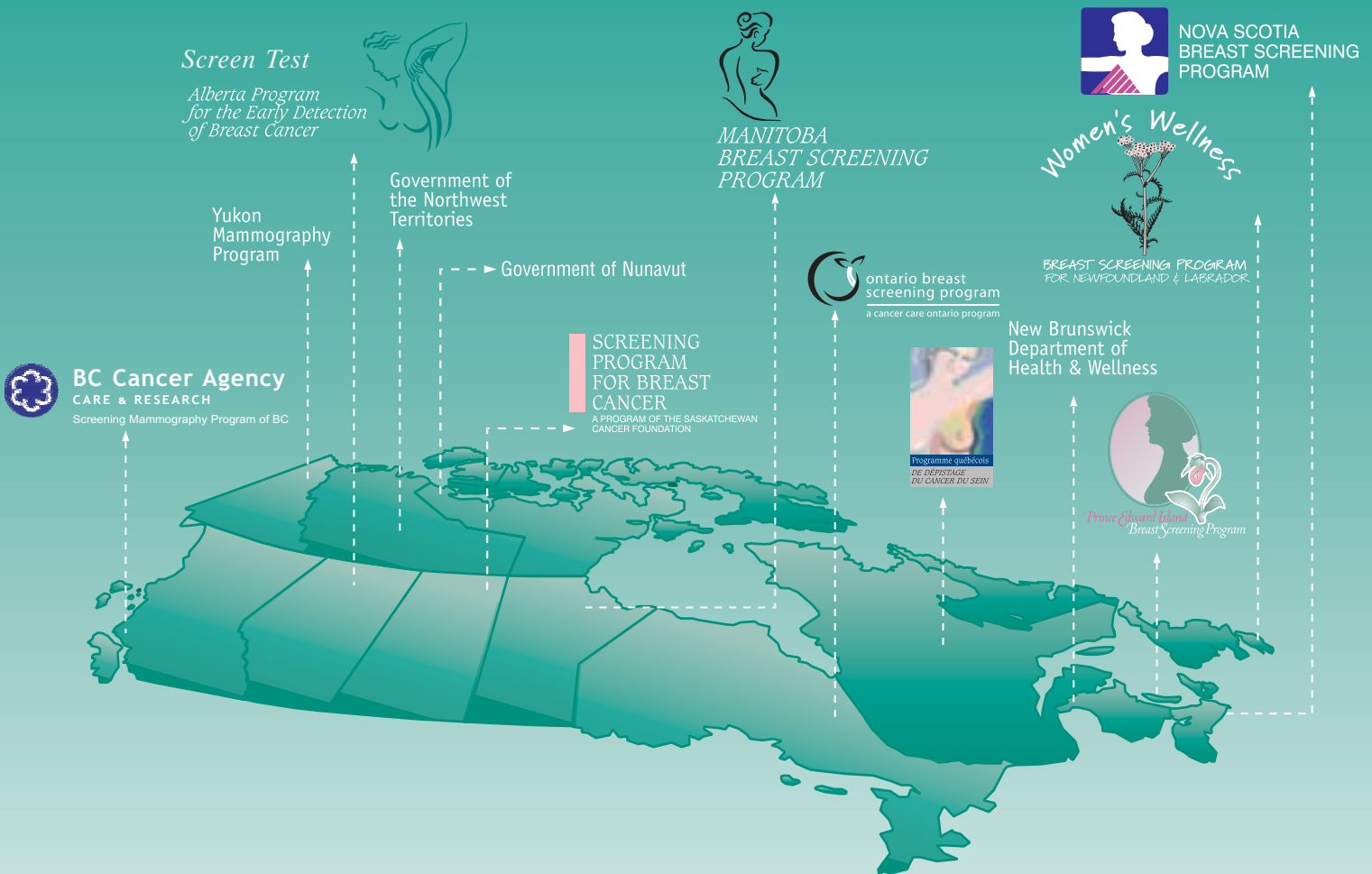


# Quality Determinants of Organized Breast Cancer Screening Programs in Canada



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# Introduction

## **Background**

In March 1988, a national workshop on the early detection of breast cancer was held in Ottawa. The report from the workshop, which was presented to the Conference of Deputy Ministers of Health in December 1988, had an underlying theme:

“Screening mammography is here to stay and it is urgent for governments to move quickly to develop strategies for dealing with it and for guiding its implementation in a way which is most cost-effective and most likely to benefit women.”

To facilitate the introduction and operation of breast cancer screening programs in Canada, it was felt to be important to promote ongoing dialogue between the provinces/territories, the federal government and national organizations. As a first step, Health Canada, in collaboration with the Canadian Cancer Society and the National Cancer Institute of Canada, organized Interchange '90, a Canadian forum to collaborate on the development of breast cancer screening programs. One of the conclusions from Interchange '90 was that the establishment of quality assurance (QA) programs would be aided by the development, revision, and updating of national guidelines in such areas as participation, film interpretation, follow-up processes, and other issues related to screening.

This commitment to the promotion of QA in breast cancer screening was renewed under the Canadian Breast Cancer Screening Initiative. In 1995, a Working Group on the Quality Determinants of Organized Breast Cancer Screening Programs was established, and the first report, *Quality Determinants of Organized Breast Cancer Screening Programs*, was published in 1998. In 2001, the working group's new mandate was to

- identify the key indicators and key activities of QA for breast cancer screening programs and translate these indicators and activities into written policies or statements for the National Committee of the Canadian Breast Cancer Screening Initiative;
- promote the adoption of QA in breast cancer screening programs;
- link with international activities with respect to QA in breast cancer screening.

## **Purposes and Scope**

Population screening for breast cancer is a major public health intervention, and experience in other countries shows that suitable performance parameters can be achieved only through strict adherence to QA guidelines. Since screening is targeted essentially at asymptomatic women, the fine balance between benefits and undesirable effects is completely dependent on program quality.

This document identifies the requirements and conditions for high-quality screening through an organized approach, an approach that relies on adoption of best practices for all aspects of a breast cancer screening program, evidence-based decision making and, if necessary, expert opinion. Furthermore, continual assessment of the screening process and outcome is an integral part of the organized approach to breast cancer screening.

To reduce mortality from breast cancer in the population, a screening program must be able to provide mammography procedures of sufficient sensitivity to detect the disease in the early stages, and it must have effective strategies to ensure that the target population accepts and uses the services offered. A high quality screening program must also try to avoid any adverse effects, such as a false sense of security for some, unnecessary anxiety and suffering for others, unnecessary biopsies, unnecessary radiation exposure, and missed breast cancers.

The success of screening is a shared responsibility best assumed with a team approach. Many groups of people contribute to the delivery of a high quality breast cancer screening program: health promoters and communicators; program managers; primary care physicians and other health professionals who advise women on screening; community organizations and the media, which inform the public about screening; radiologists; technologists; medical physicists; nurses; pathologists; surgeons; counsellors; and support staff such as receptionists. Also important is the need for a client-centred approach and a prompt, effective and sensitive means of communicating results. A clear understanding of the information collected at all stages of mammography is not only vital to women's peace of mind but may also increase the likelihood of compliance with regular screening or recommended follow-up.

The chain of events in a screening program is illustrated in Figure 1.

This document addresses the issues related to the client-centred approach, promotion of and recruitment into the program, retention, quality of mammography, reporting of results, communication of results, follow-up and diagnostic workup, and program evaluation. Also presented, as special projects, are the results of a survey on quality assurance in Canadian breast screening programs, and details of a proposed study on radiologists' performance in Canada.



# Methodology

The Working Group on Quality Determinants of Organized Breast Cancer Screening Programs is composed of representatives from Canada with expertise in various areas of breast screening.

This is the second report published by this group. The inaugural report was released in 1997 and was a first step in many respects. The main initiative was to determine areas of quality for breast cancer screening programs by reviewing program standards in the National Health Service of the United Kingdom, and the United States guidelines for mammography. These areas were as follows: uptake, client satisfaction, high-quality screening, diagnosis, information systems, and the management of programs.

After consultation with the organized breast cancer screening programs in Canadian provinces, the final focus of the 1997 report included uptake (promotion and recruitment), client satisfaction (to minimize anxiety and maintain compliance), high-quality screening, and follow-up.

In this succeeding report, we have maintained and updated relevant information but have also rebuilt the way in which sections are presented. The report ends with diagnosis (not including treatment), and new sections have been added, including program evaluation, a proposed standardized pathological report (see Appendix), and the results of a survey on quality determinants in Canadian organized breast cancer screening programs. A pan-Canadian study on standardized interpretation of abnormalities and cancer detection ratios in organized breast screening programs is on course, following approval by the working group.

Thus, the layout of this report is as follows:

- Achieving quality through a client service approach;
- Recruitment and capacity;
- Retention;
- Quality of mammography;
- Reporting;
- Communicating results;
- Follow-up and diagnostic workup;
- Program evaluation;
- Special projects.

For each topic, questions were identified and a literature review was conducted. At least one working group member or consultant reviewed each piece of literature. Parallel to this, surveys of provincial breast cancer screening programs were conducted to document actual quality practices. Documentation of the practices of other national programs, in particular those from Australia and the United Kingdom, was also collected.

After review and discussion of the information collected, key recommendations for each topic were written during and between working group meetings. Consensus was used in developing the recommendations, and working group members accepted all statements unanimously.

All provincial program directors and the members of the National Committee of the Canadian Breast Cancer Screening Initiative reviewed the final report, which was approved at a National Committee meeting in November 2002.



# **1. Achieving Quality Through a Client Service Approach**

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## **1.1 Client Service Approach**

- A client service approach should be adopted throughout the program; clients include the women, their physicians, the community, and stakeholders.
- All women should provide written consent before being screened. The women should have appropriate information (written or provided orally) about breast screening to promote informed choice and should be told that they can decline participation in the program at any time.
- Women should be made as comfortable as possible. Response to concerns should be individualized.
- Women should 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 and monitored to ensure continuing client satisfaction.
- The program should include strategies for women from special groups (e.g. women from culturally and linguistically diverse populations and women with disabilities).
- Each screening program should measure client satisfaction.
- Whenever possible, the program should assist physicians and other health care providers to support women through all stages of the screening and assessment pathway.
- To improve client satisfaction and recruitment rates, programs should have operating hours and locations that are convenient to clients.
- The program should ensure that all screening units operate in dedicated space with dedicated time, staff, and facilities.
- The program should actively encourage and support involvement of key stakeholders on committees or reference groups.

There is a responsibility to ensure that those who accept an invitation to screening do so on the basis of informed choice. The key issue in informed consent is that women understand the risks and benefits of participation – for them as individuals. The U.K. National Screening Committee has noted that the focus on achieving population coverage

of screening – which ultimately leads to a net population health gain – has resulted in inadequate communication to women that some individuals will not benefit or will suffer from adverse events. The Committee’s 2000 report states, “As more is known about the psychological consequences resulting from both false positive and false negative tests, and as social attitudes change, this approach is no longer acceptable”<sup>1</sup>.

Continuous quality improvement would be facilitated by management acceptance 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. Three specific aspects of improving patient satisfaction are discussed in the literature. These include accessibility, scheduling, and minimizing pain and anxiety. The literature was examined for the evidence on minimizing pain and anxiety. Educating women about breast cancer screening is also a patient satisfaction issue.

The language and format of information should be appropriate to the intended audience in order to encourage 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.

Special groups should be identified within the recruitment plan and their participation rates documented separately; the plan should identify general approaches to recruitment and special recruitment strategies. 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<sup>2</sup>.

Easy access to programs is another determinant of client satisfaction. Accessibility includes having extended hours as well as a convenient location for both car and bus users. Access is also improved by friendly and efficient booking systems as well as minimum waiting times for appointments. The use of mobile screening units may be a solution for convenience and accessibility<sup>3</sup>.

## **1.2 Role of Receptionists/Scheduling Personnel**

- There should be orientation or training programs for receptionists/scheduling personnel.
- Receptionists/scheduling personnel should understand the difference between screening and diagnostic mammography and be able to schedule only women who are eligible for a screening examination. This includes obtaining information regarding matters such as breast problems, implants, and prior mammograms to ensure eligibility.



- Women should be given information on the upcoming mammography visit, including how to prepare themselves and how to obtain results; commonly asked questions about breast screening should be answered.
- Personal identification of the woman should be obtained at the time of the visit.
- If a woman has no referring physician, the receptionist should provide information allowing her to obtain a qualified physician. The name, address, and telephone number of the physician selected should be recorded.

Part of the service-oriented approach is to ensure that client contact with the centre, including the initial call to the centre, is of high quality.

Screening mammography is an x-ray examination used to detect unsuspected breast cancer at an early stage. Diagnostic mammography is used to evaluate a patient with a breast mass or with other breast signs, such as skin changes or spontaneous nipple discharge. It is also used in the evaluation of abnormal or equivocal screening mammograms. Receptionists/scheduling personnel should ascertain whether screening or diagnostic mammography is required and should accept women for screening examinations only. If a woman is not eligible for screening mammography, she should be informed of the reason and encouraged to see her family physician.

If the woman reports a known symptom (e.g. lump), receptionists/scheduling personnel should suggest that she contact her family physician. If she is symptomatic but her family physician's evaluation is that her breasts are normal, then she should be screened. If a woman does not admit to a symptom before presenting herself at the program, she should undergo mammography and be referred back to her physician for proper evaluation.

Schedulers should give information to women about the upcoming visit, both to decrease anxiety and to improve the quality of the mammogram. 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.

### **1.3 Role of Mammography Technologists and Clinical Examiners**

- Mammography technologists and examiners should be sensitive to the physical and psychological needs of the woman before, during, and after the examination.
- Proper breast compression and positioning should be used to ensure that there is minimal discomfort.
- Mammography technologists should also explain that additional images may be necessary to ensure that all of the breast tissue is visualized. They should inform women of what can be expected concerning the communication of mammography results.

- The staff of the mammography facility, interpreting physicians, and women's physicians should recognize the potential for anxiety if women have to return for repeat views for technical problems. These repeat views should be done as soon as feasible to reduce anxiety.

Minimizing women's pain and anxiety can be largely achieved through the technologist's and nurse's treatment of women. They must be friendly, positive, caring, and sensitive to specific populations. Staff guidelines should reflect such approaches. Individual facilities should follow the program's guidelines on these issues. Monitoring can take place through customer surveys on satisfaction, which should be short and easy to use, and can be mailed with the results letter and a return envelope.

Although at first glance there appear to be large discrepancies in the amount of pain and discomfort reported from breast compression in mammography, some consistencies can be found, despite the differences in definitions among studies. Only a very small minority of women experience severe pain, and it is rare for a woman to decide not to return for future mammograms on that basis<sup>4-7</sup>. In one study, the positive perception about the staff was inversely related to the pain and discomfort among women without previous mammograms, and anticipation of pain and discomfort was a positive predictive factor of pain and discomfort among women with previous mammograms.<sup>8</sup>

Clinical experience has also shown that the majority of women will not refer to the compression as painful but, rather, as uncomfortable. The discomfort is brief enough not to be an issue. Patients whose breasts are very small, however, find it the most uncomfortable. In the past it was common to set a specific level of compression (e.g. 18 pounds). This led to extreme discomfort for many women, whereas adequate films could be obtained using less compression. Newer machines have a setting for optimum compression, which can be overridden by the technologist if necessary.

The greater the control over the compression, the less the perceived discomfort. Control over the application of the compression is especially helpful in minimizing discomfort in women who are very anxious. Compression should be released immediately after the films are taken.

Anxiety can be reduced by giving full explanations. These should include the fact that there may be discomfort, but that it will be brief, and that there is a need for compression to obtain a good picture.

One approach that has been used in brochures accompanying letters of invitation for rescreening is to offer suggestions for those women who have found mammography painful. Suggestions would include avoiding scheduling mammography during the week before menstruation, avoiding caffeine, and taking a pain reliever such as acetaminophen before coming to the centre.

Technologists and nurses have an important role to play in making the experience of mammography and clinical breast examination as positive as possible for the woman. Communication between staff and women is a crucial aspect of the screening test.

## 1.4 Minimizing Anxiety

- Information should be provided at every step.
- Anxiety may be reduced by telling the woman that screening is the first stage of the screening process, and that 10% of women require further tests. Information should be communicated before the visit to the screening centre, at the screening centre, and again if the woman receives a letter informing her of abnormal results.

The factors influencing nonattendance and noncompliance with repeat attendance include procrastination, forgetfulness, a perceived need for a referral from a physician, cost, fear of results, and radiation risk. Especially important factors seem to be physician recommendation, anxiety about mammography, the perceived risk of breast cancer, and a family history of breast cancer<sup>9</sup>.

The degree of anxiety may often relate to the woman's first experience with mammography. Women who fail to reattend often express more negative views about mammography and find screening significantly more uncomfortable, painful, stressful, embarrassing, and worse than expected. They are less reassured by the screening and find the clinic staff less welcoming, harder to question, or unsupportive; the radiographers less competent; and the overall experience less satisfactory and worthwhile<sup>10,11</sup>. 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<sup>12</sup>.

Evidence exists that women experience anxiety when recalled for assessment<sup>13-19</sup>. Although a woman has been informed that she does not have cancer, anxiety may persist for several months<sup>14,15,17,20</sup>. Eighteen months after a screening mammogram, women with false positive results have greater anxiety about breast cancer than women with negative screening mammograms<sup>20</sup>. Women with highly suspicious mammograms tend to be anxious about having repeat mammography, and a minority find that these worries compromise their ability to engage in their daily activities<sup>17</sup>. However, in retrospect, most women with false positive results regard this experience as one of many minor stressful experiences in their lives. They generally attend for further screenings and report the same quality of life 18 months later as women with negative screening results<sup>13</sup>. This is not true of women subjected to surgery. Approximately one-third of such women had pain from the scar and reduced sexual sensitivity in the breast<sup>10,20</sup>.

Minimizing the waiting time between the recommendation for further examinations and the time when they are carried out can reduce anxiety. Also, women should be informed of the results of screening and assessment promptly to ensure that anxiety is as brief as possible. They should also have the opportunity to talk with a counsellor in order to obtain more information about screening and discuss any concerns<sup>14</sup>.

Among high-risk women – those with first-degree relatives with breast cancer – breast cancer worries can, in fact, create a barrier to mammography, especially for those with less formal education<sup>21</sup>. High-risk women who are extremely anxious – those who have frequent intrusive thoughts about breast cancer or who find that breast cancer worries interfere with their daily functioning – are less likely to adhere to mammography screening. Thus, although some concern is needed in order to motivate women to report for mammography, excessive levels of anxiety, concern, or worry appear to be deterrents.

## **1.5 Education and Counselling**

- Both screening centre personnel and physicians should inform women that mammography is currently the most sensitive and specific screening test for breast cancer; that a negative mammogram does not rule out malignancy in the presence of a palpable mass or other breast abnormality; and that a biopsy may sometimes be needed even with a negative mammogram.
- Information should be available at screening centres on the benefits and the limitations of screening mammograms. This would help women make an informed choice about participating in the program. The main benefit is that of reduced mortality from breast cancer. Limitations of screening mammograms include the following: finding cancer does not always mean saving lives (for instance, in cases of aggressive cancers that have already spread or small tumours that may not progress); the screening may result in a false negative result (the mammogram appears normal even though breast cancer is present ); and there may be a false positive result (mammograms are read as abnormal, but no cancer is actually present).
- Screening centre personnel and physicians should inform women that they should have both a clinical breast examination and mammography as part of their breast cancer screening. Mammography technologists and nurse examiners should be able to discuss with women the issues of clinical breast examination and breast self-examination.
- Educational materials, including brochures and videotapes, should be used to supplement staff members' discussions with women.
- Screening centre personnel should inform women that mammography is part of a routine “well-woman” program, not a singular event, and that it is thus necessary to be screened at regular intervals.

In screening programs in which clinical breast examination is not performed, screening centre personnel should inform women that they should have a clinical breast examination performed by their physician, even though they are having a mammogram. It is most important to stress that mammography is part of a routine well-woman program, not just a once only event. This helps increase reattendance for future mammography.

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.

## 1.6 References

1. National Screening Committee. *Second Report of the UK National Screening Committee*. Departments of Health for England, Scotland, Northern Ireland and Wales, 2000. URL: [www.doh.gov.uk/nsc/pdfs/secondreport.pdf](http://www.doh.gov.uk/nsc/pdfs/secondreport.pdf) (accessed October 25, 2002).
2. National Quality Management Committee of BreastScreen Australia. *National Accreditation Standards, BreastScreen Australia Quality Improvement Program*. Draft. June 2001.
3. Decker KM, Harrison M, Tate RB. Satisfaction of women attending the Manitoba Breast Screening Program. *Prev Med* 1999; 29:22-27.
4. Jackson VP, Lex AM, Smith DJ. Patient discomfort during screen-film mammography. *Radiology* 1988;168:421-423.
5. Leaney BJ, Martin M. Breast pain associated with mammographic compression. *Australas Radiol* 1992;36:120-123.
6. Cockburn J, Cawson J, Hill D, De Luise T. An analysis of reported discomfort caused by mammographic X-ray amongst attenders at an Australian pilot breast screening program. *Australas Radiol* 1992;36:115-119.
7. Elwood M, McNoe B, Smith T, Bandaranayake M, Doyle TCA. Once is enough – why some women do not continue to participate in a breast cancer screening programme. *NZ Med J* 1998;111:180-183.
8. Aro AR, Absetz-Ylöstalo P, Eerola T, Pamilo M, Lönnqvist J. Pain and discomfort during mammography. *Eur J Cancer* 1996;32A:674-679.
9. Schapira DV, Kumar NE, Clark RA, Yag C. Mammography screening credit card and compliance. *Cancer* 1992;70:509-512.
10. Baines CJ, To T, Wall C. Women's attitudes to screening after participation in the National Breast Screening Study. A questionnaire survey. *Cancer* 1990;65:1663-1669.

