The ROSA PROJECT

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

Chapter 1. Executive Summary and project overview (abridged)

20 March 2023, abridged 1 May 2024

The Daffodil Centre

A partnership between

Cancer Council | The University of Sydney

Produced by the Daffodil Centre for Cancer Council Australia.

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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.

CONTENTS

1 Executive summary

1.1 Breast cancer in Australia

For Australian females, breast cancer is the most commonly diagnosed cancer and the second-leading cause of cancer death.[1] Studies have shown that Australia's BreastScreen program, introduced from 1991, has contributed to an estimated 41% to 52% reduction in breast cancer mortality in participants.[2] This reduction in breast cancer mortality at a population level is estimated to be 21% to 30%, depending on the methodology used.[3]

Despite significant improvements in breast cancer outcomes over the past two decades, every three hours on average an Australian woman dies from breast cancer, with most deaths occurring in women diagnosed at later stages.[4] Projections published by the Daffodil Centre[1] estimate that between 2020 and 2044, more than 90,000 Australian women will die from breast cancer.[5]

1.2 Background to the ROSA project

In May 2018, the Australian Department of Health and Aged Care engaged Cancer Council Australia to undertake a set of activities exploring options for risk-based breast cancer screening in Australia, applying a rigorous approach to project governance and research protocols similar to that used in the development of clinical practice guidelines.

The project commenced at a time when national and international interest on this topic was gaining momentum, driven by evolving research on stratified risk, advances in breast imaging technologies, and advocacy from multi-sector stakeholders including consumers, clinicians, researchers, policy makers and commercial interests.

Much of the earlier discussion, including that led by clinicians and consumers, was outpacing the publication of peer-reviewed evidence, with some groups advocating for more intensive screening of higher-risk women, and other groups advocating for less intensive screening in order to reduce overdiagnosis (detection of asymptomatic cancers that would not have become symptomatic within a woman's lifetime).

A prominent example was the growing interest in mammographic breast density, which is an established risk factor for both breast cancer and for reduced accuracy of mammography.[6-8] There was, however, no conclusive evidence nor scientific consensus on whether breast density should be routinely assessed, how breast density should be measured and defined, how this information should be combined with other risk information, how best to communicate findings and implications to women, or optimal clinical pathways for managing women at different levels of breast density.

There was a general understanding that potential clinical pathways for different risk groups, whether based on breast density alone or incorporating other risk factors, would be likely to include tailored screening intervals and targeted use of alternative screening modalities such as magnetic resonance imaging (MRI) or adjunctive ultrasound. However, there were clear evidence gaps in relation to the costs, benefits and harms of current and alternative screening protocols in the Australian health setting and population, as well as the ethico-legal consequences of informing women of their risk and suitable methods for communicating risk.

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[1] The Daffodil Centre is a joint venture between the University of Sydney and Cancer Council NSW.

There was also limited systematic knowledge of what risk-based surveillance already occurs in clinical settings outside BreastScreen Australia, which is important given the modest participation rate (usually 55% of the target population) [9] and the potential for shifts in service utilisation between BreastScreen and other parts of the health system with changes – or indeed no changes – to current screening strategies.

Over the period 2013-2017, key stakeholders including BreastScreen Victoria, the Victorian Comprehensive Cancer Centre and the Clinical Oncology Society of Australia had convened various forums to advance the agenda on risk-based breast screening. These forums were valuable in presenting available evidence and facilitating discussion, and they demonstrated the limitations of current evidence to guide best practice and a diversity of views about the best way forward. This included an initiative (the *Towards Tailored Screening Project*) jointly led by BreastScreen Victoria and a small team of researchers which proposed a first 'roadmap' to guide a more systematic and strategic approach to address consideration of risk-based breast screening in Australia, moving beyond research-focused 'think tanks' and outlining the activities required to devise and implement a renewed, more personalised BreastScreen program. The ROSA project (Roadmap to Optimising Screening in Australia – breast cancer) emerged from this first Roadmap.

1.3 The ROSA project

Since its inception in 2018, the ROSA project[2] has conducted a strategic set of contracted activities comprising evidence reviews, data analyses, policy analysis, stakeholder surveys, mapping of clinical services and stakeholder perspectives, and clinical and health economics modelling. This has led to a series of detailed technical reports delivered since 2019 (listed in *Appendices* 1.9.1, page 14). The project has produced a set of evidence-based recommendations (listed in *Appendices* 1.9.2 (from page 15) and a Roadmap to guide considerations over the next 4-5 years (see *Appendices* 1.9.3, from page 21).

The project findings combine to improve our understanding of what risk-based breast screening might look like in Australia, the extent to which current evidence supports its introduction, and how to best work towards policy development as evidence evolves. Drawing on advice and feedback from various advisory groups and BreastScreen representatives, the recommendations and Roadmap provide an evidence-based action plan towards risk-based breast cancer screening in Australia, subject to the strength of emerging evidence and with consideration of the benefits, harms and costs for the population as a whole and for specific risk groups.

The current milestone report synthesises the core work to date in a comprehensive set of chapters as outlined in Figure 1. A combined glossary of terms used throughout the report is provided in *Appendices* 1.9.4 (from page 24), with glossaries also included in each chapter.

[2] Renamed in 2020 from 'Optimising Early Detection of Breast Cancer in Australia'.

