Report from the
Evaluation Indicators Working Group

Guidelines for Monitoring Breast Screening Program Performance

Second Edition

March 2007

Public Health Agency of Canada
Agence de la santé publique du Canada

Canada

Our mission is to promote and protect the health of Canadians through leadership, partnership, innovation and action in public health.

Public Health Agency of Canada

Ce document est aussi offert en français sous le titre :
Rapport du Groupe de travail sur les indicateurs d'évaluation : Lignes directrices pour la surveillance de la performance des programmes de dépistage du cancer du sein

Paper: HP35-5/2007E 978-0-662-46165-4
PDF: HP35-5/2007E-PDF 978-0-662-46166-1

Report from the
Evaluation Indicators Working Group

Guidelines for Monitoring Breast Screening Program Performance

Second Edition

Acknowledgments

We would like to acknowledge the following contributors:

Present members of the Quality Determinants Working Group (evolving from the Evaluation Indicators Working Group):

- Dr. Diane Major (Chair), Institut national de santé publique du Québec
- Gregory Doyle, Breast Screening Program for Newfoundland and Labrador
- Dr. Nancy Wadden, Breast Screening Program for Newfoundland and Labrador
- Dr. Andy Coldman, BC Cancer Agency
- Norah Smith, PEI Breast Screening Program
- Dr. Penny Barnes, Department of Pathology, Queen Elizabeth II HSC, Nova Scotia
- Dr. Rene Shumak, Cancer Care Ontario
- Christine LeBlanc Bennett, New Brunswick Department of Health
- Christina Bancej, Public Health Agency of Canada
- Sandra Connors, Public Health Agency of Canada
- Barb Kasprowicz, Public Health Agency of Canada
- Jay Onysko, Public Health Agency of Canada

Special thanks go to the following:

- Dr. Diane Major and colleagues, Institut national de santé publique du Québec, for reviewing the French version of the report
- Invited guests to the Quality Determinants Working Group meeting:
  - Chuck Paltiel, BC Cancer Agency
  - Vicky Majpruz, Cancer Care Ontario
  - Dr. Anna M. Chiarelli, Cancer Care Ontario
  - Zeva Mah, Alberta Cancer Board

Table of Contents

Background

Introduction

The principal goal of breast cancer screening is to reduce breast cancer mortality and morbidity. Regular mammography screening for women aged 50 to 69 is expected to prevent approximately one-third of breast cancer deaths 7 to 12 years after sufficient participation (70% of women in the target group) has been achieved[1]. Because reaching a participation rate of 70% among women aged 50 to 69 will be a gradual process, short-term reductions in mortality rates cannot be used to monitor the effectiveness of breast cancer screening. Instead, performance measures related to both the benefits and unwanted effects that are valid, reliable and feasible to collect within the screening program are required for interim evaluation of breast cancer screening. Furthermore, these measures provide a means to monitor the individual steps throughout the entire screening process in order to ensure that the short-term objectives of a successful screening program are met on an ongoing basis. This ensures that screening programs continually strive to increase the benefits of screening while minimizing the negative side effects.

The Report from the Quality Determinants Working Group: *Guidelines for Monitoring Breast Screening Program Performance, Second Edition* will serve as a guide to promote consistent calculation of key performance measures for various monitoring and evaluation efforts across programs and over time. Interim measures used for ongoing evaluation of organized breast cancer screening programs at the national level include participation rate, retention rate, abnormal call rate, cancer detection rate, rate of advanced cancers, tumour size and nodal status (detailed descriptions to follow). Provincial and territorial programs compute additional measures that are not monitored at the national level. The description of each measure includes a definition, the context in which the measure is relevant (rationale), method(s) of calculation, target objectives, the current status of the measure under evaluation, and modification history. The measures presented in this document were developed on the basis of recognized population screening principles, the experiences of professionals working in Canadian breast cancer screening programs, evidence from randomized controlled trials, demonstration projects, and observational studies (see Appendix A for a brief framework of screening principles).

Organized Breast Cancer Screening in Canada

In 1988 a national workshop, consisting of expert representatives from government as well as key professional and voluntary organizations, recommended that women aged 50 to 69 be invited to participate in an early detection program for breast cancer, every two years[2]. In Canada, however, health care delivery is under provincial/territorial jurisdiction; thus, organized screening programs have been developed and implemented independently across the country. The first screening program started in British Columbia, in 1988. Programs have since been established in all provinces and the Yukon and Northwest Territories. Each program varies in their organization, screening modalities, recruitment methods, ages targeted for screening (outside the targeted 50-69 age group), and in the arrangements for diagnostic assessment following an abnormal screen (see Table 1).

To differing degrees, most provinces/territories in Canada provide mammography services to asymptomatic women outside the structure of the organized breast cancer screening programs. It has been estimated that as much as 80% of bilateral mammography provided in this manner is for screening purposes[3]. Referred to as "opportunistic screening", no comparable data are available from screening mammograms conducted outside the structure of the screening programs. Consequently, the benefits and risks of opportunistic screening are unknown.

Table 1
Breast cancer screening programs in Canada[a] – current practices

Province/territory	Program start date	Clinical breast examination on site	Program practices for women outside the 50-69 year age group		
			Age group	Accept	Recall
Northwest Territories	2003	No	40-49 70+	Yes Yes	Annual Biennial
Yukon Territory	1990	No	40-49 70+	Yes Yes	None None
British Columbia	1988	No	<40 40-49 70-79 80+	Yes[b] Yes Yes Yes[b]	None Annual Biennial None
Alberta	1990	No	40-49 70-74 75+	Yes Yes Yes	Annual Biennial None
Saskatchewan	1990	No	40-49 70+	No Yes	N/A Biennial
Manitoba	1995	No	40-49 70+	Yes[c] Yes[c]	Biennial None
Ontario	1990	Nurse[d]	40-49 70-74 75+	No Yes Yes	N/A Biennial None
Québec	1998	No	35-49 70+	Yes[e] Yes[e]	None None
New Brunswick	1995	No	40-49 70+	Yes[b] Yes[b]	None None
Nova Scotia	1991	Technologist[f]	40-49 70+	Yes Yes	Annual None
Prince Edward Island	1998	Technologist	40-49 70-74	Yes Yes	Annual Biennial
Newfoundland and Labrador	1996	Nurse	40-49 70+	No Yes	N/A None

[a] Nunavut has not developed an organized breast cancer screening program.
[b] Accept with physician referral.
[c] Accept to mobile unit with a physician referral.
[d] Nurse provides clinical breast examination where available, but not all sites offer clinical breast examination.
[e] Accept with physician referral if done at a program screening centre, but is not considered within the program.
[f] Modified examination only, performed by technologist at time of mammography.

