The ROSA PROJECT

‘Roadmap for Optimising Screening in Australia – Breast’, investigating risk-based breast cancer screening.

Chapter 2. Current Australian health services (abridged)

20 March 2023, abridged 1 May 2024

The Daffodil Centre

A partnership between

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The Daffodil Centre acknowledges the Traditional Custodians of Country throughout NSW and recognises the continuing connection to lands, waters, and communities. We pay our respect to Aboriginal and Torres Strait Islander cultures and to Elders past, present, and emerging.

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1 Executive summary

1.1 Background

1.1.1 Document purpose

Since 1 May 2018, the Australian Department of Health has engaged Cancer Council Australia to undertake a series of activities exploring options for risk-based breast cancer screening in Australia, described collectively as the Breast ROSA (Roadmap to Optimising Screening in Australia) project. The ROSA project has delivered numerous technical reports over 2019-2021, progressing aspects of a Roadmap produced in 2019, with a majority of this technical work completed by Cancer Council NSW (now via the Daffodil Centre, a joint venture between the University of Sydney and cancer Council NSW). This chapter is part of a milestone ROSA report that synthesises the work to date, provides a set of key findings and recommendations, and delivers an updated Roadmap to help achieve risk-based breast cancer screening in Australia.

1.1.2 Current health services

Any consideration of risk-based breast cancer screening in Australia requires a good understanding of current health services involved in the delivery of breast screening, risk-based breast cancer surveillance, and breast cancer risk assessment and advice.

BreastScreen Australia

The BreastScreen Australia program aims to reduce breast cancer mortality through the early detection of breast cancer before it becomes symptomatic. The effectiveness of the program at reducing mortality is confirmed at a population level[1,2]. However, national and international evidence indicates that the current BreastScreen program is likely to provide differing levels of benefits for different risk groups based on factors such as age, breast density and family history. [3,4]

To inform consideration of risk-based breast cancer screening in Australia, it is important to understand how BreastScreen Australia currently assesses and manages women based on their risk of breast cancer, including the role of annual screening as a risk-based intervention and differences in practices between state and territory programs.

It is also important to understand the potential benefits and harms of the current BreastScreen program for different risk groups. Benefits are indicated through mortality reduction, earlier cancer detection and improvements in the prognostic profile of diagnosed cancers. Potential harms of screening include false positive screening outcomes (screens that lead to further assessment but no cancer diagnosis) and overdiagnoses (cancers detected by screening that would not have otherwise

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[1] Nickson C, Mason KE, English DR, Kavanagh AM. Mammographic screening and breast cancer mortality: a case-control study and meta-analysis. Cancer Epidemiol Biomarkers Prev. 2012 Sep;21(9):1479-88. doi: 10.1158/1055-9965.EPI-12-0468. PMID: 22956730.
[2] Morrell S, Taylor R, Roder D, Dobson A. Mammography screening and breast cancer mortality in Australia: an aggregate cohort study. J Med Screen. 2012 Mar;19(1):26-34. doi: 10.1258/jms.2012.011127. Epub 2012 Feb 18. PMID: 22345322.
[3] Independent UK Panel on Breast Cancer Screening. The benefits and harms of breast cancer screening: an independent review. Lancet. 2012 Nov 17;380(9855):1778-86. doi: 10.1016/S0140-6736(12)61611-0. Epub 2012 Oct 30. PMID: 23117178.
[4] Kavanagh AM, Byrnes GB, Nickson C, Cawson JN, Giles GG, Hopper JL, Gertig DM, English DR. Using mammographic density to improve breast cancer screening outcomes. Cancer Epidemiol Biomarkers Prev. 2008 Oct;17(10):2818-24. doi: 10.1158/1055-9965.EPI-07-2835. PMID: 18843028.

been found in a woman's lifetime). Many benefits and harms are known to vary between risk groups[5]. As detailed in Chapters 3 and 4 of this report, this includes higher program sensitivity, smaller tumours at diagnosis and likely higher overdiagnosis rates for screening participants with lower breast density, and higher rates of interval cancers, lower program sensitivity and likely lower overdiagnosis rates for with higher breast density.

Any introduction of risk-based screening would be expected to change clinical outcomes in women in different population subgroups, defined by either established risk factors for breast cancer (e.g. family history of breast cancer) or by factors important for implementing, monitoring or evaluating risk-based screening (including factors that would ensure equitable access across the Australian population). Therefore, it is important to understand current 'baseline' participation and outcomes for these factors.

1.1.3 Breast cancer surveillance outside BreastScreen

While screening of asymptomatic women for breast cancer occurs primarily within the BreastScreen Australia program, some services are delivered outside the program (described hereon as 'other early detection services'). This includes, for example:

- Breast imaging services for asymptomatic women;
- Primary care (e.g. general practitioners (GPs));
- Medicare-subsidised services directed at asymptomatic women at particularly high risk of breast cancer; and
- Specialist healthcare providers (often described as 'secondary healthcare services', as they generally require a referral from another medical professional/healthcare service, most commonly a primary care provider).

Any introduction of risk-based screening would be expected to impact on how women utilise existing services outside the BreastScreen program, and health services outside the program could potentially play a role in supporting risk assessment and risk-based screening protocols, on the condition that the integrity of BreastScreen as a population screening program is maintained. Therefore, in considering options for risk-based screening in Australia it is important to understand current practices in various health services outside BreastScreen in relation to breast cancer risk assessment and risk-based management, and how women move between health services.

1.2 Contracted activities

The ROSA project has undertaken a range of activities to gain insights about current health services as part of considering options for risk-based breast cancer screening in Australia. The topics covered in this chapter, the general approach/methods used, and how this relates to the current phase of ROSA contracted activities, is outlined in Table 1.

[5] Nickson C, Velentzis LS, Brennan P, Mann GB, Houssami N. Improving breast cancer screening in Australia: a public health perspective. Public Health Res Pract. 2019 Jul 31;29(2):2921911. doi: 10.17061/phrp2921911. PMID: 31384884.

*Table 1. Chapter sections and their related ROSA contracted activities under the current phase. *Indicates topics covered in other chapters*

Chapter section and topic	Approach/methods	Phase 2 activity
2. BreastScreen participation and outcomes by factors of interest for risk-based screening – National level (from page 6)	A scoping-level review of BreastScreen participation and outcomes (i.e. cancer diagnoses including size and stage, program sensitivity and false positive rates) according to factors of interest for risk-based screening in Australian publicly available reports and peer-reviewed literature, at a national and state and territory level.	1a) Update the summaries of evidence prepared for current project (risk assessment tools*, overdiagnosis by risk group, BreastScreen outcomes by risk group, risk-based screening modalities* and modelled estimates*) with an updated sweep and review of the literature.
3. BreastScreen participation and outcomes by factors of interest for risk-based screening – Jurisdictional level (from page 51)		
4. Overdiagnosis by risk group (from page 95)	A scoping-level review of overdiagnosis according to risk group.	
5. National linked data evaluations (from page 95)	Analyses of national linked BreastScreen, cancer registry and deaths records, in collaboration with the Australian Institute of Health and Welfare.	6. BreastScreen risk-related data project (in collaboration with the Australian Institute of Health and Welfare). c) Linked data analyses
6. Annual screening protocols (from page 126)	An evaluation of annual screening in the BreastScreen program.	6. BreastScreen risk-related data project (in collaboration with the Australian Institute of Health and Welfare). b) Focus on annual screening
7. Appendix: Environmental Scan (2019) – Clinical Services (from page 130)	An environmental scan of clinical services involved in current risk-based surveillance, including BreastScreen and other health services.	Phase 1 activity used to help inform current project findings and recommendations.

1.3 Summary of findings

Drawing from the detailed analyses and results described throughout this chapter, the project generated an itemised set of key findings which were reviewed by the ROSA Expert Advisory Group over May to July 2022, accompanied by summaries of the evidence outlined here. The final set of EAG-endorsed key findings is shown in Appendix 7.1 (page 130).

In summary, building on our 2019 environmental scan of clinical services involved in breast cancer screening and risk-based surveillance, the ROSA project has identified important findings and opportunities to inform consideration of risk-based breast screening in Australia.

Our analyses of BreastScreen participation and outcomes by factors of interest for risk-based screening confirmed differences in participation and outcomes for various population groups under the current screening program. It is important that these differences be considered and monitored with any introduction of risk-based screening, particularly to help ensure that any existing disparities in access are not worsened. We noted some variation between state and territory programs in terms of which risk information is currently collected and describe various opportunities to enhance routine data collection and reporting at BreastScreen Australia to help prepare for and support any future risk-based approaches to breast screening in Australia.

Overdiagnosis continues to be challenging to estimate, especially for population sub-groups such as women at different levels of breast cancer risk. However, it remains an important consideration for risk-based breast screening, which could potentially improve or worsen overdiagnosis for different risk groups. For example, the current masking of small tumours for women with higher mammographic breast density may reduce with the provision of more sensitive screening tests for women with dense breasts, and while this is likely to find some potentially fatal breast cancers earlier, consequently overdiagnosis may also increase. Continued effort to accurately estimate overdiagnosis rates for women in different risk groups is warranted.

Collaborative analyses with the Australian Institute of Health and Welfare of 2002-2012 linked population data highlight the value of linking BreastScreen records to population data on cancer outcomes and mortality to more fully evaluate the effectiveness of breast cancer screening and better understand screening behaviour. Additional analyses on false-positive screening outcomes and the changing profile of breast cancers over time provide helpful 'baseline' data as a comparison point for any future introduction of risk-based breast screening, ideally with updated data linkage so that the reported analyses could be repeated.

While BreastScreen Australia offers annual screening to a modest proportion of clients, our attempt to examine the effectiveness of annual screening policies at a national level was hampered by lack of available records on which women have been offered annual screening and on what basis. This is further complicated by annual screening policies differing between state and territory programs and varying over time. Our analysis of BreastScreen Victoria data (intended to help design a scaled-up analysis of national data) highlighted that uptake of annual screening can be modest and vary over time, so that annual screening participation is not an accurate proxy for invitation to annual screening. National reporting of participation and outcomes for women offered annual screening would be an important and reassuring exercise prior to any introduction of risk-based screening, for which outcomes for different risk-targeted groups should be routinely reported and evaluated.

Women aged 40-49 are eligible for but not targeted for screening by BreastScreen Australia, with some differences between state and territory programs in terms of re-invitation policies. This age group accesses around 11% of BreastScreen screens, yielding 6% of all screen-detected cancers and 19% of all interval cancers.[6] We found that reporting of outcomes for different risk groups within this age group was limited; more detailed reporting is warranted to monitor the effectiveness of current screening policies in this age group and help identify more optimal approaches in the future, such as risk-targeted screening.

To help consider, prepare for and potentially evaluate the introduction of risk-based breast cancer screening in Australia, we recommend additional resourcing to support enhanced BreastScreen data collection and reporting, updated and potentially expanded data linkage between BreastScreen and other population data sets at a national level, and additional efforts to evaluate annual screening and overdiagnosis by risk group. As identified in our 2019 environmental scan, improvements to health data collection and reporting in related health services outside BreastScreen would also assist, as would review of Medicare items for breast imaging services to differentiate diagnostic versus surveillance breast imaging (based on symptoms), and improved coordination of risk assessment and advice between health services.

[6] Derived from Australian Institute of Health and Welfare 2021. BreastScreen Australia monitoring report 2021. Cat. no. CAN 140. Canberra: AIHW

1.4 Glossary of terms

A glossary of terms used in this chapter is shown below.

Community-detected cancer	Cancer diagnosed outside the screening program, including interval cancers.
DCIS	Ductal carcinoma in situ.
False positive screen	A screening episode recalled for further assessment with a benign final outcome after assessment.
Family history of breast cancer	Some family history of breast cancer, defined in various ways.
Interval cancer	Cancer diagnosed following a negative screening episode, within a defined period of the screen (usually 12 or 24 months).
Mode of detection	Categorical description of how cancers were diagnosed e.g. screen-detected, interval cancer or other.
Negative screening episode	A screening round not recalled for further assessment.
Overdiagnosis	Cancers detected by screening that would not have otherwise been found in a woman's lifetime.
PICO/PECO framework	A framework to define an approach to a research question in terms of the population of interest (P), the intervention (I) or exposure (E) being assessed, the comparator intervention or exposure (C), and the outcomes to be reported and assessed (O).
Positive predictive value (PPV)	The proportion of recalled screens that result in a screen-detected cancer. Can report either invasive breast cancers or invasive breast cancers combined with DCIS diagnoses.
Program sensitivity	The proportion of cancers diagnosed by screening rather than as interval cancers.
Recall to assessment	Recall for further investigation by BreastScreen assessment services, following a screening mammogram.
Screen-detected cancer	Cancer detected by a population screening program.
SES	Socioeconomic status.
Strong family history of breast cancer	A strong family history of breast cancer, defined in various ways, often according to whether the family member/s with breast cancer are/were first- or second-degree relatives, and/or the age at which their breast cancer was diagnosed (so that diagnosis at a younger age is more likely to be interpreted as a strong family history).

2 BreastScreen participation and outcomes by factors of interest for risk-based screening – National level

2.1 Authors

Ms Chelsea Carle, Dr Louiza Velentzis, A/Prof Carolyn Nickson

2.2 Background

It is well-established that the Australian Institute of Health and Welfare (AIHW) produces the detailed *BreastScreen Australia Monitoring Report* (BSAMR) each year to help report on the performance of the BreastScreen Australia program. These reports include national participation data according to various factors in alignment with accreditation measures (BreastScreen Australia 2019) and summary outcomes such as rates of screen-detected invasive breast cancer and ductal carcinoma in situ (DCIS), interval cancer rates and rates of recall to assessment. These data can also be used to derive other important screening outcomes, such as program sensitivity (the proportion of cancers diagnosed by screening rather than as interval cancers).

Any introduction of risk-based breast cancer screening is likely to change clinical outcomes in women in different sub-populations, defined by either biological risk factors for breast cancer (e.g. family history of breast cancer) or by factors important for implementing, monitoring, or evaluating risk-based screening, to ensure equity for sub-populations with existing disparities in terms of access to services and cancer outcomes (e.g. geographical area of residence). Therefore, it is important to understand current, 'baseline' outcomes according to factors of interest for risk-based screening, and the capacity for current data reporting systems to support the monitoring and evaluation of any introduction of risk-based breast cancer screening in Australia. While BSAMR reports are a primary source for these data, data reported in peer-reviewed literature may also provide additional insights regarding participation and outcomes for the current screening program and suggest opportunities for enhanced data collection in the future.

In 2020 the ROSA project conducted a scoping exercise to identify current reporting of BreastScreen participation and national-level outcomes according to factors of interest for risk-based screening, including information up to January 2020.

The scoping review was used as the basis for the manuscript 'Carle, C., Velentzis, L.S. and Nickson, C. (2022). BreastScreen Australia national data by factors of interest for risk-based screening: routinely reported data and opportunities for enhancement. Australian and New Zealand Journal of Public Health, 46: 230-236. https://doi.org/10.1111/1753-6405.13203. (See Appendix, Section 7).

In updating the content for that manuscript to October 2020, we identified that the 2020 version of the BSAMR (Australian Institute of Health and Welfare 2020a) included a 'Spotlight on population groups', which included additional detail on 2017-2018 BreastScreen participation for population subgroups of interest that had not been previously presented in the ROSA technical reports. Those updates are provided here, as a supplement to the May 2020 scoping report.

2.3 Aims

1. To describe screening participation in the BreastScreen Australia program by factors of interest for risk-based screening.
2. To describe national-level screening outcomes in the BreastScreen Australia program by factors of interest for risk-based screening.

2.4 Research questions

1. How does BreastScreen participation vary by factors of interest for risk-based screening?
2. How do BreastScreen screening outcomes vary by factors of interest for risk-based screening nationally?

2.5 Methods

Methods are described as for the May 2020 scoping report, except for the supplemental information arising from the 2020 BSAMR report (Section 2.5.5), **Error! Bookmark not defined.**).

2.5.1 PICO framework

The PICO (population, intervention/exposure, comparisons, outcomes) frameworks for this summary are shown in Table 2 (PICO 1 – BreastScreen participation by factors of interest for risk-based screening) and Table 3 (revised PICO 2 – National BreastScreen outcomes by factors of interest for risk-based screening).

Table 2. PICO framework, BreastScreen participation by factors of interest for risk-based screening (PICO 1).

Population	***Intervention/ exposure***	***Comparison***	***Outcomes***	***Publication type***
Asymptomatic women aged 40+ eligible to participate in the BreastScreen Australia program.	BreastScreen participation in factor sub-strata.	BreastScreen participation in another factor sub-strata or entire cohort.	**Program participation:** Participation rates Rescreening rates by screening round where reported.	Peer-reviewed literature National BreastScreen reports.

Table 3. PICO framework, national BreastScreen outcomes by factors of interest for risk-based screening (revised PICO 2).

Population	***Intervention/ exposure***	***Comparison***	***Outcomes***	***Publication type***
Asymptomatic women aged 40+ **participating** in the BreastScreen Australia program.	BreastScreen participation in factor sub-strata.	BreastScreen participation in another factor sub-strata or entire cohort	**BreastScreen performance indicators, including cancer detection**: • Screen-detected invasive breast cancer (all size and small) and DCIS rates • Interval cancer detection rates • Recall to assessment rates • Program sensitivity. **Other program performance indicators**: • False positive rates • Positive predictive value. **Detected tumour characteristics**: • Histology • Grade • Nodal status • Size • Hormone receptor status. by screening round where reported.	Peer-reviewed literature (using national-level BreastScreen data) National BreastScreen reports.

2.5.2 Selection criteria

The selection criteria for this summary are shown in Table 4 (page 9) and Table 5 (page 11). Factors of interest were:

- Age;
- Aboriginal or Torres Strait Islander;
- Socioeconomic status (e.g. SEIFA index);
- Geographical residence (e.g. remote/regional per ARIA+ classification, or other definition) or BreastScreen service area;
- Cultural and linguistical diversity (e.g., speaking language other than English at home, and migrant and refugee populations);
- Personal history of breast cancer/DCIS or breast disease (e.g., lobular carcinoma in situ, atypical ductal hyperplasia, atypical lobular hyperplasia);
- Family history of breast cancer/DCIS;
- Mammographic breast density;
- Genetic factors e.g. BRCA1/2 status;
- Reproductive risk factors (e.g. age at menarche, menopausal age, birth status, age at first birth);
- Hormone replacement therapy (HRT) use;
- Risk assessed by formal risk assessment tool in peer-reviewed literature (e.g. GAIL model (BCRAT), iPrevent, IBIS (Tyrer-Cuzick model).

Table 4. Study selection inclusion and exclusion criteria for research question 1 (BreastScreen participation by factors of interest for risk-based screening (PICO 1).

Selection criteria	*Inclusion*	*Exclusion*
Population	Asymptomatic women aged 40+ **eligible to participate** in the BreastScreen Australia program.	Non-Australian cohort Age group excludes women aged 40+ Analyses of sub-population not representative of screening population (e.g. analyses limited to women with phyllodes tumour type).
Intervention	BreastScreen participation in factor-stratified group of women.	Breast imaging/screening undertaken outside of BreastScreen program. An international/unspecified screening program.
Comparator	BreastScreen participation in another factor-stratified group or entire cohort.	None.
Outcome	Program participation: • Participation rates • Rescreening rates Outcomes reported separately by first and subsequent screening round where data available.	Awareness of BreastScreen program/breast cancer screening. Attitudes to BreastScreen program. Other qualitative/subjective outcomes. Duplicate data i.e. same data reported in another publication. Superseded data i.e. more recent data available.
Study design	Randomized controlled trials, cohort studies (including retrospective), case-control studies.	Case-series.
Publication type	Peer-reviewed journal articles. National-level BreastScreen reports.	Conference abstracts, reviews, letters, editorials, comments, presentations.
Publication date	2008 onwards.	
Language	English.	

For the purposes of this review:

- **Participation rates** are defined as the number of women who had a BreastScreen mammogram divided by the number of women who were eligible to have a BreastScreen mammogram in a 24-month period (or 12 months if annual screening interval), expressed as a percentage;
- **Rescreening rates** are defined as the number of women who returned to have a BreastScreen mammogram within 27 months of their most recent screen (or 15 months if annual screening interval) divided by the total number of women who attended the most recent screen, expressed as a percentage.

Table 5. Study selection inclusion and exclusion criteria for research question 2 (National BreastScreen outcomes by factors of interest for risk-based screening, revised PICO 2).

Selection criteria	*Inclusion*	*Exclusion*
Population	Asymptomatic women aged 40+ **participating** in the BreastScreen Australia program.	Non-Australian cohort. Age group excludes women aged 40+. Analyses of sub-population not representative of screening population (e.g. analyses limited to women with phyllodes tumour type).
Intervention	BreastScreen participation in factor-stratified group of women.	Breast imaging/screening undertaken outside of BreastScreen program An international/ unspecified screening program
Comparator	BreastScreen participation in another factor-stratified group or entire cohort.	None?
Outcome	**BreastScreen performance indicators, including cancer detection:** • Screen-detected invasive breast cancer (all size and small) and DCIS rates • Interval cancer detection rates • Recall to assessment rates • Program sensitivity **Other program performance indicators:** • False positive rates • Positive predictive value **Detected tumour characteristics:** • Histology • Grade • Nodal status • Size • Hormone receptor status Outcomes will be reported by first and subsequent screening rounds, and by screening interval, where data is available.	Outcomes not listed (e.g. survival, mortality, burden of disease (YLL, YLD, DALY*), costs, expenditure etc.) Duplicate data i.e. same data reported in another publication Superseded data i.e. more recent data available
Study design	Randomized controlled trials, cohort studies (including retrospective), case-control studies	Case-series
Publication type	Peer-reviewed journal articles (using national-level BreastScreen data) National-level BreastScreen reports	Conference abstracts, reviews, letters, editorials, comments, presentations
Publication date	2008 onwards.	
Language	English.	

*DALY: disability-adjusted life years; YLD: years lives with disability; YLL: years of life lost.

For the purposes of this review:

- **Screen-detected invasive breast cancer and DCIS rates** were defined as the number of new (incident) cases detected by BreastScreen Australia divided by the total number of screening episodes in a specified period, expressed per 10,000 women screened.
- **Interval cancers** were defined as invasive breast cancers diagnosed following a negative screen (i.e. not screen-detected) and before the next recommended screen at 24 months (or 12 months if screening annually).
- **Interval cancer detection rates** were the number of invasive cancers diagnosed following a negative screen but before the next recommended screen, divided by the total number of screening episodes in a specified period, expressed per 10,000 women-years.
- **Program sensitivity** was defined as the number of screen-detected invasive cancers detected following a positive screen divided by the total number of invasive cancers (screen-detected + interval-detected) in a specified period, expressed as a percentage.
- **Recall to assessment rates** were defined as the number of screening episodes requiring recall for further assessment divided by the total number of screening episodes in a specified period, expressed per 100 screening episodes.

- **False positive outcomes** were defined as positive screening episodes with a benign final outcome after assessment.
- **False-positive rates** were defined as the number of false positive outcomes divided by the total number of screening episodes, expressed per 100 screening episodes.
- **Positive predictive value (PPV)** was defined as the proportion of positive screening episodes with a diagnosis of invasive breast cancer at assessment in a specified period, expressed as a percentage.
- **Jurisdiction**, unless otherwise specified, describes state and territory level programs and their respective outcomes.

2.5.3 Grey and peer-reviewed literature searches

National-level BreastScreen reports

To identify routinely reported national-level data stratified according to the factors of interest, we examined governmental BreastScreen Australia reports obtained from the Australian Government Department of Health cancer screening website (Australian Government Department of Health 2020) and the AIHW website (Australian Institute of Health and Welfare 2020b) published from 1 January 2008 to 9 January 2020. We included publications from 2008 to target studies reporting outcomes since BreastScreen's transition from film to digital mammographic screening. In addition, we subsequently reviewed the 2020 version of the BSAMR (Australian Institute of Health and Welfare 2020a) and its associated data (available from https://www.aihw.gov.au/reports/cancer-screening/breastscreen-australia-monitoring-report-2020/data) noting that this version of the report included more detailed participation information for population subgroups of interest than that available in previous reports. That more detailed information is reported here however other results already reported were not updated due to resource limitations.

Peer-reviewed literature

To identify additional factor-stratified participation and outcome data that could potentially be routinely reported, on 9 January 2020 we searched for relevant peer-reviewed journal articles on Medline and Embase databases published from 1 January 2008 to 7 January 2020. Search terms were combined for breast, DCIS, screening, mammography and Australia and states/territories. For details of the search strategy see Appendix 2.10.3 (page 48).

For completeness, the AIHW BreastScreen Reference Database (Australian Institute of Health and Welfare 2019b) version dated 11 December 2019 was used as a secondary source to identify relevant peer-reviewed literature.

2.5.4 Study selection and data extraction

Publications were selected systematically. The full text of any articles that might meet the inclusion criteria were collected. Articles were included if they reported a relevant outcome stratified by a factor of interest for populations of women aged 40 years and above eligible to participate or participating in the BreastScreen Australia program. Eligible peer-reviewed publications included randomised controlled trials, cohort studies, case-control studies, or systematic reviews thereof. Articles that did not meet selection criteria were excluded with the reasons for exclusion documented.

For included studies, prespecified study details and data were extracted.

BreastScreen participation was summarised at a national level, with some jurisdiction-level findings included to help characterise participation by factors where no national data was available.

Outcomes were reported only at a national level. Outcomes within jurisdictions or regions are provided in a separate section within this chapter (Section 3, starting page 51).

2.6 Results

2.6.1 Data sources

BreastScreen reports

Data meeting the inclusion criteria were extracted from the annual BSAMR 2019 (Australian Institute of Health and Welfare 2019a, and two one-off reports i.e: 'AIHW Analysis of Breast Cancer Outcomes and Screening Behaviour for BreastScreen Australia Report 2018' (AIHW 2018) (Australian Institute of Health and Welfare 2018a) and 'BreastScreen Australia Evaluation: Evaluation Final report 2009' (BSA-E 2009) (Australian Institute of Health and Welfare 2009). Previous BSAMRs were deemed ineligible as data of interest were superseded, however, notable year-on-year changes were highlighted.

Peer-reviewed literature

Searches retrieved 1074 deduplicated records for screening: 1074 from Medline and Embase databases and none from the BreastScreen Reference Database. Of these, 976 were excluded based on title, abstract or publication type and the full texts of 98 references collected for further screening.

Of these 98 references, 92 were excluded (see list of excluded studies with reasons cited, Table 23, page 48), so that six relevant peer-reviewed studies published from 2012-2017 with data ranging from 1991-2017 were available for inclusion. Of these six studies, five studies (Beckmann, Roder, et al. 2013; Hughes et al. 2014; Roder et al. 2012; Savaridas et al. 2017; Weber et al. 2013) reported national or jurisdiction-level participation data (PICO 1) and two studies (Roder et al. 2012; Roder et al. 2014) reported national-level outcomes data (PICO 2).

2.6.2 Data availability

Data availability is summarised for participation (Table 6, page 24), cancer detection (Table 7, page 25), BreastScreen and other program performance indicators (Table 8, page 26), and tumour characteristics at detection (Table 9, page 26).

BreastScreen participation

Data from national-level BreastScreen reports and peer-reviewed literature are summarised in various tables (Table 10 to Table 18, starting page 28). Findings are summarised by factors of interest below.

Age

Nationally, participation was predictably higher in the target age range (50-74 years, at 54.5% 2016-17) than in younger (14%) or older (7%) women (Table 10, page 28). Participation by women aged 40-49 varied greatly between jurisdictions (over 3.1-fold for women aged 40-49 years in QLD and TAS, compared to NSW and NT) (Table 11, page 29). All age groups demonstrated a 'loyalty effect' with increasing rescreening rates with each screening round (first, second, and third or subsequent) both nationally (Table 13, page 31) and by jurisdiction (Table 14, page 32) (Australian Institute of Health and Welfare 2019a).

Indigenous women

Nationally, Indigenous women had markedly low participation rates (41% overall, compared to 54% for non-Indigenous women; 2016-17) (Table 10, page 28) (Australian Institute of Health and Welfare 2019a). and were less likely to return for rescreening (average 60% for all rounds, compared to 70% for non-Indigenous women; 1996-2005) (Table 13, page 31) (Roder et al. 2012). Given the 'loyalty effect' described above, it would be useful to report these figures by screening round (first, second, subsequent). A 2017 study found that in Western Australia, Indigenous women had lower rescreening rates after their first-round participation than non-Indigenous women (52% versus 69%; 2007-13) (Table 15, page 33) (Savaridas et al. 2017).

Socioeconomic status

Participation varied slightly between socioeconomic groups. 2016-17 national data showed women in the middle quintile of socioeconomic status were slightly less likely to participate than other women (52% versus 54%-56%) (Table 10, page 28); this was a change from 2015-16 data which showed women in the lowest socioeconomic quintile participated least (Australian Institute of Health and Welfare 2019a, 2018b). A 2017 Western Australia study showed women in the lowest socioeconomic quintile were least likely to return for a second-round screen (61% versus 67%-71% in other quintiles; 2007-13), with only minor differences between other socioeconomic groups (Table 15, page 33) (Savaridas et al. 2017).

Location of residence or screening

At a national level, participation was markedly lower (43% in 2016-17) among women living in remote locations with only slight variation between other remoteness categories (ASGS postcode-of-residence) (Table 10, page 28). Western Australian studies found rescreening after first round participation was lower for women living in the 'Southwest' region (70% metropolitan, 68% rural, 59% Southwest; 2007-13) (Table 15, page 33) (Savaridas et al. 2017), and that all-round rescreening was slightly lower for following screening episodes provided by mobile (van) rather than at clinic-based services (65% versus 68%; 1999-2007) (Table 15, page 33) (Hughes et al. 2014). In NSW, self-reported screening participation was lower among women residing in major cities (70% versus 75% for remote and very remote women; 2006-10) (Table 12, page 30) (Weber et al. 2013).

CALD women

Nationally, women speaking a language other than English at home were overall less likely to participate in screening (46% versus 56%; 2016-17) (Table 10, page 28), declining further from the previous year (from 50%) (Australian Institute of Health and Welfare 2018b). These results were mirrored at jurisdiction-level; e.g. in NSW in 2006-10 English speaking women reported 73% participation within the last 24 months compared to 65% of non-English speaking women (Table 12, page 30) (Weber et al. 2013). For migrant women in NSW, participation in screening was higher for women born in a predominantly English-speaking country (Weber et al. 2013). Western Australian women born outside Australia were slightly more likely to rescreen (70% versus 68%; 2007-13) (Table 15, page 33) (Savaridas et al. 2017).

Personal or family history of breast cancer

During 2000-2012, on average 1.2% (Australian Institute of Health and Welfare 2018a, published Table 6.3.7, page 105) of all screening participants reported a personal history of breast cancer or DCIS at the time of screening, and 10% of young women (40-49 years) and 6.4% of women in the target age group (50-69 years) reported a family history of breast cancer at the time of screening ((Australian Institute of Health and Welfare 2018a, published Table 6.3.1, page 102).

Personal history of cancer

Western Australian women reporting a personal history of breast cancer were slightly more likely to rescreen with BreastScreen (71% versus 69% without a personal history; 2007-13), while women with a history of ovarian cancer were less likely to rescreen with BreastScreen (63% versus 69% without a personal history of ovarian cancer; 2007-13) (Table 15, page 33) (Savaridas et al. 2017).

Family history of breast cancer

A large NSW study conducted in 2006 found self-reported participation (within the last 24 months) in breast cancer screening was greater among women who had a family history of breast cancer (81%, compared to 73% for family history of non-breast cancers and 70% for women without a family history) (Table 12, page 30) (Weber et al. 2013). A small 2012 study in South Australia found self-reported history of BreastScreen participation (ever) did not vary with family history of breast cancer (Table 12, page 30) (Beckmann, Roder, et al. 2013).

Reproductive risk factors

A 2012 South Australian study found that self-reported BreastScreen participation (ever) was higher among women who had their first child when younger than 30 years old (68% versus 53%, p=0.001) or had undergone menopause at 55 years or older (88% versus 62%, p<0.001), and did not vary between women who had or hadn't given birth or by age at menarche (Table 12, page 30) (Beckmann, Roder, et al. 2013). With a wide age range (40-84 years) of respondents, some differences may have been due to cohort effects, rather than due to the factors described.

HRT use

Self-reported participation in BreastScreen was been found higher for women who had ever used HRT compared to non-users in both NSW (42% of respondents, 82% versus 66%; within the last 24 months; 2006-10) (Weber et al. 2013) and South Australia (28% of respondents, 91% versus 55%, p<0.001; ever-screened) (Table 12, page 30) (Beckmann, Roder, et al. 2013).

Breast density, BRCA 1/2 status or risk assessment tools

No data on BreastScreen participation were identified according to breast density, BRCA 1/2 status or for women formally assessed by a risk assessment tool.

2.6.3 Cancer detection, detected tumour characteristics and BreastScreen performance

Age

National BreastScreen reports (Table 16, page 34) showed that screen-detected invasive cancer rates (among screening participants in 2017) increased with age at both first and subsequent round of screening, with approximately two-fold increases from younger women (40-49) to the target age range (50-74) and then to older women (75+). The effects were similar for first-round screen-detected DCIS, but not for subsequent-round DCIS (Table 16, page 34) (Australian Institute of Health and Welfare 2019a). Of note, first-round rates among women aged 75+ increased between 2016 and 2017, from 214.3 to 258.9 invasive breast cancers and from 42.9 to 54.5 DCIS per 10,000 women screened (Australian Institute of Health and Welfare 2018b, 2019a). Participation rates stratified by age and screening round may help to explain this difference but were not available.

Around half of screen-detected invasive cancers and a third of interval cancers were small (≤15mm in diameter) at the time of detection (between 2002-12) with the majority (68%-84%) invasive ductal carcinoma subtype (Table 18, page 37)(Australian Institute of Health and Welfare 2018a).

Rates of interval-detected cancers, defined as invasive breast cancers diagnosed following a negative screen (i.e. not screen-detected) and before the next recommended screen, were particularly high in older women (70+) attending their first round of screening (16 vs 8 interval cancers per 10,000 women-years in women aged 70+ and 50-69 years, respectively; 2012-14) (Table 16, page 34)(Australian Institute of Health and Welfare 2019a). This was likely to be at least partly due to overall increased breast cancer risk with age. Nationally, however, 2000-12 data as analysed by the AIHW, showed program sensitivity and positive predictive value increased with age (Table 17, page 35) (Australian Institute of Health and Welfare 2018a). This effect, i.e. improved precision of detecting cancers on screening, may have been driven by reduced masking as breast density decreases with age, however this cannot be directly inferred from this data. Recall to assessment rates (in 2017) and false positive screening rates (in 2012-14) were similar at all ages examined (Table 17, page 35) (Australian Institute of Health and Welfare 2018a, 2019a).

Screening round

Interval cancer rates among screened women were comparable between first and subsequent round screening in the target age range of 50-69 years (8.1 versus 9.1 per 10,000 women-years, Table 16, page 34)(Australian Institute of Health and Welfare 2019a).

Nationally, women in the target age range (50-74 years in 2017) had higher rates of both invasive breast cancer (2.2-fold) and DCIS (2.5-fold) at first round screening compared to subsequent round screening (Table 16, page 34) (Australian Institute of Health and Welfare 2019a). This was likely to be driven by the 'mop-up' effect of prevalent (first-round) screening compared to subsequent round screening, where first round screening detects more slow growing tumours and subsequent round screening is more likely to detect incident cancers arising since previous screens. These differences were smaller for younger women (40-49 years) for both screen-detected invasive breast cancers (1.9, versus 2.2 for ages 50-74) and DCIS (1.5, versus 2.5 for ages 50-74); this may have been driven by lower rates of prevalent cancers in this age group at their first screen. For older women (75+), screen-detected invasive breast cancer and DCIS rates were more similar between first (2.2 versus 2.2) and subsequent round (3.0 versus 2.5) of screening than for the target age range (50-74 years) (Table 16, page 34) (Australian Institute of Health and Welfare 2019a).

Population-level outcomes by mode of detection

Of interest to this project, data linked and analysed by the AIHW (Australian Institute of Health and Welfare 2018a) provided national figures of the distribution of invasive breast cancers in the historical target age range for screening, according to mode of detection and/or screening history (screen-detected, interval cancer (i.e. detected within BreastScreen), detected outside of BreastScreen (ever screened, never screened)) (see supplementary Figure 9 to Figure 12, starting page 45) and supplementary data available in Table 21, page 47). Note the proportion of interval cancers was markedly low in this report as interval cancers were defined as breast cancers *"diagnosed after a negative screen through BreastScreen in the interval between screens"* (page 15, (Australian Institute of Health and Welfare 2018a)). This differs from the standard definition of interval cancers (see page 6 of this report) whereby the majority of interval cancers are detected outside of BreastScreen and would be captured in this data as breast cancers detected outside of BreastScreen in women who have ever screened.

These data show (Australian Institute of Health and Welfare 2018a):

- For women aged 50-69 years participating in BreastScreen from 2000-2012, 43.5% of all Australian cancers were detected through the BreastScreen program.
- Approximately 27% of cancers diagnosed outside BreastScreen were in women who had attended BreastScreen at some point (Figure 9, page 45).

- Cancers detected outside of the BreastScreen program were greatest for women aged 40-49 who had never screened (Figure 10, page 46).
- Women living more remotely, compared to regionally or in major cities, and women of higher socioeconomic status (SEC), compared to median or lower SES, were less likely to have a cancer detected by BreastScreen (Figure 10, page 46).

Indigenous women

The 2020 BSAMR reported that Indigenous women were less likely to participate in BreastScreen than non-Indigenous women (25% versus 34% of eligible women aged 40+; Table 19, page 38). Age-stratification of the data showed the disparity in participation was greatest in women aged 50-74 years (38% Indigenous versus 54% non-Indigenous; Table 19, page 38), whilst participation was similar by Indigenous status among women aged 40-49 years (~13%) and 75+ years (~9%) (Figure 4, page 39). Participation by 5-yearly age and Indigenous status was also reported (data not shown) (Australian Institute of Health and Welfare 2020a, published Table S 1.9). For women in the target age range for BreastScreen (50-74 years), participation was lower among Indigenous than non-Indigenous women in all states and territories (Figure 4, page 39). South Australia had the highest participation rate for Indigenous women (45%), versus 55% for non-Indigenous women. The Northern Territory had the lowest participation for both groups (26% for Indigenous women, 42% for non-Indigenous women). The biggest disparity was seen in Western Australia, with 30% Indigenous participation compared to 56% for non-Indigenous women (Figure 4, page 39). Participation by 10-yearly age, Indigenous status and jurisdiction was also reported (data not shown) (Australian Institute of Health and Welfare 2020a, published Table A3.11).

Historical national data from 2001-05, showed that invasive screen-detected cancer rates in women aged 50-69 were lower for Aboriginal or Torres Strait Islander women compared to all women at both first round of screening (38 vs 63 per 10,000 women screened) and subsequent round of screening (34 vs 43) (Table 16, page 34) (Australian Institute of Health and Welfare 2009). National data from 1996-2005 showed positive predictive values were lower in Indigenous women aged 50-69 (6.5% compared to 8.1% for non-Indigenous women), but not for DCIS (both 2%) (Table 17, page 35) (Roder et al. 2012). This publication also reported that screen-detected cancers among Indigenous women were larger (48% small (<=15mm) versus 56% in non-Indigenous women, p=0.003) and more likely to involve the nodes (55% vs 44%, p<0.001) (national BreastScreen data; women aged 50-69 years in 1991-2006; (Table 18, page 37).

Among women aged 50-74 years, BreastScreen participation by Indigenous women was lower across all areas (determined by residential postcode) compared to non-Indigenous women (Figure 4, page 40). Indigenous women residing in inner regional areas had the highest participation (42%), and those living in remote areas has the lowest participation (32%). Non-Indigenous participation was highest for women residing in outer regional areas (57%), and lowest for women living in very remote areas (53%).

When stratifying the data according to 10 year age groups, the lowest participation rates among Indigenous women in the BreastScreen target age range (50-74 years) were observed for remote and very remote areas compared to urban and very remote areas for non-Indigenous women (Figure 4, page 40).

Across ages 50-59, 60-69, and 70-74 years, there was greater disparity in participation by Indigenous status across remoteness categories. For example, in women aged 60-69 years, participation in inner regional areas compared to remote areas was 48% to 35% for Indigenous women, and 62% to 60% for non-Indigenous women, respectively (Table 20, page 40). In women

aged 40-49 years living remotely and very remotely, Indigenous participation was approximately half the rate of non-Indigenous women (13-16% versus 24-29%) (Table 20, page 40).

