

4. BREASTSCREEN AUSTRALIA BACKGROUND

4.1 BREASTSCREEN AUSTRALIA

BreastScreen Australia is Australia's national population-based breast cancer screening program using mammography. Screening is provided at no cost at 2-yearly intervals for women without symptoms of breast cancer. The target age group is women aged 50–69 years, although women aged 40–49 years and 70 years and over are also eligible to attend.

During the 1970s and 1980s results from a number of RCTs were published, demonstrating that breast cancer screening using mammography could reduce deaths from breast cancer among women aged 50–69 years. At this time, small-scale breast cancer screening services in the private and public sectors were being established across Australia.

In 1987, the National Breast Cancer Screening Evaluation was established as a joint initiative of the Commonwealth, state and territory governments under the auspices of AHMAC to evaluate the feasibility and cost effectiveness of a national screening program in Australia. Specifically the evaluation aimed to assess the possibility of providing a high-quality service that was acceptable and accessible to women, and represented value for money. The evaluation was piloted jointly with the states and territories in 11 sites over a 3-year period from 1987 to 1990. The evaluation report (AHMAC 1990) concluded that sufficient evidence existed to support the development of a national screening program, and in June 1990, AHMAC agreed to jointly fund a national breast cancer screening program with state and territory governments. The Program, known as the National Program for the Early Detection of Breast Cancer, was established in 1991 and became fully operational by 1995. Since 1996, the Program has been known as BreastScreen Australia.

The aims of BreastScreen Australia are to:

- ensure the Program is implemented so that significant reductions can be achieved in morbidity and mortality attributable to breast cancer;
- maximise the early detection of breast cancer in the target population;
- ensure that screening for breast cancer in Australia is provided in dedicated, accredited Screening and Assessment Services (SASs); and
- ensure equitable access to the Program for women aged 50–69 years.

The Program also aims to achieve high standards of Program management, service delivery, monitoring and evaluation and accountability. The aims and objectives of the Program are provided in detail at Appendix 16.3

The target age range for the Program is women aged 50–69 years. Women aged 40–49 years and 70 years and over are also eligible to attend the Program. Different protocols are applied at the jurisdictional level regarding attendance of women outside the target age range.

The number of women participating in the Program has increased over time, from 1.2 million women in 1996–1997 (AIHW 1998) to over 1.6 million in 2004–2005 (AIHW 2008). The proportion of women in the target age group has increased over time, from 858,303 women (68%) in the target age group in 1996–1997 to just over 1.2 million (74%) in 2004–2005.

4.2 GOVERNANCE AND REPORTING ARRANGEMENTS

BreastScreen Australia is funded jointly by the Commonwealth, state and territory governments under the Public Health Outcome Funding Agreements (PHOFAs).⁷ State and territory governments have responsibility for implementation of the Program within each jurisdiction while the Commonwealth government undertakes overall coordination of policy formulation, national data collection, quality control, monitoring and evaluation.

Overall leadership and direction is provided to the Program through the Screening Subcommittee (SSC), a subcommittee of AHMAC's Australian Population Health Development Principal Committee (APHDPC). The SSC is a jurisdictional committee comprising Commonwealth, state and territory government representatives, replacing previous governance arrangements in 2006.

Within each state and territory, a state coordination unit (SCU) has responsibility for coordination and oversight of Program implementation within its jurisdiction. While arrangements vary by jurisdiction, state- and territory-level functions include Program management, funding, strategic planning, policy development, quality assurance, accreditation, data management, maintenance of registries, communication strategies (including social marketing), service development, workforce planning and jurisdictional Program performance monitoring and evaluation. Each jurisdiction has a Program governance structure in place to support these functions.

Program performance is monitored through various levels of reporting:

- SASs provide site visit reports and annual data reports as part of accreditation applications;⁸
- the AIHW and BreastScreen Australia produce annual monitoring reports, using de-identified data provided by the states and territories, reporting on eight agreed performance indicators (Figure 4.1);
- under the PHOFAs, states and territories report against a set of key performance indicators annually;
- annual reports on government services prepared by the Productivity Commission include high-level information on BreastScreen Australia; and
- states and territories provide performance monitoring reports to SASs and produce a jurisdictional statistical report.

