

# 1. INTRODUCTION

## 1.1 BACKGROUND

The aim of population-based breast screening is to reduce mortality and morbidity from breast cancer by detecting breast cancers while they are still small and confined to the breast, at a time when treatment will be most effective (Porter et al. 1999), and without harm to program participants (EU Guidelines 2006). In the absence of evidence on which to base primary preventive strategies for breast cancer, early detection is believed to represent the best approach for reducing mortality from this disease (Blamey, Wilson and Patnick 2000).

In Australia, the national BreastScreen Australia program provides free screening mammograms at two-yearly intervals for women without symptoms of breast cancer. The program actively targets women aged 50–69 years. Women aged 40–49 years and women aged over 70 years are also eligible to attend.

The BreastScreen Australia program was introduced in 1991 and is funded and coordinated jointly through federal, state and territory governments. Policy formulation, data collection, quality control, monitoring, and evaluation are primarily the responsibility of the Australian Government, while state- and territory based Coordination Units implement the program locally and have responsibility for approximately five hundred fixed and mobile Screening and Assessment Services across the country.

BreastScreen Australia aims to achieve significant reductions in mortality and morbidity due to breast cancer in the target population through early detection of the disease. The program has a target participation rate of 70%. In 2004–2005, 1,614,871 women participated in screening mammography through the BreastScreen Australia program – a participation rate of 56.2%. Of these women, 1,188,720 (74%) were in the target age group of 50–69 years (AIHW 2008). Some women undertake screening privately, outside the BreastScreen Australia program; although the exact number of women who participate in private screening in Australia is not known. The mortality rate for breast cancer among women aged 50–69 years has declined from 61.5 per 100 000 women in 1996 to 51.8 per 100 000 women in 2005 (AIHW 2008).

## 1.2 BREASTSCREEN AUSTRALIA EVALUATION

All BreastScreen Australia programs are reviewed regularly against nationally agreed accreditation standards (BreastScreen Australia 2004), and all states and territories collect and report data in accordance with a National Standardised Data Set. Individual state and territory programs produce an annual report each year. In addition, the Australian Institute of Health and Welfare (AIHW) publishes national data monitoring reports on BreastScreen Australia that include national data on program participation, detection of small and invasive cancers, recall to assessment, detection of non-invasive cancers (including ductal carcinoma *in situ* (DCIS)), re-screening, incidence of breast cancer and mortality. While these reports provide valuable data about program efficiency and performance, they do not provide a measure of the impact of the program on health outcomes.

Health outcomes due to screening mammography, in particular reductions in mortality, can only be assessed after several cohorts of women have participated in screening over a period of time. In 2005, the Australian Health Ministers Advisory Council (AHMAC) determined that the BreastScreen Australia program had been in operation long enough for its impact to be measured, and future directions determined. The Terms of Reference for a comprehensive evaluation of the program were endorsed by AHMAC in June 2006, and the Department of Health and Ageing was charged with undertaking the evaluation with guidance from an independent Evaluation Advisory Committee (EAC).

The aim of the BreastScreen Australia Evaluation is to assess the appropriateness, efficiency and effectiveness of the program and identify opportunities for overall improvement, giving due consideration to available evidence, current and emerging issues, and national and international policies and procedures.

The BreastScreen Australia Evaluation comprises 10 projects:

1. Mortality Study (Methodology)
2. Mortality Study (Ecological)
3. Participation and Performance Trends Project
4. Review of BreastScreen Australia Infrastructure and Capacity
5. Policy Analysis Project
6. Review of BreastScreen Australia Accreditation System
7. Participation Qualitative Study
8. Economic Evaluation and Modelling
9. Program Governance and Management
10. Medicare Mammography Project