Location of residence or screening

The 2020 BSAMR reported that remoteness (determined by residential postcode) appeared to have differing effects on BreastScreen participation for different age groups. For example, for women aged 40-49 years participation increased with increasing remoteness, at 13% for women living in major cities, compared to 21% for women living remotely and very remotely (Figure 6, page 41). By contrast, in women aged 50-74 years, women living most remotely were least likely to participate (43%) when compared to other areas (53-57%). Participation by 5-yearly age and remoteness was also reported (data not shown) (Australian Institute of Health and Welfare 2020a, published Table S1.5).

Historical national data showed that women in the target age group (50-69 years in 2005-05) living remotely had the highest rates of invasive screen-detected cancers compared to all women (85 vs 63 per 10,000 women screened). In the same women, those living in 'very remote' locations had a notably lower rate of small cancers detected at first round screening (20 per 10,000 women screened vs 35 for all women) and DCIS detection rates were also notably lower in women from very remote areas (Table 16, page 34) (Australian Institute of Health and Welfare 2009).

Among women aged 40 and above, rates of screen-detected cancers (62-67 per 10,000 women screened), small screen-detected cancers (28-30 per 10,000 women screened) and interval cancers (6-7 per 10,000 women-years) at first round were similar across screening service locations (i.e. metropolitan, non-metropolitan or state/territory wide) (Table 16, page 34)(Roder et al. 2014).

Socioeconomic status

The 2020 BSAMR reported little variance in BreastScreen participation by socioeconomic area according to age, with participation ranging from 13-15% for women aged 40-49 years, and 52-55% for women aged 50-74 years across socioeconomic areas (Figure 5, page 41). Participation by 5-yearly age and socioeconomic area was also reported (data not shown) (Australian Institute of Health and Welfare 2020a, published Table S 1.7).

CALD women

The 2020 BSAMR reported that women speaking a main language other than English at home participated less in BreastScreen at ages 40-49 years, and 50-74 years (Figure 7, page 42). AIHW stated that analysis based on main language spoken at home should be interpreted with caution as some jurisdictions did not use the 'not stated' category, and there may have also been differences in how these data were collected. Participation by 5-yearly age and language spoken at home is also reported (data not shown) (Australian Institute of Health and Welfare 2020a, published Table S1.11).

Historical national invasive screen-detected cancer rates were lower in women of non-English speaking households compared to all women aged 50-69 years in 2001-05 at first round screening (56 vs 63 per 10,000 women) and at subsequent screens (34 versus 43) (Table 16, page 34) (Australian Institute of Health and Welfare 2009).

Personal or family history of breast cancer

Compared to women with no personal history of breast cancer, national screen-detected invasive breast cancer rates were higher for women aged 40+ (in 2000-12) reporting a personal history of breast cancer (invasive or DCIS) (128 vs 64 per 10,000 women screened) or family history of breast cancer (invasive or DCIS) (90 vs 61) (Table 16, page 34)(Australian Institute of Health and Welfare

2018a). These data were not available by screening round, however this would be of interest to better understand the impact of annual screening offered to women with a personal or family history of breast cancer.

Breast density, BRCA 1/2 status, Reproductive risk factors, HRT use or Risk assessment tools

No national BreastScreen outcomes data were reported by breast density, BRCA 1/2 status, reproductive risk factors or HRT use, or for women formally assessed by a risk assessment tool.

2.7 Discussion

2.7.1 BreastScreen participation

BreastScreen participation is driven by service access and uptake. Understanding and monitoring BreastScreen participation with any introduction of risk-based screening would be critical to help ensure that the expected benefits are delivered to all women living in Australia.

Data availability

We reported in May 2020 that BreastScreen participation data were available nationally by age, Indigenous status, socioeconomic status, geographical residence, and for culturally and linguistically diverse groups. Age-stratified participation rates were available for all jurisdictions. Peer-reviewed literature provided some additional insights for participation in New South Wales (NSW), South Australia (SA) and Western Australia (WA). BreastScreen programs stratified by geographical residence, culturally and linguistically diverse groups, and for women with a personal or family history of breast cancer, reproductive risk factors and history of HRT use. Rescreening rates were available nationally by age and Indigenous status, for all jurisdictions by age, and for WA by Indigenous status, socioeconomic status, geographical residence, BreastScreen service area and for women of culturally and linguistically diverse background or with a personal history of breast or ovarian cancer.

Findings

Compared to national-level screening participation in women aged 50-74 (55%), BreastScreen participation was markedly lower in women identifying as Indigenous (41%), women living very remotely (43%), and women living in non-English-speaking households (46%), with only minor differences among women in middle to lowest SEIFA[7] quintiles of socio-economic status (52-54%, respectively) (Table 10, Page 28). Across jurisdictions, participation rates were similar (53-58%) for women in the BreastScreen target age range (50-74 years), except for NT (38%) which the AIHW notes has limited BreastScreen coverage to remote areas ((Australian Institute of Health and Welfare 2019a), Table S1.2 footnote, *Indicator 1: Participation Supplementary data tables*). Participation rates among women aged 40-49 varied greatly between jurisdictions (e.g. 30% in Tasmania compared to 14% nationally) (Table 11, page 29).

Self-reported BreastScreen participation was available in the peer-reviewed literature for migrant women and women reporting a history of HRT use and reproductive risk factors (Beckmann, Roder, et al. 2013; Weber et al. 2013), however caution should be applied when interpreting these data as the populations may have been small or highly selected.

[7] Socio-Economic Indexes for Areas, produced by the Australia Bureau of Statistics.

We did not find evidence for participation rates regarding different breast cancer risk assessment scores such as could be generated using a range of tools. We did find a study of South Australian women aged 50-69 which reported that, compared to women who had not participated in any screening, BreastScreen participants had more established breast cancer risk factors, higher risk scores on the 'Pfeiffer' risk prediction model, and no significant difference in 'Gail' risk model scores (Beckmann et al. 2013). This finding was not reported in our results as it did not fit the PICO framework, but it is of interest and it would be useful to know the participation rates for different population levels of the 'Pfeiffer' risk prediction model.

Our review indicated that rescreening rates could be lower for Indigenous women, women living in more remote locations or in major cities, women living in areas of lower socioeconomic status, and women attending their first 1-2 screening rounds (compared to women attending later-rounds of screening). We found some evidence of higher rescreening among women reporting a personal history of cancer.

Current patterns in BreastScreen participation are an important consideration for any potential introduction of risk-based breast screening in Australia. Risk-based screening could potentially improve or worsen existing disparities in participation, depending on how it may be delivered and communicated and what it requires of women seeking breast screening. Lower rescreening rates in first rounds of screening than in later rounds (i.e. the 'loyalty effect') could be impacted by more risk-based approaches to screening, although it is difficult to assess whether this would improve or worsen participation and outcomes overall.

Update from the 2020 BSAMR

The BSAMR 2020 'Spotlight on population groups' provided additional BreastScreen participation (performance indicator 1) for 2017-18 by the following factors of interest:

- Indigenous status and age;
- Indigenous status and jurisdiction;
- Indigenous status and remoteness;
- Indigenous status, remoteness, and age;
- Socioeconomic area and age;
- Remoteness and age;
- Main language spoken at home (as an indicator of cultural and linguistic diversity) and age.

These new national-level data indicated that Indigenous women aged 50-74 years had a lower overall participation rate in BreastScreen (2016-17) compared to non-Indigenous women (participation 38% Indigenous versus 54% non-Indigenous) (Table 19, page 38), whereas participation rates for Indigenous women aged 40-49 and 75+ years were approximately equivalent to rates in non-Indigenous women. Indigenous participation was also lower than non-Indigenous participation in all states and territories, with some jurisdictions having greater disparities than others (Figure 4, page 39).

Stratification of Indigenous and non-Indigenous participation by remoteness, and further by age, provides insights into which subgroups may benefit from targeted interventions to improve BreastScreen attendance. The data indicated that Indigenous participation was lower in women aged 50-74 years living remotely or very remotely compared to regional or urban areas (Figure 4, page 40).

There was little variance in BreastScreen participation by socioeconomic area when stratified by age. Participation according to remoteness appears to be associated with age. For example, in younger women (40-49 years) participation increased with increasing remoteness, while for women

in the target age range (50-74 years) participation decreased as women live more remotely (Figure 6, page 41).

The following caveats should be considered when interpreting information from the 2020 BSAMR:

(1) Data were for one reporting year (2017-18) and may not be representative of all reporting years. Year-on-year reporting would be useful to analyse emerging trends in participation for the population subgroups of interest.
(2) Limitations of how information was collected and recorded may impact the accuracy of the data. For example, Indigenous status was self-reported, and therefore accuracy of Indigenous participation rates would be affected if women choose not to identify as Indigenous at the time of screening. For main 'language spoken at home' some jurisdictions did not use the 'not stated' category, resulting in differences in how these data were collected and reported (Australian Institute of Health and Welfare 2020a).
(3) The AIHW noted that due to higher proportions of Indigenous Australian participants living in the lowest socioeconomic areas (with 'most disadvantage' and in 'Very remote' areas), there was "significant overlap" of women across population subgroups (Australian Institute of Health and Welfare 2020a).

Despite these limitations, detailed reporting of participation for these population subgroups will help achieve the BreastScreen objective to provide services that are equitable, acceptable, and appropriate to the needs of the population and equally accessible to all women in the target age group (BreastScreen Australia 2019). These data provide a benchmark for BreastScreen attendance for these population subgroups and can act as a template for potential future routine monitoring. This may reveal emerging trends for further investigation, including monitoring and, ideally, improving existing disparities in participation.

2.7.2 Cancer detection, detected tumour characteristics and BreastScreen performance

Data availability

At the time of our May 2020 scoping review, national-level cancer detection (outcomes) data were partially available for age, Indigenous status, socioeconomic status, geographical residence, BreastScreen service area, culturally and linguistically diverse groups, and for women with a personal or family history of breast cancer. Other national-level outcomes data were only available by age (tumour histology and size, recall rates, program sensitivity, false positive screening rates and positive predictive value[8] (PPV)) and Indigenous status (tumour histology, nodal status and size, and recall rates and PPV).

BreastScreen routinely collects information about many factors of interest (e.g. Indigenous status, language spoken at home, personal and family history of breast cancer, and socioeconomic status as estimated from reported postcode of residence) (Australian Institute of Health and Welfare 2019a), but not reproductive risk factors (such as, age at menarche, birth history, age at menopause). It would be of value, if feasible, to expand BreastScreen routine reporting to include outcomes according to these factors.

[8] Positive predictive value (PPV) as used here refers to proportion of recalled screens that result in a screen-detected cancer.

Findings

Increasing cancer detection rates, program sensitivity and PPV highlight the increasing impact of BreastScreen with age. Age outcomes are often reported according to targeting of BreastScreen services (e.g. 40-49, 50-74 and 75+), however outcomes for smaller age groups would provide additional information about the impact and experience of BreastScreen across 25 years of targeted participation. Reporting outcomes stratified by age and other factors of interest (e.g. family history of breast cancer by 5-yearly age) would enable better monitoring and evaluation of outcomes with the introduction of any risk-based screening protocols.

Nationally, women with a personal or family history of breast cancer have higher rates of screen-detected invasive breast cancers (Table 16, page 34). Larger cancers and increased nodal involvement among Indigenous women is of concern (Table 18, page 37).

The first round of screening is an important screen for identifying prevalent cancers particularly in the target age group, with markedly higher rates of cancer detection (in 2017, national rates of screen-detected cancers in women aged 50-74 were 108 at first round screening and 49 at subsequent rounds of screening) (Table 16, page 34). Higher program sensitivity observed in first round screening is driven by higher rates of screen-detected cancers rather than reduced interval cancer rates (Table 16, page 34); this means that any risk-based protocols aiming to reduce the incidence of interval cancers are equally important at all screening rounds. DCIS detection at subsequent round screening is particularly common in older women, consistent with reduced masking through lower breast density and increasing breast cancer risk with age. It is highly likely that some of these DCIS cases would not have been detected without screening in the woman's lifetime (i.e. they are 'overdiagnosed').

2.7.3 Gaps and opportunities

This scoping review identified several gaps in publicly available information on national-level BreastScreen screening outcomes by factors of interest for risk-based screening. For example, interval cancers and screen-detected tumour characteristics were not reported according to key breast cancer risk factors including personal or family history or breast cancer, or mammographic breast density.

A separate analysis of jurisdiction-level data (see Section 3 of this chapter), bridges some of these evidence gaps, but not all. Age-stratified information for cancer detection and BreastScreen performance indicators was available for all states and territories in the annual BSAMR. Some outcomes were reported in the peer-reviewed literature for women attending BreastScreen NSW, Victoria, and SA. For example, women using HRT attending BreastScreen SA had higher cancer detection rates (both invasive/DCIS screen-detected cancers and interval cancers) (Beckmann et al. 2013), and based on data from BreastScreen Victoria, program sensitivity was reduced for women currently using HRT (Kavanagh et al. 2008).

Overall, the findings of these analyses indicate age-stratified information is routinely collected and reported for BreastScreen performance indicators (including cancer detection) nationally (and for all state and territory programs) as published annually in the BSAMR. Invasive breast cancer detection is available nationally for some population subgroups of interest, for example, according to personal or family history of breast cancer, Indigenous status, remoteness, and language spoken at home, however, data is from 2012 or earlier and, thus, would benefit from being updated.

Some data was only available from survey data, and the reported associations should be interpreted with an understanding of the study design. For example, the South Australian survey (Beckmann et al. 2013) of women aged 40-84 found that women with a history of HRT use or older

age at menopause reported higher BreastScreen participation rates, but these figures should be interpreted with caution as these factors are possibly related, and the differences in outcomes may be influenced by cohort effects (e.g. the comparator for menopause onset over the age of 55 was women with earlier menopause or women who had not yet reached menopause).

The data availability summary tables presented here (Table 6 through to Table 9, starting page 24) could be used as templates for target levels (and currency) of reported BreastScreen data. Some data could be extracted from existing, routinely collected BreastScreen data (as is currently done for many factors and outcomes for the regular, and extremely valuable, AIHW 'BreastScreen Australia Monitoring Reports'). Devising this data collection and analysis would best be done in consultation and collaboration with all BreastScreen services, AIHW, and data custodians such as state cancer registries.

Other data would require either additional routine data collection or collection and reporting of specific survey data (e.g. outcomes according to mammographic density or reproductive history). Data linked by AIHW (Australian Institute of Health and Welfare 2018a) provides further insights. Some outcomes for factors in BreastScreen participants additional to those routinely collected by BreastScreen could feasibly be reported from the lifepool cohort (http://www.lifepool.org/) with the limitation that this cohort is mostly Victorian women recruited at subsequent rounds of screening, with very low representation from younger women.

2.8 Tables and figures

2.8.1 Data availability

Table 6. Data available in national-level BreastScreen reports and peer-reviewed literature published from 2008 onwards for PICO 1 (BreastScreen participation), by factors of interest for risk-based screening.

	Participation rate		***Rescreening rate***	
	Publication	***Jurisdiction, Data year(s)***	***Publication***	***Jurisdiction, Data year(s)***
Reported in national-level BreastScreen reports (overall)	BSAMR 2019	AUS 2016-17	BSAMR 2019	AUS 2015
	AIHW 2018	AUS 2015-16	AIHW 2018	AUS 2013
	BSA-E 2009	AUS 1996-2005	BSA-E 2009	AUS 2000-03
Reported by factors of interest for risk-based screening				
Age	BSAMR 2019	AUS, all jurisdictions 2016-17	BSAMR 2019	AUS, all jurisdictions 2015
	BSA-E 2009	AUS 1996-2005	AIHW 2018	AUS 2013
	Weber 2013	NSW 2006-10	Savaridas 2017	WA 2007-13
Aboriginal or Torres Strait Islander	BSAMR 2019	AUS 2016-17	Roder 2012	AUS 1996-2005
	AIHW 2018	AUS 2015-16	Savaridas 2017	WA 2007-13
	BSA-E 2009	AUS 1996-2005		
	Roder 2012	AUS 1996-2005		
Socioeconomic status	BSAMR 2019	AUS 2016-17	Savaridas 2017	WA 2007-13
	AIHW 2018	AUS 2015-16		
	BSA-E 2009	AUS 1996-2005		
Geographical residence/ BreastScreen service area	BSAMR 2019	AUS 2016-17	Savaridas 2017	WA 2007-13
	AIHW 2018	AUS 2015-16	Hughes 2014	WA 1999-2007
	BSA-E 2009	AUS 1996-2005		
	Weber 2013	NSW 2006-10		
Culturally and linguistically diverse	BSAMR 2019	AUS 2016-17	Savaridas 2017	WA 2007-13
	AIHW 2018	AUS 2015-16		
	BSA-E 2009	AUS 1996-2005		
	Weber 2013	NSW 2006-10		
Personal history of breast cancer or DCIS	Not available		Savaridas 2017	WA 2007-13
Personal history of breast disease	Not available		Not available	
Family history of breast cancer or DCIS	Beckmann 2013	SA 2012	Not available	
	Weber 2013	NSW 2006-10		
Breast density	Not available		Not available	
BRCA 1/2 status	Not available		Not available	
Reproductive risk factors	Beckmann 2013	SA 2012	Not available	
HRT use	Beckmann 2013	SA 2012	Not available	
	Weber 2013	NSW 2006-10		
Risk measured by an assessment tool	Not available		Not available	

Table 7. Cancer detection data in national-level BreastScreen reports and peer-reviewed literature published from 2008 onwards for PICO 2 (national-level breast cancer outcomes), by factors of interest for risk-based screening.

	Breast cancer detection							
	Screen-detected invasive breast cancer rates		***Screen-detected DCIS rates***		***Screen-detected small (≤15mm) invasive breast cancer rates***		***Interval (invasive) breast cancer rates***	
	Publication	***Data year(s)***	***Publication***	***Data year(s)***	***Publication***	***Data year(s)***	***Publication***	***Data year(s)***
Reported in national-level BreastScreen reports (overall)	BSAMR 2019	2017	BSAMR 2019	2017	BSAMR 2019	2017	BSAMR 2019	2012-14
	BSA-E 2009	2001-05	BSA-E 2009	2001-05	BSA-E 2009	2001-05	BSA-E 2009	1996-2003
Reported by factors of interest for risk-based screening								
Age	BSAMR 2019	2017	BSAMR 2019	2017	BSAMR 2019	2017	BSAMR 2019	2012-14
	BSA-E 2009	2001-05	BSA-E 2009	2001-05	BSA-E 2009	2001-05	BSA-E 2009	2000-03
Aboriginal or Torres Strait Islander	BSA-E 2009	2001-05	BSA-E 2009	2001-05	BSA-E 2009	2001-05	Not available	
	Roder 2012	1996-2005	Roder 2012	1996-2005				
Socioeconomic status	Not available		Not available		Not available		Not available	
Geographical residence	BSA-E 2009	2001-05	BSA-E 2009	2001-05	BSA-E 2009	2001-05	Not available	
BreastScreen service area	Roder 2014	2002-10	Not available		Roder 2014	2002-10	Roder 2014	2002-10
Culturally and linguistically diverse	BSA-E 2009	2001-05	BSA-E 2009	2001-05	BSA-E 2009	2001-05	Not available	
Personal history of breast cancer or DCIS	AIHW 2018	2002-12	Not available		Not available		Not available	
Personal history of breast disease	Not available		Not available		Not available		Not available	
Family history of breast cancer or DCIS	AIHW 2018	2002-12	Not available		Not available		Not available	
Breast density	Not available		Not available		Not available		Not available	
BRCA 1/2 status	Not available		Not available		Not available		Not available	
Reproductive risk factors	Not available		Not available		Not available		Not available	
HRT use	Not available		Not available		Not available		Not available	
Risk measured by an assessment tool	Not available		Not available		Not available		Not available	

Table 8. BreastScreen and other program performance indicator data available in national-level BreastScreen reports and peer-reviewed literature published from 2008 onwards for PICO 2 (national-level breast performance indicators), by factors of interest for risk-based screening.

	BreastScreen and other program performance indicators							
	Recall to assessment		***Program sensitivity***		***False positive rates***		***Positive predictive value***	
	Publication	***Data year(s)***	***Publication***	***Data year(s)***	***Publication***	***Data year(s)***	***Publication***	***Data year(s)***
Reported in national-level BreastScreen reports (overall)	BSAMR 2019	2017	BSAMR 2019	2012-14	BSAMR 2019	2017	BSAMR 2019	2017
	BSA-E 2009	2001-05	BSA-E 2009	2000-03			AIHW 2018	2000-12
Reported by factors of interest for risk-based screening								
Age	BSAMR 2019	2017	BSAMR 2019	2012-14	AIHW 2018	2000-12	AIHW 2018	2000-12
	BSA-E 2009	2001-05	BSA-E 2009	2000-03				
Aboriginal or Torres Strait Islander	Roder 2012	1996-2005	Not available		Not available		Roder 2012	1996-2005
Socioeconomic status	Not available		Not available		Not available		Not available	
Geographical residence /	Not available		Not available		Not available		Not available	
BreastScreen service area	Not available		Not available		Not available		Not available	
Culturally and linguistically diverse	Not available		Not available		Not available		Not available	
Personal history of breast cancer or DCIS	Not available		Not available		Not available		Not available	
Personal history of breast disease	Not available		Not available		Not available		Not available	
Family history of breast cancer or DCIS	Not available		Not available		Not available		Not available	
Breast density	Not available		Not available		Not available		Not available	
BRCA 1/2 status	Not available		Not available		Not available		Not available	
Reproductive risk factors	Not available		Not available		Not available		Not available	
HRT use	Not available		Not available		Not available		Not available	
Risk measured by an assessment tool	Not available		Not available		Not available		Not available	

Table 9. Data available in national-level BreastScreen reports and peer-reviewed literature published from 2008 onwards for PICO 2 (national-level breast cancer outcomes: tumour characteristics), by factors of interest for risk-based screening.

	Tumour characteristics at detection									
	Histology		***Tumour grade (1-3)***		***Node(s) involved***		***Size***		***Hormone receptor status***	
	Publication	***Data year(s)***	***Publication***	***Data year(s)***	***Publication***	***Data year(s)***	***Publication***	***Data year(s)***	***Publication***	***Data year(s)***
Reported in national-level BreastScreen reports (overall)	BSAMR 2019	2015	Not available		Not available		BSAMR 2019	2017	Not available	
	AIHW 2018	2002-12					AIHW 2018	2002-12		
							BSA-E 2009	1996-2005		

	Tumour characteristics at detection									
	Histology		***Tumour grade (1-3)***		***Node(s) involved***		***Size***		***Hormone receptor status***	
	Publication	***Data year(s)***	***Publication***	***Data year(s)***	***Publication***	***Data year(s)***	***Publication***	***Data year(s)***	***Publication***	***Data year(s)***
Reported by factors of interest for risk-based screening										
Age	AIHW 2018	2002-12	Not available		Not available		BSAMR 2019	2017	Not available	
							AIHW 2018	2002-12		
Aboriginal or Torres Strait Islander	Roder 2012	1991-2006	Not available		Roder 2012	1991-2006	Roder 2012	1991-2006	Not available	
Socioeconomic status	Not available		Not available		Not available		Not available		Not available	
Geographical residence /	Not available		Not available		Not available		Not available		Not available	
BreastScreen service area	Not available		Not available		Not available		Not available		Not available	
Culturally and linguistically diverse	Not available		Not available		Not available		Not available		Not available	
Personal history of breast cancer or DCIS	Not available		Not available		Not available		Not available		Not available	
Personal history of breast disease	Not available		Not available		Not available		Not available		Not available	
Family history of breast cancer or DCIS	Not available		Not available		Not available		Not available		Not available	
Breast density	Not available		Not available		Not available		Not available		Not available	
BRCA 1/2 status	Not available		Not available		Not available		Not available		Not available	
Reproductive risk factors	Not available		Not available		Not available		Not available		Not available	
HRT use	Not available		Not available		Not available		Not available		Not available	
Risk measured by an assessment tool	Not available		Not available		Not available		Not available		Not available	

2.8.2 BreastScreen participation

Table 10. PICO 1 National BreastScreen participation by factors of interest for risk-based screening: national BreastScreen reports. Figures are age-standardised rates for 2016-17, for all screening rounds.

Study ***Data source***	***Age (y)***	***Factor***	***Participation rate (%)***
Age			
BSAMR 2019 Retrospective National BS data N=2,112,388 Screens=2,112,388		Age (y)	2016-17; ASR; All R
	40-49	40-49	13.9
	50-74	50-74	54.5
	75+	75+	7.4 #
	All 40+	All 40+	34.7
Aboriginal or Torres Strait Islander			
BSAMR 2019 Retrospective National BS data N=2,112,388 Screens=2,112,388		Indigenous status	2016-17; ASR; All R
	50-74	Indigenous	40.7
		Non-Indigenous	54.2
Socioeconomic status			
BSAMR 2019 Retrospective National BS data N=2,112,388 Screens=2,112,388		SEIFA quintile (for 2016)	2016-17; ASR; All R
	50-74	Q1 (lowest)	54.0
		Q2	55.7
		Q3	51.7
		Q4	55.5
		Q5 (highest)	55.2
Geographical residence			
BSAMR 2019 Retrospective National BS data N=2,112,388 Screens=2,112,388		ASGS postcode (for 2011)	2016-17; ASR; All R
	50-74	Very remote	43.4
		Remote	52.6
		Outer regional	57.0
		Inner regional	55.9
		Major cities	53.4
Culturally and linguistically diverse			
BSAMR 2019 Retrospective National BS data N=2,112,388 Screens=2,112,388		Language spoken at home	2016-17; ASR; All R
	50-74	Non-English	45.8
		English	56.4

Table footnote: ASGS = Australian Statistical Geographical Standard; ASR = Age-standardised rates; BS= BreastScreen; R= screening rounds; SEIFA = Socio-Economic Indexes for Areas; y = years. Age-standardised rates are the number of women screened as a percentage of the eligible female population calculated as the average of the 2016 and 2017 Australian Bureau of Statistics' estimated resident population and age standardised to the Australian population at 30 June 2001. Indigenous status is self-reported; therefore, accuracy of Indigenous participation rates will be affected if women choose not to identify as Indigenous at the time of screening. Language spoken at home may be collected differently among jurisdictions; therefore, data should be interpreted with caution. # Crude rate calculated by Systematic Reviewer

Table 11. PICO 1 Jurisdictional BreastScreen participation by factors of interest for risk-based screening: national BreastScreen reports. Figures are age-standardised rates for 2016-17, for all screening rounds.

Study ***Data source***	***Age (y)***	***Factor***	***Participation rate (%)*** ***2016-17; ASR; All R***							
Age										
BSAMR 2019 Retrospective BS Australia data		Age (y)	NSW N=633,333	VIC N=498,647	SA N=177,425	WA N=222,391	QLD N=475,152	TAS N=61,151	ACT N=33,130	NT N=11,159
	40-49	40-49	8.4	8.8	15.2	15.7	26.1	30.2	14.0	8.4
	50-74	50-74	53.2	53.7	59.1	55.8	55.1	58.4	57.1	37.8
	75+	75+	5.6 #	5.9 #	9.6 #	10.0 #	10.9 #	4.6 #	7.4 #	6.0 #
	All 40+	All 40+	31.9	32.4	38.0	36.3	39.6	41.8	36.1	23.6

Table footnote: ACT = Australian Capital Territory; ASR = age-standardised rates; BS = BreastScreen; NSW = New South Wales; NT = Northern Territory; QLD = Queensland; SA = South Australia; TAS = Tasmania; VIC = Victoria; y = years; WA = Western Australia. Age-standardised rates are standardised to the population of women attending a BreastScreen Australia service in 2008. BreastScreen Australia services are not provided in some remote areas of the Northern Territory; this may affect the Northern Territory's participation. # Crude rate calculated by Systematic Reviewer

Table 12. PICO 1 BreastScreen participation by factors of interest for risk-based screening: peer-reviewed literature.

Study ***Data source***	***Age (y)***	***Factor***	***Participation rate (%)***
NEW SOUTH WALES			
Geographical residence			
Weber 2013 Cross-sectional survey in 45 and Up cohort study, NSW N=96,711 women		ARIA+	Self-reported; Survey data; 2006-10; CR
			Within last 24 mo
	50+	Remote and very remote n=1,853	75.4
		Outer Regional n=17,697	74.7
		Inner Regional n=34,676	73.2
		Major City n=42,402	70.1
		Unspecified n=83	71.1
Culturally and linguistically diverse			
Weber 2013 Cross-sectional survey in 45 and Up cohort study, NSW N=96,711 women		Language spoken at home	Self-reported; Survey data; 2006-10; CR
			Within last 24 mo
	50+	Non-English n=8,671	65.3
		English n=88,039	72.8
		Unspecified n=1	0.0
Weber 2013 Cross-sectional survey in 45 and Up cohort study, NSW N=96,711 women		Country of birth	Self-reported; Survey data; 2006-10; CR
			Within last 24 mo
	50+	Australia n=73,198	73.4
		Other English-speaking n=11,848	71.6
		Other n=10,720	65.4
		Unspecified n=945	60.3
Family history of cancer			
Weber 2013 Cross-sectional survey in 45 and Up cohort study, NSW N=96,711 women		Family history of cancer	Self-reported; Survey data; 2006; CR
			All rounds (ever)
	50+	Breast cancer n=9,937	80.7
		Non-breast cancers n=32,109	73.1
		None n=52,588	69.8
		Unspecified data NR	
HRT use			
Weber 2013 Cross-sectional survey in 45 and Up cohort study, NSW N=96,711 women		HRT use	Self-reported; Survey data; 2006-10; CR
			Within last 24 mo
	50+	Ever used HRT n=40,641	81.5
		Never n=53,905	65.8
		Unspecified n=2,165	55.6
SOUTH AUSTRALIA			
Family history of BC			
Beckmann 2013 Cross-sectional Health Omnibus Survey, SA N=1,148		Family history of BC	Self-reported; Survey data 2012; CR
			All rounds (ever) (p=0.444 NS)
	40-84	All women	65.2
		Family history BC n=360	67.2
		None n=788	64.2
		May include % multiply imputed data	
Reproductive risk factors			

Study ***Data source***	***Age (y)***	***Factor***	***Participation rate (%)***
Beckmann 2013 Cross-sectional Health Omnibus Survey, SA N=1,148		Reproductive risk factors	Self-reported; Survey data 2012; CR
			All rounds (ever)
	40-84	All women	65.2
		Menarche age	(p=0.348 NS)
		<12 n=161	68.9
		12+ n=987	64.5
		May include % multiply imputed data	
		Menopausal age	(**p<0.001**)
		<55* n=1,019	62.2
		55+ n=129	87.6
		May include % multiply imputed data	
		Birth status	(p=0.514 NS)
		Nulliparous n=90	62.2
		Has given birth n=1,058	65.4
		May include % multiply imputed data	
		Age at birthing first child	(p=0.001)
		<30 n= 874	68.1
		30+ n=184	52.7
		May include % multiply imputed data	
HRT use			
Beckmann 2013 Cross-sectional Health Omnibus Survey, SA N=1,148		HRT use	Self-reported; Survey data 2012; CR
			All rounds (ever) (**p<0.001**)
	40-84	All women	65.2
		Ever used HRT n=323	91.3
		Never n=825	54.8
		May include % multiply imputed data	

Table footnote; ARIA+ = Accessibility and Remoteness Index of Australia; BC = breast cancer; BS = BreastScreen; CR = crude rates; mo = months; NSW = New South Wales; NS = not significant; SA = South Australia; y = years. *Includes pre-menopausal women. P-values in bold are significant.

*Table 13. PICO 1 National BreastScreen **rescreening** by factors of interest for risk-based screening: national BreastScreen reports and peer-reviewed literature.*

Study ***Data source***	***Age (y)***	***Factor***	***Rescreening rate (%)***		
Age					
BSAMR 2019 Retrospective National BS data N=794,709 Screens=794,709		Age (y)	2015; ASR; Within 27 mo		
			R1	R2	R3+
	40-49	40-49	43.9	63.9	80.2
	50-72	50-72	60.9	69.8	84.6
	75+	75+	17.4 (CR)	29.1 (CR)	40.9 (CR)
Aboriginal or Torres Strait Islander					
Roder 2012 Retrospective National BS data* N=5,366,938 Screens=NR		Indigenous status	1996-2005; CR; Within 27 mo		
			All R		
	50-69	Indigenous n=36,204	60.1		
		Non-Indigenous/other n=5,330,779	70.4		

Table footnote; ASR = Age-standardised rates; BS = BreastScreen; CR = crude rates; mo = months; R1 = first screening round; R2+/R3+ = subsequent screening rounds; y = years. Age-standardised rates are standardised to the population of women attending a BreastScreen Australia service in 2008. *Roder 2012: No data for ACT. The target age group used for rescreening (prior to 2014) was 50–67 rather than 50–69, because women aged 68–69 at the time of their screen would be outside the target age group of 50–69 when they would be due for their rescreen. The target age group for women screened from 2014 onwards has changed to 50–72 (Australian Institute of Health and Welfare 2019a)

*Table 14. PICO 1 Jurisdictional BreastScreen **rescreening** by factors of interest for risk-based screening: national BreastScreen reports. Figures are age-standardised rates for 2016-17, by screening round.*

Study Data source	***Age (y)***	***Factor***	***Rescreening rate (%)***							
Age										
BSAMR 2019 Retrospective BS Australia data		Age (y)	NSW N=239,385	VIC N=177,322	SA N=66,944	WA N=81,973	QLD N=189,296	TAS N=24,154	ACT N=12,068	NT N=3,567
			2015; ASR; Within 27 mo; **R1**							
	40-49	40-49	29.6	27.0	67.3	46.7	60.0	66.0	24.4	40.4
	50-72	50-72	63.9	59.9	66.4	51.4	58.3	65.7	63.0	43.9
	75+	75+	13.3 (CR)	7.7 (CR)	8.6 (CR)	29.3 (CR)	24.0 (CR)	15.4 (CR)	18.2 (CR)	33.3 (CR)
			2015; ASR; Within 27 mo; **R2**							
	40-49	40-49	46.9	47.3	77.9	63.3	71.6	74.6	45.9	62.9
	50-72	50-72	72.9	71.1	67.2	60.9	67.5	71.8	67.9	58.7
	75+	75+	26.4 (CR)	23.3 (CR)	36.1 (CR)	32.6 (CR)	32.9 (CR)	25.0 (CR)	16.7 (CR)	66.7 (CR)
			2015; ASR; Within 27 mo; **R3+**							
	40-49	40-49	70.3	68.7	87.1	76.5	82.2	84.8	68.4	84.9
	50-72	50-72	85.9	85.5	86.2	79.8	83.9	84.7	82.8	79.5
	75+	75+	42.5 (CR)	32.2 (CR)	47.1 (CR)	49.9 (CR)	41.1 (CR)	20.0 (CR)	38.8 (CR)	43.9 (CR)

Table footnote: ACT = Australian Capital Territory; ASR = age-standardised rates; BS = BreastScreen; CR = crude rate; NSW = New South Wales; mo = months; NT = Northern Territory; QLD = Queensland; R= screening round; SA = South Australia; TAS = Tasmania; VIC = Victoria; y = years; WA = Western Australia. Age-standardised rates are standardised to the population of women attending a BreastScreen Australia service in 2008. BreastScreen Australia services are not provided in some remote areas of the Northern Territory; this may affect the Northern Territory's participation.

*Table 15. PICO 1 Jurisdictional BreastScreen **rescreening** by factors of interest for risk-based screening: peer-reviewed literature.*

Study ***Data source***	***Age (y)***	***Factor***	***Rescreening rate (%)***
WESTERN AUSTRALIA			
Aboriginal or Torres Strait Islander			
Savaridas 2017 Retrospective BS WA data N=160,028 160,028 R1 screens		Indigenous status	2007-2013; CR; Within 23-27 mo
			R1
	50-69	Indigenous n=1820	51.6
		Non-Indigenous n=157,354	69.4
Socioeconomic status			
Savaridas 2017 Retrospective BS WA data N=160,028 160,028 R1 screens		SEIFA quintile	2007-2013; CR; Within 23-27 mo
			R1
	50-69	Q1 (most dis.) n=6,087	60.8
		Q2 n=24,114	68.7
		Q3 n=42,466	67.2
		Q4 n=33,820	68.8
		Q5 (least dis.) n=53,222	70.9
Geographical residence			
Savaridas 2017 Retrospective BS WA data N=160,028 160,028 R1 screens		WA residence (Postcode)	2007-2013; CR; Within 23-27 mo
			R1
	50-69	Rural n=21,229	68.0
		Metropolitan n=124,026	70.2
		Southwest n=13,829	59.1
BreastScreen service area			
Hughes 2014 Retrospective BS WA data N=NR 760,027 screens		BreastScreen WA location	1999-2007; CR; Within 27 mo
	50-67		All R
		Rural (van) 545,699 screens	64.9
		Metro (clinic) 214,328 screens	68.3
Culturally and linguistically diverse			
Savaridas 2017 Retrospective BS WA data N=160,028 160,028 R1 screens		Country of origin	2007-2013; CR; Within 23-27 mo
			R1
	50-69	AU/NZ n=96,946	68.2
		Other (migrant) n=63,082	70.0
Personal history of cancer			
Savaridas 2017 Retrospective BS WA data N=160,028 160,028 R1 screens		Personal history of cancer	2007-2013; CR; Within 23-27 mo
			R1
	50-69	Breast cancer n=3,386	71.2
		None n=156,440	69.0
		Ovarian cancer n=472	62.5
		None n=159,555	69.0

Table footnote: AU = Australia; BS = BreastScreen; CR = crude rates; dis. = disadvantaged; mo = months; NZ = New Zealand; NR = not reported; R1 = first screening round; R2+/R3+ = subsequent screening rounds; SEIFA = Socio-Economic Indexes for Areas; WA = Western Australia; y = years. Savaridas 2017: Geographic regions (metropolitan, southwest, and rural) are based on postcode. Information on missing data NR. Hughes 2014: No missing data.

2.8.3 BreastScreen outcomes

Table 16. PICO 2 Breast cancer detection (outcomes) – national-level BreastScreen data. ***Invasive breast cancer (all-size and small), DCIS and interval breast cancer detection rates*** *by factors of interest for risk-based screening: national BreastScreen reports and peer-reviewed literature.*

Study ***Data source***	***Age (y)***	***Factor***	***Recall to assessment rates***	***Program sensitivity (%)***	***False positive rates***	***Positive predictive value (%)***
Grey literature						
Age						
BSAMR 2019 Retrospective National BS data^ N=NR Screens=NR		Age (y)	2017 ASR; per 100 screens; Recalled for "for mammographic reasons"	2012-14; CR; 0-24 mo* Invasive BC	NR	NR
			R1 R2+	R1 R2+		
	40-49	40-49	10.5 5.2	67.3 58.7		
	50-69	50-69		85.8 (ASR) 72.2 (ASR)		
	50-74	50-74	11.3 3.6			
	70+	70+		86.5 82.4		
	75+	75+	11.2 (CR) 4.3 (CR)			
AIHW 2018 Retrospective National BS data N=NR Screens=NR		Age (y)	NR	NR	2000-12; CR False positive **screening** rates†; per 100 screens	2000-12; CR Invasive BC
					R1 R2 R3	R1 R2+ All R
	40-49	40-49			6.9 3.5 3.1	
	50-69	50-69			8.0 3.6 3.2	
	40-44	40-44				3.4 4.7 3.7
	45-49	45-49				5.0 6.7 5.9
	50-54	50-54				5.8 8.1 7.1
	55-59	55-59				9.4 11.6 11.2
	60-64	60-64				12.9 15.3 15.1
	65-69	65-69				14.6 17.9 17.6
	70-74	70-74				17.5 21.1 20.9
	75-79	75-79				23.1 22.7 22.8
	80-84	80-84				26.6 25.6 25.7
	85+	85+				26.8 24.7 25.2
	All 40+	All 40+				6.5 13.3 11.3
Peer-reviewed literature						
Aboriginal or Torres Strait Islander						

Study ***Data source***	***Age (y)***	***Factor***	***Recall to assessment rates***	***Program sensitivity (%)***	***False positive rates***	***Positive predictive value (%)***
Roder 2012 Retrospective National BS* data N=5,366,983 Screens=NR		Indigenous status	1996-2005; CR; per 100 screens	NR	NR	1996-2005; CR; Invasive BC or DCIS
			All R			All R
						Invasive BC / DCIS / Invasive BC or DCIS
	50-69	Indigenous n=36,204	4.7			6.5 / 2.0 / 8.4
		Non-Indigenous/other n=5,330,779	5.8			8.1 / 2.0 / 10.0

Table footnote: ASCG = Australian Standard Geographic Classification; ASR = age-standardised rate; BC = breast cancer; BS = BreastScreen; CALD = culturally and linguistically diverse; CR = crude rate; mo = months; NR = not reported; R = rounds; R1 = first screening round; R2+= subsequent screening rounds; SAS = screening assessment services; y = years. *denotes 95% confidence interval. Age-standardised rates are standardised to the population of women attending a BreastScreen Australia service in 2008. ^BSAMR 2019: Interval cancers data for Queensland data for 2013 and 2014 were not available to be included in this report. *Roder 2012: No data for ACT.+ The denominator for the interval cancer rate, it is the 'number of years at risk' of being diagnosed with an interval cancer, and takes into account women who screen annually rather than every 2 years (who would be at risk for the first year after their screen but not the second).

