Catalogue no. 82-003-X
ISSN 1209-1367

Health Reports

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Release date: May 20, 2026

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DOI: https://www.doi.org/10.25318/82−003−x202600500002−eng

ABSTRACT

Background

Breast cancer is the most commonly diagnosed cancer among women in Canada. Breast density substantially influences breast cancer risk and mammography performance. However, OncoSim-Breast, a Canadian microsimulation model representing breast cancer control, including cancer onset, screening, and survival, has not previously explicitly accounted for breast density. This study describes the incorporation of density-specific parameters into the OncoSim-Breast model.

Data and methods

Breast density-specific inputs were integrated into OncoSim-Breast using data from five Canadian provinces. Three key parameters—prevalence, relative risk of breast cancer, and digital mammography performance (sensitivity and specificity)—were estimated by age group and breast density category, following the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS) classification (categories A to D). Calibration experiments and internal validations were conducted to ensure the updated OncoSim-Breast model aligned with observed data from the Canadian Cancer Registry.

Results

The prevalence of dense breasts declined with age: BI-RADS categories C and D accounted for 58% of women younger than 50 years and 26% of those aged 70 and older. Digital mammography sensitivity also decreased with increasing density: among women younger than 50 years, sensitivity was 88% for Category A and 69% for Category D. The updated OncoSim-Breast model accurately replicated age-specific incidence, age-adjusted incidence, and stage distribution based on historical data from the Canadian Cancer Registry (2010 to 2019).

Interpretation

Incorporating breast density-specific parameters substantially improved the accuracy and policy relevance of OncoSim-Breast. The updated model provides a validated tool to inform screening policy decisions for Canadian women, allowing consideration for the effect of the variability of breast density among women.

Keywords

Breast cancer in Canada, breast density, simulation modeling, screening mammography, supplemental breast cancer screening

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What is already known on this subject?

- The OncoSim-Breast model, developed by the Canadian Partnership Against Cancer with Statistics Canada, integrates high-quality Canadian demographic, epidemiologic, and clinical data, providing a comprehensive population-based tool for evaluating outcomes of breast cancer screening strategies in Canada.
- Mammographic breast density is associated with increased breast cancer risk and lower sensitivity of mammography.
- OncoSim-Breast has not previously incorporated breast density-specific data from Canadian populations.

What does this study add?

- This study presents a major update to OncoSim-Breast that includes Canadian-specific breast density prevalence, risk estimates, and mammography performance data.
- The updated model accurately reflects historical incidence and stage distributions of breast cancer, offering improved precision for informing and evaluating screening policies tailored by breast density.

Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer-related death among women in Canada.[1] Population-based mammography screening plays a crucial role in detecting breast cancer at earlier, more treatable stages and remains the only screening approach with mortality reduction benefits demonstrated in randomized controlled trials.[2] Despite advancements in screening mammography technology, research indicates that its effectiveness varies across patient characteristics, with breast density being one of the most significant factors affecting breast cancer risk and screening accuracy.[3] Women with higher breast density face an increased risk of developing breast cancer while also experiencing reduced sensitivity in mammography screening.[3,4]

OncoSim, developed by the Canadian Partnership Against Cancer with Statistics Canada, is a suite of microsimulation models based on real-world data that can address complex questions to improve patient outcomes and optimize the use of cancer system resources.[5] OncoSim has helped cancer agencies and programs by providing relevant information to support policy, practice, and resource allocation decisions at the jurisdictional level.[5] Users can access OncoSim via a web interface and develop customized scenarios to inform current and future health policy decisions.[5]

OncoSim-Breast is a specific OncoSim model that focuses on modelling the development, screening, diagnosis, and treatment of breast cancer.[6] OncoSim-Breast was calibrated using historical age- and year-specific cancer incidence data from the National Cancer Incidence Reporting System (1969 to 1991) and the Canadian Cancer Registry (CCR) (1992 to 2020).[6] OncoSim-Breast successfully represents the population-level breast cancer burden in Canada.[6]

Despite the well-established association of breast density with breast cancer risk and screening accuracy, previous versions of OncoSim-Breast did not explicitly incorporate these relationships. As a result, the model was limited in its ability to evaluate screening strategies tailored to women with differing breast densities. Specifically, it was difficult to use the model to assess the potential benefits, harms, or cost effectiveness of supplemental screening modalities, such as breast ultrasound, magnetic resonance imaging (MRI), contrast-enhanced mammography, or digital breast tomosynthesis, which are increasingly considered for women with dense breast tissue because of the reduced sensitivity of conventional mammography.[7]

This study aimed to enhance the OncoSim-Breast model by incorporating Canadian data on breast density and validating the updated model, strengthening its ability to evaluate and compare screening policies tailored to breast density. To the best of the authors' knowledge, OncoSim-Breast remains the only microsimulation model specifically designed to represent Canadian breast cancer epidemiology.