The Canadian Breast Cancer Screening Database

The Canadian Breast Cancer Screening Database (CBCSD) is a national breast screening surveillance system that permits the monitoring and evaluation of organized breast cancer screening across Canada. The CBCSD, derived from provincial breast screening program data, was developed in 1993 through a collaborative effort of the federal, provincial and territorial governments through the National Committee for the Canadian Breast Cancer Screening Initiative (CBCSI). It contains the data from all 10 provinces from program inception, and is updated every two years, providing consistent data for program evaluation. Data from the Northwest Territories is available in the CBCSD from the end of 2006. Data from the Yukon are not available in the CBCSD. Nunavut has not developed an organized breast cancer screening program.

History of the Evaluation Indicators in Canada

The Evaluation Indicators Working Group (EIWG) was formed in 1999 under the guidance of the National Committee for the CBCSI. The EIWG was comprised of members from both the Quality Determinants Working Group and the National Committee. In February 2000, the seven-member working group held a national workshop to assemble a group of knowledgeable stakeholders from the provinces/territories to refine the available indicators and evaluate their applicability in Canada. The efforts of this workshop resulted in the identification of 30 core performance and quality indicators, target outcomes for some of these indicators, as well as recommendations on practical means to gather and report this data.[4]

The Report from the Evaluation Indicators Working Group: Guidelines for Monitoring Breast Cancer Screening Program Performance documented the first set of guidelines for reporting a key set of "performance indicators"[5]. This second edition of the guidelines has been developed by the Quality Determinants Working Group and invited guests. The objective of this working group is to continually assess and develop performance and quality measures and indicators to fulfill present and future recommendations, with the assistance of members from the Database Technical Subcommittee.

Performance Measure Development

In order to achieve reductions in breast cancer mortality and morbidity and to minimize the unwanted effects of screening, the delivery of organized screening must be of high quality. The performance measures and targets presented in this document were selected on the basis of their utility for assessing program progress toward these goals. The 14 performance measures detailed here generally met the following criteria:

- Data for the measure were regularly available;
- Data available for the measure were of high quality;
- Meaningful targets could be defined on an evidentiary basis*;
- Measures and targets would be useful for national comparison;
- Monitoring on a regular basis would be valuable; and
- Each measure was widely accepted for use in program evaluation.

**No targets were set for in situ cancer detection rate, given the controversy surrounding the natural history of the condition (see Performance Measures under Review in Future Directions).*

Data Sources and Collection

The monitoring of screening programs requires reliable, standardized information that is comparable across provinces. Collaboration with external practitioners and data sources to ensure women obtain appropriate follow-up is part of the services provided by organized breast cancer screening programs. This collaboration, however, presents certain challenges for programs to coordinate and therefore evaluate. The Canadian Breast Cancer Screening Database (CBCSD) is a national breast screening surveillance system that permits the monitoring and evaluation of organized breast cancer screening across Canada. Performance measures are calculated using data from the CBCSD along with routinely available national statistics, and population estimates. Currently, the CBCSD is enabled through the continued collaboration of the provinces and territories and the Centre for Chronic Disease Prevention and Control, Public Health Agency of Canada. Through the Canadian Breast Cancer Screening Initiative, the CBCSD is managed by the Database Management Sub-Committee (DMC) and implemented by the Database Technical Subcommittee.

Many, but not all, programs are directly linked to their provincial cancer registries so that cancer outcome data can be obtained. Further complicating the evaluation process, some programs experience delays in obtaining registry data. In addition, analyses have suggested that prognostic data vary from one program to another because of the different ways in which breast tumours are assessed and staged. This must be taken into account when the results of the performance measures across programs are integrated and compared.

Application

Through its monitoring and reporting role, the DMC of the National Committee for the CBCSI produces a routine biennial report: *Organized Breast Cancer Screening in Canada*[6]*.* The purpose of this report is to provide formal feedback to the programs regarding their relative performance and to assess the national picture. The approach to standardized performance assessment established in this document will serve as a consistent template for reporting progress over time, as well as providing a set of targets for programs to strive toward.

