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EXECUTIVE SUMMARY

BreastScreen Australia is Australia's national screening mammography program, offering free two-yearly screening mammograms to asymptomatic women. The program targets women aged 50–69 years but all women aged 40 years and over are eligible to attend. The BreastScreen Australia program was introduced in 1991 and is funded and coordinated jointly through federal, state and territory governments.

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. A comprehensive national evaluation was approved in 2006 with a view to 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 Policy Analysis Project is one of ten BreastScreen Australia Evaluation projects and was conducted to examine the following key policy areas:

- 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 inconsistent application of policy across jurisdictions?

The project comprised of a literature review, a review of current practice in Australia, and stakeholder interviews to determine the impact of current policy both in Australia and overseas.

LITERATURE REVIEW

The literature review examined the evidence base for best practice in relation to the key policy areas outlined above and provided a summary of the evidence on the relative benefits and harms of screening women in different age cohorts. (Eligibility criteria applied for selection of information for the literature review are provided in Table 3.)

A summary of the key policy findings from the literature review is provided below.

Women at population risk

- Evidence from randomised clinical trials and screening mammography programs supports the continued inclusion of asymptomatic women at population risk in the current target age range of 50–69 years.
- Evidence to assist in deciding whether to include younger women (aged 40–49 years) and older women (aged 70+ years) in the target group is less clear (see table below for details).
- The balance between reducing absolute risk of death from breast cancer and the harm caused by false positives and false negatives grows more favourable closer to the target age range. The age at which this trade-off becomes acceptable is a subjective judgement that cannot always be answered with available data.
- Limited comparative information is available on the benefits of screening intervals of one, two or three years.
- Overall, for women aged 50–69 years there appears to be no demonstrated mortality benefit or risk from extending screening intervals from two years to three years, or reducing screening intervals to one year. It has been suggested that there may be benefit in considering different screening intervals for younger and older women.

Summary of evidence on effectiveness of screening by age group

Age of screening	Detail	Level of evidence*
50–69 years	<ul style="list-style-type: none">• 2-yearly screening reduces mortality from breast cancer	Level Ia
40–49 years	<ul style="list-style-type: none">• Evidence is less clear• Randomised controlled trials suggest there may be a reduction of mortality of about 15% but this difference is not statistically significant• Screening mammography programs in younger women have poorer performance characteristics, so the balance of benefits to risks for this age group is not as favourable as for women aged 50–69 years• The balance of benefits to risks for breast screening is considered to improve as women age over the decade of 40–49 years	Level Ia evidence is not conclusive
70+ years	<ul style="list-style-type: none">• Little evidence available from randomised controlled trials• Women in this age group have the highest incidence of breast cancer• Screening mammography programs in these women have the best performance characteristics• Women in this age group have higher levels of co-morbidity resulting in fewer years of life saved for each cancer detected• Mortality benefits shown in population based screening• Overall, mammography screening is probably still beneficial for women aged over 70 years	Level Ib

*Oxford levels of evidence, see Table 4.

Women at potentially increased risk of breast cancer

- There is little evidence to guide best practice for screening mammography in women with a strong family history of breast cancer, particularly with regard to screening intervals and what age at which to commence screening. Current Australian and international practice is typically guided by expert consensus and emphasises the importance of:
 - taking a detailed family history for women with a suspected family history of breast cancer
 - tailored screening and surveillance (including MRI) for women at potentially moderate or high risk of breast cancer as a result of a family history of breast cancer.
- There is evidence that magnetic resonance imaging (MRI) may be a more effective screening tool for breast cancer than mammography for women with a strong family history, in particular for younger women.
- There is limited evidence to guide approaches to screening for women with dense breast tissue. For women with very dense breast tissue, screening using digital mammography has been shown to be better than film mammography. Other imaging techniques including ultrasound and MRI may also be useful.
- Limited evidence is available about the risk of breast cancer in women exposed *in utero* to diethylstilboestrol (DES). While exposure to DES *in utero* may confer a slight increase in risk, the level appears to be similar to that of a range of other risk factors that do not require more intensive screening or management protocols.
- The approach to assessment of women with significant breast symptoms (lump, blood-stained discharge, nipple change) is fundamentally different to that used for asymptomatic women. Some international evidence suggests there may be advantages in developing a separate symptomatic stream for screening programs that encourages women to identify symptoms and ensures that negative mammograms are followed up appropriately for women with significant symptoms.

