

The ROSA Project – summary.

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

27 October 2023

The ffodil Centre

A partnership between



THE UNIVERSITY OF
SYDNEY

Produced by the Daffodil Centre for Cancer Council Australia.

The Daffodil Centre

153 Dowling St, Woolloomooloo, NSW 2011

PO Box 572 Kings Cross NSW 1340

info@daffodilcentre.org

daffodilcentre.org

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The project 'Roadmap for Optimising Screening in Australia – Breast' was funded by the Australian Government Department of Health and Aged Care (formerly the Department of Health). The project lead was Associate Professor Carolyn Nickson, with contributions from an extensive team of project personnel and various advisory and reference groups as described herein.

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Suggested citation: The Daffodil Centre (2023). The ROSA Project – summary. Summary of 'Roadmap for Optimising Screening in Australia – Breast', investigating risk-based breast cancer screening. Produced by the Daffodil Centre on behalf of Cancer Council Australia.

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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Background

Breast cancer

Breast cancer is the most common cancer in Australian women. In the year 2021, there were 19,886 new breast cancer diagnoses (accounting for more than one in four female cancer cases), and an estimated 3,138 women died from breast cancer.^[1] A further 20,428 cases were diagnosed in 2022,^[2] with **Daffodil Centre** projections estimating that more than 90,000 Australian women will die from breast cancer between 2020 and 2044.^[3] Breast cancer is relatively rare in males, with 164 cases diagnosed in 2021.^[1]

Detecting and treating breast cancer at an early stage is key to saving lives and ensuring that women have the best possible quality of life after treatment. Given the burden of breast cancer in Australia, improvements in early detection could make a real difference to many people.



At a population level, incremental improvements in early detection could significantly reduce the burden of breast cancer in Australia and make a real difference to many people.

BreastScreen Australia

The **BreastScreen Australia** program (BreastScreen) offers free two-yearly mammograms (breast x-rays) for asymptomatic women aged 50-74 years (available from age 40), aiming to detect breast cancers before they become symptomatic.

BreastScreen was introduced from 1991 and is a joint initiative of the Australian and state and territory governments. BreastScreen is jointly funded by the Australian Government and state and territory governments and delivered at a state and territory level by accredited service providers. The age-standardised participation rate remained between 53% and 54% from 2014–2015 to 2018–2019 and decreased due to the impact of the COVID-19 pandemic from March 2020 to 48% over 2020-2021.^[4]

1 Australian Institute of Health and Welfare 2021. Cancer in Australia 2021. Cancer series no. 133. Cat. no. CAN 144. Canberra: AIHW. Accessed 09 March 2023.

2 Australian Institute of Health and Welfare. Cancer: web article. URL: www.aihw.gov.au/reports/australias-health/cancer Released 7 July 2022, last updated 15 August 2023. Accessed 20 September 2023.

3 Luo Q, O'Connell DL, Yu XQ, Kahn C. et. al. Cancer incidence and mortality in Australia from 2020 to 2044 and an exploratory analysis of the potential effect of treatment delays during the COVID-19 pandemic: a statistical modelling study. *Lancet Public Health*. 2022 Jun;7(6):e537-e548.

4 Australian Institute of Health and Welfare (2023) Cancer screening programs: quarterly data, AIHW, Australian Government, accessed 09 March 2023.

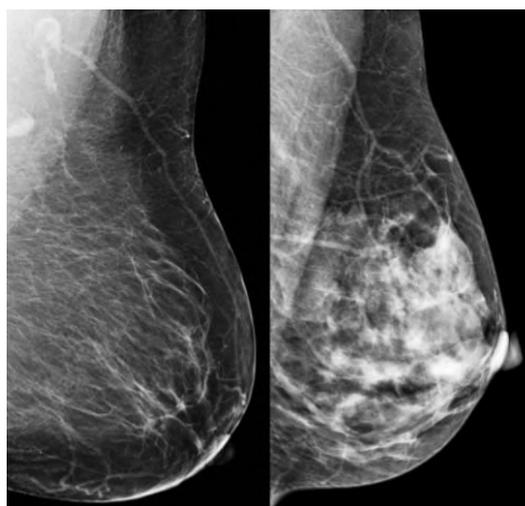
The primary purpose of BreastScreen is to reduce breast cancer mortality, and thanks to the nearly 2 million women who attend every two years, BreastScreen has led to a 21% reduction in population-level breast cancer mortality ^[5], with screened women having a 41–52% reduced risk of dying from breast cancer ^[6].

