

Quality Determinants of Breast Cancer Screening with Mammography in Canada

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Alberta Breast Cancer Screening Program



BC Cancer Agency

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An agency of the Provincial Health Services Authority

Screening Mammography Program



Breast Screening Program
Programme de dépistage du cancer du sein

Government of Nunavut

MANITOBA BREAST SCREENING PROGRAM



PROGRAMME MANITOBAIN DE DÉPISTAGE DU CANCER DU SEIN

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ontario breast screening program
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PROGRAMME QUÉBÉCOIS DE DÉPISTAGE DU CANCER DU SEIN

SCREENING PROGRAM FOR BREAST CANCER
A PROGRAM OF THE SASKATCHEWAN CANCER FOUNDATION



Yukon Mammography Program

CANADIAN PARTNERSHIP AGAINST CANCER



PARTENARIAT CANADIEN CONTRE LE CANCER

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**TO PROMOTE AND PROTECT THE HEALTH OF
CANADIANS THROUGH LEADERSHIP, PARTNERSHIP,
INNOVATION AND ACTION IN PUBLIC HEALTH.**

— Public Health Agency of Canada

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Preamble

The Canadian Task Force on Preventive Health Care released an updated guideline for breast cancer screening in average risk women aged 40 – 74 years (November 21, 2011). Although the updated guideline may have implications for provincial/ territorial screening programs in the future, for the purpose of the current report the Quality Determinants Working Group collectively decided to continue to assess the existing provincial/territorial screening practices.

During the report preparation the Working Group was very mindful of the requirement for women to make an informed decision about whether or not to participate in breast screening using mammography. This recognises the autonomy of the individual to make a decision about her own health care. Working group members are also aware that programs have been established to provide screening services to Canadian women and that these programs are funded by governments and have established targets for the participation of eligible women. Public funding is built upon the notion that participation in screening is for the public good and is therefore encouraged and promoted. The informed decision making and promotion viewpoints are not necessarily contradictory but as currently

practiced in Canada do involve some conflict. In reviewing literature on screening it is common to view high levels of participation as the objective and to analyse factors which promote participation without regard to whether it was “informed”. Women who decline screening are often viewed as a problem to be addressed. The working group endorses the concept of informed decision making and recommends that it be layered into approaches for program promotion and awareness. Approaches where this cannot be done are to be treated with caution.

The majority of the working group are employees of breast screening programs or their host organisations.

Introduction

The purpose of this report is to propose standards and make recommendations to promote quality assurance in all aspects of breast cancer screening with mammography in Canada. The target audience includes cancer screening program administrators, health care professionals working in screening programs and relevant policy personnel. The report is a joint production of the Quality Determinants Working Group from the Canadian Breast Cancer Screening Initiative and key experts in the field of screening mammography and connected disciplines. This is the third edition of the document, which was first published in 1997 and updated in 2003.

In Canada, screening is performed within and outside of formal organized programs. In 2012, all Canadian provinces and territories, except Nunavut, have organized breast cancer screening programs. These programs differ slightly from one another in their organization, the range of services they provide and their population coverage.

Important innovations, such as navigators and digital mammography, have been introduced in recent years and are quickly becoming a valuable addition to screening programs. Moreover, as we gain more experience with mammography screening on a large scale, both its desirable and adverse effects are better recognized. This underlines the current movement to promote informed decision making and informed consent to participate. Finally, with the recognition of the financial and human costs of screening, the need to develop efficient strategies for the identification and monitoring of individuals at higher risk of breast cancer (including women with dense

breast, familial history, exposure to repeated radiation due to treatment, etc.) becomes more obvious. This edition of the report therefore attempts to reflect these important aspects of breast cancer screening.

The report starts with a brief description of the principles of screening as they apply to breast cancer screening with mammography. Following, there is a brief summary of the methods used for the literature review and update of the recommendations. The sections of the report summarize the current state of knowledge and make recommendations for quality assurance that cover the whole spectrum of the screening process, from uptake to definitive diagnosis (including diagnostic workup, guidelines for pathology, reporting of the results and program evaluation). [Figure 1](#) illustrates these steps as they apply to organized programs in Canada.

The words *must* and *should* in this report have been chosen with purpose. The word *must* indicates a requirement that is essential to meet the currently accepted quality standards, while *should* indicates an advisory recommendation that is highly desirable and is to be implemented where possible. Each section of the report begins with a text box that summarizes the key recommendations; these points are elaborated in the body text.

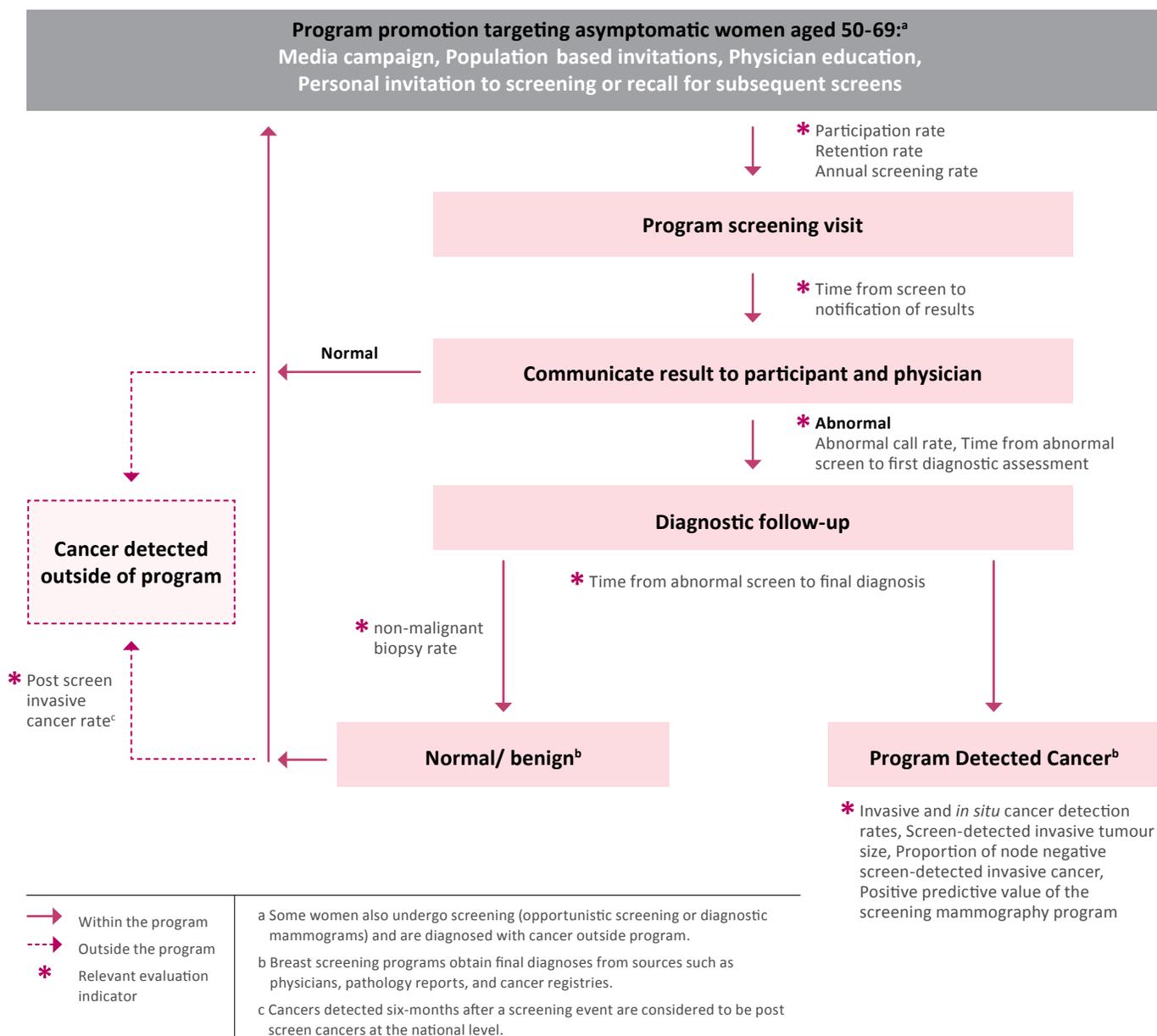
Principles of Screening

Screening for breast cancer in Canada is viewed as a public health intervention and principles of public health assessment are applied. These ideas were originally captured in the seminal report by Wilson and Jungner¹ and included 10 guiding considerations. These principles have subsequently been modified by several authors (e.g., Miller²) however their original intent and scope remain unchanged. The general principles for providing cancer screening indicate that:

- the disease should be an important health problem,
- the natural history of the disease should be known,
- the benefits of screening should outweigh the harms,
- the screening test should be acceptable to the population,
- the follow-up services required for screened individuals should be well understood and available; and
- the resources required for screening should not be disproportionate to other expenditures of similar impact in the health system.

The adoption of these principles has resulted in considerable uniformity in screening provision in most Canadian jurisdictions, although some variation exists. Overall, a coordinated approach to screening is a key factor associated with program success. The essential components of a coordinated approach include the provision of consistent, high quality service, effective monitoring of program elements, integration of the screening program with diagnostic and treatment services, and high enrolment and participation among Canadian women.

Figure 1: Pathway of a Breast Cancer Screening Program



Methodology of Report Creation

The membership of the Working Group on Quality Determinants of Organized Breast Cancer Screening Programs is drawn from the Screening and Early Detection section of the Public Health Agency of Canada and the Canadian Breast Cancer Screening Initiative (CBCSI). The CBCSI is composed of individuals representing Canadian regional breast cancer screening programs, professional societies and the Public Health Agency of Canada. Members of the working group have expertise in various areas of breast cancer screening. This is the third report published by this group.

The contents of the current edition of the report have been defined through successive rounds of discussions between members of the Quality Determinants Working Group commencing during the summer of 2009. As a first step, all topics covered in the previous version of the report were listed and additional ones were proposed in an attempt to incorporate new knowledge and significant developments in the field since 2003. The initial table of contents was approved by members of the Working Group attending the September 22-23, 2010 meeting in Ottawa, Ontario. The final table of contents was approved by members of the Working Group attending the May 3, 2011 meeting in Montreal, Québec.

Using as a model the fourth edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, each section was assigned to a specific expert or group of experts responsible for supervising the relevant literature review and drafting the corresponding section of the report. Ms. Dana Riley collaborated with working group members to update the literature review and create draft versions of the report.

The search for new scientific publications was limited to the period between 2000 and 2011. The search strategy is available upon request to the Public Health Agency of Canada.

In this succeeding report, relevant information has been updated and the sections have been reorganized. Each recommendation for quality control from the second edition was revised and new ones were added as necessary. Documentation of the practices of other national programs, in particular those from Europe, Australia and New Zealand, was also collected.