Although the Program is monitored regularly, to date there has not been a comprehensive evaluation of health outcomes delivered by the Program.

⁷ The PHOFAs are due to expire at the end of June 2009; future funding arrangements will be incorporated into the National Healthcare Agreements

⁸ These reports relate to achievements against the national accreditation standards; see Chapter 4 section 4.5

Figure 4.1 Agreed performance indicators for the BreastScreen Australia Program

1. **Participation** The proportion of the eligible population attending the screening Program within the recommended screening interval.
2. **Detection of invasive cancers** A measure of the rate of women with invasive breast cancers that are 15mm or less in size detected at a BreastScreen Australia service.
3. **Sensitivity**
 - 3a. **Interval cancer rate** – the rate of invasive breast cancers diagnosed after a screening episode that detected no cancer and before the next scheduled screening episode.
 - 3b. **Program sensitivity** – the percentage of women with screen-detected invasive breast cancer among all Program-screened women diagnosed with invasive breast cancer during the screening interval (screen-detected and interval cancers).
4. **Detection of DCIS** The rate of DCIS diagnosed in women attending a BreastScreen Australia service.
5. **Recall to assessment** The rate of women who are recalled for assessment following attendance for a routine screening at a BreastScreen Australia service.
6. **Rescreening** The proportion of all women screened in a given year whose screening outcome was a recommendation to return for screening in 2 years and who returned for a screen within 27 months.
7. **Incidence**
 - 7a. **Incidence of breast cancer** – a measure of the number of new cases of breast cancer in the community each year.
 - 7b. **Incidence of DCIS** – a measure of the number of new cases of DCIS in the community each year.
8. **Mortality** A measure of the number of deaths caused by breast cancer in the community each year.

Source: AIHW 2008

4.3 PROGRAM DELIVERY

The BreastScreen Australia Program provides breast cancer screening services from the initial mammogram up to the point of histological diagnosis of breast cancer. The screening and assessment pathway is outlined in Figure 4.2. Screening uses two-view mammography, taking cranio-caudal and medio-lateral views of each breast, as these views have been shown to have optimal sensitivity, particularly for small cancers and cancers of low grade.

The state and territory Programs provide breast cancer screening and assessment services through a SAS or network of services. States and territories have established SASs in ways that best meet the needs of the different geographic and demographic characteristics of their populations. Each SAS is based on the same service model with a clearly defined geographical catchment, one or more designated assessment services and a range of satellite, mobile or relocatable screening service sites. In smaller services, SASs may be co-located. Each SAS must be accredited to provide breast cancer screening in the Program.

There are currently 33 accredited BreastScreen Australia services across Australia, operating in over 500 locations nationwide. Services vary in size: some cover vast geographical areas and involve relocatable and mobile screening units; others only cover part of a city. Services may be located wholly in the public sector or contracted to the private sector. Some services are a mix of both public and private arrangements.