Table 17. PICO 2 BreastScreen and other program performance indicators (outcomes) – national BreastScreen data. ***Recall to assessment, program sensitivity, false positive rates, and positive predictive value*** *by factors of interest for risk-based screening: national BreastScreen reports and peer-reviewed literature.*

			BreastScreen and other program performance indicators					
Study ***Data source***	***Age (y)***	***Factor***	***Recall to assessment rates***		***Program sensitivity (%)***		***False positive rates***	***Positive predictive value (%)***
Grey literature								
Age								
BSAMR 2019 Retrospective National BS data^ N=NR Screens=NR		Age (y)	2017 ASR; per 100 screens; Recalled for "for mammographic reasons"		2012-14; CR; 0-24 mo* Invasive BC		NR	NR
			R1	R2+	R1	R2+		
	40-49	40-49	10.5	5.2	67.3	58.7		
	50-69	50-69			85.8 (ASR)	72.2 (ASR)		
	50-74	50-74	11.3	3.6				
	70+	70+			86.5	82.4		
	75+	75+	11.2 (CR)	4.3 (CR)				

			BreastScreen and other program performance indicators							
Study ***Data source***	***Age (y)***	***Factor***	***Recall to assessment rates***	***Program sensitivity (%)***	***False positive rates***			***Positive predictive value (%)***		
AIHW 2018 Retrospective National BS data N=NR Screens=NR		Age (y)	NR	NR	2000-12; CR False positive **screening** rates†; per 100 screens			2000-12; CR Invasive BC		
					R1	R2	R3	R1	R2+	All R
	40-49	40-49			6.9	3.5	3.1			
	50-69	50-69			8.0	3.6	3.2			
	40-44	40-44						3.4	4.7	3.7
	45-49	45-49						5.0	6.7	5.9
	50-54	50-54						5.8	8.1	7.1
	55-59	55-59						9.4	11.6	11.2
	60-64	60-64						12.9	15.3	15.1
	65-69	65-69						14.6	17.9	17.6
	70-74	70-74						17.5	21.1	20.9
	75-79	75-79						23.1	22.7	22.8
	80-84	80-84						26.6	25.6	25.7
	85+	85+						26.8	24.7	25.2
	All 40+	All 40+						6.5	13.3	11.3
Peer-reviewed literature										
Aboriginal or Torres Strait Islander										
Roder 2012 Retrospective National BS* data N=5,366,983 Screens=NR		Indigenous status	1996-2005; CR; per 100 screens	NR	NR			1996-2005; CR; Invasive BC or DCIS		
			All R					All R		
								Invasive BC	DCIS	Invasive BC or DCIS
	50-69	Indigenous n=36,204	4.7					6.5	2.0	8.4
		Non-Indigenous/other n=5,330,779	5.8					8.1	2.0	10.0

Table footnote: ASR = age-standardised rate; BC = breast cancer; BS = BreastScreen; CR = crude rate; mo = months; NR = not reported; R = rounds; R1 = first screening round; R2 = second screening round; R3 = third screening round; R2+ = subsequent screening rounds; (y) = years. Age-standardised rates are standardised to the population of women attending a BreastScreen Australia service in 2008. ^AIHW 2019 Program sensitivity data: Queensland data for 2013 and 2014 were not available to be included in this report. † AIHW 2018: False positive rate data calculated as false positive screening rate (number of false positive screens divided by total number of screens, by round and age), assuming number of women equal to number of screens in first, second and third screening round. Number of women recalled NR. *Roder 2012: No data for ACT.

Table 18. PICO 2 Detected tumour characteristics (outcomes) – national-level BreastScreen data. ***Tumour histology, grade, nodal involvement, and size*** *by factors of interest for risk-based screening: national BreastScreen reports and peer-reviewed literature.*

			Detected tumour characteristics (as % cancers)				
Study Data source	***Age (y)***	***Factor***	***Histology***	***Tumour grade (G1-G3)***	***Nodal status***	***Size (small ≤15mm)***	***Hormone receptor status***
Grey literature							
Age							
BSAMR 2019 Retrospective National BS data N=NR Screens=NR		Age (y)	NR	NR	NR	2017 Invasive BC	NR
						All R	
	40-49	40-49				46.4	
	50-74	50-74				59.0	
	75+	75+				54.1	
AIHW 2018 Retrospective National BS data N=NR Screens=NR		Age (y)	2002-2012 D = Invasive ductal carcinoma L = Invasive lobular carcinoma	NR	NR	2002-2012 Invasive or in situ BC	NR
			All R			All R	
	40-49	40-49, Screen-detected	D 84.4, L 9.4, Unknown 0.8			≤15mm 47.1, Unknown 11.6	
		40-49, Interval	D 82.0, L 10.7, Unknown 0.8			≤15mm 33.9, Unknown 12.0	
	50-69	50-69, Screen-detected	D 80.9, L 11.3, Unknown 1.0			≤15mm 55.3, Unknown 10.7	
		50-69, Interval	D 77.1, L 12.9, Unknown 2.7			≤15mm 33.7, Unknown 13.6	
	70+	70+, Screen-detected	D 76.4, L 13.1, Unknown 1.2			≤15mm 54.5, Unknown 16.0	
		70+, Interval	D 68.4, L 20.1, Unknown 2.3			≤15mm 28.7, Unknown 22.4	
	All 40+	All 40+, Screen-detected	D 80.5, L 11.4, Unknown 1.0			≤15mm 54.5, Unknown 11.6	
		All 40+ Interval	D 77.3, L 13.1, Unknown 2.2			≤15mm 33.2, Unknown 14.2	
Peer-reviewed literature							
Aboriginal or Torres Strait Islander							
Roder 2012 Retrospective National BS data* N=NR Screens=NR		Indigenous status	1991-2006 D = “Ductal” L = “Lobular”	NR	1991-2006 Positive; Invasive BC	1991-2006 Invasive BC	NR
			All R (p=0.212 NS)		All R (**p<0.001**)	All R (**p=0.003**)	
	50-69	Indigenous	D 81.8, L 9.2 (/445)		54.9 (/288)	48.4 (/312)	
		Non-Indigenous/other	D 80.0, L 11.8 (/62,076)		43.6 (/35,327)	56.2 (/41,513)	
		Excludes missing/unknown data (NR)					

Table footnote: BC = breast cancer; BS = BreastScreen; G = grade; mo = months; NR = not reported; NS = not significant; R = rounds; y = years. *Roder 2012: No data for ACT. P-values in bold are significant.

2.8.4 Update from the 2020 BSAMR

For these data, as specified in the 2020 BreastScreen Australia Monitoring Report:

- Age-standardised rate was the number of women screened as a percentage of the eligible female population calculated as the average of the 2017 and 2018 Australian Bureau of Statistics estimated resident population and age standardised to the Australian population at 30 June 2001.
- Indigenous status was self-reported; therefore, accuracy of Indigenous participation rates would be affected if women chose not to identify as Indigenous at the time of screening.
- Remoteness areas were assigned using the woman's residential postcode according to the Australian Statistical Geography Standard (ASGS) for 2016.
- Women were allocated to a socioeconomic area using their residential postcode according to the Socio-Economic Indexes for Areas (SEIFA) Index of Relative Socio-Economic Disadvantage for 2016. Caution is required when examining differences across socioeconomic area.

Participation by Indigenous status and age

Table 19. BreastScreen Australia participation rate (age-standardised), by age and Indigenous status, 2017-18 (Australian Institute of Health and Welfare 2020a, Table S1.9).

Study ***Data source***	***Age (y)***	***Participation rate (%); ASR; all screening rounds***		
		National (all women)*	Indigenous status Self-reported	
			Indigenous	Non-Indigenous
BSAMR 2020 Retrospective National BreastScreen data N=2,142,939 Screens=2,142,939	40-49	13.7	12.7	13.6
	50-74	54.3	37.6	54.4
	All 40+**	34.6	25.3	34.4

Table footnotes: ASR = Age-standardised rates; BSAMR = BreastScreen Australia monitoring report; y = years. *Includes women in the 'not stated' category for Indigenous status. **Rates are directly age-standardised to the Australian 2001 standard population in 5-year age groups up to age 75+ for women aged 40+.

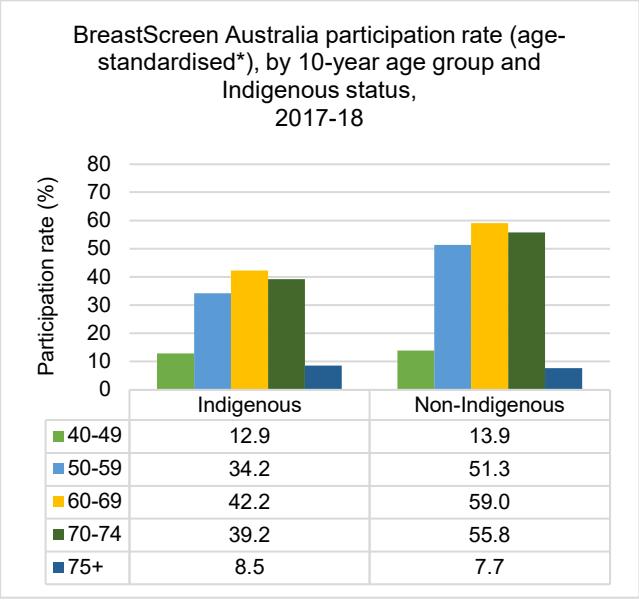
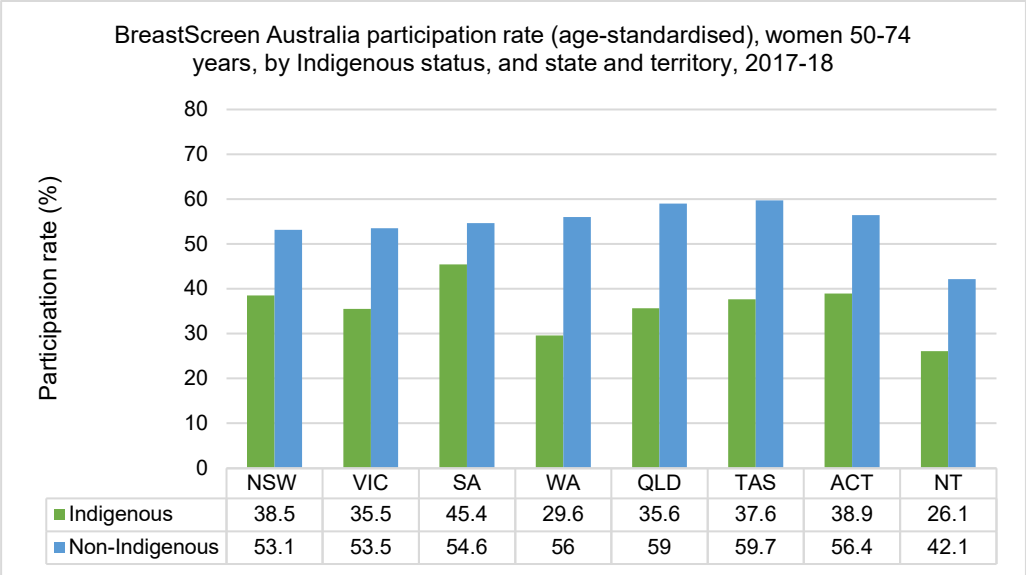


Figure 1. BreastScreen Australia participation rate (age-standardised), by 10-year age group and Indigenous status, 2017-18 (Australian Institute of Health and Welfare 2020a, Table A3.11).

*Rates are directly age-standardised to the Australian 2001 standard population in 5-year age groups up to 65+. This can result in small differences between these data and data in other tables, which are age-standardised to 75+.

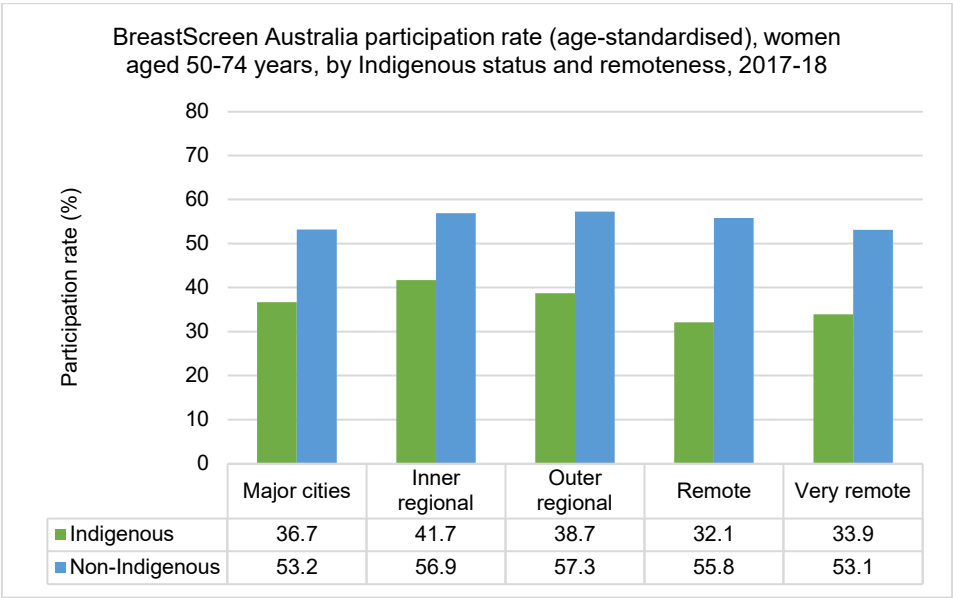
Participation of women aged 50-74 years by Indigenous status and jurisdiction



	NSW	VIC	SA	WA	QLD	TAS	ACT	NT
Indigenous	38.5	35.5	45.4	29.6	35.6	37.6	38.9	26.1
Non-Indigenous	53.1	53.5	54.6	56	59	59.7	56.4	42.1

Figure 2. BreastScreen Australia participation rate (age-standardised), women 50-74 years, by Indigenous status, and state and territory, 2017-18 (Australian Institute of Health and Welfare 2020a, Table A3.11).

Participation by Indigenous status, remoteness, and age



	Major cities	Inner regional	Outer regional	Remote	Very remote
Indigenous	36.7	41.7	38.7	32.1	33.9
Non-Indigenous	53.2	56.9	57.3	55.8	53.1

Figure 3. BreastScreen Australia participation rate (age-standardised), women aged 50-74 years, by Indigenous status and remoteness, 2017-18 (Australian Institute of Health and Welfare 2020a, Table A3.13).

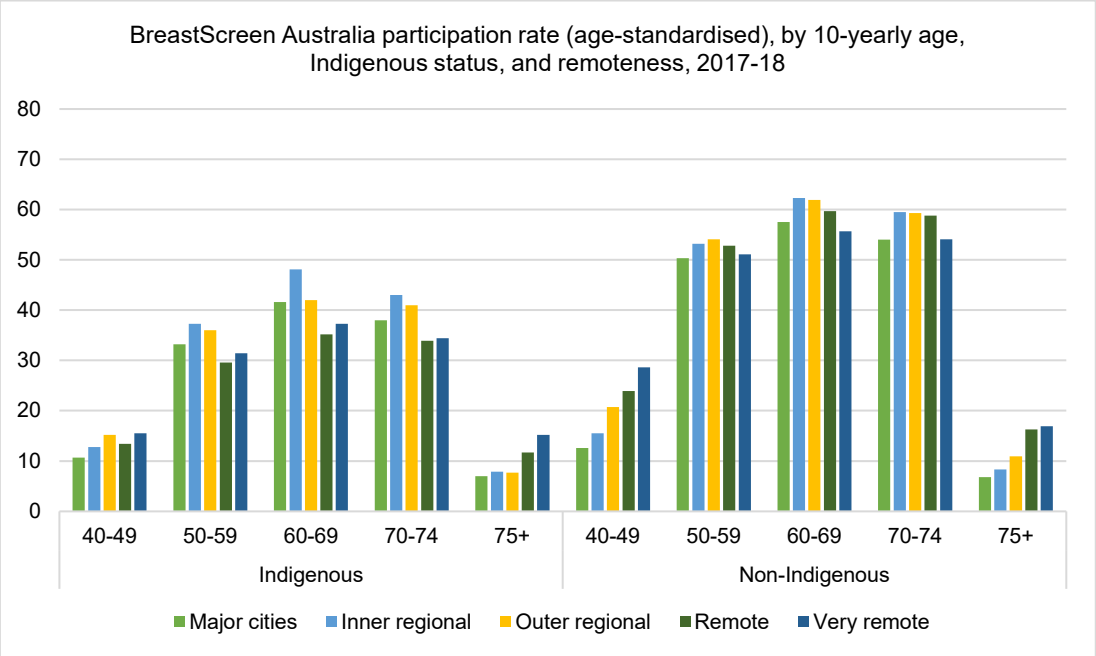


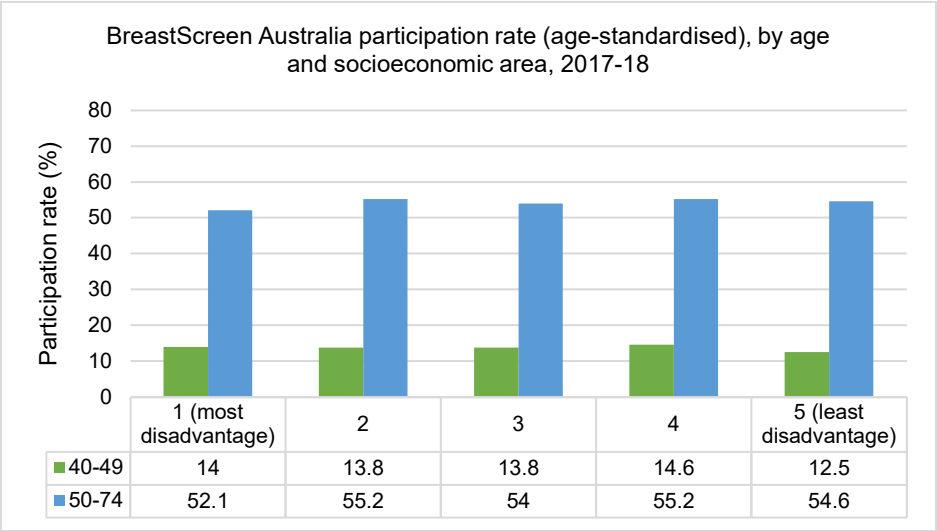
Figure 4. BreastScreen Australia participation rate (age-standardised), by 10-year age groups, Indigenous status, and remoteness, 2017-18 (Australian Institute of Health and Welfare 2020a, Table A3.13).

Table 20. BreastScreen Australia participation rate (age-standardised), by 10-year age groups, Indigenous status, and remoteness, 2017-18 (Australian Institute of Health and Welfare 2020a, Table A3.13).

Study ***Data source***	***Age (y)***	***Indigenous status***	***Participation rate (%); ASR; all screening rounds***				
			Remoteness (ASGS postcode for 2016)				
			Major cities	Inner regional	Outer regional	Remote	Very remote
BSAMR 2020 Retrospective National BreastScreen data N=2,142,939 Screens=2,142,939	40-49	Indigenous	10.7	12.8	15.2	13.4	15.5
	50-59		33.2	37.3	36.0	29.6	31.4
	60-69		41.6	48.1	42.0	35.2	37.3
	70-74		38.0	43.0	41.0	33.9	34.4
	75+		7.0	7.9	7.7	11.7	15.2
	40-49	Non-Indigenous	12.6	15.5	20.7	23.9	28.6
	50-59		50.3	53.2	54.1	52.8	51.1
	60-69		57.5	62.3	61.9	59.7	55.7
	70-74		54.0	59.5	59.3	58.8	54.1
	75+		6.8	8.3	10.9	16.3	16.9

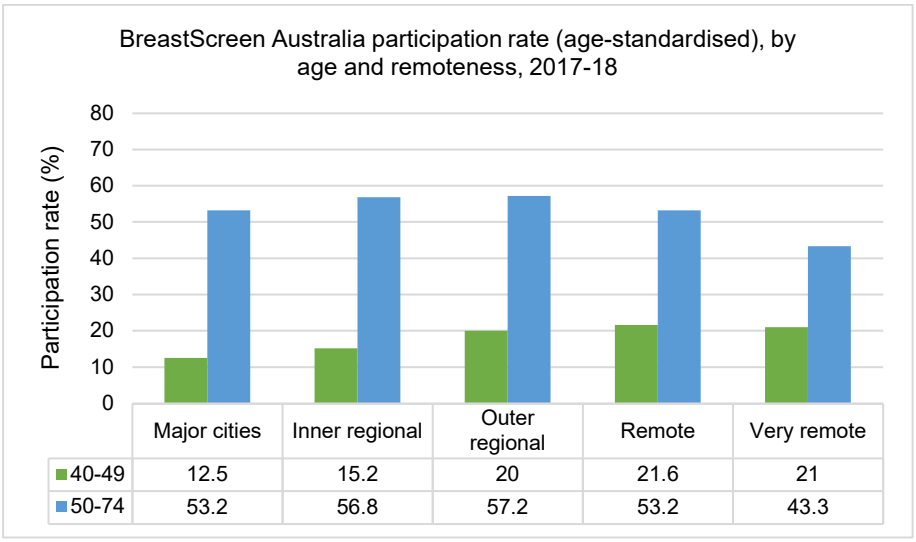
Table footnotes: ASGS = Australian Statistical Geographical Standard; ASR = Age-standardised rate; BSAMR = BreastScreen Australia monitoring report; y = years.

Participation by age and socioeconomic area, remoteness, and main language spoken at home



	1 (most disadvantage)	2	3	4	5 (least disadvantage)
40-49	14	13.8	13.8	14.6	12.5
50-74	52.1	55.2	54	55.2	54.6

Figure 5. BreastScreen Australia participation rate (age-standardised), by age and socioeconomic status, 2017-18 (Australian Institute of Health and Welfare 2020a, Table S1.7).



	Major cities	Inner regional	Outer regional	Remote	Very remote
40-49	12.5	15.2	20	21.6	21
50-74	53.2	56.8	57.2	53.2	43.3

Figure 6. BreastScreen Australia participation rate (age-standardised), by age and remoteness, 2017-18 (Australian Institute of Health and Welfare 2020a, Table S1.5).

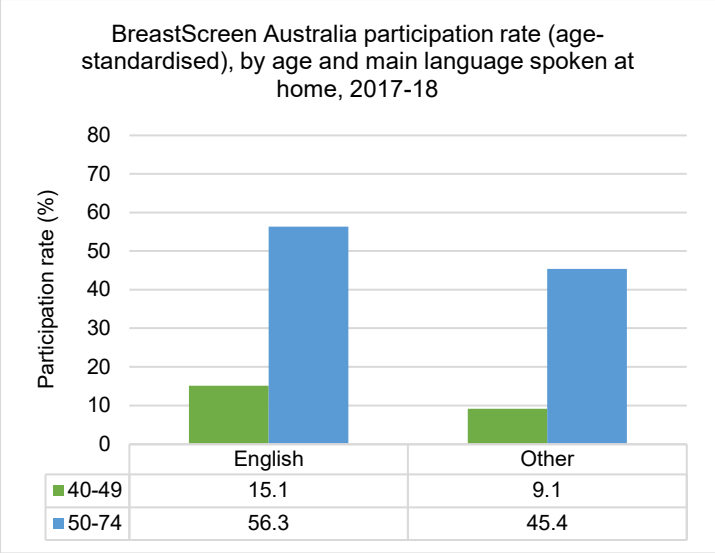


Figure 7. BreastScreen Australia participation rate (age-standardised), by age and main language spoken at home, 2017-18 (Australian Institute of Health and Welfare 2020a, Table S1.11).

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2.9.1 Supplementary figures and data

Participation

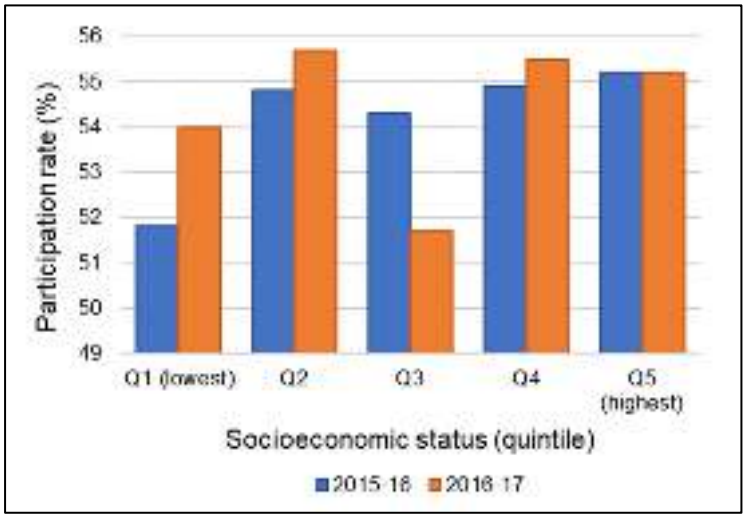


Figure 8. BreastScreen participation in women aged 50-74 years, by socioeconomic status, 2015-16 and 2016-17 (Australian Institute of Health and Welfare 2018b, 2019a)

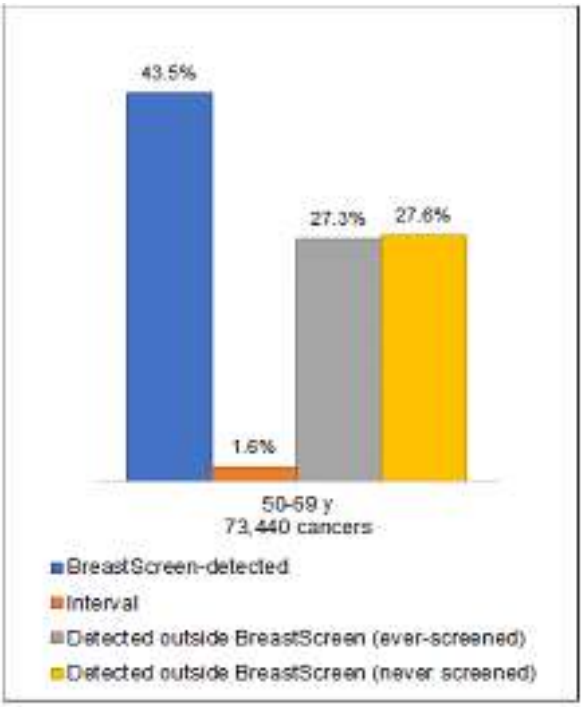


Figure 9 Distribution of invasive breast cancers in Australian women aged 50-69 years by screening status, 2000-2012 (Australian Institute of Health and Welfare 2018a)

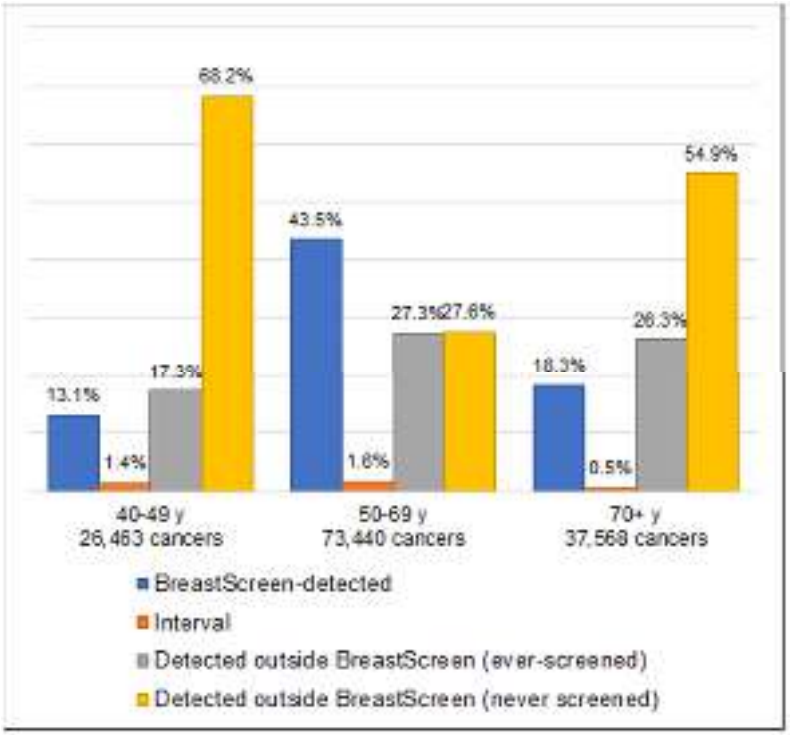


Figure 10. Distribution of invasive breast cancers by age and screening status, 2000-2012 (Australian Institute of Health and Welfare 2018a)

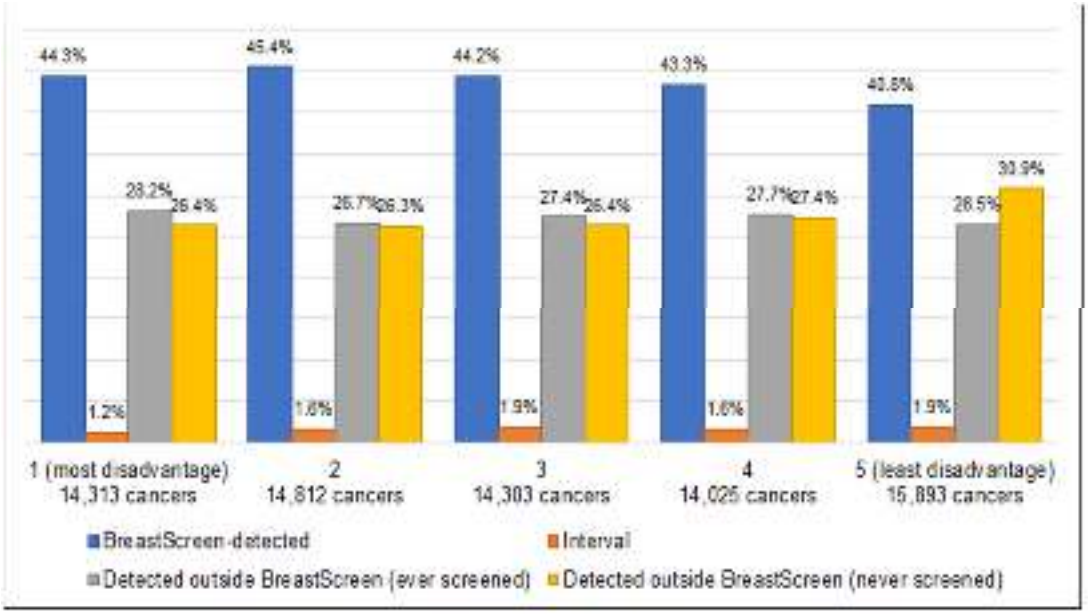


Figure 11. Distribution of invasive breast cancers in women aged 50-69 years by socioeconomic status and screening status, 2000-2012 (Australian Institute of Health and Welfare 2018a)

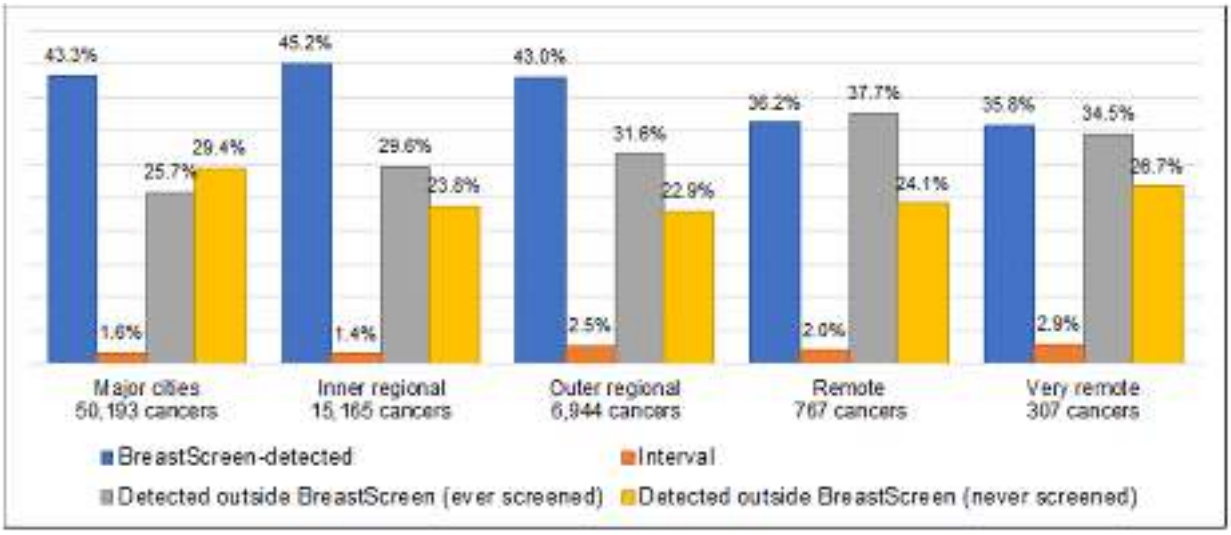


Figure 12 Distribution of invasive breast cancers in women aged 50-69 years by geographical residence and screening status, 2000-2012 (Australian Institute of Health and Welfare 2018a)

Table 21. Proportion of screen-detected and interval breast cancers detected by BreastScreen and breast cancers detected outside of BreastScreen in 2000-2012, by factors of interest for risk-based screening (Australian Institute of Health and Welfare 2018a)

Study and data source: AIHW 2018a (Australian Institute of Health and Welfare 2018a); retrospective; national BreastScreen data						
			BreastScreen cancer detection		**Cancer detection outside of BreastScreen program**	
Factor	**Age (y)**	**No. cancers**	**% screen-detected invasive BC 2000-12 All R**	**% interval (invasive) BC 2000-12 All R**	**% invasive BC in ever-screened women 2000-12 All R**	**% invasive BC in never-screened women 2000-12 All R**
Age (years)	40-49	26,463	13.1	1.4	17.3	68.2
	50-69	73,440	43.5	1.6	27.3	27.6
	70+	37,568	18.3	0.5	26.3	54.9
	All 40+	137,471	30.8	1.3	25.1	42.9
Socioeconomic status						
SEIFA quintile	50-69					
Q1 (most dis.)		14,313	44.3	1.2	28.2	26.4
Q2		14,812	45.4	1.6	26.7	26.3
Q3		14,303	44.2	1.9	27.4	26.4
Q4		14,025	43.3	1.6	27.7	27.4
Q5 (least dis.)		15,893	40.8	1.9	26.5	30.9
Geographical residence						
ARIA+						
Very remote	50-69	307	35.8	2.9	34.5	26.7
Remote		767	36.2	2.0	37.7	24.1
Outer regional		6,944	43.0	2.5	31.6	22.9
Inner regional		15,165	45.2	1.4	29.6	23.8
Major cities		50,193	43.3	1.6	25.7	29.4

55TARIA+ = Accessibility and Remoteness Index of Australia; BC = breast cancer; dis. = disadvantaged; mo = months; R = rounds; SEIFA = Socio-Economic Indexes for Areas; y = years.

2.9.2 Search strategy

Search strategy

Table 22 Database(s): Embase Classic+Embase 1947 to 2020 January 07, Ovid MEDLINE(R) ALL 1946 to January 07, 2020.

#	Searches	Results
1	(breast* or ductal carcinoma in situ or DCIS).tw.	1055556
2	(screen* or mammogra*).tw.	1779052
3	(Australia* or New South Wales or Queensland or Northern Territory or West* Australia* or South* Australia* or Australian Capital Territory or Victoria* or Tasmania* or Sydney or Brisbane or Darwin or Perth or Adelaide or Canberra or Melbourne or Hobart).tw.	386369
4	1 and 2 and 3	1592
5	(population* or nation* or state* or territor* or jurisdiction*).tw.	7943918
6	australia.in.	1419439
7	1 and 2 and 5 and 6	1266
8	BreastScreen*.tw.	387
9	4 or 7 or 8	2308
10	limit 9 to yr="2008 -Current"	1635
11	remove duplicates from 10	1083

2.9.3 Table of excluded studies

Table 23 Potentially relevant articles collected and excluded.

