Breast Cancer Risk Assessment and Screening Guideline

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Last guideline approval: September 2017

Guidelines are systematically developed statements to assist patients and providers in choosing appropriate health care for specific clinical conditions. While guidelines are useful aids to assist providers in determining appropriate practices for many patients with specific clinical problems or prevention issues, guidelines are not meant to replace the clinical judgment of the individual provider or establish a standard of care. The recommendations contained in the guidelines may not be appropriate for use in all circumstances. The inclusion of a recommendation in a guideline does not imply coverage. A decision to adopt any particular recommendation must be made by the provider in light of the circumstances presented by the individual patient.

This evidence-based guideline was developed by Kaiser Permanente Washington (KPWA). It was adapted from the 2016 U.S. Preventive Services Task Force guideline and the 2015 American Cancer Society guideline.
Major Changes as of September 2017

- The 2017 guideline update emphasizes early identification of women at high risk for breast cancer.
- Risk screening questions are asked of women at regular intervals starting at age 18 and continuing through age 74. The results are used to guide screening decisions, including screening interval and age to begin screening.
- The Bellcross tool has been replaced by the expansion of risk screening questions in:
  - Online Health Profile—completed prior to well visits,
  - Well Visit Questionnaire—given at well visits, and
  - Breast Cancer Risk Questionnaire (BCRQ)—given at each screening mammogram visit.
- A new shared decision making tool has been incorporated.
- The guideline format has been simplified and an algorithm has been provided to clarify the screening recommendations by risk group.

Background and Principles

Mammography is currently the best radiographic screening tool available for the early detection of breast cancer and the reduction of breast cancer mortality. Kaiser Permanente Washington is committed to ensuring that women have access to screening mammography and to shared decision making for choices about initiation, frequency, and eventual discontinuation of screening.

Family history is also a very important tool for identifying high-risk women who might need further evaluation from Genetics or Oncology to determine if they need specialized screening (such as genetic testing) or preventive medications or surgery.

Breast cancer screening should begin with taking a good family and personal history when a woman is in young adulthood to assess her risk and determine her screening strategy and whether she needs genetic screening or counseling. At Kaiser Permanente Washington, this risk assessment is carried out via a customized questionnaire that is administered at regular intervals to women, beginning at age 18. Women who are identified as being at high risk at an early age may go on to engage in preventive measures (e.g., chemoprevention or surgical prevention) and early mammography/MRI screening before the age of 40.

When to start routine mammography screening for breast cancer, and how often to screen, should be an informed decision between a woman and her physician, depending in part on her individual risk factors and her level of concern. The two biggest risk factors are family history and increasing age. Shared decision making is also appropriate to help determine when, after age 75, a woman will stop being screened. Growing consensus in the professional practice community supports the use of shared decision making, with women being informed of both the benefits and potential harms of mammography performed at different age intervals.

What matters most is that women be screened regularly for breast cancer. Clinicians should also promote breast health awareness, encouraging women to know how their breasts normally look and feel and present for clinical examination if they notice breast changes or a lump.
Risk Assessment

The following questions are used to identify women at increased risk for breast cancer (see Table 1 for definitions of risk levels). The results can help identify which women should be offered a referral to Genetics or Oncology for counseling about genetic testing and eligibility for chemoprevention, surgical prevention, and/or MRI screening. The results can also be used to guide screening decisions, including screening interval, age to begin screening, and screening method(s).

Because risks may change over time, these risk assessment questions should be asked of women at regular intervals, starting at age 18 and continuing through age 74. The questions are incorporated into the online Health Profile and the Well Visit Questionnaire and are also asked at each visit for a screening mammogram with the Breast Cancer Risk Questionnaire (see Appendix 1).

Questions

**Personal history of:**
1. Breast biopsy
2. Radiation therapy to the chest between the ages of 10 and 30 years for Hodgkin’s disease
3. Breast cancer at age 50 or older
4. Breast cancer before age 50
5. Ovarian cancer at any age
6. Known BRCA1 or BRCA2 gene mutation or Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome

**Family history**
7. Patient has had a mother, sister, or daughter with:
   a. Breast cancer before age 50, or
   b. Breast cancer in both breasts, or
   c. Breast and ovarian cancer
   d. Known BRCA1 or BRCA2 gene mutation or Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome
8. Patient has had:
   a. At least 3 female family members (mother, grandmother, sister, daughter, or aunt) with breast cancer, regardless of age at onset
   b. At least 2 female family members on same side with ovarian cancer, regardless of age at onset
   c. One female family member with breast cancer and another female family member with ovarian cancer on same side, regardless of age at onset
   d. At least 2 female family members on the same side with breast cancer before age 50
   e. At least 1 female family member of Ashkenazi ancestry with breast or ovarian cancer, regardless of age at onset
9. At least 1 male family member with breast cancer.