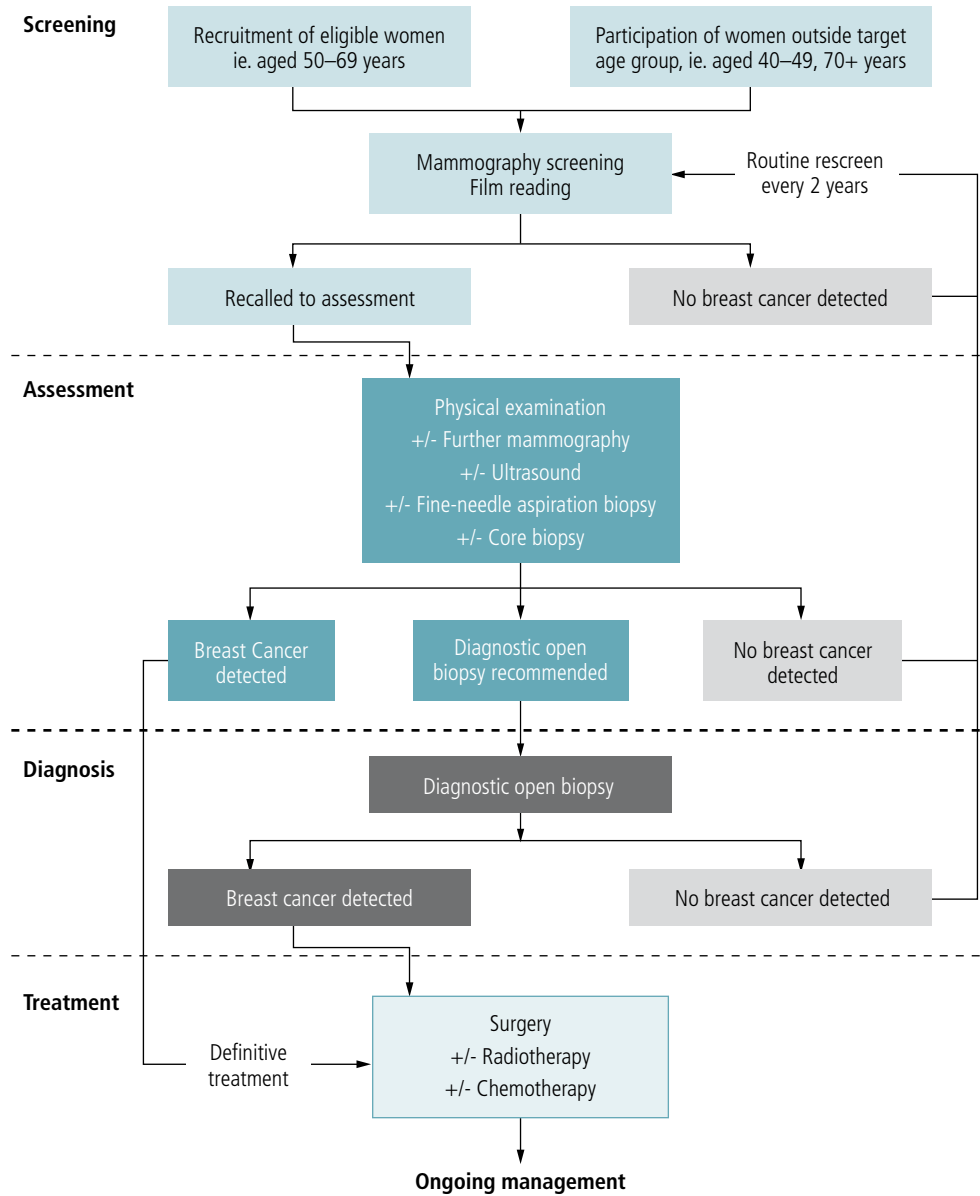
The initial mammogram is performed in a screening unit. Every screen is read by two specially trained readers, one of whom must be a radiologist. Non-radiologist readers are medical officers trained in mammography reading. Women with screen-detected abnormalities are recalled to the assessment centre, where the abnormality is assessed by a multidisciplinary team consisting of a radiologist, surgeon, medical officer, nurse/counsellor and radiographer/sonographer. Assessment consists of a range of investigations, which may include a clinical examination, additional mammographic views, ultrasound, fine needle aspiration (FNA) and/or a core biopsy, depending on the clinical abnormality being assessed. Women with a diagnosis of breast cancer are referred outside the Program⁹ for management and treatment. Where a diagnosis is not ascertained, a small proportion of women will be referred for open biopsy, generally outside the Program.¹⁰ Follow-up information on primary treatment is collected for all women screened to enable collation of assessment and treatment outcomes for quality assurance.

Women who have a negative outcome from screening and assessment are re-invited for rescreening 2 years from their date of attendance.

9 Generally referral is to a breast surgeon in the private or public sector

10 Only a few services are able to offer open biopsy within the Program

Figure 4.2 BreastScreen Australia screening and assessment pathway



Note: Activities above the dotted line are generally performed within the Program. Treatment is generally conducted outside the Program. Diagnostic open biopsy may or may not be performed within the Program.

