False-positive Screening Mammograms and Biopsies Among Women Participating in a Canadian Provincial Breast Screening Program

Andrew J. Coldman, PhD, Norman Phillips, MSc

ABSTRACT

Background: Mammography screening results in false positives that cause anxiety and utilize scarce medical resources for their resolution. Determination of screening recommendations requires knowledge of the population risk of false positives.

Methods: Data were extracted from the Screening Mammography Program of British Columbia and analyzed to determine the influence of personal factors including age, ethnic group and screening history, and the centre where screening was performed, on the likelihood a new screen would result in a false positive and whether a biopsy was required. The resulting probabilities were combined to provide values for lifetime screening algorithms.

Results: Age, screen sequence number, history of previous abnormal screens and centre where screening was performed were significantly related to the likelihood a new screen would be a false positive. British Columbia women screened biennially between the ages of 50 and 69 have a projected 41% chance of a false-positive screen and a 5.6% risk of a related biopsy, with the best performing centres having rates of 26% and 3%, respectively.

Interpretation: Model projections for BC overall are comparable to other North American estimates. Estimates varied depending upon screening centre attended.

Key words: Mass screening; mammography; sensitivity and specificity; breast neoplasms

La traduction du résumé se trouve à la fin de l'article.

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Mammography screening is performed to identify asymptomatic disease in order to initiate early treatment and reduce the risk of death from, and other associated complications of, breast cancer. Mammography screening may also result in harms, including false-positive (FP) screening results, over-diagnosis with associated treatment and radiation-induced cancers.[1,2] Screening guidelines weigh harms and benefits in making recommendations.[3,4] Population-based estimates of the likelihood of benefits and harms are a key component in developing such recommendations.[5]

Different jurisdictions have varying mammography screening abnormal call rates,[5,6] which is primarily the result of variation in FPs. Research has demonstrated that individual radiologists differ significantly in their abnormal call rates.[7-9] It would therefore be anticipated that the likelihood of experiencing a FP will vary both between and within jurisdictions.

A factor influencing the impact of a FP will be the timing and nature of follow-up tests. Most FPs may be resolved with imaging alone, but some will require tissue assessment. The experience of an abnormal mammogram, regardless of the method of resolution, leads to some anxiety in most women.[10]

The Screening Mammography Program of British Columbia (SMPBC) provides screening mammography to the British Columbia population through centres and mobile services. Radiologists performing screening within the SMPBC are credentialed with the program and must demonstrate appropriate performance on a blinded test set before being permitted to screen. Radiologists are also required to be associated with at least one screening centre which will enable them to maintain an annual volume of 1,500 screen interpretations. Women aged 40-79 without a history of breast cancer are able to self-refer for screening and book an appointment. Participants aged 40-49 are reminded to return annually. All women aged 50-79 are reminded to return biennially but are permitted to initiate a new appointment 1 year after a preceding screen. Women outside this age range may be screened if referred by their family physician. Letters of first invitation are sent to women at age 50 if they have not previously participated.[11] Follow-up of an abnormal screening mammogram is performed within the general medical system and not by the SMPBC. Within SMPBC, there is no ability to recall women earlier than their routine screening interval. Data on follow-up of abnormal screening results are available through ongoing linkage with the provincial medical services plan in BC.

The primary objective of this research was to predict the cumulative risk of FPs or false positives requiring biopsy (FPB) for different lifetime screening recommendations (LSR) as defined by the age range of eligibility and frequency of screening (annual or biennial) for the population. In order to do this, an analysis was conducted of the impact of select factors, available at screening appointments, on the likelihood that a screening episode will result in a FP and the likelihood that the FP will require biopsy resolution. The results of these analyses are used to form predictive models of the probability that a screening episode would result in a FP or FPB and then used to predict the cumulative risks of multiple screening episodes as prescribed in a LSR.

Author Affiliations

Cancer Surveillance and Outcomes, Population Oncology, BC Cancer Agency, Vancouver, BC

Correspondence: Andrew Coldman, BC Cancer Agency, #800 – 686 W Broadway, Vancouver, BC V5Z 1G1, Tel: 604-877-6143, Fax: 604-660-3645, E-mail: acoldman@bccancer.bc.ca

Conflict of Interest: One of the authors (AJC) previously held an administrative position within the Screening Mammography Program of BC and both authors are employed by the BC Cancer Agency which manages this program.