After review and discussion of the information collected, key recommendations for each topic were written during and between working group meetings. Each chapter was reviewed by at least two members of the working group to ensure appropriateness, completeness and clarity. Consensus was used in developing the recommendations, and working group members accepted all statements unanimously.

The final set of recommendations and the final version of the complete report were approved by all members of the Quality Determinants Working Group. All provincial program directors and the members of the National Committee of the CBCSI reviewed the final report, which was approved at the meeting in Toronto on January 24-25, 2012.

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Organization of Breast Cancer Screening in Canada

Public medical services in Canada are generally organized and administered by Provincial and Territorial governments except for distinct populations under Federal government jurisdiction, e.g. registered First Nations, Canadian Forces, Royal Canadian Mounted Police. Breast screening services are developed and operated by Provincial or Territorial governments and all, except Nunavut, have an organized breast screening program. Canada does not have a national breast cancer screening program with common policies but has an aggregate of regionally based programs.

All organized screening programs provide mammographic screening to women free-of-charge without requiring physician referral. All programs include educational and promotional components to encourage informed participation in screening among the target population. All regional programs (except Yukon) monitor outcomes and report standardized data to a national database maintained at the Public Health Agency of Canada.

There are differences between regional organized programs. Some organized programs provide screening to a wider age-range or more frequent screening to subgroups and may include clinical breast examination. Organized programs may differ in other respects, such as scope and use of invitation letters. Organized programs provide screening mammograms through a mixture of publicly and privately managed facilities. Typically, organized programs are not the sole provider of mammography and physicians may refer women to imaging facilities for breast screening without going through an organized program. The management of follow-up of women with abnormal screening mammograms is usually the responsibility of her primary care provider although several programs manage elements of follow-up using various mechanisms. Treatment of identified cases of breast cancer, again, varies by region. In most cases provincial cancer agencies or cancer care programs organize follow-up care for patients diagnosed with cancer requiring surgery, radiation and/or chemotherapy.

Program Elements

Organized breast cancer screening programs offer screening to asymptomatic women without a previous diagnosis of breast cancer. Organized programs typically involve five elements:

Identification and invitation of the target population

High quality programs must identify the target population using a systematic approach. This should be the most efficient process available while maintaining appropriate privacy concerns.

A number of methods are used to invite women to a screening examination and include population-based invitations, personal invitations, physician education to increase referrals, and media campaigns targeting women.

Provision of a screening examination

The screening examination must be accessible to all eligible women. Screening mammograms may be provided at both fixed and mobile facilities. Fixed mammography centres are located in population-dense centres while mobile services are typically used to provide service to lower density areas. Mobile units may also be used to supplement capacity at existing fixed mammography centres. Results of a screening mammogram must be provided to both the woman and her primary care provider.

Follow-up of any abnormalities detected at screening

All abnormalities identified through the screening process must be assessed. The primary care provider or the screening program then provides coordination of assessment. This process varies by region. The follow-up process is resolved when a final diagnosis of cancer or normal / benign is concluded.

Recall after a normal or benign screening episode

In general, women who have normal screening results are invited back at regular intervals for subsequent screening through a recall letter. Some women are invited back earlier based on their age, breast density, family history, and/or results of their last screening mammogram. After receipt of normal results, women should be reminded to contact their primary care provider if they become symptomatic prior to their next scheduled screening visit.

The preceding is a brief summary of the systematic methods by which the individual moves through organized breast cancer screening programs. In addition, some of the advantages that organized screening provides over opportunistic breast cancer screening include population-based engagement, automatic recall / reminders for subsequent screening, coordinated follow-up for abnormal screening results, systematic quality assurance, and the ability to provide monitoring and evaluation of program performance.

Monitoring and evaluation

Monitoring and evaluation of organized breast cancer screening programs through the systematic collection, analysis, and interpretation of health data allows for the enhancement of programs and is essential to ensure women are receiving high quality services. Higher quality services result in the reduction of morbidity and mortality from breast cancer while minimizing the unwanted effects of screening. The results of monitoring and evaluation from the Canadian Breast Cancer Screening Database (CBCSD) are used to enhance the performance of organized screening programs in Canada. The CBCSD contains data on breast cancer screening events from organized breast cancer screening programs all across Canada.

Glossary

Asymptomatic woman

A woman who does not have any symptoms of breast disease.

Breast density

Describes the relative amount of fat and glandular/connective tissue visible during mammography. A dense breast has less fat and more glandular/connective tissue and appears white on mammography which may obscure the detection of cancer. High breast density is recognized as an independent risk factor for breast cancer.

Cancer

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

Core biopsy

A needle biopsy of the breast used to remove samples of tissue for microscopic evaluation. Most core biopsies are image guided.

Date of definitive diagnosis

The date of definitive diagnosis for cancer is the date of the first core or open biopsy to diagnose cancer (ductal carcinoma in situ (DCIS) or invasive carcinoma), or the first definitive fine needle aspiration (FNA) if there was no prior core or open biopsy prior to treatment. The date of definitive diagnosis for benign cases is the last test before a return to screening or before the recommendation for early recall.

Ductal carcinoma *in situ* (DCIS)

DCIS is 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 (FNA)

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

Initial screen

The first screen provided to a woman in an organized screening program.

Invitation letter

A letter sent to an eligible woman prior to her first screen at an organized breast screening program inviting her to participate.

Invasive cancer

Cancer which has invaded beyond the walls of the milk duct or lobule. A DCIS component may also be present in cases of invasive cancer.

Open biopsy

Surgical removal of a breast mass under local or general anesthesia to determine the diagnosis with subsequent microscopic examination by a pathologist.

Post-screen cancer

A cancer detected outside the program after a normal or benign screen. This includes cancers which may be classified as true interval (new cancer), missed at screen (false negative), missed at diagnosis (false negative) or non-compliant.

Quality assurance

The systematic monitoring and evaluation of the various aspects of a screening facility to maximize the probability that minimum standards of quality are being attained throughout the screening process.

Quality control

The routine performance and interpretation of equipment function tests and of corrective actions taken.

Recall letter

A letter sent to a woman who has been screened by the program in the past indicating that she is due or overdue for screening.

Screening episode

Refers to the completed screen, including assessment of any abnormality identified at screening.

Screen-detected cancer

Cancer detected by screening.

Subsequent screen

Successive screens (screening rounds) after the initial (first) screen under the organized program. This includes women who miss a scheduled round of screening.

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.

SCREENING PATHWAY — CHAPTER 1

Promotion and Access

1.1

Promotion of Public Awareness

- *Programs should have an enrolment objective of at least 70% of eligible women in the target group.*
- *Organized screening programs must collect statistics on the proportions of women screened in the target age group.*
- *Screening programs should have an engagement plan that outlines how eligible women will be informed about screening, including how specific populations will be reached.*
- *Screening programs must ensure that women are provided with adequate information in order to take an informed decision regarding participation.*

Screening needs to be undertaken by a significant proportion of the target population to reduce mortality rates from breast cancer. Planning for this requires establishing appropriate levels of participation among target age groups, utilizing effective engagement strategies, ensuring screening is accessible, including providing adequate capacity within the health care system to provide screening and necessary follow-up.

Program participation is an important interim measure of effectiveness because it provides an indication of the potential for mortality reduction; although there is no internationally standardized approach for its

measurement.^{1,2} In Canada, the target participation rate in the screening program is $\geq 70\%$ (within a 30-month period), which is consistent with participation targets from other countries. Participation rates in screening programs among women aged 50 to 69 years old varied among the Canadian provinces from 10.4% to 59.2% in 2005 and 2006; however, when non-programmatic (opportunistic) screening is included the estimated rates are closer to 70% and the variation between provinces and territories is small.³

The plan should consider approaches that can be used to facilitate women's informed participation, including personal invitation, community information programs, non-governmental organizations, involvement of physicians, primary care providers and other health professionals, and strategies targeting groups of women with lower participation rates.

Many factors influence informed participation. These factors should be considered when inviting women for screening, for example the writing of pamphlets and letters, planning outreach initiatives, determining where a mobile unit will be set up, and determining messages.

Among Canadian women, individual factors that may influence participation include past and present behaviours, personal attributes of the woman (e.g. age), and socioeconomic status.⁴ A woman's participation in other screening tests, such as Pap tests, is highly

correlated with participation in mammography, which suggests that preventive health behaviours cluster together.⁵ Higher education and higher income are positively associated with mammography use.⁶⁻⁸ However, one Danish study found that the relationship between education and screening was U-shaped, such that the least and most educated segments of the population were less likely to be screened.⁹ In Canada, Caucasian women are usually more likely than women of ethnic minorities to have mammograms, as are urban versus rural women.⁴ Married or common-law women are more likely to participate in screening than those never-married, divorced, separated or widowed.¹⁰

A lack of knowledge of the recommended screening interval and the misconception that a referral from a physician was necessary are associated with never having or being overdue for a mammogram.¹⁰ In a review of barriers among minority women, the most commonly identified limiting factors included: fear of pain and embarrassment, a lack of resources (i.e. financial), poor knowledge about breast cancer screening, lack of

physician recommendation, lack of trust in hospitals and doctors, language barriers, and lack of transportation.¹¹

In the Canadian context, a recent report based on the 2008 Canadian Community Health Survey states that the most common reason for women not having a mammogram in the past two years was that they did not think it was necessary.¹² Other factors that were significantly related to not using mammography included: being an immigrant, living in a lower income household, not having a regular doctor and smoking.¹² According to a Canadian survey, factors predictive of never having had a mammogram include: higher age level, living in a rural area, being born in an Asian country, nonparticipation in volunteer groups, no regular physician or recent medical visit, smoker, no regular physical activity, and nonuser of hormone replacement therapy.¹³ Many of these factors interact and may be additive for particular individuals. Screening programs need to be aware of the factors that influence participation and should take those factors into consideration in their plan.

1.1.1

Promotion Aimed at Individual Women

Screening programs should accurately identify eligible women in their region and maintain a database with up-to-date addresses and status.

- *Screening programs must use the most complete, up-to-date sources of information regarding contact details of eligible women. Such lists should be available to the program itself so that it, and not a third party, can issue invitations. Screening programs must ensure the confidentiality of these lists.*
- *Organized breast cancer screening programs should send invitations to all eligible women in the target age group. Program non-participants should be sent a repeat invitation at least every five years.*
- *The invitation should contain information regarding how to access balanced information related to screening.*
- *Women who have not booked appointments should be sent a reminder letter 3 to 6 weeks after the initial invitation.*

- *Organized breast cancer screening programs must include a mechanism to opt-out of the invitation process.*

Screening programs need to have accurate, up-to-date access to population lists to identify eligible women. A link with a population register offers the possibility of daily updates. In this way, women who move into or out of the screening area or women who have died can be identified and included or excluded from the invitation scheme. Other sources of information to keep the screening register up-to-date may also be required.¹⁴ Lists of eligible women should be cross-referenced with cancer registry lists and vital statistics. Further crossreferencing should be done with the screening program so that women who already participate in the screening program do not receive the same letter as women who are being invited for the first time.