Source: Review of BreastScreen Australia Infrastructure and Capacity

4.4 RECRUITMENT STRATEGIES

A range of strategies are used to encourage women in the target population to join the BreastScreen Australia Program. Direct mail strategies are used for women in the target age group, with women invited to participate through invitation letters usually based on the electoral roll.¹¹ Follow-up letters are sent to women who do not respond to the invitation letters.

Recruitment strategies are supported at the SAS level by a range of community-based strategies and local activities, implemented by health promotion officers, and developed to respond to the characteristics of the women in that particular service catchment. Some services may have a high proportion of women from culturally and linguistically diverse backgrounds, while others will have differing socio-economic profiles or a higher proportion of women of Aboriginal and Torres Strait Islander origin. Strategies are tailored to ensure that women in the target age group and their health care providers are informed about the Program to encourage participation.

There have been a number of national and state and territory social marketing campaigns designed to recruit women in the target age group to join the Program or to remind lapsed participants to return to the Program. These campaigns have typically included mass media communication using television and radio in conjunction with print media advertising, for example the Sara Henderson campaign, which ran from 1995 to 1997.

Women aged 40–49 years and 70 years and over who are eligible to attend the Program are informed about the Program through communication activities, resource materials and public relations strategies. Different protocols exist at the jurisdictional level regarding routine invitation for rescreening of women and allocation of appointments for women outside the target age range.¹² In most instances, these women do not receive a routine reminder for their 2-yearly rescreen.

4.5 QUALITY MANAGEMENT AND ACCREDITATION

BreastScreen Australia aims to ensure quality is maintained across the screening and assessment pathway. The quality management framework for the Program is underpinned by a national accreditation system based on a set of evidence-based NAS, a risk assessment-based decision tool, electronic forms to support the use of the tool, and site visitor training. The accreditation process aims to ensure that the Program offers a high-quality service to women. This is achieved through periodic independent review, including service-level performance reviews, site visits, data audits and ongoing quality improvement strategies overseen by the state accreditation committees (SACs) and the National Quality Management Committee (NQMC). The NQMC is responsible for accreditation decision making and standard setting. It comprises 15 representatives from stakeholder groups both within and outside the Program. Services without accreditation cannot provide breast cancer screening and assessment under the Program.

¹¹ The electoral roll is not used in all jurisdictions; see Chapter 12 for more detail on recruitment strategies used by each jurisdiction

¹² See Chapter 12 for further information

There are currently 173 NAS against which the performance of each service is measured. The NAS are set using Australian data to maintain a high-quality breast cancer screening program at a level that provides safe quality services within the Australian context. The NAS address all aspects of the screening pathway, including recruitment, management, technical quality assurance, education, counselling, screening, multidisciplinary assessment, clinical outcomes, data management and training. The NAS focus primarily on women in the target age group, but the principles of quality apply to all eligible women.

4.6 MAMMOGRAPHY OUTSIDE THE BREASTSCREEN AUSTRALIA PROGRAM

The Medicare Benefits Schedule (MBS) provides a rebate for diagnostic mammography where there is a reason to suspect the presence of a malignancy, for example in women with breast symptoms and women with a personal or family history of breast cancer.

The MBS item description is:

MBS Item 59300: MAMMOGRAPHY OF BOTH BREASTS, if there is a reason to suspect the presence of malignancy because of:

- (i) the past occurrence of breast malignancy in the patient or members of the patient's family; or
- (ii) symptoms or indications of malignancy found on an examination of the patient by a medical practitioner. Unless otherwise indicated, mammography includes both breasts (DoHA 2007).

The MBS specifically excludes rebates for mammography for screening purposes. However, it is apparent that some mammography services accessed through the MBS are for non- diagnostic purposes. Additional screening mammography may also occur in the private sector on a user-pays basis, for which a MBS rebate cannot be claimed.