Study	PubMed ID or link	Reason for exclusion
Anikeeva 2012	PMID 22104630	Inappropriate intervention (BreastScreen not in factor-stratified group) and no outcome metric of interest
AIHW 2015	PMID 26264473	Inappropriate intervention (BreastScreen not in factor-stratified group) and superseded data
Baglietto 2014	PMID 24169466	No outcome metric of interest
Banham 2019	PMID 31200700	No outcome metric of interest
Beckmann 2015	PMID 25896926	Superseded data (more recent age participation data in BSAMR 2019 as extracted)
Beckmann 2013a Ca Causes Control	PMID 23649232	No outcome metric of interest (no participation data and jurisdiction-level outcome data only)
Bell 2019	PMID 30623584	No outcome metric of interest
Bennett 2010	PMID 20108093	Inappropriate population and intervention (not limited to BreastScreen participants)
Buckley 2017	PMID 28271574	No outcome metric of interest
Buckley 2016	PMID 27001547	No outcome metric of interest
Buckley 2015	PMID 25681318	No outcome metric of interest (not limited to BreastScreen-detected cancer rates)
Carey 2019	PMID 31581885	Inappropriate population and intervention (not limited to BreastScreen participants)
Centre for Epidemiology and Research, NSW DoH	https://www.health.nsw.gov.au /surveys/Pages/default.aspx	Incorrect publication type (not peer-reviewed)
Chealsey 2019	PMID 30746706	No outcome metric of interest (no participation data and jurisdiction-level outcome data only)
Cheung 2011	PMID 21819359	Inappropriate comparator (no within study direct comparison performed)
Craft 2013	PMID 24194985	Inappropriate intervention (BreastScreen not in factor-stratified group)
Darcey 2019	PMID 30977028	No outcome metric of interest
Elder 2018	PMID 29717421	Inappropriate intervention (BreastScreen not in factor-stratified group)
Farshid 2018	PMID 30046938	Inappropriate intervention (BreastScreen not in factor-stratified group)
Farshid 2008	PMID 18382460	Inappropriate population (narrow population not representative of screening population) and intervention (BreastScreen not in factor-stratified group), and no outcome metric of interest
Flegg 2010	PMID 20822548	Inappropriate population (narrow population not representative of screening population) and no outcome metric of interest
Fong 2011	PMID 21630124	No outcome metric of interest

Study	*PubMed ID or link*	*Reason for exclusion*
Gayde 2012	PMID 22289153	Inappropriate intervention (BreastScreen not in factor-stratified group of interest)
Gibson-Helm 2014	PMID 24742007	Inappropriate population (women aged <40 years) and no outcome metric of interest
Heliat 2019	PMID 31845467	No outcome metric of interest
Houssami 2019	PMID 31448816	Inappropriate intervention (current BreastScreen protocol does not include tomosynthesis)
Houssami 2016	https://doi.org/10.1007/s12609-012-0070-z	Incorrect publication type (non-systematic review)
Houssami 2011	PMID 22004397	No outcome metric of interest (no participation data and jurisdiction-level outcome data only)
Hsieh 2016	PMID 27149274	No outcome metric of interest
Jacklyn 2018	PMID 28882419	Superseded data (more recent participation data in BSAMR 2019 reports as extracted)
Jacklyn 2017	PMID 28882419	No outcome metric of interest
Kavanagh 2008	PMID 18843028	No outcome metric of interest (no participation data and jurisdiction-level outcome data only)
Kricker 2012	PMID 22020871	Inappropriate population and intervention (not limited to BreastScreen participants and narrow population not representative of screening population), and no outcome metric of interest
Kricker 2008	PMID 18770865	Inappropriate population (narrow population not representative of screening population) and inappropriate intervention (BreastScreen not in factor-stratified group)
Krishnan 2017a	PMID 28062399	No outcome metric of interest
Krishnan 2017b	PMID 29246131	No outcome metric of interest
Krishnan 2016	PMID 27316945	No outcome metric of interest
Kurniawan 2008	PMID 18618180	No outcome metric of interest
Kwok 2019	PMID 31025150	No comparator
Kwok 2016	PMID 26645110	No comparator
Kwok 2015	PMID 26051075	No comparator
Kwok 2014	PMID 23357890	No comparator
Kwok 2012a	PMID 22151348	No comparator
Kwok 2012b	PMID 21767988	No comparator
Lam 2018	PMID 29235719	Inappropriate comparator (no within study direct comparison performed)
Lammert 2019	PMID 31657879	Inappropriate population and intervention (not BreastScreen)
Leung 2015	PMID 26844118	No outcome metric of interest
Leung 2014	PMID 24439940	Superseded data (more recent participation data in BSAMR 2019 reports as extracted)
Li 2019	PMID 31855779	No outcome metric of interest
Mall 2018	PMID 29846804	Inappropriate intervention (current BreastScreen protocol does not include tomosynthesis)
McLean 2019	PMID 30819215	No outcome metric of interest (no participation data and jurisdiction-level outcome data only)
Mizukoshi 2019	PMID 31554381	No outcome metric of interest (no participation data and jurisdiction-level outcome data only)
Morrell 2012	PMID 22345322	No outcome metric of interest
Muir 2010	PMID 20152275	Inappropriate intervention (BreastScreen not in factor-stratified group of interest)
Nguyen 2019	PMID 31609476	No outcome metric of interest
Nguyen 2018	PMID 30545395	No outcome metric of interest
Nicholls 2017	PMID 27878855	Inappropriate intervention (BreastScreen not in factor-stratified group of interest)
Nickson 2018	PMID 30572910	No outcome metric of interest
Nickson 2014	PMID 24327331	Superseded data (more recent participation data in BSAMR 2019 reports as extracted)
Nickson 2009	PMID 19805755	No outcome metric of interest (no participation data and jurisdiction-level outcome data only)
O'Hara 2018	PMID 30087259	Inappropriate population and intervention (not limited to BreastScreen participants)
Ogunsiji 2017	PMID 28412942	No comparator

Study	***PubMed ID or link***	***Reason for exclusion***
Pape 2016	PMID 27350887	No outcome metric of interest
Peter 2016	PMID 27083056	Inappropriate population and intervention (not BreastScreen)
Peters 2008	PMID 18373823	Inappropriate population and intervention (not BreastScreen)
Pilkington 2017	PMID 28893225	No outcome metric of interest
Price 2010	PMID 20364401	Inappropriate population and intervention (not BreastScreen)
Price 2009	PMID 19453531	Inappropriate population and intervention (not BreastScreen)
Protani 2012	PMID 22225652	No outcome metric of interest
Randall 2009	PMID 19015941	No outcome metric of interest (no participation data and jurisdiction-level outcome data only)
Roder 2017	PMID 27654906	Inappropriate intervention (BreastScreen not in factor-stratified group for outcomes data) and superseded data (more recent participation data in BSAMR 2019 reports as extracted)
Roder 2014	PMID 24709287	No outcome metric of interest
Roder 2008	PMID 18351455	No outcome metric of interest
Salagame 2016	PMID 26599391	No outcome metric of interest
Saunders 2009	PMID 19769556	Inappropriate population and intervention (not BreastScreen)
Seaman 2018	PMID 27682335	No outcome metric of interest
Sim 2012	PMID 22708767	No outcome metric of interest
Suwankhong 2018	PMID 29699369	No comparator and no outcome metric of interest
Tallis 2009	PMID 19383066	Inappropriate intervention (BreastScreen not in factor-stratified group) and no outcome metric of interest
Tapia 2019a	PMID 31268228	No outcome metric of interest
Tapia 2019b	PMID 30941443	No outcome metric of interest
Team 2013	PMID 22951044	No comparator and no outcome metric of interest
Tervonen 2019	PMID 30933888	No outcome metric of interest
Tracey 2008	PMID 18521714	Inappropriate population and intervention (not limited to BreastScreen participants)
Villanueva 2008	PMID 18194528	Superseded data (more recent participation data in BSAMR 2019 reports as extracted)
Walpole 2019	PMID 31808149	Inappropriate population and intervention (not limited to BreastScreen participants)
Weber 2009	PMID 19442312	Superseded data (more recent migrant participation data in Weber 2013 as extracted)
Winch 2015	PMID 25476499	No outcome metric of interest (no participation data and jurisdiction-level outcome data only)
Wong-Brown	PMID 25682074	Inappropriate population and intervention (not BreastScreen)
Woods 2016a	PMID 26756181	No outcome metric of interest
Woods 2016b	PMID 26756306	Inappropriate population and intervention (not limited to BreastScreen participants) and no outcome metric of interest
Woods 2009	PMID 19180628	Inappropriate population and intervention (not BreastScreen) and no outcome metric of interest
Youl 2016	PMID 27869758	Inappropriate population and intervention (not BreastScreen) and no outcome metric of interest
Zhang 2012	http://hdl.handle.net /10137/540	Incorrect publication type (not peer-reviewed)

3 BreastScreen participation and outcomes by factors of interest for risk-based screening – Jurisdictional level

3.1 Authors

Chelsea Carle, Dr Louiza Velentzis, A/Prof Carolyn Nickson

3.2 Background

3.2.1 Rationale

There is no current national BreastScreen policy for risk-based screening of women in Australia. Policies for breast cancer risk assessment and management vary by jurisdiction (state and territory).

As reported in 2019 (Cancer Council Australia 2019a), all jurisdictions offer annual rather than biennial screening to some clients, according to the client's history of pre-malignant breast disease, personal or family history of breast or ovarian cancer, or genetic mutations known to increase their breast cancer risk (Table 24, below). Some women are also referred to services outside the BreastScreen program.

Table 24. Overview of current criteria for annual re-screening, as provided by the ROSA BreastScreen Reference Group in 2019 (Cancer Council Australia 2019a)

Criterion	*NSW*	*Vic*	*Qld*	*WA*	*SA*	*Tas*	*ACT*	*NT*
LCIS	✓	✓	✓	✓	✓	✓	✓	
ADH, ALH	✓	✓	✓	✓	✓	✓	✓	
Strong family history of breast cancer	✓	✓	✓	✓	✓	✓	✓	✓
Personal history of breast cancer	✓	✓	✓	✓	✓	✓	✓	✓
Ovarian cancer		✓	✓	✓		✓		
Genetic					✓	✓		✓

LCIS: lobular carcinoma in situ; ALH: atypical lobular hyperplasia; ADH: atypical ductal hyperplasia

Given the resources that are directed into BreastScreen for annual screening of specific client groups, it would be highly valuable to understand how current risk assessment and management is associated with clinical outcomes. This requires a direct analysis of routinely collected data, with appropriate epidemiological design and statistical methods.

To inform the development of such an analysis, in this report we summarise current information about jurisdiction-level outcomes for women in different population sub-groups, defined either by biological risk factors (e.g. family history of breast cancer) or by factors important for implementing, monitoring or evaluating risk-based screening, to ensure equity for sub-populations with existing disparities in terms of access to services and cancer outcomes (e.g. geographical residence).

3.2.2 Aim

To describe jurisdiction-level screening outcomes in the BreastScreen Australia program by factors of interest for risk-based screening.

3.2.3 Research questions

1. What information is available by factors of interest for risk-based screening in different jurisdictions?
2. How do BreastScreen outcomes vary by factors of interest for risk-based screening in different jurisdictions?

3.3 Methods

3.3.1 PICO protocol

The PICO framework for this summary is shown in Table 25, below.

Table 25. PICO framework, jurisdictional BreastScreen outcomes by factors of interest for risk-based screening.

Population	***Intervention/ exposure***	***Comparison***	***Outcomes***	***Publication type***
Asymptomatic women aged 40+ **participating** in the BreastScreen Australia program in a specific state or territory	BreastScreen in factor sub-strata	BreastScreen in another factor sub-strata or entire cohort	**BreastScreen performance indicators, including cancer detection:** • Screen-detected invasive breast cancer (all size and small) and DCIS rates • Interval cancer detection rates • Recall to assessment rates • Program sensitivity **Other program performance indicators:** • False positive rates • Positive predictive value **Detected tumour characteristics:** • Histology • Grade • Nodal status • Size • Hormone receptor status by screening round where reported	Peer-reviewed literature BreastScreen reports (jurisdiction-level data in publicly available BreastScreen reports)

3.3.2 Selection criteria

Detailed selection criteria for the PICO is shown in Table 26, page 53). Factors of interest were:

- Age;
- Aboriginal or Torres Strait Islander;
- Socioeconomic status (e.g. SEIFA index);
- Geographical residence (e.g. remote/regional per ARIA+ classification, or other definition) or BreastScreen service area;
- Cultural and linguistical diversity (e.g., speaking language other than English at home, and migrant and refugee populations);
- Personal history of breast cancer/DCIS or breast disease (e.g. lobular carcinoma in situ, atypical ductal hyperplasia, atypical lobular hyperplasia);
- Family history of breast cancer/DCIS;
- Mammographic breast density;
- Genetic factors e.g. BRCA1/2 status;
- Reproductive risk factors (e.g. age at menarche, menopausal age, birth status, age at first birth);

- Hormone replacement therapy (HRT) use;
- Risk assessed by formal risk assessment tool in peer-reviewed literature e.g. Gail model (BCRAT), iPrevent, IBIS (Tyrer-Cuzick model)

Publications from 2008 onwards were included, but we did not exclude studies reporting older data, reasoning that these may provide insights that are either still relevant for the current screening program or indicate potential shifts over time.

Table 26. Study selection inclusion and exclusion criteria for jurisdictional BreastScreen outcomes by factors of interest for risk-based screening.

Selection criteria	***Inclusion***	***Exclusion***
Population	Asymptomatic women aged 40+ **participating** in the BreastScreen Australia program in a specific state or territory	Non-Australian cohort Age group excludes women aged 40+ Analyses of sub-population not representative of screening population (e.g. analyses limited to women with phyllodes tumour type)
Intervention	BreastScreen in factor-stratified group of women	Breast imaging/screening undertaken outside of BreastScreen program An international/unspecified screening program
Comparator	BreastScreen in another factor-stratified group or entire cohort	None specified.
Outcomes	**BreastScreen performance indicators, including cancer detection:** • Screen-detected invasive breast cancer (all size and small) and DCIS rates • Interval cancer detection rates • Recall to assessment rates • Program sensitivity **Other program performance indicators:** • False positive rates • Positive predictive value **Detected tumour characteristics:** • Histology • Grade • Nodal status • Size • Hormone receptor status Outcomes will be reported by first and subsequent screening rounds, and by screening interval, where data is available	Outcomes not listed (e.g. survival, mortality, burden of disease (YLL, YLD, DALY), costs, expenditure etc.) Duplicate data i.e. same data reported in another publication Superseded data i.e. more recent data available
Study design	Randomized controlled trials, cohort studies (including retrospective), case-control studies	Case-series
Publication type	Peer-reviewed journal articles BreastScreen reports (jurisdiction-level data in publicly available BreastScreen reports)	Conference abstracts, reviews, letters, editorials, comments, presentations
Publication date	2008 onwards	
Language	English	

For the purposes of this review:

- **Screen-detected invasive breast cancer and DCIS rates** were defined as the number of new (incident) cases detected by BreastScreen Australia divided by the total number of screening episodes in a specified period, expressed per 10,000 women screened.

- **Interval cancers** were defined as invasive breast cancers diagnosed following a negative screen (i.e. not screen-detected) and before the next recommended screen at 24 months (or 12 months if screening annually).
- **Interval cancer detection rates** were defined as the number of invasive cancers diagnosed following a negative screen but before the next recommended screen divided by the total number of screening episodes in a specified period, expressed per 10,000 women-years.
- **Recall to assessment rates** were defined as the number of screening episodes requiring recall for further assessment divided by the total number of screening episodes in a specified period, expressed per 100 screening episodes.
- **Program sensitivity** was defined as the number of screen-detected invasive cancers detected following a positive screen divided by the total number of invasive cancers (i.e. screen-detected + interval-detected) in a specified period, expressed as a percentage.
- **False positives** were defined as positive screening episodes with a benign final outcome.
- **False-positive rates** were defined as the number of false positives divided by the total number of screening episodes, expressed per 100 screening episodes.
- **Positive predictive value (PPV)** was defined as the number of positive screening episodes leading to a diagnosis of invasive breast cancer divided by the total number of positive screening episodes (also number of women recalled) in a specified period, expressed as a percentage.
- **Jurisdiction**, unless otherwise specified, describes state and territory level programs and outcomes.

3.3.3 Grey and peer-reviewed literature searches

BreastScreen reports

To identify routinely reported jurisdiction-level outcome data stratified according to the factors of interest, we examined governmental BreastScreen Australia reports obtained from the Australian Government Department of Health cancer screening website (Australian Government Department of Health 2022) and the Australian Institute of Health and Welfare (AIHW) website (Australian Institute of Health and Welfare 2022) published from 1 January 2008 to 7 January 2022. We included publications from 2008 to target studies reporting outcomes since BreastScreen's transition from film to digital mammographic screening.

Peer-reviewed literature

To identify additional outcome data that could potentially be routinely reported according to factors of interest, on 8 January 2022 we searched for relevant peer-reviewed journal articles in Medline and Embase databases published from 1 January 2008 to 7 January 2022. Search terms were combined for breast, DCIS, screening, mammography, and Australia and states/territories. For details of the search strategy see Appendix 3.7.1 (page 88).

For completeness the AIHW BreastScreen Reference Database (Australian Institute of Health and Welfare 2021a), latest available version dated 30 June 2021, was used as a secondary source to identify relevant peer-reviewed literature.

3.3.4 Study selection and data extraction

Publications were selected systematically. The full text of any articles that might meet the inclusion criteria were collected. Articles were included if they reported a relevant outcome stratified by a factor of interest for populations of women aged 40 years and above participating in the BreastScreen Australia program. Eligible peer-reviewed publications included randomised

controlled trials, cohort studies, case-control studies, or systematic reviews thereof. Articles that did not meet selection criteria were excluded with reasons for exclusion documented in Table 35 (page 92).

For included studies prespecified study details and data were extracted.

3.4 Results

3.4.1 Data sources

3.4.2 BreastScreen reports

Data from 2014-2019 meeting the inclusion criteria were extracted from the annual BreastScreen Australia monitoring report (BSAMR) 2021 (Australian Institute of Health and Welfare 2021b). Previous BSAMRs were ineligible as data of interest were superseded. No other AIHW and BreastScreen reports identified on the websites searched reported data meeting the inclusion criteria.

3.4.3 Peer-reviewed literature

Searches retrieved 1412 deduplicated records for screening: 1376 from Medline and Embase databases and 36 from the BreastScreen Reference Database. Of these, 1281 references were excluded based on title, abstract or publication type and the full texts of 131 references were collected for screening.

Of these, 120 texts were excluded and 11 relevant peer-reviewed studies published from 2008-2021 with data ranging from 1993-2017 were included (Beckmann et. al. 2013; Cheasley et al. 2020; Cheasley et. al. 2019; El-Zaemey et al. 2021; Houssami et. al. 2011; Hughes et. al. 2014; Kavanagh et. al. 2008; McLean et. al. 2019; Mizukoshi et. al. 2019; Noguchi et al. 2021; Winch et. al. 2015).

3.4.4 Data availability

Data availability by factors of interest is summarised overall (Table 27, page 70) and then separately in more detail for cancer detection (Table 28, page 72), BreastScreen and other program performance indicators (Table 29, page 73), and tumour characteristics at detection (Table 30, page 74).

Overall, except for age-stratified outcomes, the availability of data of interest for risk-based screening varied and for some jurisdictions was limited (starting Table 27, page 70).

In the grey literature, age-stratified data was available for all jurisdictions in the annual BSAMR (Australian Institute of Health and Welfare 2021b) for rates of screen-detected invasive breast cancer (by all-size and small), DCIS, interval cancers and recall to assessment, and for program sensitivity.

Peer-reviewed literature provided some additional information for select periods and jurisdictions, specifically:

- Cancer (screen-detected or interval-detected) or DCIS detection data according to age (WA), Indigenous status (WA), SES (WA), BreastScreen service area (rural van or metro clinic, WA), personal history of breast cancer (WA), personal history of benign breast disease (WA), family history of breast cancer (WA), mammographic breast density (WA), and HRT use (SA and WA) (Table 28, page 72).

- Program performance data (e.g. recall to assessment rates, program sensitivity, false positive rates or PPV) by age (WA), SES (WA), BreastScreen service area (WA), migrant status (NSW), personal history of breast cancer (WA), personal history of benign breast disease (WA), family history of breast cancer (Vic and WA), mammographic breast density (Vic and WA), and HRT use (SA, Vic and WA) (Table 29, page 73).
- Information on tumour characteristics (e.g. tumour histology, grade, size, hormone receptor status or nodal status) according to BreastScreen service area (rural van or metro clinic, WA), personal history of breast cancer (WA), and for samples of women in the lifepool cohort according to mammographic breast density (Vic.) and with a confirmed genetic mutation, including BRCA1/2 (Vic.) (Table 30, page 74).

When grey literature and peer-reviewed literature were combined, the available information on outcomes for different factors of interest varied greatly between jurisdictions. This can be summarised as follows (noting that some information was available only for selected time periods):

- BreastScreen NSW: Rates of screen-detected invasive breast cancer, DCIS, interval cancers, and recall to assessment are partially available stratified by age or for a small sample of migrant women.
- BreastScreen WA: Rates of screen-detected invasive breast cancer, DCIS, and interval cancers, tumour characteristics (histology, grade, size), recall to assessment rates, program sensitivity, PPV and false positives data were partially available by age, SES, BreastScreen service area, mammographic breast density, and HRT use, and for Aboriginal women, women with a personal history of breast cancer, women with a personal history of benign breast disease, and women with a family history of breast cancer. Some data were further stratified by age.
- BreastScreen VIC: Program sensitivity data was available for women with a family history of breast cancer and by age, mammographic breast density and HRT use. Hormone receptor status data was available for a small sample of women with a confirmed genetic mutation (including BRCA1/2). Tumour histology, grade, hormone receptor status and nodal status were available for a small sample of women in the lowest and highest quintile of percent mammographic breast density.
- BreastScreen SA: Rates of screen-detected invasive breast cancer, DCIS, interval cancers and recall to assessment were available stratified by HRT use.

3.4.5 Outcomes by age

Screen-detected invasive breast cancer

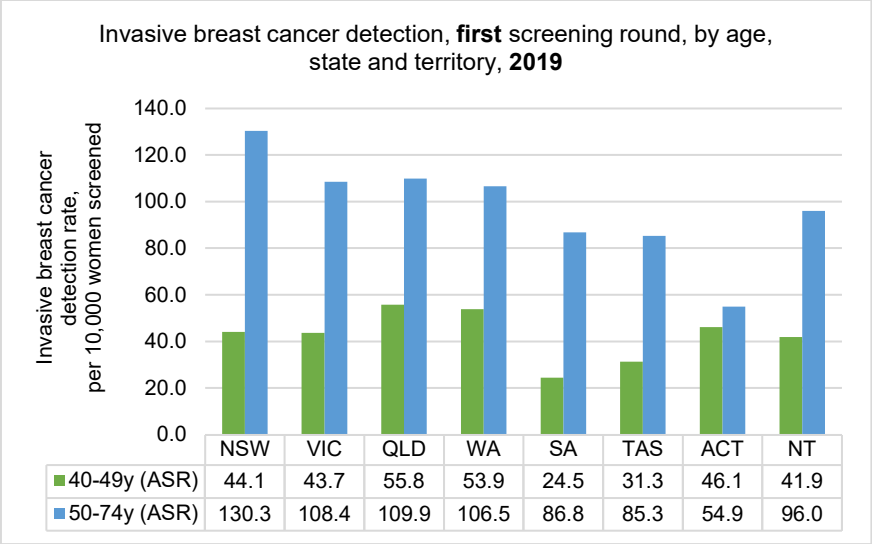
Based on 2019 data from all jurisdictions reported in the annual BSAMR, rates of screen-detected invasive breast cancer (by all-size and small) increased with age at both first and subsequent screening rounds (Figure 13, page 57 and Figure 14, page 57 and Supplementary Figure 23, page 89)(Australian Institute of Health and Welfare 2021b).

However, rates of screen-detected invasive breast cancers by age and round vary between jurisdictions.

For example, at first round screening (Figure 13, below):

- Age-standardised rates for younger women (40-49 years) ranged from 24.5 cancers per 10,000 women screened (SA) to 55.8 (Qld); and

- Age-standardised rates in women aged 50-74 ranged from 54.9 (ACT) to 130.3 (NSW) per 10,000 women screened

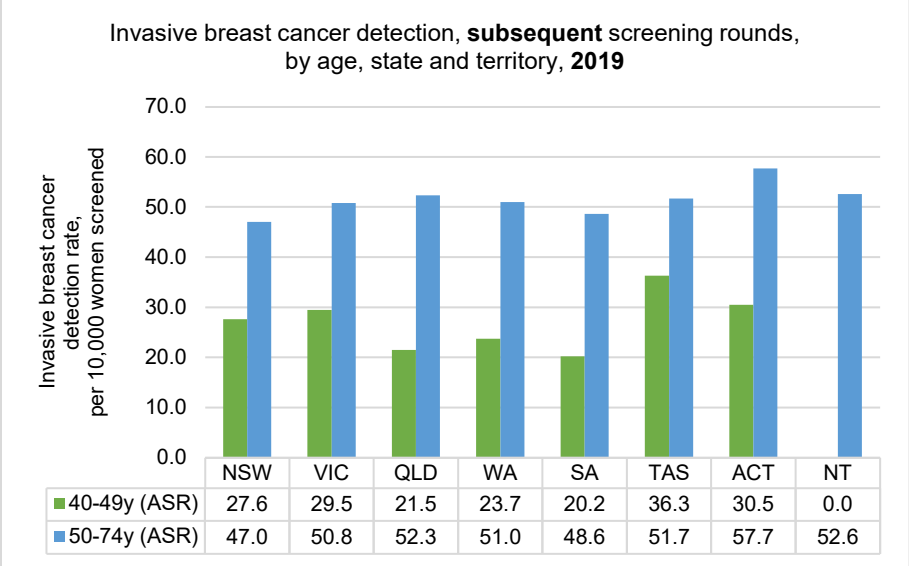


	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
40-49y (ASR)	44.1	43.7	55.8	53.9	24.5	31.3	46.1	41.9
50-74y (ASR)	130.3	108.4	109.9	106.5	86.8	85.3	54.9	96.0

Figure 13. Invasive breast cancer detection, first screening round, by age, state and territory, 2019; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).

At subsequent round screening (refer Figure 14):

- Age-standardised rates for women aged 40-49 ranged from 0 cancers per 10,000 women screened (NT) to 36.3 (Tas.).
- In the target age range (50-74 years) age standardised rates ranged from 47.0 (NSW) to 57.7 (ACT) per 10,000 women screened.



	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
40-49y (ASR)	27.6	29.5	21.5	23.7	20.2	36.3	30.5	0.0
50-74y (ASR)	47.0	50.8	52.3	51.0	48.6	51.7	57.7	52.6

Figure 14. Invasive breast cancer detection, subsequent screening rounds, by age, state and territory, 2019; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).

Differences by age were also observed in the peer-reviewed literature.

A study (El-Zaemey et al. 2021) evaluating the effect of expanding BreastScreen's target age to include women aged 70-74 (previously to age 69) reported that rates of all-size and small (≤15mm)

screen-detected invasive cancers increased with a 5-year age increment, from 65, to 81, to 114 cancers detected per 10,000 women screened for ages 65-69, 70-74 and 75+ years in 2015-17, respectively (Table 28, page 72). Women in each age group defined as 'high risk' based on the presence of one or more factors (including personal history of breast cancer, family history of breast cancer, presenting breast symptoms, or HRT use during the last six months) were 58-64% (depending on age group) more likely to have an invasive cancer detected than those without a listed factor (Table 28, page 72).

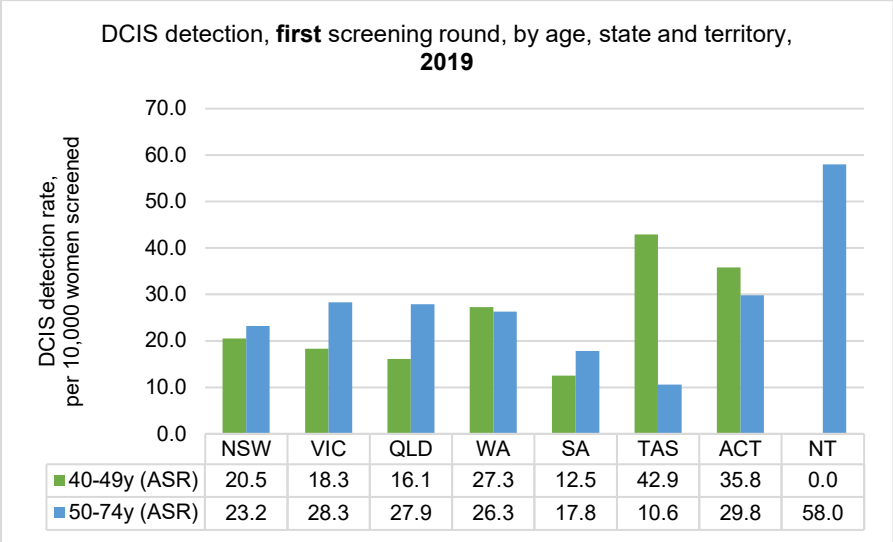
A NSW study (Winch et al. 2015) reporting historical data from a single clinic found that rates of screen-detected invasive cancers among BreastScreen participants in 1993-2008 increased with age at first and subsequent rounds of screening. For example, at first round screening, there was approximately a 2.5-fold increase in cancers detected in women aged 50-69 years (59 cancers per 10,000 women screened) compared to younger women (40-49 years; 24 cancers per 10,000 women screened), and a further 2-fold increase in cancers detected in older women (70-79 years; 118 cancers per 10,000 women screened) (Table 31, page 75).

Screen-detected DCIS

DCIS detection rates (in 2019) were more variable across states and territories, noting however, for subsequent screening rounds all age-standardised rates for women aged 40-49, except for Qld, were based on fewer than 20 cases and, therefore, should be interpreted with caution (Figure 16, page 59)(Australian Institute of Health and Welfare 2021c).

At first screening round:

- Younger women (40-49 years) had 0 (NT) to 42.9 (Tas.) DCIS detected per 10,000 women screened, while women aged 50-74 years had 10.6 (Tas.) to 58.0 (NT) per 10,000 women screened (Figure 15, below).



	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
40-49y (ASR)	20.5	18.3	16.1	27.3	12.5	42.9	35.8	0.0
50-74y (ASR)	23.2	28.3	27.9	26.3	17.8	10.6	29.8	58.0

Figure 15. DCIS detection, first screening round, by age, state and territory, 2019; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).

At subsequent round screening (refer Figure 16, below):

- The range of DCIS detection rates was narrower than at first round screening, ranging from 1.6 (SA) to 30.5 (ACT) per 10,000 women screened for women aged 40-49 years, and 9.3 (Tas.) to 14.2 (WA) per 10,000 women screened for women aged 50-74 years

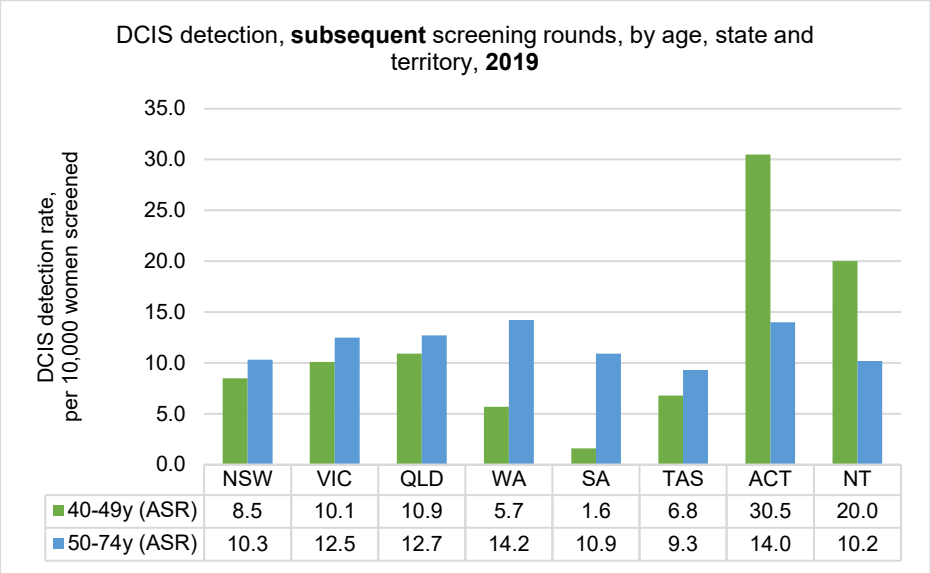


Figure 16. DCIS detection, subsequent screening rounds, by age, state and territory, 2019; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).

In the peer-reviewed literature, a WA study (El-Zaemey et al. 2021) of women aged 65+ attending BreastScreen WA found DCIS detection rates in 2015-17 increased from 16 per 10,000 women screened for women aged 65-69 to 20 per 10,000 women screened in women aged 70-74, but decreased in older ages (75+: 13 DCIS per 10,000 women screened) (Table 28, page 72).

In a NSW study (Winch et al. 2015) from a single clinic, among BreastScreen participants in 1993-2008 DCIS detection rates nearly doubled between age groups at first round screening (from 7 per 10,000 women screened aged 40-49 years, to 10-12 for women aged 50-59 and 60-69, and to 25 per 10,000 women screened for women aged 70-79 years); this effect was not observed for subsequent-round DCIS outcomes (Table 31, page 75).

Screen-detected invasive cancers or DCIS

A WA study (Noguchi et al. 2021) of BreastScreen WA participants, based on data from over one million screening episodes (in 2007-17) reported that detection rates of invasive cancer or DCIS (combined) steadily increased with increasing age from 46, to 56, to 78, to 114 cancers detected per 10,000 women screened for women aged 40-49, 50-59, 60-69 and 70+ years, respectively (Table 28, page 72).

Interval cancers

Age-standardised interval cancer rates for 2014-16 at both first and subsequent screening rounds were variable across jurisdictions. Within jurisdictions rates were similar between women aged 50-74 years attending BreastScreen compared to rates for women aged 40+ (5.4-11.1 versus 4.9-11.7 interval cancers per 10,000 women-years) (Figure 17 and Figure 18, below) (Australian Institute of Health and Welfare 2021b).

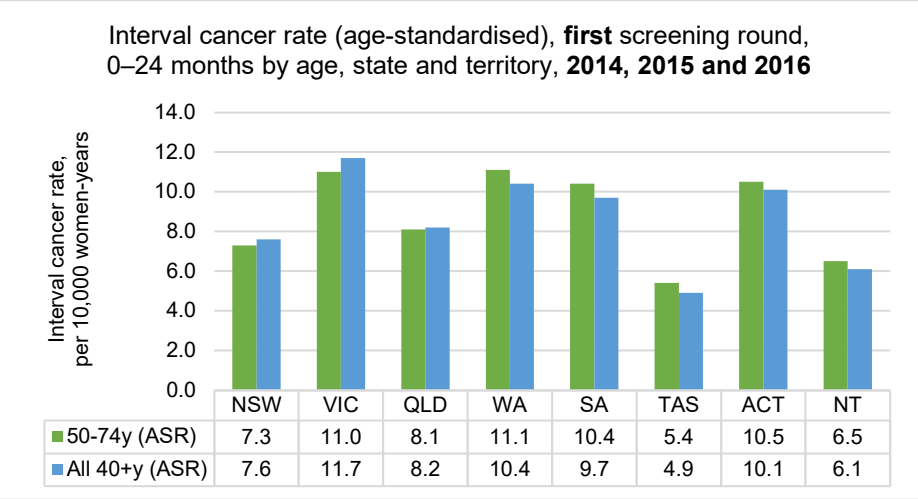


Figure 17. Interval cancer rate (age-standardised), first screening round, 0–24 months by age, state and territory, 2014, 2015 and 2016; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).

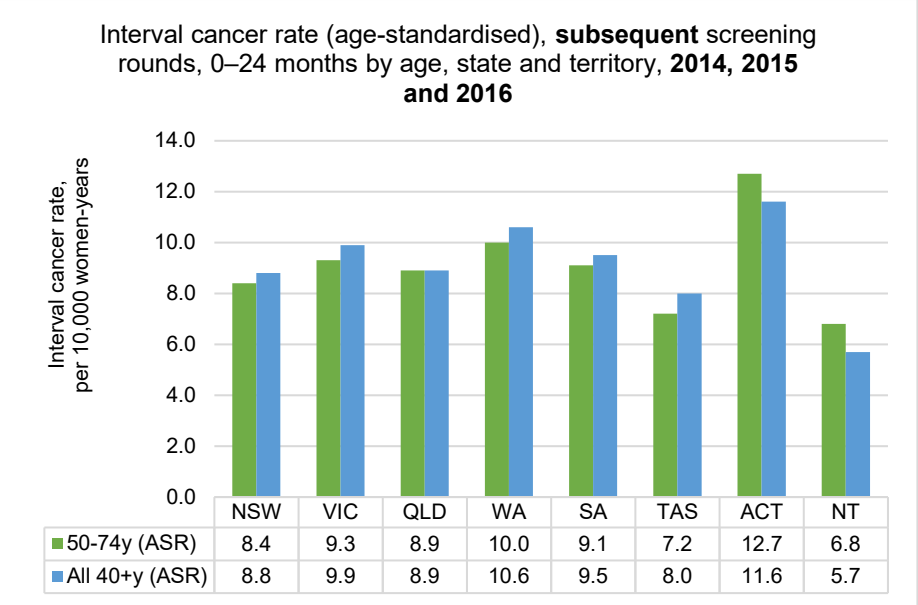


Figure 18. Interval cancer rate (age-standardised), subsequent screening rounds, 0–24 months by age, state and territory, 2014, 2015 and 2016; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).

Crude interval cancer rates available by age group (40-49, 50-74, and 75+ years) were also variable (Figure 24, page 89 and Figure 25, page 90), and for many jurisdictions were based on fewer than 20 cases and, therefore, should be interpreted with caution (Australian Institute of Health and Welfare 2021d).

A WA study (Noguchi et al. 2021) of BreastScreen WA participants found interval cancer rates were similar across age groups, at 11 per 10,000 women-years for younger women aged 40-49, approximately 9 per 10,000 women-years for women aged 50-69, and 12 per 10,000 women-years for older women aged 70+ (Table 28, page 72).

Also using BreastScreen WA data, El-Zaemey et al. (2021) found interval cancer rates were slightly higher for women aged 70-74 years (at 22 interval cancers per 10,000 women-years), compared to

women aged 65-69 and 75+, at 17 and 15 interval cancers per 10,000 women-years, respectively (Table 28, page 72).

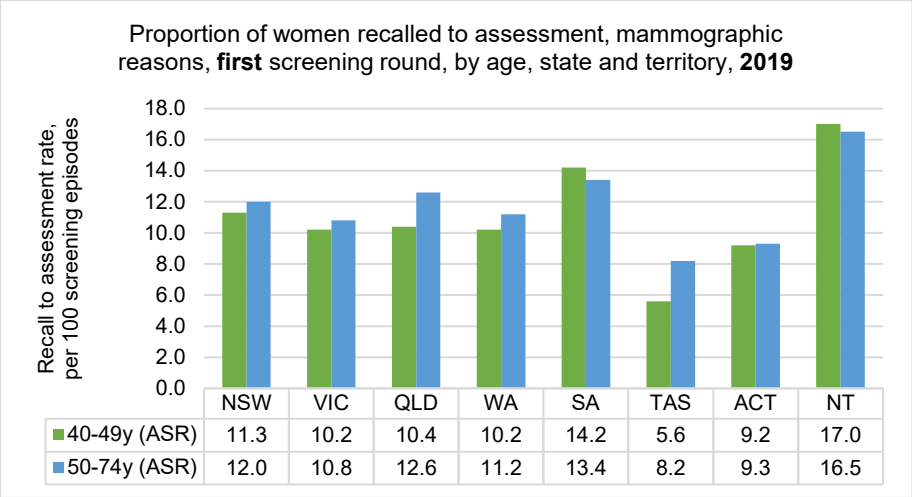
Among women attending NSW BreastScreen clinics in 1993-2008, interval cancer rates were constant across age groups when stratified by 0-12 month or 13-24 month intervals at first round screening (ranging from 6-9 and 7-12 interval cancers per 10,000 women-years, respectively) (Table 31, page 75) (Winch et al. 2015).

Recall to assessment rates

Recall to assessment rates at first round were highly variable across jurisdictions but were similar for women aged 40-49 years compared to 50-74 years in the majority of states and territories. At subsequent screening rounds women aged 40-49 years were more likely to be recalled to assessment than women aged 50-74 years (Australian Institute of Health and Welfare 2021b).

For example, at first round screening (Figure 19, below):

- The proportion of women aged 40-49 years recalled to assessment ranged from 5.6% (Tas.) to 17.0% (NT), compared to 8.2% (Tas.) to 16.5% (NT) for women aged 50-74 years



	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
40-49y (ASR)	11.3	10.2	10.4	10.2	14.2	5.6	9.2	17.0
50-74y (ASR)	12.0	10.8	12.6	11.2	13.4	8.2	9.3	16.5

Figure 19. Proportion of women recalled to assessment, mammographic reasons, first screening round, by age, state and territory, 2019; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).

At subsequent round screening (Figure 20, below):

- Recall to assessment rates were approximately a third of rates found at first round screening and were generally lower for women in the target age range. Between 3.3% (Tas) and 7.1% (SA) of women aged 40-49 years were recalled, compared to 3.1% (WA) to 4.7% (SA) of women aged 50-74 years.

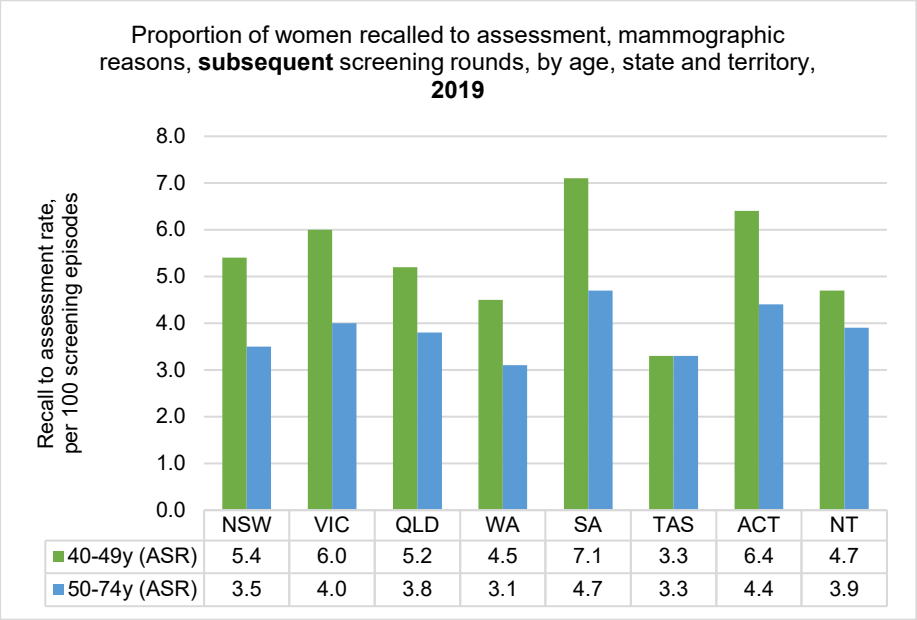


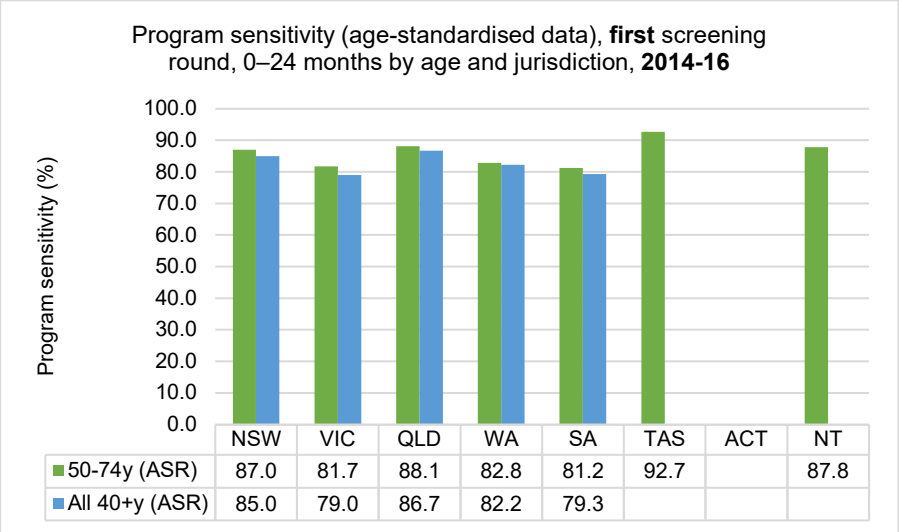
Figure 20. Proportion of women recalled to assessment, mammographic reasons, subsequent screening rounds, by age, state and territory, 2019; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).

In a WA study (Noguchi et al. 2021) of BreastScreen WA participants screened 2007-17, recall to assessment rates were highest for younger women (6.3% for women aged 40-49 years), compared to women aged 50 and above (ranging from 2.7-3.9% per 10-year age group) (Table 32, page 80).