Screening programs must comply with existing privacy legislation in their jurisdiction. Screening programs must ensure that the personal information received is used only for the purposes for which it was provided.

Personal invitations are a simple and efficient tool to inform women of their eligibility to participate in screening.¹⁵⁻¹⁷ Research from the Quebec Breast Cancer Screening Program found that sending a personalized letter signed by a regional program physician to every woman in the province 50 to 69 years of age significantly increased the observed participation rates over the expected rates.¹⁸ All Canadian organized breast screening programs currently use invitation letters at least to some groups of women and consider them a key component of an organized screening program. However, there may be special population groups, such as Aboriginal and immigrant communities, for whom invitation letters are not appropriate or sufficient. Screening programs in such areas may wish to examine the value of invitations in comparison with other methods.

The content of the invitations has implications for attendance. Invitations should inform women about the benefits and risks of screening to support an informed choice.¹⁹ The idea of screening as a continuum of steps should be addressed, indicating the possibility of further assessment. Invitations should be accompanied by informational brochures that generally describe the program and answer the common questions and concerns women have about mammography.

Other countries, such as the United Kingdom and Finland, include scheduled appointments in the invitations, which have been shown to improve adherence with screening.^{19,20} Scheduled appointments with invitations are not used in Canada and there is no indication of the factors that may determine acceptance of such an approach. Prescheduled appointment times may undermine a program's attempt to let women make an informed choice, since it assumes that the choice will be "yes".²¹

Endorsement by the primary care provider may yield somewhat higher screening rates, but cost-effectiveness and practicality have not been established. There is not a large difference in response rates to invitations for screening from general practitioners and from sources not personally known to women.²² For most Canadian screening programs, it is impractical to have invitations

sent from general practitioners. The implementation of electronic health records may improve the feasibility of using practice based lists which should be explored in the future.

Reminders target women who have not responded to an invitation. Reminders are generally sent between 4 and 8 weeks after the initial invitation. Women receiving a reminder are more likely to have mammography than those who do not receive one.²²⁻²⁴ Strategies can include letters or telephone calls, which can improve the response from those who do not reply to the initial invitation.²⁴ A letter of invitation followed by a telephone call is an effective strategy and could be helpful in reaching groups of women from different ethnic backgrounds or those of lower socioeconomic status.^{15,24,25} For women being contacted for their first screen, telephone follow-up is typically not possible, since the women are not yet registered in the screening programs. One study found an electronic notification system (e-mail) was as effective as mail and could provide an efficient, cost-effective system for delivery of reminders to clients.²⁶ Some programs may issue more than one reminder using various methods, therefore it may not be possible to ascertain the success of individual types of reminders.¹⁴

There is no real evidence in the literature as to the timing of the reminder. Such reminders have generally been sent between 4 and 8 weeks after the first invitation. Most bookings take place in the first week after receipt of the invitation. Thus, a 3 to 6 week interval between letters may be more appropriate. For mobile units, it may be difficult to anticipate too far in advance the exact time when the unit will be in the community. The time between the initial letter and the reminder letter may therefore need to be shorter.

Interventions may be implemented to overcome some of the barriers to participation. A recent meta-analysis found that tailored interventions (e.g. tailored to age, ethnicity, barriers to care, etc.), particularly those that employ the Health Belief Model and use a physician recommendation, are effective in promoting mammography screening.²⁷ Access-enhancing strategies (i.e. strategies that address structural, geographic and/or financial barriers) are an important complement to awareness strategies, particularly among underserved women.²⁸

1.1.2

Community Promotion Strategies

- *Promotional programs should be evaluated for their effectiveness.*
- *Promotional programs may target specific groups depending upon local conditions.*

Promotional campaigns have been used extensively to increase attendance at screening and to improve knowledge and understanding. However, it is often difficult to quantify and measure the impact of promotional awareness campaigns. Publicity alone is insufficient to achieve the high attendance rates necessary for a screening program to be effective; further strategies are needed.

Based on a systematic review of the most effective interventions for increasing screening rates for breast, cervical and colorectal cancer, an expert panel recommended the following interventions to increase the uptake of breast cancer screening:

- Client reminders and media campaigns
- One-on-one education
- Reducing structural barriers
- Provider assessment and feedback.²⁹

Beyond general promotional campaigns, certain special groups may need additional interventions to improve knowledge of breast cancer screening. These groups include older women, recent immigrants, women with language barriers, women of lower educational and socioeconomic status, rural women, ethnic minorities, high

risk women and single women. A recent meta-analysis of intervention studies designed to promote mammography screening in minority women found that access-enhancing strategies (e.g. mobile units) had the largest effect, followed by individually directed approaches such as individual counselling or education.³⁰ A bigger effect was seen for tailored, theory-based interventions compared with nontailored interventions.³⁰ These results are consistent with an earlier meta-analysis that also found that access-enhancing interventions combined with individually directed approaches had the largest impact on increasing mammography screening rates.²⁸

The internet is a large potential source of information and promotion regarding breast cancer screening. Most programs in Canada currently have a dedicated website; screening programs should maintain a website that clearly indicates contact information and booking procedures. In addition, outreach methods such as newspapers, radio, TV, video, newsletters, and media panels are commonly used. All programs use brochures, posters, group presentations, health fairs, information displays, public meetings, and physician education. Some programs use interpersonal strategies, with community volunteers contacting underserved populations, and then one-to-one teaching by public health nurses or lay educators. Some programs also coordinate with national or regional non-governmental organizations (NGOs) which can provide alternate means of reaching the target population or special groups of women. Screening programs should use a variety of outreach methods.

1.1.3

Program Promotion Aimed at Health Professionals

- *Screening programs should have ongoing liaison with appropriate health care organizations, professional associations and colleges.*
- *Screening programs must provide balanced information to primary care providers.*
- *The screening program should assist primary care providers in supporting eligible women to take an informed decision.*

Some of the most important factors associated with whether or not women have a mammogram are related to primary care providers. Improved frequency and consistency of communication about mammography by primary care providers is a critical factor for promoting screening participation.³¹ Having a usual source of care or a regular physician is the first step: women are about three times more likely to have had a mammogram in the previous two years if they have a regular physician.⁶ Some women are not aware of recommendations on screening, thus primary care providers play an important role in increasing women's knowledge. Although Canadian breast screening programs do not require physician referral, studies from other countries indicate that having regular contact with a physician is highly predictive of the use of screening mammography.⁸⁻¹⁰ This suggests that physicians' encouragement remains an important factor in women's decision to be screened.

Provider reminder systems are effective for increasing breast screening by mammography.³² Manual prompts in medical records or computer-generated reminders to tell primary care providers the date of the last screen and when the next is due appear to be an effective approach for improving preventive practices.^{22, 33} Whenever a woman consults her primary care provider there is an opportunity to discuss screening.^{23, 34}

A systematic review on the impact of information technology on the delivery of cancer preventive services in primary care offices found that the effectiveness of information technology on increasing cancer screening was modest.³⁵ The authors argue that audit and feedback of professional activity have the potential to change practice but there has been limited use of computer-generated audits, feedback or report cards. The review recommends further study of new technologic approaches to understand the impact and acceptance by providers and patients.

Educating primary care providers about mammography screening needs to focus not only on the need for screening but also on the advantages of having the screening performed in an organized screening centre, rather than in a diagnostic unit. Mammography through screening programs is oriented toward the asymptomatic client and can provide high-quality, efficient service at substantially lower cost than mammography outside the organized screening program. Primary care providers also need to be educated about the potential benefits, harms and limitations of breast cancer screening with mammography so that they can accurately convey these messages to their patients to aid in informed decision-making.

The involvement of physicians and other primary health care providers is key to the success of screening programs. Involvement is beneficial from the program's inception and should be facilitated through liaison with organizations such as medical associations.

1.2

Enabling Informed Decisions

- *Women must have balanced information about breast screening to promote informed choice. A decision aid tool is available for women contemplating breast screening and can be used to support women to take informed decisions on their own, or in collaboration with their primary care provider (i.e., shared decision-making).*
- *Women must be told that participation is voluntary.*
- *Screening centres should have staff available who can answer questions about consent including screenings benefits, harms and limitations.*
- *Women should provide written informed consent prior to screening.*

In order for women to take informed decisions to be screened for breast cancer they must have the opportunity to consider the potential benefits, harms and limitations associated with screening mammography. In doing so, their decisions are more likely to match up with their preferences, needs, values, and concerns.³⁶ Appropriate information in suitable formats (e.g. written materials, websites, information phone lines, etc.) should be available and accessible to all women (including disadvantaged and/or under-represented groups) who are in the target group for breast screening.¹⁴

Not all women will want to take their screening decisions alone. Decision aid tools can support women at average risk and their health care providers to share in the decision-making process. Women who are older, at higher risk of developing breast cancer (e.g. family history, high breast density, exposure to repeated radiation to chest due to treatment, etc.), physically or mentally challenged, from an ethnic minority, or speak a different language other than English or French may also benefit from the shared decision making process in terms of understanding their personal risk, the benefits of screening and deciding about screening.³⁶ Research has shown that satisfaction with screening increases and anxiety decreases when women take an informed decision to screen.

Since women's risk profiles vary, the likelihood of experiencing a benefit or adverse outcome from screening is not equal for all women. Use of decision aid tools can lead to more optimal screening utilization. The process of decision making is most important before screening is initiated. A Decision Aid for Breast Cancer Screening in Canada (www.publichealth.gc.ca/decisionaids) is the first of its kind in Canada to provide women with information on breast cancer screening using mammography and to help them decide whether to be part of breast cancer screening or not.³⁷

1.3

Ensuring Equitable Access

- *Screening programs should ensure adequate training and availability of tools to staff to provide comprehensive care.*
- *Screening centres should ensure that operational and physical impediments to mammography are minimized.*
- *Screening programs should develop a guideline to help identify which women cannot adequately undertake screening mammography and identify alternative pathways of care available (example: women with implants or breast cancer).*

- *Screening programs should consider strategies for women from special groups (e.g. women from culturally and linguistically diverse populations and women with disabilities).*
- *Screening programs should ensure geographic accessibility.*

There is a lack of validated indicators of accessibility to screening.^{37, 38} Analyses of geographic accessibility using geographic information systems are currently under way in Nova Scotia and Quebec. In addition, both national and regional client satisfaction surveys have documented perceived disincentives or potential barriers to participation, as well as the positive aspects and appreciation of their screening episode by attendees. Such information is essential in order to adjust service delivery to the needs of women targeted by screening recommendations.