5. BACKGROUND AND CONTEXT OF THE EVALUATION

5.1 PURPOSE OF THE EVALUATION

Although the performance of the BreastScreen Australia Program against agreed indicators is monitored and reported regularly, there has not been a comprehensive evaluation of outcomes delivered by the Program to date. The purpose of the Evaluation was to provide a comprehensive assessment of the outcomes and performance of the Program for consideration by AHMAC.

5.2 SCOPE OF THE EVALUATION

The Evaluation assessed the appropriateness, efficiency and effectiveness of the BreastScreen Australia Program. It also assessed and addressed ongoing and emerging issues that have an impact on the Program, and identified opportunities for overall improvement.

The Evaluation examined the benefits of the Program in terms of a reduction in breast cancer mortality rates, through a study of the association between mortality and participation, and also the potential harms associated with screening. It considered the appropriate target age range, screening interval, issues impacting on Program capacity, and Program performance to date. The Evaluation included an examination of participation rates and factors affecting participation.

The Evaluation also addressed issues that have emerged as the Program has matured, including:

- low participation rates in some areas, including small decreases in participation, despite overall increases in the number of women participating in the Program;
- workforce shortages;
- availability of new technologies, for example digital mammography;
- sustained community pressure to provide screening for women outside the current target age group;
- jurisdictional variations in Program policies, governance and recall protocols;
- variations in policy response to women with a personal or family history of breast cancer or symptoms of breast cancer;
- capacity for increases in the efficiency of the Program; and
- effectiveness of the Program in reducing mortality.

The Evaluation comprised ten projects analysing different aspects of the Program and was also informed by stakeholder consultation and communication. This report draws together and synthesises the findings from the projects and stakeholder communication. A summary of the projects is provided at Appendix 16.3. Details of stakeholder communication are included in Chapter 5.4.

5.2.1 POPULATION SCREENING

BreastScreen Australia is a population screening program, implemented in the context of the World Health Organization (WHO) screening principles. It is within this overarching framework that the performance of the Program is considered.

Screening for a disease involves performing tests on members of a population without symptoms of the disease. Screening is used to identify individuals who may have the disease and who require further investigation to determine the presence or absence of disease. An implicit assumption underlying the concept of screening is that early detection, before the development of symptoms, will lead to a more favourable prognosis, and that if treatment is started before the disease becomes clinically manifest, it will be more effective than treatment provided at a later date.

The aim of screening for breast cancer is to reduce the incidence of advanced disease and the rate of invasive disease in a population. The ultimate value of a cancer screening program is evaluated by its effect on mortality rates.

Screening has the potential to prevent the development of disease, prevent premature death and disability and to improve quality of life through the early detection of disease or its precursors. However, it also has costs and the potential to cause harm, for example through false-positive and false-negative results. Screening programs should be based on good quality evidence that the benefits are greater than the potential harms and that the program can be provided at reasonable cost. As screening has the potential to cause harm to individuals, screening programs should be delivered within the context of an effective quality assurance program.

Population screening is a complex process spanning a pathway that includes invitation and recruitment, information and education for consumers and health professionals, disease detection, recall, and follow-up diagnosis and management. In addition, monitoring and evaluation is required in the longer term to determine outcomes.

Decisions about screening require a consistent framework of principles that can be applied to any screening strategy. Australia adopted a Population-Based Screening Framework developed by the SSC of the APHDPC in 2008 to provide guidance for assessment of whether a potential screening program for a disease or condition should be introduced (AHMAC 2008). The framework has been adapted from the WHO principles developed by Wilson and Junger (1968) and takes into account:

- the need for a strong evidence base in making decisions about the introduction of a screening program, including evidence of the safety, reproducibility and accuracy of the screening test and the efficacy of treatment; and
- the requirement that a screening program offers more benefit than harm to the target population.

The decision to introduce a screening program needs also to consider whether outcomes obtained in the research setting can be reproduced in population screening settings.

The Australian Population-Based Screening Framework principles of early disease detection are outlined below.