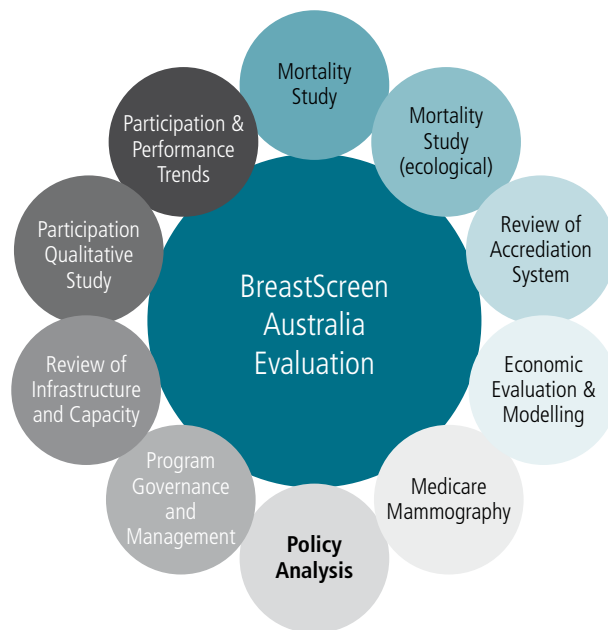
Through these projects, the Evaluation is examining:

- The impact of the screening program on breast cancer mortality
- Risks associated with screening mammography
- Appropriate target age range
- Appropriate screening interval
- Issues impacting on the program's capacity (eg workforce)
- Program performance to date.

The Evaluation also includes an examination of participation rates, and factors affecting participation.

Each individual project may answer particular evaluation questions in full or in part, depending on project scope (Figure 1). This report summarises outcomes from the Policy Analysis Project.

**Figure 1** Overview of BreastScreen Australia Evaluation



### 1.3 BREASTSCREEN AUSTRALIA EVALUATION POLICY ANALYSIS PROJECT

The BreastScreen Australia Evaluation Policy Analysis Project was designed to address, in full or in part, the following Evaluation Terms of Reference questions relating to policy outcomes:

- Is the current BreastScreen Australia policy on age range and screening interval appropriate?
- What is the best practice evidence for the management of women presenting with symptoms?
- What is the best practice evidence for the management of women identified as being at higher personal risk?
- What is the impact of inconsistency in application of policy across jurisdictions?

The Project was undertaken by HDG Consulting Group as an independent consultancy appointed by the Department of Health and Ageing following a public tendering process.

## 1.4 DEFINITIONS USED IN THE REPORT

Table 1 provides definitions for terms used throughout this report. While some of these are general terms, definitions are provided as they relate to breast cancer and screening mammography.

**Table 1** Definitions for terms used in the rep

<b>Term</b>	<b>Definition</b>
Population risk	The risk of breast cancer in the general population; women are considered to retain population risk status if their combined risk factors confer 'no greater than a 1.5-fold increase' in relative risk of developing breast cancer <sup>a</sup>
Risk factor	A characteristic that confers an increased risk of developing breast cancer
False-negative result	Refers to breast cancers that are present but not detected during screening mammography
False-positive result	Refers to screen-detected abnormalities that are not due to breast cancer
Overdiagnosis	Describes the situation when screening identifies a cancer that would not have become clinically evident during a patient's lifetime
Overtreatment	Describes the harms that result from detecting and treating inconsequential disease
Sensitivity	The ability of a test to accurately identify all women with breast cancer
Specificity	The ability of a test to accurately identify all women who do not have breast cancer
Positive predictive value	The proportion of women with a positive mammogram who are subsequently diagnosed with breast cancer
Relative risk (RR)	The risk of an event occurring in one group compared with another group (for example the risk of mortality in women who are screened for breast cancer compared with those who are not screened); a relative risk of 1 means there is no difference between the groups
Absolute risk	The risk of an event occurring over a specified time period (for example the risk of dying from breast cancer for women aged 50–69 years)
Screening interval	The duration of time between mammography screenings
Interval cancer	A cancer that develops in the time period between two screening sessions
Contralateral breast cancer	Cancer that occurs in the breast other than the one in which the first primary cancer occurred
Lead time	The amount of time by which a diagnosis of breast cancer is advanced as a result of screening
Sojourn time	The time from when a breast cancer would have become detectable by screening and when it becomes symptomatic