Data and methods

Overview of the OncoSim-Breast model

OncoSim-Breast, a Canadian microsimulation model designed to inform breast cancer control policies, has been previously described[6] and is briefly summarized here. OncoSim-Breast simulates the onset, growth, detection, progression, and outcomes of invasive breast cancer and ductal carcinoma in situ among women. The model integrates Canadian data on cancer incidence, mortality, screening practices, costs, and quality of life, enabling the projection of population-level outcomes under alternative scenarios.

The model simulates individual women in the Canadian population, incorporating demographics, risk factors (e.g., BRCA1 and BRCA2 mutations, family history, hormone replacement therapy), tumour biology, and natural history. The natural history component is structured similarly to that of the University of Wisconsin Breast Cancer Simulation Model.[8]

Table 1
Breast density- and age-specific inputs and calibration targets in OncoSim-Breast

Inputs and calibration targets	BI-RADS Category A: Mainly fatty	BI-RADS Category B: Scattered	BI-RADS Category C: Heterogeneously dense	BI-RADS Category D: Extremely dense
Prevalence (%)				
Age group				
Younger than 50 years	9	33	46	12
50 to 59 years	10	50	33	7
60 to 69 years	14	56	26	4
70 years or older	16	58	23	3
Relative risk of breast cancer (indexed to the age-specific Canadian average)				
Age group				
Younger than 50 years	0.38	0.73	1.18	1.49
50 to 64 years	0.52	0.87	1.30	1.59
65 years or older	0.62	0.95	1.29	1.47
Sensitivity of digital mammography (in %)				
Age group				
Younger than 50 years	88	80	76	69
50 to 64 years	93	91	83	76
65 years or older	92	91	88	77
Relative specificity of digital mammography (indexed to the age-specific Canadian average)				
Age group				
Younger than 50 years	1.05	1.01	0.98	1.00
50 to 59 years	1.03	1.00	0.99	1.00
60 to 69 years	1.03	1.00	0.99	1.01
70 years or older	1.02	1.00	0.99	1.01

Notes: BI-RADS = Breast Imaging Reporting and Data System. Prevalence and sensitivity targets were derived from data collected in 2024 from five provincial screening programs. Relative risk and specificity patterns were based on published data then reweighted and anchored to the Canadian density distribution. Relative risks and relative specificity are indexed, so the prevalence-weighted mean equals 1 within each age group.
Source: Authors' calculations using data from five provincial screening programs and the Breast Cancer Surveillance Consortium.

Tumours develop and grow according to Gompertz functions, may spread to lymph nodes or metastasize, and can be detected clinically or through screening. At detection, stage and subtype-specific tumour characteristics are assigned based on CCR data. Disease progression is modelled using stage-specific survival and recurrence risks, calibrated with Canadian national and provincial cohort data.

OncoSim-Breast was externally validated against the UK Age trial, which compared annual screening among women aged 40 to 49 with usual care in the United Kingdom.[6] The model was also cross-validated against the United States' Cancer Intervention and Surveillance Modeling Network (CISNET) breast cancer models,[9] which informed the United States Preventive Services Task Force (USPSTF) breast cancer screening recommendations in 2009, 2016, and 2024.[10,11]

Representing breast density

Breast density refers to the proportion of fibroglandular (dense) tissue relative to fatty (non-dense) tissue in a woman's breasts, as visualized on a mammogram. Although breast density is inherently a continuous variable ranging from 0% to 100%, in clinical practice it is classified using the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS), 5th edition, which defines four qualitative density categories based on the visual assessment of fibroglandular tissue:[12]

- Category A: Almost entirely fatty
- Category B: Scattered fibroglandular density
- Category C: Heterogeneously dense
- Category D: Extremely dense.

Consistent with the literature and the structure of the OncoSim-Breast modelling framework, the updated model incorporates breast density using the four BI-RADS categories.

Breast density is modelled using age-specific prevalence distributions defined for the following age groups: younger than 50, 50 to 59, 60 to 69, and 70 and older. In the model, each woman is assigned an initial breast density before age 40, which remains fixed until age 50; density may transition at ages 50, 60, and 70 and remains constant within each age band. Breast density parameters are adjusted to reproduce observed cross-sectional, age-specific distributions. Longitudinal density changes are generated through a simplified transition process that produces plausible age-related declines in density; however, the process is not empirically calibrated to individual-level longitudinal data.

Estimation of breast density-specific inputs and targets for parameter calibration

To incorporate breast density into OncoSim-Breast, this study used one direct input and two targets for parameter calibration (Table 1). Age-specific prevalence of breast density was used as a direct model input, while relative risk of developing breast cancer by BI-RADS category and digital mammography performance (sensitivity and specificity) by age and density served as targets for the calibration of internal model parameters. The age group categories vary across the input and targets because of differences in data sources and the need to ensure adequate statistical power within each group. Some key OncoSim-Breast input parameters were revised to align model projections with the targets described above and observed Canadian breast cancer trends, thereby improving the model's ability to assess screening strategies tailored to breast density.

