

Guidance for High Risk Ontario Breast Screening Program (OBSP) Sites – Genetic Risk Assessments and Personal Cancer History – 2021-10-15

| То: | OBSP-affiliated genetics clinics and High Risk OBSP sites |
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| From: | OBSP, Ontario Health (Cancer Care Ontario) |
| Re: | Genetic risk assessment of individuals (proband) with a personal history of cancer |

The <u>CanRisk</u> and International Breast Cancer Intervention Study (<u>IBIS</u>) breast cancer risk assessment tools are used by OBSP-affiliated genetics clinics as part of a genetic risk assessment to evaluate High Risk OBSP eligibility. Questions have been received from the genetics community regarding the use of these risk assessment tools for individuals (proband) with a history of cancer. This document provides clarifications on using these tools for the purposes of determining eligibility for the High Risk OBSP, based on the risk factors included in each tool and guidance from the risk assessment tool developers.

Background

The CanRisk tool is a web-based software that incorporates the newest version of the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA) as well as a new ovarian cancer model. For the proband, CanRisk includes personal history of breast, invasive epithelial ovarian and pancreatic cancer, as well as other personal, family and lifestyle risk factors in its risk prediction model. Depending on the risk factors entered, CanRisk will estimate the following risks:

- 5-year, 10-year and lifetime risk (up to age 80) of developing breast and ovarian cancer
- 5-year, 10-year and lifetime risk of contralateral breast cancer (up to age 80) in individuals that have had a history of unilateral invasive breast cancer
- Mutation probability for several hereditary breast and ovarian cancer associated genes (e.g., BRCA1, BRCA 2, PALB2)

For the proband, the IBIS tool includes personal history of ovarian cancer and other personal, family and lifestyle risk factors in its risk prediction model. However, the model does not include personal history of breast cancer. IBIS calculates the 10-year and lifetime risk (to be calculated up to age 80) of breast cancer for individuals being assessed.

Individuals with a lifetime breast cancer risk of ≥25% are eligible for the High Risk OBSP, provided they meet other program eligibility criteria. More details on High Risk OBSP eligibility can be found on the High Risk OBSP requisition form.

Risk assessment guidance based on personal cancer history

Genetic counsellors may opt to use either the CanRisk or IBIS tools for genetic risk assessments when evaluating individuals with no personal cancer history. However, the tools have different usage recommendations for individuals with a personal history of cancer.

Table 1 provides a summary of risk assessment tools that should be used to assess probands with a personal history of cancer. Table 2 provides more detailed risk assessment guidance.

The recommendations provided are general rules that may not account for all scenarios encountered by genetic counsellors in the clinic setting. Genetic counsellors are advised to use their clinical judgement when assessing probands with very specific or rare personal and family history presentations.

| Personal cancer history* | Risk assessment tool | | |
|---------------------------------|----------------------|---|--|
| (proband) | IBIS | CanRisk | |
| Invasive breast cancer | No | Yes | |
| Ductal carcinoma in situ (DCIS) | No | Yes [†] | |
| Ovarian cancer | Yes | No. [§] Hereditary cancer genetic testing recommended. Refer to Table 2. | |
| Pancreatic adenocarcinoma | Yes | No. [§] Hereditary cancer genetic testing recommended. Refer to Table 2. | |
| Other cancers | Yes | Yes | |

| Table 1: Summary of applicable risk assessment tools for | probands with a personal history of cancer |
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[†]Do not include personal history of DCIS in CanRisk assessment.

[§]Only the individual's mutation probability is calculated, not lifetime breast cancer risk.

*There are several considerations when deciding to assess or screen individuals with advanced or metastatic cancer, including how long the person is expected to live, whether they are willing and able to do follow up tests and treatments for breast cancer, and if they have additional health concerns that may take priority over screening. Genetic counsellors should encourage their patients with metastatic cancer to discuss the benefits and limitations of risk assessment and subsequent breast screening with their health care team (e.g., oncologist, primary care provider) so that they may make a personal decision about whether the tests are right for them. There is limited evidence on the benefits of early cancer detection in individuals with incurable, metastatic cancer.

Additional information

More information about CanRisk and IBIS can be found at <u>CanRisk Knowledgebase</u> and the "Documentation" tab of the <u>IBIS tool</u>, respectively.

For questions related to this guidance, please contact <u>cancerscreening@ontariohealth.ca</u>



| Personal cancer history* (proband) | Risk assessment guidance |
|--|--|
| Invasive breast cancer | CanRisk should be used to calculate risk of developing cancer in the contralateral breast and the mutation probability. Genetic testing should be recommended if the individual meets hereditary cancer testing criteria.[†] |
| | Individuals with ≥25% lifetime risk of contralateral breast cancer, or who are known mutation carriers, are eligible for the High Risk OBSP. |
| Ductal carcinoma in | CanRisk should be used to calculate the risk of developing breast cancer and the mutation probability. |
| situ (DCIS) | CanRisk only considers invasive breast cancer history in its model; therefore, the individual's DCIS history <u>should not be entered</u>.[‡] |
| | Genetic testing should be recommended if the individual meets hereditary cancer testing criteria.[†] |
| | Individuals with ≥25% lifetime risk of breast cancer, or who are known mutation carriers, are eligible for the High Risk OBSP. |
| Ovarian cancer | Genetic testing should be recommended for individuals with epithelial ovarian cancer as they are eligible.⁺ |
| | IBIS can be used to calculate the risk of developing breast cancer if appropriate. Individuals with ≥25% lifetime risk of breast cancer, or who are known mutation carriers, are eligible for the High Risk OBSP. |
| Pancreatic adenocarcinoma | Genetic testing should be recommended as individuals with pancreatic adenocarcinoma are eligible[†]. |
| | IBIS can be used to calculate risk of developing breast cancer if appropriate. Individuals with ≥25% lifetime risk of breast cancer, or who are known mutation carriers are eligible for the High Risk OBSP. |
| Other cancers | An individual with a personal history of other cancers not outlined above can be assessed using either IBIS or CanRisk. |
| | Genetic testing should be recommended if the individual meets hereditary cancer testing criteria.⁺ |
| | Individuals with ≥25% lifetime risk of breast cancer, or who are known mutation carriers, are eligible for the High Risk OBSP. |

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[†]Ontario Health (Cancer Care Ontario). 2021 Hereditary Cancer Testing Eligibility Criteria Version 2.0. Toronto 2021 Sept 13. Downloaded from: <u>https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/70161</u>

[†]Ontario Health (Cancer Care Ontario) recognizes that the existing risk assessment tools do not consider personal history of DCIS in their risk prediction models. Ontario Health (Cancer Care Ontario) will continue to monitor any updates to the risk assessment tools and revise the guidance as appropriate.