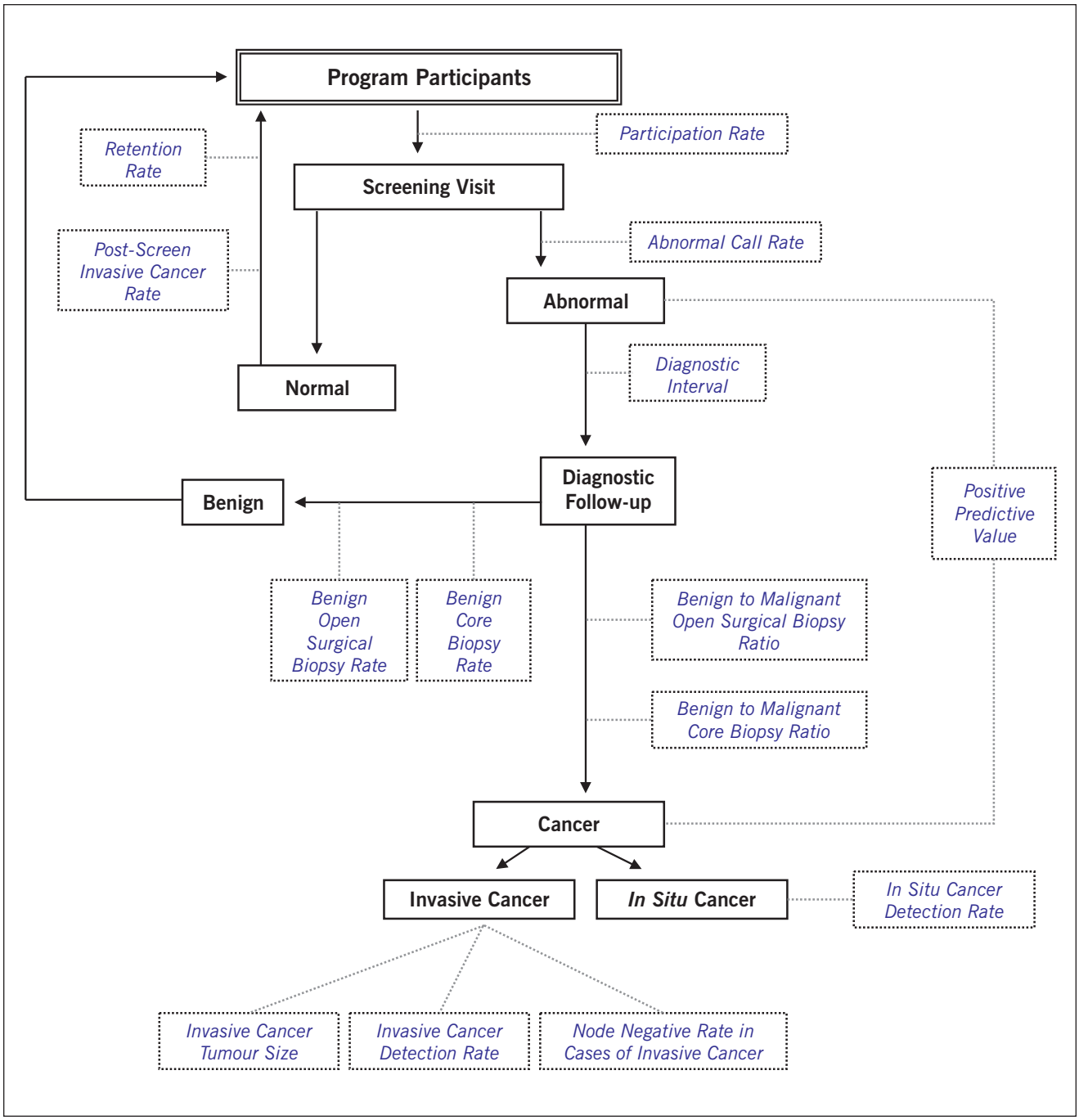
Context of Performance Measures

For the purposes of these guidelines for reporting performance measures, the target population for evaluation is the same as the national target population for organized screening. This population is defined as asymptomatic women between the ages of 50 and 69 years with no prior diagnosis of breast cancer.

The targets and standards established in this document are intended to apply to the programs' target group as a whole. It is recognized, however, that for some evaluation purposes it may be appropriate to further stratify the target group in terms of demographic characteristics, screening history, or referral of abnormal result by modality. When measures are used for comparison among Canadian programs or with programs in other countries, it may be necessary to age-standardize the results using the appropriate population as the standard.

Many of the performance measures presented here only provide meaningful measures of program progress when considered in a broader context. In some cases, meeting ideal targets involves achieving a balance rather than continually working to increase or decrease a particular rate or measure. For example, while increased participation and retention will always be desirable, targets set for measures such as positive predictive value and biopsy yield ratio are set with the realization that we must tolerate some false-positive results in order to maximize cancer detection. At the same time, performance measures and targets are not necessarily meaningful on their own, and must be considered in relation to each other and (in some circumstances) in relation to other relevant data. For instance, the cancer detection rate must be considered in relation to the underlying cancer incidence rate in the general population before programmatic screening was implemented. An illustration to clarify the relations among the performance measures is presented in Figure 1.

Figure 1


Program Participants
Participation Rate
Retention Rate
Screening Visit
Abnormal Call Rate
Post-Screen Invasive Cancer Rate
Abnormal
Diagnostic Interval
Normal
Diagnostic Follow-up
Benign
Positive Predictive Value
Benign Open Surgical Biopsy Rate
Benign Core Biopsy Rate
Benign to Malignant Open Surgical Biopsy Ratio
Benign to Malignant Core Biopsy Ratio
Cancer
Invasive Cancer
In Situ Cancer
In Situ Cancer Detection Rate
Invasive Cancer Tumour Size
Invasive Cancer Detection Rate
Node Negative Rate in Cases of Invasive Cancer

Program Performance Measures

Participation Rate

Definition	Percentage of women who have a screening mammogram (calculated biennially) as a proportion of the eligible population.
Context	In order for a screening program to reduce mortality in a population, that population must participate in the program in sufficient numbers. Many factors can influence the participation rate, such as acceptability, accessibility, promotion of screening and the capacity of a screening program. A participation rate of 70% and over was achieved in trials reporting substantial mortality reductions. Note that program participation rate does not represent all breast cancer screening in Canada. In most provinces "opportunistic screening" occurs outside the structure of the program.
Calculations	$\frac{\text{Number of women screened at least once (per 2-year period)}}{\text{Target population (1st \& 2nd year populations averaged from census/forecast)}} \times 100 = \text{Participation Rate (\%) (biennial)}$
Details	In the case of multiple screens, age at the first screen is the criterion used to determine whether the woman was in the target population. Target population (denominator) should be obtained from the most recent census results and/or population estimates available from Statistics Canada.
Targets	**Canada** ≥ **70% of the eligible population (age 50-69).** Europe[7] > 70% of invited women age 50-64 (acceptable level). United Kingdom[8] ≥ 70% of invited women age 50-70 (minimum standard). Australia[9] ≥ 70% of women screened in most recent 24 month period (age 50-69).
Status	33.9% of Canadian women (age 50-69, 2001-2002) received a program screen.[6] Note: From the results of the 2003 Canadian Community Health Survey it is estimated that 60.7% of Canadian women aged 50-69 self reported receiving a (program or non-program) mammogram.[6]
Evidence	Based on basic principles of population screening[10,11]. Extrapolation from the results of randomized controlled trials[12,13].
Modification History	Introduced in 2002. Context updated in 2006.