The density-specific input and targets were estimated as follows.

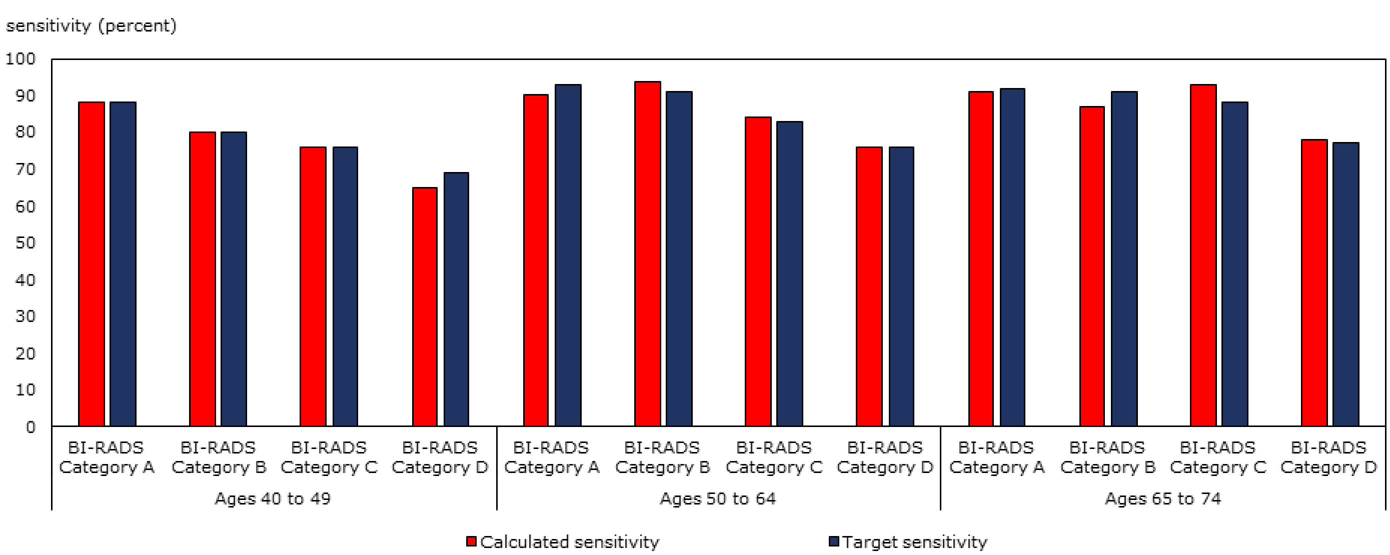
(1) Prevalence of breast density: The most critical input for representing breast density in the model is its prevalence among women in Canada. Because breast density changes as women age, it is essential to estimate its distribution across different age groups.[13] OncoSim-Breast first included the prevalence of breast density in model version 3.1.1.1 (December 2018), and the estimates were subsequently updated using more recent data. To achieve this, primary data on breast density distribution were collected from five Canadian provinces (Ontario, British Columbia, Nova Scotia, Manitoba, and Prince Edward Island) in November and December 2024: these five provinces represented approximately 60% of the Canadian female population in 2025.[14] These data, spanning varying timeframes across provinces from 2018 to 2023, were stratified into four age groups (younger than 50, 50 to 59, 60 to 69, and 70 and older). Using these estimates and weighting by the female population distribution in each contributing province, weighted averages were computed across the four age groups and by density.

(2) Relative risk of breast cancer: There is strong evidence that the risk of developing breast cancer varies by age, making it essential to estimate relative risk by age group.[15] To generate target values tailored to Canadian women, a literature review was conducted to identify studies involving Canadian populations. While some studies reported density-specific breast cancer risk in Canada,[3,16] none provided relative risk estimates stratified by breast density (using the BI-RADS classification) and age group. Because of this limitation, data from the Breast Cancer Surveillance Consortium (BCSC) in the United States were used to estimate the relative risk of developing breast cancer by breast density and age group for use in OncoSim-Breast.[11] These values have also been used in analyses conducted by the CISNET breast cancer models to inform the USPSTF breast cancer screening recommendations in 2016 and 2024.[11,17] To reflect the Canadian context, the BCSC-derived estimates were reweighted based on Canadian breast density prevalence to generate relative risk values anchored to the average density distribution in Canada.

(3) Mammography performance by density: The second set of calibration targets is the performance of screening mammography based on density. While OncoSim-Breast accounts for different mammography technologies, including film and digital mammography, this study focused exclusively on digital mammography, as it is the predominant screening method used in Canada. Mammography performance is influenced not only by breast density but also by age group, making age-specific estimates necessary.[18] Different approaches were used to estimate the sensitivity and specificity of digital mammography.