11. Orton M, Fitzpatrick R, Fuller A, Mant D, Mylnek C, Thorogood M. Factors affecting women's response to an invitation to attend for a second breast cancer screening examination. *Br J Gen Pract* 1991;41:320-322.
12. Marshall G. A comparative study of re-attenders and non-re-attenders for second triennial National Breast Screening Programme appointments. *J Public Health Med* 1994;16:79-86.
13. Brett J, Austoker J, Ong G. Do women who undergo further investigation for breast screening suffer adverse psychological consequences? A multi-centre follow-up study comparing different breast screening result groups five months after their last breast screening appointment. *J Public Health Med* 1998;20(4):396-403.
14. Ong G, Austoker J. Recalling women for further investigation of breast screening: women's experiences at the clinic and afterwards. *J Public Health Med* 1997;19(1):29-36.
15. Cockburn J, Staples M, Hurley SF, De Luise T. Psychological consequences of screening mammography. *J Med Screen* 1994;1:7-12.
16. Rimer BK, Bluman LG. The psychosocial consequences of mammography. *J Natl Cancer Inst Monogr* 1997;22:131-138.
17. Lerman C, Trock B, Rimer EK, Boyce A, Jepson C, Engstrom PF. Psychological and behavioral implications of abnormal mammograms. *Ann Intern Med* 1991;114:657-661.
18. Gilbert, FJ, Cordiner CM, Affleck IR, Hood DB, Mathieson D, Walker LG. Breast screening: the psychological sequelae of false-positive recall in women with and without a family history of breast cancer. *European J Cancer* 1998;34(13):2010-2014.
19. Scaf-Klomp WR, Sanderman R, van de Wiel HBM, Otter R, van den Heuvel WJA. Distressed or relieved? Psychological side effects of breast cancer screening in the Netherlands. *J Epidemiol Community Health* 1997;51:705-710.
20. Gram IT, Lund E, Slenker SE. Quality of life following a false positive mammogram. *Br J Cancer* 1990;62:1018-1022.
21. Lerman C, Daly M, Sands C, Balshem A, Lustbader E, Heggan T, Goldstein L, James J, Engstrom P. Mammography adherence and psychological distress among women at risk for breast cancer. *J Natl Cancer Inst* 1993;85(13):1074-1080.

## **2. Recruitment and Capacity**

### **2.1 Enrollment Objectives**

- An organized breast cancer screening program should have an enrollment objective of a minimum of 70% of eligible women in the 50-69 age group. In order to achieve a 30% mortality reduction through breast screening, this goal should be reached as soon as possible.
- Organized screening programs should collect appropriate statistics on the proportions of women screened in the target age groups.
- Screening programs should have a strategic plan that will outline how women will be recruited and how specific populations will be reached.

The success and effectiveness of a population screening program is dependent on obtaining high participation rates. The aims of organized screening programs include maximizing the early detection of breast cancer and ensuring equitable access to the program for women in the target age groups. To achieve these aims, organized screening programs need to allocate sufficient resources for the recruitment of women in order to achieve high recruitment rates.

The primary target age group of breast cancer screening programs is 50-69 years of age. Although programs may choose to screen women 40-49 or 70 and over, this should not detract from meeting the enrollment targets in the 50-69 age group. Screening is recommended at 2-year intervals for women in this age group. Programs that choose to screen more often should ensure that they are first meeting the target of screening 70% of women 50-69 every second year. Screening programs should monitor statistics to measure participation.

The recruitment plan should cite all strategies that can be used to encourage women's participation, including personal invitation, community information programs, involvement of physicians and other health professionals, and strategies targeted at groups of women with lower participation rates. Strategies for retention should also be outlined.

Participation rates vary by screening program, from 54% to 89%:

- 89% of women from 50 to 59 years old, 1987-1997, Finland<sup>1</sup>;
- 81% of women from 40 to 74 years old, 1995-1996, Sweden<sup>2</sup>;
- 78% of women from 50 to 69 years old, 1990-1995, the Netherlands<sup>3</sup>;
- 75% of women from 50 to 64 years old, 1999-2000, United Kingdom<sup>4</sup>;
- 54% of women from 50 to 69 years old, 1997-1998, Australia<sup>5</sup>.

In Canada, participation rates among women from 50 to 69 years old varied among the provinces from 11.5% to 54.7% in 1997 and 1998<sup>6</sup>.

## **2.2 Capacity**

- Programs should have the capacity to screen all the eligible population.

In order to offer screening and investigation services and to reach 100% of eligible women, the program needs the capacity to offer these services, i.e. facilities, workforce, and infrastructure. A lack of centres, staff, or radiologists will limit capacity and delay implementation of the program and access to screening for women<sup>2</sup>.

In Canada, in addition to the above organizational barriers, some programs face problems such as difficulty in obtaining lists of women who are eligible for screening and substantial delays between the invitation for screening mammography and the mammogram itself<sup>6-8</sup>.

Over the next 20 years, an increase in the number of eligible women will put more pressure on screening services.

## **2.3 Promotion – Strategies to Recruit Women**

### **Letters of invitation**

- Organized breast cancer screening programs in the provinces/territories should send letters of invitation to all women in target age groups.
- It is vital to the success of the screening program that it use the most complete, up-to-date sources of information. 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 and allow no access to them for any purposes other than invitational letters.

### **Content of letter/information package/brochure**

- Invitational letters should be reassuring in tone.
- A brochure, which should contain information about the possibility of extra tests in the event of an abnormal screen result or other information, should be included with the letter.
- In referring to the possibility of an abnormal screening result, women should be informed that this is a normal part of screening, that a certain number of women require further investigation, and that the program will ensure that women with abnormalities have their problem identified to a responsible party.



- The written information should be easily readable, and all written information should be tested and evaluated before it is widely used.

## Reminders

- Women who have not booked appointments should be sent a reminder letter 3 to 6 weeks after the initial letter of invitation.
- Reminder letters should be short, and the risk of breast cancer should not be emphasized.

### 2.3.1 Letter of invitation

The letter of invitation is a simple and efficient tool to promote participation in screening<sup>9-11</sup>, as demonstrated by repeated studies in several countries<sup>12-17</sup>. Individualized invitations have also been shown to be far more cost-effective than other promotional efforts<sup>18</sup>.

All Canadian organized breast screening programs currently use letters of invitation 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 which letters of invitation are not appropriate or sufficient. Programs in such areas may wish to examine the value of letters of invitation in comparison with other methods.

For invitation systems to be successful, there must be an accurate listing of the target population with current addresses<sup>15</sup>. Because of the mobility of the population, lists that are several years out of date will result in a high proportion of women not receiving invitations. This can have a substantial impact on the ultimate screening rates achieved.

Sources of population lists include health insurance plans, electoral lists, physician practice lists, and motor vehicle licensing lists. Obtaining lists from physician practices is by far the most complicated and the most costly. Although drivers' licences may be up to date, there are many women, especially in the older groups, who do not drive. The best option would be to receive up-to-date lists from the province or territory's health insurance plan.

Although some provinces/territories are able to receive up-to-date lists from their provincial/territorial health insurance plans, confidentiality of information is of extreme concern. In some provinces/territories, screening programs cannot access such lists. Confidentiality is a concern for the screening programs as well, as they must ensure that the list received is used only for invitational letters and for no other purpose.

To avoid sending letters of invitation to families of deceased patients or to patients with previous breast cancer, health insurance plan lists should be cross-referenced with cancer registry lists and vital statistics. Further cross-referencing 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.

In provinces where names are not released to the screening centres but letters are sent directly to the women, mass mailings are often done. Since the centres cannot control the rate of mail outs, women may have to wait lengthy periods of time for an appointment. This compromises the efficiency of the centres.

### **2.3.2 Content of letter/brochures**

The content of the invitational letter has implications for attendance and even reattendance. Letters should be reassuring in their tone and include informational brochures<sup>19</sup>. The idea of screening as a continuum of steps should be addressed, indicating the possibility of further assessment. Brochures generally describe the program and answer the common questions and concerns women have about mammography.

Although the differences were not large, it has been found that women were less likely to worry about recall for further assessment if they had received information about the possibility of recall in the initial invitational letter<sup>19</sup>. They were more likely to worry if the word “cancer” was used in the context of recall in the letter of invitation<sup>19</sup>.

Information about recall should be given in more than one way, beginning with the initial invitation package and then later by the screening technologist at first screening<sup>19</sup>.

Other countries, such as the United Kingdom, include scheduled appointments in the letters of invitation. This has been shown to improve compliance with screening<sup>20-23</sup>. Offering a specific appointment date and time, and including a paid reply card to indicate acceptance<sup>24</sup> make it easier for women to respond; it may also eliminate the effects of social class by not requiring women to exercise social skills they may not possess<sup>14</sup>. The organization of appointments may be especially important for older women, women from lower socioeconomic strata, and those from non-English-speaking backgrounds<sup>24</sup>.

However, including an appointment time may not be the most cost-effective approach. Hurley and colleagues<sup>18</sup> have shown that when the cost of reserving an appointment is considered, an invitational letter without a specific appointment time followed by a second letter to nonattenders is a more cost-effective approach. However, costs may vary depending on the situation of each individual program. One study has demonstrated that by considering clients' previous history of screening mammography it was possible to maximize the number of appointments by day and thus reduce the required time, especially in mobile units<sup>25</sup>.

Scheduled appointments with invitational letters are not used in Canada, and there is no indication of the factors that may determine acceptance of such an approach. It would be advantageous if one of the programs were to undertake a trial of letters with and without appointment times.

Endorsement by the family physician 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 (GPs) and from sources not personally known to women<sup>15,22,23</sup>.

The literature is split on whether tailoring of letters improves attendance. Physicians' recommendations for mammography tailored to individual women's specific perceptions about mammography and breast cancer, their risk factors for breast cancer, and their mammography screening status have been shown to be a more effective medium for delivering the message. Tailored letters were more likely to be remembered and, among women who remembered the letters, were more thoroughly read<sup>12</sup>. However, tailored letters may have had a greater chance of capturing attention at first glance because of their tailored pictures, captions, and headlines, so that it may not be the tailoring itself that is effective. In the United States, context-tailored letter receipt was associated with higher mammography rates among women with incomes below \$26,000 and among Black women<sup>12</sup>. Among women with a family history of breast cancer, the personalized risk invitation has also been associated with significantly higher participation<sup>13</sup>. However, tailored letters that made reference to the woman's screening history had no significant effect on uptake rates<sup>26</sup>.

For most Canadian screening programs, it is impractical to have invitational letters or reminder letters sent from GPs. Unless a practice-based approach is used to begin with, such letters cannot be used. There is no evidence to justify the additional cost of building up practice-eligible lists in provinces where other lists are available.

### **2.3.3 Reminders**

Reminders target specific women who have not responded to an initial invitation. Strategies include letters, appointments, telephone calls, or personal contacts.

A second letter of invitation results in increased screening rates. In Australia, Hurley et al. found only a 13% response to the initial invitation, but there was an additional 26% response rate among those sent a second invitation after 4 weeks. A telephone follow-up instead of a second invitational letter yielded similar results<sup>18</sup>. A study conducted by the Ontario Breast Screening Program in a rural family practice yielded a 16% response to the initial invitational letter (after 8 weeks), an additional 22% response rate to a reminder letter, and a further 19% response to a telephone call, for a cumulative response rate of 50%. Three-quarters of the women attending for screening in response to the first or second invitations had not heard of the program before receiving the letter of invitation.

Women receiving a reminder letter are more likely to have mammography than those who do not receive one<sup>21,22,27</sup>. As in the case of the first invitational letter, offering an appointment in the reminder letter should promote participation<sup>28</sup>. In a Scottish study, which compared a reminder letter from the screening program alone to one accompanied by a letter signed by the woman's own physician, the accompanying letter doubled the attendance rate, from 10% to 21%<sup>29</sup>.

A letter of invitation followed by a telephone call is also an effective strategy<sup>9,30</sup> and could be helpful in reaching groups of women from different ethnic backgrounds or those in lower socioeconomic circumstances<sup>9</sup>.

For women who do not participate after an invitational letter followed by a reminder letter, telephone counselling<sup>31</sup> or a home visit<sup>32</sup> should benefit participation more than a second reminder letter. In one study carried out in a lower socioeconomic area in England, a personal letter from the GP was found to be at least as effective as visits by a nurse at increasing the uptake of breast screening in nonattenders. Following a letter from their own GP, 13% of previous nonattenders participated in breast screening<sup>33</sup>. In a British study, a telephone call or letter from specially trained receptionists also proved to be effective<sup>34</sup>.

Invitational letters are an effective recruitment strategy only when followed up with letters or telephone calls to those who do not respond to the initial invitation. For women being recruited for their first screen, the option of a telephone follow-up is not available, as the women are not yet registered in the screening programs.

There is no real evidence in the literature as to the timing of this second letter. Such reminders have generally been sent between 4 and 8 weeks after the first letter. However, most bookings take place in the first week after receipt of the letter. 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 even shorter.

A card sent 6 months after the initial letter, asking for reasons for nonattendance, serves two purposes: it is an additional reminder, and it yields information for the program about its nonattenders.

#### **2.3.4 Other recruitment strategies**

Sending informational material and making telephone calls are other ways of encouraging participation in screening<sup>9</sup>. Telephone counselling is considered effective<sup>22</sup> but may be no more so than the usual methods when targeting women who do not attend mammography screening or attend irregularly<sup>35</sup>.

With regard to home visits, one meta-analysis based on studies of nonparticipating Asian women or black women of low income concluded that such visits are not adequate.<sup>9</sup> However, in a Spanish study involving poor income women, a home visit by a nonprofessional person led to better participation (63.5%) than a program invitational letter (52.1%)<sup>36</sup>. Results from studies on home visits remain equivocal because of difficulties in recruiting subjects<sup>37</sup>.

Yabroff and Mandelblatt<sup>38</sup> have reviewed studies on interventions targeting women for screening mammography. The authors categorized them by type of intervention and concluded that behavioural interventions (e.g. telephone calls, letters of invitation) increased screening in comparison to usual practices (by 13.2%) and to active controls (by 5.6%). Theory-based cognitive interventions and sociologic interventions also improved participation (by 23.6% and 12.6% respectively as compared with usual practices).

Cognitive strategies aimed to improve knowledge and to clarify perceptions (perceived risk, benefits, barriers), and sociologic interventions used social norms or peers (friends, counsellors, the media).

Yabroff and Mandelblatt's results may give the impression that some interventions are more efficient than others. However, using a different model of analysis (PRECEDE), Ratner et al. concluded that receiving an intervention, no matter what type, promotes participation, but that screening rates do not significantly differ according to whether the intervention targets predisposing, facilitating, or enforcing factors<sup>39</sup>. After taking into account some methodological factors, however, the authors noted that recent studies (from 1990 to 1996 versus 1980 to 1989) reported increased screening rates and that interventions based in the community (versus in the clinic) were the most effective.

According to Sin and St Leger, simple and efficient interventions promoting screening do exist, but studies on organizational aspects, social networks, or a combination of several strategies are rare<sup>23</sup>. In inner city areas, the approach most likely to offer good results would involve several strategies together.

### **2.3.5 Factors related to participation**

Many factors influence participation. For all aspects of promotion and recruitment, including the writing of pamphlets and letters, planning outreach initiatives, determining where a mobile will be set up, determining promotion messages, etc, these factors should be considered.

The most important factors related to women's participation in breast cancer screening include age, education, having a consistent source of health care, being told by a physician to have a mammogram, perceiving the need for mammography, and fear of a positive screen result<sup>40</sup>.

Demographic factors associated with mammography screening include age, race, income, education, urban living, and marital status. Women 65 years of age and older are less likely than younger women to have ever had a mammogram or to have had a recent mammogram<sup>41-47</sup>, and rates drop even more substantially among women over 75 years of age<sup>48</sup>. Higher education and higher income are also positively associated with mammography use<sup>41,42,45,47,49-52</sup>. White women are more likely than women of racial minorities to have mammograms<sup>41,42</sup>, as are urban versus rural women<sup>53</sup> and married versus never-married women<sup>41,50,54,55</sup>.

Explanations women give for not having mammography include having "put it off", cost or lack of insurance, embarrassment, and concerns about radiation<sup>41,45,47,56-60</sup>. Statements showing significant differences between compliers and noncompliers include the following: "I have no symptoms, so I don't need a mammogram"; "It's too much trouble, I don't have the time for one"; "I'd rather not think about it"; "I'm worried about radiation"; and "Getting a mammogram would be inconvenient"<sup>57</sup>. Apathy, lack of concern, lack of perceived need and lack of knowledge about screening mammography are thus important reasons for nonattendance, as is the fear of a positive screen result<sup>61</sup>.

Additional barriers that have been noted include poor personal health practices<sup>51</sup>, general fear of medical tests and unwillingness to know if cancer is present<sup>62</sup>, lack of transportation (especially for rural women), lack of time (especially for working women and care givers), lack of high-quality facilities, the need for mammography equipment that meets the special needs of women with disabilities, and health beliefs<sup>63,64</sup>.

Many of these factors interact and may be additive for particular individuals. Women of higher socioeconomic status are more likely to be influenced by the print media and less likely to be influenced by what their physicians think<sup>52</sup>. Women with less of a preventive orientation, as measured by smoking status, who have concerns about screening or who believe that symptoms are a prerequisite for a mammogram are less likely to have mammograms<sup>65</sup>.

According to a Canadian survey, factors predictive of never having had a mammogram are 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<sup>66</sup>.

## **2.4 Promotion – Family Physicians and Screening**

- Screening programs should have ongoing liaison with their medical associations.
- Screening programs should inform physicians about mammography screening programs.
- Screening programs should offer organized recruitment programs, high-quality service, and follow-up on patients in order to encourage physicians to refer their patients.
- The recruitment plan should include approaches to ensure that referring physicians and other relevant health and community service providers understand the program and encourage women in the target group to participate.

Some of the most important factors associated with whether women have or do not have a mammogram are related to physicians. The most important is whether the physician mentions mammography to the woman<sup>67</sup>. Having a usual source of care or a regular physician is the first step<sup>40,45,54,55,68,69</sup>: women are about three times more likely to have had a mammogram in the previous 12 months if they have a regular physician or report an annual check-up<sup>55,69</sup>. The woman's belief that her doctor advocates regular mammography is another important predictor of compliance<sup>57</sup>. Doctors' instructions not to have a mammogram or lack of any instruction are major reasons quoted for not undergoing mammography<sup>41,45,47,56,59</sup>. Another closely related reason is not being aware of the need for a mammogram. Physicians and women may also be concerned about "unnecessary" biopsies and over-diagnosis<sup>59</sup>.

Women who perceive that their physicians have some enthusiasm for mammography are far more likely to have a mammogram: physician encouragement increases mammography use by at least fourfold<sup>70,71</sup>, and this effect is even more dramatic in older women (7 to 12 fold)<sup>43</sup>.

Although Canadian breast screening programs do not require physician referral, studies from other countries on women's use of mammography indicate that women rely on physicians to tell them whether they need the test and how often<sup>40</sup>, and suggest that physician factors are likely to be important in this country as well. Physicians' encouragement remains an important factor in women's decision to be screened.

Since referral to screening programs requires a change from established referral patterns, education of physicians about mammography screening needs to focus not only on the need for screening but also on the advantages of having the screening done in a screening centre, rather than in a diagnostic unit. Mammography through screening programs is oriented toward the asymptomatic patient and can provide high-quality, efficient service at substantially lower cost than the same service in a diagnostic unit.

Some of the current confusion about diagnostic centres has arisen as a result of screening centres not being available in many locations when provincial programs are started. It is then difficult to break referral habits. If provincial programs are province-wide from inception, this confusion could be prevented. Physicians will also be more likely to refer to screening programs if they present an advantage by offering organized recruitment programs, high-quality service, and follow-up of patients.

Mandelblatt and Yabroff<sup>72</sup> have analyzed the efficiency of interventions aimed at physicians or health professionals. Interventions were categorized as behavioural, cognitive, or sociological: for example, a behavioural intervention might be a reminder system in effect in a physician's office; cognitive interventions are concerned especially with perception, information, and educational material; sociological interventions are, for example, interventions done by a nurse in a medical centre. All types were found to be effective, increasing rates of mammography utilization by up to 13.2%, 18.6%, and 13.1% respectively. Interventions targeting women and health professionals at the same time were not significantly more efficient than those targeting health professionals only. Moreover, multiple-strategy interventions (for example, both behavioural and cognitive) were no more efficient than a single-strategy intervention.

Manual prompts in medical records or computer-generated reminders or flags to tell physicians the date of the last screen and when the next is due appear to be an effective approach to improving preventive practices<sup>22,73,74</sup>. Whenever a woman consults her doctor there is an opportunity for the doctor to discuss screening<sup>27,75</sup>.

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

Ongoing liaison with the Canadian College of Family Physicians occurs in Canada through the External Advisory Committee of the Canadian Breast Cancer Initiative. Further efforts could be made to keep physicians informed about the benefits and value of breast screening through articles and notices appearing in the *Canadian Family Physician*.