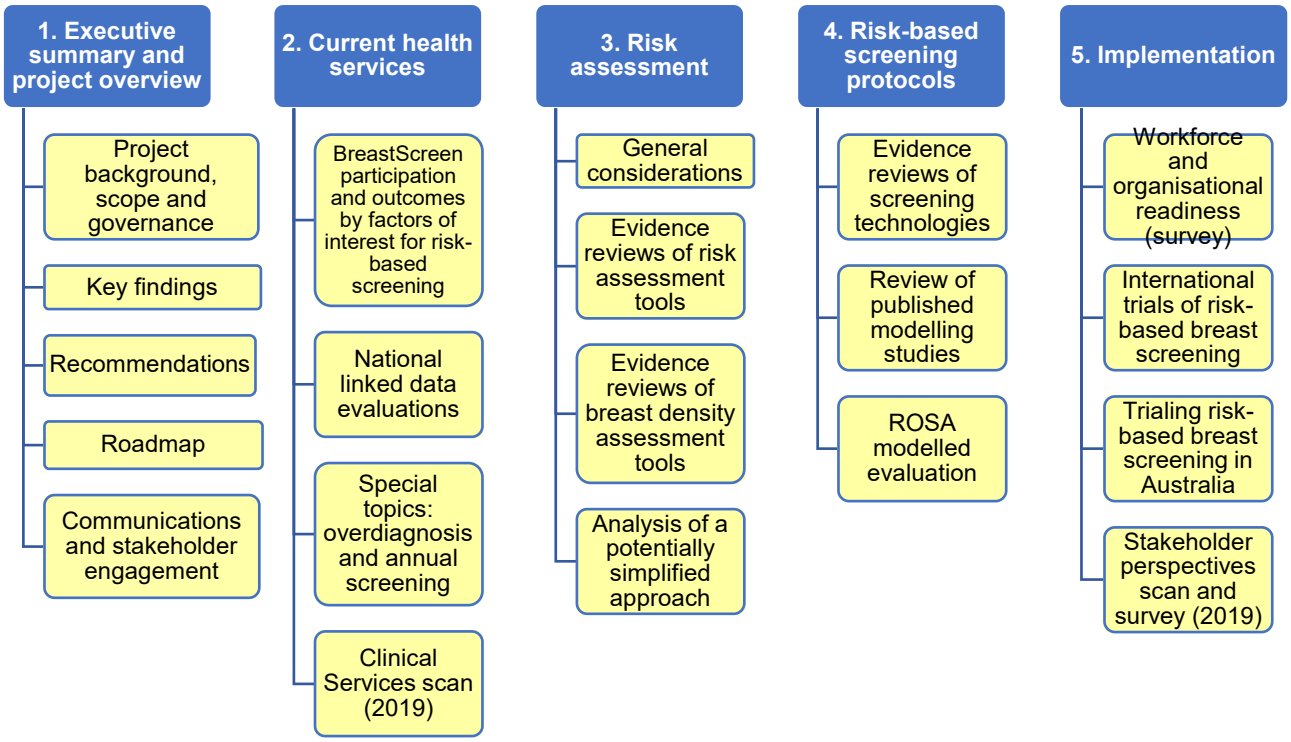


Figure 1. An outline of the chapters included in the milestone ROSA report. Each chapter has its own pagination, references, and appendices so that they can be self-standing documents as needed.

Additionally, the ROSA project has delivered various supplemental reports (see *Appendices* 1.9.1, page 14), including a recent report in collaboration with the Australian Institute of Health and Welfare (AIHW) outlining potential enhancement of routine BreastScreen Australia data collection and reporting to support risk-based breast cancer screening.[3]

1.4 Key findings

The ROSA project findings are listed in detail within the Chapter 1 project overview, with reference to their source technical chapters. In summary, we found that a more personalised approach to population breast cancer screening, adjusted to estimated breast cancer risk and breast density and potentially extended to women aged 40-49, has the potential to save lives at a population level and help ensure that screening is as effective as possible for different groups of women.

As detailed in the report chapters (and supported by the detailed references and analyses therein), key findings 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.

[3] Australian Institute of Health and Welfare & Cancer Council Australia. *Enhanced BreastScreen data collection and reporting: An activity under the Roadmap for Optimising Screening in Australia (ROSA).* 21 December 2021

- There is widespread and varied activity in breast cancer detection and referral within and outside the BreastScreen Australia program.
- 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 current tailoring of services within and outside BreastScreen Australia according to identified risk and some evidence of outcomes, however data is limited and varied. This includes current annual screening by BreastScreen Australia, which requires significant resourcing yet is difficult to evaluate using currently available data.
- 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 framework for evidence and consensus-based guidelines to support incremental changes in policy and practice towards risk-based breast cancer screening.
- Clinical and health economics modelling indicates 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 risk-based screening to younger age groups (40-74 or 45-74). The greatest differences are noted for the approximately 20% of women allocated to the highest risk group in the modelled scenarios. In terms of harms, modelled estimates indicate that more intensive screening in high-risk women would involve increased false positive screening results and overdiagnoses, while less intensive screening of lower risk women could potentially reduce these harms.
- 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.
- 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. We found no published evidence for estimated overdiagnosis for different risk groups, while our modelling indicates that risk-based screening could potentially improve or worsen overdiagnosis for different risk groups.
- A 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.

Drawing on these findings and the stakeholder engagement and expert reviews throughout the project, the ROSA project recommendations and Roadmap offer a mechanism and proposed timelines to achieve the levels of evidence required to make clear policy decisions, while maintaining engagement with key stakeholders and starting work to prepare health services and systems for any widespread implementation.

1.5 Recommendations

The ROSA project recommendations comprise a set of consensus-based considerations and actions. These recommendations draw on the key findings described throughout this report, combined with

input from the project Expert Advisory Group, co-opted expert panel and the project BreastScreen Australia Reference Group, and with feedback from the BreastScreen Australia Program Management Group.

As summarised in Figure 2, recommended actions 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 also include insights from COVID-19 disruptions to BreastScreen including insights from prioritising client groups during periods of reduced throughput and recovery, and evidence related to extended screening intervals.

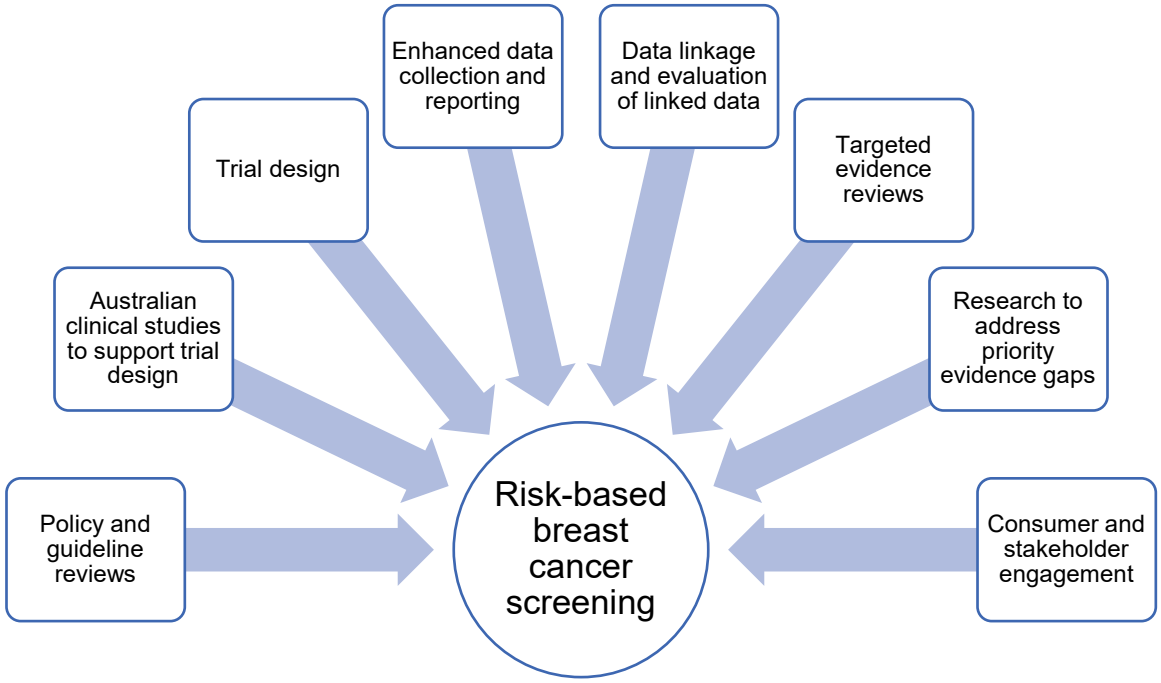


Figure 2. Types of recommended actions generated by the ROSA Breast project

The ROSA recommendations are detailed in the *Appendices* (Section 1.9.2, starting page 15), and summarised below.