What is risk-based breast screening?

BreastScreen is targeted to females aged 50-74 on the basis that this population group will benefit most from regular mammographic screening. Within this age group, annual mammographic screening is offered to some participants based on risk factors such as their personal or family history of breast or ovarian cancer. Therefore, BreastScreen is already based on risks, to some degree.

However, with developments in both risk assessment and screening technologies, it is possible that BreastScreen could be more effective by providing more personalised screening protocols that are tailored according to risk ('risk-based' or 'risk-stratified' screening), aiming to find more breast cancers at an early stage before they spread or become symptomatic.

Many options are possible for identifying risk groups and then what might be offered to those risk groups. Important risk factors include high breast density (radiographically opaque breast tissue - see figure below), various genetic mutations (such as the BRCA1/2), hormonal and reproductive histories (e.g. age at first period, childbearing and breastfeeding history), alcohol consumption, some types of menopausal hormone therapy, and being overweight.



Mammograms (breast x-rays) showing low breast density (left) and high breast density (right)

Potential imaging tests include supplemental ultrasound, 3-D mammography, and imaging involving contrast (such as MRI tests and contrast-enhanced mammography). It is possible that risk-targeted use of additional or alternative breast imaging technologies could find more breast cancers earlier. It is also possible that different screening intervals could be offered, based on breast cancer risks.

Breast density is of particular interest because it is both a risk factor for breast cancer and higher breast density can also reduce the accuracy of mammograms. Some alternative breast imaging tests can be more accurate than mammography for women with dense breasts, so they are potential options for risk-based approaches to screening.

5 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.

6 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;21(9):1479-88.

Changing a well-established and effective national program like BreastScreen Australia to offer risk-based screening protocols incorporating different risk assessments and screening tests would be a major undertaking. The evidence is complex and there are many considerations, including the potential benefits, harms and costs of different screening scenarios and what might be feasible and equitable in the Australian health and population setting.

The ROSA Project

In May 2018, the Australian Department of Health and Aged Care commissioned Cancer Council Australia to explore options for potential risk-based breast cancer screening in Australia.

After establishing and consulting a panel of expert advisors, the project commenced a set of targeted evidence reviews, stakeholder mapping, surveys and engagement, and a mapping of current clinical services and policies, and how people access those services.

In 2019, the project produced a 4–5-year roadmap towards using risk-based population screening to improve early detection of breast cancer in Australia. This set the path for the landmark project Roadmap to Optimising Screening in Australia project (ROSA Breast).

The ROSA Breast project is the first initiative in Australia to combine evidence reviews, data analysis, population modelling, health service provider surveys, policy analysis and stakeholder engagement to systematically investigate options for risk-based screening in Australian health policy and practice.

Over its four-year timeframe, the ROSA Breast project submitted eight comprehensive technical reports to the Australian Department of Health and Aged Care, including additional reports in response to the COVID-19 pandemic.

In March 2023, the project finalised a substantial report synthesising all findings to date, with a set of recommended actions and an updated 5-year roadmap designed to guide Australia towards risk-based breast cancer screening.

This submission was carefully prepared with the advice of an independent multidisciplinary Expert Advisory Group, an extensive network of co-opted experts, and input from BreastScreen state and territory senior personnel.