In a NSW study (Winch et al. 2015) from a single clinic, among BreastScreen participants screened 1993-2008, recall to assessment rates were slightly lower in older women e.g. 2.9% aged 70-79 years versus 4.5-5.1% for women aged between 50-69 years) (Table 32, page 80).

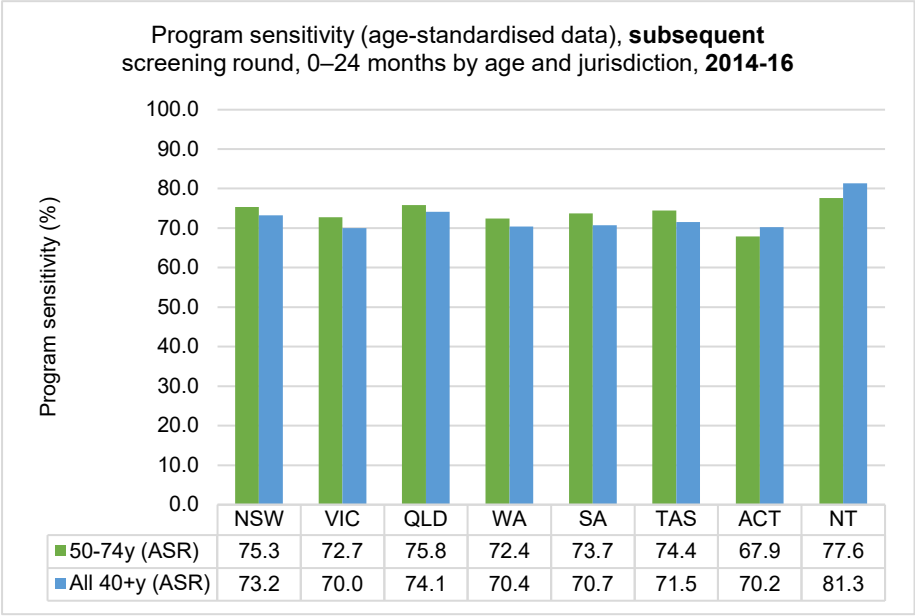
Program sensitivity

Program sensitivity based on age-standardised data across a 24-month period from 2014-16 varied between jurisdictions. For example, program sensitivity ranged from 81.2% to 92.7% across jurisdictions for women aged 50-74 years, compared to 79.0% to 86.7% for all women aged 40+ (Figure 21 and Figure 22, starting page 63) (Australian Institute of Health and Welfare 2021b). Program sensitivity based on crude data steadily increased with increasing age group (from 40-49 years, to 50-74 and 75+ years) in most jurisdictions at both first and subsequent screening rounds (Figure 26 and Figure 27, from page 90) (Australian Institute of Health and Welfare 2021d).



	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
50-74y (ASR)	87.0	81.7	88.1	82.8	81.2	92.7		87.8
All 40+y (ASR)	85.0	79.0	86.7	82.2	79.3			

Figure 21. Program sensitivity (age-standardised data), first screening round, 0–24 months by age and jurisdiction, 2014-16; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b). Blank data cells indicate data were not available.



	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
50-74y (ASR)	75.3	72.7	75.8	72.4	73.7	74.4	67.9	77.6
All 40+y (ASR)	73.2	70.0	74.1	70.4	70.7	71.5	70.2	81.3

Figure 22. Program sensitivity (age-standardised data), subsequent screening round, 0–24 months by age and jurisdiction, 2014-16; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).

An earlier study of a small sample of women attending BreastScreen Victoria in 1994-96 (when film mammography was performed) found that program sensitivity increased with increasing age for all-size and small (≤15mm) screen-detected breast cancers (Table 32, page 80)(Kavanagh et al. 2008). We found no more recent reporting of program sensitivity according to tumour size and age, within the scope of our literature search.

False positive rates

In a WA study (Noguchi et al. 2021) of BreastScreen WA examining over 1 million screening episodes in 2007-17, false positives among those recalled to assessment decreased as women got older. For example, false positives were highest in women aged 40-49 years, at 5.8 per 100 women

screened, decreasing to 3.3, 1.9 and 2.0 false positives per 100 screens for women aged 50-59, 60-69 and 70+ years, respectively (Table 32, page 80).

In contrast, an earlier study among women attending NSW BreastScreen clinic in 1993-2008 found that there did not appear to be a graded association between age and false positive screening rates, defined as a positive screening episode with a benign final outcome (Winch et al. 2015). For example, across ages 40-79 false positive rates per 100 women screened ranged between 4.3 to 5.7 at first round screening, and 2.6 and 3.1 at subsequent rounds of screening (Table 32, page 80).

Positive predictive value

Among BreastScreen WA participants screened in 2007-17, the positive predictive value (PPV: the proportion of invasive cancers or DCIS detected among women with a positive screen recalled to assessment) increased with increasing age, doubling with each 10-year age group up to 70 years (from 7.3, to 14.5, to 28.7 per 100 screens for women aged 40-49, 50-59, and 60-69 years, respectively) and continued to rise for ages 70+ (37.4 per 100 screens) (Table 32, page 80) (Noguchi et al. 2021).

3.4.6 Outcomes according to specific factors of interest

Indigenous women

In WA, higher rates of screen-detected invasive breast cancers (269 vs 218 per 10,000 women) and interval cancers (67 vs 32 per 10,000 women-years) were observed in non-Aboriginal women attending BreastScreen, compared to Aboriginal women (Table 31, page 75) (McLean et al. 2019).

Socioeconomic status

In the peer-reviewed literature, a study of BreastScreen WA participants screened in 2007-17 (Noguchi et al. 2021) detection rates of invasive cancer or DCIS (combined) were similar across SES quintiles, with slightly higher detection rates found in those most disadvantaged (quintiles 1-3, at 70-73 cancers detected per 10,000 women screened), compared to those least disadvantaged (quintiles 4-5, at 65-67 cancers detected per 10,000 women screened) (Table 31, page 75). Conversely, interval cancer rates were lower in the most disadvantaged women compared to women with the least disadvantage, at 7.9 (95% CI 6.7-9.3) versus 10.7 (95% CI 9.9-11.5) per 10,000 women-years. Recall to assessment rates and false positive recall rates were similar across SES quintiles, at 3-4% and 3%, respectively, and PPV decreased slightly with decreasing disadvantage (from 19.5 to 17.6 per 100 screens from quintile 1 to 5) (Table 32, page 80)(Noguchi et al. 2021).

Location of screening

A WA study (Hughes et al. 2014) found women attending rural (van) BreastScreen services were recalled for further ‘diagnostic review’ at a greater rate (62%) than women attending metropolitan clinics (30%) (Table 32, page 80), while screen-detected cancer rates were markedly lower (31 vs 70 invasive breast cancers detected per 10,000 women attending van and clinic services, respectively) (Table 31, page 75).

CALD women

In NSW, a small sample of Japanese-born migrant women participating in BreastScreen were found to have slightly higher recall to assessment rates than Australian-born women (8% versus 5%) (Table 32, page 80) (Mizukoshi et al. 2019).

Personal history of breast cancer

A WA study (Noguchi et al. 2021) of BreastScreen WA participants screened in 2007-17 found that detection rates of invasive cancer or DCIS (combined) increased by 1.7-fold for women aged 40+ with a personal history of breast cancer, compared to women without a personal history (111 versus 67 cancers or DCIS per 10,000 women screened) (Table 31, page 75). This increase remained after exclusion of first round screens and further stratifying by 10-year age group (up to age 69). Detection rates were similar by personal history status for women aged 70+. For women aged 40+ at all screening rounds, recall to assessment rates and false positive recall rates were similar by personal history status, while PPV doubled for women with a personal history of breast cancer (35.6%, compared to 17.8% for women with no personal history of breast cancer) (Table 32, page 80) (Noguchi et al. 2021). Small numbers of cancers (21 screen-detected and 3 interval cancers) were also reported for women with personal histories of ovarian cancer (data not shown) (Noguchi et al. 2021).

An earlier study of BreastScreen WA data from 1996-2006 showed markedly higher rates of invasive breast cancers or DCIS were screen-detected in BreastScreen participants with a personal history of breast cancer at all rounds (e.g. 1.6-fold in women aged 50-69, and 3.2-fold in women aged 40-49) (Table 31, page 75) (Houssami et al. 2011). Women without a personal history had lower grade tumours detected than women with a personal history (32% vs 19%), and this result was statistically significant (Table 33, page 84) (Houssami et al. 2011).

Personal history of benign breast disease

Cancer detection and program performance indicators were reported for women attending BreastScreen WA in 2007-2017 who had previously undergone breast surgery or biopsy for benign breast conditions (Noguchi et al. 2021). Rates of invasive cancer or DCIS (combined) were slightly higher for women aged 40+ with a prior surgery or biopsy for benign conditions, compared to women with none (88 versus 64 cancers per 10,000 screens), and results were similar at subsequent round screening when stratified by 10-year age group (Table 31, page 75). Interval cancer rates were markedly higher in women with prior surgery or biopsy for benign breast conditions for all age groups at subsequent screening round. For women aged 40+ at all screening rounds, recall to assessment rates and false positive recall rates were similar across groups, while PPV was slightly higher for women with a prior surgery or biopsy for benign breast conditions (21.8% versus 17.5% for women without) (Table 32, page 80) (Noguchi et al. 2021).

Family history of breast cancer

A study (Noguchi et al. 2021) of BreastScreen WA participants screened in 2007-17 found detection rates of invasive cancer or DCIS (combined) increased by 1.2 to 1.4-fold for women with a first-degree family history of breast cancer, compared to women without a family history (at all screening rounds for all women aged 40+, and when stratified by 10-year age groups at subsequent screening rounds only) (Table 31, page 75). Interval cancer rates were greater for younger women aged 40-49 years with a family history, at 14.1 interval cancers per 10,000 women-years (95% CI 11.2-17.7), compared to 9.6 (95% CI 8.4-11.0) for younger women without a family history. For women aged 40+ at all screening rounds, recall to assessment rates and false positive recall rates were similar by family history status, while overall accuracy of screening was slightly higher for women with a family history of breast cancer (PPV 21.6% versus 17.5% for women with no family history) (Table 32, page 80) (Noguchi et al. 2021).

A 2008 study based on BreastScreen Victoria participants with a family history of breast cancer cited slightly lower program sensitivity (70% versus 74%) (Table 32, page 80) (Kavanagh et al. 2008).

Mammographic breast density

Screen-detected rates of cancer or DCIS among women attending BreastScreen WA (2007-17) appeared to be slightly higher for women with heterogeneously or extremely dense breasts, as measured by radiologist visual assessment of the preceding mammogram, compared to women without dense breasts, for all ages, and when stratified by 10-year age group [65 versus 53 cancers or DCIS per 10,000 women screened for women with dense versus non-dense breasts, respectively (age 40+ at all screening rounds). (Table 31, page 75) (Noguchi et al. 2021). Interval cancer rates were markedly higher for women with dense breasts in all age groups at subsequent screening round, increasing by 2.4- to 2.7-fold in women with dense breasts (e.g. for women aged 70+, 26.2 versus 9.6 interval cancers per 10,000 women-years for women with dense breasts compared to women with non-dense breasts). Among women with dense breasts, recall to assessment and false positive rates were slightly higher, while PPV was slightly lower, compared to women with non-dense breasts (Table 32, page 80). Of note, differences between groups were assessed based on 95% confidence intervals around rates rather than statistical tests of group-level differences or trends.

Cheasley et al. (2020) reported on selected women in the lifepool cohort study who attended BreastScreen Victoria in 2010-18 and had an invasive breast cancer diagnosis (screening- or interval-detected) and a preceding mammogram available for density calculation by AutoDensity software (n=670). Compared to women in the lowest mammographic breast density quintile (n=142), women in the highest quintile (n=119) had greater proportions of invasive lobular carcinoma (9% versus 5%) and lower grade (1-2) tumours (80% versus 73%), however these differences were not statistically significant (Table 33, page 84). Hormone receptor status (e.g. triple negative versus luminal) and positive nodal involvement were similar across the two density groups (Cheasley et al. 2020). Note, 3 out of 261 women in this analysis were defined as ‘lapsed screeners’ (Table 33, page 84).

An older (1994-1996 data) case-control study of Victorian women aged 40-79 showed program sensitivity for all screening rounds for women with the least dense breasts (the lowest quintile) compared to the highest quintile was 85% versus 54%. Similar differences were observed for small (≤15mm) cancers only (Table 32, page 80) (Kavanagh et al. 2008), and when data was restricted to women aged 50-69 and by screening round (Nickson and Kavanagh, 2009) (data not shown but available in a previous ROSA technical report (Cancer Council Australia, 2019b)). Note, these studies were from film mammographic screening.

Genetic factors

In women in the lifepool cohort study who attended BreastScreen Victoria in 2010-2018 with genetic mutation data available (n=442), 12 women (3%) with invasive or in situ cancers detected had an actionable hereditary breast or ovarian cancer mutation: 7 BRCA2, 1 ATM, 3 CHEK2, and 1 PALB2 (Cheasley et al. 2019). One third were interval-detected cancers. Most (42%) screen- or interval-detected cancers were of luminal subtype (ER+ PR+ HER2-) and 2 women had triple negative (ER-PR- HER2-) invasive breast cancer (1 screen-detected and 1 interval-detected) (Table 30, page 84).

HRT use

Among BreastScreen WA participants (2007-17), detection rates of cancer or DCIS were higher, by approximately 1.2- to 1.3-fold, for women aged 50+ who used HRT in the past 6 months compared to non-users for the same time period (Table 31, page 75) (Noguchi et al. 2021). Interval cancer rates doubled for women using HRT in the past 6 months for women aged 60+ at subsequent screening rounds, as well as increasing with age, (e.g. 17.2 (users) versus 8.4 (non-users) interval cancers per 10,000 women-years for ages 60-69, and 21.8 (users) versus 10.7 (non-users) interval

cancers per 10,000 women-years for ages 70+). Recall to assessment rates, false positive rates and PPV were, however, similar across HRT use groups (Table 32, page 80) (Noguchi et al. 2021).

In SA, higher rates of screen-detected invasive breast cancers (60 vs 49 per 10,000 women-years) and interval cancers (29 vs 16 per 10,000 women-years) but not DCIS were seen in women aged 40+ currently using HRT, compared to never-users at first round of screening (Table 31, page 75) (Beckmann et al. 2013). Older data (1994-1996) from BreastScreen Vic. showed program sensitivity was reduced for women currently using HRT, compared to non-users (78% to 60%) (Table 32, page 80) (Kavanagh et al. 2008).

Geographical residence, reproductive risk factors and risk assessment tools

No jurisdiction-level BreastScreen outcomes data were found stratified by geographical residence, reproductive risk factors, or for women assessed using a breast cancer risk assessment tool.

3.5 Discussion

This scoping review highlights that the information collected and/or reported for the factors of interest for consideration of risk-based screening differs between state and territory BreastScreen services, and many of these factors have a strong association with screening outcomes. Although some information on BreastScreen outcomes according to different factors of interest is currently reported at a national level by the AIHW in the BSAMR, findings from various peer-reviewed studies suggest that some jurisdictions collect, or have collected, additional valuable data.

3.5.1 Data availability

We found that all BreastScreen performance indicators considered (i.e. screen-detected invasive cancers and DCIS, interval cancers, recalls to assessment and program sensitivity) were reported on an annual basis by age for all jurisdictions in the BSAMR, for selected periods across 2014 to 2019.

Outcomes reported in peer-reviewed literature according to other factors of interest were more limited, and were found for women attending BreastScreen NSW, Vic, WA and SA only. These included some outcomes among Indigenous women, small samples of CALD migrant women and women with a confirmed genetic mutation (including BRCA1/2), with some outcomes also reported according to socioeconomic status, personal history of breast cancer or procedures for benign breast disease, family history of breast cancer, HRT use, mammographic breast density and location of screening service (fixed versus mobile units).

These findings indicate the potential feasibility of routine or *ad hoc* collection and reporting of additional information by various state and territory BreastScreen services, producing information of considerable value for potential future risk-based screening protocols.

We did not find outcomes reported by location of residence (a measure of remoteness derived by reported postcode of residence), which is known to be routinely collected by all BreastScreen services. Limited information was available for other factors known to be collected, including for Indigenous status, socioeconomic status, language spoken at home (capturing some information of cultural and linguistical diversity), and personal history of breast disease (as determined by history of self-reported or screen-detected benign breast disease). It would be of value, if feasible, to expand routine reporting to include outcomes according to these factors.

BreastScreen outcomes were not available for reproductive risk factors or for women assessed by a breast cancer risk assessment tool; to our knowledge these factors are not routinely collected by

any BreastScreen services and would, therefore, require consideration of additional data collection requirements.

3.5.2 BreastScreen and other program performance indicators

Screen-detected cancers and program sensitivity generally increased with increasing age at all screening rounds; overall rates and the magnitude of increase across age groups varied across jurisdictions (Australian Institute of Health and Welfare 2021b, El-Zaemey et al. 2021, Winch et al. 2015). Invasive cancer detection increased further for women classified as 'high-risk' based on the presence of one or more listed cancer risk factors (personal history of breast cancer, family history of breast cancer, symptomatic, or HRT use; El-Zaemey et al. 2021). DCIS detection rates were more variable across age groups and jurisdictions (Australian Institute of Health and Welfare 2021b, El-Zaemey et al. 2021, Winch et al. 2015), although some rates were based on small case numbers. The likelihood of being recalled to assessment tended to decrease with increasing age (Australian Institute of Health and Welfare 2021b, Noguchi et al. 2021, Winch et al. 2015). Interval cancer rates were mostly similar across the age groups compared but differed across jurisdictions. Interval cancers (and program sensitivity) were influenced by varying jurisdictional policies for managing symptomatic women and women returning to screening within six months for early view, as well as how the program ascertains interval cancers, e.g. through data linkage, notification, or via self-report (Australian Institute of Health and Welfare 2021b, El-Zaemey et al. 2021). National-level data available in the annual BSAMR provided an overall picture of cancer detection and BreastScreen performance by age group (Australian Institute of Health and Welfare 2021b).

Many outcomes were available according to several factors of interest for BreastScreen WA, including from a recent study of over 1 million screening episodes performed from 2007-2017 (Noguchi et al. 2021). Higher rates of invasive cancer or DCIS were detected among women with a personal history of breast cancer compared to those without in 2007-17, consistent with findings from an earlier study using 1997-2006 data (Houssami et al. 2011). Positive predictive values doubled for women with a personal history of breast cancer (Noguchi et al. 2021). At subsequent screening round, interval cancer rates were markedly higher in women with prior surgery or biopsy for benign breast conditions for all age groups, and for women aged 40-49 with a first-degree family history of breast cancer, compared to women without these factors (Noguchi et al. 2021). False positive recall rates were highest in younger women aged 40-49, with screening accuracy (PPV) improving with increasing age (Noguchi et al. 2021). Rates of screen-detected and interval cancers were lower among Indigenous women than non-Indigenous women (McLean et al. 2019). Invasive cancer or DCIS detection was similar according to SES, but interval cancer rates were lower in women with the least disadvantage (Noguchi et al. 2021). Women attending mobile BreastScreen WA services were recalled for assessment more often but were less likely to have a screen-detected cancer. These differences were attributed to lower incidence of breast cancer in rural women (Hughes et al. 2014), although information was not provided regarding screening round, which may explain some of the observed difference.

BreastScreen performance indicators were available by mammographic breast density from two studies. BreastScreen WA routinely collects and reports breast density as measured by radiologist visual assessment. Based on this data, women with heterogeneously or extremely dense breasts had higher rates of interval cancers and false positive recalls to assessment than women without dense breasts (Noguchi et al. 2021). This may be attributable to the masking effect of breast density on mammographic screening (Ciatto et al. 2013, Kerlikowske et al. 2013, 2010) as both dense tissue and tumours appear white on a mammogram. Calculated program sensitivity was lower in women with more dense breasts attending BreastScreen Victoria, where breast density was categorised into quintiles based on retrospective measurements from film mammograms using automated software (Kavanagh et al. 2008). Breast density information is not yet collected (or

assessed) nationally; the current position by BreastScreen Australia (Australian Government Department of Health 2020) is that more evidence is required on how breast density is best assessed and managed, including evidence to support clinical pathways. Routinely reported outcomes by breast density – ideally assessed using an automated, standardised method obtained prospectively via digital mammograms – would aid evaluation of the current program and generate important baseline information for any risk-based screening protocols that incorporate mammographic breast density. However, this is a complex matter particularly without the provision of screening protocols tailored according to breast density (as discussed elsewhere in this report).

HRT use (now more specifically described as menopausal hormone therapy use) is a well-established risk factor for breast cancer. We found HRT users attending BreastScreen WA and SA had higher cancer detection rates (of both invasive/DCIS screen-detected cancers and interval cancers) (Noguchi et al. 2021, Beckmann et al. 2013), and based on data from BreastScreen Victoria calculated program sensitivity was reduced for women currently using HRT (Kavanagh et al. 2008).

3.5.3 Tumour characteristics

Tumour characteristics were described according to some factors of interest in peer-reviewed research studies. Hormone receptor status of screen-detected and interval cancers was available for a small sample of women with confirmed genetic mutations in the lifepool cohort (Vic.) (Cheasley et al. 2019), and tumour histology, grade, and nodal status were available for women with a personal history of breast cancer (WA) (Houssami et al. 2011) and for women in the lowest and highest mammographic density groups (Vic.) (Cheasley et al. 2020). Cancer registries now routinely collect some tumour information, such as grade and hormone receptor status, as they are known important indicators of prognosis and early detection and help guide treatment options. Routinely reported information on tumour characteristics at diagnosis would provide valuable insights concerning the impact of the BreastScreen Australia program.

3.5.4 Conclusion

The findings of this scoping review indicate age-stratified information is routinely reported for BreastScreen performance indicators (including cancer detection) for all state and territory programs, as published annually in the BSAMR. In the peer-reviewed literature, information on other factors of interest for risk-based screening (such as personal or family history of breast cancer, HRT use, and mammographic breast density) has been reported for various outcomes for some jurisdiction-level services, however it is unclear whether collection of information is performed routinely or on an ad hoc basis. Overall, our findings highlight opportunities to enhance collection and reporting of BreastScreen data with the view of establishing baseline outcomes prior to any introduction of risk-based screening protocols and monitoring for any changes that might arise.

This work directly informed current ROSA collaborative work with the AIHW, in consultation with state and territory BreastScreen services, to explore options for routine enhanced BreastScreen data collection and reporting for factors of interest for risk-based screening (Chapter 5.3 BreastScreen Australia Data enhancement report).

3.6 Tables

3.6.1 Data availability

Table 27. Jurisdiction-level data availability (BreastScreen performance indicators including cancer detection, other program performance indicators and tumour characteristics) in publicly available BreastScreen reports and peer-reviewed literature published from 2008 onwards, by factors of interest for risk-based screening.

	State/Territory	Age	Aboriginal or Torres Strait Islander	SES	Geographical residence	BreastScreen service area	CALD	Personal history of BC or DCIS	Personal history of breast disease	Family history of BC or DCIS	Mammographic breast density	Genetic factors	Reproductive risk factors	HRT use	Risk assessment tool
BreastScreen performance indicators including cancer detection															
Screen-detected invasive breast cancer rates	NSW	✓													
	Vic	✓													
	Qld	✓													
	WA	✓	✓	✓		✓		✓	✓	✓	✓			✓	
	SA	✓												✓	
	Tas	✓													
	ACT	✓													
	NT	✓													
Screen-detected DCIS rates	NSW	✓													
	Vic	✓													
	Qld	✓													
	WA	✓		✓				✓	✓	✓	✓			✓	
	SA	✓												✓	
	Tas	✓													
	ACT	✓													
	NT	✓													
Screen-detected small (≤15mm) invasive breast cancer rates	NSW	✓													
	Vic	✓													
	Qld	✓													
	WA	✓													
	SA	✓													
	Tas	✓													
	ACT	✓													
	NT	✓													
Interval (invasive) breast cancer rates	NSW	✓													
	Vic	✓													
	Qld	✓													
	WA	✓	✓	✓		✓			✓	✓	✓			✓	
	SA	✓												✓	
	Tas	✓													
	ACT	✓													
	NT	✓													
Recall to assessment rates	NSW	✓					✓								
	Vic	✓													
	Qld	✓													
	WA	✓		✓		✓		✓	✓	✓	✓			✓	
	SA	✓												✓	
	Tas	✓													
	ACT	✓													
	NT	✓													
Program sensitivity	NSW	✓													
	Vic	✓								✓	✓			✓	
	Qld	✓													
	WA	✓													
	SA	✓													
	Tas	✓													
	ACT	✓													

	State/Territory	Age	Aboriginal or Torres Strait Islander	SES	Geographical residence	BreastScreen service area	CALD	Personal history of BC or DCIS	Personal history of breast disease	Family history of BC or DCIS	Mammographic breast density	Genetic factors	Reproductive risk factors	HRT use	Risk assessment tool
	NT	✓													
Other program performance indicators															
False positive rates	NSW	✓													
	Vic														
	Qld														
	WA	✓		✓				✓	✓	✓	✓			✓	
	SA														
	Tas														
	ACT														
	NT														
Positive predictive value	NSW														
	Vic														
	Qld														
	WA	✓		✓		✓		✓	✓	✓	✓			✓	
	SA														
	Tas														
	ACT														
	NT														
Tumour characteristics															
Tumour histology	NSW														
	Vic										✓				
	Qld														
	WA							✓							
	SA														
	Tas														
	ACT														
	NT														
Tumour grade	NSW														
	Vic										✓				
	Qld														
	WA							✓							
	SA														
	Tas														
	ACT														
	NT														
Tumour nodal involvement	NSW														
	Vic										✓				
	Qld														
	WA							✓							
	SA														
	Tas														
	ACT														
	NT														
Tumour size	NSW														
	Vic														
	Qld														
	WA					✓									
	SA														
	Tas														
	ACT														
	NT														
Tumour hormone receptor status	NSW														
	Vic										✓	✓			
	Qld														
	WA														
	SA														
	Tas														
	ACT														
	NT														

Table 28. Cancer detection data in publicly available BreastScreen reports and peer-reviewed literature published from 2008 onwards, by factors of interest for risk-based screening.

	Breast cancer detection							
	Screen-detected invasive breast cancer rates		***Screen-detected DCIS rates***		***Screen-detected small (≤15mm) invasive breast cancer rates***		***Interval (invasive) breast cancer rates***	
	Publication	***Jurisdiction, data year(s)***	***Publication***	***Jurisdiction, data year(s)***	***Publication***	***Jurisdiction, data year(s)***	***Publication***	***Jurisdiction, data year(s)***
Reported in publicly available **B**reastScreen reports (overall)	BSAMR 2021	All jurisdictions, 2019	BSAMR 2021	All jurisdictions, 2019	BSAMR 2021	All jurisdictions, 2019	BSAMR 2021	All jurisdictions, 2014-16
Reported by factors of interest for risk-based screening								
Age	BSAMR 2021	All jurisdictions, 2019	BSAMR 2021	All jurisdictions, 2019	BSAMR 2021	All jurisdictions, 2019	BSAMR 2021	All jurisdictions, 2014-16
	Noguchi 2021	WA 2007-2017					Noguchi 2021	WA 2007-2017
	El-Zaemey 2021	WA 2015-2017	El-Zaemey 2021	WA 2015-2017	El-Zaemey 2021	WA 2015-2017	El-Zaemey 2021	WA 2015-2017
	Winch 2015	NSW 1993-2008	Winch 2015	NSW 1993-2008			Winch 2015	NSW 1993-2008
Aboriginal or Torres Strait Islander	McLean 2019	WA 2000-16	Not available		Not available		McLean 2019	WA 2000-16
Socioeconomic status	Noguchi 2021	WA 2007-2017			Not available		Noguchi 2021	WA 2007-2017
Geographical residence	Not available		Not available		Not available		Not available	
BreastScreen service area	Hughes 2014	WA 1999-2008	Not available		Not available		Hughes 2014	WA 1999-2008
Cultural and linguistical diversity	Not available		Not available		Not available		Not available	
Personal history of breast cancer or DCIS	Noguchi 2021	WA 2007-2017			Not available		Not available	
	Houssami 2011	WA 1997-2006						
Personal history of breast disease	Noguchi 2021	WA 2007-2017			Not available		Noguchi 2021	WA 2007-2017
Family history of breast cancer or DCIS	Noguchi 2021	WA 2007-2017			Not available		Noguchi 2021	WA 2007-2017
Mammographic breast density	Noguchi 2021	WA 2007-2017			Not available		Noguchi 2021	WA 2007-2017
Genetic factors	Not available		Not available		Not available		Not available	
Reproductive risk factors	Not available		Not available		Not available		Not available	
HRT use	Noguchi 2021	WA 2007-2017					Noguchi 2021	WA 2007-2017
	Beckmann 2013	SA 1998-2009	Beckmann 2013	SA 1998-2009	Not available		Beckmann 2013	SA 1998-2009
Risk measured by an assessment tool	Not available		Not available		Not available		Not available	

Table 29. BreastScreen and other program performance indicator data in publicly available BreastScreen reports and peer-reviewed literature published from 2008 onwards, by factors of interest for risk-based screening.

	BreastScreen and other program performance indicators							
	Recall to assessment rates		***Program sensitivity***		***False positive rates***		***Positive predictive value***	
	Publication	***Jurisdiction, data year(s)***	***Publication***	***Jurisdiction, data year(s)***	***Publication***	***Jurisdiction, data year(s)***	***Publication***	***Jurisdiction, data year(s)***
Reported in publicly available **B**reastScreen reports (overall)	BSAMR 2021	All jurisdictions, 2019	BSAMR 2021	All jurisdictions, 2014-16	Not available		Not available	
Reported by factors of interest for risk-based screening								
Age	BSAMR 2021	All jurisdictions, 2019	BSAMR 2021	All jurisdictions, 2014-16				
	Noguchi 2021	WA 2007-2017			Noguchi 2021	WA 2007-2017	Noguchi 2021	WA 2007-2017
	Winch 2015	NSW 1993-2008	Kavanagh 2008	Vic 1994-96	Winch 2015	NSW 1993-2008		
Aboriginal or Torres Strait Islander	Not available		Not available		Not available		Not available	
Socioeconomic status	Noguchi 2021	WA 2007-2017			Noguchi 2021	WA 2007-2017	Noguchi 2021	WA 2007-2017
Geographical residence	Not available		Not available		Not available		Not available	
BreastScreen service area	Hughes 2014	WA 1999-2008	Hughes 2014	WA 1999-2008	Not available		Hughes 2014	WA 1999-2008
Cultural and linguistical diversity	Mizukoshi 2019	NSW 2014-15	Not available		Not available		Not available	
Personal history of breast cancer or DCIS	Noguchi 2021	WA 2007-2017			Noguchi 2021	WA 2007-2017	Noguchi 2021	WA 2007-2017
	Houssami 2011	WA 1997-2006					Houssami 2011	WA 1997-2006
Personal history of breast disease	Noguchi 2021	WA 2007-2017			Noguchi 2021	WA 2007-2017	Noguchi 2021	WA 2007-2017
Family history of breast cancer or DCIS	Noguchi 2021	WA 2007-2017			Noguchi 2021	WA 2007-2017	Noguchi 2021	WA 2007-2017
			Kavanagh 2008	Vic 1994-96				
Mammographic breast density	Noguchi 2021	WA 2007-2017			Noguchi 2021	WA 2007-2017	Noguchi 2021	WA 2007-2017
			Kavanagh 2008	Vic 1994-96				
Genetic factors	Not available		Not available		Not available		Not available	
Reproductive risk factors	Not available		Not available		Not available		Not available	
HRT use	Noguchi 2021	WA 2007-2017			Noguchi 2021	WA 2007-2017	Noguchi 2021	WA 2007-2017
	Beckmann 2013	SA 1998-2009	Kavanagh 2008	Vic 1994-96				
Risk measured by an assessment tool	Not available		Not available		Not available		Not available	

Table 30. Detected tumour characteristic data in publicly available BreastScreen reports and peer-reviewed literature published from 2008 onwards, by factors of interest for risk-based screening.

	Tumour characteristics at detection									
	Histology		***Tumour grade***		***Node(s) involved***		***Size***		***Hormone receptor status***	
	Publication	***Jurisdiction, data year(s)***	***Publication***	***Jurisdiction, data year(s)***	***Publication***	***Jurisdiction, data year(s)***	***Publication***	***Jurisdiction, data year(s)***	***Publication***	***Jurisdiction, data year(s)***
Reported in publicly available **B**reastScreen reports (overall)	Not available		Not available		Not available		Not available		Not available	
Reported by factors of interest for risk-based screening										
Age	Not available		Not available		Not available		Not available		Not available	
Socioeconomic status	Not available		Not available		Not available		Not available		Not available	
Geographical residence	Not available		Not available		Not available		Not available		Not available	
BreastScreen service area	Not available		Not available		Not available		Hughes 2014	WA 1999-2008	Not available	
Cultural and linguistical diversity	Not available		Not available		Not available		Not available		Not available	
Personal history of breast cancer or DCIS	Houssami 2011	WA 1997-2006	Houssami 2011	WA 1997-2006	Houssami 2011	WA 1997-2006	Not available		Not available	
Personal history of breast disease	Not available		Not available		Not available		Not available		Not available	
Family history of breast cancer or DCIS	Not available		Not available		Not available		Not available		Not available	
Mammographic breast density	Cheasley 2020	Vic 2010-18	Cheasley 2020	Vic 2010-18	Cheasley 2020	Vic 2010-18	Not available		Cheasley 2020	Vic 2010-18
Genetic factors	Not available		Not available		Not available		Not available		Cheasley 2019	Vic 2010-18
Reproductive risk factors	Not available		Not available		Not available		Not available		Not available	
HRT use	Not available		Not available		Not available		Not available		Not available	
Risk measured by an assessment tool	Not available		Not available		Not available		Not available		Not available	

3.6.2 Cancer detection, BreastScreen and other program performance indicators, and detected tumour characteristics

Table 31. Invasive breast cancer (all-size and small), DCIS and interval breast cancer detection rates by factors of interest for risk-based screening.

Study ***Data source***	***Age (y)***	***Factor***	***No. screens***	***Screen-detected invasive breast cancer rates - all size unless specified (95% confidence interval)***		***Screen-detected DCIS rates***		***Interval (invasive) breast cancer rates*** *(95% confidence interval)*			
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		Age		Invasive BC **or** DCIS 2007-2017; CR; per 10,000 women screened				2007-2017; CR; per 10,000 women-years			
				All R				All R			
	40-49	40-49y	142,700	46 (42-49)				10.5 (9.3-11.7)**			
	50-59	50-59y	424,213	56 (54-58)				9.1 (8.5-9.8)**			
	60-69	60-69y	356,073	78 (75-81)				9.5 (8.8-10.2)**			
	70+	70+y	103,151	120 (113-127)				11.7 (10.3-13.4)**			
El-Zaemey 2021 Retrospective BS WA data (2015-2017 cohort) N=69,211 Screens=75,081		Age and risk based on presence of ≥1 other factor		2015-2017; CR; per 10,000 women screened		2015-2017; CR; per 10,000 women screened		2015-2017; CR; per 10,000 women-years			
				All size	Small (≤15mm)						
				All R	All R	All R		All R			
	65-69	65-69y	39,886	65 (58-74)	39 (33-46)	16 (13-21)		17 (13-22)			
		High risk#	NR	86 (72-103)							
		Not high risk#	NR	54 (46-64)							
	70-74	70-74y	26,432	81 (71-93)	51 (44-61)	20 (15-27)		22 (18-29)			
		High risk#	NR	108 (89-130)							
		Not high risk#	NR	66 (55-80)							
	75+	75+y	8,763	114 (93-139)	64 (49-83)	13 (7-22)		15 (9-25)			
		High risk#	NR	141 (110-182)							
		Not high risk#	NR	89 (66-121)							
Winch 2015 Retrospective BS NSW (Sydney West) data N=231,824 Screens=801,636; 792,015 40-79y		Age		1993-2008; CR; per 10,000 women screened		1993-2008; CR; per 10,000 women screened		1993-2008; CR; per 10,000 women-years			
								0-12mo		13-24mo	
				R1	R2+	R1	R2+	R1	R2+	R1	R2+
	40-49	40-49y	R1 75,486 / R2+ 85,281	24.0	13.0	7.0	5.0	6.0	5.0	9.0	10.0
	50-59	50-59y	R1 79,543 / R2+ 256,632	53.0	32.0	10.0	7.0	6.0	7.0	9.0	10.0
	60-69	60-69y	R1 36,729 / R2+ 183,637	70.0	46.0	12.0	10.0	4.0	5.0	7.0	8.0
	70-79	70-79y	R1 11,630 / 63,077 R2+	118.0	55.0	25.0	10.0	9.0	6.0	12.0	8.0
	50-69	50-69y	NR	59.0	38.0	NR	NR	NR		NR	

Study ***Data source***	***Age (y)***	***Factor***	***No. screens***	***Screen-detected invasive breast cancer rates - all size unless specified (95% confidence interval)***	***Screen-detected DCIS rates***	***Interval (invasive) breast cancer rates*** *(95% confidence interval)*
McLean 2019 Retrospective BS WA data N=NR Screens=311,317		Aboriginal or Torres Strait Islander status		2000-16; CR; per 10,000 women screened	NR	2000-14; CR; per 10,000 women-years; 0-24 mo
				All R		All R
	All 40+	Aboriginal	4,722	218.1		32.0 (/4,060 screens)
		Non-Aboriginal	306,595	269.4		66.5 (/275,321 screens)
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		Socioeconomic status		Invasive BC **or** DCIS 2007-2017; CR; per 10,000 women screened		2007-2017; CR; per 10,000 women-years
		SES (SEIFA IRSD) quintile		All R		All R
	All 40+	1 (most disadvantaged)	98,683	70 (65-75)		7.9 (6.7-9.3)**
		2	231,500	73 (69-76)		9.8 (8.9-10.8)**
		3	199,763	70 (66-74)		9.0 (8.2-10.1)**
		4	160,137	67 (63-71)		9.4 (8.4-10.6)**
		5 (least disadvantaged)	331,041	65 (62-68)		10.7 (9.9-11.5)**
		Postcode unclassifiable or missing: 5,013 screens				
Hughes 2014 Retrospective BS WA data N=NR Screens=760,027		BreastScreen WA service location		1999-2008; CR; per 10,000 women screened	NR	1999-2008; CR; per 10,000 women-years
						0-12mo 13-24mo
				All R		All R All R
	50-69	Rural (van)	545,699	30.7		0.16** 0.54**
		Metro (clinic)	214,328	70.4		0.70** 0.76**
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		Personal history of breast cancer		Invasive BC **or** DCIS 2007-2017; CR; per 10,000 women screened		NR – Noguchi et al report interval cancer rate by personal history of breast cancer could not be estimated because recurrent and second breast cancers are not routinely reported to cancer registries.
				All R R2+		
	All 40+	Yes	39,086	111 (101-122)		
	40-49	Yes	922	65 (29-145)		
	50-59	Yes	8688	77 (61-98)		
	60-69	Yes	16,710	122 (107-140)		
	70+	Yes	10,609	123 (104-146)		
	All 40+	No	987,049	67 (65-68)		
	40-49	No	78,958	36 (32-40)		
	50-59	No	343,085	46 (44-49)		
	60-69	No	328,517	73 (71-76)		
	70+	No	90,147	116 (110-124)		
Houssami 2011 Retrospective BS WA data		Personal history of breast cancer		Invasive BC **or** DCIS 1997-2006; CR; per 10,000 women screened		NR
				All R R1 R2+		