In the sensitivity calculations, mammograms were considered false negatives if a cancer was diagnosed within 12 months of a

Chart 1
Comparison of sensitivity calculated by OncoSim-Breast and target estimates, stratified by age group and breast density



Note: BI-RADS = Breast Imaging Reporting and Data System.
Source: Authors' calculations using OncoSim-Breast and data from provincial screening programs.

negative screening examination. To estimate density-specific sensitivity, primary data were collected from five provinces—Ontario, British Columbia, Nova Scotia, Manitoba, and Prince Edward Island—in November and December 2024. However, because of the low number of reported cancers in Manitoba and Prince Edward Island, only data from Ontario, British Columbia, and Nova Scotia were used for the sensitivity estimates. Using these data and applying weights based on the female population distribution in each contributing province, a weighted average sensitivity was calculated across breast density categories, age groups, and screening sequences (i.e., initial versus subsequent screening examinations). This estimation did not account for the confounding effects of other factors, such as race and ethnicity, on breast density. To simplify the calibration of density-specific inputs in OncoSim-Breast, a final overall weighted average sensitivity estimate was derived by combining values across screening sequences within each density and age group.

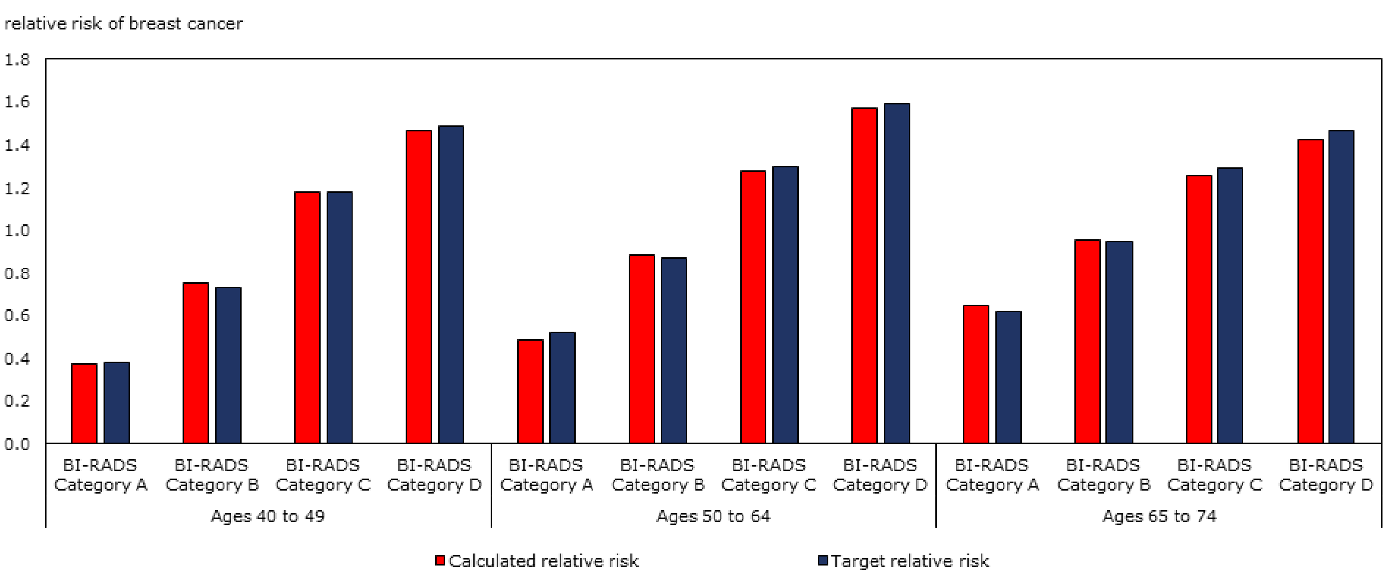
To estimate specificity by breast density, a different approach was used. In the OncoSim-Breast model, mammography specificity is specified only at the aggregate level by age group and is not stratified by breast density. Therefore, no baseline density-specific specificity values were available for direct implementation. Instead, age-specific relative specificity estimates by breast density from the BCSC were used. These estimates report specificity for BI-RADS breast density categories A, C, and D relative to Category B.[18] Using these relative specificity ratios, density-specific specificity was anchored to Category B, and the baseline specificity for Category B was solved such that the prevalence-weighted average specificity across density categories matched the age-specific aggregate specificity already used in OncoSim-Breast. Age-specific breast density prevalence estimates from five Canadian provinces were used as weights in this calibration. This approach disaggregated the existing aggregate specificity inputs in OncoSim-Breast into density-specific values while preserving the overall specificity observed in the Canadian population.

