

Guidance on Including Breast Density in Genetic Risk Assessments – 2022-05-09

To: OBSP-affiliated genetics clinics and High Risk OBSP sites

From: OBSP, Ontario Health (Cancer Care Ontario)

Re: Including breast density in genetic risk assessments

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 to assess High Risk OBSP eligibility of individuals referred for genetic risk assessments. The genetics community has highlighted the need for more specific guidance on the inclusion of breast density measurements into risk assessments. This document provides information on breast density and breast cancer risk, and guidance on incorporating breast density measurements into risk assessments (based on each tool and guidance from the risk assessment tool developers), for the purposes of determining eligibility for the High Risk OBSP.

Breast Density and Breast Cancer Risk

Breast tissue density is a mammographic measure of the amount of fibroglandular (dense) tissue (made up of ducts, glands for milk production and connective tissue) relative to fatty tissue in the breast. A breast is considered dense when it has a lot of fibroglandular tissue. Having some dense breast tissue is normal and very common. However, high mammographic density has been identified as a risk factor for the development of breast cancer because dense breast tissue makes it more difficult to detect cancers on a mammogram¹ (both appear white) and research shows that the risk of breast cancer increases as the amount of dense tissue in the breast increases². For additional information about breast density, please see the OBSP's breast density educational webpage for healthcare providers.

Breast Density Measurements in Mammogram Reports

To assess breast density, the two most common methods include percent mammographic density³ and the American College of Radiology (ACR)'s Breast Imaging Reporting and Data Systems (BI-RADS) classification

¹ Boyd N, Berman H, Zhu J, Martin LJ, Yaffe MJ, Chavez S, et al. The origins of breast cancer associated with mammographic density: a testable biological hypothesis. Breast Cancer Res. 2018;20(1):17.

² McCormack VA, dos Santos Silva I. Breast density and parenchymal patterns as markers of breast cancer risk: a meta-analysis. Cancer Epidemiology and Prevention Biomarkers. 2006 Jun 1;15(6):1159-69.

³ Boyd NF, Martin LJ, Yaffe MJ, Minkin S. Mammographic density and breast cancer risk: current understanding and future prospects. Breast Cancer Res. 2011;13(6):223.

(5th edition)⁴. Percent mammographic density is a visual estimate of the percentage of dense breast tissue on the mammogram, reported in the OBSP as <75 percent or ≥75 percent. BI-RADS density categories are descriptions of the amount of dense breast tissue on the mammogram based on a visual estimation⁵. The categories provide clinicians with awareness of the limitations of mammography because they help indicate whether masses may be obscured by dense tissue. Table 1 provides the four possible categories reported as a letter, from A to D, and their associated descriptions.

Since June 2021, all OBSP screening mammogram reports (i.e., paper-based OBSP Screening Report forms and dictated reports) should include both the <or ≥ 75 percent mammographic density measurement and one of the four BI-RADS breast density categories. Figure 1 shows the recently updated paper-based OBSP Screening Report Form. Outside the OBSP, breast density information is usually reported using the BI-RADS classification.

Table 1: ACR BI-RADS Classification (5th edition) Reporting System

| BI-RADS classification | Associated Description |
|------------------------|---|
| А | The breasts are almost entirely fatty. |
| В | There are scattered areas of fibroglandular density. |
| С | The breasts are heterogeneously dense, which may obscure small masses. |
| D | The breasts are extremely dense, which lowers the sensitivity of mammography. |

Inclusion of Breast Density in the CanRisk and IBIS Risk Assessment Tools

The CanRisk and IBIS tools have been updated to allow for input of breast density information in their respective risk assessment models. CanRisk accepts breast density information based on the BI-RADS classification (i.e., A-D), while IBIS accepts breast density information based on the BI-RADS, Volpara and Visual Assessment Scale (VAS) classifications. Neither risk assessment tool provides the option to enter breast density information based on the percent mammographic density measurement.

Genetic counsellors are encouraged to input as much accurate risk factor information as possible for the individual being assessed, based on the availability of the information (and the individual clinic's resource capacity to be able to obtain this information). As such, it is recommended that genetic counsellors retrieve the most recent mammogram reports to record breast density information for individuals being assessed for High Risk OBSP eligibility. Where clinic resources are limited, counsellors may prioritize the retrieval of mammogram reports for individuals in whom breast density information is more likely to impact High Risk OBSP eligibility (e.g., people who self-report that they have mostly fatty or very dense breasts).

Table 2 provides guidance for including breast density information in CanRisk and IBIS.

Table 3 provides specific guidance on entering breast density information in the risk assessment tools.

⁵ Sickles EA, d'Orsi CJ, Bassett LW, Appleton CM, Berg WA, Burnside ES. ACR BI-RADS® mammography. ACR BI-RADS® atlas, breast imaging reporting and data system, Vol. 5. 2013.



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⁴ American College of Radiology. ACR BI-RADS atlas - reporting system [Internet]. Silver Spring, MD: American College of Radiology; 2013 [accessed 2021 Nov 25]. Available from: https://www.acr.org/-/media/ACR/Files/RADS/BI-RADS/Mammography-Reporting.pdf.