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Table 1. Distribution of Screens and Outcomes in the Study Sample

Factor	Level	Number of Screens	Number of False Positives (FP)	Proportion of FPs (%)	Number of Biopsied FPs	Proportion of Biopsied FPs (%)
First screen – Age (years)	40-49	184,014	26,552	14.43	2970	1.61
	50-59	60,640	9622	15.87	1179	1.94
	60-69	23,305	3288	14.11	378	1.62
	70-79	8717	1045	11.99	118	1.35
Subsequent screens – Age	40-49	490,069	30,687	6.26	2214	0.45
	50-59	492,321	27,028	5.49	2413	0.49
	60-69	346,142	16,544	4.78	1579	0.46
	70-79	204,423	8965	4.39	884	0.43
Screen sequence	1	276,676	40,507	14.64	4645	1.68
	2	214,064	13,446	6.28	1003	0.47
	3	224,274	13,551	6.04	1098	0.49
	4-5	402,428	22,498	5.59	1861	0.46
	6-10	576,600	28,703	4.98	2651	0.46
	11-15	108,648	4747	4.37	458	0.42
	16+	6941	279	4.02	19	0.27
Interval between screens for ages 40-49	10-17 months	418,264	25,527	6.10	1811	0.43
	18-29 months	71,805	5160	7.19	403	0.56
Interval between screens for ages 50-79	10-17 months	260,058	13,146	5.06	1133	0.44
	18-29 months	782,828	39,391	5.03	3743	0.48

MATERIAL AND METHODS

Data were extracted for the period from January 1, 2000 to December 31, 2009 in women aged 40-79 attending any of 22 SMPBC centres, excluding mobiles, where screening mammography was performed throughout the period. Cases of breast cancer were identified through linkage between the SMPBC database and the British Columbia Cancer Registry (BCCR).

The following data were extracted from the linked data for each subject: public health plan identifier (PHN), subject-recorded ethnicity and educational attainment, date of birth; and for each screen: screening centre, sequence number, and result of the screen. Screens where further investigation was recommended were classified as true positives if breast cancer (invasive or in-situ) was diagnosed within 6 months, otherwise they were classified as FP. Subsequent tests after a FP were classified by the procedures used: if surgery or a core or open biopsy was performed, it was classified as requiring biopsy (FPB).

For each screening episode, the outcome was: no false-positive (NFP), false positive not requiring biopsy (FPA) and FPB. Statistical analyses of first and subsequent screens were conducted separately. Subsequent screens were categorized by time since preceding screen as annual (10-17 months) or biennial (18-29 months) and number of earlier screens, including those performed prior to 2000. All analyses of screening episodes included: patient identifier, age, ethnic group (European, First Nations or Asian), education level (not graduated high school, graduated), screening centre and outcome. Analysis of first screens also included self-reported preceding non-program mammography (yes/no). Analysis of subsequent screens also included screening interval, number of earlier screens, outcome of preceding screening episode and outcome of earlier screening episodes (no false positives, one or more false positives but no biopsies, one or more false positives requiring biopsy). Analysis of first screens was undertaken for women aged 40-69: one with the binary outcome of FP v NFP and one of FPB v NFPB (=NFP or FPA). General Linear Mixed (GLM) models[12] were used to develop the predictive model and included covariates as fixed effects and screening centre as a random effect with normal distribution of mean zero and unknown variance. The same approach was used for analysis of subsequent screens for ages 40-79. MCMCglmm[13] was used to obtain confidence intervals for the screening centre random effect.

Commonly proposed LSR were used as scenarios for the calculation of cumulative risk and expected numbers of false positives and false positives requiring biopsy. A Markov chain (MC) approach was used whereby the probability of being in a state was updated at each screening episode of the LSR being modeled. The result of the earlier modeling of the likelihood of FP and FPB resulting from a single screening episode was used to specify probability of transitions between states of the MC. Withdrawal of women due to death or diagnosis of breast cancer between screens was modeled using population age-specific mortality and breast cancer incidence rates for the period 2000-2009: other sources of drop out were not included. The starting point for the MC calculation was age 40 for all cases, irrespective of whether screening began at that age in the LSR being considered. Calculation continued up to age 79 for each LSR.

Ethical approval for the conduct of this study was provided by the University of British Columbia – British Columbia Cancer Agency (BCCA) Research Ethics Board. Support was provided by Cancer Surveillance and Outcomes, BCCA.