Women with special needs may be less likely to receive screening mammography compared to other populations,^{39, 40} and ultimately may be diagnosed at a more advanced stage of the disease.⁴¹ The literature is incomplete on what types of special needs are associated with poor attendance. Women with limitations related to walking, standing and climbing stairs appear more likely than the general population to receive screening

mammography⁴² whereas women who experience long-term difficulties with activities of daily living are less likely.⁴³ Women with special needs that result in social isolation appear least likely to receive screening mammography, as are women with severe mental health illness.⁴²

Women with special needs may encounter a variety of obstacles in relation to breast cancer screening.^{39, 40, 44-47} Obstacles to participation may occur at various points throughout the breast cancer screening process including entry into the program, and with the mammography procedure itself.⁴⁸ Obstacles to entry into the program may include a lack of appropriate information for informed decision making, physical inaccessibility of facility, lack of personal assistance within the facility, and poor previous mammography experience.⁴⁸ Obstacles with the procedure itself may include difficulty with communication and physical positioning.⁴⁸

Special groups should be identified within the engagement plan, their needs should be addressed, and their participation rates documented separately. Women from different cultural backgrounds may have beliefs, attitudes, feelings, and emotions stemming from underlying cultural perceptions of illness and well-being. Such issues must be taken into account by providing screening and assessment that is appropriate to these groups.⁴⁹

1.4

Capacity

- *Screening programs must have sufficient capacity (e.g. facilities, staff, infrastructure) to provide services to all eligible women who wish to participate.*
- *Screening programs should adapt the delivery of services to ensure timely access to mammography for all participants.*

In order to offer screening services and to reach all eligible women who wish to participate, the program needs the capacity to provide these services, i.e. sufficient facilities, workforce, and infrastructure. A lack of centres, staff,

medical radiation technologists or radiologists will limit capacity and reduce access.⁵⁰ Insufficient capacity has been shown to result in lower screening rates and late-stage diagnosis of breast cancer.⁵¹ Increases in the number of eligible women place more pressure on screening services. However, technological innovations such as digital mammography and tomosynthesis may have a positive impact on capacity.

Capacity and timely access to mammography can also be increased by screening with mobile units. In Canada, just over half of the programs, including British Columbia, Alberta, Manitoba, Saskatchewan, Ontario, Quebec and

Nova Scotia use this resource.⁵² Screening performance is usually not reported separately for fixed centres and mobile units. However, a recent study from Quebec, where mobile units have operated since 2002, showed that their introduction had a major impact on participation in areas without fixed screening centres.⁵³ In 2006, the participation rate reached 52.0% and 69.9% in the northern regions of Nunavik and Terres-Cries-dela-Baie-James. Preliminary analysis of performance, although limited in statistical power due to the small number of screen-detected cancers in mobile units, supports the notion that screening done through these units could lead to equivalent cancer detection and lower referral as a result of centralized reading by a limited number of high-volume radiologists.⁵³ Mobile units represent an effective tool to ensure equity of access and increase capacity to screen eligible women.

Capacity and timely access to mammography in the

target group may be affected when there is extended eligibility or a high rate of annual screening. Yearly mammography screening continues to be offered by most provincial screening programs for subgroups of women due to increased risk of breast cancer (based on patient or screening history), provincial screening policy or other factors.

Many screening mammography facilities also provide diagnostic mammography and other follow-up diagnostic procedures. Diagnostic mammography is different from screening mammography in that additional views may be required. These can include spot compression and/or magnification views of an area of concern and are generally more time consuming than screening mammography. A lower abnormal call rate would reduce the number of diagnostic mammograms required and thereby increase the capacity for performing additional screening mammograms.

1.5

Indicators*

Participation Rate:

- *≥70% of the target population screened within a 30-month.*

*For complete information on calculation methods, definitions and context please refer to the following report: Public Health Agency of Canada. Report from the Evaluation Indicators Working Group: Guidelines for Monitoring Breast Cancer Screening Program Performance: Third edition. Ottawa: Minister of Health (currently in press).

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SCREENING PATHWAY — CHAPTER 2

The Screening Visit

2.1

Booking an Appointment – identification, access, information, eligibility

- *A client service-oriented approach should be adopted throughout the program; clients include the women, their primary care providers, the community, and stakeholders.*
- *Centres should obtain previous mammograms prior to the appointment.*
- *Women must be given information prior to the mammography visit, including how to prepare themselves and how to obtain results; commonly asked questions about breast screening should be answered.*
- *Each screening program should measure client satisfaction.*
- *Educational materials, including brochures and DVDs, should be available to supplement staff members' discussions with women.*
- *Screening centre personnel should inform women that mammography is not a singular event, and that it is thus necessary to be screened at regular intervals.*

Part of the client service-oriented approach that screening programs should adopt is to ensure that initial client contact is of high quality. Communication between reception staff and women should be professional, friendly and welcoming. Telephone and reception staff

should be mindful that women may have different expectations and understandings of the screening program.¹ Receptionists/scheduling personnel should understand the difference between screening and diagnostic mammography. Receptionists/scheduling personnel should obtain information to ensure eligibility. If a woman is not eligible for screening mammography, she should be informed of the reason and encouraged to see her primary care provider. Receptionists should identify women who require language assistance and provide access to these services whenever possible. During the appointment-making process, any special needs, disabilities or impairments should be identified so that appropriate arrangements may be made.

Women should be given information on the upcoming mammography visit, both to decrease anxiety and to improve the quality of the mammography experience, including the informed consent process. Answers to commonly asked questions about breast screening should be provided. Women should be advised about the length of the visit, asked to wear a two piece outfit, and told that they may be asked to remove their deodorant.

Easy access to programs is another component of a client service approach. Accessibility includes having extended hours, parking available (if needed) as well as a convenient

location for both car and public transit users. Efficient booking systems as well as minimum waiting times for appointments improve program access. The use of mobile screening units may increase convenience and accessibility.² Access can be further improved by offering screening mammography outside of regular business hours (i.e. during evenings) and on weekends.

Timely access to mammography is essential to the success of the screening program. In most Canadian jurisdictions, appointments for screening mammography

are initiated by the woman who requires screening. When a woman calls to schedule an appointment, they will be offered appointment options but there will be a minimum wait until the first available appointment. Depending on the location of residence the “waiting time to next appointment” will vary. Currently there are no Canadian standards for an appropriate upper limit to this waiting time. The National Committee of the CBCSI is currently working to establish common wait time targets among programs.

2.2

Arriving at the Centre – receptionists, identification, registration, special needs, language, education and information

- *Personal identification (2 identifiers) of the woman must be obtained at the time of the visit. All screening centre staff who interact with the woman must ensure that the woman has been appropriately identified.*
- *Women must be offered the opportunity to ask questions in private and health care providers should be available to respond to questions. All staff should be sensitive to women’s concerns and be trained to ensure continuing client satisfaction.*

Continuous quality improvement is facilitated through the implementation of a client service approach. Such an approach would involve all aspects of providing service to the client’s satisfaction – from being accessible, to minimizing pain and anxiety during the visit. It includes training and supervision of personnel, measuring patient satisfaction through questionnaires, and addressing complaints. It also includes ongoing management of the

program to make sure that the approach of the staff is positive and caring. All services delivered by the screening program should be provided in a professional manner.

Each program must provide women with sufficient, balanced information about screening mammography to respond to questions that may arise at the screening appointment. This includes breast cancer risk factors (e.g. family history, high breast density, exposure to repeated radiation due to treatment, etc.), the benefits of screening, the potential harms, and the possibility of recall for additional follow-up. This information must be made available to women prior to screening to enable informed decision-making and consent.

The language and format of information should be appropriate to the intended audience in order to facilitate participation in the program. Women from the relevant population should be involved in the development of information resources, perhaps through consultation with local consumer groups.

2.3

Having a Mammogram – technologists, history review, pain/discomfort, anxiety, special needs, education

- *The mammography technologist must ensure that the client is correctly identified.*
- *The mammography technologist must be available to answer any questions related to the procedure.*
- *Mammography technologists should be sensitive to the physical and psychological needs of the client before, during, and after the mammogram.*
- *Prior to the mammogram, mammography technologists should communicate the need for compression and possibility of discomfort and the possibility of follow-up tests.*

Screening centre staff plays an important role in making the experience of mammography as pleasant as possible for the woman, minimizing discomfort and anxiety. Communication between staff and women is a crucial aspect of the screening test. They must be friendly, positive, caring, and sensitive to all clients. Staff guidelines should reflect such approaches.

An integrative literature review reveals that pain continues to be a barrier to mammography for some Canadian women.³ Cochrane systematic review evidence indicates that providing written or verbal information about the

mammogram prior to the examination may help to reduce pain and discomfort.⁴ Increasing women's control over compressions and the use of breast cushions appear to reduce pain and discomfort, however these mechanisms may affect the quality of the image obtained, therefore further research is required before these techniques are put into routine practice.⁴ To maintain the quality of the images produced, the technologist should control the first compression.⁴ According to one study that was included in the Cochrane review, pre-medication with acetaminophen does not reduce the pain associated with mammography.⁴ However, in a subsequent study, pre-medication with 4% lidocaine gel provided a significant reduction in discomfort.⁵

The degree of anxiety felt may often relate to the woman's first experience with mammography. Women who fail to re-attend often express more negative views about mammography and find screening significantly more uncomfortable, painful, stressful, embarrassing, and worse than expected. In a British study, 50% of women attributed their failure to return for second round screening to their first visit experience, 41% indicating that it was due to the pain of the initial mammogram. Other research also found an association between discomfort and intention to rescreen.⁶

2.4

Completing the Visit – informed about next steps, education

- *Screening centre personnel must inform women of the next steps in the screening process, including timely communication of results and how to follow-up with questions and/or concerns.*

Upon completion of the screening mammogram, women must be informed about the next steps in the process. Screening staff should provide women with contact information and details about how to followup with questions and/or concerns. Women should be informed about how and when screening results will be communicated. Screening centre personnel must advise women when to expect results and should suggest that they call if the results have not been received within the specified time period.

If a woman was previously screened in another facility and the corresponding images were not obtained prior to the visit, the woman should be forewarned of the potential

delay associated with obtaining the previous images. Women should be reminded about the possibility of requiring further examinations. It is important to indicate to the woman at the time of the mammogram that most abnormalities found with mammography prove to be benign. If a woman is recalled for further examinations, minimizing the waiting time between the recommendation for further examinations and the time when they are carried out can reduce anxiety. An analysis of records in the Canadian Breast Cancer Screening Database found that there is considerable variation between and within programs in the time from abnormal screening to diagnosis.⁷

Women may be overly reassured by a negative mammogram and thereby delay seeking medical assistance for breast symptoms. It is therefore important to instruct women that a negative mammogram does not rule out malignancy in the presence of a palpable mass or other breast abnormality.