## 2.5 Community Promotion

- Promotional programs should be evaluated for their effectiveness.
- Promotional programs should be targeted to specific groups depending upon local conditions.

Promotional campaigns have been used extensively to increase attendance at screening and to improve knowledge and attitudes. At this time, there is no substantial evidence of the effectiveness of such campaigns in relation to mammography. Even extensive promotional campaigns using mass media, community approaches, and physician education have achieved attendance rates of only 20%-28%<sup>76-79</sup>.

Publicity alone is thus insufficient to achieve the high attendance rates necessary for a screening program to be effective. Further strategies are needed. Letters of invitation are one such strategy.

Does publicity increase knowledge and receptivity to letters of invitation and thereby add to compliance? Several studies have shown some limited success of public campaigns in this regard. An Australian study demonstrated that promotion did increase attendance at mammography screening sites, although there was little change in acquisition of appropriate knowledge about breast cancer as a result of the campaign<sup>76</sup>. In North Carolina, there was a greater increase in the percentage of women who reported receiving a mammogram in the previous year in an experimental community (35% to 55%) than in the control community (30% to 40%)<sup>80</sup>.

One of the potential adverse effects of a massive screening campaign is heightened anxiety about breast cancer in the population. Neither the Australian nor the North Carolina programs found any indications of a negative psychological impact from the promotion<sup>76,80</sup>.

The type of promotion is likely an important feature. Although it is difficult to isolate the elements in many campaigns, an Australian study was able to examine separately the effects of local newspaper articles, promotion of the program to the community, and promotion of the program to GPs<sup>18</sup>. A particular article in a local newspaper increased the baseline attendance rate by 14% in the month in which it was published and by 49% over the ensuing 3 months, whereas no effect on attendance rates was detected as a result of promotion to physicians, and there was little effect from community promotion<sup>18</sup>.

An exception to these rates is a study from Australia in which attendance rates following media promotion were 34%, but increased to 51% and 63% with community participation and to 68% with family practitioner intervention<sup>81</sup>.



Other attempts to increase mammography use have involved educational and psychological programs. Reynolds et al. built an educational and psychological program around the Health Belief Model<sup>82</sup>. The educational program communicated accurate information about breast cancer, mammography, and potential barriers to obtaining a mammogram. The educational plus psychological program included four components designed specifically to reduce the perceived barriers to compliance with mammography. However, although both the educational and the educational plus psychological programs increased knowledge successfully and increased the intention to comply with mammography, there were no differences in actual compliance. This study may have been too small or too short to be able to properly detect these differences. However, it does not provide encouragement that such educational programs are effective or likely to be cost-effective in increasing mammography use.

Beyond general promotional campaigns, certain special groups may need additional interventions to improve compliance with breast screening. These groups include older women, nonwhite women, women of lower educational and socioeconomic status, rural women, and single women. Unfortunately, very few studies have sufficiently large samples of these groups to examine them specifically. However, the barriers to breast cancer screening in these groups seem to be the same as in other populations, although accentuated.

Although cost has been identified as an issue in the United States, the association of lower income with lower screening rates persists even when cost is not a barrier. Comparing mammography rates within the previous year among 23,521 women in Ontario and 23,932 women in the United States, one study found that the odds ratio of being screened was 2.7 in the United States and 1.8 in Ontario for women with incomes greater than US\$45,600<sup>83</sup>.

Most breast cancer public education programs in the United States target specific groups, low-income women being the most common target audience. Other target audiences are racial minorities, rural women and high-risk women<sup>67</sup>.

The most common means of delivering educational messages to these groups are presentations held in clinics, churches, shelters for battered and homeless women, and work sites, and at meetings of women's organizations and business association educators. Outreach methods have included radio and television public service announcements, newspaper advertisements and articles, bus advertisements, posters, brochures, health fairs, press conferences, billboards, house-to-house recruitment, and targeted mailings. Some programs use interpersonal strategies, with community volunteers contacting women at risk, and then one-to-one teaching by public health nurses or lay educators. Unfortunately, only 30% of the programs are undergoing evaluation, and many count only the numbers of women screened or reached by the educational message.

With special groups, as in general population studies, it is often difficult to identify the specific components of successful programs. For example, several successful programs to reduce barriers to breast cancer screening have been described in the literature. Ansell and colleagues set up a breast cancer screening program in two public clinics and used nurse clinicians and public health workers to recruit women to the clinics. Their

intervention addressed the barriers of accessibility to screening, knowledge about breast and cervical cancers, access to follow-up screening examinations, and access to treatment<sup>84</sup>. Although they screened over 10,000 women and detected 84 cases of breast cancer, the study was not a randomized trial and the intervention had multiple components, so it is difficult to identify the aspects that were successful.

One component that has been shown to increase attendance is ease of access to the program<sup>18,85</sup>. Accessibility can be a particular barrier for lower income women and rural women, for whom transportation is more difficult.

The use of lay health advisors may be an efficient means of promoting breast cancer screening in populations that are difficult to reach, as reported by some U.S. studies<sup>37,86,87</sup>.

Currently in Canada there is wide use of newspapers, radio, TV, video, newsletters, and media panels. All programs use newspaper advertising and articles, TV and radio public service announcements, and interviews. Most programs also use TV and radio advertising, media panels, video productions, and newsletters. All programs use brochures, posters, group presentations, health fairs, information displays, public meetings, and physician education.

Although the literature does not show cost-effective results from promotional programs compared with letters of invitation, such programs may improve compliance when combined with letters of invitation. Moreover, the increase in mammography screening is due, in part, to media coverage over the last several years. In general, media coverage seems to be more effective than media advertising of programs. However, both media coverage and letters of invitation will recruit the “easy to reach” women. There has to be special consideration for recruitment of “hard to reach” groups, and the methods used need to take into account any problems of language and culture.

## 2.6 References

1. Dean PB, Pamilo M. Screening mammography in Finland – 1.5 million examinations with 97 percent specificity. Mammography Working Group, Radiological Society of Finland. *Acta Oncol* 1999;38 Suppl 13:47-54.
2. Olsson S, Andersson I, Karlberg I, Bjurstam N, Frodis E, Håkansson S. Implementation of service screening with mammography in Sweden: from pilot study to nationwide programme. *J Med Screen* 2000;7:14-18.
3. Fracheboud J, de Koning HJ, Beemsterboer PMM, Boer R, Hendriks JHCL, Verbeek ALM, van Ineveld BM, de Bruyn AE, van der Maas PJ. Nation-wide breast cancer screening in the Netherlands: results of initial and subsequent screening 1990-1995. National Evaluation Team for Breast Cancer Screening (NETB). *Int J Cancer* 1998;75(5):694-698.

4. NHS Cancer Screening Programmes. *Informing Choice in Breast Screening – Breast Screening Programme Annual Review 2001*. Sheffield, NHS Breast Screening Programme, 2001.
5. Australian Institute of Health and Welfare (AIHW). *BreastScreen Australia Achievement Report 1997 and 1998*. Canberra: Australian Institute of Health and Welfare, 2000.
6. Health Canada. *Organized Breast Cancer Screening Programs in Canada 1997 and 1998 Report*. Ottawa: Minister of Public Works and Government Services Canada, 2001.
7. Olivotto IA, Kan L, d’Yachkova Y, Warren Burhenne LJ, Hayes M, Hislop TG, Worth AJ, Basco VE, King S. Ten years of breast screening in the screening mammography program of British Columbia, 1988-97. *J Med Screen* 2000;7(3):152-159.
8. Paquette D, Snider J, Bouchard F, Olivotto I, Bryant H, Decker K, Doyle G. Performance of screening mammography in organized programs in Canada in 1996. *Can Med Assoc J* 2000;163(9):1133-8.
9. Bonfill X, Marzo M, Pladevall M, Martí J, Emparanza JI. Strategies for increasing women’s participation in community breast cancer screening (Cochrane Review). In: *The Cochrane Library* 2001;issue 3. Oxford: Update Software.
10. Wagner TH. The effectiveness of mailed patient reminders on mammography screening: a meta-analysis. *Am J Prev Med* 1998;14(1):64-70.
11. Fett M. *Description of Breast and Cervical Cancer Screening Programs in British Columbia (Canada), England, Sweden, Finland and the Netherlands*. Canberra: Australian Institute of Health, Winston Churchill Memorial Trust, 1989.
12. Skinner CS, Strecher VJ, Hospers H. Physicians’ recommendations for mammography: Do tailored messages make a difference? *Am J Public Health* 1994;84:43-49.
13. Curry SJ, Taplin SH, Anderman C, Barlow WE, McBride C. A randomized trial of the impact of risk assessment and feedback on participation in mammography screening. *Prev Med* 1993;22:350-360.
14. Dorsch MM, Cheok F, Ingham HM. The effectiveness of invitations from general practitioners in recruiting women to mammographic screening. *Med J Aust* 1991;155:623-625.

15. Turnbull D, Irwig L, Adelson P. A randomised trial of invitations to attend for screening mammography. *Aust J Public Health* 1991;15:33-36.
16. Hobbs P, Kay C, Friedman EHI, St Leger AS, Lambert C, Boggis CR, Howard TM, Owen AW, Asbury DL. Response by women aged 65-79 to invitation for screening for breast cancer by mammography: a pilot study. *BMJ* 1990;301(6764):1314-1316.
17. Somkin CP, Hiatt RA, Hurley LB, Grushkin E, Ackerson L, Larson P. The effect of patient and provider reminders on mammography and Papanicolaou smear screening in a large health maintenance organization. *Arch Intern Med* 1997;57(15):1658-1664.
18. Hurley SF, Jolley DJ, Livingston PM, Reading D, Cockburn J, Flint-Richter D. Effectiveness, costs, and cost-effectiveness of recruitment strategies for a mammographic screening program to detect breast cancer. *J Natl Cancer Inst* 1992;84:855-863.
19. Austoker J, Ong G. Written information needs of women who are recalled for further investigation of breast screening: results of a multicentre study. *J Med Screening* 1994;1:238-244.
20. Wilson A, Leeming A. Cervical cytology screening: a comparison of two recall systems. *BMJ* 1987;295:181-182.
21. Williams EMI, Vessey MP. Randomised trial of two strategies offering women mobile screening for breast cancer. *BMJ* 1989;299:158-159.
22. Jepson R, Clegg A, Forbes C, Lewis R, Sowden A, Kleijnen J. The determinants of screening uptake and interventions for increasing uptake: a systematic review. *Health Technol Assess* 2000;4(14).
23. Sin JP, St Leger AS. Interventions to increase breast screening uptake: Do they make any difference? *J Med Screen* 1999;6(4):170-181.
24. Hobbs P. The behavioural aspects of breast and cervical screening. *Radiography* 1986;52:287-290.
25. Tinkler C, Pegington K, Baldwin R. Breast screening attendance: making better use of an appointment system. *J Med Screen* 2001;8(1):36-38.
26. Meldrum P, Turnbull D, Dobson HM, Colquhoun C, Gilmour WH, McIlwaine GM. Tailored written invitations for second round breast cancer screening: a randomised controlled trial. *J Med Screening* 1994;1:245-248.

27. Bankhead C, Richards SH, Peters TJ, Sharp DJ, Hobbs FD, Brown J, Roberts L, Tydeman C, Redman V, Formby J, Wilson S, Austoker J. Improving attendance for breast screening among recent non-attenders: a randomised controlled trial of two interventions in primary care. *J Med Screen* 2001;8(2):99-105.
28. Stead MJ, Wallis MG, Wheaton ME. Improving uptake in non-attenders of breast screening: selective use of second appointment. *J Med Screen* 1998;5:69-72.
29. Turner KM, Wilson BJ, Gilbert FJ. Improving breast screening uptake: persuading initial non-attenders to attend. *J Med Screening* 1994;1:199-202.
30. Taplin SH, Barlow WE, Ludman E, MacLehos R, Meyer DM, Seger D, Herta D, Chin C, Curry S. Testing reminder and motivational telephone calls to increase screening mammography: a randomized study. *J Natl Cancer Inst* 2000;92(3):233-242.
31. King ES, Rimer BK, Seay J, Balshem A, Engstrom PF. Promoting mammography use through progressive interventions: Is it effective? *Am J Public Health* 1994;84(1):104-106.
32. Seow A, Straughan PT, Lee HP. A randomized trial of the use of print material and personal contact to improve mammography uptake among screening non-attenders in Singapore. *Ann Acad Med Singapore* 1998;27(6):838-842.
33. Sharp DJ, Peters TJ, Bartholomew J, Shaw A. Breast screening: a randomised controlled trial in UK general practice of three interventions designed to increase uptake. *J Epidemiol Community Health* 1996;50:72-76.
34. Atri J, Falshaw M, Gregg R, Robson J, Omar RZ, Dixon S. Improving uptake of breast screening in multiethnic populations: a randomised controlled trial using practice reception staff to contact non-attenders. *BMJ* 1997;315(7119):1356-1359.
35. Stoddard AM, Fox SA, Costanza ME, Lane DS, Andersen MR, Urban N, Lipkus I, Rimer B for the NCI Breast Screening Consortium. Effectiveness of telephone counseling for mammography: results from five randomized trials. *Prev Med* 2002;34(1):90-99.
36. Segura JM, Castells X, Casamitjana M, Macia F, Porta M, Katz SJ. A randomized controlled trial comparing three invitation strategies in a breast cancer screening program. *Prev Med* 2001;33:325-332.
37. Sung JFC, Blumenthal DS, Coates RJ, Williams JE, Alema-Mensah E, Liff JM. Effect of a cancer screening intervention conducted by lay health workers among inner-city women. *Am J Prev Med* 1997;13(1):51-57.

38. Yabroff KR, Mandelblatt JS. Interventions targeted toward patients to increase mammography use. *Cancer Epidemiol Biomarkers Prev* 1999;8(9):749-757.
39. Ratner PA, Bottorff JL, Johnson JL, Cook R, Lovato CY. A meta-analysis of mammography screening promotion. *Cancer Detect Prev* 2001;25(2):147-60.
40. Smith RA, Haynes S. Barriers to screening for breast cancer. *Cancer* 1992;69:(7 Suppl):1968-1978.
41. Dawson DA, Thompson GB. *Breast Cancer Risk Factors and Screening: United States, 1987*. National Center for Health Statistics, 1989.
42. Marchant DJ, Sutton SM. Use of mammography: United States, 1990. *MMWR* 1990;39:621-630.
43. Fox SA, Murata PJ, Stein JA. The impact of physician compliance on screening mammography for older women. *Arch Intern Med* 1991;151:50-56.
44. Harris RP, Fletcher SW, Gonzalez JJ, Lannin DR, Degnan D, Earp JA, Clark R. Mammography and age: Are we targeting the wrong women? A community survey of women and physicians. *Cancer* 1991;67(7):2010-2014.
45. NCI Breast Cancer Screening Consortium and National Health Interview Survey Studies. Screening mammography: A missed clinical opportunity? *JAMA* 1990;264:54-58.
46. Burg MA, Lane DS, Polednak AP. Age group differences in the use of breast cancer screening tests. *J Aging Health* 1990;2:514-530.
47. Rubenstein L. Strategies to overcome barriers to early detection of cancer among older adults. *Cancer* 1994;74:(7 Suppl):2190-2193.
48. Caplan LS, Wells BL, Haynes S. Breast cancer screening among older racial/ethnic minorities and whites: barriers to early detection. *J Gerontol* 1992;47:Spec No:101-110.
49. Buechner JS, Fulton JP, Feldman JP, DeBuono BA, Kovenock D. Trends in breast cancer screening: Rhode Island, 1987-1989. *MMWR* 1989;38:569-571.
50. Zapka JG, Stoddard AM, Costanza ME, Greene HL. Breast cancer screening by mammography: utilization and associated factors. *Am J Public Health* 1989;79:1499-1502.

51. Anda RF, Sienko DG, Remington PL, Gentry EM, Marks JS. Screening mammography for women 50 years of age and older: practices and trends, 1987. *Am J Prev Med* 1990;6:123-129.
52. Kruse J, Phillips DM. Factors influencing women's decision to undergo mammography. *Obstet Gynecol* 1987;70:744-748.
53. Bryant H, Mah Z. Breast cancer screening attitudes and behaviors of rural and urban women. *Prev Med* 1992;21:405-418.
54. Fox SA, Stein JA. Effect of physician-patient communication on mammography utilization by different ethnic groups. *Med Care* 1991;29:1068-1082.
55. Fulton JP, Buechner JS, Scott HD, DeBuono BA, Feldman JP, Smith RA, Kovenock D. A study guided by the Health Belief Model of the predictors of breast cancer screening of women ages 40 and older. *Public Health Rep* 1991;106(4):410-420.
56. Buechner JS, Fulton JP, Kaufmann RB, et al. Use of mammography for breast cancer screening: Rhode Island, 1987. *MMWR* 1989;37:357-360.
57. Rimer BK, Kemtz MK, Kessler HB, Engstrom PF, Rosan JR. Why women resist screening mammography: patient-related barriers. *Radiology* 1989;172:243-246.
58. Routledge DN, Hartmann WH, Kinman PO, Winfield AC. Exploration of factors affecting mammography behaviors. *Prev Med* 1988;17:412-422.
59. Howard J. Using mammography for cancer control: an unrealized potential. *CA Cancer J Clin* 1987;37:33-48.
60. Vogel VG, Graves DS, Vernon SW, Lord JA, Winn RJ, Peters GN. Mammographic screening of women with increased risk of breast cancer. *Cancer* 1990;66:1613-1620.
61. Munn EM. Nonparticipation in mammography screening: apathy, anxiety or cost? *N Z Med* 1993;106:284-286.
62. Hammond JA, Stewart M. Female patients' attitudes to mammography screening. *Can Fam Physician* 1994;40:451-455.
63. American Cancer Society. *Older Women's Breast Cancer Education Interventions Workshop Report*. 1992 (Abstract).

64. American Association of Retired Persons. *You Can Make a Difference: Educating Older Women About Mammography*. Washington, DC: American Association of Retired Persons, 1993.
65. McBride CM, Curry SJ, Taplin S, Anderman C, Grothaus L. Exploring environmental barriers to participation in mammography screening in an HMO. *Cancer Epidemiol Biomarkers Prev* 1993;2:599-605.
66. Maxwell CJ, Bancej CM, Snider J. Predictors of mammography use among Canadian women aged 50-69: findings from the 1996/97 National Population Health Survey. *Can Med Assoc J* 2001;164(3):329-334.
67. Coyne CA, Hohman K, Levinson A. Reaching special populations with breast and cervical cancer public education [review]. *J Cancer Educ* 1992;7:293-303.
68. Fajardo LL, Saint-Germain M, Meakem TJ, 3d, Rose C, Hillman BJ. Factors influencing women to undergo screening mammography. *Radiology* 1992;184:59-63.
69. Zapka JG, Stoddard AM, Maul L, Costanza ME. Interval adherence to mammography screening guidelines. *Med Care* 1991;29:697-707.
70. Fox SA, Siu AL, Stein JA. The importance of physician communication on breast cancer screening of older women. *Arch Intern Med* 1994;154:2058-2068.
71. Grady KE, Lemkau JP, McVay JM, Reisine ST. The importance of physician encouragement in breast cancer screening of older women. *Prev Med* 1992;21:766-780.
72. Mandelblatt JS, Yabroff KR. Effectiveness of interventions designed to increase mammography use: a meta-analysis of provider-targeted strategies. *Cancer Epidemiol Biomarkers Prev* 1999;8(9):759-767.
73. Shea S, DuMouchel W, Bahamonde L. A meta-analysis of 16 randomized controlled trials to evaluate computer-based clinical reminder systems for preventive care in the ambulatory setting. *J Am Med Inform Assoc* 1996;3(6):399-409.
74. Kupets R, Covens A. Strategies for the implementation of cervical and breast cancer screening of women by primary care physicians. *Gynecol Oncol* 2001;83(2):186-97.



75. Valanis BG, Glasgow RE, Mullooly J, Vogt TM, Whitlock EP, Boles SM, Smith KS, Kimes TM. Screening HMO women overdue for both mammograms and pap tests. *Prev Med* 2002;34(1):40-50.
76. Turnbull D, Irwig L, Simpson JM, Donnelly N. The psychosocial impact of implementing a mammography screening campaign in an Australian community. *Soc Sci Med* 1994;39:543-551.
77. Haiart DC, Henderson J, McKenzie L, Kirkpatrick AE. A mobile breast screening project in Scotland: lessons learned for national screening. *Int J Health Plan Management* 1990;15:201-213.
78. Haiart DC, McKenzie L, Henderson J, Pollock W, McQueen DV, Roberts MM, Forrest AP. Mobile breast screening: factors affecting uptake efforts to increase response and acceptability. *Public Health* 1990;104(4):239-247.
79. Williams EM, Vessey MP. Compliance with breast cancer screening achieved by the Aylesbury Vale mobile service (1984-1988). *J Public Health Med* 1990;12:51-55.
80. Fletcher SW, Harris RP, Gonzalez JJ, Degnan D, Lannin DR, Strecher VJ, Pilgrim C, Quade D, Earp JA, Clark RL. Increasing mammography utilization: a controlled study. *J Natl Cancer Inst* 1993;85(2):112-120.
81. Clover K, Redman S, Forbes J, Sanson-Fisher R, Callaghan T. Two sequential randomized trials of community participation to recruit women for mammographic screening. *Prev Med* 1996;25:126-134.
82. Reynolds KD, West SG, Aiken LS. Increasing the use of mammography: a pilot program. *Health Educ Q* 1990;17:429-441.
83. Katz SJ, Hofer TP. Socioeconomic disparities in preventive care persist despite universal coverage. Breast and cervical cancer screening in Ontario and the United States. *JAMA* 1994;272:530-534.
84. Ansell D, Lacey L, Whitman S, Chen E, Phillips C. A nurse-delivered intervention to reduce barriers to breast and cervical cancer screening in Chicago inner city clinics. *Public Health Rep* 1994;109:104-111.
85. Schofield PE, Cockburn J, Hill DJ, Reading D. Encouraging attendance at a screening mammography programme: determinants of response to different recruitment strategies. *J Med Screening* 1994;1:144-149.