Retention Rate

Definition	The estimated percentage of women who are re-screened within 30 months of their previous screen.
Context	Optimal benefits of screening are brought about by regular participation in the screening program (at least every 2 years). At present there is no indication that the benefits of screening are lost if re-screening occurs up to 6 months after the recommended interval (i.e., 30 month interval).
Calculations	Actuarial Method for Survival Data $s_t = 1 - p_0 p_1 p_2 \ldots p_t$ where $p_t = 1 - q_t$ $q_t = e_t / n^*_t$ $n^*_t = n_t - \frac{1}{2} c_t$ s_t = the estimated cumulative probability of returning from baseline to the end of the study interval that begins at t; p_t = the estimated probability of not returning during the study interval that begins at time t; q_t = the estimated probability of women returning during the study interval that begins at time t; e_t = the number of women returning in the study interval that begins at time t; n_t = the number of women present at the beginning of the study interval that begins at time t; c_t = the number censored (because of death, breast cancer, or age limit—68 years) during the interval which begins at time t.
Targets	**Canada** **≥ 75% initial re-screen within 30 months;** **≥ 90% subsequent re-screens within 30 months (age 50-69).** Europe[7] > 95% re-invited within specified screening interval (acceptable level) United Kingdom[8] ≥ 90% within 36 months of previous screen (minimum standard) Australia[9] ≥ 75% initial re-screen within 27 months; ≥ 90% subsequent re-screens within 27 months.
Status	68.7% initial re-screen within 30 months; 87.5% subsequent re-screens within 30 months (age 50-69, 2001-02)[6]. <u>Broken down by age groupings:</u> 67.8% initial re-screen within 30 months; 89.6% subsequent re-screen within 30 months (age 50-59, 2001-02)[6]. 71.8% initial re-screen within 30 months; 89.3% subsequent re-screen within 30 months (age 60-69, 2001-02)[6].
Evidence	Related to participation rate, sojourn time, screening interval studies[14], and randomized controlled trials[12,13].
Modification History	Introduced in 2002. Targets modified in 2006.

Abnormal Call Rate

Definition

Percentage of women screened who are referred for further testing because of abnormalities found with a program screen.

Context

Abnormal call rate is a meaningful indicator when considered in the context of positive predictive value and cancer detection rate. Also, relative to the underlying breast cancer incidence rate, it is an indicator of the quality of mammography image or interpretation. Abnormal call rate will generally be higher for first-time screens (which detect prevalent cancers) than for re-screens.

Calculations

$$\frac{\text{Number of recalls due to abnormal screens}}{\text{Number of women screened}} \times 100 = \text{Abnormal Call Rate (\%)}$$

Targets

Canada	< **10% (initial screen)** < **5% (subsequent screens) (age 50-69).**
Europe[7]	< 7% (initial screen); < 5% (subsequent screens) (age 50-64) (acceptable level).
United Kingdom[8]	< 10% (initial screen); < 7% (subsequent screens) (age 50-70) (minimum standard).
Australia[9]	< 10% (initial screen); < 5% (subsequent screens) (age 50-69).

Status

Abnormal recall rates by mode of detection, 2001 and 2002 screen years[6]

Mode of Screening		Age 50-69 (%)
Abnormal by mammography	Initial screen	12.0
	Subsequent screens	6.6
Abnormal by mammography and/or CBE	Initial screen	13.1
	Subsequent screens	7.4

Evidence

Measured in randomized controlled trial.[12]

Modification History

Introduced in 2002.

Invasive Cancer Detection Rate

Definition	Number of invasive cancers detected per 1,000 screens.
Context	Cancer detection rate is meaningful for program evaluation when considered in relation to the abnormal call rate, post-screen cancer detection rate, and the underlying breast cancer incidence rate. The cancer detection rate in an organized screening program should generally exceed the cancer incidence rate in the population prior to organized screening, because some cancers would remain asymptomatic in the absence of screening. As screening programs become more established, the incidence rate will decrease. Cancer detection rates will generally be higher for initial screens (which detect prevalent cancers) than for re-screens. Women screening before the age of 50 and women receiving extra "opportunistic screening" outside the programs will reduce the invasive cancer detection rates as well.
Calculations	$\frac{\text{Number of invasive cancers detected}}{\text{Number of screens}} \times 1000 = \text{Invasive Cancer Detection Rate per 1,000}$
Targets	**Canada** > **5.0 per 1,000 (initial screen);** > **3.0 per 1,000 (subsequent screens) (age 50-69).** Europe[7] 90% of total screen detected cancers United Kingdom[8] > 2.7 per 1,000 (initial screen); > 3.1 per 1,000 (subsequent screens) (age 50-70) (minimum standard). Australia[9] > 5.0 per 1,000 (initial screen); > 3.5 per 1,000 (subsequent screens) (age 50-69).
Status	**Invasive cancer detection rates per 1,000 screens, 2001 and 2002 screen years[6]**

Mode of Screening		Age 50-69 (%)
Detected by mammography alone	Initial screen	4.9
	Subsequent screens	3.8
Detected by mammography and/or CBE	Initial screen	5.0
	Subsequent screens	3.9

NOTE: 2001 population incidence rate for invasive cancer is 2.7 per 1,000 women (50-69 years).[15]

Evidence	Based on randomized controlled trials[12,13], and the experience of other breast cancer screening programs[8,9].
Modification History	Introduced in 2002. Context modified in 2006.

In Situ Cancer Detection Rate

Definition	Number of ductal carcinoma *in situ* cancers (rather than invasive cancer) during a screening episode per 1,000 screens.
Context	*In situ* carcinoma is a heterogeneous disease and not all cases of *in situ* carcinoma will progress to invasive carcinoma. *In situ* cancer detection may be interpreted as an indicator of screening quality when considered in relation to the cancer detection rate and underlying cancer incidence rate.
Calculations	$\frac{\text{Number of } \textit{in situ} \text{ cancers detected}}{\text{Number of screens}} \times 1000 = \textit{In Situ}$ Cancer Detection Rate per 1,000
Targets	**Canada** — **Surveillance and Monitoring Purposes Only** (see Future Directions) United Kingdom[8] ≥ 0.4 per 1,000 (initial screen); ≥ 0.5 per 1,000 (subsequent screens) (minimum standard). Australia[9] 1.2 per 1,000 (initial screen); 0.7 per 1,000 (subsequent screens).
Status	1.2 per 1,000 (initial screen); 1.0 per 1,000 (subsequent screens) (age 50-69, 2001-2002).[6]
Evidence	It seems inappropriate to set targets for DCIS given the heterogeneity of this disease and the current paucity of evidence concerning the transition of all forms of DCIS to invasive cancer and the continually increasing sensitivity of screening techniques.[16]
Modification History	Introduced in 2002.