2.5

Client Satisfaction

- *Screening programs must solicit client opinions on the services provided.*
- *Screening programs must clearly identify the policies and procedures to be used for dealing with client satisfaction issues.*

Client satisfaction with mammographic screening is an important indicator of high quality service. Satisfaction with services is particularly important since the client population does not have symptoms or ill health to motivate them to adhere to mammography screening recommendations. Client satisfaction with screening is associated with intention to rescreen.⁸ Screening programs must measure satisfaction with services provided.

A qualitative study found that client satisfaction with mammography was associated with factors according to seven primary themes:

- 1) appointment scheduling
- 2) facility
- 3) general exam
- 4) embarrassment
- 5) exam discomfort/pain
- 6) treatment by the technologist, and
- 7) reporting results.⁹

The screening program should also monitor the extent to which the services are perceived as acceptable and appropriate to the needs of the eligible population.¹⁰ Regular surveys should be conducted in order to assess satisfaction with information, waiting time, the physical environment, pain and discomfort, and interactions with staff.^{1, 10} The results of client surveys and client comments should be used to improve service provision. Satisfied clients are more likely to return for rescreening and to provide positive comments to others.

2.6

Indicators*

- *Retention Rate: percentage of women who are screened within 30 months of their previous screen*
 - *≥75% screened within 30 months of an initial screen;*
 - *≥90% screened within 30 months of a subsequent screen.*
- *Timely notification of results*
 - *≥ 90% screening result notifications are sent within 2 weeks of the screen.*

*For complete information on calculation methods, definitions and context please refer to the following report: Public Health Agency of Canada. Report from the Evaluation Indicators Working Group: Guidelines for Monitoring Breast Cancer Screening Program Performance: Third edition. Ottawa: Minister of Health (currently in press).

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SCREENING PATHWAY — CHAPTER 3

Following the Screening Visit

3.1

Communicating Screening Results to the Primary Health Care Provider

- *A standardized radiology screening report must be issued for both normal and abnormal results in a timely fashion. This report must document the specific findings and follow-up recommendations.*
- *The report conveying normal results should advise primary care providers of the limitations of mammography.*
- *The report providing abnormal results must be specific as to type of abnormality detected, the number of significant abnormalities, their size, location, and the type of subsequent examinations to be performed to define the nature of the abnormality.*
- *The abnormal mammography report should provide a list of accredited diagnostic facilities.*
- *Women without a primary care provider must be assisted by the screening program in accessing follow-up care.*

The radiology report's primary purpose is to communicate the results of the screening mammogram to the primary care provider. It is essential that the radiology report is

timely, accurate, clear, and thorough using unambiguous language.¹ If a woman has no referring primary health care provider, the screening centre must provide information assisting her to obtain a qualified one.

The screening program must provide the primary care provider with a report documenting the specific findings and follow-up recommendations. The following should be included in the synoptic report:

- pertinent clinical history;
- comparison with previous studies;
- mammographic breast density;
- a description of the findings, including specific details about masses and calcifications; and
- an overall assessment and recommendation.²

The report should conclude with one of three overall assessments/recommendations:

- the screening mammogram is normal or has benign findings and a routine return to screening recommendation is made;

- the screening mammogram is abnormal and a work-up recommendation is made such as breast imaging (e.g. diagnostic mammography, breast ultrasound) or surgical consultation;
- the lesion is highly suspicious of malignancy, and mammographic localization and biopsy are required.

The interpretation of the mammogram and the clarity with which the information is disseminated is important for high-quality care. The screening program is responsible for communicating the screening results to the woman and to her primary care provider.

Computerized notification systems to alert primary care providers of abnormal results through electronic medical records have been evaluated.^{3,4} Although computerized notification systems and electronic medical records may facilitate the transmission of imaging results to health care providers, imaging results continue to be lost to follow-up.^{3,4} There continues to be a need for multiple failsafe procedures to ensure women with abnormal screening results receive follow-up.

3.2

Communicating Screening Results to the Woman

- *The woman must receive written notification of her mammography results in a timely fashion.*
- *Written notification of mammography results should be in simple language and indicate the next steps. The letter should indicate where further information can be obtained.*
- *Programs should consider providing communication in the languages of minority populations.*
- *With normal results, the letter must state the limitations of mammography. It must state that if the woman develops any suspicious signs or symptoms before the next screening date, she should see her primary care provider. The letter must also emphasize the importance of continued participation in screening.*
- *With abnormal results, the notification should balance the need for work-up with reassurance that the majority of abnormalities turn out to be benign after further investigation.*

All Canadian organized breast screening programs communicate screening results to women. Screening programs have adopted a variety of methods of sending results to women and their primary care providers. Normal reports are generally mailed simultaneously to the woman and her primary care provider. Results should be mailed as soon as possible. The timing and reporting of

mammography results is an important determinant of client satisfaction with mammography screening.⁵

Some women experience inadequate communication of mammography results.⁶ Mammography result notification letters should not be written in a format that is difficult to understand⁷; screening programs should ensure that results (both normal and abnormal) are being communicated in a clear, simple manner.

If the mammogram is normal, the letter should state that there is a small percentage of cancers not detected with mammography, and that if the woman develops symptoms before the next screening date, she should see her primary care provider. The letter should also emphasize the importance of regular participation in screening.

If the mammogram is abnormal, the letter should inform women that an abnormality has been found and explain the abnormality as clearly as possible. The letter should include a pamphlet describing diagnostic mammography. The letter should emphasize the importance of follow-up while also indicating that the majority of abnormalities turn out to be benign after further investigation. For screening facilities with a diagnostic assessment service, the letter should include a specific appointment time for further tests.

Whether abnormal results are mailed or telephoned to women is somewhat controversial. Most programs do not

telephone the woman directly. Women who are notified of their mammography results in person or by telephone may have better comprehension of their results, particularly if the results are abnormal.⁸ Direct communication of mammographic results to the client has been advocated, as it results in better adherence with recommendations for additional imaging, follow up examinations, and biopsies. Direct communication with the woman may reduce the anxiety associated with waiting for the results of the mammographic examination and may improve satisfaction.⁸

Some women may experience anxiety when receiving an abnormal result and being called for assessment.⁹ Two recent systematic reviews regarding the psychological impact of mammography screening confirm that women who are recalled for further investigation experience significant anxiety in the short term, and possibly in the long term.^{10,11} In addition, one of these reviews found that Canadian women who receive a false-positive result are

less likely to return for screening, compared to American women who are more likely to return following a false-positive result and European women whose re-attendance rates are not affected by false-positive results.¹¹ A retrospective study from the UK National Health Service found that women who experienced false-positive mammograms at their first screening visit were less likely to return for a second screen, yet they were more likely to develop postscreen cancers or cancers at second screen, and their cancers were larger.¹² Minimizing the waiting time between the recommendation for further examinations and the time when they are carried out may reduce anxiety. An analysis of records in the Canadian Breast Cancer Screening Database found that there is considerable variation between and within programs in the time from abnormal screening to diagnosis.¹³ Also, women should be informed of the results of screening and assessment promptly to ensure that anxiety is as brief as possible.

3.3

Assessment of Abnormal Screening Results, Imaging, Biopsy

- *Screening programs must establish a systematic approach to follow women up to the conclusion of the assessment.*
- *There must be a timely mechanism to ensure that follow-up of the screening abnormality has been initiated. The screening program should verify that this has occurred within a reasonable timeframe.*
- *After an abnormal mammogram, women should be followed up in an accredited diagnostic facility.*
- *Screening centres should be linked with diagnostic sites to facilitate liaison and continuity of care.*
- *The screening program must ensure that evaluation and assessment of the woman with an abnormal result has been completed in a timely fashion.*
- *Screening programs should receive follow up reports from the diagnostic centres and surgeons so that they can evaluate program effectiveness and determine who should be re-invited for screening.*

At the initial screen and at rescreen, 12% and 6% respectively of Canadian women screened within organized breast screening programs were referred for additional assessment.¹⁴ Among these women with abnormal screens, between 5% and 8% subsequently received a diagnosis of cancer.¹⁴

All organized breast screening programs in Canada must have a systematic mechanism to ensure that all women

with abnormal mammograms are followed to diagnosis. The screening program is responsible for monitoring women whose results are abnormal and for establishing protocols with the diagnostic facilities to ensure communication. Screening programs must ensure that women who require a work-up following an abnormal mammogram are transitioned to a diagnostic site in a timely manner. The screening program should verify that the follow-up with the diagnostic site has been initiated. Ideally, women should receive follow-up in an accredited diagnostic facility to ensure the highest quality of service. Screening programs should have systems and protocols in place to ensure that the transition to a diagnostic facility occurs, that delays are minimized as the woman progresses, and that communication between the screening program and diagnostic site remains intact. In order to facilitate the work-up, screening centres must ensure that the diagnostic site receives the screening mammogram prior to the work-up date. Screening programs must also ensure that the diagnostic site can provide access to needle core biopsy and can facilitate a timely core biopsy if required.

A timely follow-up that ensures a definitive diagnosis with the minimum number of interventions should be provided in order to reduce morbidity for women, especially the anxiety, discomfort, time, and expense required by additional tests. Women should be reassured as quickly as possible when no significant problems are diagnosed or given a diagnosis without delay in the presence of cancer.

Most Canadian organized programs have mechanisms that trigger an inquiry when activities related to the follow-up of an abnormal mammogram have not been registered in the information system. For example, a primary care provider will be contacted to determine if a woman with an abnormal mammogram received follow-up services. Screening programs should implement an automatic system for ensuring abnormal mammography results are followed up. A system should be in place to ensure that the primary care provider is contacted if the screening centre does not receive results.

3.4

Closure of the Screening Episode

- *Programs must record the final screening episode result (cancer or normal/benign) and implement appropriate recall to screening.*

Once the follow-up has been completed, screening programs must record the final screening episode result (cancer or normal/benign) and implement appropriate recall to screening. Women who previously required diagnostic workup for a mammographic abnormality may be hesitant to return for future mammography. A letter

stating that the screening centre is aware that the woman has been evaluated and the results are normal may provide positive closure. The letter should restate the limitations of mammography and emphasize that it is still the best method available for the early detection of breast cancer. The woman should be reminded to see her primary care provider before the next screening date if she develops symptoms. The letter of closure should also tell the woman to expect a letter for her next screening examination.

3.5

Indicators*

- *Time from screen to notification of screening results*
 - 100% to be notified
 - ≥ 90% within 2 weeks.
- *Time from abnormal screen to first diagnostic assessment*
 - ≥ 90% within 3 weeks.
- *Time from abnormal screen to definitive diagnosis*
 - ≥ 90% within 5 weeks if no tissue (core or open) biopsy performed
 - ≥ 90% within 7 weeks if tissue (core or open) biopsy performed.

*For complete information on calculation methods, definitions and context please refer to the following report: Public Health Agency of Canada. Report from the Evaluation Indicators Working Group: Guidelines for Monitoring Breast Cancer Screening Program Performance: Third edition. Ottawa: Minister of Health (currently in press).