- 86 Navarro AM, Senn KL, McNicholas LJ, Kaplan RM, Roppe B, Campo MC. Por La Vida model intervention enhances use of cancer screening tests among Latinas. *Am J Prev Med* 1998;15(1):32-41.
87. Slater JS, Ha CN, Malone ME, McGovern P, Madigan SD, Finnegan JR, Casey-Paal AL, Margolis KL, Lurie N. A randomized community trial to increase mammography utilization among low-income women living in public housing. *Prev Med* 1998;27(6):862-870.

# **3. Retention**

## **3.1 Return Visits to Mammography Screening Programs**

- Programs should try to reach close to 100% attendance for rescreening in order to reduce mortality from breast cancer through screening.

Reductions in breast cancer mortality as evidenced in screening trials require mammographic screening to be routinely repeated<sup>1-5</sup>, as cancers are frequently detected even after several normal screens have been achieved<sup>3,6</sup>.

Despite the benefits of early detection obtainable through mammography, regular screening according to guidelines has not yet been widely attained. Although in most settings the majority of women report having had a mammogram, fewer report having had one recently, and still fewer (20%-27%) report having had multiple screens or an age-appropriate number<sup>7-9</sup>. Although repeated screening seems to be more prevalent in organized programs, results from nine rounds of screening in Nijmegen, the Netherlands, showed that less than 40% of women completed all rounds, despite 90% participating at least once<sup>5,6</sup>.

Participation in screening programs declines at subsequent screening rounds<sup>5,10</sup>, although women who do return are more compliant<sup>10,11</sup>. Women are more receptive of mammography if they have previously had a mammogram, and prior screening is strongly predictive of return for further screening<sup>12-15</sup>. Previous attenders are more likely to reattend than those who previously did not attend or who were previously ineligible to do so<sup>16</sup>. In a variety of settings, the proportion of previous attenders returning for rescreen was high (70%-90%), depending on the interval measured and the number of examinations considered<sup>14,17-24</sup>.

Despite the fact that prior screening increases the likelihood that women will return, in some settings even these women are unlikely to be rescreened, with reported frequencies of repeat screening as low as 25% to 57%<sup>25-29</sup>. The statistical cutoff interval for considering women as having returned for screening can have a major influence on the actual rate of repeat screening<sup>28,30</sup>.

Although many programs have successfully achieved high levels of attendance at rescreening, attendance within the recommended time intervals for rescreening is lower. Regardless of the recommended screening interval specified by the program, compliant attendance appears to be a further challenge. In a study of the National Health Service breast screening program in the United Kingdom, fewer than half of screened women had been rescreened within the recommended 3-year interval, although by 38 months nearly three-quarters had been rescreened and eventually nearly 90% returned for rescreen<sup>19</sup>. In

an Australian program with a recommendation for biennial screening, the median time from first to second screen was 27 months, so more than half the returning women were noncompliant with program recommendations<sup>17</sup>.

Compliance with mammography screening recommendations can be affected by a number of factors, and achieving compliant attendance in programs that screen annually may be even more difficult. In a Canadian screening trial, half the participants preferred screening every 2-3 years over annual screening, but despite this preference many women can comply with annual screening regimens or at least return for future screening<sup>12</sup>. Still, in the British Columbia screening program, of the women who returned within 15 months, only 41% returned in the recommended annual interval<sup>29</sup>, and in another U.S. program that provided women with annual reminders, a substantial number of women waited up to 2 years to have a repeat mammogram<sup>28</sup>.

Previous studies of regular adherence to mammographic screening have been limited. Some, particularly those from the United States, have relied on self-reported information<sup>8-9,26,28,31-34</sup>. This method is likely to overestimate mammography use because of social desirability biases and to underestimate the time that has elapsed since previous mammography as a result of telescoping biases. Others studies are unable to distinguish the extent to which participation in subsequent rounds is due to reattenders or new recruits and thus have not distinguished determinants of participation from determinants of reattendance<sup>5,10,13</sup>. However, the most prominent factor limiting comparisons among both programs and prior studies is the use of varying definitions of reattendance and compliance.

Disentangling the separate effects of reattendance, compliance with recommended intervals, and long-term compliance has been hampered by a lack of quantitative data<sup>19</sup>, but efforts have been made to assess these various factors independently<sup>19,30,35</sup>. Some studies have looked at repeat mammography but provided limited or no information about the timing of such return visits or reattendance patterns outside of the chosen time interval, and therefore did not consider that women may return within an interval that will still offer some advantages of early detection<sup>7,8,25,26,28</sup>. Sometimes reattendance and compliance issues are not considered separately. For example, the proportion of eligible women receiving a screen in the previous 3 years (“coverage”) is a performance indicator in breast screening programs in the United Kingdom<sup>19</sup> and can be adversely affected if women do not attend for initial or repeat screening or if they do not do so within the recommended interval.

Finally, a number of factors come into play that challenge or aid programs in maintaining participation for subsequent screening.

## 3.2 Factors Associated with Reattendance and/or Compliance

- Programs should identify the factors (age, demographic variables, facility) that play a role in reattendance.
- Programs should plan recruitment strategies to address the identified gaps in achieving reattendance.

Age, demographic variables, facility characteristics, provider factors, health history, prior mammography, psychosocial factors and recruitment factors are all associated with reattendance or compliance.

Participation, reattendance, and compliance with mammography have been reported to occur less frequently in both younger<sup>29,36,37</sup> and older women<sup>3,5,10,14,18,22</sup>. Consistent with these results is the finding that repeat screening is highest among women aged 55-64 as compared with levels of screening among both younger and older groups<sup>9,25</sup>. However, the findings are inconsistent: some have found that younger women are more likely to participate in a full series of four annual mammograms<sup>11</sup>, adhere to screening guidelines<sup>8,13</sup>, drop out of screening trials after just one or two screens<sup>37</sup>, and obtain annual mammograms<sup>33</sup>. Others have reported that age is unrelated to having repeat mammograms<sup>17,26,38</sup>.

Various studies<sup>8,11,26,27,32,33,37,39,40</sup> have shown that women with higher socioeconomic status are more likely to have multiple mammograms, to return for repeat mammography, and to adhere to screening guidelines. However, education seems to be the most consistent factor, as negative findings have been demonstrated for several other factors such as employment status and home ownership<sup>11,17</sup>. Being married has been shown to be both unrelated to rescreening<sup>11</sup> and related to compliance with annual mammography and to long-term repeated screening<sup>26,37,39</sup>. Various ethnic and cultural factors have been examined<sup>9,11,40,41</sup>, and findings have been inconsistent, though foreign-born women were less likely to participate in rescreens<sup>11,41</sup>.

Several facility-related factors have been examined, and accessibility of the screening clinic has been prominently associated with reattendance and compliance with rescreening recommendations<sup>11,12,17,29</sup>. One study found that hospital sites were preferable to clinics<sup>25</sup>. Staff at screening facilities also appear to play a role in promoting reattendance: compared with reattenders, non-reattenders have reported finding clinic staff less courteous, less welcoming, unhelpful, harder to question, or unsupportive with problems arising from the test and, with regard to technologists, less competent<sup>12,20,21</sup>. When reminder systems are in place, women are more likely to adhere to screening guidelines<sup>8</sup>, but the capacity of the centre also plays a role. Overwhelmed centres are unable to screen women within the time recommended by guidelines without increased resources<sup>19</sup>. If women must wait a long time between their physician's recommendation and the mammography screening appointment they may be less likely to get rescreened<sup>7,12</sup>.

A woman's usual physician plays a major role in whether women reattend and comply with mammography intervals. Physician referral for a mammogram is a strong promotor of screening. Increased referrals for mammography result in increased screening mammography and are strongly associated with women having had repeat mammograms<sup>7,27,32</sup>. Women with a regular physician and women who had visited a physician in the year before recruitment have been shown to be more likely to comply with repeat mammography screening<sup>11,42</sup>. Having a physician who criticizes or does not encourage screening is a barrier to reattendance and compliance<sup>12,29</sup>. The type of practitioner may also have an impact. One study found that routinely visiting a gynecologist was positively associated with having multiple screens<sup>34</sup>. Women were more likely to adhere to screening guidelines if they reported participating with their doctor in the decision to be screened<sup>8</sup>.

A woman's health status can also affect her attendance and compliance with screening. Those who fail to reattend have frequently cited acute illness as the reason<sup>20</sup>, and women who did return for repeat screening had better self-reported health<sup>11</sup>. A family history of breast cancer is a commonly reported factor associated with increased likelihood of reattending<sup>21,27</sup> and long-term compliance with a program<sup>35</sup>, although some evidence shows that this has no impact<sup>11,17</sup>.

Women who have had previous mammography, either screening or diagnostic, are more likely to reattend and comply with recommended screening intervals<sup>15,17,6,35</sup>. Reporting breast problems (e.g. lumps) did not affect reattendance at a second round of screening in one study<sup>17</sup>, but women were less likely to reattend in another<sup>40</sup>. In others studies, reporting of breast problems was associated with adhering to screening guidelines<sup>8,9</sup>. Regular performance of clinical breast examination has a positive association with mammography adherence<sup>9,33,35</sup>.

Despite indications that women suffer long-term morbidity, increased anxiety about breast cancer<sup>43</sup>, and recent unnecessary biopsy<sup>12</sup>, most studies show that women are either equally likely<sup>16,17,20,21,26,43-45</sup> or more likely<sup>25,44,46</sup> to return or intend to return if they experienced prior false-positive mammography results. Few contrary findings have been published. One study found that women who returned annually for screening were more likely to have had a normal initial study than were late compliers or noncompliers<sup>47</sup>. Another found that a false-positive screening result was associated with nonattendance at the next round in six screening rounds<sup>5</sup>. In both cases, it is uncertain whether this was the result of a negative attitude toward screening or toward continued clinical follow-up<sup>5</sup>. However, in a British study, 15% of women who had had an initial false-positive result did not attend for subsequent mammography, as compared with 8% of women whose first mammogram was negative<sup>48</sup>.

Although previous attenders appear to reattend more frequently, previous experience with mammography may result in nonattendance. Some disincentives to return have included radiation concerns<sup>12,29</sup> and negative views of initial screening, for example, that it was uncomfortable, painful, stressful, embarrassing, distressing, worse than expected, or not reassuring and that attendance was not worthwhile<sup>12,20,21,49</sup>.

Whether women's concern over their breast cancer risk influences reattendance and compliance is uncertain: it has been shown to be associated with both a higher<sup>11</sup> and a lower likelihood of reattending<sup>26</sup>. Some studies have found that women who perceive a higher susceptibility to breast cancer or are knowledgeable about lifetime risk are more likely to reattend<sup>27,32,34</sup>. Others report that perceived breast cancer risk has no effect on reattendance<sup>20</sup>. Women who perceive greater benefits of mammography have a higher frequency of mammography and shorter time interval since the last mammogram<sup>50</sup>. Guideline adherence is associated with a belief that breast cancer is curable<sup>31</sup>, and reattenders are more likely to believe that mammography is efficacious in detecting and curing breast cancer<sup>20,21</sup>. Women who have had multiple screens are more likely to express a willingness to pay \$75-\$100 for a mammogram, possibly indicating their view of its worth. On the other hand, women who express more anxiety about mammography or associate physical examinations with worry are less likely to obtain repeat mammography<sup>11,27</sup>.

Women who are preventively oriented may be more likely to reattend and comply with recommended screening intervals<sup>17,50</sup>. Other positive practices, such as participation in cervical screening<sup>8</sup>, regular breast self-examination<sup>12,29</sup>, and being a nonsmoker<sup>32</sup>, have been associated with screening guideline adherence and repeat screening, although these findings have been contradicted elsewhere<sup>17</sup>.

Social support may influence a woman's decision to return<sup>12</sup>. However, some studies have reported that the influence of a woman's friends, partner, children, co-workers, and physician did not affect second round attendance<sup>17</sup>, contrary to much of the literature on the role of the physician.

Women who do not reattend may be less aware of screening guidelines. Knowledge of the screening guideline recommendations has been found to be associated with adherence to screening within the recommended interval<sup>31</sup>. Some studies have shown that women who failed to reattend did not believe in or were unaware of the need for further screening<sup>20,21,29</sup>. In some cases this view was supported by their physician<sup>29</sup>.

Ease of recruitment plays a major role in women's reattendance and compliance with recommended rescreening intervals, as indicated by the literature on the "reluctant participant". Women who require repeated recruitment efforts are less likely to reattend or return for a series of screens than women who require minimal effort<sup>11,17,18,35,51</sup>. Despite a reduced tendency to reattend, recruitment of reluctant participants has been demonstrated to be worthwhile in elevating participation levels and improving prognosis in detected breast cancers<sup>11</sup>.

Even if women are invited in a timely fashion, compliance with recommended rescreen intervals may be adversely affected if there is delay in making an appointment or a change in the appointment time<sup>19</sup>. Women have cited lack of time and inconvenient appointment times as reasons for not reattending<sup>12,20</sup>.

### 3.3 Recall

- Women should be sent a recall letter before their next screening date.
- The recall letter should stress the benefit of regular screening.
- Letters for rescreening should be tailored to the results of the most recent mammogram.

For 20 years of their lives women will have access to regular screening by mammography. Interventions aimed at maintaining this habit have an important role in the fight against breast cancer. Relatively simple interventions that can be maintained over the years should be the objective.

The advantages of invitations as a recruitment approach have been previously discussed. Recall letters, whether signed by the physician or the screening program, significantly increase participation in mammography as compared with no letter<sup>52,53</sup>. Invitation by telephone can also be a useful strategy<sup>54</sup>.

Use of tailored letters containing information about previous screening history is not effective, although such letters may be more helpful than a standard letter in improving reattendance of women with prior false-positive findings<sup>16</sup>. A tailored leaflet enclosed with every invitation and directed at women who had previously undergone mammography did not enhance reattendance<sup>55</sup>.

A telephone follow-up can be considered for women who do not respond to the letter of invitation for rescreening. Use of the telephone carries the advantage that the reasons why women are not returning can be discussed and barriers can be addressed. Relative costing needs to be examined more formally.

A further concern regarding rescreening after the first screen is the tendency to increase the screening intervals. By scheduling an appointment one might minimize the chances of delays past 2 years. Other alternatives might be to schedule the next appointment for 2 years' time at the initial mammogram. A reminder card can be issued. The program can also advise women that when their rescreen is due, they will be sent an appointment letter with a time that could be changed if they so choose. An invitational letter with a scheduled appointment could then be sent out 1 to 2 months beforehand. Programs may want to consider trials of such alternatives.



### 3.4 References

1. Alexander FE, Anderson TJ, Brown HK, Forrest APM, Hepburn W, Kirkpatrick AE, Muir BB, Prescott RJ, Smith A. Fourteen years of follow-up from the Edinburgh randomised trial of breast-cancer screening. *Lancet* 1999;353:1903-1908.
2. Olson KL, Chapman JA, Thurston WE, Milligan CD. Promotion of breast cancer screening in communities. *Cancer Prev Control* 1997;1(3):213-221.
3. Peeters PH, Verbeek AL, Hendriks JH, van Bon MJ. Screening for breast cancer in Nijmegen. Report of 6 screening rounds, 1975-1986. *Int J Cancer* 1989;43(2):226-230.
4. Roberts MM, Alexander FE, Anderson TJ, Chetty U, Donnan PT, Forrest P, Hepburn W, Huggins A, Kirkpatrick AE, Lamb J, Muir BB, Prescott RJ. Edinburgh trial of screening for breast cancer: mortality at seven years. *Lancet* 1990;335(8684):241-246.
5. Scaf-Klomp W, van Sonderen FLP, Stewart R, van Dijck JAAM, van den Heuvel WJA. Compliance after 17 years of breast cancer screening. *J Med Screening* 1995;2:195-209.
6. Otten JDM, van Dijck JAAM, Peer PGM, Straatman H, Verbeek ALM, Mravunac M, Hendriks JHCL, Holland R. Long term breast cancer screening in Nijmegen, the Netherlands: the nine rounds from 1975-92. *J Epidemiol Community Health* 1996;50(3):353-358.
7. Howe HL. Repeat mammography among women over 50 years of age. *Am J Prev Med* 1992;8:182-185.
8. Phillips KA, Kerlikowske K, Baker LC, Chang SW, Brown ML. Factors associated with women's adherence to mammography screening guidelines. *Health Serv Res* 1998;33:29-53.
9. Zapka JG, Stoddard A, Maul L, Costanza ME. Interval adherence to mammography screening guidelines. *Med Care* 1991;29:697-707.
10. Van Dijck JAAM, Broeders MJM, Verbeek ALM. Mammographic screening in older women – Is it worthwhile? *Drugs and Aging* 1997;10(2):69-79.
11. Fink R, Shapiro S, Roester R. Impact of efforts to increase participation in repetitive screenings for early breast cancer detection. *Am J Public Health* 1972;62:328-336.

12. Baines C, To T, Wall C. Women's attitudes to screening after participation in the National Breast Screening Study. *Cancer* 1990;65(7):1663-1669.
13. Lechner L, de Vries H, Offermans N. Participation in a breast cancer screening program: influence of past behavior and determinants of future screening participation. *Prev Med* 1997;26:473-482.
14. Parker JD, Sabogal F. Relationship between earlier and later mammography screening – California Medicare, 1992 through 1994. *Western J Med* 1999;170(1):Jan 25-27.
15. Rutter DR. Attendance and reattendance for breast cancer screening: a prospective 3-year test of the Theory of Planned Behaviour. *Br J Health Psychol* 2000;5:1-13.
16. Meldrum P, Turnbull D, Dobson HM, Colquhoun C, Gilmour WH, McIlwaine GM. Tailored written invitations for second round breast cancer screening: a randomised controlled trial. *J Med Screen* 1994;1:245-248.
17. Cockburn J, Schofield P, White V, Hill D, Russel I. Predictors of returning for second round screening at a population based mammographic screening programme in Melbourne, Australia. *J Epidemiol Community Health* 1997;51(1):62-66.
18. De Waard F, Collette HJA, Romback JJ, Baanders-van Halewijn EA, Honing C. The DOM project for the early detection of breast cancer, Utrecht, the Netherlands. *J Chronic Dis* 1984;37:1-44.
19. Faux AM, Lawrence GM, Wheaton ME, Wallis MG, Jeffery CL, Griffiths RK. Slippage in the NHS breast screening programme: an assessment of whether a three year screening round is being achieved. *J Med Screen* 1998;5(2):88-91.
20. Marshall G. A comparative study of re-attenders and non-re-attenders for second triennial National Breast Screening Program appointments. *J Public Health Med* 1994;16(1):79-86.
21. Orton M, Fitzpatrick R, Fuller A, Mant D, Mlynek C, Thorogood M. Factors affecting women's response to an invitation to attend for a second breast cancer screening examination. *Br J Gen Pract* 1991;41:321-323.
22. Van Dijck JAAM, Hendriks JHCL, Holland R, Mravunac M. Mammographic screening after the age of 65 years: early outcomes in the Nijmegen programme. *Br J Cancer* 1996;74(11):1838-1842.

23. Blanks RG, Moss SM, Patnick J. Results from the UK NHS breast screening programme 1994-1999. *J Med Screen* 2000;7(4):195-8.
24. Fracheboud J, de Koning HJ, Beemsterboer PMM, Boer R, Hendriks JHCL, Verbeek ALM, van Ineveld BM, de Bruyn AE, van der Maas PJ. Nation-wide breast cancer screening in the Netherlands: results of initial and subsequent screening 1990-1995. National Evaluation Team for Breast Cancer Screening (NETB). *Int J Cancer* 1998;75(5):694-698.
25. Bastani R, Kaplan CP, Maxwell AE, Nisenbaum R, Pearce J, Marcus AC. Initial and repeat mammography screening in a low income multi-ethnic population in Los Angeles. *Cancer Epidemiol Biomarkers Prev* 1995;4:161-167.
26. Lerman C, Trock B, Rimer BK, Boyce A, Jepson C, Engstrom PF. Psychological and behavioral implications of abnormal mammograms. *Ann Intern Med* 1991;114(8):657-661.
27. Lerman C, Rimer B, Trock B, Balslem A, Engstrom PF. Factors associated with repeat adherence to breast screening. *Prev Med* 1990;19(3):279-290.
28. Jepson C, Baudin JL, Weiner JR. Variability in the timing of repeat screening mammography. *Prev Med* 1997;26(4):483-485.
29. Kan L, Hislop G, Skippen D. Early breast cancer: compliance to rescreening: the Screening Mammography Program of BC. *BC Med J* 1991;33:241-246.
30. Partin MR, Casey-Paal AL, Slater JS, Korn JE. Measuring mammography compliance: lessons learned from a survival analysis of screening behaviour. *Cancer Epidemiol Biomarkers Prev* 1998;7:681-687.
31. Glanz K, Resch C, Lerman C, Blake A, Gorchov PM, Rimer BK. Factors associated with adherence to breast cancer screening among working women. *J Occup Med* 1992;34(11):1071-1078.
32. Rimer BK, Trock B, Engstrom PF, Lerman C, King E. Why do some women get regular mammograms? *Am J Prev Med* 1991;7:69-74.
33. Solomon LJ, Mickey RM, Rairikar CJ, Worden JK. Three-year prospective adherence to three breast cancer screening modalities. *Prev Med* 1998;27(6):781-786.
34. Taylor VM, Taplin SH, Urban N, White E, Peacock S. Repeat mammography use among women ages 50-75. *Cancer Epidemiol Biomarkers Prev* 1995;4:409-413.