RESULTS

There were 580,669 women aged 40-79 who had study-eligible screening episodes; of these, 27,040 (4.7%) did not provide consent for the collection of follow-up data and therefore were not included. Of the 1,809,631 eligible screens, 276,676 were first screens and the maximum number of screens on any individual was 22. There were 123,731 false positives with the following final assessment procedures: 11,735 had a core or open biopsy, 4,497 had fine needle aspiration, 105,056 had imaging assessment alone, 542 had a physician consult only and 1,901 had no follow-up recorded. Among the women included, 480,940 (87%) had all their screens performed at a single centre, 66,079 (12%) at two centres and 6,610 (1%) at three or more centres. Of the 225,917 women who had four or more screens performed within the study period, 177,465 (79%) had them all performed at a single centre.

All centres used conventional mammography at study start year 2000; by the end of 2009, five sites had converted to digital technology, with the first converting in 2006. Three percent of all study screens were performed in digital format. Four centres contributed <50,000 study screens, 10 contributed 50-100,000 and 8 contributed >100,000. Of the 91 radiologists who interpreted screens in

Figure 1a. Scatterplot of false-positive rates and 95% confidence bars for first and subsequent screens by screening centre

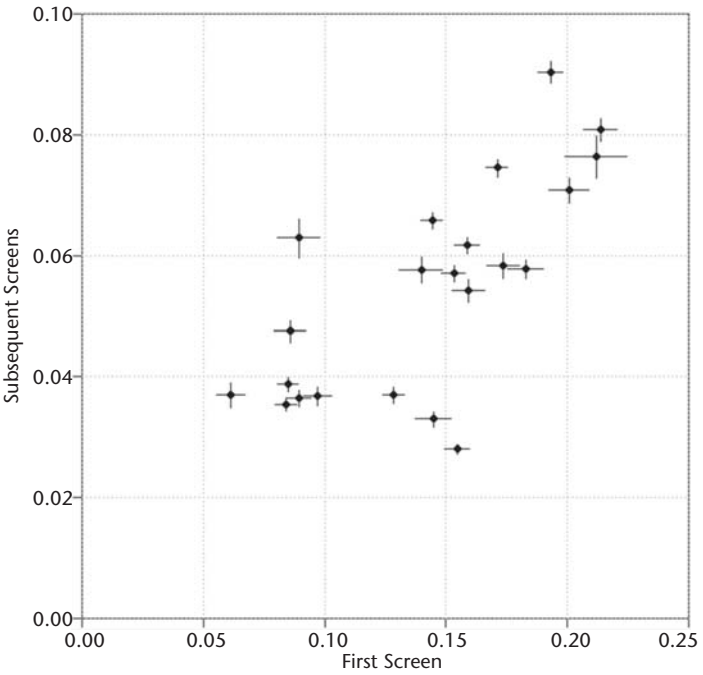
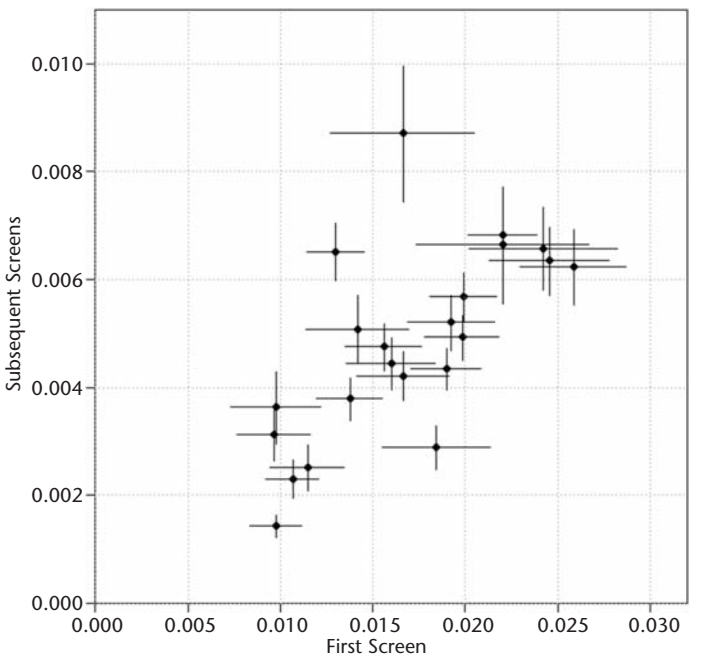


Figure 1b. Scatterplot of false-positive associated biopsy rates and 95% confidence bars for first and subsequent screens by screening centre



the study data, 44 interpreted at only one centre, 33 at two centres and 14 at three or more centres. Twenty-four radiologists interpreted <10,000 study screens, 26 interpreted 10,000-20,000, 38 interpreted 20,000-50,000 and 3 interpreted >50,000.