3.6

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SCREENING PATHWAY — CHAPTER 4

Facilities, Staff and Supporting Services

4.1

Accreditation of Mammography Facilities

- *Mammography facilities must be accredited to facilitate high quality screening.*

Accreditation is a way to ensure that facilities deliver high quality mammography. Accreditation of mammography facilities is a systematic evaluation that provides peer review and feedback on relevant factors, including staff qualifications, equipment, quality control and assurance, image quality and radiation dose. All provincial and territorial screening programs should attain accreditation for their facilities by an organization such as the Canadian Association of Radiologists (CAR).

The benefits of accreditation include:

- formal evaluation of practice
- identification and documentation of a need for equipment repairs, personnel training or continuing education requirements
- expert assessment of image quality
- uniform, consistent service delivery over time and across locations
- regular assessment by a physicist

In Ontario, a study of 100 mammography machines across the province found that quality was improved among accredited facilities participating in a province-wide screening program.¹ There is further evidence in support of accreditation from the United States, where the mandatory accreditation program has led to an overall increase in the quality of mammography services.^{2,3}

4.2

Quality Control – Analogue and Digital

- *An organized screening program must have a quality assurance (QA) program.*
- *An organized screening program must implement acceptance testing and a quality control (QC) monitoring program.*
- *A procedure manual outlining the methodology for these tests must be accessible to technologists performing the tests for standardization purposes.*
- *These tests must be periodically reviewed by the radiologist and by the physicist.*

An organized screening program must have a quality assurance (QA) program in order to ensure that the mammography examination is performed with consideration given to the optimal balance between the radiation dose and the image quality. Ideally, the best image should be obtained using the lowest possible dose of radiation.

A QA program for mammography includes quality control (QC) procedures for the monitoring and testing of film screen and/or digital equipment and related components, and administrative actions to ensure that monitoring, evaluation, and corrective actions are properly performed.

QC is defined as the routine performance and interpretation of equipment function tests and of corrective actions taken.⁴ It is used to detect, identify, and correct equipment-related problems before they have an effect on clinical images. Together with the radiologist, the medical physicist, and qualified service personnel, the mammography technologist can eliminate these problems before client care is affected.

Acceptance testing and a QC monitoring program must be implemented to:

- detect defects in new equipment and establish a baseline performance and reference test image;
- detect changes in equipment performance before the changes can be seen radiographically;
- detect defects in repaired equipment and verify that equipment problems have been corrected.

Administrative procedures should also be instituted in order to:

- identify the personnel responsible with regard to the operation of the QA program;
- set record-keeping requirements;
- set testing frequency, evaluation of data, and limits of acceptability;
- set corrective actions.

QC procedures should involve all radiologists, the physicist, the mammography technologists trained in quality control procedures, and equipment service personnel. QC tests on various items of equipment should be carried out with the frequency recommended by the CAR Mammography Accreditation Program (CAR-MAP) requirements. The CAR regularly updates its program; this information is available directly from the CAR.

Health Canada is currently updating its Safety Code for Radiation Protection and Quality Standards in Mammography. Screening programs should review and follow the Safety Code.

In addition to regular equipment testing, appropriate tests should be carried out when equipment is new, when problems are suspected, and after servicing or preventive maintenance. A procedure manual outlining the methodology for these tests must be accessible to technologists performing the tests for standardization purposes. The radiologist and the physicist must periodically review test results.

The mammography technologist and radiologist must look at every image with quality control in mind. Deviations in quality control may occur quickly or gradually. Detection of gradual changes requires regular testing for detection.

The effectiveness and success of breast screening depends on consistent production of high-resolution, high-contrast mammographic images. Poor quality mammography can lead to missed breast cancers or give rise to unnecessary additional tests that increase patient anxiety and decrease the public's confidence in the effectiveness of mammograms.

4.3

Data Management and Evaluation

- *Organized programs must maintain a longitudinal database on screening clients.*
- *The screening database must include demographic information, screening results and subsequent investigations.*
- *The screening database must be linked (periodically) to the cancer registry.*
- *The screening database should be linked to a population register.*
- *Organized programs must monitor, measure and report program performance*

Screening is a large complex undertaking in which the likelihood of benefit or harm to an individual participant is small. Screening is not a one-time event and takes place over a significant proportion of a participant's life. Benefits accrue slowly and cannot be reliably ascertained from individual experiences. It is therefore imperative that mechanisms exist to evaluate benefits and harms in all participants over a substantial period of time. This is most efficiently performed by maintaining a client database which is linked to population registers including the provincial cancer registry. The client database should include all current and past clients and women eligible to be screened. The database should include the following information where applicable:

- Demographic – birth date, location of residence, ethnic group, cause and date of death, eligibility dates
- Screening – dates of mammograms, findings
- Assessment of abnormal results – procedures and dates, results of procedures
- Cancer – cancer diagnoses and date, modes of detection, stage

In Canada organized screening programs maintain screening information in program-specific databases. All data is depersonalized and sent securely from the participating program to the CBCSD, a national database administrated by the Public Health Agency of Canada (PHAC). While participating in the CBCSD, the province/territory owns their data, and thus provinces/territories have unrestricted rights over their data. Variables include client factors, screen event information, referral reasons, diagnostic test information, and where applicable, cancer information. At the present time the Yukon does not submit records to the CBCSD and Nunavut does not have an organized program. The CBCSD is currently used for monitoring, evaluation, and applied screening research. Biennial reports comparing all provinces and the Northwest Territories on selected performance indicators are published by PHAC.

Programs should ensure there is sufficient information to measure performance at the centre level. The Evaluation Indicators Working Group of the CBCSI selected 13 performance measures and targets (see Appendix 1). These measures were developed on the basis of recognized population screening principles, evidence from randomized controlled trials, demonstration projects, and observational studies.

4.4

Roles, Education, Training and Performance of Medical Radiation Technologists

- *Medical radiation technologists involved in the performance of mammography must hold a valid provincial licence or certification by the Canadian Association of Medical Radiation Technologists (CAMRT) if their province does not provide provincial licensing.*
- *Mammography units should be accredited.*
- *Training requirements for technologists employed in a screening program should include 1) CAMRT Mammography I & II courses or equivalent and 2) a minimum of 1 year's experience in mammography.*
- *To maintain their standing in the program, technologists should have a minimum of 15 hours of continuing education every 3 years and perform a minimum of 1,000 mammograms per year. These represent minimal criteria, and screening programs should endeavour to maximize the number of examinations performed per technologist.*
- *The repeat rate should be less than 3%.*
- *Mammography technologists affiliated with screening programs should abide by the Safety Code for Radiation Protection and Quality Standards in Mammography (final draft expected Fall 2012).*

Medical radiation technologists involved in the performance of mammography must hold a valid provincial licence or certification by the Canadian Association of Medical Radiation Technologists (CAMRT) if their province does not provide provincial licensing. In addition, the technologist must also have undergone a minimum of 15 hours special training in breast imaging either through a training curriculum or through continuing professional development courses.

For renewal of accreditation, technologists involved in the performance of mammography must have earned 15 hours of Continuing Professional Development (CPD) credits in breast imaging within a three year period prior to the accreditation application.

The repeat/rejection rate of screening mammograms should be less than 3% in the analogue environment. The domains for the repeat/reject analysis in the analog environment include: static, mechanical problems, double exposure, artifacts, black film, dark film, fog, light film motion and positioning. The repeat/rejection rate should be lower using digital technology; however an exact repeat/rejection rate for digital mammography is yet to be established. The domains for the repeat/rejection analysis in the digital environment include: positioning, patient motion, poor compression, improper detector exposure, x-ray equipment failure, equipment artifacts, blank image, clinical artifacts, incorrect view marker, quality control/acceptance test/calibration and other.

4.5

Roles, Education, Training and Performance of Radiologists

- Radiologists must meet the qualifications as outlined in the CAR-MAP Guidelines.
- Screening programs should include quality control procedures to continually assess the screening performance of radiologists in the program
- To maintain standing in a screening program, in addition to CAR requirements, radiologists should meet the following minimum conditions:
 - Participate in quality assurance review rounds at least quarterly; and
 - Read at least 2,000 screening mammograms annually.
- A screening program's overall abnormal recall rate should be <10% for first screens and <5% for subsequent screens. An individual radiologist's abnormal recall rate should be within +/-5% of the program target; the individual radiologist's abnormal recall rate will likely be slightly higher in their first year reading screening mammograms.
- The radiologist should participate in the institutional multi-disciplinary breast team involved in breast cancer screening, diagnosis and management.
- Radiologists should review their individual feedback regarding cancer detection rates, sensitivity, specificity, and interval cancers that is provided by the screening program.

Mammographic screening is a radiological procedure. One cannot have a high-quality screening program without experienced radiologists. The setting of minimum standards of training and performance for radiologists is therefore an important starting point for a high-quality program. Setting such standards enables screening programs to meet their objectives of maximizing detected cancers, and minimizing post-screen cancers, recall, unnecessary invasive procedures, and anxiety.

Initial standards should be complemented by ongoing monitoring of performance with regular feedback displaying individual performance in relationship to a relevant peer-group and national standards. Ongoing monitoring should include, volumes, demographic distribution of clients, standardized cancer detection rates and standardized abnormal call rates. Although it is important to keep the abnormal recall rate down it is equally important to compare cancer detection rates with the abnormal recall rates. Where possible programs should provide trend data and relate this to provincial trends. Programs should have ranges for radiologist performance and include systems to support and educate radiologists considered to be performing outside the designated ranges.

Screening mammography is a further specialization within mammography. Thus, although licensed radiologists certified by the College of Physicians and Surgeons may be permitted to read mammograms, a higher standard for radiologists may be required in screening programs.

As indicated in the CAR-MAP guidelines, radiologists in screening programs must:

- 1) Possess any relevant federal/provincial/territorial regulations and statutes;
- 2) Be certified in Diagnostic Radiology by the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Equivalent foreign radiologist qualifications are acceptable if the radiologist is certified by a recognized certifying body and holds a valid provincial license;
- 3) Have 40 hours of Continuing Professional Development (CPD) credits in breast imaging; and
- 4) Interpret and/or second read a preferred minimum of 1,000 mammograms per year^a and maintain records concerning outcome data for correlation of positive mammograms to biopsies performed and the number of cancers detected.

a) A minimum of 480 reads per year is still accepted.