35. Weinberg AD, Lane M, Cooper HP, Kripalani S. Screening behaviours and long-term compliance with mammography guidelines in a breast cancer screening program. *Am J Prev Med* 1997;13(1):29-35.
36. Screening Mammography Program of British Columbia. *Annual Reports for 1994/95, 1995/96, 1996/97, 1997/98*.
37. Baker L. Breast cancer detection demonstration project: five-year summary report. *CA Cancer J Clin* 1982;32:194-225.
38. Fletcher SW, Black W, Harris R, Rimer BK, Shapiro S. Report of the international workshop on screening for breast cancer. *J Natl Cancer Inst* 1993;85:1644-1656.
39. Ulcickas Yood M, McCarthy BD, Lee NC, Jacobsen G, Johnson CC. Patterns and characteristics of repeat mammography among women 50 years and older. *Cancer Epidemiol Biomarkers Prev* 1999;8(7):595-599.
40. O'Byrne AM, Kavanagh AM, Ugoni A, Diver F. Predictors of non-attendance for second round mammography in an Australian mammographic screening programme. *J Med Screen* 2000;7(4):190-194.
41. Fink R, Shapiro S. Significance of increased efforts to gain participation in screening for breast cancer. *Am J Prev Med* 1990;6(1):34-41.
42. Barr JK, Franks AL, Lee NC, Herther P, Schachter M. Factors associated with continued participation in mammography screening. *Prev Med* 2001;33:661-667.
43. Gram IT, Lund E, Slenker SE. Quality of life following a false positive mammogram. *Br J Cancer* 1990;62:1018-1022.
44. Pisano ED, Earp J, Schell M, Vokaty K, Denham A. Screening behavior of women after a false-positive mammogram. *Radiology* 1998;208(1):245-249.
45. O'Sullivan I, Sutton, S, Dixon S, Perry N. False positive results do not have a negative effect on reattendance for subsequent breast screening. *J Med Screen* 2001;8(3):145-148.
46. Benedict S, Williams RD, Baron PL. The effect of benign breast biopsy on subsequent breast cancer detection practices. *Oncol Nurs Forum* 1994;21(9):1467-1475.
47. Johnson MM, Hislop TG, Kan L, Coldman AJ, Lai A. Compliance with the screening mammography program of British Columbia: Will she return? *Can J Public Health* 1996;87:176-179.

48. Brett J, Austoker J. Women who are recalled for further investigation for breast screening: psychological consequences 3 years after recall and factors affecting re-attendance. *J Public Health Med* 2001;23(4):292-300.
49. Elwood M, McNoe B, Smith T, Bandaranayake M, Doyle TCA. Once is enough – why some women do not continue to participate in a breast cancer screening programme. *NZ Med J* 1998;111:180-183.
50. Holm CJ, Frank DI, Curtin J. Health beliefs, health locus of control, and women's mammography behaviour. *Cancer Nurs* 1999;22(2):149-156.
51. Fink R, Shapiro S, Lewison J. The reluctant participant in a breast cancer screening program. *Public Health Rep* 1968;83:479-490.
52. Wagner TH. The effectiveness of mailed patient reminders on mammography screening: a meta-analysis. *Am J Prev Med* 1998;14:64-70.
53. Mayer JA, Lewis EC, Slymen DJ, Dullum J, Kurata H, Holbrook A, Elder JP, Williams SJ. Patient reminder letters to promote annual mammograms: a randomized controlled trial. *Prev Med* 2000;31(4):315-322.
54. Barr JK, Franks AL, Lee NC, Antonucci DM, Rifking S, Schachter M. A randomized intervention to improve ongoing participation in mammography. *Am J Managed Care* 2001;7(9):887-894.
55. Drossaert CH, Boer H, Seydel ER. Health education to improve repeat participation in the Dutch breast screening programme: evaluation of a leaflet tailored to previous participants. *Patient Educ Couns* 1996;28:121-131.

# **4. Quality of Mammography**

## **4.1 Education and Training**

### **Radiologists**

- In addition to the accreditation requirements of the Canadian Association of Radiologists (CAR), minimum requirements for a radiologist starting in a screening program should include (1) 30 hours of continuing medical education in breast imaging in the previous 5 years, of which 15 hours are at a screening course, and 15 hours within the previous 3 years; (2) minimum of 1 year's experience in reading mammograms; (3) having read at least 1,000 mammograms during that year.
- Radiologists reading screening mammograms should pass a standardized test in screening mammography.
- To maintain standing in a screening program, in addition to CAR requirements, radiologists should meet the following minimum conditions: (1) participate in quality assurance review rounds at least quarterly; and (2) read at least 3,000 screening mammograms annually. These represent optimal criteria, and screening programs should endeavour to maximize the number of readings per radiologist by optimizing the number of radiologists.
- During a radiologist's first year in an organized screening program, his/her abnormal recall rate should be less than 15%. In subsequent years, the recall rate should be reduced to less than 10% for first screens and less than 5% for repeat screens.
- Screening programs should periodically evaluate interval cancers. Screening radiologists should receive individual feedback regarding cancer detection rates, sensitivity, specificity, and interval cancers.

### **Mammography technologists**

- Requirements for technologists entering training in a screening program should include (1) Canadian Association of Medical Radiation Technologist (CAMRT) Mammography I & II courses or equivalent and (2) a minimum of 1 year's experience in mammography.
- Before the independent performance of mammography, technologists should perform (1) hands-on training at a specialized site for a minimum of 5 days, with a minimum of 50 mammograms performed under direct supervision; (2) 250 mammograms under close supervision, to be evaluated using guidelines and standards established by each program.

- 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%.

#### **4.1.1 Radiologists**

Mammographic screening is a radiological procedure. One cannot have a high-quality screening program without expert 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, minimizing interval cancers, and minimizing recall, unnecessary invasive procedures, and anxiety.

Although there is no direct evidence of optimal training for screening mammography, the literature does provide evidence that dedicated mammography courses improve radiologists' performance and alter their interpretive approach<sup>1</sup>. Such courses can increase the number of diagnosed breast cancers. There is also evidence that residency training in breast imaging is too short, in that over a third of radiology residents felt that they could not practise mammography independently after this training<sup>2</sup>. Screening mammography is a further specialized field within mammography. Thus, although licensed radiologists certified by the College of Physicians and Surgeons may be permitted to read mammograms, it is felt that quality assurance in screening programs requires a higher standard for radiologists.

In developing these recommendations, the Working Group considered the standards in other countries with screening programs. 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<sup>3</sup>. The United Kingdom requires a screening radiologist to participate in initial and in-service training: an initial training program developed by the Royal College of Radiologists, and in-service training (minimum of 2 weeks' practical training); additional 2-week courses are recommended<sup>4</sup>. Regular participation in multidisciplinary meetings, case review including post-screen cancers, and performance audits are recommended in several screening programs<sup>3-5</sup>.

For the annual number of mammography readings, the Working Group considered the volumes in other countries (2,000 in Australia and 5,000 in the United Kingdom) but also considered sensitivity calculations performed in the Screening Mammography Program of British Columbia. These estimated the number of readings per year that it would take to detect a large enough number of cancers such that any performance by the radiologist that was significantly different from established standards could be identified.

Moreover, radiologists who read large numbers of mammograms reach higher levels of sensitivity and specificity<sup>6</sup>, have lower recall rates at screening<sup>7</sup>, and detect cancers more often<sup>8-9</sup>, especially small cancers<sup>9</sup>. However, it has also been found that radiologists reading large numbers of mammograms show both detection and recall rates that are higher than the mean<sup>7</sup>, or that the increase in detection rate is associated with an increase in the false-positive rate<sup>9</sup>.

#### **4.1.2 Mammography technologists**

Both Australia and the United Kingdom have set a minimum standard for repeat films of less than 3%.

Australia requires its screening technologists to be trained in screening mammography through courses in accordance with national and State training programs<sup>3</sup>. Technologists are encouraged to undertake training towards a Certificate of Clinical Proficiency in Mammography, and trainees are required to be directly supervised by a designated radiographer. Quality review and/or educational sessions for radiographers with a designated radiologist occur every 3 months.

The United Kingdom requires that technologists have a certificate of competence from the College of Radiographers, that they do screening and investigation examinations at least 2 days a week, and that they perform mammography in an acceptable way for at least 95% of the time<sup>10</sup>. Technologists should also maintain and improve their abilities by participating in continuing education, research, and audit activities.

According to European guidelines, all technologists participating in screening programs should attend a training program, including an academic component (from 3 days to 1 week) and a clinical component (from 2 to 6 weeks), the duration depending on the abilities of the technologist<sup>11</sup>. Continued training should take place for at least 1 day every 2 or 3 years in an accredited centre.

There are minimum standards required of screening technologists in some countries. In Australia, technologists must do 1,000 screenings, and those who are film readers must read 2,000 annually. The United Kingdom requires a screening technologist to work a minimum of 2 days a week doing screening. Finally, European guidelines recommend that technologists work at least 2 days per week, carrying out about 22 mammography examinations daily.

The recommendations proposed here represent minimal criteria. Screening programs should endeavour to maximize the number of examinations performed per technologist.



## 4.2 Quality Control

- An organized screening program should have a quality assurance (QA) program instituted in order to ensure that
  - the mammography examination is performed with the lowest possible radiation dose to the patients consistent with clinical diagnostic requirements;
  - the mammograms produced allow accurate clinical assessment; and
  - all steps leading to accurate diagnosis are taken, and the information is made available in a timely fashion to the patient's physician.
- Acceptance testing and a quality control (QC) monitoring program should be instituted 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
  - set the level of responsibility for personnel 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 *Canadian Mammography Quality Guidelines*.
- 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 should be accessible to technologists performing the tests for standardization purposes.
- The radiologist and the physicist should periodically review test results.

A QA program for mammography includes QC procedures for the monitoring and testing of X-ray equipment and related components, and administrative actions to ensure that monitoring, evaluation, and corrective actions are properly performed.

Quality control is defined as the routine performance and interpretation of equipment function tests and of corrective actions taken<sup>12</sup>. 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 patient care is affected.

QC tests should be performed at the frequencies recommended by the *Canadian Mammography Quality Guidelines*<sup>13</sup>. A list of test methods can be found in the 1999 ACR *Mammography Quality Control Manual*<sup>12</sup> or Quebec's *Manuel de contrôle de la qualité*<sup>14</sup>. These tests are presented in Table 1.

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

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 can give rise to unnecessary additional tests that increase patient anxiety and decrease the public's confidence in the efficacy of mammograms.

**Table 1**  
**Mammographic Quality Control Tests**

<b>Test</b>	<b>Minimum Frequency</b>	<b>Corrective Action To Be Taken</b>
<b>Technologist Tests</b>		
Darkroom cleanliness	Daily	–
Processor quality control	Daily	Immediately
Mobile unit quality control	Daily	Immediately
Screen and cassette cleanliness	Weekly	–
Viewboxes and viewing conditions	Weekly	–
Phantom images	Weekly	Immediately
Visual checklist of equipment	Monthly	–
Processor temperature display	Monthly	–
Replenishment rate	Monthly	–
Repeat analysis	Quarterly	Within 30 days of the test date
Analysis of fixer retention in film	Quarterly	Within 30 days of the test date
Darkroom fog	Semi-annually	Immediately
Screen-film contact	Semi-annually	Immediately
Compression	Semi-annually	Immediately
<b>Medical Physicist Tests</b>		
Mammographic unit assembly evaluation	Annually	Within 30 days of the test date
Collimation assessment	Annually	Within 30 days of the test date
Evaluation of system resolution	Annually	Within 30 days of the test date
AEC system performance	Annually	Within 30 days of the test date
Uniformity of film/screen speed	Annually	Within 30 days of the test date
Artifact evaluation	Annually	Within 30 days of the test date
Image quality evaluation	Annually	Immediately
Tube voltage accuracy and reproducibility	Annually	Within 30 days of the test date
Beam quality assessment	Annually	Within 30 days of the test date
Breast exposure and AEC reproducibility	Annually	Within 30 days of the test date
Average glandular dose	Annually	Immediately
Radiation output rate	Annually	Within 30 days of the test date
Measurement of viewbox luminance and room illuminance	Annually	–

### 4.3 References

1. Linver MN, Paster SB, Rosenberg RD, Key CR, Stidley CA, King WV. Improvement in mammography interpretation skills in a community radiology practice after dedicated teaching courses: 2-year medical audit of 38,633 cases. *Radiology* 1992;184:39-43.
2. Garvin GJ, Taves DH, McCurdy LI. Resident training in breast imaging in Canada: current status. *Can Assoc Radiol J* 1992;43:188-190.
3. National Program for the Early Detection of Breast Cancer. *National Accreditation Requirements Approved: March 1994*. Canberra (Australia): Commonwealth Department of Human Services and Health, 1994.
4. NHS Breast Screening Radiologists Quality Assurance Committee. *Quality Assurance Guidelines for Radiologists*. Publication no 15, update. Sheffield, United Kingdom: NHS Breast Screening Programme, 1997.
5. Rosselli Del Turco M, Hendriks J, Perry N. Radiological guidelines. In: Perry N, Broeders M, de Wolf C, Törnberg S (eds.) *European Guidelines for Quality Assurance in Mammography Screening*, 3rd edition. Luxembourg: Office for Official Publications of the European Communities, 2001: 143-158.
6. Esserman L, Cowley H, Eberle C, Kirkpatrick A, Chang S, Berbaum K, Gale A. Improving the accuracy of mammography: volume and outcome relationships. *J Natl Cancer Inst* 2002;94(5):369-375.
7. Kan L, Olivotto IA, Warren Burhenne LJ, Sickles EA, Coldman AJ. Standardized abnormal interpretation and cancer detection ratios to assess reading volume and reader performance in a breast screening program. *Radiology* 2000;215:563-567.
8. Ciatto S, Ambrogetti D, Catarzi S, Morrone D, Rosselli Del Turco M. Proficiency test for screening mammography: results for 117 volunteer Italian radiologists. *J Med Screening* 1999;6:149-151.
9. Elmore JG, Wells CK, Howard DH. Does diagnostic accuracy in mammography depend on radiologists' experience? *J Women's Health* 1998;7:443-449.
10. NHS Breast Screening Programme Radiographers Quality Assurance Coordinating Group. *Quality Assurance Guidelines for Radiographers*. Publication no. 30, 2nd edition. Sheffield: NHS Breast Screening Programme, March 2000.

11. Rijken H, Caseldine J. Radiographical guidelines. In: Perry N, Broeders M, de Wolf C, Törnberg S (eds.) *European Guidelines for Quality Assurance in Mammography Screening*, 3rd edition. Luxembourg: Office for Official Publications of the European Communities, 2001: 127-141.
12. American College of Radiology. *Mammography Quality Control Manual 1999*. Reston, VA: American College of Radiology, 1999.
13. Health Canada. *Canadian Mammography Quality Guidelines*. Ottawa, Ontario: Health Canada, 2002.
14. Noël, F, Tremblay R. *Manuel de contrôle de la qualité en mammographie. Programme québécois de dépistage du cancer du sein, Volume 1 : Technologue en radiologie*. Québec : ministère de la Santé et des Services sociaux, juin 2001.

# **5. Reporting**

## **5.1 Screening Report**

- A standardized radiology screening report should be used.
- The abnormal mammography report should be specific as to type of abnormality detected, the number of significant abnormalities, their size in millimetres, location of the lesion, degree of suspicion for malignancy, and the type of subsequent examinations to be performed to define the nature of the abnormality.

The decision to order a biopsy for a mammographically detected abnormality is the responsibility of the interpreting physician. This requires clear reporting and specific recommendations. Several sets of recommendations exist in the literature in terms of the content of the radiologist's report. Kopans has offered a classification scheme for mammographic findings<sup>1</sup>, which has been adopted by the ACR's Breast Imaging Reporting and Data System (BI-RADS)<sup>2</sup>. Some Canadian programs have adopted this system:

0. Need additional imaging evaluation
1. Negative
2. Benign finding
3. Probably benign finding
5. Suspicious abnormality
6. Highly suggestive of malignancy

Sterns<sup>3</sup> suggests that the report conclude with one of three recommendations:

- the abnormality represents benign change, and no further immediate investigations are required;
- the abnormality is probably benign, but a repeat mammogram is required within a specific interval;
- the lesion may be malignant, and mammographic localization and biopsy are required.

Objective criteria should support the assessment<sup>1</sup>. In addition, the basic format of the breast imaging report should include the following information:

- pertinent clinical history;
- the type of study performed;

- an indication as to whether the present examination has been compared with previous studies;
- a general summary of the distribution of breast tissue (as an indication of the expected sensitivity of the study);
- a description of the findings, including specific details about masses and calcifications.

Follow-up recommendations may include breast imaging (e.g. diagnostic mammography, breast ultrasound), fine needle aspiration/core biopsy, or surgical consultation.

## 5.2 Pathology Report

- All breast specimens with in-situ or invasive carcinoma should be examined and reported as detailed in Appendix A, *Guidelines for the Pathological Examination and Reporting of Breast Specimens*. Elements essential for monitoring breast cancer screening programs are
  - tumour type – in situ and invasive;
  - tumour size – size of invasive component in millimetres, confirmed by microscopy;
  - tumour grade;
  - lymph node involvement – sentinel node(s) – positive or negative for metastases;
  - axillary content:
    - total number of nodes removed,
    - number of nodes positive for metastases,
    - size of largest metastasis.
- For nonmalignant breast specimens, consensus should be developed among radiologists, pathologists, and surgeons (and possibly family physicians) on the pathological findings required for the management of patients with histologic predictors of increased cancer risk and for correlation with or monitoring of diagnostic imaging. Until such agreement is reached it is recommended that pathology reports include an indication of presence or absence of at least the following:
  - moderate/florid ductal epithelial hyperplasia;
  - atypical ductal and lobular hyperplasia;
  - radial scar;
  - calcification.

### 5.3 References

1. Kopans DB. Standardized mammography reporting. *Radiol Clin North Am* 1992;30:257-264.
2. American College of Radiology. *Breast Imaging Reporting and Data System* (BI-RADS®), 3<sup>rd</sup> ed. Reston, Va: American College of Radiology, 1998.
3. Sterns EE. The abnormal mammogram in women with clinically normal breasts. *Can J Surg* 1995;38:168-172.



# **6. Communicating Results**

## **6.1 Communicating Results to the Physician**

- Self-referred women should be assisted in finding a physician who will assume follow-up responsibility.
- The screening program should endeavour to send a screening report to the woman's physician within 10 business days.
- An appropriate professional from the screening program will send the woman's physician a report documenting the specific findings and follow-up recommendations. The screening program may telephone the referring physician if the result is highly suspicious for cancer. Other abnormal results may be conveyed by telephone or mailed to the physician.
- The abnormal screening report should accompany the letter to the referring physician.
- The abnormal mammography report should provide a list of accredited diagnostic facilities.
- The letter conveying normal results should advise physicians of the limitations of mammography.

The interpretation of the mammogram and the clarity with which the information is relayed is important for high-quality care. It has also become the subject of medicolegal actions. As the referring physician does not anticipate an abnormal report, he/she will be less likely to seek the results of a delayed test. It is essential that a system be in place to ensure that the results are received. The screening program bears full responsibility for communicating the screening results to the patient and her doctor<sup>1,2</sup>.

Robertson and Kopans documented problems with the communication of results<sup>3</sup>. In their study of abnormal breast cancer screening examinations, 63% of patients had either had no workup or an incomplete workup 2.5 months after the abnormal mammogram. The authors traced what could go wrong with reports. Even though the results of all abnormal reports were given by telephone *and* mailed to the referring physician, they found the following problems:

1. Doctors complained that they had not received the report. Investigations showed that office personnel had noted the report and it was subsequently misplaced.
2. The report was misunderstood, and follow-up mammography was not ordered immediately, as suggested by the radiologist, but in 6 months' time.

3. Physicians might have more than one address, and several reports were sent to the wrong addresses.
4. At teaching hospitals, the house staff physician requesting the study could leave the clinical service. Reports would then be filed without being seen or acted upon.
5. Patients may have moved, may not have had a telephone, or may not have been able to speak English.
6. Patients contacted and referred to a surgeon did not understand the referral. They did not see the surgeon for a variety of reasons, refused the recommendation of the first surgical referral, and/or were lost to follow-up.

Monticciolo and Sickles<sup>4</sup> achieved excellent compliance rates among referred patients by sending computer generated follow-up letters to the referring physicians. In patients who were self-referred and received their mammogram reports directly, Monsees and colleagues<sup>5</sup> reported a 93% 3-month compliance rate. Cardenosa and Eklund scheduled additional mammographic studies directly with patients within 24 hours of mammographic interpretation and contacted the referring physician when a biopsy was recommended<sup>6</sup>. This resulted in a high compliance rate in a short period: 98% and 92% respectively of the patients had completed the examinations within 30 days of the recommendations.