1.5.1 Recommendations in summary

Current health services

- That a framework for data collection and analysis is established to inform potential policy and practice options towards risk-based breast cancer screening.
- That national BreastScreen Australia data on participants aged 40-49 is utilised to inform long-term considerations for targeted approaches to risk-based breast cancer screening.
- That BreastScreen data and data on *ad hoc* breast cancer screening (where feasible) are linked and analysed in relation to hospital admissions, Medicare, PBS and other datasets (including, potentially, through use of deidentified My Health Record data).
- That linked data is used to evaluate *ad hoc* risk-based breast cancer screening occurring in asymptomatic women outside BreastScreen.

- That BreastScreen Australia guidelines are developed including current policies and practices in relation to women with different risk factors, as work continues towards risk-based breast cancer screening.

Risk assessment

- 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 ongoing evidence review includes a focus on optimal analysis of factors such as participant/patient history, genetic tests, breast density and evolving technologies.
- That a well-validated automated breast density assessment tool is evaluated on a large scale in a BreastScreen Australia setting, reporting on outcomes, the setting such as cancer diagnosis rates, interval cancer rates and false positive screening rates for defined breast density groups.
- That evidence on the effectiveness of breast density tools be continually collected towards developing policy and practice for risk-based breast cancer screening.

Risk-based screening protocols

- 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, magnetic resonance imaging and contrast-enhanced mammography as primary or supplemental screening tools in some risk-stratified screening group/s.
- That well-validated breast imaging techniques for improved cancer staging at diagnosis are evaluated in a BreastScreen Australia setting.
- That evidence on risk-based breast cancer screening is continually reviewed in relation to risk-based screening protocols.
- 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.
- That modelled evaluations of risk-based breast cancer screening protocols in the Australian setting be used to help identify priority screening protocols to consider for real-world evaluation.

Evidence-based implementation

- 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.
- 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 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.

1.5.2 Additional considerations

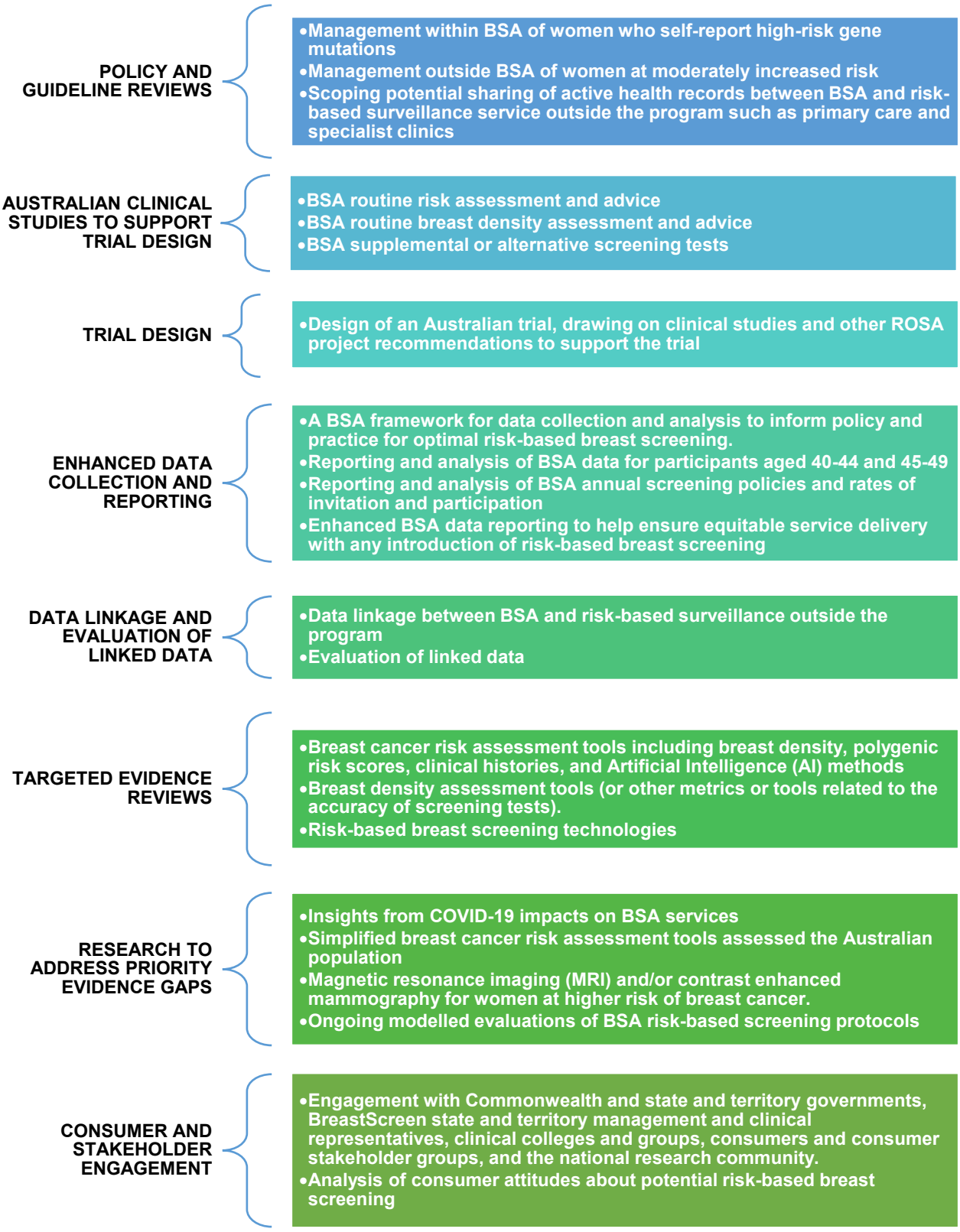
For all recommendations, Australia needs to carefully consider its own health services and population profile to determine the best options for Australian women, including specific consideration of population groups such as women living in regional and remote areas, culturally and linguistically diverse women, Indigenous women, and women of lower socioeconomic status. Understanding and supporting population health literacy around breast cancer risk, cancer screening and the expected benefits and harms of any risk-based approach to screening would be an important aspect of any implementation.