Table 1 provides the distribution of the screens used in the analysis. The distribution of age at first screen was bi-modal at ages 40-41 (23.8%) and 50-51 (8.3%), corresponding to the ages of first eligibility and postal invitation, respectively. The overall rate of false positives was 14.6% for first and 5.4% for subsequent screens: the corresponding proportions undergoing biopsy were 1.68% and 0.46%, respectively. False-positive (Figure 1a) and biopsy (Figure 1b) rates varied across centres and these differences were statistically significant, as is indicated by the confidence intervals for the centre-specific rates.

Examination of the data on subsequent screens revealed that the rates of FPs decreased with increasing preceding screens, making it important to include this factor in the analyses. Less than 7,000 screens were performed in women with a history of 15 or more preceding screens (Table 1). In order to estimate the cumulative rates of LSR which prescribed annual screening, estimates would be required for screening episodes with 20 or more preceding screens. To accommodate this need, it was necessary to be able to extrapolate the effect of the number of preceding screens: a logarithmic function was chosen that fit the available data.

GLM models were fit with different levels of interaction between the factors. Many interactions were significant, however the predicted probability of a false-positive outcome did not differ by more than 1% between the models examined and a model consisting of first-order effects alone (Tables 2a and 2b) which was selected for use. For education, ethnic group, and screening-centre effect, the relationship to false-positive outcomes was similar for first and subsequent screens (Tables 2a and 2b); for age, it differed with lower rates seen in women 40-49 for first screens (Table 2a) whereas rates declined with age for subsequent screens (Table 2b). Women with a self-reported history of mammography before their first screen had lower rates of false-positive outcomes than women without a history (Table 2a). For subsequent screens, the likelihood of a false-positive outcome increased with interval length and decreased with number of earlier screens (Table 2b). A history of a FP or a FPB on the preceding or earlier screen increased the likelihood of a FP at a screening episode to a similar degree (Table 2b). A history of a FPB at preceding or earlier screens had a stronger relationship to a FPB than to a FP (Table 2b).

The fitted parameters from Tables 2a and 2b were used to project the probabilities of a false-positive screen and biopsy for selected LSR. The screening scenarios considered are provided in Table 3, which also provides the projected outcomes for women following these scenarios. Table 3 further provides ranges in the quantities corresponding to the projected 90% range in results across centres, assuming continued attendance at the given centre throughout the screening period.

DISCUSSION

British Columbia has had the longest-operating (established in 1988) breast screening program in Canada, and had the lowest proportion of non-program screening utilization among the seven provinces reported in 2005-6.[14] Of all provincial screening programs, BC's allows the widest age group (40-79) to participate. This provides an opportunity to estimate the likelihood of false-positive results; those presented here are the first long-term results for a Canadian screening program. Nevertheless, predicting cumulative false-positive rates for algorithms where more than 15 screens are included relied upon model extrapolation[15] and assumptions about the representativeness of those who have attended screening.[16]

Women experiencing a positive screening mammogram suffer anxiety which can persist beyond resolution of a false positive.[10] False-positive screening results are the most common of the poten-

Table 2a. Odds Ratios (OR) With Confidence Intervals (95% CI) From Model Fitting to False-positive and Biopsy Outcomes of First Screens

		Outcome			
		False Positive		Biopsy (FPB)	
Factor	**Level**	**OR**	**95% CI**	**OR**	**95% CI**
Age (years) (Baseline: 40-49)	50-59	1.15	1.12-1.18	1.27	1.18-1.36
	60-69	1.03	0.99-1.08	1.08	0.97-1.21
Education (Baseline: Non-high school graduate)	High school graduate	1.04	1.01-1.07	1.04	0.96-1.13
Ethnicity (Baseline: European)	South & East Asian	0.83	0.80-0.85	0.89	0.82-0.96
	First Nations	0.98	0.88-1.10	0.94	0.69-1.27
Preceding non-SMPBC mammography (Baseline: No)	Yes	0.87	0.85-0.90	0.85	0.78-0.92
Centre	1 Standard Deviation	1.51	1.35-1.76	1.35	1.23-1.53

Table 2b. Odds Ratios (OR) With Confidence Intervals (95% CI) From Model Fitting to False-positive and Biopsy Outcomes of Subsequent Screens