Key findings

The ROSA Breast project found that momentum towards risk-based breast cancer screening is critical in a context of various changes and developments already underway. These include increasing advocacy for Australian women to be notified about their breast density, improved tools for assessing breast cancer risk at a population level, and changes to breast imaging technologies available outside BreastScreen for surveillance of a significant population of higher-risk women. It is also notable that under current health service policies and practices, women can receive different risk assessment, advice and management depending on who they see and where they live.

Key findings in relation to current evidence and practices include:

- Multiple factors in addition to age (and in relation to age) increase breast cancer risk in individual women, however evidence on how to identify, screen and manage women in high-risk groups at a programmatic level remains in development.
- Breast density is an important consideration in relation to risk-based breast screening, given its association with both breast cancer risk and potential reduced accuracy of screening tests.
- There is widespread and varied activity in breast cancer detection and referral within and outside the BreastScreen Australia program, with various pathways between services.

- There is a wide range of professionals involved in early detection of breast cancer, including multiple medical and health disciplines, diagnostic technologies and familial cancer centres, yet coordination between disciplines is limited.
- There are ongoing studies in a wide range of related areas from biology to behavioural research, however gaps in the evidence remain in relation to translation and implementation options.
- There is significant international activity relating to risk-based breast cancer screening, but insufficient evidence to inform changes to Australian policy.
- There is some *ad hoc* tailoring of services within and outside BreastScreen Australia according to identified risk, and some evidence of improved outcomes, however data is limited and varied. This includes current annual screening by BreastScreen Australia, which requires significant resourcing but is not routinely reported or evaluated in detail.

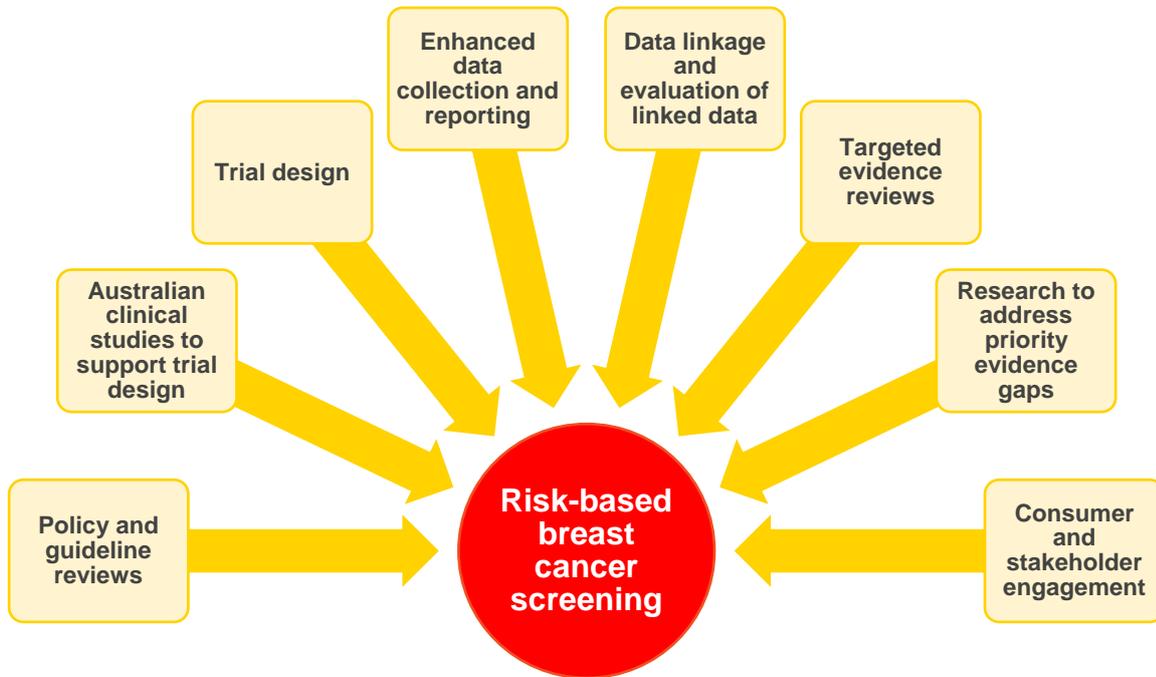
In terms of the consideration of how risk-based screening might be implemented in Australia, project findings include:

- There are key opportunities to improve data collection and analysis to inform incremental approaches towards risk-based breast cancer screening within BreastScreen Australia.
- There is no current national framework for evidence-based and consensus-based guidelines to support incremental changes in policy and practice towards risk-based breast cancer screening.
- Clinical and health economics modelling indicates tailored screening pathways based on different risk profiles (risk-based screening) for the current target age range of 50-74 years from 1 Jan 2025 could, in the first 10 years of implementation, reduce population level breast cancer mortality, with further reductions possible through extending screening on a risk-targeted basis to younger age groups (40-74 or 45-74). The modelled scenarios allocated approximately 20% of women to the higher risk group, and this group was expected to benefit most from risk-based screening.
- There is strong support among key stakeholders for a roadmap towards risk-based breast cancer screening in Australia.
- Uncertainty remains about how screening behaviour might change with the introduction of risk-based screening.
- Based on other areas of cancer screening reform and advice from stakeholders, real-world pilot study in Australia would be required to publish the level of evidence to underpin programmatic policy reform and related changes in clinical practice.

Overall, the ROSA project findings indicate that risk-based breast cancer screening could save lives, and the broader context suggests that risk-based breast screening would help future-proof BreastScreen. The ROSA report includes a roadmap and key recommendations for collecting that evidence as technologies continue to evolve, and engaging with key stakeholders to ensure any changes are feasible, equitable and widely supported.

Recommendations

Drawing on its key findings, the ROSA project recommended a set of activities to address priority evidence gaps and guide and support future implementation of risk-based screening in Australia. The types of activities recommended by the ROSA Breast project are summarised in the diagram below.



Types of recommended activities generated by the ROSA Breast project.

These activities include, for example, clinical studies to support the design of a large-scale trial, enhancements to BreastScreen data collection and reporting to support future risk-based screening, and improved management across health services of women at moderately higher risk.

Priority evidence gaps include ongoing review of emerging evidence as well as insights from COVID-19 disruptions to BreastScreen including analyses related to prioritising client groups during periods of reduced throughput and recovery, and evidence related to extended screening intervals.

The project also recommended a staged clinical trial program to evaluate routine risk assessment and the targeted use of emerging and established screening technologies, in ways yet to be tested in Australia at a population level, commencing with pilot studies.

Key recommendations (summarised, paraphrased and organised by topic) are shown below.

1. Policy and guideline reviews

That national BreastScreen Australia guidelines are developed including current policies and practices in relation to women with different risk factors, including women presenting with known high-risk mutations.

That current management outside BreastScreen Australia of women assessed at moderately higher breast cancer risk be reviewed, aiming for clear and consistent guidelines and management pathways.

That health data sharing to support risk-based breast screening be planned and coordinated between health services.

2. Clinical studies to support trial design

That a well-validated automated breast density assessment tool is evaluated on a large scale in a BreastScreen Australia setting, reporting on outcomes in the setting such as cancer diagnosis rates, interval cancer rates and false positive screening rates for defined breast density groups.

That well-validated breast cancer risk assessment tools are evaluated in BreastScreen Australia settings to continue to build the evidence base towards risk-based breast cancer screening.

That priorities for future targeted research include a focus on the expected benefits and risks of potentially important technologies in relation to risk-based breast cancer screening.

That technologies for consideration in this context include digital breast tomosynthesis, ultrasound, MRI and contrast-enhanced mammography as primary or supplemental screening tools in some risk-stratified screening group/s.

3. Trial design

That ongoing monitoring and critical appraisal of international trials be used to inform the design of a prospective Australian trial, supported by observational studies where appropriate, recognising that international trials will not provide sufficient data to inform policy and practice without Australia-based trials/pilots. An Australian trial should capture both the benefits and harms of interventions, and carefully evaluate changes in screening behaviour.