Sensitivity calibration

A structured approach was followed to find proper density-specific inputs for OncoSim-Breast, ensuring consistency with the existing version during this process. Breast density prevalence was incorporated directly, whereas density-specific relative risks of developing breast cancer required rescaling of the baseline risk in OncoSim-Breast to preserve the BCSC-derived relative risk relationships by density in the final simulated outcomes. In contrast, integrating density-specific digital mammography performance required extensive sensitivity calibration experiments. This complexity arose because OncoSim-Breast does not allow direct input of screening exam sensitivity. Instead, it uses a tumour-size-specific cancer detection function.[6] To address this, various values for this detection function were tested, and those most closely aligned with the target sensitivity estimates, based on Canadian provincial data, were selected for each breast density category and age group.

Assumptions about screening participation rates were required for the sensitivity calibration experiments. Participation rates before 2015 were not modified in the model. Starting in 2015, screening participation was assumed to be constant over time. This assumption was made because annual participation rates by province over time were not consistently available, or were reported for selected multi-year intervals (e.g., 2018 to 2019 and

Chart 2
Comparison of relative risks of breast cancer calculated by OncoSim-Breast and target estimates, stratified by age group and breast density



Note: BI-RADS = Breast Imaging Reporting and Data System. Relative risks are indexed to the average breast density for the corresponding age group in Canada.
Source: Authors' calculations using OncoSim-Breast and data from provincial screening programs and published data from the Breast Cancer Surveillance Consortium.

2020 to 2021), with coverage varying across provinces.[19] Using time-varying participation under these circumstances would introduce artificial temporal variation driven by data gaps rather than true changes in screening behaviour. Therefore, an assumption of constant participation was adopted for model consistency and transparency. Participation rates were structured separately for high-risk women (defined as those with a first- or second-degree family history of breast cancer) and for all other women, as Canadian evidence indicates that screening retention and return are higher among high-risk women.[20] These assumptions were based on province-specific participation rates, which ranged from 35% to 66% as reported by the Canadian Partnership Against Cancer for the 2018-to-2019 and 2020-to-2021 periods.[19] However, in the model, these rates were applied uniformly across all provinces within OncoSim-Breast.

Internal validation

Internal validation was conducted by comparing updated projections from OncoSim-Breast (age-specific incidence, age-adjusted incidence, and stage distribution) to observed data. Specifically, age-adjusted and age-specific incidence rates projected by the density-specific OncoSim-Breast (OncoSim-Breast version 3.6.7.3) were compared against observed data from the CCR (2010 to 2019).[21] The stage distribution of breast cancer cases projected by the density-specific OncoSim-Breast was compared against observed data from the CCR (2010 to 2017)[22,23] across different age groups. Although the CCR reported stage distributions through 2019, different staging systems were used from 2010 to 2017 and from 2018 to 2019. Therefore, comparisons were restricted to the 2010-to-2017 period.

Analyses

All numerical experiments were conducted using OncoSim version 3.6.7.3, with a simulation size of 32 million individuals. Age-standardized rates were calculated using direct standardization to the July 1, 2011, Canadian standard population, consistent with Statistics Canada's reporting of age-standardized incidence and mortality rates at the time of analysis, and expressed per 100,000 women.[24]