The interpretation of mammograms by radiologists is a complex process and it is recognized that one must continually practice mammographic interpretation to maintain skills.⁵ In Canada, the recommendation for a minimum annual interpretation volume of 1,000 mammograms per year is still relatively low compared with the 2,000 mammograms required in Australian and New Zealand screening programs^{6,7} and the 5,000 mammograms required in United Kingdom screening programs.⁸ There is evidence that a higher minimum interpretative volume leads to better results.⁹

In developing these recommendations, standards in other countries with screening programs were considered. For example, in addition to radiological certification, Australia requires radiologists to have an acceptable level of formal training in the radiological assessment of women with abnormal screening mammograms; to attend an approved State or national training course in screening; and to attend regular, multidisciplinary conferences for review of screening and assessment service activities.⁶ In New Zealand, radiologists must undertake further 1 A minimum of 480 reads per year is still accepted. training prior to commencing screening mammography within the program, including: 1) attendance at one teaching course within the last two years; 2) completion of 300 dummy third reads within the three months prior to commencement with a recall rate of not more than 12% is required; 3) participation as an observer at the full clinical multidisciplinary team meetings and the process of resolution, of discordant readings during the period of training as a third reader; 4) demonstration of reader sensitivity of 80% from a cancer seeded set of films; and

5) reporting of a minimum of 2,000 mammograms.⁷ Regular participation in multidisciplinary meetings, case review including post-screen cancers and performance audits are recommended in several screening programs.^{6,7,10}

For the annual number of mammography readings, two Canadian studies examined the relationship between radiologist screening program reading volumes and interpretation results.^{11,12} Main results of these studies revealed that the breast cancer detection rate ratio for facilities performing 4,000 or more screenings per year, compared with those performing fewer than 2,000, was 1.28 (95% confidence interval [CI] 1.07–1.52) and that the average positive predictive value (PPV) for individual radiologists increased as reading volume rose up to 2,000 mammograms per year. Radiologists who worked in larger facilities and read more screening mammograms had higher breast cancer detection rates while maintaining lower false-positive rates. Radiologists' and facilities' caseloads showed independent and complementary associations with performance of screening mammography.^{11,12} An American study on the influence of interpretive volumes on screening mammography performance found that increasing the minimum interpretive volume requirements (to 1,000 or 1,500) while adding a minimal requirement for diagnostic interpretation could reduce the number of falsepositive work-ups (a significant cost saving) without hindering cancer detection.⁹ Taken together, these results support the requirement that radiologists must read a minimum of 1,000 mammograms per year; ideally, radiologists should read at least 2,000 mammograms per year.

4.5.1

Double Reads

- *Radiologists should participate in double reads as a quality control measure.*

There are multiple methods of double reading. A double read program could involve the mammography technologist as the first reader and a radiologist as the

second reader, it could involve independent readings by two radiologists, or it could involve a radiologist and computer aided detection (CAD), with CAD being either the first read or the second read.

Essentially, a double read program serves either one of two purposes 1) to decrease the false negative rate (increase sensitivity) or 2) to decrease the false positive

rate (increase specificity). The design of the program, with respect to the resolution of discordances, establishes the purpose of the program. There are three methods of resolving discordant readings:¹³

- 1) abnormal if either read indicates abnormal (highest reader – i.e. increased sensitivity)
- 2) consensus (discordance resolved by consensus of readers – increased specificity)
- 3) arbitration by third reader (increased specificity)

For mammography screening, as it is currently practiced in North America, the achievement of higher sensitivity at the expense of lower specificity is an accepted philosophical goal.¹⁴ Double reading is not the standard of care but it should be encouraged in practice, since it reduces the false negative rate, and accomplished efficiently, so that there is no significant increase in cost.¹⁵

Double reading by technologist and/or radiologist may be cost effective in screening programs with very low abnormal call rates (i.e. < 2%), even using highest reader resolution of discordance, and it will increase the cancer detection rate (CDR).¹⁵ The highest reader approach may be more effective in programs with a small proportion of prevalent screens. (i.e. More prevalent screens infers higher referral rate).¹³

In a study looking at the effect of recall rates on the earlier detection of breast cancer, increasing the abnormal call

rate from 1% to 4% would reduce the number of post-screen cancers, and enable the earlier detection of previous false negative findings; however with recall rates of > 5% the CDR levelled off and result in a disproportionate rise in false positive findings.¹⁶

In the context of breast screening in Canada, where recall rates are presently >5%, the value (i.e. cost/ benefit) of radiologist double reading 100% of the screening images would appear to be marginal. Independent double reading of mammograms does not always produce beneficial results and is dependent on individual practices. There may be an increase in sensitivity but there is a resultant decrease in specificity.¹⁷

The breast screening program for Newfoundland and Labrador has a double read program that performs a second radiologist read on at least ten percent of all images as a component of the overall quality assurance of the program. The images are selected by the mammography technologist and/or nurse examiner based on suspicion; in addition, other random images are selected for double read to make up the ten percent. The highest reader approach is used to resolve discordance. Using this approach, the recall rate went from 6.6% to 7.2% and there was a 3.9% increase in the number of cancers detected through screening.¹⁸ Provincial breast screening programs in Nova Scotia also double read ten percent of all screening mammograms.

4.6

Roles, Education & Training of Physicist

- *Medical physicists affiliated with screening programs should abide by the CAR Mammography Accreditation Program Requirements.*
- *Physicists affiliated with screening programs should abide by the Safety Code for Radiation Protection and Quality Standards in Mammography (final draft expected Fall 2012).*

As stated in the CAR-MAP requirements, medical physicists must be certified in mammography by the Canadian College of Physicists in Medicine (CCPM) or its equivalent.

4.7

Roles of Pathologists

- *The pathologist must ensure appropriate handling and sampling of breast surgical and cytological specimens.*
- *The pathologist must provide timely reports which include accurate diagnosis with appropriate correlation with imaging and clinical findings.*
- *The pathologist should participate as a member of the institutional multi-disciplinary breast team involved in diagnosis and management of breast lesions.*
- *Atypical ductal hyperplasia*
- *Atypical lobular hyperplasia/lobular carcinoma in situ*

Pre-operative assessment of screen-detected breast lesions includes evaluation of needle core biopsies, and less commonly, fine needle aspiration cytology and open excisional biopsy specimens. It is essential that the pathologic findings be correlated with the diagnostic imaging findings to ensure the abnormality has been sampled appropriately. Any discordant cases must be resolved between radiology and pathology, and ideally should be reviewed at a multidisciplinary conference to determine appropriate treatment or follow-up.

For non-malignant lesions, institutional multidisciplinary consensus should be developed amongst pathologists, radiologists and surgeons on the management of lesions associated with an increased breast cancer risk, especially when identified by needle core biopsy. There should be guidelines for the management of the following lesions, which may consist of conservative local excision or clinical and radiologic follow-up depending on estimated breast cancer risk and the patient's co-morbidities:

- Atypical ductal hyperplasia
- Atypical lobular hyperplasia/lobular carcinoma in situ
- Flat epithelial atypia
- Mucinous lesions
- Radial scar
- Papillary lesions
- Fibroepithelial lesions with cellular stroma
- Spindle cell lesions.^{19,20}

4.7.1

Pathology Reporting

- *All breast specimens with in-situ or invasive carcinoma should be examined and reported according to standard protocols.*
- *Synoptic reporting templates for invasive and in-situ breast cancer should be utilized to assist in the reporting of all relevant information.*
- *Pathology reports should include prognostic factors essential for monitoring the performance and impact of breast cancer screening programs.*
- *A separate checklist/synoptic report should be employed in cases where DCIS without invasion is diagnosed.*

The Canadian Association of Pathologists (CAP-ACP) has endeavoured to improve quality assurance and quality control measures in surgical pathology at a national level by promoting the use of synoptic reporting for breast cancer pathology and supporting the development of

national standards for immunohistochemistry (IHC).²¹ Details of the organization's initiatives can be accessed on their website: www.cap-acp.org.

Accurate pathological assessment is essential for diagnosis and for monitoring breast cancer screening program performance. A number of protocols for the examination and reporting for specimens from patients with breast cancer have been produced. Comprehensive guidelines have been published by the College of American Pathologists which has been endorsed and promoted by the Canadian Association of Pathologists (CAP-ACP). Links to this document and a web-based seminar outlining changes in the latest (7th edition) AJCC TNM cancer staging system can be found on the Canadian Association of Pathologists website:

http://www.cap-acp.org/protocols_and_checklists.cfm

Synoptic reports improve the content and consistency of pathology reporting.²² Checklists ensure that clinically relevant variables are assessed and reported, and the format is easier to interpret by clinicians and data entry personnel in cancer registries and breast cancer screening programs. The College of American Pathologists protocol for the examination of specimens from patients with breast carcinoma includes the pertinent prognostic and predictive factors required by oncologists and surgeons to guide further management of patients with breast cancer.^{23, 24} Pathologists should adapt these guidelines/checklists in consultation with their clinical colleagues to capture all pathologic data of clinical importance for their patient population. The checklists/synoptic reports should include pathological characteristics outlined in the most recent edition of the AJCC TNM Cancer Staging manual (presently the 7th edition).²³

Prognostic factors essential for monitoring the performance and impact of breast cancer screening programs are:

- Tumour type (*in situ*, invasive)
- Tumour size (size of invasive component in millimetres, measured microscopically if feasible)
- Tumour grade (Nottingham histologic grading scheme)
- Lymph node status (number of nodes positive for metastasis, number of nodes removed, size of largest metastatic deposit)

- Lymphovascular invasion
- Resection margin involvement
- Skin involvement (direct skin invasion with ulceration, dermal lymphatic invasion, Paget's disease)
- Chest wall involvement
- Hormone receptor status (estrogen and progesterone receptors)
- Her2/neu status

The pathologist must ensure the laboratory team participates in quality assurance initiatives to provide for accurate assessment of breast biomarkers, including External Quality Assurance programs for breast biomarkers (hormone receptor and Her2/neu immunohistochemistry and Her2/neu in situ hybridization if performed in-house). The performance in these programs should be monitored.

The pathologist should participate as a member of the institutional multi-disciplinary breast team involved in breast cancer diagnosis and management. This team should include radiologists, pathologists, surgeons, oncologists and nurses as appropriate. The multidisciplinary team ideally should meet weekly to discuss all cases requiring multidisciplinary expertise. The venue should allow for pathologic and radiologic images to be projected for presentation. One member of the team should be responsible for recording the discussion and team decisions. It is important to correlate the pathology of the excised lesion with the pre-operative findings during discussions of post-operative cases; a case review may be necessary if there is sufficient discordance.¹⁰

4.8

Indicators*

- *Abnormal call rate:*
 - < 10% (initial screen);
 - < 5% (subsequent screens).
- *Invasive cancer detection rate:*
 - > 5 per 1,000 (initial screen);
 - > 3 per 1,000 (subsequent screens).
- *Positive predictive value of the screening mammography program:*
 - ≥5% (initial screen);
 - ≥6% (subsequent screens).
- *Post-screen invasive cancer rate:*
 - < 6 per 10,000 person-years (0 to < 12 months);
 - < 12 per 10,000 person-years (12-24 months).
- *Screen-detected invasive tumour size:*
 - >50% screen-detected invasive tumours are ≤15mm
- *Proportion of Node Negative Screen-detected Invasive Cancer:*
 - >70% screen-detected invasive cancers are node negative.