Diagnostic Interval

Definition	Total duration from abnormal screen to resolution of abnormal screen.
Context	An abnormal screen result can induce morbidity, given the negative psychological impact it can have on a client, even if follow-up is ultimately negative. Moreover, excessive delay to diagnosis may worsen prognosis. Work-up should therefore be completed expeditiously[17]. Note that some Canadian programs do not have integrated diagnostic capabilities, making measurement of diagnostic interval more difficult.
Calculations	(Date of diagnosis) – (screen date) = Diagnostic Interval $\frac{\text{Number of diagnostic intervals within the target time-range}}{\text{Total number of abnormal screens}} \times 100 = \%$ of clients within the target time-range
Targets	**Canada** ≥ **90% within 5 weeks if no tissue biopsy* performed;** ≥ **90% within 7 weeks if tissue biopsy* performed (age 50-69).** Australia[8] > 90% to have first assessment within 10 working days; 70% to be provided with definitive diagnosis or recommendation for biopsy within 2 working days of first assessment. *Tissue biopsy does not include fine needle aspiration (FNA).
Status	72.1% within 5 weeks if no tissue biopsy performed; 49.4% within 7 weeks if tissue biopsy performed (age 50-69, 2001-02).[6]
Evidence	Based on basic principles of screening[10,11] and screening program evaluation research[18].
Modification History	Introduced in 2002. Targets modified in 2006.

Positive Predictive Value

Definition

Proportion of abnormal cases with completed follow-up found to have breast cancer (invasive or *in situ*) after diagnostic work-up.

Context

Positive predictive value (PPV) is an indicator of the predictive validity of screening. The factors that influence cancer detection rate and abnormal call rate must also be taken into consideration when evaluating a program's PPV. PPV tends to improve with re-screening because the initial screen establishes a normal baseline. Consequently, PPV tends to be lower among initial screens relative to re-screens.

Calculations

$$\frac{\text{Number of screen detected cancers}}{\text{Number of abnormal screens with complete work-up}} \times 100 = \text{Positive Predictive Value (\%)}$$

Targets

Canada ≥ **5% (initial screen);**
≥ **6% (subsequent screens) (age 50-69).**

Status

Positive predictive value by mode of detection, 2001 and 2002 screen years[6]

Mode of Screening		Age 50-69 (%)
Detected by mammography alone	Initial screen	5.1
	Subsequent screens	7.3
Detected by mammography and/or CBE	Initial screen	4.8
	Subsequent screens	6.6

Evidence

Based on methodology in screening program evaluation studies.[19]

Modification History

Introduced in 2002.

Benign to Malignant Open Surgical Biopsy Ratio

Definition	Among open surgical biopsies, the ratio of number of benign cases to the number of malignant cancer cases.
Context	Benign to malignant open surgical biopsy ratios provide an indication of the quality of the pre-surgical assessment. Diagnostic specificity and sensitivity are reciprocal. Consequently there is a limit to the extent to which biopsy yield ratios can be improved. This indicator is most meaningful when considered in relation to the underlying breast cancer incidence rate and the post-screen detected cancer rate.
Calculations	$\frac{\text{Number of benign cases detected by open surgical biopsy}}{\text{Number of malignant cancers cases detected by open surgical biopsy}} : 1$ Benign to Malignant Open *Note: Each open surgical biopsy performed represents a case. It may be useful to present these figures with confidence intervals when small numbers of cases are observed.*
Targets	**Canada** ≤ **1:1 (initial screen);** ≤ **1:1 (subsequent screens) (age 50-69).** Europe[7] ≤ 1:1 (first screen); ≤ 1:1 (subsequent screens) (acceptable level). United Kingdom[8] < 3:1 (first & subsequent screens combined). Australia[9] ≤ 2:1 (first screen); ≤ 1:1 (subsequent screens).
Status	1.0:1 Benign to malignant open surgical biopsy ratio (initial screen); 0.9:1 Benign to malignant open surgical biopsy ratio (subsequent screens) (age 50-69, 2001-02).
Evidence	The targets are based on experience from research trials (e.g., Swedish Two County study)[20].
Modification History	Introduced in 2002. Targets modified in 2006.

Benign Open Surgical Biopsy Rate

Definition	The number of benign open surgical biopsies per 1,000 screens
Context	The benign open surgical biopsy rate provides an indication of the quality of the pre-surgical assessment. Diagnostic specificity and sensitivity are reciprocal. Consequently there is a limit to the extent to which benign open surgical biopsy rates can be improved. This indicator is most meaningful when considered in relation to the underlying breast cancer incidence rate and the post-screen detected cancer rate. The prevalence of the use of core biopsy within a program may also influence the benign open surgical rate.
Calculations	$\frac{\text{Number of benign open surgical biopsies during the period under review}}{\text{Total number of program screens during the period under review}} \times 1{,}000 = \text{Benign Open Surgical Rate per 1,000}$
Targets	**Canada** — **Surveillance and Monitoring Purposes Only** United Kingdom[8] < 3.6 (initial screen); < 2.0 (subsequent screens) per 1,000 screens (age 50-70). Australia[9] ≤ 4.0% of women undergoing assessment (initial screen); ≤ 3.2% of women undergoing assessment (subsequent screens).
Status	4.3 per 1,000 screens (initial screen); 2.7 per 1,000 screens (subsequent screens) (age 50-69, 2001-2002).
Evidence	This indicator is currently for surveillance and monitoring purposes only. The impact of the increased utilization of core biopsy is only beginning to appear in the Canadian Breast Cancer Screening Database and is expected to increase steadily after 2002.
Modification History	Introduced in 2006.

Benign to Malignant Core Biopsy Ratio

Definition	Among core biopsies, the ratio of number of benign cases to the number of malignant cancer cases.
Context	Benign to malignant core biopsy ratios provide an indication of the quality of the pre-surgical assessment. Diagnostic specificity and sensitivity are reciprocal. Consequently there is a limit to the extent to which biopsy yield ratios can be improved. This indicator is most meaningful when considered in relation to the underlying breast cancer incidence rate and the post-screen detected cancer rate.
Calculations	$\frac{\text{Number of benign cases detected by core biopsy}}{\text{Number of malignant cancers cases detected by core biopsy}} : 1$ Benign to Malignant Core *Note: Each core biopsy performed represents a case. It may be useful to present these figures with confidence intervals when small numbers of cases are observed.*
Targets	**Canada** **Surveillance and Monitoring Purposes Only**
Status	2.9:1 Benign to malignant core biopsy ratio (initial screen); 1.5:1 Benign to malignant core biopsy ratio (subsequent screens)(age 50-69, 2001-02).
Evidence	Based on evidence provided by the Nova Scotia Breast Screening Program, 1991-2001.[21]
Modification History	Introduced in 2006.