<sup>a</sup> Willey & Cocilovo 2007

## 2. METHODOLOGY

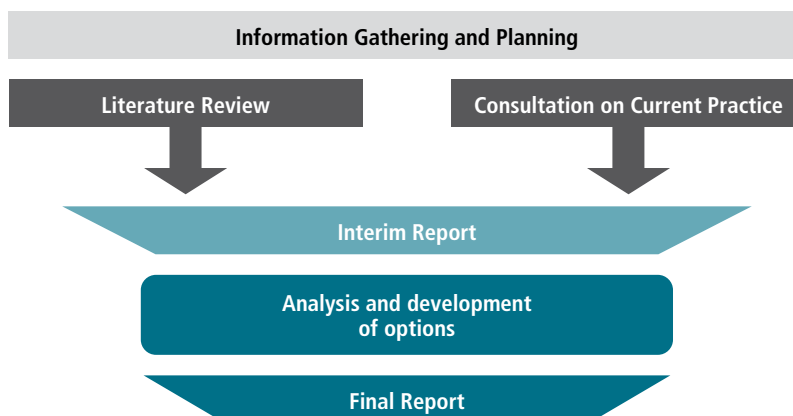
### 2.1 PROJECT STAGES

The Policy Analysis Project was undertaken by independent consultants and followed six project stages:

1. Preparation and planning
2. Conduct of literature review
3. Consultation for review of current practice
4. Development of interim report
5. Analysis, discussion and development of conclusions
6. Development of final report.

An interim report was submitted to the Department of Health and Ageing in April 2008 and provided information on outcomes from the literature review and consultation process (Figure 2). Building on this information, a detailed analysis of potential policy options was undertaken. This report represents the completion of the project.

**Figure 2** Project reporting processes and method



## 2.2 LITERATURE REVIEW

The aim of the literature review was to identify and analyse high-quality literature relevant to the project aims with a focus on key meta-analyses and reviews. The tender briefing document called for a review of international evidence and an analysis of the cost-effectiveness, benefits and risks of:

- Screening women at population risk of breast cancer in different age groups:
  - 50–69 years (current target age range for BreastScreen Australia)
  - 40–49 years
  - 70 years and over
- Screening intervals for asymptomatic women at population risk of breast cancer:
  - annual
  - two years (current screening interval for BreastScreen Australia)
  - three years
- Screening women in the following three higher risk sub-population groups at intervals of one, two and three years:
  - strong family history of breast cancer
  - personal history of breast cancer
  - dense breast tissue.

Subsequently the requirement for inclusion of information relating to cost-effectiveness was removed from the project scope. In addition, the requirement was for the review to explore international literature to identify:

- Definitions of symptoms of breast cancer, family history, dense breasts and higher personal risk
- Current best practice for identifying and managing women with:
  - breast symptoms
  - a family history of breast cancer
  - dense breasts and
  - other groups of women identified as being at higher personal risk, including, but not limited to, women exposed to diethylstilboestrol (DES) and women with a personal history of breast cancer.

## 2.2.1 SEARCH STRATEGIES

Searches were undertaken using the following electronic databases and the search terms listed in Table 2:

- OVID MEDLINE, 1950–2008
- Proquest, 1986–2008
- Web of Science, 1900–2008.

**Table 2** Search terms used

Major search terms*	Minor search terms**
"breast cancer"	"age"
"mammography"	"age group"
"screening"	"risk"
	"family history"
	"personal history"
	"density"
	"diethylstilboestrol"
	"symptomatic"
	"lump"
	"nipple discharge"

\*searches included spelling variations and acronyms

\*\*used in combination with each of the major search terms

A search of the internet was also conducted to identify guidelines and policies relating to screening mammography in Australia and overseas (UK, USA, the Netherlands, Canada and Sweden). Additional references were also recommended by evaluation stakeholders, including Department of Health and Ageing, the Evaluation Advisory Committee and BreastScreen Australia service staff.

Table 3 lists the eligibility criteria for articles included in the review. In general, references primarily comprised of articles from peer-reviewed publications and international clinical guidelines. Where possible, evidence was used from randomised controlled trials. Some grey literature was also included.