- The condition should:
 - be an important health problem;
 - have a recognisable latent or early symptomatic stage.
- The test should:
 - be highly sensitive;
 - be highly specific;
 - be validated;
 - be safe;
 - have a relatively high positive predictive value; and
 - be acceptable to the target population including important sub-groups.
- Systems should be in place for evidence-based follow-up assessment of all people with a positive screening test regardless of place of residence, cultural beliefs, ethnicity, and socio-economic status.
- Treatment should be effective, available, easily accessible and acceptable to all people with the recognised disease or condition.

5.3 TERMS OF REFERENCE FOR THE EVALUATION

The Evaluation addressed the following objectives endorsed by AHMAC in June 2006:

1. assess the outcomes delivered by the BreastScreen Australia Program;
2. assess the extent to which the Program has achieved its aims and objectives;
3. assess the appropriateness, efficiency and effectiveness of the Program;
4. assess and address the ongoing and unresolved issues impacting on the Program; and
5. identify opportunities to improve the Program overall.

To achieve these objectives, and in particular, Evaluation objective 1, the Evaluation focused on three outcomes:

- health outcomes: the benefits and risks of the Program;
- process outcomes: the efficiency of the implementation of the Program; and
- economic outcomes: the cost-utility, cost-benefit and cost-effectiveness of the Program.

5.3.1 EVALUATION QUESTIONS

A series of key Evaluation questions were developed to assess Program outcomes and ongoing unresolved policy issues, and Evaluation projects were designed to address these questions.

1. What are benefits and harms in participating in the Program?
2. What impact has the Program had on breast cancer mortality?
3. To what extent is the Program an appropriate response to the incidence and prevalence of breast cancer?
4. What impact has the Program had on breast cancer morbidity?
5. What are the trends of participation in the Program?
6. To what extent is the Program available and accessible to all eligible women, in particular, to sub-populations of women where the participation is lower than the national average?
7. To what extent is the Program acceptable to women and other stakeholders?
8. What are the barriers to improving participation? What are the strategies to address these barriers?
9. What impact have BreastScreen Australia communication activities had on participation rates?
10. Do the current BreastScreen Australia communication mechanisms help women to make an informed choice about screening and rescreening?
11. What are the factors contributing to women choosing mammography outside the Program?
12. What are the trends in MBS-funded mammography over time and how do they relate to BreastScreen Australia participation rates?
13. What are the trends in MBS-funded breast cancer diagnostic procedures since the beginning of the BreastScreen Australia Program in 1991?
14. To what extent are women using MBS-funded mammography when they could be accessing BreastScreen Australia services?
15. What is the impact, on the Program, of mammography outside the Program?
16. How appropriate are the reporting mechanisms and key performance indicators for the Program?
17. How is the Program performing and what are the trends relating to performance indicators?
18. To what extent are women screened and rescreened in accordance with the Program's recommended screening interval? (note also Q21)
19. What aspects of governance and management contribute to better outcomes?
20. Are the current Program management and governance arrangements delivering the best possible outcomes?
21. Are quality assurance mechanisms ensuring a high standard of quality within BreastScreen Australia?

22. How effective is the Program in responding to new evidence and research?
23. What are the impacts of infrastructure and workforce issues on Program capacity?
24. To what extent are women screened and rescreened in accordance with the Program's recommended screening interval? To what extent is this related to capacity?
25. What is the impact on the Program of incorporating new technologies, in particular, digital mammography?
26. What is the net cost per woman screened?
27. What is the net cost per life year saved through the Program?
28. What are the factors influencing any variation in costs?
29. What is the cost per quality adjusted life year?
30. What are the marginal costs of the Program over marginal benefits?
31. Is the current Program policy on target age range and screening interval appropriate?
32. What is the best practice evidence for the management of women identified as being at higher risk?
33. What is the best practice evidence for the management of women with symptoms who present for screening?
34. What is the impact of inconsistent application of policy across jurisdictions?
35. Do the Program objectives continue to be appropriate?

A map of the Evaluation questions linked to Evaluation projects is provided at Appendix 16.4. Questions were answered in full or in part by one or more of the Evaluation projects.