Benign Core Biopsy Rate

Definition	The number of benign core biopsies per 1,000 screens
Context	The benign core biopsy rate provides an indication of the quality of the pre-surgical assessment. Diagnostic specificity and sensitivity are reciprocal. Consequently there is a limit to the extent to which benign core biopsy rates can be improved. This indicator is most meaningful when considered in relation to the underlying breast cancer incidence rate and the post-screen detected cancer rate.
Calculations	$\frac{\text{Number of benign core biopsies during the period under review}}{\text{Total number of program screens during the period under review}} \times 1{,}000 = \text{Benign Core Biopsy Rate per 1,000}$
Targets	**Canada** **Surveillance and Monitoring Purposes Only**
Status	10.8 per 1,000 screens (initial screen); 4.1 per 1,000 screens (subsequent screens) (age 50-69, 2001-2002).
Evidence	Based on evidence provided by the Nova Scotia Breast Screening Program, 1991-2001.[21]
Modification History	Introduced in 2006.

Invasive Cancer Tumour Size

Definition	Percentage of invasive cancers with tumour size of ≤10mm and ≤15mm in greatest diameter as determined by the best available evidence: 1) pathological, 2) radiological, and 3) clinical.
Context	Invasive tumour size is one of the best known prognostic indicators. The purpose of mammography screening is to detect pre-clinical cancers before symptoms are apparent.
Calculations	$\frac{\text{Number of invasive tumours} \leq 10\text{mm}}{\text{Total number of invasive tumours}} \times 100 = \%$ of Invasive Tumours ≤ 10mm $\frac{\text{Number of invasive tumours} \leq 15\text{mm}}{\text{Total number of invasive tumours}} \times 100 = \%$ of Invasive Tumours ≤ 15mm
Targets	**Canada** > **25%** ≤ **10mm;** > **50%** ≤ **15mm (age 50-69).** Europe[6] ≥ 20% ≤ 10mm (initial screen); ≥ 25% ≤ 10mm (subsequent screens); > 50% < 15mm (initial and subsequent screens). United Kingdom[7] ≥ 1.5 per 1,000 (≤ 15mm, initial screen); ≥ 1.7 per 1,000 (≤ 15mm, subsequent screens). Australia[8] ≥ 2.5 per 1,000 (≤ 15mm, initial and subsequent screens).
Status	36.4% of tumours ≤ 10mm[6] 64.6% of tumours ≤ 15mm (age 50-69, 2001-02).
Evidence	Stage-specific prospective studies and trials[20,22,23].
Modification History	Introduced in 2002. Calculations and Targets modified in 2006.

Node Negative Rate in Cases of Invasive Cancer

Definition	Proportion of invasive cancers in which the cancer has not invaded the lymph nodes.
Context	The purpose of mammography screening is to detect breast cancer as early as possible – before it spreads to the lymph nodes.
Calculations	$\frac{\text{Number of cases of invasive cancer with negative lymph nodes}}{\text{Total number of invasive cancer cases in which lymph nodes were assessed}} \times 100 = \%$ with negative lymph nodes
Targets	**Canada** > **70% (all screens) (age 50-69).** Europe[7] 70% (initial screen); 75% (subsequent screens) (age 50-69).
Status	72.9% node negative in assessed cases of invasive cancer (age 50-59); 77.9% node negative in assessed cases of invasive cancer (age 60-69) (2001-02).
Evidence	Stage-specific prospective studies and trials[20,22,23].
Modification History	Modified in 2006. This indicator replaced the "Positive Lymph Nodes in Cases of Invasive Cancer" indicator that was introduced in 2002.

Post-Screen Invasive Cancer Rate

Definition

Number of women with a diagnosis of invasive breast cancer after a normal screening within 12 AND 24 months of the screen date.

Context

Post-screen invasive cancer rate is an indicator of the sensitivity of the screening program. This rate is affected by population incidence, age, rate of disease progression, opportunistic screening, and screening interval recommendation. A high rate may negatively affect the mortality reduction expected for a successful, organized screening program. The accuracy of this measure is dependent on the completeness of cancer registration.

Calculations

$$\frac{\text{Number of cancers detected in the 0-12 month interval after a normal screening episode}}{\text{Total person-years at risk (0-12 months post screen)}} \times 10{,}000 = \text{12-month Post-Screen Invasive Cancer Rate per 10,000}$$

$$\frac{\text{Number of cancers detected in the 0-24 month interval after a normal screening episode}}{\text{Total person-years at risk (0-24 months post screen)}} \times 10{,}000 = \text{24-month Post-Screen Invasive Cancer Rate per 10,000}$$

Targets

Canada	**< 6 per 10,000 person-years (within 12 months); < 12 per 10,000 person-years (within 24 months) (age 50-69).**
United Kingdom[8]	12 per 10,000 (within 24 months); 14 per 10,000 (within 36 months).
Australia[9]	< 6.5 per 10,000 (within 12 months)

Status

Cancers outside of program after normal screening episode* among program participants aged 50-69 at screening, 1998 and 1999 screen years[6]

Months After Screening	0-12 Months	0-24 Months
Rate per 10,000 person-years at risk	5.6	8.2

* The normal screening episode is up to 6 months from a program screen and does not include diagnostic follow-up with a benign result.

Evidence

Studies of interval cancer.[24,25]

Modification History

Introduced in 2002. Modified in 2006. A direct comparison with targets set by other countries may not be appropriate based on how the post screen invasive cancer rate is calculated. In Canada, only normal screening episodes are included in the numerator whereas the targets set by other countries may include abnormal screens with a benign result (previously referred to as a negative screening episode).

Future Directions

The development of a set of performance measures for organized breast cancer screening programs is an ongoing process. The body of research pertaining to organized breast cancer screening is constantly evolving, as is the technology and methodology used to screen, diagnose and treat the disease. The quality of evidence used to support the use of performance measures presented in this document varies greatly from measure to measure and is subject to change with the continual introduction of new research evidence. The data used in the calculation of these measures, and possible future measures, are still maturing in terms of quality and timely availability. Consequently, it is a challenge to establish comprehensive, long-term evaluation plans with valid, reliable performance measures.

Monitoring Performance Measures

The formal use of these measures will be in subsequent releases of *the Biennial Report on Organized Breast Cancer Screening Programs in Canada*[6]. The Quality Determinants Working Group reassessed the 11 performance measures, the measures that were under review as well as the proposed measures that were all identified in the Report from the Evaluation Indicators Working Group in terms of progress made towards achieving the national targets. From this work, 3 new indicators were identified and a few modifications were made to some of the existing performance measures. Targets were adjusted or redefined by consensus and supported by new research or expert opinion. Changes to the definitions of the measures and methods of calculation were also considered on the same basis.