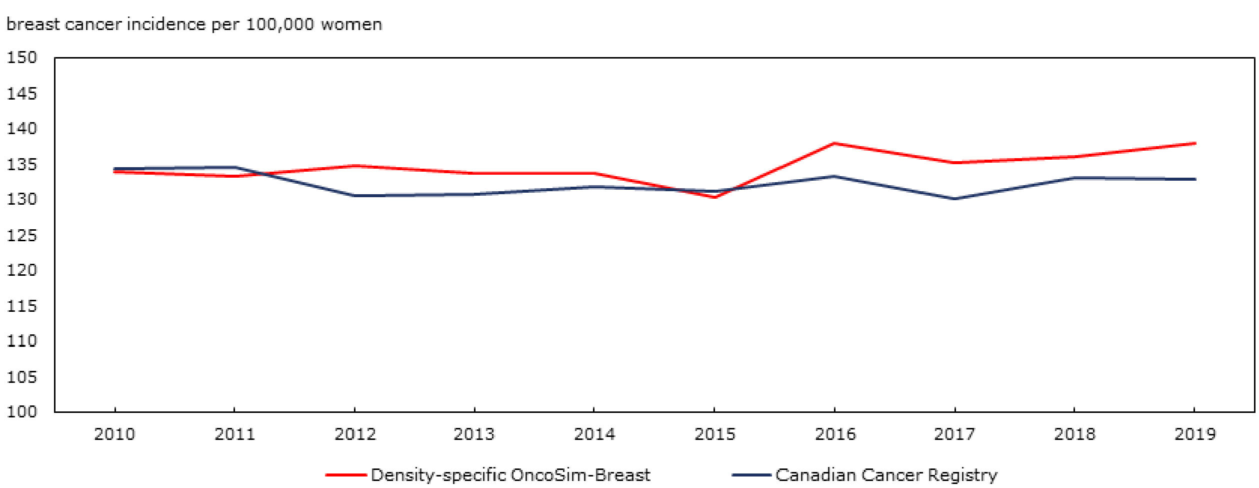
Results

Table 1 presents the density-specific input and target values used to update OncoSim-Breast. The prevalence of women with dense breasts in Canada declines with age. For example, the proportions of women with BI-RADS Category C and Category D breast density were 46% and 12% at ages younger than 50 years, 33% and 7% at ages 50 to 59, 26% and 4% at ages 60 to 69, and 23% and 3% at ages 70 and older, respectively (Table 1). Furthermore, mammography sensitivity decreases significantly with increasing breast density. For example, among women younger than 50 years, the target sensitivity of digital mammography by breast density was 88% for Category A, 80% for Category B, 76% for Category C, and 69% for Category D. In most cases, sensitivity increases with age among women with dense breasts. For instance, for Category D density, the target sensitivity of digital mammography increases from 69% at ages younger than 50 years to 76% at ages 50 to 64 and to 77% at ages 65 and older.

Calibration results

Chart 1 compares the calculated mammographic sensitivity values with the target values (Table 1). The results indicate that the average deviation between the estimated and target

Chart 3
Comparison of age-adjusted breast cancer incidence from density-specific OncoSim-Breast projections and the Canadian Cancer Registry, 2010 to 2019



Source: Authors' calculations using OncoSim-Breast and data from the Canadian Cancer Registry.

sensitivity values was less than 2% across all breast density categories and age groups, consistent with the sensitivity calibration results of the CISNET breast cancer models (Chart 1).[25] This confirms that the tumour-size-specific inputs used in OncoSim-Breast to represent density-specific sensitivity accurately replicate the sensitivity of digital mammography observed in Canada. Chart 2 compares density-specific relative risks with target values (Table 1). Deviations are minimal across all density categories and age groups, indicating that OncoSim-Breast closely reproduces estimated density-specific risks.

Validation results

Chart 3 compares the age-adjusted incidence rates projected by the density-specific OncoSim-Breast with observed data from the CCR (2010 to 2019),[21] demonstrating that the updated model successfully replicated real-world incidence trends in Canada over this period. Similarly, Chart 4 compares the age-specific incidence rates from the updated model with observed data from the CCR (2010 to 2019), confirming that the model accurately reflects real-world trends across different age groups. In addition, Chart 5 compares the stage distribution of breast cancer cases projected by the density-specific OncoSim-Breast with observed data from the CCR (2010 to 2017).[22,23] Because stage distribution varies by age group, comparisons were made across different age groups. The results indicate that the stage distribution projected by the model closely aligns with the reported data.

Finally, Chart 6 compares the age-adjusted breast cancer mortality rates projected by the density-specific OncoSim-Breast with observed data from the Canadian Vital Statistics – Death database from 2010 to 2019,[26] showing close alignment between model projections and observed mortality patterns.

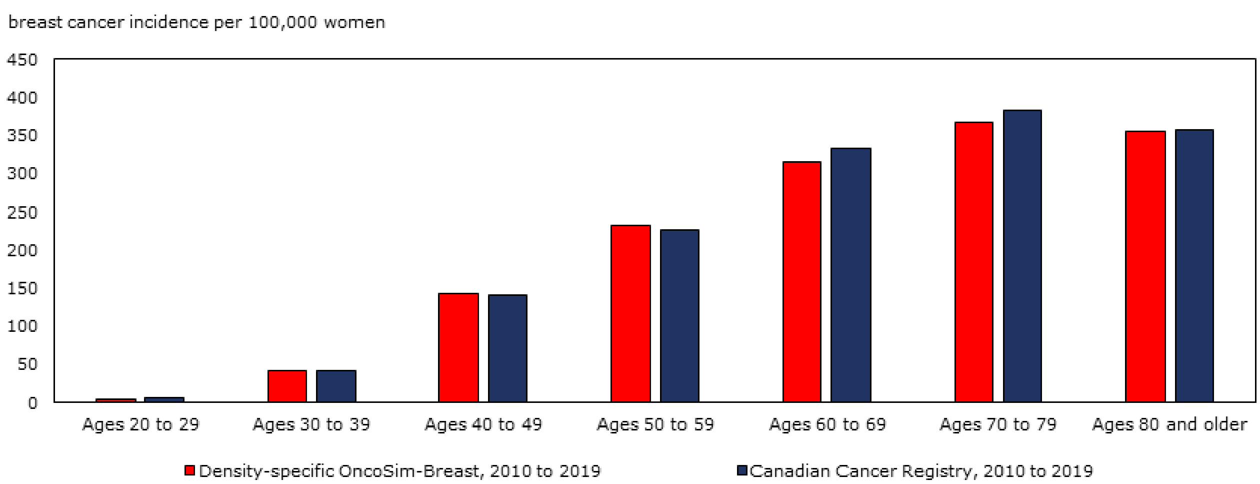
Discussion

This study describes the estimation and integration of key breast density-specific Canadian data into OncoSim-Breast, enhancing its ability to model breast cancer screening outcomes more accurately. Comprehensive comparisons with observed data confirm the reliability of the updated model, which incorporates breast density prevalence, density-specific relative risk of breast cancer, and density-specific digital mammography performance. These enhancements have strengthened OncoSim-Breast's capacity to model the influence of breast density on risk and screening outcomes.