Table 2: Guidance for Including Breast Density Information in CanRisk and IBIS

| Consideration | Guidance | |
|-----------------------------------|---|--|
| | | |
| Age on | The inclusion of breast density in CanRisk and IBIS has only been validated for individuals | |
| mammogram | 40 and older. Breast density information should not be entered if the mammogram was | |
| report | performed when the individual was less than 40 (e.g., the individual is 41 but had a | |
| | mammogram when they were 39). | |
| Recency of breast | Breast density information should be retrieved from the person's most recent screening o | |
| density information | diagnostic mammogram report. When several reports are available, use the report with | |
| | the most recent date. | |
| | Breast density information from the mammogram report can be entered in the risk | |
| | assessment tools if the report is within 5 years of the risk assessment date. | |
| | If the mammogram report is more than 5 years from the risk assessment date, do not | |
| | enter the breast density information. | |
| Availability of | If a recent mammogram report is available, the breast density information should be | |
| mammogram | included in the risk assessment tool. | |
| report | If a recent mammogram report is not available, the breast density field should be left | |
| | blank in the risk assessment tool. When breast density information is left blank, the | |
| | risk assessment tools will account for missing data within their respective algorithm | |
| E Localina BL BABC | (e.g., by providing an average value). | |
| Extracting BI-RADS | If the dictated mammogram report only contains a description of breast density (i.e., a BI- | |
| density information from dictated | RADS classification letter A-D is not specified): • Choose the BI-RADS classification letter which most closely resembles the reported | |
| reports | • Choose the BI-RADS classification letter which most closely resembles the reported density description (as outlined in Table 1) to include in the risk assessment tool (e.g., | |
| reports | if "heterogeneous density" has been recorded on the dictated report, then enter BI- | |
| | RADS C [the breasts are heterogeneously dense, which may obscure small masses]). | |
| | If the density description cannot be interpreted (e.g., if "moderately dense" has been | |
| | recorded on the dictate report), if possible, consult with the facility where the | |
| | mammogram was done. Otherwise, the breast density field in the risk assessment | |
| | should be left blank. | |
| Using percent | Percent mammographic density measurements are not accepted in the risk assessment | |
| mammographic | tools. However, the following convention can be used: | |
| density information | If breast density is reported as ≥75 percent, enter BI-RADS D in the risk assessment | |
| | tool. Although the two measurement methods are not equivalent, both BI-RADS D and | |
| | ≥75 percent density are indicative of extremely dense breasts*. | |
| | If breast density is reported as <75 percent, the breast density field should be left | |
| | blank. This measure indicates that the breasts are not dense, however, a BI-RADS | |
| | category cannot be assigned as an equivalent measure. | |
| Breast density | Breast density information should be retrieved from mammogram reports only. Breast | |
| information from | density measurements from other imaging modalities (e.g., magnetic resonance imaging) | |
| other imaging | have not been validated for use in the tools. | |
| modalities | This | |

*The OBSP recognizes that percent mammographic density and BI-RADS are not equivalent breast density measures. This guidance has been provided only for the purposes of the risk assessment tools. A recent rapid review conducted by Ontario Health (Cancer Care Ontario) found that systematic reviews have reported similar breast cancer risk estimates for BI-RADS D and 75 to 100 percent mammographic density.



Table 3: Specific Guidance for Entering Breast Density Information in CanRisk and IBIS

| Breast density information | Guidance for Entering Breast Density Information in Cankisk and ibis Guidance | | |
|----------------------------|---|--|--|
| available? | CanRisk | IBIS | |
| Yes* | In the "Breast screening" section, answer "Yes" to the following questions: Have you ever had a mammogram[‡]? Some women may have been told about their breast density, have you? Was the breast density measured using BI-RADS? Under "What was the result?" select the appropriate BI-RADS category[§] from the dropdown options. | In the "Mammographic density (age 40+)" section, select the "BI-RADS® ATLAS Density" box and select the appropriate BI-RADS density category§ from the dropdown options. | |
| No [†] | In the "Breast screening" section, answer "No" to the question "Have you ever had a mammogram?" The tool will then allow you to proceed without having to enter breast density information. | The "Mammographic density (age 40+)" section can be left blank. | |

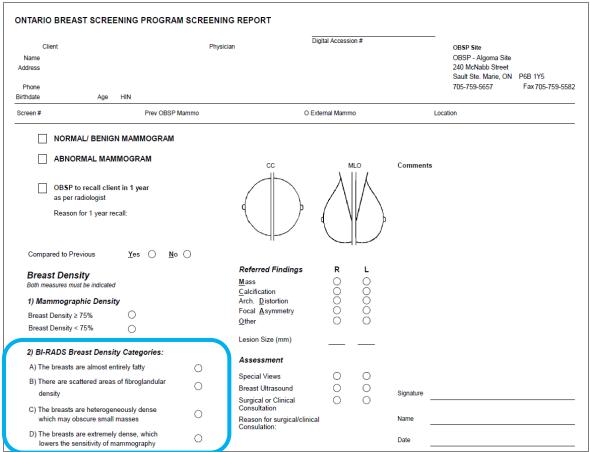
^{*}Individual age 40 or older who has had a screening or diagnostic mammogram and for which BI-RADS breast density information is available (or can be interpreted).



[†]Individual below the age of 40, has not had a screening or diagnostic mammogram, or density information is unavailable and cannot be retrieved.

 $[\]S$ Refer to Table 2 for guidance on including breast density in the risk assessment tools

Figure 1: Updated OBSP Screening Report Form



Additional information

For questions related to this guidance, please contact cancerscreening@ontariohealth.ca