Performance Measures under Review

***In situ* cancer detection rate:** While ductal carcinoma *in situ* (DCIS) is widely accepted as an obligate precursor of invasive disease, the timeframe in which this occurs is not firmly established. The potential for cases of DCIS to remain asymptomatic throughout the individual's natural lifespan suggests a potential for *over diagnosis* with its attending negative consequences. The Working Group will continue to monitor *in situ* cancer detection rates and will consider defining a target under the appropriate circumstances. It has been proposed that the Working Group will look into the possibility of collecting data on low, intermediate and high-grade DCIS, in order to provide more meaningful data for setting targets.

Proposed Performance Measures

While the best possible assessment of the morbidity and mortality reducing potential of breast cancer screening was the foremost priority in the selection of these measures, the timely availability of high-quality data was also an influential factor. Meaningful targets, useful for national comparison through frequent monitoring, were also requisite. These criteria do not, however, fully cover the range of performance measures needed to establish comprehensive long-term evaluation plans. From that perspective, factors such as equitable access, representative participation, acceptability of services to clients, cost minimization, and program promotion must be assessed. In recognition of the need for a more complete inventory of indicators for use in future evaluation initiatives, the Quality Determinants Working Group will meet regularly, to reconsider the feasibility of adding new measures or including measures previously explored (but not published) in subsequent editions of this document.

References

1. Kerlikowske K, Grady D, Rubin SM, Sandrock C, Ernster VL. *Efficacy of screening mammography. A meta-analysis*. JAMA 1995;273:149-54.
2. The Workshop Group. *Reducing deaths from breast cancer in Canada*. Can Med Assoc J 1989;141;199-201.
3. Gaudette LA, Altmayer CA, Nobrega KMP, Lee J. *Trends in mammography utilization, 1981 to 1994*. Health Reports 1996;8(3).
4. Horne T, Evaluation Indicators Working Group. *Proposed indicators for performance and quality of breast screening programs in Canada.* Ottawa: Health Canada, April 2000.
5. Health Canada. *Evaluation Indicators Working Group: Guidelines for Monitoring Breast Screening Program Performance*. Ottawa: Minister of Public Works and Government Services Canada, 2002.
6. Health Canada. *Organized breast screening programs in Canada 2001 and 2002 report*. Ottawa: Minister of Public Works and Government Services Canada. 2005
7. Europe Against Cancer. *European guidelines for quality assurance in mammographic screening*. Luxembourg: Office for Official Publications of the European Commission, January 2001.
8. *Consolidated Guidance on Standards for the NHS Breast Screening Programme.*April 2005 Sheffield, England: NHSBSP publication.
9. National Quality Management Committee of BreastScreen Australia. Draft National Accreditation Standards: BreastScreen Australia Quality Improvements Program. June 2001.
10. Wilson JMG, Jungner G. *Principles and practice of screening for disease*. Geneva: World Health Organization, 1968.
11. Day NE, Williams DRR, Khaw KT. *Breast cancer screening programs: the development of a monitoring and evaluation system.* Br J Cancer 1989;59:954-58.
12. Tabar I, Fagerberg G, Chen HH, Duffy SW, Smart CR, Gad A, et al. *Efficacy of breast cancer screening by age: new results from the Swedish two-county trial*. Cancer 1995;75:2507-17.
13. Nyström L, Rutqvist LE, Wall S, Lindgren A, Lindqvist M, Ryden S et al. *Breast cancer screening with mammography: overview of the Swedish randomized trials.* Lancet 1993;341:973-8.
14. Duffy SW, Hill C, Estève J. *Quantitative methods for the evaluation of cancer screening*. London: Arnold, 2001.
15. Canadian Cancer Society/National Cancer Institute of Canada: *Canadian Cancer Statistics 2005*, Toronto, Canada, 2005.
16. Evans AJ, Pinder SE, Ellis IO, Wilson ARM. *Screen detected ductal carcinoma in situ (DCIS): overdiagnosis or an obligate precursor of invasive disease?* J Med Screen 2001;8:149-51.

17. Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer. *Clinical practice guidelines for the care and treatment of breast cancer: 1. The palpable breast lump: information and recommendations to assist decision-making when a breast lump is detected.* Can Med Assoc J 1998;158(suppl):3S-8S.

18. Olivotto IA, Bancej C, Goel V, Snider J, McAuley RG, Irvine B, Kan L, Mirsky D, Sabine MJ, McGilly R, Caines JS. *Waiting times from abnormal breast screen to diagnosis in 7 Canadian provinces.* Can Med Assoc J. 2001;165(3):303-4.

19. Blanks RG, Moss SM, Wallis MG, *Monitoring and evaluating the UK National Health Service Breast Screening Programme: evaluating the variation in radiological performance between individual programmes using PPV-referral diagrams*. J Med Screen 2001;8:24-8.

20. Tabar L, Fagerberg G, Duffy SW, Day NE, Gad A, Grontoft O. *Update of the Swedish two-county program of mammographic screening for breast cancer*. Radiol Clin North Am 1992;30:187-209.

21. Caines JS, Schaller GH, Iles SE, Woods ER, Barnes PJ, Johnson AJ, Jones GR, Borgaonkar JN, Rowe JA, Topp TJ, Porter GA. *Ten years of breast screening in the Nova Scotia Breast Screening Program, 1991-2001. experience: use of an adaptable stereotactic device in the diagnosis of screening-detected abnormalities.* Can Assoc Radiol J 2005:56(2):82-93.

22. Europe Against Cancer. *European guidelines for quality assurance in mammographic screening*. Luxembourg: Office for Official Publications of the European Commission, June 1996.

23. Commonwealth Department of Human Services and Health. National program for the early detection of breast cancer: national accreditation requirements. Canberra, Australia: Commonwealth Department of Human Services and Health, March 1994.

24. Moss SM, Blanks RG. *Calculating appropriate target cancer detection rates and expected interval cancer rates for the UK NHS Breast Screening Programme*. J Epidemiol Community Health 1998;52:111-15.

25. Rickard MT, Taylor RJ, Fazli MA, El Hassan N. *Interval breast cancers in an Australian mammographic screening program.* Med J Aust 1998;169:184-87.