Study ***Data source***	***Age (y)***	***Factor***	***No. screens***	***Screen-detected invasive breast cancer rates - all size unless specified (95% confidence interval)***			***Screen-detected DCIS rates***	***Interval (invasive) breast cancer rates*** *(95% confidence interval)*	
N=NR Screens=713,191	All 40+	Yes	R1 1,191 / R2+ 11,167	95.5*	125.9	92.2			
	40-49	Yes	R1 161 / R2+ 423	102.7	0	141.8*			
	50-69	Yes	R1 767 / R2+ 8,634	95.7	143.4	91.5			
	70+	Yes	R1 263 / R2+ 2,110	92.7	152.1	85.3*			
	All 40+	No	R1 135,072 / R2+ 565,761	57.2*	67.4	54.7			
	40-49	No	R1 57,978 / R2+ 68,874	31.7	37.8	26.6*			
	50-69	No	R1 71,290 / R2+ 462,646	59.4	82.0	55.9			
	70+	No	R1 5,174 / R2+ 34,241	109.1	197.1	95.8*			
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		Personal history of breast surgery/ biopsy for benign breast conditions		Invasive BC **or** DCIS 2007-2017; CR; per 10,000 women screened				2007-2017; CR; per 10,000 women-years	
				All R	R2+			All R	R2+
	All 40+	Yes	182,562	88 (94-92)				14.6 (13.3-16.0)**	
	40-49	Yes	11,572		41 (31-54)				16.1 (12.4-21.1)**
	50-59	Yes	62,208		61 (55-67)				13.2 (11.4-15.3)**
	60-69	Yes	69,330		95 (88-103)				14.2 (12.3-16.4)**
	70+	Yes	21,152		148 (132-165)				19.0 (15.2-23.9)**
	All 40+	No	843,575	64 (62-66)				8.6 (8.2-9.1)**	
	40-49	No	68,308		35 (21-40)				9.7 (8.5-11.0)**
	50-59	No	289,557		44 (42-47)				8.3 (7.6-9.0)**
	60-69	No	275,897		71 (68-74)				8.3 (7.6-9.1)**
	70+	No	79,604		109 (102-117)				9.8 (8.3-11.5)**
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		First degree family history of breast cancer		Invasive BC **or** DCIS 2007-2017; CR; per 10,000 women screened				2007-2017; CR; per 10,000 women-years	
				All R	R2+			All R	R2+
	All 40+	Yes	211,742	82 (79-86)				10.9 (9.9-12.1)**	
	40-49	Yes	20,840		42 (34-51)				14.1 (11.2-17.7)**
	50-59	Yes	70,402		56 (51-62)				10.4 (8.8-12.3)**
	60-69	Yes	72,424		89 (92-96)				10.3 (8.6-12.3)**
	70+	Yes	25,294		147 (133-163)				10.1 (7.5-13.6)**
	All 40+	No	814,395	65 (63-67)				9.4 (8.9-9.9)**	
	40-49	No	59,040		34 (30-39)				9.6 (8.4-11.0)**

Study ***Data source***	***Age (y)***	***Factor***	***No. screens***	***Screen-detected invasive breast cancer rates - all size unless specified (95% confidence interval)***	***Screen-detected DCIS rates***	***Interval (invasive) breast cancer rates*** *(95% confidence interval)*
	50-59	No	281,373	45 (42-47)		8.9 (8.2-9.6)**
	60-69	No	272,803	72 (69-76)		9.3 (8.5-10.1)**
	70+	No	75,462	107 (100-115)		12.2 (10.5-14.1)**
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		Mammographic breast density "Dense breasts" (BI-RADS 3-4 heterogeneously or extremely dense breasts by ≥1 radiologist)		Invasive BC **or** DCIS 2007-2017; CR; per 10,000 women screened		2007-2017; CR; per 10,000 women-years
				All R R2+		All R R2+
	All 40+	Yes	235,476	65 (61-70)**		17.3 (16.1-18.6)**
	40-49	Yes	18,561	46 (38-57)		15.9 (13.6-18.5)**
	50-59	Yes	56,491	53 (47-59)		15.8 (14.2-17.6)**
	60-69	Yes	36,458	84 (75-94)		19.4 (17.0-22.1)**
	70+	Yes	6,507	124 (100-155)		26.2 (20.7-33.2)**
	All 40+	No	703,213	53 (52-56)**		7.1 (6.7-7.6)**
	40-49	No	27,829	28 (22-35)		6.2 (5.1-7.6)**
	50-59	No	152,678	38 (35-41)		6.5 (5.9-7.2)**
	60-69	No	182,695	63 (78-95)		7.4 (6.7-8.2)**
	70+	No	43,748	86 (78-95)		9.6 (5.1-7.6)**
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		HRT use		Invasive BC **or** DCIS 2007-2017; CR; per 10,000 women screened		2007-2017; CR; per 10,000 women-years
		in past 6 months		All R R2+		All R R2+
	All 40+	Yes	121,189	80 (75-85)		14.6 (13.1-16.2)**
	40-49	Yes	4882	23 (12-41)		7.8 (4.4-13.8)**
	50-59	Yes	52,021	59 (53-66)		12.4 (10.5-14.6)**
	60-69	Yes	42,710	97 (89-107)		17.2 (14.6-20.2)**
	70+	Yes	9,056	145 (122-171)		21.8 (15.9-30.0)**
	All 40+	No	904,850	67 (65-69)		9.0 (8.6-9.5)**
	40-49	No	74,993	37 (33-42)		10.6 (9.4-12.0)**
	50-59	No	299,707	45 (43-48)		8.6 (7.9-9.3)**

Study ***Data source***	***Age (y)***	***Factor***	***No. screens***	***Screen-detected invasive breast cancer rates - all size unless specified (95% confidence interval)***		***Screen-detected DCIS rates***		***Interval (invasive) breast cancer rates*** *(95% confidence interval)*	
	60-69	No	302,484	73 (70-76)				8.4 (7.6-9.1)**	
	70+	No	91,695	114 (108-122)				10.7 (9.3-12.4)**	
Beckmann 2013 Retrospective BS SA data N=234,370 Screens=819,722		HRT use		1998-2009; CR; per 10,000 women screened		1998-2009; CR; per 10,000 women screened		1998-2009; CR; per 10,000 women-years; 0-24 mo	
				R1	R2+	R1	R2+	R1	R2+
	All 40+	Current	R1 24,547 / R2+ 206,263~	60.3	56.1	13.0	11.1	28.9	28.1
		Past use/never	R2+ 489,938		42.6		10.3		14.5
		Never	R1 98,970	49.0		12.5		16.0	
		All women		51.2	46.6	12.6	10.5	18.5	18.3
		~Data missing: 4 screens							

Table footnote: BC = breast cancer; BS = BreastScreen; CR = crude rate; mo = months; NR = not reported; R = rounds; R1 = first screening round; R2+= subsequent screening rounds; SEIFA IRSD = Socio-Economic Indexes for Areas Index of Relative Socio-economic Disadvantage; y = years. #El-Zaemey 2021: 'High risk' refers to screens where at least one of these risk factors was recorded: family history of breast cancer; a personal history of breast cancer; presented with breast symptoms; or used HRT during the last six months (otherwise screens were considered 'not high-risk' where none of the above factors was recorded). Winch 2015: Size of screen-detected invasive BC rates reported per American Joint Committee on Cancer staging classification (T1mi ≤1mm to T1b ≤10mm and T1c >10mm but ≤20mm) but not extracted as no ≤15mm data, which is the BreastScreen Australia definition of small breast cancers (Australian Institute of Health and Welfare 2021b). *Houssami 2011: 1996-2007 data with an asterisk is superseded by 2007-17 data reported by Noguchi 2021. **Noguchi 2021; Hughes 2014: Data extracted as reported in article.

Table 32. Recall to assessment rates, program sensitivity, false positive rates, and positive predictive value by factors of interest for risk-based screening.

				BreastScreen and other program performance indicators			
Study Data source	***Age (y)***	***Factor***	***No. screens***	***Recall to assessment rates***	***Program sensitivity (%)***	***False positive recall rates***	***Positive predictive value***
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		Age		2007-2017; CR; per 100 screens	NR	2007-2017; CR; per 100 screens	2007-2017; CR; per 100 screens
				All R		All R	All R
	40-49	40-49y	142,700	6.3 (6.13-6.38)		5.8^	7.3^^
	50-59	50-59y	424,213	3.9 (3.8-3.91)		3.3^	14.5^^
	60-69	60-69y	356,073	2.7 (2.66-2.77)		1.9^	28.7^^
	70+	70+y	103,151	3.2 (3.1-3.31)		2.0^	37.4^^
Winch 2015 Retrospective BS NSW (Sydney West) data N=231,824 Screens=801,636 all women; 792,015 40-79y		Age		1993-2008; CR; per 100 screens†	NR	1993-2008; CR; per 100 women screened†	NR
				R1 R2+		R1 R2+	
	40-49	40-49y	R1 75,486 / R2+ 85,281	4.5 2.8		4.8 2.9	
	50-59	50-59y	R1 79,543 / R2+ 256,632	5.1 2.7		5.7 3.1	
	60-69	60-69y	R1 36,729 / R2+ 183,637	3.7 2.5		4.5 3.1	
	70-79	70-79y	R1 11,630 / R2+ 63,077	2.9 2.0		4.3 2.6	
Kavanagh 2008 Case-control study# BS Vic, Victorian Cancer Registry N=1,394 cases Screens=1,394		Age		NR	1994-96; 0-24 mo	NR	NR
					All R All R		
					All-size Small BC ≤15mm		
	All 40+	All 40+			73.5 (1,025/1,394) 64.9 (683/1,052)		
	40-49	40-49y n=103			49.5 (51/103) 37.3 (31/83)		
	50-69	50-69y n=1,039			73.2 (761/1,039) 64.9 (513/791)		
	70+	70+y n=252			84.5 (213/252) 78.1 (139/178)		
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		Socioeconomic status		2007-2017; CR; per 100 screens	NR	2007-2017; CR; per 100 screens	2007-2017; CR; per 100 screens
		SES (SEIFA IRSD) quintile					
				All R		All R	All R
	All 40+	1 (most disadvantaged)	98,683	3.6		2.9^	19.5^^
		2	231,500	3.7		3.0^	19.6^^
		3	199,763	3.8		3.1^	18.4^^
		4	160,137	3.8		3.1^	17.5^^
		5 (least disadvantaged)	331,041	3.7		3.0^	17.6^^

				BreastScreen and other program performance indicators			
Study ***Data source***	***Age (y)***	***Factor***	***No. screens***	***Recall to assessment rates***	***Program sensitivity (%)***	***False positive recall rates***	***Positive predictive value***
		Postcode unclassifiable or missing: 5,013 screens					
Hughes 2014 Retrospective BS WA data N=NR Screens=760,027		BreastScreen WA service location		1999-2008; CR; per 100 screens Recalled for 'diagnostic further view'	1999-2008; CR; 0-24 mo	NR	1999-2008; CR; Invasive BC per 100 women recalled
				All R	All R		All R
	50-69	Rural (van)	545,699	62.4	0.95**		10.9
		Metro (clinic)	214,328	29.6	0.91**		13.1
Mizukoshi 2019 Retrospective BS NSW data N=677 Screens=677		Cultural and linguistical diversity		2014-15; CR; per 100 screens	NR	NR	NR
		Country of birth		All R			
	40-69	Australia n=200		5.0			
		Japan n=198		8.1			
	Excludes missing data (n=7) and subgroup of Japanese-born women living in Japan (n=272)						
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		Personal history of breast cancer		2007-2017; CR; per 100 screens	NR	2007-2017; CR; per 100 screens	2007-2017; CR; per 100 screens
				All R		All R	All R
	All 40+	Yes	39,086	3.1		2.0^	35.6^^
		No	987,049	3.8		3.1^	17.8^^
Houssami 2011 Retrospective BS WA data N=NR Screens=713,191		Personal history of breast cancer		1997-2006; CR; per 100 screens	NR	NR	1997-2006; CR; Invasive BC **or DCIS** per 100 women recalled
				All R R1 R2+			All R
	All 40+	Yes	R1 1,191 / R2+ 11,167	3.9 6.7 3.5			24.8 (95%CI 21.0,28.9)*
	40-49	Yes	R1 161 / R2+ 423	5.7 5.6 5.7			
	50-69	Yes	R1 767 / R2+ 8,634	3.8 6.6 3.5			
	70+	Yes	R1 263 / R2+ 2,110	3.8 7.6 3.3			
	All 40+	No	R1 135,072 / R2+ 565,761	5.0 10.4 3.8			11.2 (95%CI 10.9,11.6)*
	40-49	No	R1 57,978 / R2+ 68,874	7.8 11.0 5.1			
	50-69	No	R1 71,290 / R2+ 462,646	4.4 10.1 3.6			
	70+	No	R1 5,174 / R2+ 34,241	4.3 9.3 3.6			
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		Personal history of breast surgery/ biopsy for benign breast conditions		2007-2017; CR; per 100 screens	NR	2007-2017; CR; per 100 screens	2007-2017; CR; per 100 screens
				All R		All R	All R
	All 40+	Yes	182,562	4.0		3.2^	21.8^^
		No	843,575	3.7		3.0^	17.5^^

				BreastScreen and other program performance indicators			
Study ***Data source***	***Age (y)***	***Factor***	***No. screens***	***Recall to assessment rates***	***Program sensitivity (%)***	***False positive recall rates***	***Positive predictive value***
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		First degree family history of breast cancer		2007-2017; CR; per 100 screens	NR	2007-2017; CR; per 100 screens	2007-2017; CR; per 100 screens
				All R		All R	All R
	All 40+	Yes	211,742	3.8		3.0^	21.6^^
		No	814,395	3.7		3.1^	17.5^^
Kavanagh 2008 Case-control study# BS Vic, Victorian Cancer Registry N=1,394 cases Screens=1,394		Family history of breast cancer		NR	1994-96; 0-24 mo	NR	NR
					All R / All R		
					All-size / Small BC ≤15mm		
	40-79	Yes n=152			70.4 (107/152) / 60.5 (69/114)		
		No n=1,242			73.9 (918/1,242) / 65.5 (614/938)		
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		Mammographic breast density		2007-2017; CR; per 100 screens	NR	2007-2017; CR; per 100 screens	2007-2017; CR; per 100 screens
		"Dense breasts" (BI-RADS 3-4 heterogeneously or extremely dense breasts by ≥1 radiologist)		All R		All R	All R
	All 40+	Yes	235,476	1.6		1.3^	20.3^^
		No	703,213	1.3		1.0^	23.5^^
Kavanagh 2008 Case-control study# BS Vic, Victorian Cancer Registry N=1,394 cases Screens=1,394		Mammographic breast density		NR	1994-96; 0-24 mo	NR	NR
					All R / All R		
	40-79	Percent breast density (visually measured on digitized mammograms by 2 radiologists) by quintile:			All-size / Small BC ≤15mm*		
		Q1 <2.1% n=196			84.7 (166/196) / 82.4 (140/170)		
		Q2 2.1-6.3% n=268			82.8 (222/268) / 76.9 (153/199)		
		Q3 6.3-14.0% n=308			79.6 (246/309) / 70.8 (153/216)		
		Q4 14.0-26.5% n=328			70.7 (232/328) / 59.5 (141/237)		
		Q5 >26.5% n=293			54.3 (159/293) / 41.7 (96/230)		
		D9 26.5-37.0% n=140			60.0 (84/140) / 48.1 (52/108)		
		D10 >37.0% n=153			49.0 (75/153) / 36.1 (44/122)		
Noguchi 2021 Retrospective BS WA data N=323,082 Screens=1,026,137		HRT use		2007-2017; CR; per 100 screens	NR	2007-2017; CR; per 100 screens	2007-2017; CR; per 100 screens
		in past 6 months		All R		All R	All R
	All 40+	Yes	121,189	4.1		3.3^	19.8^^

				BreastScreen and other program performance indicators			
Study ***Data source***	***Age (y)***	***Factor***	***No. screens***	***Recall to assessment rates***	***Program sensitivity (%)***	***False positive recall rates***	***Positive predictive value***
		No	904,850	3.7		3.0^	18.2^^
Beckmann 2013 Retrospective BS SA data N=234,370 Screens=819,722		HRT use		1998-2009; CR; per 100 screens	NR	NR	NR
				R1 R2+			
	All 40+	Current	R1 24,547 / R2+ 206,263~	5.1 2.8			
		Past use/never	R2+ 489,938	2.1			
		Never	R1 98,970	4.9			
		All women		5.0 2.3			
		~Missing data for 4 screening episodes					
Kavanagh 2008 Case-control study# BS Vic, Victorian Cancer Registry N=1,394 cases Screens=1,394		HRT use		NR	1994-96; 0-24 mo	NR	NR
		Current use			All R All R		
					All-size Small BC ≤15mm		
	40-79	Yes n=304			59.2 (180/304) 49.0 (119/243)		
		No n=1,090			77.5 (845/1,090) 69.7 (564/809)		

Table footnote BC = breast cancer; BS = BreastScreen; CI = confidence interval; mo = months; NR = not reported; R = rounds; R1 = first screening round; R2+= subsequent screening rounds; y = years. †Winch 2015: Recall to assessment rates extracted from Table 1 “Recall from screening”, False positive screening rates extracted from Table 1 "An abnormal mammogram (BI-RADS 3 or above) was defined as recall from screening if no cancer was detected after further assessment (imaging ± biopsy)”. *Houssami 2011: 1996-2007 data with an asterisk is superseded by 2007-17 data reported by Noguchi 2021. **Hughes 2014: Data extracted as reported in article. #Kavanagh 2008: Cases R1 n=866 (1994-95), R2+ n=538 (1995-96); Controls R1 n=2,052, R2+ n=3,264. Excludes women with personal history of BC/DCIS, symptoms, or if any data missing required for regression model. ^Noguchi 2021: False positive recall rates calculated by review team from Table 1 (n recalls minus n screen-detected cancers, divided by total screens, per 100 screens). ^^Noguchi 2021: PPV calculated by review team from Table 1 (n screen-detected cancers divided by n recalls, per 100 screens).

Table 33. Screen-detected tumour histology, grade, nodal involvement, size, and hormone receptor status by factors of interest for risk-based screening.

				Detected tumour characteristics (as % cancers)				
Study ***Data source***	***Age (y)***	***Factor***	***No. screens***	***Histology***	***Tumour grade (G1-G3)***	***Nodal status***	***Size (small ≤15mm)***	***Hormone receptor status***
Hughes 2014 Retrospective BS WA data N=NR Screens=760,027		BreastScreen WA service location		NR	NR	NR	1999-2008; <15mm; Invasive BC (no. cancers NR)	NR
							All R	
	50-69	Rural (van)	545,699				60.6	
		Metro (clinic)	214,328				57.8	
Houssami 2011 Retrospective BS WA data N=NR Screens=713,191		Personal history of breast cancer		1997-2006	1997-2006	1997-2006	NR	NR
				All R (p=0.74 NS)	All R (**p=0.02**)	All R (p=0.16 NS)		
	All 40+	Yes n=118	12,358	IDC: 56.8, DCIS: 26.3, Other 16.9	G1 18.8, G2 52.5, G3 28.7 Excludes unspecified/ missing n=17	Positive 1.7		
		No n=4007	700,833	IDC: 59.1, DCIS: 23.2, Other 17.5 Excludes unspecified n=10	G1 31.8, G2 45.1, G3 23.1 Excludes unspecified/ missing n=480	Positive 4.4		
						No missing data		
Cheasley 2020 Retrospective BS Vic data, Vic Cancer Registry data, Lifepool study N=842; of which n=670 invasive BC cases had preceding mammogram available for density calculation by AutoDensity software Screens=NR		Mammographic breast density		2010-18	2010-18	2010-18	NR	2010-18
		Percent breast density (quintile):		All R (p=0.3523 NS)	All R (p=0.4003 NS)	All R (p>0.9999 NS)		All R (p=0.9450 NS)
	All 40+	Q1 n=142 Screen-detected invasive n=130 Interval invasive n=10 Cancer in lapsed screener n=2	NR	IDC: 82.4, ILC: 4.9, Unspecified 12.7	G1 25.6, G2 47.0, G3 27.3 Excludes unspecified/ missing n=10	Positive 21.2 Excludes unspecified/ missing n=38		Triple negative 7.5 ER- HER2+ 1.5 Luminal HER2+ 6.0 Luminal 85.1 Excludes unspecified/missing n=8
		Q5 n=119 Screen-detected invasive n=91 Interval invasive n=27 Cancer in lapsed screener n=1	NR	IDC: 76.5, ILC: 9.2, Unspecified 14.3	G1 29.0, G2 51.4, G3 19.6 Excludes unspecified/ missing n=12	Positive 20.2 Excludes unspecified/missing n=25		Triple negative 5.7 ER- HER2+ 1.9 Luminal HER2+ 6.7 Luminal 85.7 Excludes unspecified/missing n=14
		Lapsed screeners not defined (screened >27 months?). Authors do not report data for Q2, Q3 or Q4						
				All R (p>0.9999 NS)	All R (p=0.5845 NS)			

				Detected tumour characteristics (as % cancers)				
Study ***Data source***	***Age (y)***	***Factor***	***No. screens***	***Histology***	***Tumour grade (G1-G3)***	***Nodal status***	***Size (small ≤15mm)***	***Hormone receptor status***
	All 40+	Q1 n=31 in situ	NR	DCIS 80.6 Unspecified 19.4	G1 9.5, G2 28.6, G3 61.9 Excludes unspecified/ missing n=10	NR	NR	NR
		Q5 n=58 in situ	NR	DCIS 81.0 Unspecified 19.0	G1 18.9, G2 18.9, G3 61.2 Excludes unspecified/ missing n=21	NR	NR	NR
		Authors do not report data for Q2, Q3 or Q4, or if screen- or interval-detected						
Cheasley 2019 Retrospective BS Vic data, Vic Cancer Registry data, Lifepool study N=1,146; of which n=442 BC cases had genetic mutation data available; of which n=12 BC cases had "actionable" HBOC mutation Screens=NR		Genetic factors: "Actionable" HBOC mutation (n=12)	NR	NR	NR	NR	NR	2010-18; Interval within 27 mo
								All R
	40-89	BRCA2 n=7/442 (1.6%)						
		Screen-detected invasive BCs n=2/276						ER+ PR+ HER2- (Luminal) 0.4, ER- PR- HER2- (Triple negative) 0.4
		Screen-detected in situ BC n=2/76						ER+ PR+ HER2- (Luminal) 2.6 (includes 1 HER2 not ordered)
		Interval invasive BC n=2/77						ER+ PR+ HER2- (Luminal) 2.6
		Interval in situ BC n=1/13						ER+ PR+ HER2- (Luminal) 7.7 (HER2 not ordered)
		ATM n=1/442 (0.2%)						
		Screen-detected invasive BC n=1/276						ER+ PR+ HER2- (Luminal) 0.4
		CHEK2 n=3/442 (0.7%)						
		Screen-detected invasive BC n=2/276						ER- PR- HER2+ 0.4, ER+ PR- HER2- 0.4
		Screen-detected in situ BC n=1/76						ER- PR- HER2+ 1.3
		PALB2 n=1/442 (0.2%)						
		Interval invasive BC n=1/77						ER- PR- HER2- (Triple negative) 1.3

Table footnote: BC = breast cancer; BS = BreastScreen; DCIS: ductal carcinoma in situ; ER = estrogen receptor; G = grade; HBOC = hereditary breast and ovarian cancer; HER2 = human epidermal growth factor receptor 2; IDC = invasive ductal carcinoma; ILC: invasive lobular carcinoma; mo = months; NR = not reported; NS = not significant; PR = progesterone receptor; Q = quintile; R = rounds; y = years. P-values in bold are significant.

3.7 References

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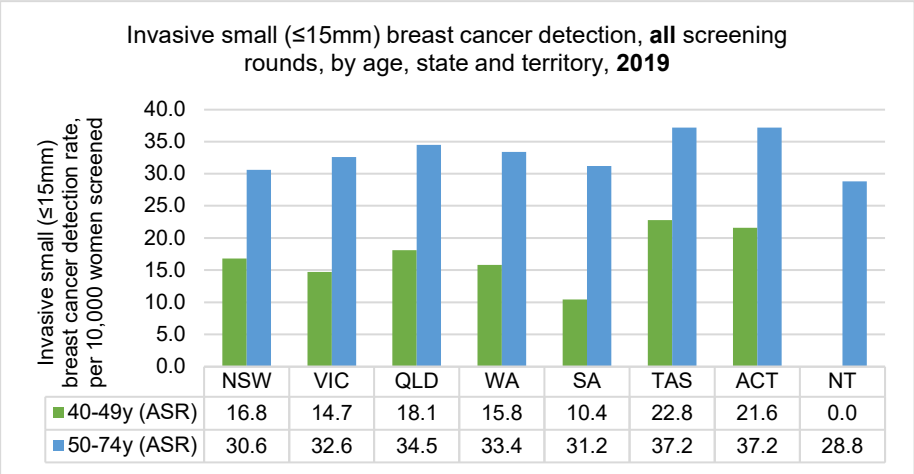
3.8 Appendix

3.8.1 Search strategy

Table 34. Search strategy. Database(s): Embase Classic+Embase 1947 to 2022 January 07, Ovid MEDLINE(R) ALL 1946 to January 07, 2022

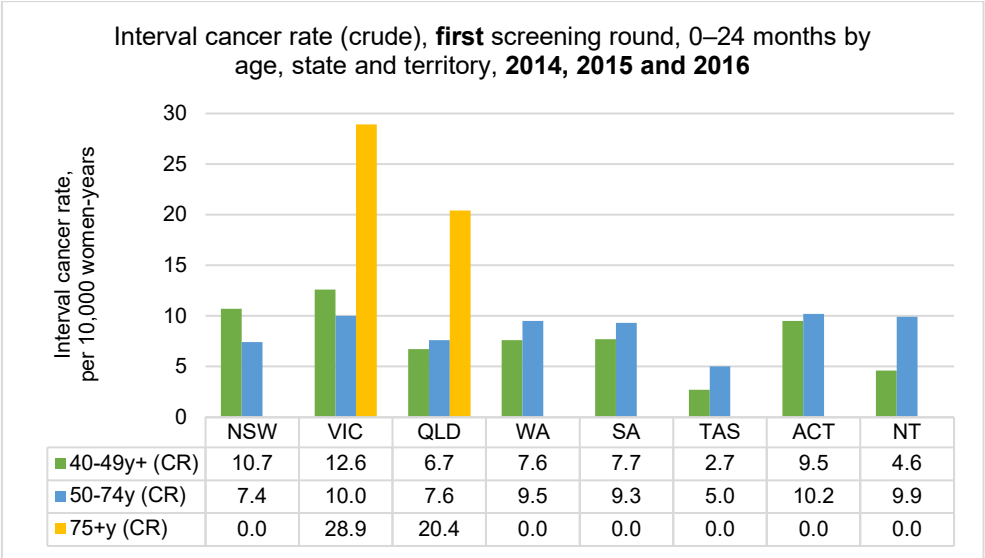
#	Searches	Results
1	(breast* or ductal carcinoma in situ or DCIS).tw.	1202564
2	(screen* or mammogra*).tw.	2096154
3	(Australia* or New South Wales or Queensland or Northern Territory or West* Australia* or South* Australia* or Australian Capital Territory or Victoria* or Tasmania* or Sydney or Brisbane or Darwin or Perth or Adelaide or Canberra or Melbourne or Hobart).tw.	444457
4	1 and 2 and 3	1849
5	(population* or nation* or state* or territor* or jurisdiction*).tw.	9200042
6	australia.in.	1670383
7	1 and 2 and 5 and 6	1531
8	BreastScreen*.tw.	509
9	4 or 7 or 8	2776
10	limit 9 to yr="2008 -Current"	2105
11	remove duplicates from 10	1376

3.8.2 Supplementary figures



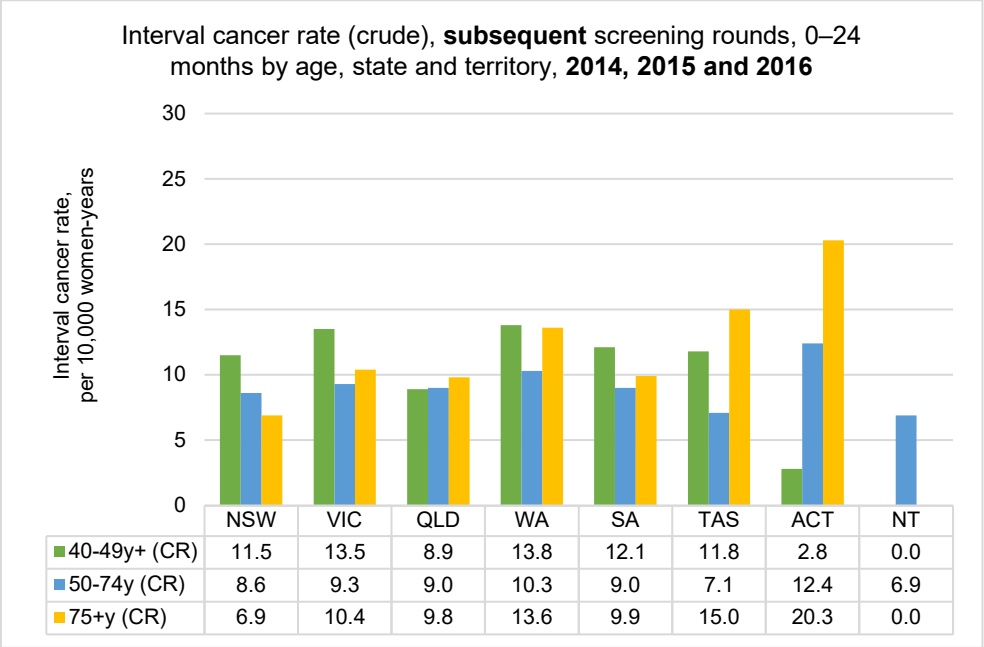
	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
40-49y (ASR)	16.8	14.7	18.1	15.8	10.4	22.8	21.6	0.0
50-74y (ASR)	30.6	32.6	34.5	33.4	31.2	37.2	37.2	28.8

Figure 23. Invasive small (≤1 5mm) breast cancer detection, all screening rounds, by age, state and territory, 2019; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).



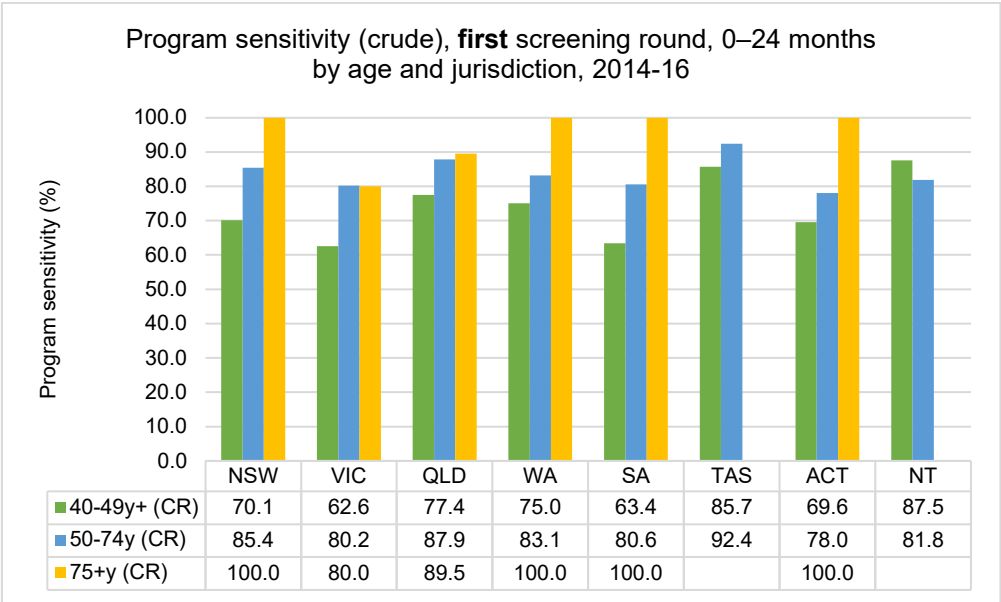
	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
40-49y+ (CR)	10.7	12.6	6.7	7.6	7.7	2.7	9.5	4.6
50-74y (CR)	7.4	10.0	7.6	9.5	9.3	5.0	10.2	9.9
75+y (CR)	0.0	28.9	20.4	0.0	0.0	0.0	0.0	0.0

*Figure 24. Interval cancer rate (crude), **first** screening round, 0–24 months by age, state and territory, 2014, 2015 and 2016; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).*



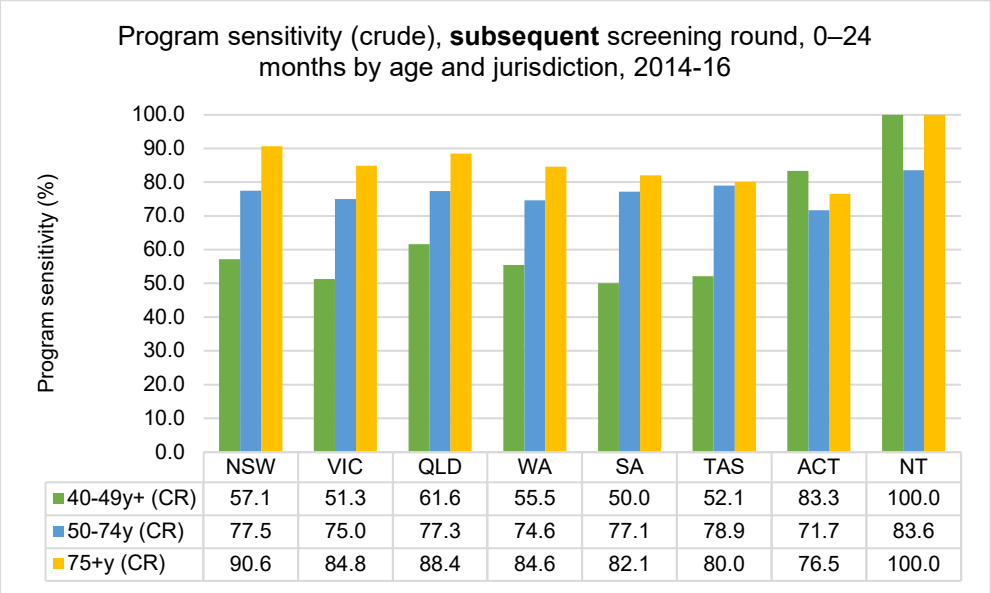
	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
40-49y+ (CR)	11.5	13.5	8.9	13.8	12.1	11.8	2.8	0.0
50-74y (CR)	8.6	9.3	9.0	10.3	9.0	7.1	12.4	6.9
75+y (CR)	6.9	10.4	9.8	13.6	9.9	15.0	20.3	0.0

*Figure 25. Interval cancer rate (crude), **subsequent** screening rounds, 0–24 months by age, state and territory, 2014, 2015 and 2016; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b).*



	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
40-49y+ (CR)	70.1	62.6	77.4	75.0	63.4	85.7	69.6	87.5
50-74y (CR)	85.4	80.2	87.9	83.1	80.6	92.4	78.0	81.8
75+y (CR)	100.0	80.0	89.5	100.0	100.0		100.0	

*Figure 26. Program sensitivity (crude data), **first** screening round, 0–24 months by age and jurisdiction, 2014-16; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021b). Blank data cells indicate data were not available.*



	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
40-49y+ (CR)	57.1	51.3	61.6	55.5	50.0	52.1	83.3	100.0
50-74y (CR)	77.5	75.0	77.3	74.6	77.1	78.9	71.7	83.6
75+y (CR)	90.6	84.8	88.4	84.6	82.1	80.0	76.5	100.0

Figure 27. Program sensitivity (crude data), subsequent screening round, 0–24 months by age and jurisdiction, 2014-16; in BreastScreen Australia monitoring report 2021 (Australian Institute of Health and Welfare 2021.

3.8.3 Excluded studies

Table 35. Potentially relevant articles collected and excluded

Study	PubMed ID or link	Reason for exclusion
Anikeeva 2012	PMID 22104630	No intervention of interest (BreastScreen not in factor-stratified group) and no outcome metric of interest
AIHW 2015	PMID 26264473	No intervention of interest (BreastScreen not in factor-stratified group) and superseded data
Baglietto 2014	PMID 24169466	No outcome metric of interest
Banham 2019	PMID 31200700	No outcome metric of interest
Beauchamp 2020	PMID 31923178	No outcome metric of interest
Beckmann 2015	PMID 25896926	No outcome metric of interest (no jurisdiction-level outcomes data)
Beckmann 2013	PMID 24153439	No outcome metric of interest (no jurisdiction-level outcomes data)
Bell 2019	PMID 30623584	No outcome metric of interest
Bennett 2020	PMID 33000553	No population or intervention of interest (not limited to BreastScreen participants)
Bennett 2010	PMID 20108093	No population or intervention of interest (not limited to BreastScreen participants)
Buckley 2017	PMID 28271574	No outcome metric of interest
Buckley 2016	PMID 27001547	No outcome metric of interest
Buckley 2015	PMID 25681318	No outcome metric of interest (not limited to BreastScreen-detected cancer rates)
Burton 2020a	http://dx.doi.org/10.1136/bmjebm-2019-POD.94	Excluded publication type (conference abstract)
Burton 2020b	PMID 32573707	No population or intervention of interest (not limited to BreastScreen participants), and no outcome metric of interest
Carey 2019	PMID 31581885	No outcome metric of interest (no jurisdiction-level outcomes data)
Cheung 2011	PMID 21819359	No comparator of interest (no within study direct comparison performed)
Chung 2020	http://dx.doi.org/10.1111/1754-9485.13299	Excluded publication type (conference abstract)
Craft 2013	PMID 24194985	No intervention of interest (BreastScreen not in factor-stratified group)
Darcey 2021	PMID 32754972	No outcome metric of interest
Darcey 2019	PMID 30977028	No outcome metric of interest
Elder 2018	PMID 29717421	No intervention of interest (BreastScreen not in factor-stratified group)
Farshid 2020	PMID 32366941	No population or intervention of interest (not BreastScreen)
Farshid 2018	PMID 30046938	No intervention of interest (BreastScreen not in factor-stratified group)
Farshid 2008	PMID 18382460	No population (narrow population not representative of screening population) or intervention (BreastScreen not in factor-stratified group) of interest, and no outcome metric of interest
Flegg 2010	PMID 20822548	No intervention of interest (narrow population not representative of screening population) and no outcome metric of interest
Fong 2011	PMID 21630124	No outcome metric of interest
Gayde 2012	PMID 22289153	No intervention of interest (BreastScreen not in factor-stratified group)
Gibson-Helm 2014	PMID 24742007	No population of interest (women aged <40 years) and no outcome metric of interest
Goodwin 2020	PMID 32075173	No outcome metric of interest (no jurisdiction-level outcomes data)
Heliat 2019	PMID 31845467	No outcome metric of interest
Houssami 2021	PMID 33997729	No population or intervention of interest (not BreastScreen)
Houssami 2019	PMID 31448816	No intervention of interest (current BreastScreen protocol does not include tomosynthesis)
Houssami 2012	https://doi.org/10.1007/s12609-012-0070-z	Excluded publication type (non-systematic review)
Hsieh 2016	PMID 27149274	No outcome metric of interest
Jacklyn 2018	PMID 28882419	Superseded data (more recent participation data in 2019 AIHW reports as extracted)
Jacklyn 2017	PMID 28882419	No outcome metric of interest

Study	*PubMed ID or link*	*Reason for exclusion*
Kaviratna 2021	PMID 33607596	Excluded study design (case-series of women with metastases to the breast attending BreastScreen)
Khan 2021a	PMID 34450190	No outcome metric of interest
Khan 2021b	PMID 34769794	No outcome metric of interest
Khan 2021c	PMID 33858869	No outcome metric of interest
Kou 2020	PMID 32926317	No population of interest (not limited to BreastScreen participants - screening mammography or MRI)
Kricker 2012	PMID 22020871	No population or intervention of interest (not limited to BreastScreen participants and narrow population not representative of screening population), and no outcome metric of interest
Kricker 2008	PMID 18770865	No population (narrow population not representative of screening population) or intervention (BreastScreen not in factor-stratified group) of interest
Krishnan 2017a	PMID 28062399	No outcome metric of interest
Krishnan 2017b	PMID 29246131	No outcome metric of interest
Krishnan 2016	PMID 27316945	No outcome metric of interest
Kurniawan 2008	PMID 18618180	No outcome metric of interest
Kwok 2019	PMID 31025150	No comparator of interest
Kwok 2016	PMID 26645110	No comparator of interest
Kwok 2015	PMID 26051075	No comparator of interest
Kwok 2014	PMID 23357890	No comparator of interest
Kwok 2012a	PMID 22151348	No comparator of interest
Kwok 2012b	PMID 21767988	No comparator of interest
Lam 2018	PMID 29235719	No comparator of interest (no within study direct comparison performed)
Lammert 2019	PMID 31657879	No population or intervention of interest (not BreastScreen)
Leung 2015	PMID 26844118	No outcome metric of interest
Leung 2014	PMID 24439940	Superseded data (more recent participation data in 2019 AIHW reports as extracted)
Lewis 2020	https://doi.org/10.1117/12.2560290	Excluded publication type (conference abstract)
Li 2021	PMID 34850484	No population of interest (not limited to participants with BreastScreen-detected or interval cancers) and no comparative data for outcome of interest
Li 2020a	PMID 32595164	No population or intervention of interest (not BreastScreen)
Li 2020b	PMID 31855779	No outcome metric of interest
Li S 2021	PMID 33977228	No population or intervention of interest (not BreastScreen)
Lindsay 2020	PMID 33283606	No intervention of interest (trial setting - current BreastScreen protocol does not include remote radiology assessments)
Mall 2018	PMID 29846804	No intervention of interest (current BreastScreen protocol does not include tomosynthesis)
Marinovich 2022	PMID 34980622	Excluded study design (study protocol)
Morrell 2012	PMID 22345322	No outcome metric of interest
Muir 2010	PMID 20152275	No intervention of interest (BreastScreen not in factor-stratified group of interest)
Nguyen 2020	PMID 33197272	No comparator and no outcome metric of interest
Nguyen 2019	PMID 31609476	No outcome metric of interest
Nguyen 2018	PMID 30545395	No outcome metric of interest
Nguyen-Dumont 2020	PMID 32060697	No population or intervention of interest (not BreastScreen)
Nicholls 2017	PMID 27878855	No intervention of interest (BreastScreen not in factor-stratified group of interest)
Nickson 2018	PMID 30572910	No outcome metric of interest
Nickson 2014	PMID 24327331	Superseded data (more recent participation data in 2019 AIHW reports as extracted)
Nickson 2009	PMID 19805755	Duplicate data (subgroup of cases already reported in Kavanagh 2008 as extracted)
O'Hara 2018	PMID 30087259	No outcome metric of interest (no jurisdiction-level outcomes data)
Ogunsiji 2017	PMID 28412942	No comparator of interest
Pape 2016	PMID 27350887	No outcome metric of interest

Study	*PubMed ID or link*	*Reason for exclusion*
Peter 2016	PMID 27083056	No population or intervention of interest (not BreastScreen)
Peters 2008	PMID 18373823	No population or intervention of interest (not BreastScreen)
Pilkington 2017	PMID 28893225	No outcome metric of interest
Price 2010	PMID 20364401	No population or intervention of interest (not BreastScreen)
Price 2009	PMID 19453531	No population or intervention of interest (not BreastScreen)
Protani 2012	PMID 22225652	No outcome metric of interest
Randall 2009	PMID 19015941	No outcome metric of interest (outcome data by screening interval not factor-stratified)
Roder 2017	PMID 27654906	No intervention of interest (BreastScreen not in factor-stratified group for outcomes data) and superseded data (more recent participation data in 2019 AIHW reports as extracted)
Roder 2014a	PMID 25081720	No outcome metric of interest (no jurisdiction-level outcomes data)
Roder 2014b	PMID 24709287	No outcome metric of interest
Roder 2012	PMID 22502658	No outcome metric of interest (no jurisdiction-level outcomes data)
Roder 2008	PMID 18351455	No outcome metric of interest
Salagame 2016	PMID 26599391	No outcome metric of interest
Saunders 2009	PMID 19769556	No population or intervention of interest (not BreastScreen)
Savaridas 2017	PMID 29273227	No outcome metric of interest (no jurisdiction-level outcomes data)
Saxby 2020	PMID 32311194	No intervention of interest (BreastScreen not in factor-stratified group of interest)
Seaman 2018	PMID 27682335	No outcome metric of interest
Sim 2012	PMID 22708767	No outcome metric of interest
Slimings 2021	PMID 33567162	No outcome metric of interest (no jurisdiction-level outcomes data)
Southey 2021	PMID 34887416	No population or intervention of interest (not BreastScreen)
Suwankhong 2018	PMID 29699369	No comparator or outcome metric of interest
Tallis 2009	PMID 19383066	No intervention of interest (BreastScreen not in factor-stratified group) and no outcome metric of interest
Tapia 2019	https://hdl.handle.net/2123/21989	Excluded publication type (thesis)
Tapia 2019a	PMID 31268228	No outcome metric of interest
Tapia 2019b	PMID 30941443	No outcome metric of interest
Team 2013	PMID 22951044	No comparator or outcome metric of interest
Tervonen 2019	PMID 30933888	No outcome metric of interest
Tracey 2008	PMID 18521714	No population or intervention of interest (not limited to BreastScreen participants)
Trainer 2018	https://dx.doi.org/10.3747/co.25.4243	Excluded publication type (conference abstract)
Tong 2020	PMID 33198883	No population of interest (not limited to participants with BreastScreen-detected or interval cancers) and no comparative data for outcome of interest
Villanueva 2008	PMID 18194528	Superseded data (more recent participation data in 2019 AIHW reports as extracted)
Walpole 2019	PMID 31808149	No population or intervention of interest (not limited to BreastScreen participants)
Weber 2013	PMID 23641775	No outcome metric of interest (no jurisdiction-level outcomes data)
Weber 2009	PMID 19442312	No outcome metric of interest (no jurisdiction-level outcomes data)
Wong-Brown	PMID 25682074	No population or intervention of interest (not BreastScreen)
Woods 2016a	PMID 26756181	No outcome metric of interest
Woods 2016b	PMID 26756306	No population or intervention of interest (not limited to BreastScreen participants), and no outcome metric of interest
Woods 2009	PMID 19180628	No population or intervention of interest (not BreastScreen) and no outcome metric of interest
Yeasmeen 2020	PMID 32764828	No outcome metric of interest (no jurisdiction-level outcomes data)
Youl 2016	PMID 27869758	No population or intervention of interest (not BreastScreen) and no outcome metric of interest
Young 2021	http://dx.doi.org/10.1017/thg.2021.9	Excluded publication type (conference abstract)

4 Overdiagnosis by risk group

4.1 Authors

Victoria Freeman, Suzanne Hughes, Dr Louiza Velentzis & A/Prof Carolyn Nickson.