The Canadian breast density prevalence data included in the updated OncoSim-Breast model exhibit similar age-related trends to those observed in other countries, including those in Europe,[27] South Korea,[28] and the United States,[13] as well as to previously reported estimates for Canadian women.[29] Specifically, the prevalence of women with dense breasts (i.e., BI-RADS categories C and D) declines with age, and category D (extremely dense) is consistently less common than Category C (heterogeneously dense) across all age groups. For example, among women younger than 50, the proportion with Category C density is 47% in the United States versus 46% used in this update, 39% versus 33% at ages 50 to 59, 33% versus 26% at ages 60 to 69, and 29% versus 23% at ages 70 and older.[13] Similarly, the proportions of women with Category D density in the United States and in the prevalence data used to update OncoSim-Breast were 15% and 12%, respectively, among women younger than 50 years, 8% and 7% at ages 50 to 59, 5% and 4% at ages 60 to 69, and 3% in both cases at ages 70 and older.[13]

To the authors' knowledge, no previous study has reported density-specific estimates for the sensitivity of mammography

Chart 4
Comparison of age-specific breast cancer incidence from density-specific OncoSim-Breast projections and the Canadian Cancer Registry, 2010 to 2019

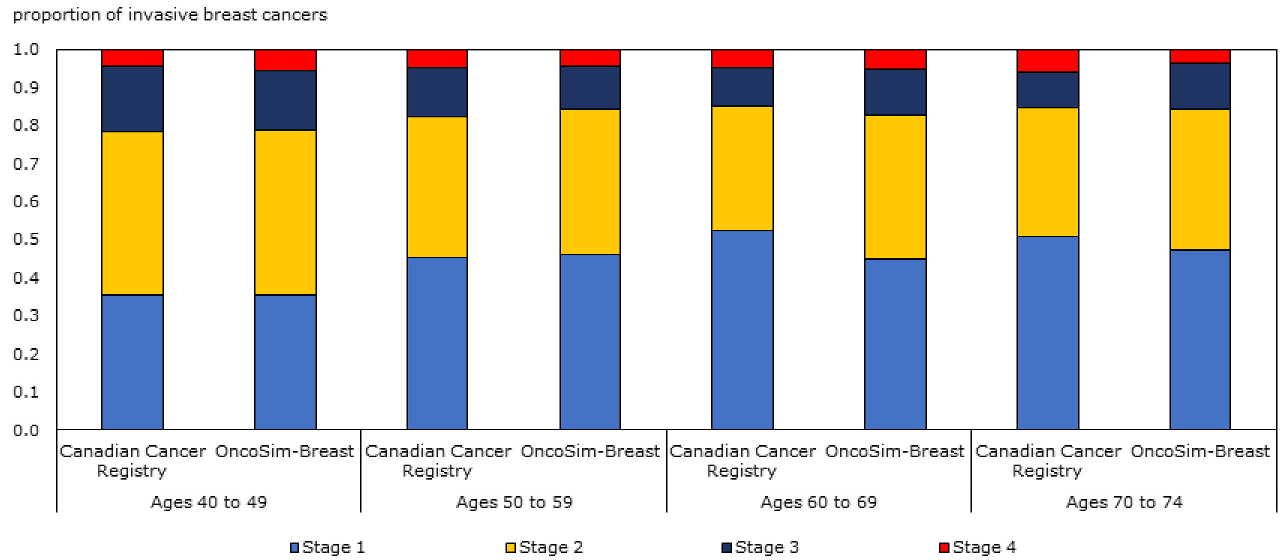


Source: Authors' calculations using OncoSim-Breast and data from the Canadian Cancer Registry.

from multiple provinces in Canada; therefore, a direct comparison of the estimates in this article is not possible. Previous studies using screening data from British Columbia[29] and Ontario[30] found that mammography sensitivity declines as breast density increases, and this is consistent with the estimates in this study. Estimated sensitivity values from provincial data in Canada also follow similar trends with those observed in the United States.[11]