Summary of evidence on individual risk factors

Risk factor	Detail	Level of evidence*
Strong family history	<ul style="list-style-type: none"> Women with a family history of breast or ovarian cancer should be evaluated as to their level of risk due to family history using an established assessment tool 	Level IV
	<ul style="list-style-type: none"> Those identified as being at high risk should be managed in a similar way to those with a genetic mutation 	Level V
	<ul style="list-style-type: none"> Those at lower or population risk should be managed in the BreastScreen Australia program with screening protocols as per the general population 	Level V
	<ul style="list-style-type: none"> Those at moderate risk may need review and specific management protocols including possibly annual screening, which could be provided within the BreastScreen Australia program 	Level V
Known gene mutation	<ul style="list-style-type: none"> Women with a known genetic mutation are at high risk of developing breast cancer and should be managed in a specialist clinic with different protocols including use of MRI 	Level Ia
Dense breasts	<ul style="list-style-type: none"> Women with dense breasts are at an increased risk of breast cancer 	Level IIb
	<ul style="list-style-type: none"> Mammography is less sensitive in women with dense breasts 	
	<ul style="list-style-type: none"> Clear evidence of best practice for screening is lacking and, in particular, a practical method to accurately measure breast density in a screening setting is not yet available 	
	<ul style="list-style-type: none"> Digital mammography appears to offer benefits for these women 	Level Ib
Exposure to DES <i>in utero</i>	<ul style="list-style-type: none"> Women who were exposed to DES <i>in utero</i> may have a slightly increased risk of breast cancer The level of risk is similar to exposure to a range of other risk factors that would not generally require more intensive screening or management protocols 	
Significant breast symptoms (breast lumps, blood-stained nipple discharge or nipple change)	<ul style="list-style-type: none"> Women with significant symptoms are at increased risk of breast cancer 	Level IIb
	<ul style="list-style-type: none"> A fundamentally different approach is required for women with symptoms to those who are asymptomatic 	
	<ul style="list-style-type: none"> Evaluations of other national screening programs (e.g. UK) suggest that there may be benefits in developing a co-located symptomatic stream 	Level V

REVIEW OF CURRENT PRACTICE

The review of current practice in BreastScreen Australia services involved an examination of current written policies and procedures and focused on identifying potential variations in practice between individual jurisdictions. This information was compiled and endorsed by BreastScreen Australia state and territory Program Managers.

Findings from the review of current practice suggested that the variations in practice appear to be greater in those areas where there is no national policy or guideline. In the absence of a stated national policy position, jurisdictions are required to make policy decisions independently. When the evidence for any given practice in an area is inconclusive, there is further room for variation.

Key findings in relation to variations in practice across jurisdictions included:

- National policies in relation to screening women of population risk in the target age range (50–69 years) are applied with a high degree of consistency.
- All jurisdictions provide screening for women in the eligible age range (40+ years), but do not actively recruit women aged 40–49 years. There is some variation in relation to sending reminders for re-screening to women in this age group after the initial screening: three jurisdictions, including the two largest jurisdictions, do not currently send reminders for re-screening to women aged 40–49 years once they have attended an initial screening session.
- With the exception of one jurisdiction, reminders for re-screening are not sent to women over the age of 70 years.
- Practices in relation to the management of women who present with symptoms, or women with a strong family history of breast cancer, vary between jurisdictions.
- Criteria for accepting women with a personal history of breast cancer into the program vary significantly and practices in some jurisdictions may be contradictory to those implemented in other jurisdictions.
- There are few jurisdictional policies to provide some guidance in relation to the screening of women with dense breasts.
- There are no specific policies in relation to screening women exposed to DES *in utero*.

For consumers, the current variations are likely to lead to confusion and may impact on equity of access to services across jurisdictions. Particularly for an increasingly mobile population, it is confusing for women if a national service does not provide consistent advice on their eligibility for the program or on the management of potential risks. On the other hand, there is a need for some flexibility in the implementation of policies which may be affected by jurisdictional differences in the health system, or due to differences between metropolitan and rural settings.

ANALYSIS AND OPTIONS

The final stage of the project included analysis of the information obtained on current practice and evidence for best practice. As the Policy Analysis project forms part of the overall Evaluation of BreastScreen Australia, the purpose of this study was to assess the evidence to support various policy options which can be tested in the context of information from other projects. As a result, this report does not outline specific recommendations, but suggests a range of policy options which, together with the findings from other projects, can be considered by the Evaluation Advisory Committee.

The options are summarised in Chapter 5 of this report.

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