		Outcome			
		False Positive		Biopsy (FPB)	
Factor	**Level**	**OR**	**95% CI**	**OR**	**95% CI**
Age (years) (Baseline: 40-49)	50-59	0.87	0.85-0.88	1.00	0.93-1.07
	60-69	0.77	0.75-0.79	0.93	0.86-1.01
	70-79	0.72	0.70-0.75	0.91	0.83-1
Preceding screening interval length (Baseline: <18 months)	18-29 months	1.08	1.06-1.1	1.2	1.13-1.27
Previous result (Baseline: No false positives)	False positive	1.43	1.4-1.47	1.45	1.33-1.58
	Biopsy	1.49	1.38-1.61	3.0	2.51-3.58
Earlier result: (Baseline: No false positives)	False positive	1.53	1.5-1.56	1.64	1.54-1.73
	Biopsy	1.62	1.55-1.70	2.57	2.3-2.88
Natural logarithm of sequence number	Unit change	0.83	0.82-0.85	0.85	0.80-0.91
Education (Baseline: Non-high school graduate)	≥High school graduate	1.06	1.04-1.08	1.07	1.01-1.13
Ethnicity (Baseline: European)	South & East Asian	0.79	0.77-0.81	0.82	0.77-0.89
	First Nations	0.92	0.84-1.02	1.31	1.00-1.72
Centre	1 Standard Deviation	1.38	1.3-1.61	1.47	1.35-1.76

tial harms of breast screening, and thus an appreciation of their magnitude is important when considering breast screening recommendations. However, an abnormal screening finding infrequently results in a recommendation for biopsy as the next step and is usually resolved with another non-invasive imaging. Approximately one in ten women with an abnormal screen will have a biopsy with no cancer detected. Where biopsy is required, core biopsy is increasingly used as it offers accuracy and is less invasive than open biopsy. However, the increased availability of core biopsy may carry the hazard of increased use of biopsy as its perceived risks have diminished. Rapid resolution of abnormal screening results is a key strategy to reducing harm in the majority of women. In Canada, targets for time to resolution are typically long and, in a recent national report, were not met by any provincial screening program.[14]

When estimating the magnitude of extra testing using data from screening episodes, as has been presented here, no data are included on the use of such tests in comparable women not participating in screening. Also the effect of screening participation on the use of breast diagnostic imaging and biopsy not caused by a positive screen is not identified. These two influences can be expected to alter the net contribution of breast screening to diagnostic testing.

Our findings indicate that annual screening has between 50%-70% more false positives and biopsies than biennial screening over the same age range. That annual rates are not doubled results primarily from the lower false-positive rates per screening episode for 1-year versus 2-year screening intervals. However, without proven benefits from annual screening compared to biennial screening,[3] the increased false-positive results entailed make it contraindicated.

Screening women aged 40-49 has attracted a lot of attention in the professional and lay media. Recent evidence reviews of randomized trials indicate that such women randomized to receive screening enjoy about 15% lower breast cancer mortality rates than women randomized not to receive mammography.[3] The effect of including screening in this age range can be seen by subtracting the results of screening women 50-79 from those for screening women 40-79, as presented in Table 3. As may be anticipated, the increase in the total number of screens increases the average number of false positives, although the effect on the likelihood of ever having a false positive was less marked. False-positive rates per screening episode vary by age, with rates being highest for women 40-49 for subsequent screens but lowest for first screens. The reason for the unexpected finding that first-screen FP rates are lowest in women 40-49 is not clear.

The results of these analyses predict that a woman screened biennially between the ages of 50 and 69 has a 41% chance of a false-positive screen and her risk of a screening-related biopsy is 5-6%. These results differ slightly from predictions from some US models, which have higher predicted false-positive rates and lower biopsy rates.[5] As is common, our calculations assume that women comply with the designated algorithm. As could be anticipated, the number of screens performed is the major determinant of a false-positive screen and associated biopsy, therefore these events increased with more frequent screening and wider age eligibility.