Since most radiologists work part-time at Canadian screening centres, on-site results are not practical. Normal results may be mailed to both the physician and the woman simultaneously. Results should be sent as soon as possible. It is recognized that there may not be sufficient volume for radiologists to read screening films daily. Several days may be required to obtain previous mammograms.

## **6.2 Communicating Results to the Woman**

- Women should be informed, at the time of the examination, when they should receive the results of their mammogram, regardless of whether or not it is normal.
- Women should receive written notification of their mammography results in a timely fashion, normally within 10 working days. For abnormal reports, the letter may be delayed up to 2 days to ensure that the physician has received the report.
- The screening centre should be sensitive, supportive, and appropriate in communicating results.
- Written notification of mammography results should be in simple language and include the next steps. The letter should include the name and telephone number of a contact person at the screening centre who can provide further information.

- The written information should be easily readable. All written information should be routinely tested and evaluated before it is used.
- With normal results, the letter should state the limitations of mammography. It should state that if the woman develops any suspicious signs or symptoms before the next screening date, she should see her physician. The letter should also emphasize the importance of rescreening. A comment card could also be enclosed.
- With abnormal results, the letter or follow-up telephone call should reassure the woman that, in the majority of cases, further investigation is negative. Key information should be communicated in the letter and additional information by leaflet or by telephone call.
- Women should be informed that to ensure high-quality assessment it is important to go to an accredited mammographic facility.
- A letter of closure should be sent to the woman whose abnormal result has been shown to be benign. The letter should confirm the normal result of the workup and encourage the woman to return to the screening program at an appropriate time.

Direct communication of mammographic results to the patient has been advocated, as it results in better compliance with recommendations for additional imaging, follow-up examinations, and biopsies<sup>6-8</sup>. Direct communication with the woman reduces the anxiety associated with waiting for the results of the mammographic examination<sup>7,8</sup>.

Surveys have shown that the majority of women feel that the radiologist should give them the mammographic results directly, whether the results are normal or abnormal. They feel that this constitutes their right to be treated as an adult and to avoid being a victim of mishaps that can occur with the traditional communication and reporting methods<sup>8</sup>. Although clinical physicians may agree with patients and their families, radiologists have felt less comfortable in this role<sup>9,10</sup>. Although desirable, it is recognized that this procedure is not practical, since radiologists are not always available on site in Canadian screening centres.

Canadian screening programs have adopted a variety of methods of sending results to women and their physicians. Normal reports are generally mailed simultaneously to the woman and her physician. Results should be mailed as soon as possible.

Screening centre personnel should 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 previous films are required, the woman should be forewarned of the potential delay.

Whether abnormal results are mailed or telephoned to women is somewhat controversial. Most programs do not telephone the woman directly. There is evidence indicating that use of the telephone increases compliance with assessment<sup>6-8</sup>.

Receipt of abnormal results has significant negative psychological implications. It is important to indicate to the woman at the time of the mammogram that most abnormalities found with mammography prove to be benign.

The content of letters that indicate the need for further testing has been carefully studied by Austoker and Ong. These authors examined the amount and type of information a woman needs when being recalled for further investigation<sup>11</sup>. They assessed such letters and accompanying leaflets for coverage of the following nine topics:

1. Why the women had been recalled.
2. How to get to the centre.
3. Who could accompany them.
4. How to change the appointment.
5. How long the appointment would be.
6. Whom they would see at the centre.
7. What tests would be carried out.
8. When the results would be available.
9. How to get more information.

More information was desired. Great detail was not necessary, but the above points should be mentioned. Four in 10 women wanted further information about the reason for recall, and less than 1% felt that too much information was provided on any topic. The exception was the desire for detailed information about fine needle aspiration. More information was desired by distressed women regarding the reason for recall, the length of the appointment, and ways to access more information.

The receipt of a letter with abnormal results can be extremely distressing: it has been found that 58% of women were distressed or very distressed on receiving such a letter. Other studies have shown that the time of greatest anxiety is between receipt of the letter and the follow-up appointment. Attention needs to be given to these letters to minimize anxiety during this period.

It was found that receiving, with the letter, a leaflet describing assessment was especially reassuring. It was also comforting to be informed in the recall letter of when the results of the assessment would be received, and that

- more information could be obtained by telephoning the centre;
- further investigation was part of routine screening;
- the great majority of results are normal;
- a breast care professional at the centre could be contacted.

Most reassuring was to hear that assessment was “part of routine screening” and that the majority of further investigations were usually negative.

Presentation was important in determining whether the information was remembered. Reassuring phrases on the front cover separated from the rest of the text in a different typeface were more likely to be remembered and found reassuring. Women were also more likely to have read the leaflet if it was referred to in the letter.

On the other hand, certain aspects of the letter were anxiety provoking:

- an extended waiting time between receipt of the abnormal results letter and the appointment for further investigation;
- being given vague reasons for recall;
- being told not to worry, that the X-rays had been unclear, or that the reason for being recalled would be given to the woman when she was seen at the centre;
- use of the word “cancer”;
- stating that with the second visit the majority of women were shown not to have cancer, rather than stating that most results are normal;
- being told that assessment was at a hospital, that the woman would be seen by a team of specialists, or that she could contact a nurse “counsellor” (rather than a breast care nurse);
- being given a detailed description of fine needle aspiration.

Giving a reason for further investigation was better than promising a reason at assessment, not giving one, or giving a vague reason.

Since most Canadian screening programs are not linked to assessment centres, some of the information about details of follow-up is not applicable. Of special concern is the possibility of delayed time to diagnosis due to lack of diagnostic facilities at the screening site.

If the mammogram is normal, the letter should state the limitations of mammography, i.e. 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 physician. The letter should also emphasize the importance of rescreening.

If the results are 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. At this point, there should be no mention of cancer. It should be stated that only a small number of abnormalities (1%-4%) will be malignant. Reassuring statements should be used. For screening facilities with a diagnostic assessment service, the letter should include a specific appointment time for further tests.

Anxiety will be decreased if the woman knows at the time of screening that she may be recalled for further evaluation. It should be emphasized that this evaluation most often provides normal results and it is not necessary to see a surgeon at this time.

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 result in 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 physician 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.

### 6.3 References

1. Brenner RJ. Medicolegal aspects of breast imaging. *Radiol Clin North Am* 1992;30:277-286.
2. Kopans DB. Standardized mammography reporting. *Radiol Clin North Am* 1992;30:257-264.
3. Robertson CL, Kopans DB. Communication problems after mammographic screening. *Radiology* 1989;172:443-444.
4. Monticciolo DL, Sickles EA. Computerized follow-up of abnormalities detected at mammography screening. *AJR Am J Roentgenol* 1990;155:751-753.
5. Monsees B, Destouet JM, Evens RG. The self-referred mammography patient: a new responsibility for radiologists. *Radiology* 1988;166:69-70.
6. Cardenosa G, Eklund GW. Rate of compliance with recommendations for additional mammographic views and biopsies. *Radiology* 1991;181:359-361.
7. Hoffman NY, Janus J, Destounis S, Logan-Young W. When the patient asks for the results of her mammogram, how should the radiologist reply? *AJR Am J Roentgenol* 1994;162:597-599.
8. Fletcher SW, Black W, Harris R, Rimer BK, Shapiro S. Report of the International Workshop on Screening for Breast Cancer. *J Natl Cancer Inst* 1993;85:1644-1656.
9. Song HH, Park SH, Shinn KS. Radiologists' responses to patients' inquiries about imaging results. *Invest Radiol* 1993;28:1043-1048.

10. Levitsky DF, Frank MS, Richardson ML, Schneidman RJ. How should radiologists reply when patients ask about their diagnoses? A survey of radiologists' and clinicians' preferences. *AJR Am J Roentgenol* 1993;161:433-436.
11. Austoker J, Ong G. Written information needs of women who are recalled for further investigation of breast screening: results of a multicentre study. *J Med Screening* 1994;1:238-244.

## **7. Follow-up and Diagnostic Workup**

- The screening program's responsibility does not end with screening. The screening program should ensure that evaluation and assessment of the woman with an abnormal result has been undertaken.
- 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.
- There should be a timely, fail-safe mechanism to ensure that follow-up of the screening abnormality has occurred. The screening program should verify within 8 weeks that this has occurred.

In some countries, assessment of abnormal results occurs within the screening program, where the diagnostic process is undertaken at specialized centres<sup>1-3</sup>. In Canada, the woman and her family physician are usually notified about the abnormal result, and the family physician is responsible for subsequent referrals.

At the initial screen and at rescreen, 12% and 5% respectively of Canadian women screened within organized breast screening programs were referred for additional assessment<sup>4</sup>. Among these women with abnormal screens, between 6% and 7% subsequently received a diagnosis of cancer.

The assessment of abnormal results may involve clinical examination, imaging (other mammographic studies and ultrasonography), and needle sampling for cytology or histology<sup>2,5</sup>. Assessment centres should use clinical guidelines for the investigation of lesions detected by mammography. The Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer made recommendations to facilitate decision-making when a mammographic abnormality is detected by screening<sup>5</sup>. These guidelines are evidence-based and are regularly revised.

A timely follow-up that ensures a firm 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 and given a diagnosis without delay in the presence of cancer.

In Canada, timeliness targets were set by consensus among members of the Working Group on the Integration of Screening and Diagnosis for the Canadian Breast Cancer Screening Initiative<sup>6</sup>. After review of international and existing program standards in Canada and the time to diagnosis already achieved in organized breast screening programs in 1996, the following targets were recommended:



- Abnormal screen to notification of the client
  - 100% to be notified
  - ≥ 90% to be notified within 2.0 weeks
- Notification of the client to first assessment
  - ≥ 90% within 2.0 weeks
- The total duration from abnormal screen to first assessment
  - ≥ 90% within 3.0 weeks
- First assessment to diagnosis *if no open biopsy*
  - ≥ 70% within 1.0 week
  - ≥ 90% within 2.0 weeks
- First assessment to diagnosis *if open biopsy performed*
  - ≥ 70% within 3.0 weeks
  - ≥ 90% within 4.0 weeks
- The total duration from abnormal screen to diagnosis *if no open biopsy*
  - ≥ 70% within 4.0 weeks
  - ≥ 90% within 5.0 weeks
- The total duration from abnormal screen to diagnosis *if open biopsy performed*
  - ≥ 70% within 6.0 weeks
  - ≥ 90% within 7.0 weeks
- Diagnosis to notification of the client
  - ≥ 90% within 1.0 week

These intervals still constitute a long time to wait for a diagnosis. Programs with dedicated interdisciplinary assessment clinics affiliated with screening centres should easily achieve these timeliness targets.

Although the referring health care provider is primarily responsible for follow-up, it is the responsibility of the screening program to communicate a recommendation for short-interval follow-up, diagnostic mammography, or adjunctive diagnostic procedures. The screening program is responsible for monitoring and tracking women whose results are abnormal and for establishing protocols with the diagnostic facilities to ensure communication. Such follow-up is essential to the quality assurance of the program, since it is the only way to ascertain detection rates and specificity. As far as possible, the screening program should work with diagnostic facilities and ultrasound facilities to ensure that results are automatically forwarded to screening centres. A system should be in place to ensure that the family physician is contacted if the screening centre does not receive results after a designated period of time (approximately 6 weeks). Such a system would require that the screening centre receive prior consent from women to obtain their results. The results of the assessment should be available within 3 months. Assessment and evaluation of screen-detected abnormalities should be closely linked to organized screening programs.

## 7.1 References

1. National Program for the Early Detection of Breast Cancer. *National Accreditation Requirements Approved: March 1994*. Canberra (Australia): Commonwealth Department of Human Services and Health, 1994.
2. Wilson R, Asbury D, Cooke J, Michell M, Patnick J (eds). *Clinical Guidelines for Breast Cancer Screening Assessment*. Publication No 49. Sheffield, United Kingdom: NHS Cancer Screening Programmes, 2001.
3. EUSOMA. The requirements of a specialist breast unit. *Eur J Cancer* 2000;36(18):2288-2293.
4. Health Canada. *Organized Breast Screening Programs in Canada 1997 and 1998 Report*. Ottawa: Minister of Public Works and Government Services Canada, 2001.
5. The Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer. Clinical practice guidelines for the care and treatment of breast cancer: 2. Investigation of lesions detected by mammography. *Can Med Assoc J* 1998;158(3 Suppl):S9-S14.
6. Health Canada. *Waiting for a Diagnosis After an Abnormal Breast Screen in Canada*. Report of the Working Group on the Integration of Screening and Diagnosis for the Canadian Breast Cancer Screening Initiative. Ottawa: Minister of Public Works and Government Services Canada, 2000.

## **8. Program Evaluation**

- Organized programs should build and use a database.
- Organized programs should monitor and measure program performance and outcomes.
- Organized programs should evaluate client satisfaction.

In order to achieve reductions in breast cancer mortality and morbidity and to minimize the unwanted effects of screening, the delivery of organized screening must be of high quality. The Evaluation Indicators Working Group of the National Committee for the Canadian Breast Cancer Screening Initiative (CBCSI) selected 11 performance measures and targets according to their utility for assessing program progress toward these goals<sup>1</sup>. These measures were developed on the basis of recognized population screening principles, evidence from randomized controlled trials, demonstration projects, and observational studies (see Table 2).

The target population for evaluation is the same as the national target population for organized screening. This population is defined as asymptomatic women between the ages of 50 and 69 years with no prior diagnosis of breast cancer.

The screening programs should also monitor the extent to which the services are perceived as acceptable and appropriate to the needs of the eligible population<sup>2</sup>. Regular surveys should be conducted in order to assess satisfaction with information, waiting time, the physical environment, pain and discomfort, and interactions with staff<sup>2,3</sup>. The results of client surveys and client comments will be used to improve service provision. Satisfied clients are more likely to return for rescreening and to provide positive comments to others.

**Table 2**  
**Breast Screening Program Performance Measures**  
**(February 2002)**

<b>Indicator</b>	<b>Definition</b>	<b>Target* (age 50-69)</b>
1. Participation Rate	Percentage of women who have a screening mammogram (calculated biennially) as a proportion of the eligible population	≥ 70% of the eligible population
2. Retention Rate	The estimated percentage of women who are rescreened within 30 months of their previous screen	≥ 75% rescreened within 30 months
3. Abnormal Call Rate (%)	Percentage of women screened who are referred for further testing because of abnormalities found with a program screen	< 10% (initial screen) < 5% (rescreens)
4. Invasive Cancer Detection Rate	Number of women detected with invasive cancer during a screening episode per 1,000 women screened	> 5 per 1,000 on initial screen > 3 per 1,000 on rescreens
5. In Situ Cancer Detection Rate	Number of women detected with ductal carcinoma in situ cancer (rather than invasive cancer) during a screening episode per 1,000 women screened	Surveillance and monitoring purposes only
6. Diagnostic Interval	Total duration from abnormal screen to resolution of abnormal screen	≥ 90% within 5 weeks if no open biopsy ≥ 90% within 7 weeks if open biopsy
7. Positive Predictive Value	Proportion of abnormal cases with completed follow-up found to have breast cancer (invasive or in situ) after diagnostic workup.	≥ 5% (initial screen) ≥ 6% (rescreen)
8. Benign to Malignant Open Biopsy Ratio	Among open biopsies, the ratio of number of benign cases to the number of malignant cancer cases	≤ 2:1 open (initial and rescreen combined)
9. Invasive Cancer Tumour Size	Percentage of invasive cancers with tumour size of ≤ 10 mm in greatest diameter as determined by the best available evidence: 1) pathological, 2) radiological, 3) clinical	> 25% ≤ 10 mm
10. Positive Lymph Nodes in Cases of Invasive Cancer	Proportion of invasive cancers in which the cancer has invaded the lymph nodes	< 30% node positive
11. Post-screen Detected Invasive Cancer Rate	Number of women with a diagnosis of invasive breast cancer after a negative screening episode per 10,000 person-years at risk, within 12 AND 24 months of the screen date.	< 6 per 10,000 person-years (within 12 months) < 12 per 10,000 person-years (within 24 months)

\* Canadian targets obtained by consensus and based on evidence supported by literature

## 8.1 References

1. Health Canada. *Report from the Evaluation Indicators Working Group: Guidelines for Monitoring Breast Screening Program Performance*. Ottawa: Minister of Public Works and Government Services Canada, 2002.
2. National Quality Management Committee of BreastScreen Australia. *National Accreditation Standards, BreastScreen Australia Quality Improvement Program*, June 2001. Draft.
3. Decker KM, Harrison M, Tate RB. Satisfaction of women attending the Manitoba Breast Screening Program. *Prev Med* 1999;29:22-27.

# **9. Special Projects**

## **9.1 Quality Assurance Survey**

Fulfilling a request by the National Committee of the Canadian Breast Cancer Screening Initiative, the subset Working Group on Quality Determinants of Organized Breast Cancer Screening Programs developed the Quality Assurance Survey as a means of assessing current practices across Canada. The first wave of the survey was carried out in 1998, the second in 2002, with 11 provinces and territories participating in both surveys. It is evident that there had been a notable advance in organized screening program practices, even within the short interval between the two sets of results. For instance, all organized breast cancer screening programs are now established and continue to grow at a rapid rate. Yet it is likely that there will always remain some areas needing further improvement.

Quality assurance for screening programs is mainly implemented on a provincial/territorial basis. In 1996, six programs had at least one designated individual responsible for data quality assurance; nine programs now have assigned individuals. Programs maintain documentation related to screening as needed, including a standard set of relevant definitions, data collection procedure manuals, data coding manuals/data dictionary, and protocols for quality assurance in data collection. These are reviewed on an annual or biennial basis. The quality of data for surveillance purposes is improving with time and better technology. All but one province use a combination of automated and manual processes to perform data quality tests, including checks for missing values, duplicate records, valid ranges of values, intra-record agreement, coding procedures, and checks against medical records.

On a screening facility level many components are collected in the clinical database, including client registration, risk factor information, recruitment information, history of breast procedure, the results of clinical examination and screening tests, and information on further assessments. Also, information on detected cancers, treatment, and recurrence is also collected, but not as widely across the country. The number of programs that amalgamate regional clinical database information on a provincial or territorial basis varies, which may simply be a reflection of program organization. For instance, one program has a system that automatically combines information into both a local and provincial database; another program maintains a provincial database that is accessible at a screening facility level. In most cases, programs have designated an individual to analyze these data and to produce program results on a monthly or annual basis.

With this information, over time we will be better able to assess program impact on breast cancer incidence and mortality. Surveillance data on case fatality, number of deaths prevented, life-years gained, quality of life, and the overall cost-effectiveness of screening can help gauge the effectiveness of screening. The use of these measures can only come

with time – years of data need to be available for analysis in order to assess outcomes. In the 1998 survey, only one province looked at one of these factors (cost-effectiveness), and four programs were planning to assess one or more. As seen in the 2002 survey, one program now assesses three of the measures, and five programs are eventually planning to do so.

Since the 1998 survey, several programs have noted some new directions in quality assurance practices. One program has been working with provincial partners to develop a province-wide screening program that collects data from both the organized screening program and other service providers. With cooperation between partners, data for the province will be more comprehensive and can be further refined. Another program has improved its quality management support to screening centres through the creation of a full-time managerial position to provide quality management and resources.

### **9.1.1 A client service approach**

In 1998, only four programs had official policies in place to ensure that women were fully informed about the screening examination procedure, although no detail was requested in the survey regarding the type of policy or how clients were prepared in the other seven programs. In 2002, 10 programs have established policies to ensure that full information is provided to clients. For the remaining program, the policies are not developed on a province-wide basis but are applied at a regional level. Programs use a variety of media to relay this information; most frequently this includes showing a video, providing a pamphlet, or communicating orally.

All programs have procedures in place to maintain the confidentiality of patient data (in both hard copy and electronic format); in 1998, only nine programs had this in place. Government regulations to protect the privacy of individuals, written policies on data confidentiality, and written procedures specifying proper handling of patient data all have a strong influence on the protection of confidentiality. Other areas that improve confidentiality include the provision of orientation and training in data confidentiality issues for program staff, and defining an approval process for the release of patient data. As well, three programs have a data confidentiality committee or officer on hand.

As in 1998, client satisfaction is monitored by 10 of the responding programs – four do so routinely, and six do so sporadically. Client satisfaction is monitored through the provision of a “comments” section on forms, the provision of a telephone number and contact information, or the circulation of “client satisfaction” questionnaires.

### **9.1.2 Recruitment**

Most provinces still quote the standard recruitment target of 70% of women aged 50-69 years within 10 years of program establishment. Currently, eight programs have dedicated personnel responsible for outreach and recruitment activities; 10 programs conduct these activities when capacity permits. Targets are always difficult to attain, but breast screening programs across Canada are aided by an ability to identify women for recruitment purposes. With the available information, programs claim 75% to 100%

accuracy (with a mean of 91%) in identifying eligible women for screening (i.e. completeness of registration, address accuracy). Previously, it ranged from 80% to 97%, with a mean of 93%. Most programs have and continue to use data from medical insurance/service plans to identify women, although motor vehicle licensing lists, community group membership lists, and provincial client registries are being used to a lesser extent. If multiple sources are used, duplicate entries are dealt with through the use of matching software or through manual resolution.