26. Public Health Papers No. 34, World Health Organization, 1968.

Appendix A

Conceptual Framework

The Conceptual Framework is an updated modification of the classic Wilson and Jungner[26] criteria:

- The target cancer should be appropriate for screening.
- The objectives of the screening must be clearly identified.
- There should be an appropriate screening test.
- There should be agreement on the appropriate management of people with positive results on the screening test.
- There must be sound evidence that screening has a favourable impact on its intended objectives.
- Screening should do more good than harm.
- The health care system should be capable of supporting all necessary elements of screening, including diagnosis and treatment.
- Screening should be endorsed only if it is provided in a continuous manner in conjunction with the necessary quality assurance and programmatic elements.

Cancer screening should incorporate all of the essential programmatic elements of the clinical trials that form its evidentiary base. These **Key Elements** include the following:

- Screening must be comprehensive, including recruitment, recall, follow-up, and timely assessment of people with positive screening tests.
- Screening must be supported by public education, including education about primary prevention when applicable.
- Screening must be supported by the education of health care workers.
- All eligible people should have reasonable access to screening, diagnostic assessment and treatment.
- The groups targeted for participation in a screening program should be selected on the basis of a realistic understanding of the harms and benefits of screening and the manner in which health information will be managed.
- All aspects of the screening program must be subject to continuous monitoring and evaluation.
- Screening programs must adopt a culture of continually striving to increase the benefits and minimize the harms of screening.
- Screening programs must have the capacity to modify screening standards, guidelines and best practices on the basis of new scientific evidence.

- The program must have an effective and efficient computerized information system.
- There must be adequate resources (financial, physical, human and informational) to support all aspects of screening.

Screening programs must include a consumer perspective in all aspects of planning and operations.

Appendix B

Quality Determinants Working Group Members (QDWG)

Dr. Diane Major, Chair QDWG
Senior Research Scientist
Institut national de santé publique du Québec
Direction Systèmes de soins et services
945 Wolfe, 5e étage
Ste-Foy (Québec) G1V 5B3

Dr. Penny Barnes
Department of Pathology
Queen Elizabeth II HSC
5788 University Ave.
Halifax, Nova Scotia B3H 1V8

Dr. Andy Coldman
Leader, Population and Preventive Oncology
BC Cancer Agency
8th Floor, 686 West Broadway
Vancouver, British Columbia V5Z 1G1

Gregory Doyle
Breast Screening Program for Newfoundland and Labrador
38 Ropewalk Lane
St. John's, Newfoundland A1E 5T2

Dr. Rene Shumak
Radiologist-in-Chief
Cancer Care Ontario
620 University Avenue
Toronto, Ontario M5G 2L7

Norah Smith
Program Coordinator
PEI Breast Screening Program
Queen Elizabeth Hospital
Department of Diagnostic Imaging
P.O. Box 6600
60 Riverside Drive
Charlottetown, Prince Edward Island C1A 8T5

Dr. Nancy Wadden
Diagnostic Imaging
St-Clare's Mercy Hospital
154 Lemarchant Road
St. John's, Newfoundland A1C 5B8

Christine LeBlanc Bennett
Provincial Cancer Consultant
New Brunswick Department of Health
P.O. Box 5100
Fredericton, New Brunswick E3B 5G8

Barb Kasprowicz
Program Manager
Chronic Disease Control and Management Division, CCDPC
Public Health Agency of Canada
7th Floor, Jeanne Mance Building, Room D717
Tunney's Pasture, P.L.: 1907D
Ottawa, Ontario

Jay Onysko
Screening and Early Detection Section
Chronic Disease Control and Management Division, CCDPC
Public Health Agency of Canada
7th Floor, Jeanne Mance Building, Room D702
Tunney's Pasture, P.L.: 1907D
Ottawa, Ontario

Christina Bancej
Screening and Early Detection Section
Chronic Disease Control and Management Division, CCDPC
Public Health Agency of Canada
7th Floor, Jeanne Mance Building
Tunney's Pasture, P.L.: 1907D
Ottawa, Ontario

Sandra Connors
Screening and Early Detection Section
Chronic Disease Control and Management Division, CCDPC
Public Health Agency of Canada
55 St. Clair Avenue East, 4th Floor
Toronto, Ontario M4T 1M2

Appendix C

Glossary

Asymptomatic

A woman who does not report symptoms and appears without signs of disease at screening.

Cancer

Includes both invasive and ductal carcinoma *in situ* (DCIS) of the breast.

Diagnosis

The first pathologic or cytological diagnosis of cancer, last known biopsy for benign cases, or last intervention prior to a recommendation to return to screening or return for early recall[1].

Ductal carcinoma *in situ*

(DCIS) a non-invasive tumour of the breast, arising from cells that involve only the lining of a breast duct. The cells have not spread outside the duct to other tissues in the breast.

Fine-needle aspiration biopsy

A needle is inserted into the lesion and material drawn out using a syringe. The material can be stained and the cells examined in a laboratory to determine whether they are benign or malignant.

Incident cancer

Cancer detected by a program screen after the initial screen.

Initial screen

The first Canadian screening program screen provided to a woman.

Interval cancer

Any invasive breast cancer diagnosed in the interval following a “normal” screening result and before the next scheduled screening examination.

Invasive cancer

Cancer cells invading beyond the basement membrane of the milk duct or lobule. A ductal carcinoma *in situ* component may also be present in cases of invasive cancer.

Open biopsy

Surgical removal of a breast mass under local or general anesthesia for subsequent microscopic examination by a pathologist.

Post-screen cancer

A cancer detected outside the program within 24 months of a negative screening episode.

Prevalent cancer

The proportion of the population with cancer at a given point in time.

Screen

Can comprise mammography, or both clinical breast examination and mammography, delivered by a program.

Screening episode (completed)

Defined for normal screens as the date of the last screen; for abnormal screens, the date of tissue diagnosis if biopsy is performed, and the date of the last test before a return to screening or before the recommendation for repeat diagnostic imaging. A "negative screening episode" can include all follow-up, provided that the end result is negative.

Re-screening

Subsequent screening, according to policy, after initial screening under the program. This includes women who miss a scheduled round of screening.

Screen-detected cancer

Cancer detected as a result of a positive test with histological confirmation attributed to the screening findings of the program.

Tissue biopsy

A biopsy which provides breast tissue for histopathologic examination (does not refer to fine-needle aspiration biopsy which provides only cells). Includes both core and open biopsies.

Total person-years at risk

Within a 12 or 24-month period after a negative screening episode, women are considered at risk for post-screen detected cancer. Women contribute a count in the denominator for each year or fraction of a year within the period of interest before a post-screen detected cancer or the next regular program screen.