Table 1. Interpretation of responses to risk assessment questions

<table>
<thead>
<tr>
<th>Risk level</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INCREASED risk based on personal history</strong></td>
<td>Yes to any: 1, 2, 3, 4, 5, 6 (#3 applies only to women 50 or older)</td>
</tr>
<tr>
<td><strong>INCREASED risk based on family history</strong></td>
<td>Yes to any: 7, 8, 9</td>
</tr>
<tr>
<td><strong>AVERAGE risk</strong></td>
<td>No to all</td>
</tr>
</tbody>
</table>
Screening Recommendations Based on Risk Assessment

**Women starting at age 18**
Breast cancer risk assessment questions are incorporated into the Health Profile and Well Visit Questionnaires (both used at well visits), and are also asked at each screening mammogram.

**AVERAGE risk**
No increased-risk factors [A]

**INCREASED risk** based on:

**PERSONAL HISTORY**
- Breast cancer *before* age 50
- Ovarian cancer at any age
- Known BRCA1 or BRCA2 mutation or Li-Fraumeni, Cowden, or Bannayan-Riley-Ruvalcaba syndrome

**RELEVANT FAMILY HISTORY**

Any one of the following:
- **Mother, sister or daughter with:** breast cancer age <50; bilateral breast cancer; breast and ovarian cancer; known BRCA1 or BRCA2 mutation or Li-Fraumeni, Cowden, or Bannayan-Riley-Ruvalcaba syndrome.
- **Female family members (mother, grandmother, sister, daughter, aunt):** ≥3 with breast cancer, regardless of age at onset; ≥2 with ovarian cancer, regardless of age at onset; 1 with breast cancer and another 1 with ovarian cancer on same side of family, regardless of age at onset; ≥2 on same side with breast cancer age <50; ≥1 of Ashkenazi ancestry with breast or ovarian cancer, regardless of age at onset.
- **Male family members:** ≥1 with breast cancer.

Refer to Genetics or Oncology for counseling, evaluation, and screening recommendations.

**At age 40,** shared decision making around screening mammograms:
- Choose any age between 40 and 50 to start
- Choose frequency: annual or every 2 years
- Continue periodic risk assessments

**Age 50–74**
- Start or continue screening mammograms
- Shared decision making around frequency: annual or every 2 years
- Continue periodic risk assessments

**At age 75,** shared decision making around whether to continue screening

[Chest radiation therapy for treatment of Hodgkin’s disease between ages 10 and 30]

Breast cancer risks may change over time. Periodic risk assessments should continue for all women through age 74.

[A] Risk factors other than those addressed in the risk assessment questionnaire—such as breast density or age at menopause—may exist, but there is insufficient evidence to support including them at this time.
Shared Decision Making for Women at Average Risk

For women who are at average risk of breast cancer, Kaiser Permanente Washington has developed a shared decision making tool to help providers discuss the risks and benefits of:
- Starting mammography at an age between 40 and 49 versus at age 50, and
- Screening annually versus every 2 years.

The tool—“Breast Cancer Screening: When to start and how often to get mammograms”—is available as an Epic SmartPhrase, .AVSMAMMOAGE40TO49.

**HealthDecision** offers an online screening mammography decision tool designed for clinicians and patients to use together. Select “Breast Cancer Screening: Benefits, harms of regular mammograms,” at:

https://www.healthdecision.org/tool.html

Designed for patients at **average risk**, this interactive tool uses the patient’s individual data to determine:
- Her chance of developing breast cancer in the next 10 years, and
- Her potential mortality reduction based on annual versus biennial screening

*Note:* This tool is **not** intended for patients who are known to be at increased risk.

Graphical displays simplify explanations of overdiagnosis, false alarms, and mortality reduction, and provide a personalized view of the patient’s risk and the possible benefits and harms of screening mammograms. Here are sample results for a 42-year-old African American woman with no increased-risk factors who chooses biennial screening:
Benefits of mammograms

- May help prevent breast cancer deaths.
- May identify some breast cancers early, when the cancer is easier to treat.
- Benefits are greatest for women at higher risk of breast cancer and for women age 50 and older.

Possible harms of mammograms

All cancer screening methods carry the possibility of harm. The likelihood of possible harm increases with each mammogram a woman has.