Within the period between the two surveys, the number of existing facilities grew from 169 to 236, with some facilities holding multiple mammography units. In addition, the number of mobile units in use continues to grow; now 15 mobile units exist to serve Canadians. Despite this, capacity is currently an issue for these established programs. Although some programs are able to serve most of their target population, with current capacity levels others can only serve 20%.

While mass recruitment approaches exist, women are mainly recruited through the issuing of personal invitations by mail. Several checks are made before issuing invitations. The majority of provinces check recruitment data against breast cancer registration, program attendance records, and death registration. The timing and frequency of these checks are varied, although all programs usually ensure that they are done when individuals are first identified and when invitations are issued. If there is no response from potential first time screening clients, five programs out of eight send second invitations, usually within 2 to 14 weeks. Most programs send first screen invitations biennially until a response is received; two programs limit the number of attempted first screen invitations to two.

### **9.1.3 Retention**

All programs issue recalls for rescreening when applicable, although one program only does this some of the time. When there is no response, a recall reminder is issued by at least seven of the programs, sent within 2 to 14 weeks, but varying by program. If there is still no response, further follow-up is taken by five of these seven programs through the use of telephone calls or reminders in subsequent years. Similar to first screen invitations, checks are performed using breast cancer registration, program appointment records, and death registration information.

As in 1998, seven programs monitor reasons for nonattendance at their breast cancer screening program. Two programs do so routinely, whereas the other five do this sporadically.

### **9.1.4 Quality of mammography**

According to the provincial and territorial programs, in 1998 CAR accreditation was mandatory in seven programs while being voluntary in the remaining four, and in 2002 it is mandatory in eight programs while remaining voluntary in three. In addition to CAR accreditation, six programs participate in provincial/regional formal accreditation processes. These processes are administered by various authorities (i.e. health district or



facility), usually renewed every 3 years, and oversee a varied combination of two or more of the following areas: technical (equipment and image quality), certification of education and experience of technologists and radiologists, communication of results, follow-up of abnormal results (diagnostic and treatment), information systems, client care, or environmental management.

Site visits were an important part of quality control in 1998, 10 programs receiving visits. In 2002, seven programs conducted periodic site visits to the mammography facilities, covering such aspects as equipment, personnel training, recruitment of target population, communication of results, client satisfaction, follow-up of abnormal results (diagnosis, treatment), and information systems. These aspects are mandatory or voluntary, varying by program, and most are done on an annual basis, once again varying by program. As in 1998, results are given to the screening program as well as to the facility that was inspected. In addition to image audits performed for formal accreditation, for five programs it is a mandatory requirement that facilities periodically submit films for internal image audit.

For most programs, X-ray machines, image receptor systems, and processor equipment are calibrated for dedicated mammography use. Each program provided detailed information on quality control tests performed on a variety of equipment. On the whole, programs are comparable in the frequency with which tests are performed as well as in the individuals who perform the tests (i.e. technologists, radiologists). The quality control guidelines most commonly followed are those specified by CAR.

Across Canada, the two most frequently listed sources of accreditation for radiologists are the Royal College of Physicians and Surgeons and CAR. Program requirements for radiologists include specialized training in mammography, success in standard tests, and documentation of 15 to 40 hours of continuing medical education (CME) credits in mammography every 3 years. Nine programs list a minimum number of mammograms to be read by radiologists. These minimums range from 480 (three programs), to 3,000 (three programs). For three programs, this minimum is required, whereas it is only recommended in two other programs. Compared with the 1998 survey, there is now less variation among programs and a move towards higher minimums.

Technologists are required to be certified (usually with CAMRT as the registered source) and are required to have completed Mammography I and II of the CAMRT quality control program. One program allows technologists to read screening mammograms as a first reader, although it is unofficially done in two other programs as well. The required training to do this includes an intensive mammography interpretation course such as that offered by Dr. Tabar. Programs list additional criteria for technologists, including preferred experience of a minimum of 1 to 2 years, initial training lasting between 35 hours and 6 weeks, and 15 hours of CME credits in mammography every 3 years. Five programs list a minimum number of screening mammograms to be performed by technologists. Minimums range from 1,000 to approximately 2,600 examinations a year. In general, these requirements are higher than they were in 1998.

Initial orientation or training is provided in all programs; training in one program varies across its regional sites. Training for clerical staff lasts from 1 day to 4 weeks. For radiologists or interpreters, eight programs provide initial training, which lasts from 1 day to 2 weeks. For technologists, initial training lasts from 1 day to 4 weeks. Additional staff, such as technologists who interpret, physicists, and examiners, are given initial training as well. Seven programs also offer continuing education to clerical staff, usually recommended when needed. Eight programs offer continuing education opportunities to radiologists (interpreters); nine programs offer this to technologists. Continuing education for radiologists and technologists is usually guided by CME credit requirements. Two programs provide continuing education to technologists who interpret, three programs offer this to physicists, and one offers it to examiners.

### **9.1.5 Screening examination procedures**

An important policy addresses the need for pain minimization during a mammogram. Only one additional program has newly created this policy since the 1998 survey, bringing the total to 7 programs with pain minimization policies. In contrast, all programs provide policies and procedures on proper positioning during the screening examination. This is an improvement from 1998, when only eight programs had these policies. However, as in 1998, only six programs currently require that feedback on the quality of positioning be given by a supervisor.

All but one program monitor the percentage of films retaken for technical reasons. The standard for repeat rates for technical reasons varied from a maximum of 2% to 5%, the majority of programs listing 5% as their maximum. Seven programs employ double reading of films; in 1998, eight programs employed this process. The process within a program remained similar from 1998 to 2002; however, it differs among programs. The percentage of films that are double read in each program varies from 5% to 100% of all films. In general, most programs use random selection for this process, and to a lesser degree films may be chosen by the radiologist, or can be a combination of random and problem cases. The tendency is to have the second reader blind to the first, while providing the results of the second reading back to the first reader. Disagreements between the two readers are resolved by soliciting advice from a third reader (blinded or nonblinded), arriving at a consensus, or keeping the most anomalous result.

Rates have been developed to monitor the progress of screening programs. Six programs have specified standards on the percentage of mammograms found to be abnormal. General (overall) standards range from 7% to 10% of all mammograms. More specifically, for first screens, standards range from 7% to 15% of all screens, and for subsequent screens, 5% to 7%. Ranges are consistent with what they were in 1998, but only five programs had set standards at that time. There are no set standards regarding the percentage of women with abnormal mammograms undergoing fine needle aspiration (FNAs); only one program monitors the rate of unsatisfactory FNAs. On the whole, programs currently do not monitor the percentage of women with abnormal mammograms undergoing core or surgical biopsies. Five programs now have standards for breast cancer detection rates, whereas in 1998 four programs did. Overall standards for breast cancer

detection are generally not reported, but for first screens, rates range from 5% to 8%, and for subsequent screens standard rates range from 2% to 5%. These ranges are wider – yet higher – than those set in 1998. Two programs that currently do not set their own standards still compare their rates against international standards.

### **9.1.6 Reporting**

In all but one program, standardized forms are used to report the interpretation of screening mammograms. For the one program without standardized forms, the required elements to be captured are specified, but the actual forms may vary from region to region.

### **9.1.7 Communicating results**

Currently, nine programs provide screening results to both the patient and physician, regardless of whether the results are normal or abnormal. In all cases, programs try to ensure that the physician is always the first to receive the news. In the two remaining programs, the communication of results to the patient is controlled. For one program, neither normal nor abnormal results are given to the patient but are given to the patient's physician. For the other program, the patient is provided only normal results, whereas the physician receives normal or abnormal results.

During the process of communicating results, seven programs monitor the timeliness of reporting normal results, five programs monitor the receipt of abnormal results, and eight programs monitor the timeliness of reporting abnormal results. Only two programs monitor the receipt of normal results.

### **9.1.8 Diagnostic workup**

All programs now have a mechanism in place to monitor follow-up investigation of an abnormal screening result. In 1998, only eight programs were able to monitor this. Previously, a time limit for investigation was given by only three programs, but five programs now do so. The time limit varies by program in detail, length, and in the manner in which adherence is monitored. Only one program currently has guidelines detailing the clinical pathway and time interval between procedures for assessing screen-detected abnormalities.

Many programs have procedures in place to help expedite the diagnostic process. These include tracking progress through the family doctor; using direct referral from screening program to diagnostic facility with prior consent of the family doctor; and arranging appointments directly with the diagnostic facility. As in 1998, five programs provide assessment services for screen-detected abnormalities at one or more of their screening facilities. The methods of referral to assessment services vary across programs, but most use direct referral or referral by the family doctor upon receipt of the screening report. Services provided include clinical breast examination, diagnostic mammography,

ultrasound, surgical consultation, fine needle aspiration, cytology service, core biopsy, or biopsy. Three programs provide all of these, one provides six of them, and one provides two of the services.

Procedures are in place for eight programs to review the diagnostic workup of cases with abnormal screening results. Five programs review all abnormal screens, and three review a selected number of the abnormal screens. These reviews are mainly performed by radiologists and/or technologists but can also be done by other members of the medical team (including resident medical staff) or at radiology quality assurance meetings.

Eight screening programs currently link to cancer registries although the amount, flexibility, timeliness, and frequency of information exchange vary; three programs do this manually, and for five programs the linkages are computerized. The approximate time lag is between 2 and 12 months, with a mode of 6 months. The comprehensiveness of breast cancer information from this source ranges from 94% upward. Work is still needed to improve data flows and two-way communication of the full range of breast cancer diagnostic information, including staging data, between registries and screening programs. Seven programs have active access to data on survival and cause of death from additional sources, including vital statistics or contact with the patient, patient's family, or family physician.

Generally, data on lesions are collected from standardized data forms completed by pathologists, reports, hospital records, and data from the cancer registry. Programs differ in the way data are accessed – actively, passively, or both. More specifically, nine programs obtain cytology data on aspirated lesions, although one only does this at the facility level. Cytology data most often come from cytology or pathology data from the cancer registry; in 1998, data were most often collected from cytology reports. Pathology data on biopsied lesions (needle core biopsies and open incisional biopsies) for both benign and malignant cases are collected by all programs except one (which collects data for malignant cases only). Pathology data were and are still obtained most often from pathology reports. The type and number of variables collected from these sources used to be inconsistent; now, almost all programs have access to many of the elements regarding biopsies obtained for preoperative diagnosis.

A wide variety of tumour, histological, and nodal information is being collected on excised breast cancers for invasive and in situ carcinomas. Tumour size is based mostly on microscopic measurements by the pathologist, although sometimes it can be obtained from gross pathological measurement, mammographic measurement, or clinical assessment before or at the time of surgery. Nodal involvement is assessed on the basis of pathological (microscopic) evaluation, although sometimes it can be based on palpation.

In 1998 as well as today, eight programs ascertain nonprogram detected breast cancers in previous program participants. Data are obtained from the cancer registry, with supplemental information from linkages with the death registry, from relatives of the client, or from pathology reports. These cancers are all subject to radiological review, but the review protocol for interval cancers is still very different across the programs. Three

programs have cases reviewed retrospectively by radiologists; four programs review cases through blind mixes at varying ratios; one program does both retrospective reviews and blind mixes.

In 1998, seven programs could ascertain cancers in the general, nonscreened population; now eight programs can do so. Sources for these data are mixed, although the majority of the information is obtained through the cancer registry. At this time, programs tend not to know whether these data are comparable to data on screen-detected cancers. Only one program adds general population cancers to the program database, but half of the programs have started to analyze these data.

## **9.2 Pan-Canadian Study**

The Working Group recognizes the need to provide minimum reading volume guidelines for organized breast cancer screening programs in Canada. A study on the subject has been performed in the Screening Mammography Program of British Columbia, but with limited data available for analysis in the low volume range<sup>1</sup>. Organized breast screening programs elsewhere in Canada could offer radiologist performance data over a wide range of annual reading volumes.

A new project was presented by Dr Nancy Wadden and accepted by medical directors of Canadian organized screening programs at the meeting of the Data Management Committee in May 2002. Financial support was approved by Health Canada in October 2002.

The purpose of the study is to determine the relation between annual screening volume and radiologists' performance in Canada. Abnormal interpretation ratios and cancer detection ratios will be used to summarize the performance. All the ratios will be adjusted for the age and screening history of the screened women (first versus subsequent screening exam). Different aspects influencing radiologist performance (e.g. years of experience, cancer detection rates) will be analyzed as well.

## **9.3 Reference**

1. Kan L, Olivotto IA, Warren Burhenne LJ, Sickles EA, Coldman AJ. Standardized abnormal interpretation and cancer detection ratios to assess reading volume and reader performance in a breast screening program. *Radiology* 2000;215:563-567.

# Appendix

## **Breast Cancer Guidelines for the Pathological Examination and Reporting of Breast Specimens**

**Dr. F. Alexander, Dr. J. Danyluk, Dr. M.P. Greeff, Dr. C. Hegedus, Dr. J. Hugh,  
Dr. M. O'Connor, Dr. D. Paslawski, Dr. V. Tron, Dr. D. Willans**

When reporting on a specimen that contains cancer and/or its recognized precursors, the pathologist's role is to provide the most accurate diagnosis and all the data required to manage the patient's condition. The unique value of checklists in increasing the consistency of such reporting by pathologists has been recognized for almost a decade<sup>1,2</sup>. Pathologists in many laboratories in Canada are using checklists and synoptic reporting. Others have been slow to embrace this quality improvement initiative, and many groups are continuing to develop their own guidelines for reporting on a local or regional basis.

The guidelines provided here are based on earlier guidelines developed by the consultant members of the Breast Tumor Panel of the Canadian Reference Centre for Cancer Pathology (March 1995)<sup>3</sup>, the National Coordinating Group for Breast Screening Pathology (1995)<sup>4</sup>, the European Guidelines for Quality Assurance in Mammography Screening (2001)<sup>5</sup>, the Association of Directors of Anatomic and Surgical Pathology (1996)<sup>6</sup>, the National Cancer Institute of Canada Consensus Conference on Synoptic Reporting (1998), and existing checklists from the British Columbia Cancer Agency and various laboratories across Canada.

**The checklists presented can be used as the official report, or as an internal laboratory working guide from which the Synoptic Report is developed as the official report, or both can be used as the official report. If only a Synoptic Report is used, record present, absent, not evaluated, or the significant findings, as appropriate for each element. A standard checklist format is preferred by the clinical community, but it is the content that is of paramount importance.**

Definitions are provided for the data elements where the meaning may be unclear (e.g. multifocal), as no definition is used universally. It is recognized that in such cases there is no correct definition, and thus a definition is provided on the checklist to enhance consistency, reproducibility and comparability. It is imperative that the clinician know that several data elements are used inconsistently in the literature and that he/she is interpreting the element in the way that is intended by the pathologist. It is also important that the clinician know whether or not the elements were defined in the same way in his/her literature derived knowledge base.

Pathologists are urged to adopt the generally applicable recommendations of the Association of Directors of Anatomic and Surgical Pathology relating to standardization of the surgical pathology report, demographic and specific information, gross and microscopic description and comment section<sup>6</sup>.

These guidelines have been developed through the Pathology Working Group of the Alberta Cancer Surgery Working Group with input from Dr. F. O'Malley, Dr. P. Barnes, Dr. B. Tetu, Dr. M. Hayes and members of the Section of Anatomic Pathology of the Canadian Association of Pathologists. They have been accepted by the surgeons and oncologists in Alberta as the minimum content required from a pathology report for proper staging (Appendix A) and for management of a patient with in-situ and/or invasive breast cancer. They are intended to be practical for everyday use. Their acceptance as Canadian guidelines is promoted by the Canadian Association of Pathologists to enhance and expedite patient care while avoiding the need for review of the pathology report to obtain missing data.

## Pathology Requisition and Specimen Submission

### Specimen Type(s)

The pathology requisition should include a summary of the “pertinent clinical history” and identify the laterality, the location of the tumor in the breast, and the surgical procedure(s) or specimen type(s) e.g.:

**Incisional biopsy** - core; mammotome; open

**Excisional**

- wire localization\*
- lumpectomy; segmental; mastectomy
- re-excision

**Sentinel node**

**axillary content** - node level may be provided

For excisional specimens, the surgeon should make every effort to remove and submit the specimen containing the lesion in one piece, surrounded by a cuff of tumor free tissue, since tumor size and the distance to the nearest margin cannot be provided when more than one piece of tissue containing tumor is received. A pathologic stage for the tumor (pT) cannot be determined if the specimen edge contains tumor grossly<sup>7,8</sup>. If more than one piece is provided the relation of each to the other should be clearly identified.

The surgeon should also orient the specimen, e.g. by using sutures to indicate two surfaces (medial or lateral, superior or inferior) when skin is not present, and one suture when skin is present.

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\* For (needle guided) wire localization specimens, close cooperation among the surgeon, radiologist and pathologist is essential. The preoperative mammograms should accompany the specimen. Whether the specimen is submitted to radiology or pathology for confirmation of removal of the mammographic lesion will depend on local circumstances. A radiologist should correlate the specimen radiograph with the preoperative mammograms. The specimen radiograph, with the radiologist's findings, should be available to the pathologist for radiologic-pathologic correlation





## Checklist 2

### Microscopic Examination of Excisional Breast Cancer Specimens

**INVASIVE CARCINOMA** Histologic type<sup>B</sup> \_\_\_\_\_ absent  Size<sup>C</sup> (max. dimension) \_\_\_\_\_

**Margin, closest** anterior  posterior  superior  medial  lateral   
inferior  not evaluable   
distance \_\_\_\_\_ mm If transected (0 mm), length of margin involved \_\_\_\_\_ mm

**Grade<sup>D</sup>** Tubule formation \_\_\_/3 Pleomorphism \_\_\_/3 Mitoses \_\_\_/10 hpf (field diam. - mm) Score \_\_\_/3

**Histologic** I/III  II/III  III/III  Total score \_\_\_\_\_ /9

**Lymphatic/vascular invasion (outside tumor)** present  absent  extensive  dermal

**Multicentric** (≥ 5 cm apart)<sup>(1)</sup> yes  no  **Multifocal** (< 5 cm apart) yes  no

**Extensive intraductal component (E.I.C.)**  
> 25% DCIS in tumor and DCIS beyond tumor present  absent   
or primarily DCIS with foci of invasion present  absent

**DUCTAL CARCINOMA IN-SITU** type \_\_\_\_\_ absent

**Nuclear grade<sup>(2)</sup>** /3  **Necrosis score: None** (1/3)  **Punctate/non-zonal** (2/3)  **Zonal** (3/3)

**Distance to nearest margin** \_\_\_\_\_ mm not evaluable   
anterior  posterior  superior  inferior  medial  lateral

**If E.I.C., estimate of size/extent<sup>(3)</sup>** \_\_\_\_\_

**Paget's disease** present  absent

**Needle localization** calcification; benign yes  no  DCIS yes  no  carcinoma yes  no

**LYMPH NODES** total # \_\_\_\_\_ # involved<sup>(4)</sup> \_\_\_\_\_ largest metastasis \_\_\_\_\_ mm  
extranodal extension present  absent  extensive

**Skin (dermal) invasion** present  absent  no section

**Nipple involvement** present  absent  no section

**Skeletal muscle invasion** present  absent  no section

**ABNORMALITIES IN REST OF TISSUE (e.g. LCIS etc.)**

**HORMONE RECEPTORS ORDERED** yes  block # \_\_\_ no  If "no," give reason

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## **Legends For Checklist 2**

B See Appendix B.

C See Appendix C.

D See Appendix D.

- (1) Microscopic findings are required for each multicentric tumor.
- (2) The nuclear grade is equivalent to the Nuclear Pleomorphism Score in Appendix D.
- (3) DCIS size/extent – maximum diameter of DCIS on any one slide and number of slides involved – if non-contiguous identify relation of slides. Cancerization of lobule is considered to be DCIS and should be so considered for measurements of size and proximity to margin.
- (4) See reference 8, page 172 “Metastatic nodules in the fat adjacent to the mammary carcinoma within the breast, without evidence of residual lymph node tissue, are classified as regional lymph node metastases.”

**Synoptic Report 1  
Invasive Breast Carcinoma in  
Excisional Specimens**

**DIAGNOSIS AND MAJOR MANAGEMENT INDICES\***

Site (laterality, location in breast) \_\_\_\_\_ Specimen type (procedure) \_\_\_\_\_

Tumor size (invasive component – max. dimension confirmed microscopically) \_\_\_\_\_

Histologic type \_\_\_\_\_ Histologic grade  
/III

Lymph nodes (sentinel, level if known)

- (# positive of total # submitted) \_\_\_\_\_ (largest metastasis) \_\_\_\_\_ mm)
- extranodal extension present or absent \_\_\_\_\_ nodes matted/fixed \_\_\_\_\_

**OTHER MANAGEMENT INDICES\***

Tubule formation /3 Pleomorphism /3 Mitoses /3 Score /9

Resection margins \_\_\_\_\_

Lymphatic/vascular invasion (present or absent) \_\_\_\_\_

Multicentric ( $\geq 5$  cm apart) \_\_\_\_\_

Multifocal ( $< 5$  cm apart) \_\_\_\_\_

Skin invasion (indicate if gross) \_\_\_\_\_

**Extensive Intraductal Component**

DCIS type \_\_\_\_\_ Nuclear grade /3 Necrosis score /3 Closest margin  
(mm)

Hormone Receptors (ordered, block I.D. or result) \_\_\_\_\_

Other significant findings \_\_\_\_\_

Copy to Cancer Registry \_\_\_\_\_

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\* The checklist may be used as the Synoptic Report. If the template/checklist for microscopic examination is not sent to the clinician, record present, absent, not evaluated or significant finding, as appropriate.