Trials and real-world pilot sites may be crucial to establishing the level of evidence required to introduce risk-based breast cancer screening, noting that BreastScreen was phased in from 1991 following successful localised trials at 10 sites Australia-wide in the late 1980s. As highlighted in our overview and critical appraisal of current trials (Chapter 5), several quality trials are underway internationally, assessing a variety of approaches to risk assessment and risk-based breast screening protocols as suited to their existing health services and populations. Trials do have limitations in terms of the range of screening protocols that can be evaluated and the reliance on interim outcome measures (such as tumour stage and interval cancer rates) because mortality outcomes cannot keep pace with advances in screening technology and improvements in cancer treatment (and potentially prevention). Modelling (such as that described in Chapter 4) can provide complementary evidence to help identify priority protocols to evaluate and to help interpret interim findings. However, trials will yield the highest-quality evidence, so that Australia should consider its own trial program.

1.5.3 Activity types

As outlined in Figure 3 (page 9), the types of activities required to implement these recommendations include policy and guideline reviews, clinical studies, trial design and complementary modelled evaluations, work to enhance data collection and reporting, data linkage and evaluation, research to address priority evidence gaps, and consumer and stakeholder engagement.

Figure 3. A summary of ROSA Project Recommendations according to the type of work required. BSA = BreastScreen Australia



1.6 The ROSA Roadmap

1.6.1 Purpose

While evidence gaps continue to be addressed, momentum towards risk-based breast cancer screening is critical in a context of 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 in Australian health services outside BreastScreen. For example, Medicare Benefits Schedule subsidies for breast imaging are now available for a significant population of higher-risk women[4], impacting on both consumer and workforce attitudes to the current screening program (see Chapter 4 of the full report).

Changing a well-established and effective national program like BreastScreen Australia would be a major undertaking, with a need to navigate challenges such as ensuring adequate resourcing in a program delivered through joint state and Commonwealth funding, ensuring sufficient workforce capacity to support changes, and considering the downstream consequences of requiring breast cancer risk assessment, including potential legal, social and ethical impacts of incorporating genetic testing into risk assessment. Additionally, overdiagnosis remains an important consideration for risk-based breast screening, which could potentially improve or worsen overdiagnosis for different risk groups.

A roadmap setting the direction for working through these complex issues in an evidence-based framework involving key stakeholders from multiple disciplines and backgrounds will be key to delivering improved outcomes in breast cancer screening.

1.6.2 2023-2027 Roadmap

In 2019, the ROSA project delivered its first 4–5-year Roadmap, identifying priority activities to help consider the best approach to risk-based breast cancer screening in Australia. Many aspects of this Roadmap have since been progressed by the ROSA project. Drawing on the project recommendations and contextual changes since 2019, we now provide an updated 2023-2027 ROSA Roadmap to help guide priorities over the next period.

The updated Roadmap covering the period 2023-2027 outlines a program of activities to ‘think big’ and ensure an evidence-based transition to risk-based breast cancer screening in Australia. Detailed in Section 1.9.3 (page 21), the Roadmap includes, for example:

- The design and implementation of a risk-based breast cancer screening trial, within a coordinated trial program
- Development and validation of pathways to routine breast cancer risk and breast density assessment and advice within the BreastScreen Australia program
- Activities to strengthen leadership and coordination to support risk-based breast cancer screening and the development of strategies to plan resourcing and workforce capacity

[4] For example, mammography and digital breast tomosynthesis are both available to asymptomatic women with a significant family history of breast or ovarian cancer (Items 59300 and 59302) and magnetic Magnetic resonance imaging (MRI) is available to asymptomatic women has an estimated lifetime risk greater than 30% or 10 year absolute risk greater than 5% using a clinically relevant risk evaluation algorithm, or a strong family history based on specific combinations of first and second degree relatives and their age at diagnosis (Item 63434). http://www.mbsonline.gov.au, accessed 20/12/22.

- Increased stakeholder engagement and external communications.

As summarised in Figure 4, the 2023-2027 ROSA Roadmap outlines five 'pillars' (Figure 4) aligning with the chapters of this report with the addition of a dedicated pillar for trialling risk-based breast cancer screening. This approach aims to attract, develop and coordinate dedicated expertise and 'champions' for each pillar to lead to the implementation of risk-based breast cancer screening in Australia in a way that is evidence-based, cost-effective, and supported by stakeholders and the Australian population. Working groups under each pillar would be guided by steering groups for each including representatives from health services within and outside BreastScreen Australia, academic research, Commonwealth and state/territory governments, and consumers and consumer organisations. This approach would help build momentum for roadmap activities.

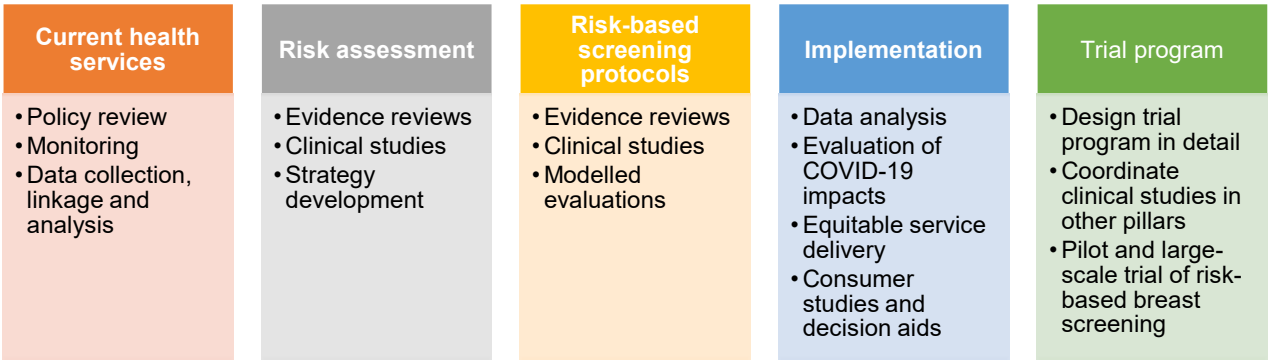


Figure 4. 2023-2027 ROSA Roadmap summary according to five 'pillars'. Each pillar could be implemented by working groups guided by steering groups comprising representatives from health services within and outside BreastScreen Australia, academic research, federal and state/territory government, and consumers and consumer organisations.