5.4 STAKEHOLDER INPUT TO THE EVALUATION

There is considerable community interest in issues relating to the BreastScreen Australia Program, in particular, the target age range, screening interval, and the benefits and potential harms associated with mammographic screening. At the inaugural meeting of the EAC, members discussed the need to engage with and seek the views of a range of stakeholders as part of the Evaluation and to ensure that effective communication strategies were in place to keep stakeholders informed about the Evaluation and its progress.

5.4.1 STAKEHOLDER COMMUNICATION STRATEGIES

The EAC put in place a range of mechanisms to ensure that stakeholders were informed about the Evaluation and had an opportunity to provide input. Key strategies included:

- information letters sent to 29 peak medical and cancer organisations;
- regular posting of progress reports about the Evaluation on the Department of Health and Ageing website;

- regular progress reports about the Evaluation provided to:
 - AHMAC
 - APHDPC
 - SSC
 - BreastScreen Australia state and territory Program manager quarterly meetings; and
- EAC workshops with representatives from breast cancer organisations and BreastScreen Australia state and territory Program managers.

5.4.2 STAKEHOLDER CONSULTATION¹³

A variety of processes were employed to consult with a range of Program stakeholders.

Individual Evaluation project consultations

Numerous meetings and consultations with a broad range of stakeholders were conducted by individual project consultants during the course of each Evaluation project. Details of stakeholders consulted and the results of these consultations can be found in each of the individual Evaluation project reports. High-level results from these consultations have been included in the relevant chapters of the Evaluation final report.

Workshop with breast cancer and other stakeholder organisations

In March 2007, the EAC conducted a workshop with representatives from various breast cancer organisations and other relevant stakeholder groups. The objectives of the workshop were to provide stakeholders with an opportunity to receive information about the Evaluation and to raise and discuss with the EAC any issues for consideration in the Evaluation.

- Delegates from the following organisations participated in the workshop:
- Breast Cancer Network of Australia (BCNA);
- Cancer Council Australia;
- DES (diethylstilboestrol) Action Australia;
- National Breast and Ovarian Cancer Centre (NBOCC); and
- National Breast Cancer Foundation (NBCF).

¹³ See Chapter 13 for the results of stakeholder consultations

Workshop with state and territory BreastScreen Australia Program managers

State and territory governments are responsible for implementation of the BreastScreen Australia Program at a jurisdictional level. Program managers are responsible for management of all Program functions at the jurisdictional level and ensure that service delivery is client-focused, efficient and of the highest standard. The role includes financial performance, statutory compliance of service delivery and management of human resources.

In March 2007, the EAC held a workshop with state and territory Program managers. The workshop provided an opportunity for Program managers to receive an update about the progress of the Evaluation and to seek information regarding specific aspects of the Evaluation projects. Importantly, the workshop was also an opportunity for Program managers to advise and discuss with the EAC relevant information about operational aspects of the Program and to highlight issues requiring consideration in the Evaluation.

Consumers

Several consumer organisations were represented in the stakeholder workshop outlined above. In addition, various consultations and focus groups were held with consumers by the individual project consultants in the course of conducting individual Evaluation projects.

Specific details of consumers consulted and the results of these consultations can be found in each of the individual Evaluation project reports. High-level results of these consultations are included in individual chapters of the Evaluation final report, and in particular Chapter 7.

Site visits to BreastScreen Australia services

EAC members spent 2 days visiting BreastScreen Australia services in South Australia and Victoria. The site visits were to services with digital and analogue equipment located in both metropolitan and regional areas, including a mobile unit.

Visits to Melbourne and Bendigo provided an insight into operational differences in digital services in metropolitan and regional environments. EAC members also visited the SCU and an assessment centre in Adelaide and a mobile unit in Tanunda. During these visits, BreastScreen Australia staff demonstrated and explained the service delivery pathway. These visits provided EAC members with a valuable opportunity to develop a greater understanding of the day-to-day operation of the Program and to meet with and gain perspectives from Program staff first-hand.