That evidence on risk-based breast cancer screening is continually reviewed in relation to risk-based screening protocols.

4. Enhanced data collection and reporting

That BreastScreen Australia develop a framework for data collection and analysis to inform policy and practice for optimal risk-based breast screening.

That national BreastScreen Australia data on participants aged 40-44 and 45-49 is utilised to inform long-term considerations for targeted approaches to risk-based breast cancer screening.

That BreastScreen Australia annual screening policies be monitored and evaluated in more detail.

That BreastScreen Australia reporting for priority populations (e.g., Indigenous, rural/remote, culturally and linguistically diverse) is enhanced to help ensure any moves towards risk-based breast cancer screening do not widen gaps in outcomes between population groups.

5. Data linkage and evaluation of linked data

That BreastScreen data and other health records are linked and analysed to help evaluate *ad hoc* risk-based breast cancer screening occurring in asymptomatic women outside BreastScreen.

6. Targeted evidence reviews

That ongoing evidence review includes consideration of factors such as participant/patient history, validation and improvement of risk tools, genetic tests, breast density and evolving technologies.

That ongoing evidence review includes estimated group-level benefits and harms of risk-based breast screening technologies.

That any implemented approaches to risk-based breast screening technologies be regularly reviewed to ensure optimal approaches to policy and practice are being applied.

7. Research to address priority evidence gaps

That learnings from the management of COVID-19 and its impact on screening participation, service responses and outcomes are considered in relation to prioritised and stratified approaches to risk-based breast cancer screening.

That further evidence be collected on the benefits and risks of simplified breast cancer risk assessment tools in the Australian population, compared to more detailed approaches to risk assessment.

That priorities for future targeted research include a focus on the expected benefits and risks of potentially important technologies in relation to risk-based breast cancer screening.

That technologies for consideration in this context include digital breast tomosynthesis, ultrasound, MRI and contrast-enhanced mammography as primary or supplemental screening tools in some risk-stratified screening group/s, with different evidence gaps remaining for different technologies.

That any evolving approaches to introducing risk-based breast cancer screening are supported in parallel by coordinated evidence review, including modelling studies and analysis of other trials and pilot studies.

8. Consumer and stakeholder engagement

That steps towards risk-based breast cancer screening include increased engagement between policy, program and research leads and consumers and other key stakeholder groups, and ongoing exchange of clear, evidence-based information.

That there be further analysis about consumer attitudes about potential risk-based breast screening, to inform communication to support any change to more risk-based breast screening.

Roadmap

Development

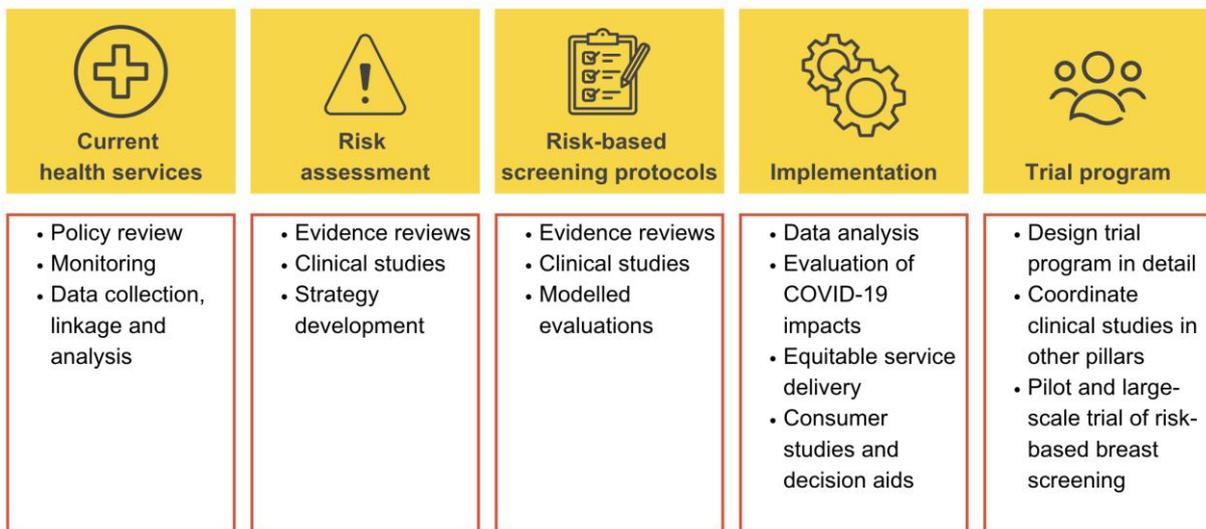
Building on the project’s recommendations and the earlier roadmap, the 5-year ROSA Breast Roadmap outlines a program of possible longer-term activities to ‘think big’ and ensure if there is a transition to risk-based breast cancer screening in Australia, it is evidence-based and the benefits, harms and costs are understood.