The established BreastScreen Australia program would be central to any shift towards risk-based breast screening. Any changes to this established effective population screening program must maintain the integrity of population screening as defined in the national framework.[10] This includes due consideration and planning for how these changes might best interact with risk-based surveillance services available to asymptomatic women outside the program, so that women receive consistent and clear advice no matter where they live and who they see, and to ensure the most effective and cost-effective use of public health budgets.

1.6.3 Roadmap principles

As an overarching principle, any approach to risk-based breast cancer screening should be done in a way that sustains or improves on usual BreastScreen participation. Research outside the ROSA project indicates general in-principle support for risk-based breast cancer screening among consumers.[11-12] It is not yet known how women would respond to a more risk-stratified approach in practice; perspectives from ROSA advisory and reference groups have been mixed. There is concern that some population groups, including those with currently lower BreastScreen participation (such as women in some culturally and linguistically diverse communities and Indigenous women) may be deterred by a requirement to provide additional risk-related information. Conversely, in the context of alternative imaging technologies widely available outside the program and community concern about the accuracy of mammography particularly for dense breasts, there is concern that women will drift away from BreastScreen if there is no change to the status quo.

Some aspects of risk-based cancer screening would require careful planning in order to ensure that existing disparities are not worsened. For example, appropriate language and cultural content and

support services may be required to ensure the quality of risk assessment for women in culturally and linguistically diverse communities and Indigenous women, if that assessment relies on self-reported information. Additionally, potential increases in false positive recall rates may have a greater impact on women who live further away from BreastScreen assessment services, and women living in remote or very remote locations may be disadvantaged if they do not have the same level of access to more personalised, risk-based breast imaging services as women living in metropolitan or regional areas.

The Roadmap includes the design and implementation of a large-scale trial, subject to emerging evidence. Of note, trials of risk-based breast cancer screening protocols that include a screening component that is less intensive than the screening currently offered (non-inferiority trials) are required to show, for ethical reasons, that mortality outcomes (or surrogates thereof) for the intervention are not inferior to those for current screening practice. This is challenging in practice because non-inferiority methods and analyses are highly sensitive to protocol deviations. Even random deviations can impact findings from non-inferiority trials. For non-inferiority trials, there is no universal agreement about whether intention-to-treat or per protocol is the best approach.

Additionally, any programmatic changes to current breast cancer screening and surveillance in Australia would require further engagement with key stakeholders in government, with BreastScreen service providers, BreastScreen clinical and management professionals and representatives, the principal council of the NHMRC, the Health Chief Executive Forum and various other entities involved in public health policy and practice.

1.7 Conclusion

The ROSA project has undertaken a comprehensive program of activities indicating opportunities for more effective, efficient, personalised breast cancer screening in Australia. The collated body of evidence combined with an overarching consensus among stakeholders suggests that changes in policy and practice will eventually be required as the evidence and technologies further evolve. However, evidence required to introduce changes in policy and practice to an established, effective program and inform clinical guidelines to underpin risk-based breast cancer screening within a program (or programs) remains inconclusive. The ROSA project recommendations and updated Roadmap set the direction for a strategy comprising targeted clinical studies, analysis and stakeholder engagement which, with good leadership, resourcing, and coordination across health services and the academic sector, can accelerate Australia on a path towards risk-based breast cancer screening.

1.8 References

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1.9 Appendices

1.9.1 Contracted activities and reports 2018-2022

Table 1. Summary of ROSA contracted activities and reporting, 2018-2022.

Contracted activity	Technical reports
Evidence reviews	Scoping-level reviews on risk assessment tools, overdiagnosis by risk group, BreastScreen outcomes by risk group, risk-based screening modalities, modelled estimates (reports on all topics provided in 2019, 2020 and 2022). Scoping-level reviews (2019) then systematic reviews (2022) on breast cancer risk assessment tools and mammographic density assessment tools.
Review and evaluation of population-level trials	Overview and quality appraisal of international trials of risk-based breast cancer screening and their potential translation to the Australian setting (2020, 2022).
Clinical and health economics modelling	Modelled evaluation of the costs, benefits and harms of various risk-based screening protocols in Australia (2022).
Analysis of current risk-based screening	Summary of evidence (2019), updated (2022).
Potential simplified approaches to BreastScreen risk assessment	Epidemiological comparison of current and feasible BreastScreen risk assessments on the lifepool cohort (2022).
BreastScreen risk-related data project (in collaboration with the AIHW).	Enhanced data collection report (2022). Annual screening analysis (2022). Linked data analysis (2022).
Clinical services scan	Desktop review (2019).
Stakeholder scan and surveys	Desktop review (2019) and stakeholder surveys (2019, 2022).
COVID impacts	Special report (2020).
ROSA and breast density	Special report (2019).
Roadmap	Roadmap document (2019, 2022).

1.9.2 List of recommendations

1. POLICY AND GUIDELINE REVIEWS

1.1. That a BreastScreen Australia policy be developed for women who self-report that they have high-risk mutations, as part of any progress towards organised risk-based breast screening.

This would address an increasingly important inconsistency between BreastScreen state and territory services in relation to how information on high-risk mutations is collected and used, and thereby help standardise BreastScreen management of the small proportion of women at significantly elevated breast cancer risk. The policy should aim to ensure that women who attend BreastScreen with known genetic mutations are given consistent and clear advice, implemented with consideration of pathways of referral to and from familial cancer clinics, and potential impacts on the genetic testing system including genetic counselling.

1.2. That, in addition to recommendations specific to BreastScreen Australia, as part of national consideration of more risk-based approaches to breast screening, current management outside BreastScreen Australia of women assessed at moderately higher breast cancer risk (for example, women at 1.5 to 3 times the population average) be reviewed, aiming for clear and consistent guidelines and management pathways.

This requires a specific focus because women at moderately higher risk are most likely to receive conflicting advice from different health services and to 'bounce' between services, including BreastScreen and other health services. This could include women with known genetic mutations associated with moderately increased risk of breast cancer.

1.3. That there be national planning and coordination to establish appropriate sharing of active health data risk assessment and advice records between health services to help coordinate, standardise and evaluate breast cancer risk assessment and advice.

Planning and coordination would include an assessment of privacy considerations, mechanisms available or required to enable sharing health data for this purpose, with reference to existing data systems such as My Health Record and population cancer registries.

2. CLINICAL STUDIES TO SUPPORT TRIAL DESIGN

2.1. To support routine risk assessment of BreastScreen Australia clients incorporating breast density, that a well-validated automated breast density assessment tool be evaluated on a large scale in a BreastScreen Australia setting before any widespread implementation, and that this evaluation include reporting of observed program sensitivity, interval cancer rates and false positive rates for each breast density group.