4.2 Background

4.2.1 Rationale

In the context of breast cancer screening and surveillance, overdiagnosis refers to cases (invasive breast cancer or DCIS) detected in asymptomatic women that would not have been diagnosed due to an investigation triggered by symptoms. Overdiagnosis does not refer to an error or misdiagnosis; it is an aspect of screening and surveillance for breast cancer. Overdiagnosis logically leads to overtreatment, so that the options for mitigating the impact of overdiagnosis include both reducing the likelihood of overdiagnosis and ensuring that treatment of all cases is minimised.

It is difficult to estimate overdiagnosis rates because it is not possible to identify with certainty which cancers are overdiagnosed. Estimates vary according to the estimation method used. Available estimates include population rates of overdiagnosis attributable to invitation to, or participation in, organised breast cancer screening programs, lifetime risk of overdiagnosis, and the proportion of screen-detected cancers that are overdiagnosed. For the purposes of this scoping review, all modes of overdiagnosis estimation were included.

It is reasonable to hypothesise that overdiagnosis rates would vary for different risk groups. For example, higher rates might be expected for older women with a shorter life expectancy, because there is more chance that a screen-detected cancer would not become symptomatic before her death. Women with lower mammographic density may have higher rates of overdiagnosis because smaller tumours and DCIS may be easier to find in less-dense breasts. Such differences will be important factors when considering the relative benefits and harms of screening within specific risk sub-groups and the minimisation of overtreatment.

The 2019 ROSA project Expert Management Group (EMG) noted that outcomes by stage/tumour sub-type, mode of detection and age reported under the topic ‘Screening outcomes by risk groups’ may help inform this question of overdiagnosis. The EMG suggested that work conducted under this topic may generate recommendations for additional data to be incorporated into routine data collection (e.g. stage data) which could provide important baseline information on outcomes under the current program and enable better monitoring of any changes under any alternative screening strategies in the future.

This summary presents a scoping level review which explores whether overdiagnosis estimates of invasive breast cancer and/or DCIS vary by risk group (e.g. by age, family history, mammographic density).

Given the high level of interest in this topic, we also summarise potentially relevant ongoing systematic reviews and trials.

4.2.2 Research question

Does overdiagnosis among women undergoing image-based screening vary by risk group?

4.2.3 Aims

To identify and summarise the results of studies and systematic reviews examining overdiagnosis rates for women with differing risks of breast cancer and to compare the rates of overdiagnosis estimates in these different risk groups.

To summarise ongoing systematic reviews and trials addressing overdiagnosis by risk group.

4.3 Methods

4.3.1 Summaries of evidence

PICO protocols

The PICO protocol used for this topic is shown in Table 31.

Table 36. PICO for the scoping review of overdiagnosis outcomes by risk group.

Population	*Intervention/exposure*	*Comparison*	*Outcome*	*Study design*
Asymptomatic women	Risk stratified breast cancer image-based screening or Specific risk group And Screening intervention/exposure is compared with no screening	Breast cancer screening which is not risk stratified or An alternative risk stratification of breast cancer screening or Another risk group based on same factor/s undergoing breast cancer imaged-based screening And Screening comparator is compared with no screening	Rate of breast cancer overdiagnosis and/or DCIS overdiagnosis derived from directly observed population	RCTs Cohort studies or Systematic review thereof

Selection criteria

Detailed selection criteria for the PICO is shown in Table 32.

Table 37. Selection criteria for the PICO for overdiagnosis outcomes by risk group.

	Inclusion	*Exclusion*
Population	Asymptomatic women	Restricted to women undergoing breast imaging as follow-up for breast cancer or DCIS, or for breast abnormalities
Intervention or exposure	Risk (including age, family history, mammographic density and risk prediction tools) stratified breast cancer image-based screening or Specific risk group (older women, family history, women with high breast density) undergoing breast cancer imaged-based screening	Personal or clinical breast examination screening Intervention differs for different risk groups
	Screening intervention/exposure is compared with no screening*	
Comparator	Breast cancer screening which is not risk stratified or An alternative risk stratification of breast cancer screening or Another risk group based on same factor/s (younger women, no family history, women with low breast density) undergoing breast cancer imaged-based screening	No comparator or comparator differs for different risk groups
	Screening comparator is compared with no screening*	
Outcome	Rate of breast cancer overdiagnosis and/or DCIS overdiagnosis derived from directly observed population	DCIS as surrogate for overdiagnosis
Study design	RCTs Cohort studies	RCTs in which non-screened were offered screening at the end of

	or Systematic review thereof	screening intervention period or where non-screened had the opportunity to undergo organised screening following the conclusion of the trial. Any modelling including life-table models, microsimulation and Markov models
Publication date	Systematic reviews published from 2008 onwards No other publication limits	
Publication type	Journal article or report	Conference abstracts, reviews, letters, editorials and comments
Language	English	

55TDCIS = Ductal carcinoma in situ *In order to calculate overdiagnosis, each arm includes a group that does not undergo screening.

Literature searches

We undertook an initial scoping search to identify published systematic reviews of studies assessing breast cancer overdiagnosis. Medline and Embase databases were searched in December 2018 from 2008 onwards, by combining terms for breast cancer/DCIS, screening/mammography, harms/overdiagnosis/overtreatment and systematic reviews/meta-analyses. The Cochrane Database of Systematic Reviews (CDSR) and Health Technology Assessments (HTA) databases were searched by combining the terms “breast cancer” and “screening” and limiting results from 1 January 2008 to 31 December 2018. Published systematic reviews assessing breast cancer overdiagnosis, and articles included in those reviews, were collected and assessed for inclusion in this scoping review.

A second search was then undertaken to identify relevant studies published after the final search dates of the most recent, relevant systematic reviews. Medline, Embase and Cochrane Central Register of Controlled Trials (CENTRAL) databases were searched in December 2018 for additional relevant primary publications by combining terms for breast cancer/DCIS, screening/mammography and harms/overdiagnosis/overtreatment. These searches were updated initially on 20 November 2019 and then subsequently on the 2nd March 2021 (covering literature until 26 February 2021) For details of the complete search strategies see Appendix.

4.3.2 Ongoing systematic reviews and trials

Ongoing systematic reviews were identified by searching for registered systematic review protocols. Searches on the following databases were updated initially in January 2020 and subsequently on 1st April 2021 (i.e. same searches were re-run).

- Cochrane Database of Systematic Reviews (CDSR) – protocols using the terms breast cancer/ductal carcinoma in situ and overdiagnosis/overtreatment.
- PROSPERO for registered prospective systematic reviews: https://www.crd.york.ac.uk/PROSPERO/searchadvanced.php using the terms breast cancer/ductal carcinoma in situ and overdiagnosis/overtreatment.

Registered, potentially relevant clinical trials were identified by searching the clinical trial registries for ongoing or recruiting trials. Relevant withdrawn or terminated trials were noted but not summarised. Databases listed below were searched in February 2019 and again in January 2020.

- Clinicaltrials.gov using the terms breast cancer OR breast neoplasms OR ductal carcinoma in situ OR ductal carcinoma in-situ for condition and overdiagnosis OR overtreatment for other terms.
- World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP) using the terms breast cancer OR breast neoplasms OR ductal carcinoma in situ OR ductal carcinoma in-situ for condition and overdiagnosis OR overtreatment for other terms.

- National Cancer Institute (https://www.cancer.gov/about-cancer/treatment/clinical-trials/) selecting breast cancer as primary cancer type and overdiagnosis or overtreatment as key words or phrases.
- Australian New Zealand Clinical Trials Registry (ANZCTR) (http://www.anzctr.org.au/TrialSearch.aspx?isBasic=false) using the terms breast cancer OR breast neoplasms OR ductal carcinoma in situ OR ductal carcinoma in-situ for the category of health condition(s) or problem(s) studied and overdiagnosis and overtreatment as search terms.

Subsequently, the Clinicaltrials.gov and ANZCTR databases were searched on the 29th April 2021 and the WHO ICTRP database on the 24th May 2021 to identify additional trials. An updated search of the National Cancer Institute database was attempted on 24 May 2021 and 10 September 2021 but was not able to be performed due to issues with the website search function.

4.4 Results

4.4.1 Scoping literature search – published relevant systematic reviews

Fourteen systematic reviews with two updates (Biesheuvel 2007; Braithwaite 2016; Carter 2015; Gøtzsche 2013; Gotzsche 2011; Hamashima 2016; Jacklyn 2016; Jorgensen 2009; Migowski 2018; Myers 2015; Nelson 2016; Nelson 2009; Oeffinger 2015; Pace 2014; Puliti, Duffy 2012; van den Ende 2017) published from 2008 onwards were identified that addressed overdiagnosis in breast cancer. However, none of these reviews reported estimates of overdiagnoses for different breast cancer risk groups nor compared overdiagnosis estimates for stratified screening with those for unstratified screening. For details of systematic reviews captured by pre-scope and initial search, see Appendix Table 35.

4.4.2 Scoping literature search – published relevant primary studies

From the 14 systematic reviews and two updates assessing breast cancer overdiagnoses, 34 articles were identified that potentially reported breast cancer overdiagnosis estimates (Andersson 1997; Baines 2016; Bjurstam 2003; Bleyer 2012; Coldman 2013; de Gelder 2011; Duffy 2010; Falk 2013; Hellquist 2012; Hofvind 2012; Jonsson 2005; Jorgensen 2009; Junod 2011; Kalager 2012; Lund 2013; Miller 2000, 2002; Miller 2014; Morrell 2010; Moss 2015; Njor 2013; Olsen 2006; Paci 2006; Paci 2004; Peeters 1989; Puliti, Miccinesi, 2012; Puliti 2009; Svendsen 2006; Waller 2007; Yen 2012; Zackrisson 2006; Zahl 2011; Zahl 2012; Zahl 2004).

Three of these articles (Baines 2016; Zackrisson 2006; Jørgensen 2009) did report overdiagnosis by age groups in their results, however, they did not meet the inclusion criteria for this report due to a) the “unscreened” control group differing for different risk groups (Baines 2016) or b) participants not having the opportunity to undergo organised screening following the conclusion of the trial (Zackrisson 2006) or c) age groups utilised were not stratified (Jorgensen 2017). The other 11 articles were commonly excluded due to inappropriate study design, or the “unscreened” control group was offered screening or due to unreported estimates of overdiagnoses for different breast cancer risk groups.

The most recent and relevant systematic review identified (Nelson 2016) searched the literature up until December 2014. Consequently, searches of more recent literature were undertaken from 2014 onwards. These searches identified an additional six articles (Beau 2017; Beckmann, Lynch, 2015; Heinavaara 2014; Johns 2017; Jorgensen 2017; Beckmann, Duffy, 2015). However, none of these articles met the inclusion criteria for this report due to inappropriate study design, unreported estimates of overdiagnoses for different breast cancer risk groups or due to the “unscreened”

control group being offered screening. In addition, the updated recommendations for the 2011 breast cancer screening guidelines by the Canadian Task Force on Preventive Health Care (Klarenbach 2018) were also identified. The systematic review underpinning these updated recommendations included articles until January 2017 which had already been considered for inclusion in this scoping review. Updated searches until the 2nd March 2021 identified one potentially relevant article for inclusion (Yang 2020), however, it did not meet the inclusion criteria after full-text assessment as estimates of breast cancer overdiagnosis rates were not cited. For details regarding the reasons for exclusion of potentially relevant articles in this scoping report see Appendix Table 36 by author, year and PubMed ID or digital object identifier (DOI).

4.4.3 Registered ongoing systematic reviews and clinical trials

Registered systematic review protocols

The initial search of the Cochrane Database of Systematic Reviews (CDSR) identified one protocol record which was potentially relevant (Jacklyn et al. 2018). The initial search of the PROSPERO database identified 13 records, of which an additional protocol was potentially relevant (Hirth et al. 2016). Both these ongoing reviews are summarised in Table 33, below. The publication status of the two potentially relevant registered systematic review protocols identified from the initial search were checked on 31 August 2021 and no updates were listed. A further protocol identified in the PROSPERO database had been listed as completed and the publication was reviewed through a full-text screen which is detailed below (Klarenbach 2018). Updated searches conducted on PROSPERO and CDSR databases until 1st April 2021 did not identify any additional records that were of potential interest.

Table 38. Summary of potentially relevant ongoing systematic reviews.

Title/Review question	*Authors*	*Record link*	*Registered*	*Status*
Overdiagnosis due to screening mammography for women aged 40 years and over [CD013076] Does not specifically mention overdiagnosis estimate by risk group or risk stratification in relation to screening but subgroup analysis by age is planned	Gemma Jacklyn, Kevin McGeechan, Nehmat Houssami, Katy Bell, Paul Glasziou, Alexandra Barratt.	www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013076/full	27/7/2018	Ongoing status as listed on 31/08/21
Harms of mammography use in women over 70 years of age [CRD42016046240] Outcomes include overdiagnosis or overtreatment, but no other risk group mentioned	Jacqueline Hirth, Shilpa Krishnan, Alai Tan, Monique Pappadis, Margaret Foster, Jeanne-Marie Guise, Linda Humphrey	www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42016046240	30/11/2016	Ongoing status as listed on 31/08/21

Registered ongoing clinical trials

A search of Clinicaltrials.gov database up to 29th April, 2021 identified 14 records, of which one (MyPeBS trial) was potentially relevant and is summarised in Table 34 below. The clinical trial record of the MyPeBS trial did not contain any interim results as of the 13th September 2021.

The searches of WHO ICTRP up to 24th May 2021 identified four records, of which none were potentially relevant. Searches of the ANZCTR up to 29th April 2021 produced one record which was not relevant. The National Cancer Institute database was searched successfully up to 22nd January 2020 and identified a total of two records that were not potentially relevant. An update search of the National Cancer Institute database could not be performed after multiple attempts due to issues with the search function.

Table 39. Summary of potentially relevant ongoing clinical trials.

Trial name and Clinicaltrials.gov ID	***Principal investigators***	***Start date***	***Planned completion date***	***Status***	***Population***	***Intervention***	***Comparator***	***Potentially relevant outcomes***
Randomized, Comparison Of Risk-Stratified versus Standard Breast Cancer Screening In European Women Aged 40-70 (MyPeBS) NCT03672331 RCT France, Italy, UK, Belgium and Israel	Study Chair: Suzette DELALOGE, Principal investigators: Paolo GORGIO-ROSSI, Corinne BALLEYGUIER, Michal GUINDY, Jean-Benoit BURRION, Fiona GUILBERT, Marta ROMÁN,	July 2019	December 2025	Recruiting	Women aged 40-70 y with no personal history of DCIS, breast cancer, atypical breast lesion, lobular carcinoma in situ or chest wall irradiation, known or suspected very high risk germline mutation, history of bilateral mastectomy, recent abnormal breast findings or psychiatric conditions affecting compliance or follow-up	Risk based screening for 4 y Risk assessment will be conducted using Mammorisk™ for women with at most one first-degree relative with breast or ovarian cancer and using Tyrer-Cuzick risk score for those women with more than one first-line first degree relative with breast or ovarian cancer. Personalised screening will include mammography and/or tomosynthesis +/- ultrasound or MRI	Standard mammogram and/or tomosynthesis +/- ultrasound or MRI screening according to guidelines in each participating country for 4y	Overdiagnoses rates in each arm measured by comparing cumulative incidence of breast cancer in each arm 15 years after the end of the interventional period for the study

4.5 Discussion

Overdiagnosis is inherently challenging to estimate due to non-identifiability at diagnosis. It is additionally challenging to estimate overdiagnosis for population sub-groups, such as women at different levels of breast cancer risk, however it remains an important consideration for risk-based breast screening, which could potentially improve or worsen overdiagnosis for different risk groups. For example, it is logical that the current masking of small tumours for women with higher mammographic breast density may reduce with the provision of more sensitive screening tests for women with dense breasts, and while this is likely to find some potentially fatal breast cancers earlier, consequently overdiagnosis may also increase. Conversely, less intensive screening of women in lower risk groups, including women with low breast density, may logically reduce overdiagnoses in that risk group. These hypotheses are supported by estimates generated by the ROSA modelling reported in Chapter 4. Ultimately, overdiagnosis needs to be considered within the context of the benefits and harms of screening, and for risk-based screening this should be considered for each risk strata.

We found that most of the identified primary articles or systematic reviews that reported estimates for overdiagnosis did not report estimates by risk group nor risk stratified screening, had an inappropriate study design or the control group was offered screening. Two primary studies that did report overdiagnosis by age (Baines 2016; Zackrisson 2006) did not meet the inclusion criteria due to the control group differing for different risk groups and/or non-screened participants having the opportunity to undergo organised screening following the conclusion of the trial. Yang et al (2020) did not estimate the rate of breast cancer overdiagnosis but aimed to estimate by 10-year age groups the maximum overdiagnosis under an unsubstantiated assumption that there were no improvements in cancer screening technology or treatment between the two periods examined (<1977 and 1999). This estimate was then used as a basis for stating that estimated overdiagnosis rates higher than this are not plausible; this is an interesting investigation, but different to the questions addressed in our review. One potentially relevant ongoing systematic review (Jacklyn 2018) includes plans for a subgroup analysis by age.

The updated searches identified the MyPeBS trial, which does aim to examine overdiagnosis, but it is still unclear whether estimates will be reported by risk group or risk-stratified screening.

Overdiagnosis continues to be an important consideration for risk-based breast cancer screening. As such, continued effort to accurately estimate overdiagnosis rates for women in different risk groups is critical.

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4.7 Appendix

4.7.1 Initial search strategy to identify breast cancer screening systematic reviews

Table 40. Search strategy. Databases: Embase 1947 to 2018 December 6, Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R)1946 to 2018 December 6th.

#	***Searches***	***Results***
1	(breast adj3 (neoplasm* or cancer* OR carcinoma* or tumo?r*)).tw	697000
2	(DCIS or ductal carcinoma in-situ).tw	19056
3	breast tumor/ or breast neoplasms/	345616
4	Or/1-3	791432
5	(screen* or mammogra*).tw or mammography/	1630242
6	(harm* or overdiagnos* or over diagnos* or overtreatment).tw	364273
7	((systematic adj (review* or overview*)).tw. or meta-analys*.tw or metaanaly*).tw.	490735
8	4 and 5 and 6 and 7	191
9	limit 8 to (english language and yr="2008 -Current")	149
10	remove duplicates from 9	93

4.7.2 Revised search strategy to identify recently published relevant studies

Table 41. Search strategy: Database(s): EBM Reviews - Cochrane Central Register of Controlled Trials January 2021, Embase Classic+Embase 1947 to 2021 February 26, Ovid MEDLINE(R) ALL 1946 to February 26, 2021

#	Searches	Results
1	(breast adj3 (neoplasm* or cancer* or carcinoma* or tumo?r*)).tw.	866381
2	(DCIS or ductal carcinoma in-situ).tw.	22702
3	breast tumor/ or breast neoplasms/	406068
4	or/1-3	975662
5	(screen* or mammogra*).tw. or mammography/	2060554
6	(harm* or overdiagnos* or over diagnos* or overtreatment).tw.	481631
7	4 and 5 and 6	3383
8	limit 7 to (english language and yr="2018 -Current")	805
9	remove duplicates from 8	520

4.7.3 Systematic Reviews reporting overdiagnosis

Table 42. Systematic reviews of breast cancer overdiagnosis that do not report overdiagnosis as a result of risk stratified screening - sources of potentially relevant articles.

Systematic review	***Reasons for exclusion***	***Superseded?***	***References reporting overdiagnoses***	
			RCT	***Observational***
Van den Ende 2017	Risk group but no comparator		Baines 2016	NA
Nelson 2016	No comparisons of risk groups or of risk stratified screening with non-stratified screening		Cites Marmot 2014 which included Miller 2000 Miller 2002 Zackrisson 2006 Miller 2014 Yen 2012	Bleyer 2012 Coldman 2013 de Gelder 2011 Duffy 2010 Falk 2013 Hellquist 2012 Jorgensen 2009 Klager 2012 Morrell 2010 Njor 2013 Olsen 2006 Paci 2004 Paci 2006 Puliti 2009 Zahl 2011 Zahl 2004
Nelson 2009	No comparisons of risk groups or of risk stratified screening with non-stratified screening	Yes	Cites Moss 2005 which included Shapiro 1977 and 1982, Tabar 1985 Duffy 2003 Bjurstam 2003 Anderson 1998 Frisell 1997 Miller 1992a Miller 2000 Miller 1992b Miller 2002 Alexander 1994 Alexander 1999 Moss 2005 Breast Screening Frequency trial group 2002	Paci 2006 Olsen 2006 Zahl 2004
Myers 2015	No comparisons of risk groups or of risk stratified screening with non-stratified screening		Andersson 1997 Miller 2014, Moss 2015 Yen 2012	Bleyer 2012 Coldman 2013 Duffy 2010 Hofvind 2012 Jonsson 2005 Jorgensen 2009 Klager 2010 Lund 2013 Morrell 2010 Njor 2013 Olsen 2006 Paci 2004 Paci 2006 Puliti 2009 Puliti 2012 Zahl 2011 Zahl 2004
Puliti 2012	No comparisons of risk groups or of risk stratified screening with non-stratified screening	Yes	NA	Duffy 2010 Jonsson 2005 Jorgensen 2009 Olsen 2006 Paci 2004 Paci 2006 Peeters 1989 Puliti 2009 Waller 2007

Systematic review	***Reasons for exclusion***	***Superseded?***	***References reporting overdiagnoses***	
			RCT	***Observational***
				Zahl 2004
Jorgensen 2009	No comparisons of risk groups or of risk stratified screening with non-stratified screening	?	NA	Jonsson 2005 (other included studies did not report overdiagnosis rates)
Gotzsche 2013 (update of 2011)	Overdiagnosis not assessed but is addressed in discussion.	?	NA	NA
Gotzsche 2011	Overdiagnosis not assessed but is addressed in discussion	Yes	NA	NA
Braithwaite 2016	Only modelling studies referred to overdiagnosis	NA	NA	NA
Pace 2014	No comparisons of risk groups or of risk stratified screening with non-stratified screening		Cites Marmot 2013 Miller 2002 Miller 2000 Zackrisson 2006 Miller 2014	Bleyer 2012 Cites SR or working group publications Gotzsche 2006, Paci 2012 and Jorgensen 2009 for observational study estimates
Jacklyn 2016	No comparisons of risk groups or of risk stratified screening with non-stratified screening	NA	NA	NA
Biesheuvel 2007	No comparisons of risk groups or of risk stratified screening with non-stratified screening		Cites reviews Moss 2005 Gotzshe 2004 Zackrisson 2006	Jonsson 2005 Peeters 1989 Paci 2006 Paci 2004 Zahl 2004
Oeffinger 2015	Did not provide overdiagnosis estimate for risk groups or of risk stratified screening with non-stratified screening.	No	NA	Jorgensen 2009 Olsen 2006 Paci 2006 Puliti 2012 Zahl 2004
Carter 2015	Interested in methods used to estimate diagnosis, did not provide overdiagnosis estimate for risk groups or of risk stratified screening with non-stratified screening.	No	Miller 2014 Zackrisson 2006	Bleyer 2012 Coldman 2013 Duffy 2010 Falk 2013 Hellquist 2012 Jorgensen 2009 Junod 2011 Kalager 2012 Morrell 2010 Njor 2013 Paci 2006 Peeters 1989 Puliti 2009 Puliti 2012 Svendsen 2006 Zahl 2004 Zahl 2012
Hamashima 2016	Did not provide overdiagnosis estimate for risk groups or of risk stratified screening with non-stratified screening.		Zackrisson 2006 Yen 2012	Bleyer 2012 Hamashima 2006 Jorgensen 2009a Jorgensen 2009b Junod 2011 Olsen 2006 Zahl 2004 Puliti 2009 Paci 2006 Morrell 2010
Migowski 2018	Used Nelson 2016 to report on overdiagnosis	N/A	N/A	N/A

NA = not applicable

4.7.4 Excluded studies

Table 43. Potentially relevant articles collected and excluded.

Article	PubMed ID/DOI	Reason for exclusion
Andersson 1997	PMID: 9709278	No risk stratified overdiagnosis estimates
Baines 2016	DOI: 10.1016/j.ypmed.2016.06.033	Unscreened control group differs for different risk groups
Beckmann 2015	PMID: 25896926	Inappropriate study design (Modelling used)
Beckmann 2015	PMID: 25098753	Inappropriate study design (Case-control)
Beau 2017	DOI: 10.1002/ijc.30758	No risk stratified overdiagnosis estimates
Bjurstam 2003	DOI: 10.1002/cncr.11361	"Unscreened" control group underwent screening at end of trial
Bleyer 2012	DOI: 10.1056/NEJMoa1206809	No risk stratified overdiagnosis estimates
Coldman 2013	DOI: 10.1503/cmaj.121791	"Unscreened" control includes those who discontinued screening
de Gelder 2011	DOI:10.1016/j.ypmed.2011.06.009	Inappropriate study design (Modelling used)
Duffy 2010	DOI: 10.1258/jms.2009.009094	"Unscreened" control group offered screening after trial
Falk 2013	DOI: 10.1002/ijc.28052	No risk stratified overdiagnosis estimates
Hellquist 2012	DOI: 10.1258/jms.2012.011104	No outcome of interest
Heinavaara 2014	DOI: 10.1038/bjc.2014.413	Inappropriate study design (Modelling used)
Hofvind 2012	DOI: 10.1007/s10549-012-2162-x	No estimate of overdiagnosis
Johns 2017	DOI: 10.1038/bjc.2016.415	No risk stratified overdiagnosis estimates
Jonsson 2005	DOI: 10.1002/ijc.21228	Inappropriate study design (Modelling used)
Jorgensen 2009	DOI:10.1186/1472-6874-9-36	Inappropriate study design (Modelling used)
Jorgensen 2017	DOI: 10.7326/M16-0270	No risk stratified overdiagnosis estimates
Junod 2011	DOI: 10.1186/1471-2407-11-401	Intervention/comparator compared to less intense screening cohorts
Kalager 2012	PMID: 22473436	No risk stratified overdiagnosis estimates
Klarenbach 2018	DOI: 10.1503/cmaj.180463	Systematic review from guidelines contain studies already excluded
Lund 2013	PMID: 29245077	Inappropriate comparator
Miller 2014	DOI: 10.1136/bmj.g366	No risk stratified overdiagnosis estimates
Miller 2000	PMID: 10995804	No comparator
Miller 2002	PMID: 12204013	No comparator
Morrell 2010	DOI: 10.1007/s10552-009-9459-z	Inappropriate study design (Modelling used)
Moss 2015	DOI: 10.1016/S1470-2045(15)00128-X	"Unscreened" control group offered screening
Njor 2013	DOI: 10.1136/bmj.f1064	No risk stratified overdiagnosis estimates
Olsen 2006	DOI: 10.1111/j.1075-122X.2006.00272.x	Inappropriate study design (Modelling used)
Paci 2006	DOI: 10.1186/bcr1625	Inappropriate study design (Modelling used)
Paci 2004	PMID: 15006110	Inappropriate study design (Modelling used)
Peeters 1989	PMID: 2788627	No risk stratified overdiagnosis estimates
Puliti 2012	PMID: 22230345	No risk stratified overdiagnosis estimates
Puliti 2009	DOI: 10.1016/j.ejca.2009.06.014	Inappropriate study design (Modelling used)
Svendsen 2006	DOI 10.1002/cncr.21823	No outcome of interest
Waller 2007	DOI:10.1158/1055-9965.EPI-07-0262	No outcomes of interest
Yang 2020	DOI: 10.21147/j.issn.1000-9604.2020.01.04	No estimate of overdiagnosis rates.
Yen 2012	DOI: 10.1002/cncr.27580	"Unscreened" control group offered screening after trial
Zackrisson 2006	DOI: 10.1136/bmj.38764.572569.7C	Comparator "unscreened" control group offered screening
Zahl 2012	PMID: 22353833	Inappropriate study design (Modelling used)
Zahl 2011	DOI:10.1016/S1470-2045(11)70250-9	"Unscreened" control group offered screening
Zahl 2004	DOI: 10.1136/bmj.38044.666157.63	Inappropriate study design (Modelling used)

5 National linked data evaluations

5.1 Authors

This report was prepared by Sam Egger, Chelsea Carle and A/Prof Carolyn Nickson.

The following personnel also contributed this project:

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5.2 Background

5.2.1 Contracted work

This report describes a data analysis undetaken in collaboration with the Australian Institute of Health and Welfare (AIHW), involving additional analyses of linked data previously reported in '*Australian Institute of Health and Welfare 2018. Analysis of breast cancer outcomes and screening behaviour for BreastScreen Australia*. Cancer series no. 113. Cat. no. CAN 118. Canberra: AIHW' (hereon referred to as the 'AIHW report').

5.2.2 Linked dataset

The linked dataset comprises linked data from BreastScreen State and Territory registers (2000-2014, for women aged 40+ years), the Australian Cancer Database (1982-2013, for invasive cancers) and the National Death Index (1980-2015). Variables included in the AIHW report and available for analysis are listed in Appendix Section 5.8.1 on page 124.

5.2.3 Timelines and consultation

The analyses were undertaken according to the following process:

- The AIHW obtained ethics approval for this analysis, up to end 2021.
- ROSA personnel proposed analyses based on the available data and the expected value to the ROSA project and the wider community.
- AIHW personnel conducted the analyses where possible, and otherwise advised if analyses were not possible.
- AIHW personnel shared the available analysis results with the BreastScreen Australia program managers, seeking approval to share the results with the ROSA project.
- AIHW personnel shared the available results with ROSA personnel.

ROSA personnel invited ROSA Expert Advisory Group (EAG) feedback on these analyses, through the Summaries of Evidence distributed in May/June 2022.

5.2.4 Analysis topics

The ROSA team reviewed the AIHW report and identified several analyses on the basis that they would generate additional or refined findings expected to be relevant to consideration of risk-based screening in Australia.

Analyses were proposed on the following topics:

- False positive screens;
- Survival analysis;
- The profile of screen-detected and other breast cancers over time;
- Interval cancers.

We provide the background (including purpose in relation to ROSA), methods and findings for each topic below.

Proposed analyses were provided by ROSA to the AIHW through a document detailing the background, aims, methods and templates for results tables. Available results were provided to ROSA (following BreastScreen Australia program management group review) between August and November 2021.

Data were not provided for the topic 'interval cancer' (and some analyses under other topics involving interval cancer information) due to data issues identified at the AIHW. However, we have included the background, aims and methods as a resource to inform a potential future analysis, should the data issue be later resolved.

Abridgement note: Research questions and methods are included as these may be of interest for future analyses of AIHW linked data, however results are withheld as the data was not for public distribution.

5.3 False positive screens

5.3.1 Background

In the BreastScreen program, women recalled to assessment following a screening mammogram will either have a cancer diagnosed through BreastScreen assessment procedures (classified as a 'screen-detected' cancer) or a benign final outcome (classified as a 'false-positive' screening episode). Some women with a false-positive screening episode will subsequently have an interval cancer diagnosis.

The BreastScreen program aims to minimise false positive screening episodes to reduce the impost on clients and the program. There is evidence that in some settings women with false positive screening mammograms are less likely to participate in subsequent screening rounds[9]. More risk-based approaches to breast cancer screening may change rates of false-positive outcomes, particularly for women offered screening technologies that have higher cancer detection rates, as false-positive rates tend to increase with screening test sensitivity. Understanding behaviours and outcomes in relation to false-positive screening episodes under the current program will provide insights about the potential consequences of changes to false-positive screening rates with the introduction of risk-based screening.

[9] Sim, M. J., Siva, S. P., Ramli, I. S., Fritschi, L., Tresham, J., & Wylie, E. J. (2012). Effect of false-positive screening mammograms on rescreening in Western Australia. The Medical journal of Australia, 196(11), 693–695. https://doi.org/10.5694/mja11.10892

Additional analyses of value

The AIHW report included a table (Table 6.2.8 in the AIHW Report) showing rescreening rates (i.e. never, rescreened within 27 months, rescreened after 27 months) after a true negative or false positive screen, according to screening round and screening outcome (true negative or false positive). The report states '*When all screening rounds were considered together, false positive screens were associated with lower rescreening rates than true negatives (73.6% compared with 77.3%; p <0.001*)'. This indicated a risk difference of 3.7%. This is an important finding that has implications about the importance placed on minimising false-positive outcomes. However, we noted that the direction of this reported difference varies according to screening rounds, so that it is negative for some rounds (-2.0% for first round screening and -0.2% for second round screening) and positive for others (1.6% for third and subsequent screening rounds). These differences average to -0.2% (and -0.2% is also the frequency weighted average), suggesting that the overall difference in risks, as presented, is confounded by lack of adjustment for screening round.

We also noted from our parallel analysis of the lifepool cohort for the ROSA project, that age at screen is strongly related to both rescreening within 27 months and the risk of a false positive. This suggests that analyses of rescreening within 27 months and false positives should be adjusted for age, to avoid a potentially extreme risk of confounding. This is consistent with our observations described above, as screening round is related to age.

We, therefore, proposed analyses that would more accurately capture the associations between false positive screens and rescreening rates. We also suggested that for Table 6.2.8 I the AIHW report, the finding should be revised to 'When all screening rounds were considered together, false positive screens were associated with a 0.2% increase in rescreening rates', where this would be reported with a 95% confidence interval and a p-value to assess if this is statistically significant. In addition, standard errors should account for repeated measures on the same women across the different screening rounds if some women are contributing to more than one of the tabulated frequencies in Table 6.2.8. This is in the public interest because the current findings may incorrectly suggest that false positive outcomes discourage rescreening.

In addition, we proposed an analysis to capture the risk of repeated false positive screening episodes. There is evidence that some women – particularly women with high breast density – experience repeated false positive screening episodes. Breast density is a key consideration in options for risk-based screening being explored through the ROSA project. While breast density is not included in the AIHW linked data, it would be valuable to understand the extent of repeated false positive screening episodes experienced by BreastScreen participants under the current program.

Finally, we considered that for false positive screening episodes, there is the potential that the information leading to the recall to assessment may indicate characteristics of future breast cancer diagnoses. If this association does exist, it suggests that false positive screens could contribute to risk assessment in some way, which may be of interest to consideration of risk-based screening.

5.3.2 Research questions

We proposed analyses to address the following research questions:

1. What is the association between false positive screens and age and screening round?
2. What is the association between false positive screens and rescreening behaviour?
3. What is the association between false positive screens and characteristics of women with breast cancer and their diagnoses?

5.3.3 Methods

Screening round and age

To examine the distribution of false positive screening episodes by age at screen and screening round, specifically to assess:

- The distribution of current false positive screening episodes (vs true negative screening episodes) by age and by screening round;
- The distribution of ever-false positive screening episodes (vs never-false positive screening episode) by age and by screening round; and
- The distribution of cumulative number of false positive screening episodes (vs never-false positive screening episodes) by age and by screening round.

To support this analysis, we requested a descriptive table for women who did not have a cancer diagnosed during the period 2002-2012 and who were observed for at least 5 screens at age 50-69 during 2002-2012, ideally reported by 5-year or 10-year age group.

This analysis accords with the PICO framework shown in Table 44 below.

Table 44. PICO framework for our analysis of false positive screens and their association with screening round and age.

Population	***Intervention/exposure***	***Comparison***	***Outcome***	***Study design***
Women aged 50-69 screening in the period 2002-2012.	Age at current screen (55–59, 60–64, 65–69) Cumulative number of false positives up to and including current screen (1 to 4+) Current false positive (False positive) Current or prior false positive (Ever false positive) Round of current screen (2 to 8+)	Age at current screen (50–54) Cumulative number of false positives up to and including current screen (0) Current false positive (True negative) Current or prior false positive (Never false positive) Round of current screen (2)	Rescreened<=27 months after current screen n (%)	Cohort

Rescreening behaviour

We sought to examine the association between false positive screens and rescreening behaviour, specifically to assess whether:

- A current false positive screen is predictive of a subsequent rescreen within 27 months;
- Ever having a false positive screening episode is predictive of a subsequent rescreen within 27 months; and
- The cumulative number of false positives (0, 1, 2, 3, 4+) is predictive of subsequent rescreen within 27 months.