Roadmap activities may include:

- The design and implementation of a risk-based breast screening trial, within a coordinated trial program, subject to emerging evidence.
- Development and validation of pathways to routine breast cancer risk and breast density assessment and advice within BreastScreen.
- Clinical studies to evaluate breast screening technologies in the Australian setting, including resourcing, workforce capacity and training, and data storage and transmission requirements.
- Activities to strengthen involvement, leadership and coordination of the people and organisations who can best support risk-based breast screening.
- The development of strategies to plan resourcing and workforce capacity.
- Increased stakeholder engagement and external communications.

Pillars to support Roadmap implementation

Development of the updated ROSA Breast Roadmap was organised under five ‘pillars’ (figure below) identified by the project team and its expert advisers as key topics for framing issues and opportunities to guide work towards risk-based breast cancer screening. These pillars provide a framework for implementation of the Roadmap, where each pillar could be guided by steering groups comprising representatives from health services within and outside BSA, academic research, federal and state/territory government, and consumers and consumer organisations.



The 2023-2027 ROSA Roadmap in summary, aligning with five 'pillars' as shown.

These pillars would then capture independent and interactive areas for ongoing collection of evidence, landscape analyses, stakeholder engagement and informing the incremental steps towards development of policy and practice in risk-based breast cancer screening. This framework would harness the best evidence, resources and people available to help Australia achieve a world-leading, evidence-based approach to risk-based breast cancer screening with the aim to reduce the burden of breast cancer in Australia.

Roadmap in summary

Table 1 provides an overview of Cancer Council Australia's proposed Roadmap towards risk-based breast cancer screening in Australia.

Table 1. The ROSA Roadmap towards risk-based breast cancer screening in Australia. 'BreastScreen' describes the BreastScreen Australia program, comprising state and territory BreastScreen programs.

ACTIVITY	FINANCIAL YEAR				
	23/24	24/25	25/26	27/28	28/29
1. Leadership, governance and resourcing					
<i>To guide and support work towards risk-based breast screening in Australia.</i>					
1.1 Working groups: Establish and coordinate a network of working groups to guide and help progress roadmap activities under five 'pillars': current health services, risk assessment, risk-based screening protocols, implementation, and a trial program.	✓	✓	✓	✓	✓
1.2 Governance: Strengthen national governance and coordination of BreastScreen state and territory programs, including mechanisms for independent, expert, evidence-based policy advice.	✓	✓			
1.3 Resourcing: Develop a strategy for increased resourcing to support direct and indirect costs of potential risk-based breast screening, tailored to suit the various funding and service delivery models of BreastScreen state and territory programs.	✓	✓			
1.4 Breast imaging workforce: Develop a strategy to increase capacity in the breast imaging workforce to provide any alternative or supplemental risk-targeted screening tests such as would be required for risk-based breast screening.	✓	✓			
1.5 BreastScreen client-facing staff: Develop a strategy to ensure capacity, training, and support for client-facing staff to enable routine risk assessment and advice within the BreastScreen program.	✓	✓			
2. Policy review					
<i>Planning and review of policies and guidelines to support risk-based breast screening.</i>					
2.1 Care pathways: Develop and validate a strategy for ensuring coordinated care pathways between BreastScreen, primary care, family cancer clinics and related services under risk-based screening protocols, potentially including the development of national guidelines for the early detection of breast cancer in asymptomatic women and strategies to standardise management of women at moderately higher breast cancer risk (for example, women at 1.5 to 3 times the population average).	✓	✓	✓	✓	
2.2 Genetic risk: Establish a BreastScreen national policy for standardised management of women who self-report that they have high-risk genetic mutations.	✓				
2.3 Health records: Map potential mechanisms for sharing active health records between BreastScreen and risk-based surveillance services outside the program, to support standardised advice for Australian women.	✓	✓	✓		