The ROSA project systematic review of externally validated breast density assessment tools indicated that breast density assessments can identify groups within breast screening population with different rates of interval cancer rates, program sensitivity, and false positive rates. This is consistent with the well-established association between breast density and both breast cancer risk and potential masking of breast abnormalities in screening mammography and confirms that breast density assessment is central to implementing risk-based breast screening in Australia. The accuracy of tools included in the ROSA project evaluation varied between settings and study groups, indicating that evaluation in an Australian breast screening setting would be required to confirm expected findings before any widespread implementation, mindful that this would require routine breast density assessment and advice without changes to usual pathways of care.

2.2. That there be further evaluation in the Australian setting of well-validated screening tests expected to improve the balance of benefits and harms for women at higher risk of breast cancer and/or higher breast density, in a cost-effective way.

The ROSA project found mixed evidence on the benefits (increased cancer detection, earlier tumour stage at diagnosis, reduced mortality), harms (interval cancers, false positive screens, overdiagnosis) and cost-effectiveness of using for the primary screening test imaging modalities other than or in addition to digital mammography across different risk groups. Some observed differences between studies are likely to be attributable in part to differences in settings, study groups and, potentially, the version of technology used. Cost-effectiveness is difficult to assess without evidence from implementation studies in Australia. Consideration of risk-based breast screening in Australia would benefit from studies evaluating screening technologies specifically in the Australian screening population setting, aiming to address evidence gaps specific to each technology. This evidence would help inform the design of an Australian trial.

2.3. That any further evaluation of ultrasound (US) as a supplemental screening test include cost-effectiveness analysis in the Australian setting.

ROSA project evidence reviews found that adding US to mammography as the primary screening test, whether hand-held or automated whole breast ultrasound (ABUS), consistently increased both benefits (cancer detection rates) and harms (false positive rates) for groups of women with higher breast density; this was also the case in general for women at very high risk of breast cancer either due to personal history or a lifelong breast cancer risk greater than 20% (excluding women with high-risk BRCA mutations). Evidence was inconclusive or unavailable for other benefits and harms. Understanding the cost-effectiveness of supplemental US in the Australian setting would help provide a more complete assessment of whether this technology could be a candidate for targeted use as part of a risk-based screening program.

3. TRIAL DESIGN

3.1. That ongoing monitoring and critical appraisal of international trials be used to help design an 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.

The ROSA project critically appraised a range of international trials of risk-based screening, and found all to be methodologically valid. However, no trial evidence is expected to translate directly to Australia's specific health systems, geography and population profile. To ensure the expected balance of benefits and harms is achieved in a way that is safe and suited to the Australian population and resource setting, Australia would require its own trial of risk-based screening protocols – even if this largely replicates an international trial – before any widespread implementation of risk-based breast screening. Various international trials have developed protocols, instruments and expertise that would help fast-track the design and implementation of an Australian trial.

3.2. To support 3.1, that existing trials of risk-based breast screening be closely monitored and any new trials critically appraised, including identification of unresolved questions and prioritisation to inform optimal planning for Australian trials.

Most international trials are awaiting primary outcomes. The ROSA project critical appraisal of current trials identified that none of the six trials reviewed were considered to have a high or provisionally high risk of bias for any of the sources of bias assessed. However, it identified that screening trials are vulnerable to contamination of the intervention or the comparator groups depending on whether the intervention is perceived as advantageous or disadvantageous, if the participants are not blinded. Careful review of how this is managed by trials and whether this affects trial findings will help ensure that emerging evidence is interpreted appropriately, and also help identify which priority questions could be most accurately assessed in an Australian trial.

3.3. To support 3.1, that well-validated breast cancer risk assessment tools be evaluated in a BreastScreen Australia setting.

The ROSA project systematic review of breast cancer risk assessment tools assessed through external validation studies (i.e. on study groups different to the study groups used to develop the tools, where expected and observed outcomes are compared) showed that some risk assessment tools can identify groups of women at higher or lower risk of breast cancer. However, marked variations in tool performance in different populations and settings suggest that any tool should be carefully evaluated in Australian target populations for risk-based breast screening before widespread implementation, including gaining a sound understanding of the implications of risk assessment outcomes.

4. ENHANCED DATA COLLECTION AND REPORTING

4.1. That BreastScreen Australia, with the advice of all key stakeholders including program managers, independent multidisciplinary experts and consumers, develop a framework for the collection and analysis of data to inform policy and practice for optimal risk-based breast screening.

This should include (i) reporting to identify and monitor subgroups where participation rates, rescreening rates and/or outcomes (e.g. larger tumours, higher rates of nodal involvement, higher rates of interval cancers, lower program sensitivity, higher false-positive recall rates) diverge significantly from the averages; and (ii) reporting of potentially overdiagnosed lesions (for example, low-grade DCIS and small, non-nodal low-grade invasive lesions) where this varies significantly from average, with information reported for the current target age range and for age groups 40-44 and 45-49 years.

4.2. That national routinely collected BreastScreen Australia data on participants aged 40-44 and 45-49 be collated and analysed to inform future directions on optimal risk-based breast cancer screening in relation to key considerations (e.g., cost-effectiveness, net health outcomes, program administration), interpreted with consideration of current recruitment methods for these age groups.

This would assist with estimating the benefits, harms and cost-effectiveness of risk-based screening for women in these age groups, and provide valuable baseline information prior to any introduction of risk-based screening for women aged 40-49. The different state and territory program policies for re-invitation to screening of women in this age group would need to be considered in the analysis and interpretation.

4.3. That BreastScreen Australia annual screening policies and rates of annual screening invitation and uptake be routinely collected and collated at a national level, with outcomes reported according to (a) women invited to annual screening and (b) women participating in annual screening, with consideration of extending the scope of AIHW screening monitoring reports for this purpose.

Annual screening requires significant resourcing and yet it is difficult to accurately estimate its effectiveness using currently available data. The recommended changes would enable monitoring and evaluation of the effectiveness of annual screening policies not currently possible, and provide a framework for future reporting of participation and outcomes for different risk-based breast screening protocols, reported by risk group.

4.4. That current BreastScreen Australia reporting be enhanced to provide more detail on outcomes according to cultural and linguistic diversity status, Indigenous status and remoteness of residence, so that population-group screening behaviour and outcomes relating to equity can be closely monitored with any introduction of risk-based breast screening.

Enhancing data collection and reporting is required to support risk-based breast screening. The ROSA collaborative activity with the AIHW with contribution from BreastScreen state and territory programs identified various opportunities to enhance data collection and reporting for this purpose, including some changes that would require very modest changes to current practices.