*For complete information on calculation methods, definitions and context please refer to the following report: Public Health Agency of Canada. Report from the Evaluation Indicators Working Group: Guidelines for Monitoring Breast Cancer Screening Program Performance: Third edition. Ottawa: Minister of Health (currently in press).

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SCREENING PATHWAY — CHAPTER 5

Future Directions

This section identifies key issues that arose during the report preparation that require additional attention in the future.

Issue 1: Informed Decision-Making

Recent research has provided more information about the nature and likelihood of potential harms of mammography. Although these harms are not unique to screening, given the large number of women involved and the limited likelihood of benefit, more attention to the potential harms should be considered in the formulation of screening recommendations. Committees responsible for developing screening guidelines have recently placed greater weight on the harms of screening and the recognition that women will not place similar weight on harms and benefits so that, in many circumstances, prescriptive recommendations are not appropriate. The situation is not assisted by the existence of many one-sided commentaries which ignore or downplay conflicting evidence. Therefore it is necessary to develop better ways to inform women of the risks and benefits of screening and be able to ensure that the process has provided them with the necessary information in an understandable format.^{1,2} Participation targets are primarily based on the absolute number of women screened and ignore the quality of the decision made to participate. While written consent is desirable it is unlikely that this alone will ensure that participants are properly informed. There is need for further work that will ensure women who participate in screening are properly informed.³

Issue 2: Waiting Time to Appointment

The waiting time to appointment refers to the time interval in between when a woman contacts a screening centre for an appointment and the scheduled date of the appointment. Currently there are no Canadian standards for an appropriate upper limit to this waiting time. The National Committee of the CBCSI is currently working to establish common wait time targets among programs.

Issue 3: Measuring Client Satisfaction

Client satisfaction is an important quality indicator for organized screening programs. The QD Working Group has developed an instrument to measure client satisfaction in the past. There is a current need for a more sensitive measurement tool and an alternative implementation method. The QD Working Group is considering the development of a valid, reliable, standardized instrument to measure client satisfaction.

Issue 4: Screening High Risk Women

Provinces and territories have different approaches to the definition of women considered at high enough risk to justify screening requiring different altered frequencies or using different modalities. The Canadian Preventive Services Task Force provides recommendations for women at average risk but has not considered women who are high risk. There is a need to review the clinical practice guidelines for screening high risk women at both the provincial and international levels to ensure that practices are based upon scientific evidence.

- The development and validation of risk prediction models for breast cancer having high predictive accuracy should represent a priority for research and development.
- Women at high risk of breast cancer (dense breast, familial history, exposure to repeated radiation due to treatment, etc.) should be followed in secondary settings of care with multimodality surveillance. A Canadian consensus on what constitutes high risk should be sought.
- The implementation of risk-adjusted screening protocols (within or outside organized screening programs) should be based on a careful analysis of the associated harms and benefits using rigorously designed evaluation studies.

Breast cancer risk is estimated on the basis of individual risk factors (e.g. age, family history, breast density) or using several risk factors either crossclassified (e.g. breast density according to family history) or combined into formal scoring algorithms (e.g. Gail model). Although criteria for the definition of high risk vary from one organization to the other, there is general consensus supporting the referral of these individuals to secondary level of care and early multimodality surveillance.^{4,5}

Issue 5: Patient Navigation

- Programs may consider establishing a systematic approach for managing and directing women who require work-up.

Since the development of breast screening programs in Canada, patient navigation has become an emerging discipline. The role of patient navigation is diverse with multiple functions and target populations. Canadian patient navigation programs have placed emphasis on providing timely access to care, empowering patients with information and education, coordinating care and/or providing links to community resources. Most studies of patient navigation utilise an individual, the navigator, to deliver the intervention; the navigator is responsible for the coordination or encouragement toward further care throughout the breast screening pathway.^{6,7} Navigation may also include advocacy with health care professionals and other service providers: however, many Canadian programs have taken an empowerment approach, in which the navigator provides information and support to enable the person to direct his or her own care.

The follow up component of the screening programs involve navigation of the client from abnormal screen to

diagnosis. Many studies have shown that for patients, the follow up process after an abnormal screen can result in considerable anxiety and emotional distress.^{8,9} Navigation of women through the screening and follow up process occurs on many levels and employs many different functions which can help promote continuity of care.

The critical points for navigation of the screening pathway in the cancer trajectory are:

- 1) notification of abnormal screen;
- 2) waiting for diagnostic work up after an abnormal screen;
- 3) waiting for surgical consult and/or biopsy;
- 4) waiting for the biopsy results;
- 5) final diagnosis.

Navigation interventions can result in timely diagnostic resolution, help decrease anxiety, increase patient satisfaction, and ultimately impact retention and recruitment to screening.¹⁰

The extent of the navigation protocol differs from province to province in terms of the personnel, expertise and resources available. The following interventions highlight the main functions of navigation in organized breast screening programs:

- 1) Facilitating workup of abnormal screens in a timely manner by proactively booking the recommended diagnostic follow up examinations. This action ensures timely diagnosis or resolution of an abnormality after an abnormal screen.
- 2) Tracking of all follow up procedures to reduce the loss to follow up of abnormal screens.
- 3) Providing information and emotional support/ counselling through the diagnostic follow-up to diagnosis.
- 4) Educating /answering questions on risk factors, pathology reports, surgical options, and/or treatment decision making (lumpectomy vs. mastectomy).

A navigation element inherent in the follow up component is critical to improving health outcomes in cancer screening. In addition, through personal contact with physicians and women, the navigator has promoted a heightened awareness of the clinical practice guidelines

for mammography and reinforces the appropriate clinical pathway. Navigators represent a defined expenditure of resources but may result in better resource utilisation of scarce diagnostic services. It is crucial that screening programs begin to identify processes and track outcomes to enable evaluation of the costeffectiveness of the navigation component within breast screening.

Issue 6: Computer Aided Detection (CAD)

CAD is evolving and improving and programs should be aware of the current level of evidence.

Issue 7: Safety Code for Radiation Protection and Quality Standards in Mammography

The Safety Code for Radiation Protection and Quality Standards in Mammography is one of a series of Safety Codes prepared by Health Canada to set out requirements for the safe use of radiation emitting equipment. The information in the Safety Code has been prepared to provide specific guidance to owners of mammography equipment, radiologists, radiation technologists, medical physicists, and other personnel concerned with the safety procedures, equipment performance, image quality, radiation protection and the overall quality of a mammography facility.

The complete Safety Code is expected to be published in the Fall 2012.

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Appendix 1

Evaluation Indicators for Organized Breast Cancer Screening Programs in Canada, Women Aged 50-69

Indicator	Definition	Target
1. Participation rate	Percentage of women who have a screening mammogram (within a 30-month period) as a proportion of the target population.	≥ 70% of the target population within a 30-month period.
2. Retention rate	The estimated percentage of women age 50-67 who returned for screening within 30 months.	≥ 75% screened within 30 months of an initial screen; ≥ 90% screened within 30 months of a subsequent screen.
3. Annual Screening Rate	The estimated percentage of women aged 50-68 who are screened within 18 months of their previous screen.	% women screened within 18 months of an initial screen; % women screened within 18 months of a subsequent screen. (Surveillance and monitoring purposes only)
4. Abnormal call rate ^a	Percentage of mammograms that are identified as abnormal at program screen.	< 10% (initial screen); < 5% (subsequent screens).
5. Invasive cancer detection rate ^b	Number of invasive cancers detected per 1,000 screens.	> 5 per 1,000 (initial screen); > 3 per 1,000 (subsequent screens).
6. <i>In situ</i> cancer detection ^b	(a) Number of ductal carcinoma in situ (DCIS) cancers detected per 1,000 screens. (b) Percentage of all cancers that are DCIS.	(a) per 1,000 screens (initial); per 1,000 screens (subsequent screen). (Surveillance and monitoring purposes only). (b) % DCIS (initial); % DCIS (subsequent screen). (Surveillance and monitoring purposes only).

7. Diagnostic interval	(a) Time from screen to notification of screen result. (b) Time from abnormal screen to first diagnostic assessment. (c) Time from abnormal screen to definitive diagnosis.	(a) ≥ 90% within 2 weeks; (b) ≥ 90% within 3 weeks; (c) ≥ 90% within 5 weeks if no tissue biopsy performed; ≥ 90% within 7 weeks if tissue biopsy performed.
8. Positive predictive value of the screening mammography program	Proportion of abnormal cases with completed follow-up found to have breast cancer (invasive or <i>in situ</i>) after diagnostic work-up.	≥5% (initial screen); ≥6% (subsequent screens).
9. Non-malignant biopsy rate	(a) Number of non-malignant open and core biopsies per 1,000 screens. (b) Percentage of non-malignant biopsies which were open. ^d	per 1,000 screens (initial); per 1,000 screens (subsequent screen). (Surveillance and monitoring purposes only).
10. Screen-detected invasive tumour size	Percentage of invasive cancers with tumour size of ≤15mm in greatest diameter as determined by the best available evidence: 1) pathological, 2) radiological, and 3) clinical.	>50% screen-detected invasive tumours.
11. Proportion of node negative screen-detected invasive cancer	Proportion of invasive screen-detected cancers in which the cancer has not invaded the lymph nodes.	>70% screen-detected invasive cancers.
12. Post-screen invasive cancer rate ^e	Number of invasive breast cancers found after a normal or benign mammography screening episode within 0 to < 12 and 12-24 months of the screen date.	< 6 per 10,000 person-years (0 to < 12 months); < 12 per 10,000 person-years (12-24 months).
13. Sensitivity of the screening mammography program	Proportion of breast cancer cases that were correctly identified as having cancer during the screening episode.	% (Subsequent screens). (Surveillance and monitoring purposes only).

a Resolution of an abnormal screen for a benign result is set at a maximum of 6 months after the screen.

b Cancers that took >6 months to diagnose (beyond the 'normal screening episode') are counted as post-screen cancers.

c Tissue biopsy does not include fine needle aspiration (FNA).

d Open surgical biopsy includes cases that went directly to an open surgical biopsy as their primary diagnostic assessment and those who underwent an inconclusive or incorrect core biopsy prior to a definitive diagnosis by open surgical biopsy.

e For calculation purposes post-screen cancers include all invasive cancers diagnosed after a normal program screen (not referred), cases referred for diagnostic follow-up with a benign result (missed at diagnosis), screen detected (referred) cancers that took >6 months to diagnose (beyond the 'normal screening episode') and non-compliant cancers diagnosed <24 months.

For complete information on calculation methods, definitions and context please refer to the following report: Public Health Agency of Canada. Report from the Evaluation Indicators Working Group: Guidelines for Monitoring Breast Cancer Screening Program Performance: Third edition. Ottawa: Minister of Health (currently in press).

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