**Table 3** Eligibility criteria for the selection of studies

	Inclusion criteria	Exclusion criteria
Date of publication	Any, concentrating on data less than 10 years old where available.	Studies pre-1995 unless widely quoted and thought to be seminal
Language	Studies published in English	Non-English texts
Client group	Any, concentrating on Australian data where available.	Clients outside the age groups under discussion. Studies from countries where the treatment and social context is significantly different to that in Australia.
Type of study	<ul style="list-style-type: none"> <li>• Reviews and meta-analyses which have found wide acceptance in the literature</li> <li>• Reports from key international health agencies (e.g. IARC) and well-established scientific organisations</li> <li>• Literature recommended by the Evaluation Advisory Group.</li> <li>• Original articles containing empirical data</li> </ul>	<p>Studies that included very small cohorts (unless they had other significance)</p> <p>Some of the studies based on modelling or on methodology that could be called into question.</p>

### 2.2.2 REVIEW PROCESS

The consultants reviewed the titles, abstracts or executive summaries of all identified publications together. Those viewed to be relevant to the topics of interest were considered further in relation to whether they provided information relating to the review questions. All relevant literature was subsequently considered by a consultant epidemiologist to assess the quality and level of evidence provided by each study. The best available evidence was then selected and analysed to provide a report on the current available evidence.

Levels of evidence were categorised according to the Oxford Centre for Evidence-Based Medicine categories (see Table 4). This internationally recognised system was chosen based on its credibility in the international research community, and because the Australian National Health and Medical Research Council (NHMRC) guidelines are currently under review and will not be finalised until later in 2009. Use of the Oxford classification system will help to avoid confusion in interpretation that could subsequently arise due to changes in the NHMRC classification.

**Table 4** Summary of description of levels of evidence

Rating	Description
Ia	Systematic review or meta-analysis of randomised controlled trials
Ib	At least one randomised controlled trial
IIa	Systematic review of cohort studies
IIb	At least one well-designed cohort study or low quality trial
IIc	Ecological studies or outcomes research
IIIa	Systematic review of case-control studies
IIIb	Individual case-control study
IV	Case series or poor quality case-control studies
V	Expert committee reports, opinions and/or clinical experience of respected authorities

Source: Oxford Centre for Evidence Based Medicine categories (2001)

## 2.3 REVIEW OF CURRENT PRACTICE

The review of current practice was designed to provide information on current policies and practices of BreastScreen Australia services across jurisdictions.


A generic set of questions was developed to ensure that all the required information was collected. Typically, information gathering included the following steps for each jurisdiction:

1. Request made for current policy and procedure manuals
2. Draft policy summary developed
3. Draft policy summary sent to relevant state/territory Program Manager
4. Discussion of policy summary at face-to-face meeting of consultants, local BreastScreen Australia services staff (managers, clinicians, administrative staff) and consultant clinicians (attendees determined by the Program Manager)
5. Development of a final policy summary
6. Development of draft comparative tables
7. Review by Program Managers of policy summaries and draft comparative tables for verification of information
8. Incorporation of information into the interim report and final report.

## 2.4 STAKEHOLDER INTERVIEWS

In addition to reviewing practice, the project also sought to better understand the impact of current policies and practices on various stakeholder groups through brief informal interviews and focus groups. As other parts of the Evaluation of BreastScreen Australia have been designed to assess consumer related issues, the consultation for this project was designed only to provide an improved understanding of current practice which could inform the development of policy options. As a result, the processes were informal and qualitative in nature. The process included:

- Interviews with BreastScreen Australia Program managers, staff, senior clinicians, consultant specialists and administrative staff during visits to jurisdictions
- Two focus groups held with approximately 25 consumers from five jurisdictions
- Site visits to rural BreastScreen Australia services in two jurisdictions.
- Informal interviews with representatives from six international screening programs (Norway, Finland, the Czech Republic, Israel, Sweden and New Zealand).



These interviews provided a further opportunity to understand the impact of current policies on consumers, potential consumers and BreastScreen services and how policy options under consideration by BreastScreen Australia had impacted other programs internationally.

## **2.5 OPTIONS FOR FUTURE POLICY DEVELOPMENT**

The analysis of options focused primarily on information provided by the literature review and the current policies and practices in BreastScreen Australia services. A number of key questions were considered:

- What are the options for BreastScreen Australia regarding target age range and screening intervals?
- What are the options for identification and management of women from higher risk sub-populations due to family or personal risk?
- What are the options for the management of women with symptoms?

For each topic area, the evidence base was analysed from an epidemiological perspective taking into account the evidence of effect, study design and a range of other factors that indicated the reliability of the information. Where evidence was limited or unavailable, models of practice and clinical guidelines were consulted. Following this analysis, a total of 24 different options for a total of ten different policy areas, were developed.