5. DATA LINKAGE AND EVALUATION OF LINKED DATA

5.1. That the feasibility of additional linkage of BreastScreen Australia and data on risk-based surveillance outside the program be assessed, with a view to ongoing analysis to inform risk-based breast screening policy considerations.

Valuable data sources include cancer registry, hospital inpatient, emergency department, and Medicare Benefits Schedule (MBS) claims. This could build on previous linkage of BreastScreen, cancer registry and mortality data coordinated and analysed by the AIHW . Revision of MBS breast imaging items to differentiate use according to symptomatic status would assist.

5.2. Following from 5.1, that any developments in health data linkage and data sharing be followed by a detailed evaluation of the effectiveness of risk-based breast screening of asymptomatic women outside BreastScreen Australia, supported by a rigorous methodology and protocol.

With suitable consideration of which populations access risk-based screening outside BreastScreen, this analysis would assist with monitoring and evaluation of the benefits, harms and cost-effectiveness of the BreastScreen program and risk-based services outside BreastScreen, and help monitor and evaluate changes arising through any introduction of risk-based screening, including screening behaviour. This would help to optimise the benefits, harms and cost-effectiveness of breast cancer surveillance services and potentially contribute to improved coordination between services and more equitable service provision.

6. TARGETED EVIDENCE REVIEWS

6.1. That evidence on the accuracy of breast cancer risk assessment tools incorporating breast density be regularly reviewed with consideration of tools that also incorporate polygenic risk scores, clinical histories, and AI methods to combine information, with consideration given to the feasibility implementing risk assessment tools in terms of resourcing, staff capacity and the impost on screening clients.

The ROSA project systematic review of breast cancer risk assessment tools assessed through external validation studies (i.e. in study groups different to the study groups used to develop the tools, where expected and observed outcomes are compared) did not find strong evidence for adding information on breast density or polygenic risk scores to questionnaire-based risk assessment tools. The review did not include risk based on Artificial Intelligence systems utilising clinical history data, additional mammographic density features, nor Artificial Intelligence methods to combine different sources of risk information. However, this a very active area of research and regular, rigorous review of high-quality emerging evidence is warranted to best inform risk-based breast screening in Australia.

6.2. That evidence on the accuracy of breast density assessment tools be regularly reviewed, potentially every 1-2 years with further consideration of optimal frequency of evidence review.

Breast density continues to be a priority issue for breast cancer screening programs. The ROSA project review of breast cancer screening outcomes (i.e. program sensitivity, interval cancer rates and false-positive screening outcomes) according to mammographic breast density reported findings available by end 2020 for two tools (BI-RADS and Volpara). This a very active area of research and regular, rigorous review of high-quality emerging evidence is warranted to best inform risk-based breast screening in Australia and to help ensure ongoing best practice with any widespread implementation of breast density assessment. Evidence could extend to other metrics or tools related to the accuracy of screening tests.

6.3. That evidence on group-level benefits and harms of risk-based breast screening technologies be regularly reviewed, potentially every 1-2 years with further consideration of optimal frequency of evidence review.

The ROSA project found a high level of interest and activity in emerging breast imaging technologies for use in population breast screening, with fourteen potentially relevant ongoing systematic reviews identified. Regular evidence reviews relevant to the Australian health setting would be of value. This includes review of evidence on digital breast tomosynthesis (DBT) combined with synthetic 2D images or

full-field digital mammography as the primary screening test in a population screening setting, for which the ROSA project review found inconclusive evidence about the balance of benefits and harms. This is a very active research area and ongoing studies may yield more conclusive evidence so that this technology, which is now widely available in Australian diagnostic services and BreastScreen Australia assessment services, could be a candidate technology for targeted use as part of a risk-based breast screening program.

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

Breast imaging technologies are rapidly evolving and expected to improve over time due to advances in technologies, incorporation of AI systems and active research studies in this domain.

7. RESEARCH TO ADDRESS PRIORITY EVIDENCE GAPS

7.1. That BreastScreen Australia capture insights from COVID-19 including prioritisation of client groups during program adaptation and recovery and the impacts of extended screening intervals in relation to cancer detection rates and interval cancer rates according to known and suspected risk factors and consider utility of these data for informing risk-based breast screening policy and practice.

BreastScreen adaptations in response to the COVID-19 pandemic have included changes in screening clinic processes, radiography positioning, client prioritisation and staffing assessment services. A systematic analysis of these adaptations is likely to provide insights about how BreastScreen could adapt to the requirements of implementing risk-based screening protocols. COVID disruptions to BreastScreen program are also expected to alter the benchmark reporting for service performance and delivery for the period commencing 2020, potentially impacting on outcomes such as participation rates, the profile of BreastScreen participants, and screen-detected cancer rates and the profile of screen-detected and interval cancers. These changes should be understood as they would impact on the comparator (standard practice) outcomes for any risk-based screening intervention.

7.2. That further evidence be collected on the benefits and risks of simplified breast cancer risk assessment tools in the Australian population, with validation tailored for Australian policy and practice setting/s.

Many breast cancer risk assessment tools require a substantial amount of self-reported information. This is an impost for women reporting their information and for health services collecting and recording those data. Requests for self-reported information should be justified, and consideration should be given to the accuracy and completeness of self-reported information and the accuracy of more simplified risk assessment tools. Evidence of the accuracy of breast cancer risk assessment based solely on breast density or polygenic risk scores was outside the scope of ROSA activities but an evidence review is warranted given emerging evidence in these domains.

7.3. That further research is undertaken on the benefits, harms, costs and feasibility of magnetic resonance imaging (MRI) and/or contrast enhanced mammography as a supplemental screening test for women at higher risk of breast cancer.

These technologies were in scope for ROSA project reviews, and all evidence identified was from studies restricted to high-risk women. The review found that adding MRI to mammography for women at high risk of breast cancer increased both benefits (cancer detection) and harms (false positive rates). Among these women, the increase in cancer detection rate appeared greater for women with various breast cancer risk factors but without a personal history of breast cancer. Evidence was inconclusive or unavailable for other benefits and harms. This is a very active research area and ongoing studies may yield more conclusive evidence so that these technologies, which are increasingly used by Australian diagnostic and risk-based surveillance services, could be a candidate technology for targeted use as part of a risk-based screening program.

7.4. That modelled evaluations of risk-based breast screening protocols in the Australian setting be considered to help identify priority screening protocols to consider for real-world evaluation.