- False-positives can cause anxiety and lead to further, unnecessary testing and treatment.
- Further testing after any positive result can cause worry and anxiety and increase the risk of harms, such as radiation exposure from additional mammography or pain, bleeding, or infection following a biopsy.
- Overdiagnosis—the detection of a cancer that would not have caused any harm if left untreated—leads to further testing and treatment that could include surgery, radiation, or chemotherapy.
- Over time, radiation exposure from regular mammograms can slightly increase cancer risk.

Lifetime benefits and harms of screening mammograms by starting age and frequency

<table>
<thead>
<tr>
<th>Table 2. Lifetime breast cancer deaths in a group of 1,000 women who are at low to average risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No mammograms</strong></td>
</tr>
<tr>
<td><strong>Mammograms every 2 years starting at age 40 and continuing through age 74</strong></td>
</tr>
<tr>
<td><strong>Mammograms every 2 years starting at age 50 and continuing through age 74</strong></td>
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</tbody>
</table>


<table>
<thead>
<tr>
<th>Table 3. Lifetime harms in a group of 1,000 women at low to average risk who had mammograms every 2 years through age 74</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>False-positives</strong></td>
</tr>
<tr>
<td>Starting at 40</td>
</tr>
<tr>
<td>Starting at 50</td>
</tr>
</tbody>
</table>

Source: Mandelblatt 2016.

<table>
<thead>
<tr>
<th>Table 4. Lifetime benefits and harms in a group of 1,000 women at low to average risk who started mammograms at age 40 and continued through age 74</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Every year</td>
</tr>
<tr>
<td>Every 2 years</td>
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</table>

Source: Mandelblatt 2016.
Screening Tests and Exams

Coverage note: Some mammograms, MRIs, or genetic assessments may not be covered by all insurance carriers. Coverage requirements and policies change regularly and women should consult Member Services to determine coverage and costs. For most women aged 40 through 74, regular screening mammograms are free with no cost-sharing.

Recommended screening test

Mammogram

Mammography is the gold standard for population-based breast cancer screening, and the default breast cancer screening test for all women.

Alternative screening tests and exams

Magnetic resonance imaging (MRI)

Breast cancer screening MRIs serve as adjuncts to mammography for some high-risk patients, and are typically ordered by Genetics or Oncology, but may also be ordered by Primary Care for patients who meet the clinical review criteria.

See Clinical Review Criteria: Breast MRI.

Indications for screening with MRI include:
- High lifetime risk (≥ 20%) determined by using validated model such as Gail Model or BRCAPro
- Personal history of chest radiation therapy at age 10–30 years
- BRCA positive
- Detailed family history suggesting high genetic risk
- Personal history or first-degree relative with Bannayan-Ridley-Ruvalcaba, Cowden, or Li-Fraumeni syndrome

Digital breast tomosynthesis (DBT)

Digital breast tomosynthesis is a modified form of digital mammography where multiple images are taken at different angles and then reconstructed to create 3D radiographic images of the breast. Technology assessments by Kaiser Permanente Washington and others have concluded that there is insufficient evidence in the published medical literature to show that DBT screening provides better long-term outcomes than standard mammography when screening asymptomatic women for breast cancer. DBT recommendations will be revisited when more evidence becomes available.


Screening clinical breast exam

Routine screening clinical breast exams are not recommended as a substitute for mammography. There is insufficient evidence regarding the accuracy of screening physical breast exams.

An exam is entirely appropriate when a woman presents with concerns about breast changes or a lump that she has detected. Expert opinion holds that an adequate clinical breast exam, if performed, should take 15–20 minutes.

Breast ultrasound

Breast ultrasonography is used is for diagnostic follow-up of abnormal screening mammograms. While breast ultrasound is under investigation as an adjunct to mammography in certain situations, currently available evidence does not support its use as a primary screening modality.
Referral to Genetics or Oncology

A referral to Genetics or Oncology for risk determination, counseling, and screening recommendations is recommended for women who have been identified as being at increased risk for developing breast cancer based on 1) personal history of breast cancer before age 50, ovarian cancer at any age, or known genetic markers, or 2) relevant family history using the Risk Assessment Tool [see p. 3]. Advise the patient that the purpose of the referral is to discuss additional assessment and evaluation options, including genetic testing for herself or relatives, the role of MRI in screening if applicable, and chemoprophylaxis if indicated.