**Synoptic Report 2**  
**DCIS, When No Invasive Carcinoma is**  
**Present in Excisional Specimens**

Site (laterality, location in breast)\_\_\_\_\_

Specimen type\_\_\_\_\_

Diagnosis – DCIS type\_\_\_\_\_

Nuclear grade\_\_\_\_\_/3

Necrosis score\_\_\_\_\_/3

Size\_\_\_\_\_

Maximum extent on slide\_\_\_\_\_

# of slides involved (identify)\_\_\_\_\_

Paget's disease (if applicable)\_\_\_\_\_

Closest margin\_\_\_\_\_(mm)

Calcification    present in DCIS             benign tissue

Other significant findings\_\_\_\_\_

Copy to Cancer Registry\_\_\_\_\_

**Synoptic Report 3**  
**Incisional Biopsy Specimens**

Site (laterality, location in breast)\_\_\_\_\_

Specimen type\_\_\_\_\_

**INVASIVE CARCINOMA** histologic type  absent

Histologic grade\_\_\_\_\_ /III

Tubule formation\_\_\_\_\_ /3 Pleomorphism\_\_\_\_\_ /3 Mitoses\_\_\_\_\_ /3

Maximum length in core/diam. in incisional biopsy\_\_\_\_\_

# of cores involved\_\_\_\_\_

Lymphatic/vascular invasion present  absent

**DCIS** type\_\_\_\_\_ absent

Nuclear grade\_\_\_\_\_ /3

Necrosis score\_\_\_\_\_ /3

Estimate of extent\_\_\_\_\_

Calcification in DCIS  benign tissue

**LCIS** present  absent

Hormone Receptors ordered and block I.D  result

Other significant findings<sup>10,11</sup>\_\_\_\_\_

Copy to Cancer Registry\_\_\_\_\_

## Appendix A

### TNM/AJCC staging<sup>7,8,12</sup>

Primary Tumor (T, pT)	Regional Lymph (pN)*
<p><b>X</b> Primary tumor cannot be assessed.</p> <p><b>TO</b> No evidence of primary tumor.</p> <p><b>Tis</b> Carcinoma <i>in situ</i>: Ductal or lobular carcinoma <i>in situ</i>, or Paget's disease of the nipple with no tumor.</p> <p><b>T1</b> Tumor 2 cm or less in greatest dimension.</p> <p><b>T1 mic</b> Largest focus of invasion <math>\leq 0.1</math> cm in greatest dimension. (Do not sum individual foci.)</p> <p><b>T1a</b> Tumor more than 0.1 but not more than 0.5 cm in greatest dimension.</p> <p><b>T1b</b> Tumor more than 0.5 cm but not more than 1 cm in greatest dimension.</p> <p><b>T1c</b> Tumor more than 1 cm but not more than 2 cm in greatest dimension.</p> <p><b>T2</b> Tumor more than 2 cm but not more than 5 cm in greatest dimension.</p> <p><b>T3</b> Tumor more than 5 cm in greatest dimension.</p> <p><b>T4</b> Tumor of any size with direct extension to (a) chest wall or (b) skin, only as described below.</p> <p><b>T4a</b> Extension to chest wall not including pectoralis muscle.</p> <p><b>T4b</b> Clinically/grossly detected edema (including peau d'orange) or ulceration of the skin of the breast or satellite skin nodules confined to the same breast. (Foci only detected histologically or microscopic invasion of the dermis not included.)</p> <p><b>T4c</b> Both (T4a and T4b).</p> <p><b>T4d</b> Inflammatory carcinoma: When pathologically staging a clinical inflammatory carcinoma, if the skin biopsy is negative and there is no localized, measurable, primary cancer, the category is pTx.</p> <p><i>Note:</i> Paget's disease associated with a tumor is classified according to the size of the tumor.</p> <p><b>Skin of Breast</b> Dimpling of the skin, nipple retraction, or any other skin change except those described under T4b and T4d may occur in T1, T2 or T3 without changing the classification.</p> <p><b>Chest Wall</b> Chest wall includes ribs, intercostal muscles, and serratus anterior muscle but not pectoral muscle.</p>	<p><b>pNX</b> Regional lymph nodes cannot be assessed (not removed for study or previously removed).</p> <p><b>pN0</b> No regional lymph node metastasis.**</p> <p><b>pN1mi</b> Micrometastasis (<math>&gt; 0.2</math> mm, but none <math>&gt; 2</math> mm in greatest dimension).***</p> <p><b>pN1</b> Metastasis in 1-3 ipsilateral axillary lymph node(s), and/or in ipsilateral internal mammary nodes with microscopic metastasis detected by sentinel lymph node dissection but not clinically apparent.</p> <p><b>pN1a</b> Metastasis in 1-3 axillary lymph node(s), including at least one larger than 2 mm in greatest dimension.</p> <p><b>pN1b</b> Metastasis in internal mammary lymph nodes with microscopic metastasis detected by sentinel lymph node dissection but not clinically apparent.</p> <p><b>pN1c</b> Metastasis in 1-3 axillary lymph nodes and internal mammary lymph nodes with microscopic metastasis detected by sentinel lymph node dissection but not clinically apparent.</p> <p><b>pN2</b> Metastasis in 4-9 ipsilateral axillary lymph nodes, or in clinically apparent ipsilateral internal mammary lymph node(s) in the absence of axillary lymph node metastasis.</p> <p><b>pN2a</b> Metastasis in 4 to 9 axillary lymph nodes (at least one tumor deposit greater than 2.0 mm).</p> <p><b>pN2b</b> Metastasis in clinically apparent internal mammary lymph nodes in the absence of axillary lymph node metastasis.</p> <p><b>pN3</b> Metastasis in 10 or more axillary lymph nodes, or in infraclavicular lymph nodes, or in clinically apparent ipsilateral internal mammary lymph nodes in the presence of 1 or more positive axillary lymph nodes; or in more than 3 axillary lymph nodes; or in ipsilateral supraclavicular lymph nodes.</p> <p><b>pN3a</b> Metastasis in 10 or more axillary lymph nodes (at least one tumor deposit greater than 2.0 mm), or metastasis to the infraclavicular lymph nodes.</p> <p><b>pN3b</b> Metastasis in clinically apparent ipsilateral internal mammary lymph nodes in the presence of 1 or more positive axillary lymph nodes; or in more than 3 axillary lymph nodes and in internal mammary lymph nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent.</p> <p><b>pN3c</b> Metastasis in ipsilateral supraclavicular lymph nodes.</p>

## Stage Grouping

<b>Stage 0</b>	Tis	NO	MO
<b>Stage I</b>	T1*	NO	MO
<b>Stage IIA</b>	TO	N1	MO
	T1	N1	MO
	T2	NO	MO
<b>Stage IIB</b>	T2	N1	MO
	T3	NO	MO
<b>Stage IIIA</b>	TO	N2	MO
	T1*	N2	MO
	T2	N2	MO
	T3	N1	MO
	T3	N2	MO
<b>Stage IIIB</b>	T4	Any N	MO
	Any T	N3	MO
<b>Stage IV</b>	Any T	Any N	M1

\*T1 includes T1 mic

Notes: \*Intramammary lymph nodes are coded as axillary lymph nodes. An isolated tumor nodule in the axillary fat of a breast cancer patient is classified as a lymph node metastasis. For nodal metastases, the size of the metastasis, not the size of the lymph node, determines pN.

\*\*Cases with only isolated tumor cells (ITC) in regional lymph nodes are classified as pNO. ITC are single tumor cells or small clusters of cells, not more than 0.2 mm in greatest dimension, usually detected only by immunohistochemistry or molecular methods but which may be verified on H&E stains. ITCs do not typically show evidence of metastatic activity, e.g. proliferation or stromal reaction. Classification based solely on sentinel lymph node dissection without axillary lymph node dissection is designated (sn) for "sentinel node."<sup>12</sup>

\*\*\*Multiple micrometastases in one node should be added up and not considered micrometastasis if larger in sum than 0.2 cm.



## **Appendix B**

### **Histologic Typing of Breast Carcinoma**

#### **Ductal Carcinoma *in Situ***

Microinvasive Carcinoma

Invasive Carcinoma

- ductal (no special type)
- lobular
- mixed
- tubular
- medullary
- mucinous
- cribriform
- papillary
- metaplastic
- other rare types

(Adenocystic, Apocrine, Clear cell [glycogen rich], Mucoepidermoid, Neuroendocrine, Secretory [juvenile], Squamous, etc.)

## Appendix C

### Tumor Size

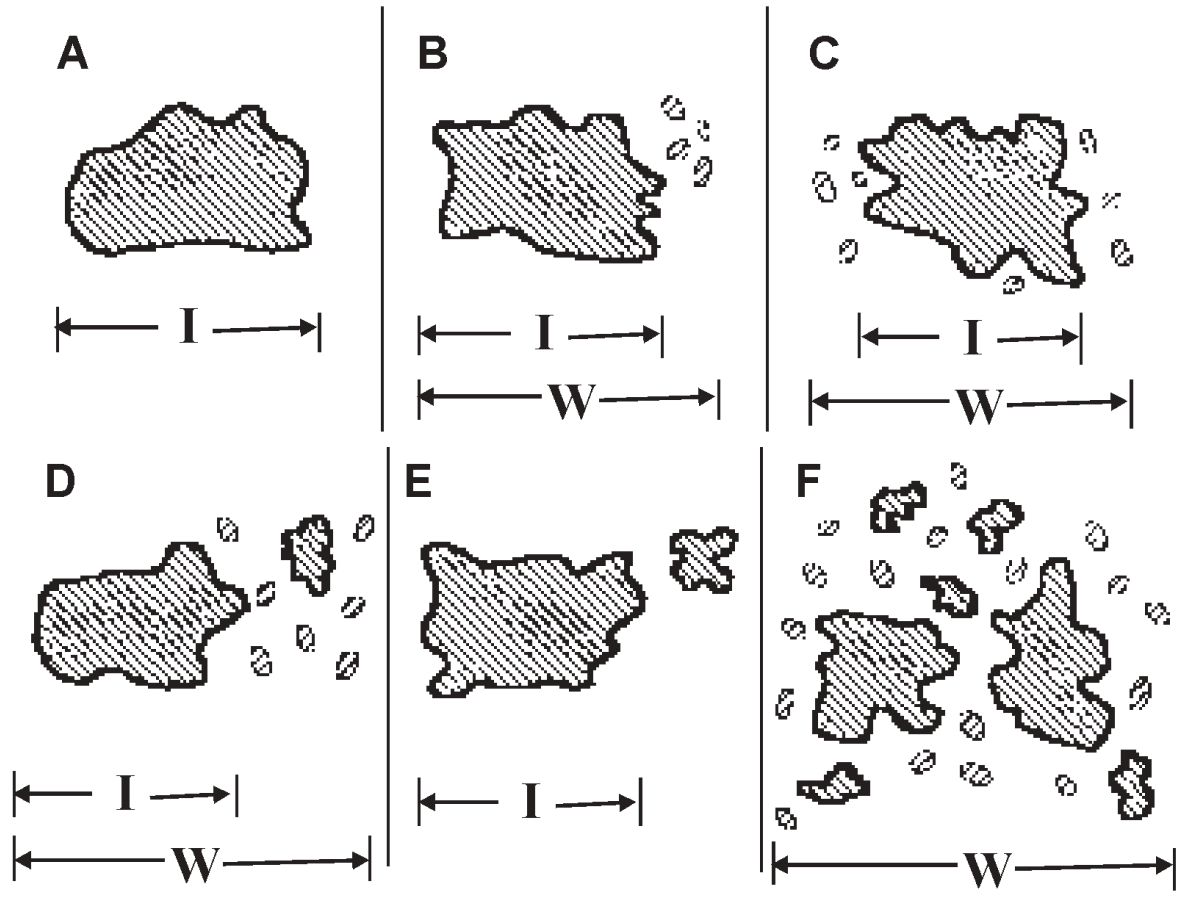
It is important to correlate gross and microscopic tumor size. If the gross size is different from the microscopic invasive component, record the microscopically confirmed size of the invasive component in the synoptic report.



The following guideline is extracted from the European Guidelines for Quality Assurance in Mammography Screening, 3<sup>rd</sup> ed (January 2001)<sup>5</sup>.

#### Maximum Diameter

All lesions should be measured in the fresh or fixed state and on the histological preparation. If the two measurements are discrepant then that obtained from histological examination should be recorded where tumours are small enough to be visualized in cross-section. This may give a small underestimation of size due to shrinkage of the tissue in processing. It is considered, however, that the slight but consistent underestimation in the size of all tumours is preferable to the larger and less predictable errors that may result from measuring poorly delineated tumours macroscopically. Clearly, sufficient blocks should be taken from the periphery of larger tumours to allow accurate estimates of their size to be made from combined histological and macroscopic examination. The largest dimension should be recorded to the nearest millimetre.

For non-invasive carcinomas, the maximum diameter should be entered in the 'Non-Invasive' section only where the tumour is of ductal type; lobular carcinoma **in situ** is not measured. For invasive carcinomas, only the invasive component needs to be recorded unless accompanying ductal carcinoma **in situ** extends more than 1 mm beyond the periphery of the infiltrative component, when the size of the infiltrative component and the overall size should be stated in the appropriate spaces of this section. This is to allow the identification of invasive carcinomas, where the **in situ** component forms a significant proportion of the lesion and may be important in determining the risk of recurrence after local excision. The largest dimension, to the nearest millimetre, is recorded in each case. The diagrams below illustrate whole and invasive tumour measurements in a variety of circumstances. Foci of lymphatic and blood vascular invasion are not included in the whole tumour measurement. If a carcinoma (either infiltrative or ductal **in situ**) is insufficiently delineated to measure reliably, give an approximate estimate of the maximum dimension of the area over which the changes extend. It may be necessary to use combined histological, macroscopic and radiological information to make a reliable estimate.



 = Invasive Tumors      **I** = Invasive Tumor Measurement  
 = Ductal Carcinoma in Situ      **W** = Whole Tumor Measurement

In E the satellite focus of invasive tumor is not included in the measurement.  
 In F the best estimate of the total size of the invasive components is given.

**Appendix D**  
**Histologic Grade**  
**Nottingham Method for Assessing**  
**Histologic Grade in Breast Carcinoma<sup>13</sup>**

<b>Tubular Formation Score</b>	<b>Score</b>
> 75% of tumor examined shows well formed tubules	1
10-75% of tumor examined shows well formed tubules	2
< 10% of tumor examined shows well formed tubules	3

**Nuclear Pleomorphism Score**

Nuclei are small, with little increase or variation in size compared with breast epithelial cell nuclei, regular outlines, uniformity of nuclear chromatin.	1
Nuclei are larger than normal, more open vesicular chromatin with visible, usually single nucleoli.	2
Marked variation in size and shape of nuclei, vesicular chromatin, prominent enlarged nucleoli, multiple nucleoli.	3

**Mitosis Score**

(Assessed in most mitotically active area; count 10 fields; count only clear morphologic stages of mitosis.)	
Dependent on the microscope field area as per the following guide.	1-3

**Grade**

- Grade I/III (well differentiated, score 3-5)
- Grade II/III (moderately differentiated, score 6-7)
- Grade III/III (poorly differentiated, score 8-9)

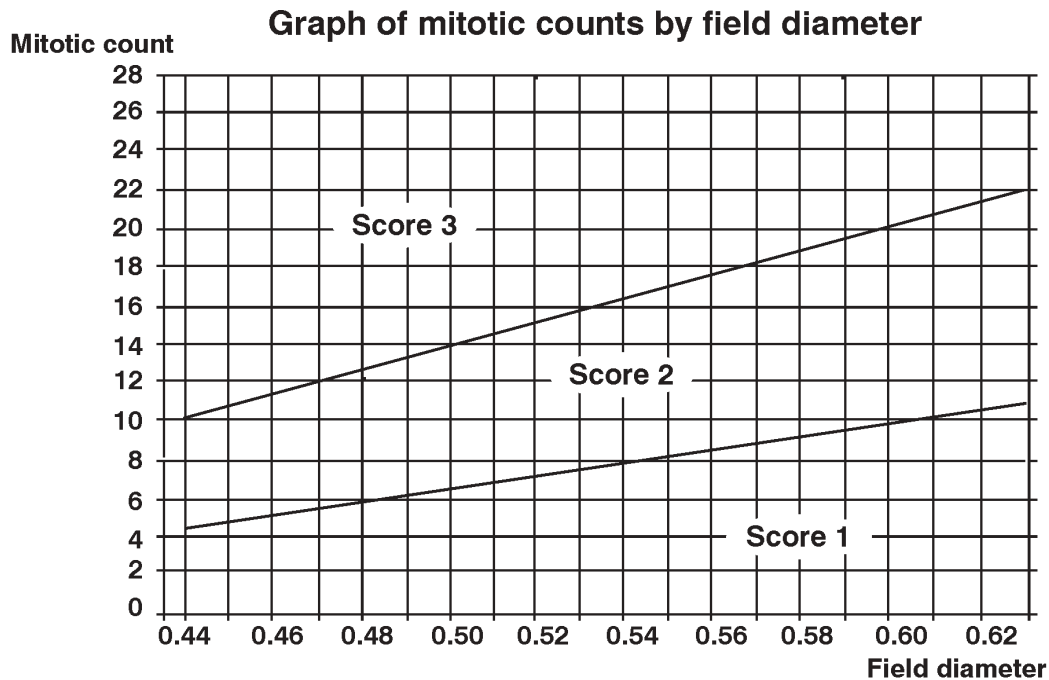
**Reference**

Based on Elston CW, Ellis IO (eds). *Systemic Pathology*, 3<sup>rd</sup> edition/vol. 13: *The breast*. Churchill Livingstone, 1998:368-377.

# European Guidelines for Quality Assurance in Mammography Screening 3<sup>rd</sup> ed. Jan. 2001.

## Mitoses

The size of high power fields is very variable and hence it is necessary to standardize the mitotic count using the graph below. In order to determine the mitotic count for an individual microscope, the following procedure should be adopted:



1. Measure the field diameter of the microscope with a graticule.
2. Plot this value on the horizontal axis of the graph.
3. Draw a vertical line at this value.
4. Read off the value **a** on the vertical axis where the line intersects the lower bold line.
5. Read off the value **b** on the vertical axis where the line intersects the upper bold line.
6. The count is then

Score	Count
3	> <b>b</b>
2	between <b>a + 1</b> and <b>b</b>
1	0 to <b>a</b>

For example, for a field diameter of 0.48, **a** = 6, **b** = 12 from graph - therefore

Score 3 = > 12 mitoses/10hpf

Score 2 = 7-12 mitoses/10hpf

Score 1 = 0-6 mitoses/10hpf

This needs to be done only once for each microscope.

## References

1. Zarbo RJ. Interinstitutional assessment of colorectal carcinoma surgical pathology report adequacy. A College of American Pathology Q-Probes study of practice patterns from 532 laboratories and 15,940 reports. *Arch Pathol Lab Med* 1992;116:1113-19.
2. Rosai J and members of the Department of Pathology, Memorial Sloan-Kettering Cancer Institute. Standardized reporting of surgical pathology diagnoses for the major tumor types. *Am J Clin Pathol* 1993;100:240-55.
3. *Guidelines for the pathologic examination and reporting of breast biopsy specimens*. 1995. Prepared by the Members of the Breast Tumor Panel of the Canadian Reference Centre for Cancer Pathology.
4. National Coordinating Group for Breast Screening Pathology. *Pathology reporting in breast cancer screening*. NHSBSP publication no. 3, 1995. ISBN 1871997 22 4.
5. Perry NM, De Wolf CJM, Broeders M, et al (eds). *European guidelines for quality assurance in mammography screening*, 3<sup>rd</sup> ed. Luxembourg: Office for Official Publications of the European Communities, January 2001.
6. Association of Directors of Anatomic and Surgical Pathology (Connolly JL, chair) et al. Recommendations for the reporting of breast carcinoma. *Mod Pathol* 1996;9:77-81.
7. Green FL, Page DL, Fleming ID et al 7. *AJCC (American Joint Committee on Cancer) cancer staging manual*, 6th ed. New York: Springer, 2002:225.
8. UICC (International Union Against Cancer), Sobin LH, Wittekind C (eds). *TNM classification of malignant tumors*, 5<sup>th</sup> ed. New York: Wiley-Liss, 1997:172.
9. Association of Directors of Anatomic and Surgical Pathology (Kempson RL, chair). Standardization of the surgical pathology report. *Am J Surg Path* 1992;16:84-6.
10. Brown TA, Wall TW, Christensen ED, et al. Atypical hyperplasia in the era of stereotactic core needle biopsy. *J Surg Onc* 1998;67:168-73.

11. Purcell CA, Norris HJ. Intraductal proliferations of the breast: a review of histologic criteria for atypical intraductal hyperplasia and ductal carcinoma in situ, including apocrine and papillary lesions. *Ann Diag Pathol* 1998;2:135-45.
12. Green FL, Page DL, Fleming ID et al *AJCC (American Joint Committee on Cancer) cancer staging manual*, 6<sup>th</sup> ed. New York: Springer, 2002:227.
13. Elston CW, Ellis IO (eds). *Systemic pathology*, 3rd ed/vol 13: *The breast*. Churchill Livingstone, 1998:368-77.