</td>
<td>Tissue diagnosis</td>
</tr>
<tr>
<td>4B - Moderate suspicion 4C - High suspicion</td>
<td>Tissue diagnosis</td>
</tr>
<tr>
<td>Category 5 – Highly suggestive of malignancy</td>
<td>Tissue diagnosis</td>
</tr>
<tr>
<td>Category 6 – Proven malignancy</td>
<td>Surgical excision when clinically appropriate</td>
</tr>
</tbody>
</table>

Adapted from D’Orsi CJ, Sickles EA, Mendelson EB, Morris EA et al. ACR BI-RADS® Atlas: Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology; 2013
Visit to Primary Care Provider

Average Risk

- Women are considered eligible for average risk screening if they are asymptomatic and meet all of the following:
  - Are 50-74 years of age
  - Have no personal history of breast cancer
  - Have not had a screening mammogram within last 11 months
  - No history of breast implants

Potential High Risk (Genetic assessment required to determine eligibility)

- Women may be eligible for high risk screening if they are asymptomatic, are 30-69 years of age AND meet one of the following criteria:
  - First degree relative of a carrier of a gene mutation (e.g. BRCA1, BRCA2) and has not had genetic counselling or testing
  - A personal or family history of at least one of the following:
    - Two or more cases of breast cancer and/or ovarian cancer in closely related relatives
    - Bilateral breast cancers
    - Both breast and ovarian cancer in the same woman
    - Breast cancer at ≤35 years of age
    - Invasive serous ovarian cancer
    - Breast and/or ovarian cancer in Ashkenazi Jewish families
    - An identified gene mutation (e.g. BRCA1, BRCA2) in any blood relatives
    - Male breast cancer

Known High Risk (Eligible for direct entry into OBSP High Risk Program)

- Women are considered eligible for high risk screening if they are asymptomatic, are 30-69 years of age and at least one of the following criteria are met:
  - Known carrier of a gene mutation (e.g. BRCA1, BRCA2)
  - First degree relative of a carrier of a gene mutation (e.g. BRCA1, BRCA2), has previously had genetic counselling, and has declined genetic testing
  - Previously assessed as having a ≥25% lifetime risk of breast cancer on basis of family history
  - Received chest radiation (not chest x-ray) before age 30 and at least 8 years previously (e.g. as treatment for Hodgkin’s Lymphoma)

Not eligible for OBSP (e.g. <30 or >74 years of age)

Discuss screening options with health care provider with regards to the benefits and risks of screening

1. Average risk patients do not require a physician referral for the OBSP.
2. Nurse practitioners can assess patient risk and complete the OBSP requisition for high risk screening, however, a MD colleague (e.g. family physician, GP oncologist, oncologist) needs to sign off on the requisition. The requisition form can be found here.
3. Women over age 74 can be screened within the OBSP; however, they are encouraged to make a personal decision in consultation with their healthcare provider. The OBSP will not recall women over age 74 to participate in the program. To continue screening throughout the OBSP, a healthcare provider will need to make a referral.
4. A genetic clinic must have used at least one of the following tools to complete this assessment – IBIS 10 Year Risk, IBIS Lifetime Risk, BOADICEA 5 Year Risk or BOADICEA Lifetime Risk. Results must be faxed with requisition form.
Patient presents with one or more symptoms of breast cancer, such as:
- Palpable mass
- Concerning nipple discharge
- New nipple retraction
- Skin changes of the nipple or breast
- Asymmetric thickening/ nodularity

From page 4

The management following the BI-RADS assessment categories are based on the recommendations from the American College of Radiology. For more information see D’Orsi CJ, Sickles EA, Mendelson EB, Morris EA et al. ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology; 2013.
Breast Cancer Screening & Diagnosis Pathway Map

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CCO Cancer Screening Recommendations and Results

Screening mammogram

Every two years or annually if required

CCO Cancer Screening Recommendations and Screening Ultrasound Position Statement

Diagnostic mammography

Screening mammogram

Every two years or annually if required

CCO Cancer Screening Recommendations and Screening Ultrasound Position Statement

Diagnostic mammography

Abnormal (e.g. BI-RADS 0)

Abnormal diagnostic assessment

Probably benign diagnostic assessment (e.g. BI-RADS 3)

Short-term imaging follow-up

Repeat imaging within 6 months based on radiologist’s recommendations

Diagnostic assessment

Ultrasound

And/Or

Results

Normal (e.g. BI-RADS 1 or 2)

Benign diagnostic assessment

(e.g. normal tissue, simple cyst, minimally complicated cyst)