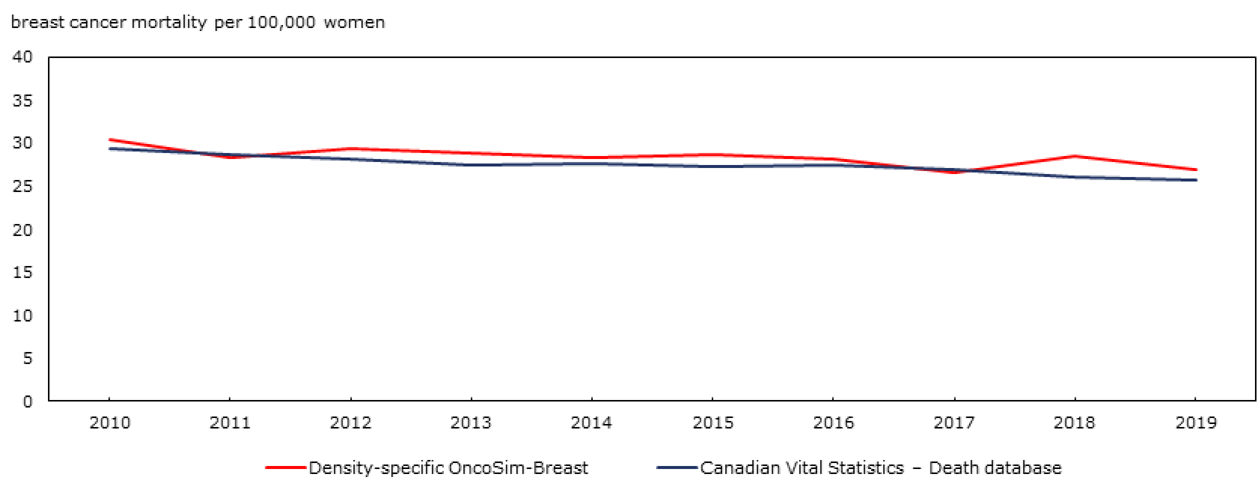
The increased risk of breast cancer and reduced accuracy of digital mammography in women with denser breasts have prompted growing interest in supplemental imaging modalities for use in breast cancer screening.[7] However, the role of supplemental screening remains controversial. There is no consensus on which technologies should be routinely recommended, which subgroups of women should be targeted, or how these approaches should be evaluated in terms of cost and effectiveness. Evidence from randomized control trials, such as the DENSE (Dense Tissue and Early Breast Neoplasm Screening) trial, demonstrates that supplemental MRI screening for women with extremely dense breasts can substantially reduce interval cancers.[31,32] Similarly, ultrasound has also been reported to improve cancer detection rates in women with denser breasts.[33] However, these modalities may also increase

Chart 5
Comparison of stage distribution from density-specific OncoSim-Breast projections and the Canadian Cancer Registry, by age group, 2010 to 2017



Source: Authors' calculations using OncoSim-Breast and data from the Canadian Cancer Registry.

Chart 6
Comparison of age-adjusted breast cancer mortality from density-specific OncoSim-Breast projections and the Canadian Vital Statistics – Death database, 2010 to 2019



Source: Authors' calculations using OncoSim-Breast and data from the Canadian Vital Statistics – Death database.

recall rates, unnecessary biopsies, patient anxiety, and healthcare system burden.[34,35] Issues of access, cost effectiveness, and equity further complicate implementation. As such, additional evidence is needed to determine which women are most likely to benefit from supplemental screening and to support the development of risk-stratified guidelines that balance benefits, harms, and resource constraints. The current work, by more accurately representing breast cancer risk and digital mammography performance in this population by density categories, provides an essential first step in equipping OncoSim-Breast to make estimates that inform policy questions related to population screening for women with varying breast densities.

A major limitation of the present study is that model updates were compared with targets derived from only five provinces. In addition, variations in data quality and content, such as how breast density is categorized, may exist across jurisdictions. Furthermore, although the density-specific inputs were successfully integrated into OncoSim-Breast and validated internally, no primary national-level data stratified by BI-RADS breast density were available to support external validation. This remains an important area for future research. Moreover, this study used national-level screening participation assumptions because the modelling update was intended to represent national breast cancer data. Extending the model to province-specific applications will require calibration using province-specific participation estimates. This work is left for future research.

In conclusion, this study describes the integration of breast density-specific data from Canada into the OncoSim-Breast model. The updated model provides a validated, breast density-informed tool to support decision-making by Canadian screening programs and policymakers. Its outputs closely align with observed cancer trends, enhancing its utility for evaluating screening policies that account for breast density.

Acknowledgements

The authors thank the members of the Canadian Breast Cancer Screening Network, including Greg Doyle (Chair), Shari Dworkin, Brian Chan, and Caitlyn Timmings from the Canadian Partnership Against Cancer, for their valuable comments that helped improve this manuscript. The authors also acknowledge the contributions of screening programs that provided crucial data from various Canadian provinces, as well as John Hutchinson from the University of Calgary for his assistance with the numerical experiments. Oguzhan Alagoz was supported in part by the National Institutes of Health under National Cancer Institute Grant U01CA253911.

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