ACTIVITY	FINANCIAL YEAR				
	23/24	24/25	25/26	27/28	28/29
3. Current health services					
<i>Activities to understand contemporary clinical practices and their role in risk-based breast cancer screening.</i>					
3.1 Monitoring developments: Monitor any studies, trials or evaluations of risk assessment, breast density assessment and/or alternative screening protocols in the BreastScreen program and any changes arising in primary care and breast cancer diagnostic and surveillance services outside BreastScreen.	✓	✓	✓	✓	✓
3.2 BreastScreen data: Collect and analyse BreastScreen data to inform policy and practice for optimal risk-based breast screening, including recommended activities focussed on women aged 40-44 and 45-49, annual screening policies, and equitable service delivery.	✓	✓	✓	✓	✓
3.3 Linked data: Map and where feasible apply mechanisms to link and evaluate national data between BreastScreen and other health services to provide insights about the benefits, harms, costs and behaviour related to population screening compared to risk-based surveillance outside the program.	✓	✓	✓	✓	✓
4. Risk assessment					
<i>To guide evidence-based implementation of routine risk assessment incorporating breast density.</i>					
4.1 Evidence reviews: Regularly review evidence on screening program outcomes by risk group (including overdiagnosis), risk assessment tools, and breast density assessment tools. Expand topics to include risk estimates based on breast density independent of other risk factors, risk assessment incorporating genetic tests and the use of clinical records analysed using AI methods.	✓	✓	✓	✓	✓
4.2 Clinical studies of risk assessment: Undertake clinical studies of routine risk assessment and advice in the BreastScreen program incorporating routine breast density assessment and downstream psychosocial impacts and health service use and advice outside the BreastScreen program. Consider using simplified breast cancer risk assessment tools assessed in the Australian population.	✓	✓	✓		
4.3 Clinical studies of breast density assessment: Undertake clinical studies of routine breast density assessment and advice in the BreastScreen program incorporating downstream psychosocial impacts and health service use and advice outside the BreastScreen program.	✓	✓			
4.4 Breast density standards: Develop and validate a strategy for standardised breast density classification and notification within the BreastScreen program, using evidence from clinical studies of routine breast density assessment and advice in the BreastScreen program.		✓	✓		
4.5 Implementation strategy: Develop and validate a strategy for standardised breast cancer risk assessment and advice in the BreastScreen program, using evidence from clinical studies of routine risk assessment and advice in the BreastScreen program.		✓	✓		