Normal assessment

Normal

Abnormal assessment

Abnormal assessment

Abnormal diagnostic assessment

Short-term imaging follow-up

Repeat imaging within 6 months based on radiologist’s recommendations

Diagnostic assessment

Ultrasound

And/Or

Results

Normal assessment

Normal

Abnormal assessment

Abnormal

Normal

Abnormal diagnostic assessment

Short-term imaging follow-up

Repeat imaging within 6 months based on radiologist’s recommendations

Diagnostic assessment

Ultrasound

And/Or

Results

Normal assessment

Normal

Abnormal assessment

Abnormal

Normal

Abnormal diagnostic assessment

Short-term imaging follow-up

Repeat imaging within 6 months based on radiologist’s recommendations

Diagnostic assessment

Ultrasound

And/Or

Results

Normal assessment

Normal

Abnormal assessment

Abnormal

Normal

Abnormal diagnostic assessment

Short-term imaging follow-up

Repeat imaging within 6 months based on radiologist’s recommendations

Diagnostic assessment

Ultrasound

And/Or

Results

Normal assessment

Normal

Abnormal assessment

Abnormal

Normal

Abnormal diagnostic assessment

Short-term imaging follow-up

Repeat imaging within 6 months based on radiologist’s recommendations

Diagnostic assessment

Ultrasound

And/Or

Results

Normal assessment

Normal

Abnormal assessment

Abnormal

Normal

Abnormal diagnostic assessment

Short-term imaging follow-up

Repeat imaging within 6 months based on radiologist’s recommendations

Diagnostic assessment

Ultrasound

And/Or

Results

Normal assessment

Normal

Abnormal assessment

Abnormal
Breast Cancer Screening & Diagnosis Pathway Map

Genetic Assessment (Counselling and/or Testing) for Potentially High Risk Patients

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Formal assessment of hereditary breast cancer risk

OBSP Breast Cancer Genetic Assessment and/or Test Results

Genetic testing eligibility

Eligible

Primary care provider discusses risk appropriate screening

 OBSP Breast Cancer Genetic Assessment and/or Test Results

Genetic test results

Carrier of pathogenic variant in BRCA 1/2 or carrier of other highly penetrant gene (e.g. TP53, CDH1, PTEN, STK11)

Primary care provider discusses risk appropriate screening

True negative result for known hereditary gene mutation in family

No deleterious mutation identified or variant of undetermined significance

Primary care provider discusses risk appropriate screening

≥25% lifetime risk of breast cancer or carrier of mutation in other moderately penetrant gene (e.g. CHEK2, PALB2)

Primary care provider discusses risk appropriate screening

<25% lifetime risk of breast cancer

Primary care provider discusses risk appropriate screening

Patient declines genetic referral

Primary care provider discusses risk appropriate screening and discusses health behaviour interventions (e.g. exercise, nutrition) to reduce breast cancer risk as appropriate

7 There is insufficient evidence to recommend appropriate screening guidelines for some risk categories (e.g. a 40 year old woman at increased but not high risk). Risk appropriate screening in these cases is a personalized decision made between the woman and her healthcare provider.

8 Lifetime risk of breast cancer should be based on family history and must have been assessed using IBIS or BOADICEA risk assessment tools, preferably by a genetic or breast cancer clinic. For more information on these tools visit http://www.ems-trials.org/riskevaluator/ for IBIS and http://ccge.medschl.cam.ac.uk/boadicea/ for BOADICEA.
Breast Cancer Screening & Diagnosis Pathway Map

Screening mammogram
To be completed every year. Women ages 70-74 should be screened with mammogram only. EBS #15-11 and Women at High Risk – Summary of Evidence

Results

Normal

Abnormal

Probably benign (BI-RADS 3)

Short-term imaging follow-up Repeat imaging within 6 months based on radiologist's recommendations

Abnormal assessment

Normal assessment

From Page 4 or 7

From Prevention Pathway Map (Page 3)

Additional imaging (e.g. second look ultrasound, repeat MRI, more mammographic views)

Abnormal assessment

Normal assessment

Proceed to Page 9

Abnormal assessment

Normal assessment

Proceed to Page 9

Abnormal assessment

Normal assessment

Proceed to Page 9

5 The management following the BI-RADS assessment categories are based on the recommendations from the American College of Radiology. For more information see D’Orsi CJ, Sickles EA, Mendelson EB, Morris EA et al. ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA, American College of Radiology; 2013.