Evidence Summary and References

To develop the Breast Cancer Risk Assessment and Screening Guideline, Kaiser Permanente Washington has adapted the following externally developed evidence-based guidelines:


The guideline team reviewed additional evidence in the following areas:
- Shared decision making tools on breast cancer screening in women ages 40–49 at average risk
- Risk assessment tools for identifying women at high risk
Guideline Development Process and Team

Development process
To develop the Breast Cancer Risk Assessment and Screening Guideline, the guideline team adapted recommendations from externally developed evidence-based guidelines and/or recommendations of organizations that establish community standards. The team reviewed additional evidence in several areas. This edition of the guideline was approved for publication by the Guideline Oversight Group in September 2017.

Team
The Breast Cancer Risk Assessment and Screening Guideline development team included representatives from the following specialties: genetics, Kaiser Permanente Washington Health Research Institute, primary care, radiology, residency, and Screening and Outreach.

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Disclosure of conflict of interest
Kaiser Permanente requires that team members participating on a guideline team disclose and resolve all potential conflicts of interest that arise from financial relationships between a guideline team member or guideline team member's spouse or partner and any commercial interests or proprietary entity that provides or produces health care–related products and/or services relevant to the content of the guideline.

The following team members have disclosed that their participation on the Breast Cancer Risk Assessment and Screening Guideline team includes no promotion of any commercial products or services, and that they have no relationships with commercial entities to report.

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Susan Carol Bradford  Robyn Mayfield  Valli Muthiah, MD
Avra Cohen, MN, RN  Molly McGinty, MD  Ann Stedronsky
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Team members listed below have provided the following disclosures of affiliation with one or more organizations:

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Grant research support from National Cancer Institute, Patient Centered Outcomes Research Institute
John Dunn, MD, MPH
Grant research support from Agency for Healthcare Research and Quality, National Institutes of Health
David Grossman, MD, MPH
U.S. Preventive Services Task Force, Vice-Chair
Appendix 1. Breast Cancer Risk Questionnaire

### Today's date: __/__/_____

#### Breast Cancer Risk Questionnaire

**Name:** __________________________

1. Have you ever had **breast cancer**?  
   - Yes  
   - No
   
   1a. If **YES**, what age were you first diagnosed:  
   - Under 50  
   - 50 or older

2. Have you ever had **ovarian cancer**?  
   - Yes  
   - No

3. Did you have any radiation therapy to the chest for Hodgkin’s disease between the ages of 10-30?  
   - Yes  
   - No

4. Have you gone through menopause (no periods for at least 1 year)?  
   - Yes  
   - No
   
   4a. If **YES**, age at menopause: ________

   4b. Was your menopause:  
   - Natural (regular aging)  
   - Surgical (ovaries removed)  
   - For other reasons:

5. Have you ever had a **breast biopsy**?  
   - Yes  
   - No

6. Do you or a blood relative have a known BRCA1 or BRCA2 gene mutation, Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome?  
   - Yes  
   - No  
   - Don't know

7. Have any of your blood relatives ever had breast OR ovarian cancer?  
   - Yes  
   - No  
   - Don't know
   
   If **NO**, STOP. You are done with this form.

   If **YES** or DON'T KNOW, please fill out the rest of this form to the best of your ability.

8. Have any of your blood relatives had breast cancer?  
   - Yes  
   - No  
   - Don't know
   
   **If No or Don't know, please skip to #9.**

   8a. Have your mother, sister, or daughter had breast cancer?  
   - Yes  
   - No  
   - Don't know

   8b. If **YES**, please check all that apply to you:  
   - My mother, sister, or daughter had breast cancer before age 50  
   - My mother, sister, or daughter had breast cancer in both breasts  
   - None of these apply to me

   8c. Have any of your other blood relatives had breast cancer?  
   - Yes  
   - No  
   - Don't know

   8d. If **YES**, please check all that apply to you:  
   - 2 or more relatives on the same side of my family had breast cancer before age 50  
   - 3 or more relatives had breast cancer (at any age)  
   - None of these apply to me

   8e. Do you have at least one male relative who has had breast cancer?  
   - Yes  
   - No  
   - Don't know

9. Have any of your blood relatives had **ovarian cancer**?  
   - Yes  
   - No  
   - Don't know
   
   9a. If **YES**, have 2 or more relatives on the same side of your family had ovarian cancer?  
   - Yes  
   - No  
   - Don't know

10. These are very specific factors that may affect your risk. Please check all that apply:  
   - My mother, sister, or daughter had both breast AND ovarian cancer  
   - I have one blood relative with breast cancer AND another blood relative with ovarian cancer from the same side of my family  
   - I have one or more blood relatives of Ashkenazi Jewish ancestry with breast or ovarian cancer  
   - None of these apply to me

All information will be kept confidential as provided by law. If you DO NOT want this information used for research, please check here:  

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