ACTIVITY	FINANCIAL YEAR				
	23/24	24/25	25/26	27/28	28/29
5. Risk-based screening protocols					
<i>To appraise emerging evidence and address evidence gaps in the Australian population and health service setting.</i>					
5.1 Evidence reviews: Regularly review evidence on risk-based breast cancer screening technologies using rigorous research methodologies such as systematic reviews and critical appraisal, in line with NHMRC guidelines as appropriate.	✓	✓	✓	✓	✓
5.2 Clinical studies of breast imaging: Undertake clinical studies of supplemental or alternative screening tests targeted to risk groups in the BreastScreen program such as digital breast tomosynthesis, supplemental ultrasound and magnetic resonance imaging (MRI) and/or contrast enhanced mammography for women at higher risk of breast cancer.	✓	✓	✓		
5.3 Modelled evaluations: Undertake modelled evaluations of risk-based screening protocols informed by evidence from implementation studies and small-scale trials and evaluation studies (see 7.3).			✓	✓	✓
6. Implementation					
<i>Evaluation and planning to support trial and implementation of risk-based breast screening.</i>					
6.1 BreastScreen data analysis: Routinely analyse BreastScreen participation and outcomes by risk group collected by BreastScreen services and provided to the AIHW, with consideration of COVID-19 impacts on routinely reported outcomes.	✓	✓	✓	✓	✓
6.2 COVID-19: Evaluate and monitor the impact of COVID-19 on jurisdictional screening services including insights from prioritising client groups and evidence related to extended screening intervals.	✓	✓			
6.3 Rural and remote regions: Assess options and considerations for risk-based screening in rural and remote communities, in consultation with stakeholders and BreastScreen state and territory programs.		✓	✓		
6.4 Stakeholder readiness: Routinely analyse consumer and workforce attitudes about potential risk-based breast screening.	✓	✓			
6.5 Decision aid: Develop and evaluate a personalised risk management decision aid for Australian women at all levels of breast cancer risk, consistent with nationally standardised policies and resourced to be updated as required.		✓	✓		
7. Staged trial program					
<i>Progressing from smaller, staged trials to generate evidence and prepare health services, to a large-scale trial of risk-based breast cancer screening, aiming to engage multiple BreastScreen jurisdictions.</i>					
7.1 Trial strategy: Building on the ROSA trial program framework, design a detailed and comprehensive Australian trial strategy.	✓	✓			
7.2 Clinical study coordination: Coordinate and support clinical studies under the pillars of risk assessment and risk-based screening protocols.	✓	✓	✓	✓	✓

ACTIVITY	FINANCIAL YEAR				
	23/24	24/25	25/26	27/28	28/29
7.3 Pilot studies: Pilot in the BreastScreen program selected protocols combining risk assessment and advice and risk-based screening protocols for women with higher breast density and/or higher risk of breast cancer. ⁷		✓	✓		
7.4 Large-scale trial program: Subject to supporting evidence and aiming to mitigate potential harms such as reduced adherence to the program in some population groups and increases in overdiagnosis, implement a large-scale trial of risk-based screening protocols compared to standard care in the BreastScreen program. ⁸				✓	✓
8. Stakeholder engagement <i>Engaging with key stakeholders in risk-based breast cancer screening to help inform and support risk-based breast screening in Australia.</i>					
8.1 Stakeholder input: For all activities, incorporate engagement with Commonwealth and state and territory governments, BreastScreen state and territory management and clinical representatives, breast cancer screening clinical groups, consumers and consumer stakeholder groups, and the national research community.	✓	✓	✓	✓	✓
8.2 Communication: Maintain and enhance communications with stakeholders and present interim findings and plans at public lectures, conferences and other stakeholder forums, subject to approval by project funders.	✓	✓	✓	✓	✓
9. Recommendations and roadmap <i>Reviews in line with emerging evidence.</i>					
9.1 Roadmap review: Adapt the Roadmap as required based on emerging evidence and recommendations.	✓	✓	✓	✓	✓
9.2 Recommendations: Produce consensus-based clinical recommendations for risk-based breast cancer screening in Australia.					✓

⁷ Targeted screening technologies with possible tailored screening intervals, potentially commencing at age 40, 45 or 50.

⁸ Primary outcome tumour stage and subtypes, secondary outcomes include interval cancer rates, false negatives, recalls to assessment, biopsy rates, treatment intensity), resource and workforce requirements and acceptability. Other aspects of trial design to be determined by evidence generated by other activities in this table.