The variation in rates between screening centres was considerable. Centre differences could arise from differences in the populations served, however we did attempt to minimize this by controlling for screening history as well as for ethnic group and educational level of women attending screening. Although other participant factors have been associated with false-positive mammograms, the largest identified effect is due to performance variability among interpreting radiologists.[17] We found that the relative variation between centres on FP rates was not significantly different from that for FPB rates and that high FP rates were associated with high FPB rates. Given that only a FP can have a FPB, this does not seem remarkable, but it does indicate that there is no compensating effect at diagnostic imaging that ameliorates increased rates of false positives among centres. However, this also indicates that decreasing the rate of FP should bring proportional reductions to the rate of biopsies. Dutch research suggests that recall rates

Table 3. Projected Cumulative Risk of a False Positive and Associated Biopsy and the Expected Number of False Positives and Associated Biopsies for Selected Screening Algorithms With 90% Percentile Range Across Screening Centre Distribution*

Screening Algorithm: Frequency and Age Range (years)	Cumulative Risk		Expected Number	
	False Positive	Biopsy	False Positive	Biopsy
Annual 50-69	0.55 (0.37-0.74)	0.081 (0.043-0.15)	0.93 (0.52-1.7)	0.088 (0.045-0.18)
Biennial 50-69	0.41 (0.26-0.6)	0.056 (0.03-0.1)	0.56 (0.32-0.99)	0.059 (0.031-0.11)
Annual 50-74	0.6 (0.41-0.78)	0.093 (0.049-0.18)	1.1 (0.6-1.9)	0.1 (0.052-0.21)
Biennial 50-74	0.45 (0.29-0.64)	0.065 (0.035-0.12)	0.66 (0.37-1.2)	0.07 (0.037-0.14)
Annual 50-79	0.63 (0.44-0.8)	0.1 (0.055-0.19)	1.2 (0.66-2.1)	0.12 (0.058-0.24)
Biennial 50-79	0.48 (0.31-0.67)	0.07 (0.038-0.13)	0.72 (0.4-1.3)	0.076 (0.039-0.15)
Annual 40-79	0.74 (0.55-0.89)	0.13 (0.07-0.25)	1.7 (0.94-3)	0.15 (0.075-0.32)
Biennial 40-79	0.57 (0.39-0.76)	0.088 (0.046-0.17)	0.98 (0.55-1.7)	0.097 (0.049-0.2)

* Model predictions are averaged over education, ethnicity, and bilateral mammography preceding first SMPBC screen.

exceeding 4% for subsequent screens do not substantially improve the sensitivity of screening.[18] Figure 1a indicates that 9 of the 22 centres currently perform close to a 4% rate. If all centres performed in this range, the average risk of a false positive and associated biopsy would be substantially reduced. For example, Table 3 indicates that for biennial screening in women 50-69, reductions of 15 (41-26) FPs and 2.6 (5.6-3.0) BFPs per hundred women would be achieved if the average performance were changed to that of the lower 5th percentile among centres.

This research has shown that the average likelihood of false-positive screening mammograms or associated biopsies in BC is not greatly different from estimates provided for the United States. However, a larger variation exists within BC, and probably Canada, than between the two country averages. Reductions in average rates are possible, as evidenced by variation across individual centres, and should be targeted in order to mitigate a major harm of mammography screening.

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RÉSUMÉ

Contexte : Le dépistage mammographique donne des faux positifs qui causent de l'anxiété et dont la résolution exige le recours à des ressources médicales limitées. La décision de recommander ou non un dépistage nécessite une connaissance du risque de faux positifs dans la population.

Méthode : Nous avons extrait nos données du programme de mammographie de dépistage de la Colombie-Britannique et nous les avons analysées pour déterminer l'influence des facteurs individuels, dont l'âge, le groupe ethnique et les antécédents de dépistage, ainsi que du centre où le dépistage a lieu, sur la probabilité qu'un nouveau dépistage donne un résultat faussement positif et sur la nécessité d'une biopsie. Les probabilités résultantes ont été combinées pour produire les valeurs d'algorithmes de dépistage au cours de la vie.

Résultats : L'âge, le numéro de séquence du dépistage, les antécédents de dépistages anormaux et le centre où se fait le dépistage étaient significativement liés à la probabilité qu'un nouveau dépistage donne un faux positif. Selon nos projections, les femmes de la Colombie-Britannique dépistées tous les deux ans entre l'âge de 50 et de 69 ans ont une probabilité de 41 % d'avoir un dépistage faux positif et un risque de 5,6 % de subir une biopsie connexe; ces taux sont de 26 % et de 3 %, respectivement, dans les centres les plus performants.

Interprétation : Les extrapolations du modèle à l'ensemble de la Colombie-Britannique sont comparables à d'autres estimations nord-américaines. Les estimations varient selon le centre de dépistage fréquenté.

Mots clés : dépistage de masse; mammographie; sensibilité et spécificité; tumeurs du sein