For this analysis we proposed the following regression model:

Units of analysis: All true negative and false positive screening episodes between 2002 and 2012 in which the woman's age at screen was 50-69.

Model: Generalized linear model with Poisson distribution and log link function and with cluster robust standard errors to account for the multiple screening observations for each woman.

Effect estimate: Relative risk of rescreening within 27 months.

Outcome variable: (suggested variable names only, where LTE denotes 'less than or equal to'):

- nextscreenLTE27 = 1 if a woman has a screening episode at row _n+1 and the time to next screening round <=27 months;
- nextscreenLTE27 = 0 if a woman has a screening episode at row _n+1 and the time to next screening round >27 months, or if a woman does not have any screening episodes after row _n but at 27 months after the screening date at row n, the woman is still alive, has not had BC, has not reached age 70, and last follow-up date has not occurred;
- Screening episodes that are followed by an interval cancer diagnosis, death or end of follow-up within 27 months are excluded from these analyses.

Covariates: Age at current screen (5-year categories as the relationship between age and screening within 27 months is non-linear), current screening round number current false positive, current or prior false positive, cumulative number of false positives up to and including current screen (the 3 false positive variables are included in separate models only).

Additional notes: Women could have multiple screening episodes (i.e. the units of analysis are screening rounds, not women).

Breast cancer diagnoses

We also sought to examine whether characteristics of women with breast cancer and their diagnoses were associated with prior false positives screening episodes.

For this analysis we proposed the following regression model:

Participants: Women diagnosed with breast cancer who had at least one screening round (exclude if possible women diagnosed in their first screening round, second breast cancer primary diagnoses and metastatic breast cancer diagnoses).

Model: Generalized linear model with Gaussian distribution and identity link function.

Effect estimate: Difference in mean number of false positive prior to cancer diagnosis.

Outcome variable: Number of false positive prior to cancer diagnosis.

Covariates: As listed in left-most column in Table 50 belo

We proposed the following analysis:.

Aim: To assess whether ever having a false positive prior to cancer diagnosis is associated with first primary breast cancer characteristics for women diagnosed with breast cancer after their first screening round.

Participants: Women diagnosed with breast cancer who have at least one screening round (exclude if possible women diagnosed in their first screening round, second breast cancer primary diagnoses and metastatic breast cancer diagnoses).

Model: Generalized linear model with binomial distribution and logit link function.

Effect estimate: Odds ratio for "ever had false positive prior to cancer diagnosis".

Outcome variable: Ever had a false positive prior to cancer diagnosis (yes vs no).

Covariates: As listed in left-most column in Table 51 below.

This analysis follows the PICO framework shown in Table 45.

Table 45. PICO framework for analysis of false positive screens and breast cancer diagnosis.

Population	Intervention/exposure	Comparison	Outcome	Study design
Women aged 50-69 diagnosed with their first primary BC in the period 2002-2012 in their second or further screening round.	Age at diagnosis (55–59 ,60–64 ,65–69) Detection mode (Interval, Non-screen-detected) Histology (Invasive lobular carcinoma, Medullar carcinoma & atypical medullary carcinoma, Tubular carcinoma & invasive cribriform carcinoma, Mucinous carcinoma, Invasive papillary carcinoma, Inflammatory carcinoma, Mesenchymal, Other) Most recent screening round before diagnosis (2-9+) Tumour size (>15mm, Unknown/Not applicable) Sub-site (Unspecified, Nipple and areola, Central portion, Upper-inner quadrant, Lower-inner quadrant, Upper-outer quadrant, Lower-outer quadrant, Axillary tail, Overlapping lesion) Year of diagnosis (2008-2012)	Age at diagnosis (50–54) Detection mode (Screen-detected,) Histology (Invasive ductal carcinoma) Most recent screening round before diagnosis (1) Tumour size (0-15mm) Sub-site (Unspecified) Year of diagnosis (2002-2007)	1. Mean number of false positives prior to dx 2. Ever had false positive prior to cx diagnosis	Cohort

Abridgement note: Results are withheld as the data analysed was not for public distribution.

5.4 The profile of screen-detected and other breast cancers over time

5.4.1 Background

The AIHW report includes some outcomes described according to year of diagnosis (2002-2007 vs 2008-2012). It describes the number of cancer outcomes for the reporting period by age group (40-49, 50-69 and 70+) and screening status (screen-detected, interval, non-screen-detected and never-screened) (Table series 4.3 in the AIHW Report) and finds a lower risk of death from breast cancer for cancers diagnosed in 2008-2012 compared to 2002-2007 (AIWH Report Table 5.2.5).

Additional analyses of value

To help understand changes in survival, it would be valuable to further explore the underlying changes between the two calendar periods for which survival was compared, according to screening status, age, patient characteristics and tumour characteristics, focusing on the historical target age range of 50-69 years.

In addition, it would be valuable to know how the profile of screen-detected cancers has changed over time in the historical target age range of 50-69 years, compared to cancers diagnosed outside the BreastScreen program. For women aged 50-69 at diagnosis, the cohort described in the report had an increased proportion of screen-detected cancers over time. With no discernible changes in screening participation rates over this period[10], these changes are likely due to a mixture of factors, such as underlying changes in breast cancer incidence and/or types of breast cancers, the changing age profile of BreastScreen participants in line with the ageing population, and changes in screening and diagnostic tests available.

Table 46. Distribution of screening status by period, 50-69 years. Adapted from report table 4.3.1.

	Screen-detected	Interval	Not screen-detected	Never screened	Total
2002–2007	42%	1%	27%	29%	100%
2008–2012	45%	2%	28%	26%	100%

BreastScreen program sensitivity has improved over the calendar period included in the AIHW report. [11]. While the primary screening test used by BreastScreen continued to be mammography throughout this period, mammography technology changed over time, with improvements in film mammography particularly in the late 1990s and, starting in the late 2000s, the introduction and ongoing refinement of digital mammography. Digital mammography has led to improved resolution of small artefacts, such as calcifications and vascularity and tools to allow the reader to adjust presentation (e.g. for contrast, brightness, zooming in etc.)[12], but anecdotal reports from screening radiologists also suggest some

[10] (Australian Institute of Health and Welfare 2020. BreastScreen Australia monitoring report 2020. Cancer series no. 129. Cat. no. CAN 135. Canberra: AIHW
[11] (Australian Institute of Health and Welfare 2020. BreastScreen Australia monitoring report 2020. Cancer series no. 129. Cat. no. CAN 135. Canberra: AIHW
[12] Nees A. V. (2008). Digital mammography: are there advantages in screening for breast cancer?. Academic radiology, 15(4), 401–407. https://doi.org/10.1016/j.acra.2008.01.004

more subtle abnormal signs may be less visible with digital mammography so that the profile of screen-detected cancers may have changed.

Table 47. Program sensitivity for women aged 50–69 years, 0–24 months follow-up (age-standardised), according to period and first or subsequent screening round.[13],[14]

	Index years of screening	
	2001–2003	2011-2013
First round screening	79.2%	86.2%
Subsequent round screening	71.0%	74.2%

ROSA project activities include national-level modelling of breast cancer screening and diagnosis over time. In the model, the probability of a cancer being screen-detected is determined by the timing of modelled screening episode, the presence of asymptomatic cancer at the time of screening, and a 'detection function' where the probability of detection is a function of tumour size and mammographic density at the time of screening. The primary aim of this modelling is to explore options for risk-based screening, where changes in outcomes would be driven largely by changes in the early detection of asymptomatic breast cancer.

It would be valuable, therefore, to understand whether the characteristics of screen-detected cancers have changed over time, and particularly how this compares to the characteristics of cancers diagnosed outside the BreastScreen program. This information may be used to calibrate the detection function in the model so that the probability of detection changes slightly over time. Additional detail about cancers diagnosed outside the program according to screening status would also be helpful in this regard.

5.4.2 Research questions

We proposed analyses to address the research questions:

1. Have the characteristics of screen-detected cancers changed over time?
2. How does this compare to the characteristics of cancers diagnosed outside the program?

5.4.3 Methods

We requested analyses aligning with the PICO framework shown in Table 48 below.

Table 48. PICO framework for analysis of cancers over time.

Population	***Intervention/exposure***	***Comparison***	***Outcome***	***Study design***
Australian women with breast cancers diagnosed between 2002 and 2012)	Age at diagnosis (55–59 ,60–64 ,65–69) Histology (Invasive lobular carcinoma, Medullar carcinoma & atypical medullary carcinoma, Tubular carcinoma & invasive cribriform carcinoma, Mucinous carcinoma, Invasive papillary carcinoma, Inflammatory carcinoma, Mesenchymal, Other) Remoteness area (Inner regional, Outer regional, Remote, Very remote, Unknown) Socioeconomic area (2, 3, 4, 5-highest, Unknown) Tumour size (>15mm, Unknown/Not applicable)	**Age at diagnosis** (50–54) **Histology** (Invasive ductal carcinoma) **Remoteness area** (Major cities) **Socioeconomic area** (1-lowest) **Tumour size** (0-15mm) **Sub-site** (Unspecified)	Diagnosis occurring between 2008-2012 (vs 2002-2007) analysed separately for screen-detected and other cancers (cancers diagnosed outside the program (including interval cancers)	Cohort study.

[13] Australian Institute of Health and Welfare 2008. BreastScreen Australia monitoring report 2004–2005. Cancer series no. 42. Cat. no. CAN 37. Canberra: AIHW.

[14] Australian Institute of Health and Welfare 2018. BreastScreen Australia monitoring report 2018. Cancer series no. 112. Cat. no. CAN 116. Canberra: AIHW.

	Sub-site (Unspecified, Nipple and areola, Central portion, Upper-inner quadrant, Lower-inner quadrant, Upper-outer quadrant, Lower-outer quadrant, Axillary tail, Overlapping lesion)			

Specifically, we proposed a descriptive table and a regression analysis, as outlined below.

Descriptive table

We proposed that the AIHW produce a descriptive table (as shown in Table 49 (similar to Table 4.3.1 of the AIHW report)), where the cells contain the number of diagnoses ('X' indicating where data would be available). Here data would be reported as per categories used in the existing report, except for age group (requested by 5-year age group, for women aged 50-69). 'Other cancers' would ideally be disaggregated by screening status, however where cell sizes do not allow (most likely for interval cancers, especially by 5-year age group), these would be aggregated as 'other cancers'.

Table 49. Proposed descriptive table for women aged 50-69 at diagnosis.

	Screen-detected cancers		**Other cancers (according to screening status where cell sizes allow)**		**Total**	
	2002-2007	2008-2012	2002-2007	2008-2012	2002-2007	2008-2012
Age at diagnosis by 5-year group	X	X	X	X	X	X
Remoteness	X	X	X	X	X	X
Socioeconomic group	X	X	X	X	X	X
Histological type	X	X	X	X	X	X
Tumour size	X	X	X	X	X	X
Sub-site	X	X	X	X	X	X

Regression analysis

We proposed the following analysis, for each of (i) Screen detected cancers, (ii) Cancers diagnosed outside the program (including interval cancers), (iii) All cancers, modelled separately according to age group (40-49, 50-59, 60-69 and 70+):

> **Model**: Logistic regression.
>
> **Outcome:** Period of diagnosis (2002-2007 vs 2008-2012).
>
> **Covariates:** Socioeconomic group, remoteness, age at diagnosis, histological type, tumour size and sub-site.

Here we proposed adjustment by year of age for each model (even within the ten-year age groups) because the age profile of screening participants has changed over time due to the ageing population. We requested two levels of adjustment to be reported, with outcomes reported from a model (i) adjusted for age only (**OR1**) and (ii) adjusted for all covariates listed above (**OR2**). In additional analyses, we requested that screen detected cancers and other cancers be analysed together in a single logistic model with all covariates listed above and with the variable "screen detected vs other" included as an interaction variable with each of the covariates. This allowed tests of whether the associations between period of diagnosis and each covariate differed according "screen detected vs other" status (i.e. p-value2 for a test of whether the OR2s differ according "screen detected vs other" status).

5.5 Survival analysis

5.5.1 Background

The AIHW report estimated survival according to screen detection status (Screen-detected, Interval, Non-screen-detected or Never-screened) from 1 Jan 2002 to 31 Dec 2012, reporting crude and adjusted rates. Outcomes were reported separately for women aged 50-69 (73,440 cancers) and women aged 40-49 (26,463 cancers) and 70+ (37,568 cancers). Overall hazards ratios for screen-detected cancers versus cancers diagnosed in never-screened women were also reported by 5-year age group in the report appendix (AIHW report Table A5).

Key outcomes were:

- Numbers of diagnoses and deaths tabulated by screen detection status;
- Survival analyses reported as tables (proportion dying by year) by screen detection status;
- Univariate Cox proportional hazards ratios for each of the variables: screen detection status, age group at diagnosis, period of diagnosis, remoteness area, socioeconomic group, histological type, tumour size and sub-site;
- Multivariate Cox proportional hazards ratios reporting survival according to screening status, adjusted for age group at diagnosis, period of diagnosis, remoteness area, SES, histological type, tumour size and sub-site;
- As a sensitivity analysis, the multivariate Cox proportional hazards regression was repeated for breast cancers diagnosed in 2000–2012, and this was also reported by 5-year age groups between 50 and 69 (but not mode of cancer detection) in AIHW report Table A5.

Additional analyses of value

Estimating survival according to mode of detection would be an important metric to monitor with any introduction of risk-based screening in Australia. To ensure the most accurate estimate is being reported, we reasoned that more information about survival according to age-adjusted results (to compare to the fully-adjusted results already reported) would indicate the total confounding of variables other than age. Such analyses would help assess: 1) the degree of overall confounding of effects (other than age) and 2) the likelihood of residual confounding remaining after multivariable adjustment. In addition, it would be valuable to have more information about overall survival according to 5-year age group (adjusted), extended to both older and younger age groups (i.e. as for AIHW report Table A5 2002-2012 but for 40-44, 45-49, 70-74, 75-79, 80-84 and 85+). As described in Table 51 (page 121) we also proposed various analyses to better understand the influence of specific variables on the fully-adjusted model, for the reasons described.

Some analyses would also be of value specifically for population modelling of breast cancer mortality following diagnosis, according to year of diagnosis, age group, mode of detection (screen-detected, interval, other) and by tumour characteristics at diagnosis (e.g. tumour size, grade, nodal involvement, hormone receptor status). For this purpose, we proposed it would be valuable to have more information about survival according to:

- 5-year age group (unadjusted). The ROSA project models the Australian population from the age of 40 years. We note that the reporting period precedes the extension of the BreastScreen target age range to 70-74, however we do model this period for women aged 40+, so additional information about younger and older age groups would be valuable;
- Tumour size by 5mm categories, if possible, rather than the BreastScreen categories of ≤15mm or >15mm). This would provide more detail in general while aligning the outcomes

with other sources of evidence where tumour size is reported by categories such as 10mm ranges;

- For screen-detected cancers (and interval cancers if data is available), other variables such as grade and symptomatic status. This would enable us to validate the model outcomes against the reported hazards.

These estimates could be used as validation targets for simulated population data reported in the same way from the microsimulation model.

5.5.2 Research questions

We proposed analyses for the following topics:

- Screen detection status and survival;
- Survival according to tumour size at detection;
- Survival according to symptomatic status.

The specific research questions are shown in Table 51 (page 121).

5.5.3 Methods

Our proposed analyses aligned with the PICO framework shown in Table 50 below. Here 'fully-adjusted' model refers to the adjusted models as included in the AIHW report (adjusted for screen detection status, age group at diagnosis, period of diagnosis, remoteness area, SES, histological type, tumour size and sub-site). 'Crude' model refers to models for each age group as reported in the AIHW report (40-49, 50-69 and 70+), unless otherwise specified. We requested the full set of model coefficients (i.e. for all variables in the model) for all models, if available.

Table 50. PICO framework for survival analyses.

Population	***Intervention/exposure***	***Comparison***	***Outcome***	***Study design***
Women screened between 1 January 2000 and 31 December 2014	(Questions 1-6) Detection mode - Screen-detected, Interval, Non-screen-detected (Questions 7-10) Tumour size - 6-10mm, 11-15mm, 16-20mm, 21-24mm, 25+mm, Unknown/Not applicable (Questions 11a-11b) Symptom status- Lump, Nipple discharge—clear, Nipple discharge—blood stained, Other breast symptoms, Not stated	(Questions 1-6) Detection mode - Never-screened (Questions 7-10) Tumour size - 0-5mm (Questions 11a-11b) Symptom status- No symptoms reported	Survival (time from diagnosis to death or lost to follow-up)	Cohort

An overview of the research questions, their purpose, and changes to previous data categories is shown in Table 51 below.

Table 51. Requested survival analyses. Note that Questions 1-8 involve variables specified to more detail than included in the AIHW report (see right column).

Topic	#	Question	Purpose	Changes to previous data categories
Screen detection status and survival	1	What is the association between screen detection status and survival, adjusted only for age group?	Comparing these models will help assess the degree of overall confounding of effects (other than age) and the likelihood of residual confounding remaining after multivariable adjustment.	Age by 5-year age group for women aged 40+ (assuming 85+ would be combined) if possible. Otherwise, by 10-year age group.
	2	What is the 'fully-adjusted' association between screen detection status and survival?		
	3	As for question 2, but without adjustment for tumour size.	To explore the direct effects of screen detection status with possible mediating effects of tumour size removed.	
	4	As for question 2, but without adjustment for tumour sub-site.	To explore the contribution of this poorly measured potential confounder, noting more than 50% of data was in the "unspecified" [missing indicator] category).	
	5	As for question 2, but without adjustment for tumour size or sub-site.	To explore the direct effects of screening status with possible mediating effects of tumour size removed, and without adjustment for the poorly measured potential confounder sub-site.	
	6	What is the crude association between age group and survival?	For ROSA modelling validation	
Survival according to tumour size at detection	7	What is the crude and adjusted association between tumour size and survival?	To explore the extent to which screen detection status mediates the effects of tumour size on survival, reported to a finer level of detail than in the AIHW report. This will also assist with ROSA modelling validation.	Tumour size defined by 5mm categories: 0-5mm, 6-10mm, 11-15mm, 16-20mm and 25+mm, if possible.
	8	As for (7) but without adjustment for screen-detection status.	The effects of tumour size on survival are somewhat mediated through mode of detection, so it would be of interest to estimate the effect of tumour size without adjustment for screen detection status. This will also assist with ROSA modelling validation.	
	9	For screen-detected cancers (and interval cancers if data is available), what is the crude and adjusted association between tumour grade at diagnosis and survival?	To help understand the causal effects of tumour grade on survival. This will also assist with ROSA modelling validation.	N/A
	10	For screen-detected cancers (and interval cancers if data is available), what is the crude and adjusted association between tumour grade at diagnosis and survival, without adjustment for tumour size?	To help assess possible collinearity between tumour grade and tumour size. This will also assist with ROSA modelling validation.	N/A
Survival according to symptomatic status	11	For screen-detected cancers (and interval cancers if data is available), what is the (a) crude and (b) 'fully-adjusted' association between symptomatic status at diagnosis and survival?	To assess the total effects of symptomatic status on survival (i.e. crude effects) and the direct effects on symptomatic status on survival (i.e. adjusted for cancer and demographic characteristics).	N/A

5.6 Interval cancers

5.6.1 Background

The AIHW report describes interval cancers in terms of:

- The number and proportion of all cancers according to screen detection status (interval cancers, screen-detected, non-screen-detected and never-screened);
- For age groups 40-49, 50-69 and 70+, cancers tabulated according to screen detection status and the standard covariates (5-year age group, year of diagnosis, remoteness, socioeconomic group, histological type, tumour size and sub-site;
- Survival according to screen detection status and age group.

Additional analyses of value

Interval cancers are an important outcome for the BreastScreen program. Interval cancers are known to be associated with age and breast density, however there may be other factors associated with interval cancers identified through the AIHW-linked data. This information would help identify opportunities to reduce interval cancer rates and help ensure that outcomes of more risk-based screening protocols are monitored to an appropriate level of detail.

Since breast density is not presently available in the linked data, to avoid confounding we are particularly interested in variables that are unlikely to be associated with breast density. Thus, we hypothesise that interval cancers may be associated with remoteness and SES due to women living more remotely and/or in most disadvantaged socioeconomic groups having less access to diagnostic and risk-based surveillance services between BreastScreen screens and, therefore, being less likely to have interval cancer diagnoses.

For the topics being explored in the ROSA project, one goal of risk-based screening would be to reduce interval cancer rates. The information described above would inform considerations of how risk-based screening might differentially impact women living more remotely and/or in most disadvantaged socioeconomic groups.

5.6.2 Research questions

We proposed analyses to address the research questions:

1. Is risk of interval cancer associated with remoteness?
2. Is risk of interval cancer associated with socioeconomic group/SES?

5.6.3 Methods

We proposed from regression modelling as follows, separately for women aged 40-49, 50-69 and 70+ at diagnosis:

Model: Multinomial logistic regression

Outcome categories defined as follows:

1. Screen detected cancer (base outcome);
2. Interval detected cancer 0-12 months after most recent screen;
3. Interval detected cancer 12-24 months after most recent screen;
4. Non-screened, non-interval detected cancer among ever screeners;

5. Non-screened, non-interval detected cancer among never screeners.

Covariates: socioeconomic group, remoteness, age at diagnosis, year of diagnosis.

The above analysis was not performed by AIHW due to data issues with interval cancer data, an issue identified during the course of this activity.

5.7 Conclusions

This collaborative analysis of national linked data highlights the value of the unique linked dataset assembled and managed by the AIHW and made possible by contributions from BreastScreen services. Building on the detailed information in the AIHW report on outcomes and behaviour in relation to breast cancer screening in Australia, the analyses made possible through the ROSA-AIHW collaboration provide additional insights to inform the potential of risk-based screening in Australia.

These insights include some recommended changes to previously reported analytic methods which we think will improve the validity of estimates in any future reports, provide additional insights about how false positive screening outcomes are associated with future screening behaviour, and an overview of how the profile of breast cancers diagnosed within and outside the BreastScreen program have changed over time in the context of a relatively unchanged screening program.

The proposed analysis on interval cancers could not be conducted due to data issues identified by the AIHW during performance of this activity. However, if this analysis does become possible in the future, it would provide important information to help understand how risk-based screening might differentially impact women living more remotely and/or in most disadvantaged socioeconomic groups.

The data available covered the period 2002-2012. Extending these data to more recent years would provide more contemporary evidence, expand the range of analysis that could be undertaken, and hopefully address the data issue for provision of interval cancer records through more recent data.

5.8 Appendix

5.8.1 Linked dataset overview

The linked dataset comprises linked data from BreastScreen State and Territory registers (2000-2014, for women aged 40+ years), the Australian Cancer Database (1982-2013, for invasive cancers) and the National Death Index (1980-2015). Analysis variables from BreastScreen (BreastScreen Australia data dictionary) were also provided.

The available fields are summarised below.

AIHW linked database (excluding variables from Australian Cancer Database)

For individuals screened between 1 January 2000 and 31 December 2014:

- Date of birth;
- Screening round;
- Family history of breast cancer;
- Previous history of breast cancer;
- Symptomatic status;
- Date of attendance for screen;

- Recommendation of screening;
- Recall to assessment status;
- Date of attendance for assessment;
- Percutaneous needle biopsy performed;
- Percutaneous needle biopsy result;
- Final result of assessment;
- Recommendation of assessment;
- Reason for histopathology;
- Histopathology of non-malignant lesions;
- Histopathology of malignant lesions;
- Size of tumour;
- Postcode.

Analysis variables from Australian Cancer Database

For individuals diagnosed with cancer between 1 January 1982 and 31 December 2012:

- Sex;
- State of Cancer Registration (State/territory of usual residence at diagnosis);
- Date of Diagnosis;
- Age at Diagnosis;
- Age Group at Diagnosis;
- Topography (ICD-O-3) and Morphology (ICD-O-3) – Invasive ductal carcinoma, Invasive lobular carcinoma, Medullary carcinoma and atypical medullary carcinoma, Tubular carcinoma and invasive cribriform carcinoma, Mucinous carcinoma, Invasive papillary carcinoma, Inflammatory carcinoma, Mesenchymal, Other—specified, Unspecified Site/Type of Cancer (ICD-10);
- Size of Tumour (Breast Cancers);
- Date of Death;
- Age at Death;
- Age Group at Death;
- Underlying Cause of Death;

6 Annual screening protocols

6.1 Authors

Sam Egger, Dr Sabine Deij, Chelsea Carle, Doris Whitmore, A/Prof Carolyn Nickson

6.2 Background

6.2.1 Aims

1. To assess whether the characteristics of incident invasive breast cancer and DCIS diagnoses vary according to eligibility for annual screening;
2. To describe the patterns of annual screening uptake among women with a personal history of breast cancer or related breast cancer disease, and how this is associated with calendar year, age, region of birth, highest level of education and remoteness of residence; and for women with a personal history of breast cancer, mode of detection and time since breast cancer diagnosis; and for women with a personal history of related breast cancer disease, type of disease.

6.3 Methods

6.3.1 Analysis design

This ROSA activity originally planned to assess the effectiveness of BreastScreen annual screening policies using the nationally collected data held by the AIHW as described in '*Australian Institute of Health and Welfare 2018. Analysis of breast cancer outcomes and screening behaviour for BreastScreen Australia. Cancer series no. 113. Cat. no. CAN 118. Canberra: AIHW*'.[15].

To help design this analysis, given that ROSA personnel could not have direct access to the linked data, AIHW and ROSA personnel agreed that the ROSA team would first analyse similar data available from through the *lifepool cohort* .[16] The goal was to generate example tables and outputs to guide scaled-up analyses of the nationally linked AIHW data, with ROSA staff leading the activity and AIHW providing input, assistance and advice. However, the collaborative team identified that it would not be feasible to scale-up the analysis of Victorian lifepool data to the AIHW linked dataset due to insufficient information available to identify women offered annual screening in line with each state and territory annual screening policy over the period of the linked data (2000-2014). The AIHW advised that, using their existing classifications, it would not be possible to compare outcomes between women who do or do not take up annual screening when offered. We explored an alternative 'intention-to-treat' analysis, with annual screening policy as exposure; however, the AIHW advised that BreastScreen annual screening policies had not been systematically collected by them and comparing across states and territories was not advisable due to differences in policies across and within jurisdictions. Finally, we considered an alternative descriptive analysis, however this was not feasible within the remaining work timeframes (as defined by data approvals) due to COVID impacts on the specialist personnel of the organisations involved.

[15] The national linked dataset comprises linked data from BreastScreen State and Territory registers (2000-2014, for women aged 50-69 years), the Australian Cancer Database (1982-2013, for invasive cancers) and the National Death Index (1980-2015).

[16] http://www.lifepool.org/

Our analysis of the lifepool data is summarised here, with further detail to be included in a peer-reviewed publication.

6.3.2 The lifepool cohort

Between 2010 and 2016, over 50,000 BreastScreen Victoria (BSV) participants enrolled in the Lifepool cohort (www.lifepool.org)— a prospective cohort study which includes completion of a detailed baseline questionnaire upon enrolment and, with consent provided by participants, regular linkage to records from BSV, the Victorian Cancer Registry (VCR) and population mortality records. BSV additionally flagged the mode of detection data for each breast cancer as:

- Screen-detected breast cancers (breast cancers diagnosed from a positive screening result through BSV);
- Interval cancers (breast cancers diagnosed outside BSV within 24 months after a negative screening test result through BSV, or diagnosed within BSV in the 24 months following a negative screening result either at early recall if the breast cancer was diagnosed more than 6 months after the negative screening result, or at early rescreen if the woman presented with a breast lump or nipple discharge);
- Lapsed screener-detected breast cancers (breast cancers diagnosed outside BSV more than 24 months after a negative screening test result through BSV).

6.3.3 Ethics approval

Ethics approval for this analysis was provided by the Peter MacCallum Cancer Centre Human Ethics Committee (#0966).

6.3.4 Statistical analysis

The following abbreviations are used below:

- IBC: Invasive breast cancer;
- DCIS: Ductal Carcinoma In Situ;
- LCIS: Lobular Carcinoma In Situ;
- ALH: Atypical Lobular Hyperplasia;
- ADH: Atypical Ductal Hyperplasia.

For Aim 1, we described the characteristics of incident invasive breast cancer and DCIS diagnoses following lifepool enrolment according to eligibility for annual screening, tumour size and nodal involvement, mode of detection and time since most recent screen. The PICO framework for Aim 1 is shown in Table 52 below.

Table 52. PICO framework for assessing whether the characteristics of incident invasive breast cancer and DCIS diagnoses vary according to eligibility for annual screening.

Population	***Intervention/exposure***	***Comparison***	***Outcome***	***Study design***
Women diagnosed with breast cancers between 1996 and 2018 at age 40-89 years.	Women eligible for annual screening due to personal history of invasive breast cancer, DCIS, LCIS, ALH or ADH.	Women not eligible or inconclusive eligibility for annual screening due to personal history of breast cancer or breast disease.	Rates of breast cancer diagnoses (invasive breast cancer and DCIS) according to tumour size nodal involvement, mode of detection and time since most recent screen.	Prospective cohort study.

For Aim 2, we used the lifepool cohort to estimate annual screening uptake separately for: (a) women with a personal history of IBC or DCIS and (b) women with a personal history of LCIS, ALH, or ADH, according to year, age, region of birth, highest level of education and remoteness of residence. For women with a personal history of breast cancer we also considered mode of

detection and time since breast cancer diagnosis. For women with a personal history of related breast cancer disease we also considered the type of disease. The PICO framework for Aim 2 is shown in Table 55 below.

Table 7. PICO for assessing the association between annual screening uptake and cancer outcomes.

Population	***Intervention/exposure***	***Comparison***	***Outcome***	***Study design***
Asymptomatic women eligible for annual screening at BreastScreen Victoria due to personal history of breast cancer or breast disease.	Non-referent group characteristics of women who are eligible for participation in annual screening.	Referent group characteristics of women who are eligible for participation in annual screening.	Participation in annual screening by year, among women eligible for annual screening, according to whether eligibility is due to (i) personal history of invasive breast cancer or DCIS or (ii) personal history of LCIS diagnosis or self-reported ALH/ADH diagnosis.	Prospective cohort study.

6.3.5 Eligibility for annual screening

Eligibility for annual screening was estimated based on age, personal history of invasive breast cancer or DCIS at least 5 years prior to screening and personal history of other breast disease (ALH, ADH or LCIS) any time prior to screening.

This was a reasonable approach because, while all other states and territories offered annual screening to women with a strong family history of breast cancer since at least 2009,[17] this was only introduced in BreastScreen Victoria in May 2017.

For women diagnosed with invasive breast cancer and DCIS, eligibility for annual screening was estimated using dates of diagnosis recorded at the Victorian Cancer Registry (1972-2018), for the period from 1996 (the year after the commencement of the program) to 2018 (the last year of BSV screening data linked to lifepool).

ALH, ADH or LCIS diagnosis dates relied on information provided in the lifepool questionnaire with no date of diagnosis provided, so the lifepool questionnaire completion date was used as a proxy. Hence, eligibility for annual screening was estimated for the period 2012 (the first full year after the earliest lifepool questionnaires in which a woman could be assessed for participation in annual screening) to 2018 (the last year of BSV screening data linked to lifepool). The analysis excluded women who were estimated to be eligible for annual screening but had no record of ever being screened.

6.3.6 Annual screening participation

Annual screening participation was estimated from BSV screening histories as screening within 15 months of a previous screen, in line with BSV policies that include a 3-month leeway for annual rescreening. For each year analysed, women were included as potential annual screening participants only if, by our estimation, they were eligible for annual screening in that year and in the previous 15 months.

6.3.7 Statistical analysis

[17] Department of Health and Ageing. BreastScreen Australia Evaluation: Policy Analysis Project. Department of Health and Ageing. 2009. Screening monograph; Retrieved from http://webarchive.nla.gov.au/gov/20140320030052/http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/br-evaluation-lp on 1 August 2019

For Aim 1, we compared tumour characteristics of all breast cancers diagnosed between 1996 and 2018 among Lifepool participants aged 40-89 at diagnosis by mode of detection (screen-detected <15 months since previous screen, screen-detected 15 to <27 months since previous screen, screen-detected 27+ months since previous screen or no previous screen, interval-detected <12 months since previous screen, interval-detected 12 to <24 months since previous screen, lapsed screener 24+ months since previous screen or diagnosed before first screen).

For Aim 2, we estimated relative risks of participation in annual re-screening among women who were eligible for annual re-screening in the calendar years in which they were eligible. This was done using regression analyses with generalised estimating equation (GEE) adjustment for repeated outcome observations within women. These analyses were performed separately according to whether estimated annual screening eligibility was due to: (i) IBC or DCIS diagnosis or (ii) LCIS, ALH or ADH diagnosis.

Abridgement note: Results will become available through a publication in progress.

6.4 Discussion

Our attempts to analyse the effectiveness of BreastScreen annual screening policies were hampered by a lack of information at a national level recording or enabling estimation of which women have been offered annual screening.

From our alternative analysis of available data from the lifepool cohort we found that, despite analysing screening behaviour and outcomes among over 50,000 women, we were unable to compare the characteristics of cancers diagnosed among BreastScreen Victoria participants eligible for annual screening compared to other BreastScreen participants due to the limited number of breast cancers identified. This highlights the importance of larger linked datasets to enable thorough evaluation of the clinical effectiveness of BreastScreen annual screening policies.

We estimated that only a portion of BreastScreen clients eligible for annual screening took up annual screening, and that uptake rates appear to fluctuate over time. This highlights that annual screening participation would not be an accurate proxy for invitation to annual screening. Fluctuations in screening uptake may also reflect potential annual screening of other BSV clients prior to policy changes introduced in 2017, as indicated by screen-detected cancers within 15 months of a prior screen among women not identified in our analysis as eligible for annual screening. This highlights the challenges of estimating BreastScreen annual screening eligibility as an ‘exposure’ based on policy documents alone, particularly when such policies are prone to change (as reported in Appendix Section 7.1). Standardised recording and reporting of both ‘invitation to’ and ‘provision’ of annual screening by BreastScreen services would enable a direct assessment of screening uptake and evaluation of the effectiveness of annual screening policies. Ideally these data would be assembled at a national level, facilitating comparison between jurisdictions.

Annual screening by BreastScreen Australia requires significant resourcing, yet it is very difficult to accurately estimate its effectiveness using currently available data. Any introduction of more risk-based approaches to screening by BreastScreen Australia should include mechanisms for routine monitoring and evaluation of the effectiveness of risk-based screening protocols as offered to different risk groups. Improving current reporting for groups of women offered annual screening and demonstrating an evaluation of annual screening policies would help prepare for any introduction of risk-based screening.

7 Appendices

7.1 Key findings

Drawing from the detailed analyses and results described throughout the chapter, the project generated a set of key findings which were reviewed by the ROSA Expert Advisory Group over May to July 2022. The final set of key findings is outlined below.

Q1. How does BreastScreen Australia currently use risk information for risk assessment, advice and risk-based management?

Key evidence

1. Breast cancer risk assessment and management varies slightly between BreastScreen state and territory services.
2. The criteria for annual screening vary between BreastScreen states and territory programs, particularly in terms of genetic risk and history of ovarian cancer.
3. Policies for re-inviting women aged under 50 years vary between BreastScreen state and territory programs.

Considerations for implementation

1. There is no BreastScreen national policy for managing women with known high-risk genetic mutations presenting for screening.
2. Two BreastScreen state and territory programs currently routinely assess breast density, one as standard practice (BreastScreen Western Australia) and one through a research study (BreastScreen South Australia).

Priority evidence gaps

1. Rates of women alternating annually between BreastScreen and surveillance breast imaging outside the program, and women supplementing BreastScreen episodes with adjunctive testing.
2. The association between surveillance breast imaging outside the BreastScreen program and place of residence.

Q2. How does BreastScreen Australia participation vary by factors of interest for risk-based screening?

Evidence statements

1. BreastScreen participation among women in the target age range of 50-74 can be lower for Indigenous women, women living very remotely, and women living in non-English-speaking households.
2. BreastScreen rescreening can be lower for women for Indigenous women, women living in more remote locations or in major cities, women living in areas of lower socioeconomic status, and women attending the first 1-2 screening rounds (compared to women attending later-round screening).
3. Participation rates among women aged 40-49 years vary greatly between BreastScreen state and territory programs.

Findings to guide implementation

1. Understanding and monitoring BreastScreen participation with any introduction of risk-based screening would be critical to help ensure that the expected benefits are delivered to Australian women.

Q3. How do BreastScreen Australia outcomes vary by factors of interest for risk-based screening?

Key evidence

1. BreastScreen outcomes (larger tumours, higher rates of nodal involvement, higher rates of interval cancers, lower program sensitivity, higher false-positive recall rates) among women in the target age range of 50-74 years are worse than average for some risk groups, at national and jurisdictional levels. For example, younger screening participants tend to have lower program sensitivity and higher recall rates, and women with higher breast density tend to have lower program sensitivity and higher rates of interval cancers and false positive recalls.
2. BreastScreen outcomes (larger tumours, higher rates of nodal involvement, higher rates of interval cancers, lower program sensitivity, higher false-positive recall rates) among women in the target age range of 50-74 years are better than average for some risk groups, at national and jurisdictional levels. For example, older screening participants tend to have higher program sensitivity and lower recall rates, and women with lower breast density tend to have higher program sensitivity and lower rates of interval cancers and false positive recalls.
3. Information on BreastScreen outcomes according to risk factors of interest for risk-based screening is sparse for women aged 40-49 years.

Priority evidence gaps

1. BreastScreen outcomes by factors of interest for risk-based breast screening for women aged 40-49 (ideally by 5-year age group).

Q4. How effective are current BreastScreen policies for annual screening?

Key evidence

1. BreastScreen annual screening uptake among eligible women can be modest and can fluctuate over time.
2. Assessing the effectiveness of BreastScreen annual screening policies requires information on both invitation and uptake of annual screening and sufficiently large datasets linking BreastScreen and cancer registry data to compare tumour characteristics according to annual screening policies.
3. Considerations for implementation as for current annual screening policies, routine evaluation of the effectiveness of risk-based screening would require information on invitation and uptake to risk-based screening protocols for each risk group.

Priority evidence gaps

1. The clinical effectiveness of BreastScreen annual screening policies.

Q5. Does overdiagnosis among women undergoing image-based screening vary by risk group?

Key evidence

1. No evidence was found for estimated overdiagnosis for different risk groups.

Considerations for implementation

1. It would be important to communicate information about overdiagnosis with any introduction of risk-based screening protocols.

Priority evidence gap

1. Estimated overdiagnosis for different risk groups in the Australian population screening setting.

Q6. How can national linked BreastScreen, cancer registry and mortality data inform risk-based screening?

Key evidence

Abridgment note: Results are withheld as they are not for public distribution.

Considerations for implementation

1. Regular linkage and analysis of national linked BreastScreen, cancer registry and mortality data can provide evidence to help inform and evaluate any implementation of risk-based breast screening.

Priority evidence gaps

1. Detailed analysis of interval cancers included in national linked BreastScreen, cancer registry and mortality data.

Q7. What Australian breast cancer surveillance services and guidelines are in place outside the BreastScreen Australia program?

Key evidence

1. There are varying guidelines and practices for breast cancer risk assessment, advice and risk-based management outside the BreastScreen program.

Considerations for implementation

1. Improved differentiation in the Medicare Benefits Schedule between diagnostic and surveillance breast imaging services would enable improved evaluation of risk-based surveillance outside the BreastScreen program.

Priority evidence gap

1. Population-level evidence on the benefits, harms and cost-effectiveness of breast cancer surveillance outside the BreastScreen program.

Q8. What are the current pathways between different Australian risk-based breast screening and surveillance services?

Key evidence

1. Australian women can receive different breast cancer risk assessment and advice depending on who they see and where they live.

Considerations for implementation

1. Health service providers are most uncertain about how to manage women at moderately increased risk of breast cancer (most often defined in guidelines as 'women with breast cancer risk 1.5 to 3 times higher than the population average').
2. There are currently no centralised records of breast cancer risk assessment and management outside the BreastScreen program.

Priority evidence gap

1. A more detailed understanding of how women at moderately increased risk of breast cancer (most often defined in guidelines as 'women with breast cancer risk 1.5 to 3 times higher than the population average') currently use and move between health services.

7.2 Publication

Please note the following article produced from work reported in this chapter:

Carle, C., Velentzis, L.S. and Nickson, C. (2022). BreastScreen Australia national data by factors of interest for risk-based screening: routinely reported data and opportunities for enhancement. Australian and New Zealand Journal of Public Health, 46: 230-236. https://doi.org/10.1111/1753-6405.13203.