9 A screening mammogram and MRI should be completed within 30 days of each other.
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There is insufficient evidence to recommend appropriate screening guidelines for some risk categories (e.g. a 40 year old woman at increased but not high risk). Risk appropriate screening in these cases is a personalized decision made between the woman and her healthcare provider.

In rare circumstances a breast MRI may be used as a problem solving tool.

An excisional biopsy may be considered for presumed isolated papillary lesions in the appropriate clinical context.

Biomarkers should be performed on core biopsies showing invasive cancer.

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**Diagnostic Procedures**

**Breast Cancer Screening & Diagnosis Pathway Map**

**From** Page 5

Suspicous clinical finding

**Primary care provider discusses risk appropriate screening or short-term imaging follow-up.**

**From Follow-up Care Pathway Map (Page 4)**

Lymph nodes indeterminate or concerning

**Surgeon**

- Fine needle aspiration
- Or
- Core biopsy

**Pathology**

- High risk/concerning benign (e.g. Atypical ductal hyperplasia, radial scars, papilloma)

**Pathology**

- Insufficient tissue sampling

**Second core biopsy**

**Cancer**

**Ductal Carcinoma In Situ**

**Invasive Breast Cancer**

**Results**

**Concordant**

Consider short-term imaging follow-up or return to risk-appropriate screening

**Discordant**

Proceed to Page 10

**Primary care provider discusses risk appropriate screening or short-term imaging follow-up.**

**From pages 5, 6 or 8**

**Suspicious clinical finding**

**Surgeon**

- Core biopsy
- Vacuum assisted with clip placement

**Pathology**

- Ultrasound suspicious mass, complex cyst, intraductal nodule, concerning calcifications

**Core biopsy**

**Concordance with pathology, imaging and clinical examination**

**Discordant**

**Second core needle biopsy or vacuum biopsy**

**Pathology**

Concordant

Discordant

**Insufficient tissue sampling**

Second core biopsy

Proceed to Page 10

**Surgeon**

**Proceed to Treatment Pathway Map (Page 3)**

**Proceed to Treatment Pathway Map (Page 5)**

**Return to Page 4**

**From Follow-up Care Pathway Map (Page 4)**

Lymph nodes indeterminate or concerning

**Surgeon**

- Fine needle aspiration
- Or
- Core biopsy

**Pathology**

- High risk/concerning benign (e.g. Atypical ductal hyperplasia, radial scars, papilloma)

**Pathology**

- Insufficient tissue sampling

**Second core biopsy**

**Cancer**

**Ductal Carcinoma In Situ**

**Invasive Breast Cancer**

**Results**

**Concordant**

Consider short-term imaging follow-up or return to risk-appropriate screening

**Discordant**

Proceed to Page 10

**Primary care provider discusses risk appropriate screening or short-term imaging follow-up.**

**From pages 5, 6 or 8**

**Suspicious clinical finding**

**Surgeon**

- Core biopsy
- Vacuum assisted with clip placement

**Pathology**

- Ultrasound suspicious mass, complex cyst, intraductal nodule, concerning calcifications

**Core biopsy**

**Concordance with pathology, imaging and clinical examination**

**Discordant**

**Second core needle biopsy or vacuum biopsy**

**Pathology**

Concordant

Discordant

**Insufficient tissue sampling**

Second core biopsy

Proceed to Page 10

**Surgeon**

**Proceed to Treatment Pathway Map (Page 3)**

**Proceed to Treatment Pathway Map (Page 5)**

**Return to Page 4**

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7 There is insufficient evidence to recommend appropriate screening guidelines for some risk categories (e.g. a 40 year old woman at increased but not high risk). Risk appropriate screening in these cases is a personalized decision made between the woman and her healthcare provider.

10 In rare circumstances a breast MRI may be used as a problem solving tool.

11 An excisional biopsy may be considered for presumed isolated papillary lesions in the appropriate clinical context.

12 Biomarkers should be performed on core biopsies showing invasive cancer.
Excisional biopsy
Or
Short-term imaging follow-up
Repeat imaging within 6 months based on radiologist’s recommendations

Pathology^12

Results
Benign

Primary care provider discusses risk appropriate screening^2

Confirmed high risk benign

Ductal Carcinoma in Situ

Invasive Breast Cancer

Cancer

There is insufficient evidence to recommend appropriate screening guidelines for some risk categories (e.g. a 40 year old woman at increased but not high risk). Risk appropriate screening in these cases is a personalized decision made between the woman and her healthcare provider.

^12 Biomarkers should be performed on core biopsies showing invasive cancer.