The ROSA modelled evaluation used the Policy1-Breast modelling platform, which is specified using data from the Australian population and health services and designed to help identify priority risk-based breast screening protocols to consider for real-world evaluation. ROSA modelling results indicate that some risk-based screening scenarios in Australia could improve clinical outcomes for a risk group comprising approximately 20% of BreastScreen clients at highest risk of breast cancer, compared to the current BreastScreen Australia program. Costs are challenging to accurately estimate in the Australian setting, so that further analysis is required to identify which scenarios would have the best balance of benefits, harms and cost-effectiveness. Additional analysis could include questions focussed on younger women or assessment of specific screening technologies as suitable estimates become available (including from the recommended clinical studies). Comparative modelled evaluations using different modelling platforms may assist with validating modelled estimates.

8. CONSUMER AND STAKEHOLDER ENGAGEMENT

8.1. That any progress towards risk-based breast screening involve engagement with Commonwealth and state and territory governments, BreastScreen state and territory management and clinical representatives, breast cancer clinical groups, the Australia, consumers and consumer stakeholder groups, and the national research community, ensuring communications are evidence-based and that information is clear, concise and consistent.

Any transition to risk-based breast screening would require significant and long-term communication strategies. As indicated by stakeholder groups in the ROSA 2019 survey, managing the risk of misinformation and improving the coordination of multiple scientific disciplines involved in optimal early detection of breast cancer are priority areas. This can be supported by ongoing and strategic stakeholder and consumer engagement, dissemination of findings to clinical and academic personnel and delivery of public-facing recommendations.

8.2. 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.

Australian research indicates a range of consumer views that warrant further investigation to help ensure that any risk-based breast screening would be well-supported by a wide range of consumers, including population groups at risk of being deterred by more complex engagement with breast screening and surveillance services.

1.9.3 The ROSA Roadmap

Table 2. Cancer Council Australia's Roadmap towards risk-based breast cancer screening in Australia. 'BreastScreen' describes the BreastScreen Australia program, comprising state and territory programs.

ACTIVITY	FINANCIAL YEAR				
	23/24	24/25	25/26	27/28	28/29
1. LEADERSHIP, GOVERNANCE AND RESOURCING *To guide and support work towards risk-based breast screening in Australia.*					
1a. 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.	✓	✓	✓	✓	✓
1b. Governance: Strengthen national governance and coordination of BreastScreen state and territory programs, including mechanisms for independent, expert, evidence-based policy advice.	✓	✓			
1c. 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.	✓	✓			
1d. Breast imaging workforce: Develop a strategy to increase capacity in the breast imaging workforce to provide any alternative or supplemental risk-targetted screening tests such as would be required for risk-based breast screening.	✓	✓			
1e. 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 *Planning and review of policies and guidelines to support risk-based breast screening.*					
2a. 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).	✓	✓	✓	✓	
2b. Genetic risk: Establish a BreastScreen national policy for standardised management of women who self-report that they have high-risk genetic mutations.	✓				
2c. 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.	✓	✓	✓		
3. CURRENT HEALTH SERVICES *Activities to understand contemporary clinical practices and their role in risk-based breast cancer screening.*					
3a. 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.	✓	✓	✓	✓	✓
3b. 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.	✓	✓	✓	✓	✓

ACTIVITY	FINANCIAL YEAR				
	23/24	24/25	25/26	27/28	28/29
3c. 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 *To guide evidence-based implementation of routine risk assessment incorporating breast density.*					
4a. 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.	✓	✓	✓	✓	✓
4b. 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 the Australian population.	✓	✓	✓		
4c. 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	✓	✓			
4d. Breast density standards: Develop and validate a strategy for standardised breast density classification and notification the BreastScreen program, using evidence from clinical studies of routine breast density assessment and advice in the BreastScreen program.		✓	✓		
4e. 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.		✓	✓		
5. RISK-BASED SCREENING PROTOCOLS *appraise emerging evidence and address evidence gaps in the Australian population and health service setting.*					
5a. 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.	✓	✓	✓	✓	✓
5b. Clinical studies of breast imaging: Undertake clinical studies of supplemental or alternative screening tests targetted 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.	✓	✓	✓		
5c. 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 *Evaluation and planning to support trial and implementation of risk-based breast screening.*					
6a. 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.	✓	✓	✓	✓	✓

ACTIVITY	FINANCIAL YEAR				
	23/24	24/25	25/26	27/28	28/29
6b. 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.	✓	✓			
6c. 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.		✓	✓		
6d. Stakeholder readiness: Routinely analyse consumer and workforce attitudes about potential risk-based breast screening.	✓	✓			
6e. 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 *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.*					
7a. Trial strategy: Building on the ROSA trial program framework, design a detailed and comprehensive Australian trial strategy.	✓	✓			
7b. Clinical study coordination: Coordinate and support clinical studies under the pillars of risk assessment and risk-based screening protocols.	✓	✓	✓	✓	✓
7c. 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. [5]			✓	✓	
7d. 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. [6]				✓	✓
8. STAKEHOLDER ENGAGEMENT *Engaging with key stakeholders in risk-based breast cancer screening to help inform and support risk-based breast screening in Australia.*					
8a. 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.	✓	✓	✓	✓	✓
8b. 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** *Reviews in line with emerging evidence.*					
9a. Roadmap review: Adapt the Roadmap as required based on emerging evidence and recommendations	✓	✓	✓	✓	✓
9b. Recommendations: Produce consensus-based clinical recommendations for risk-based breast cancer screening in Australia					✓

[5] Targeted screening technologies with possible tailored screening intervals, potentially commencing at age 40, 45 or 50.
[6] 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 Roadmap activities.

1.9.4 Glossary of terms

Specified terms used throughout the full report are collated below, and also included in each report chapter.

ABS	Australian Bureau of Statistics
ABUS	Automated breast ultrasound
ADH	Atypical Ductal Hyperplasia
AI	Artificial Intelligence
AIHW	Australia Institute of Health and Welfare
AutoDensity	Image processing software used to automatically measure breast density from mammograms.
BAU	Business-As-Usual, used in the ROSA modelling evaluation to describe current BSA protocols.
Breast density (BD)	Breast Density. Describes the extent (amount and distribution) of radiopaque tissue in the breast. This is usually perceived through mammography and quantified as either the proportion or area of the breast that is dichotomously dense, or classified through categories such as the BI-RADS breast density categories that combine quantitative and qualitative aspects of the breast density.
Better prognosis cancers	A term used in the ROSA modelling evaluation to describe invasive breast cancers that are low grade (grade 1), small (<15mm) and non-nodal at diagnosis.
Bilateral mammography	Mammography of both breasts.
BI-RADS	The American College of Radiology Breast Imaging Reporting & Data System, which includes a framework for categorising breast density through visual assessment.
BRCA1/2	The genes most commonly affected in hereditary breast (and ovarian) cancer.
Breast Density	The extent (amount and distribution) of radiopaque tissue in the breast. Usually perceived through mammography and described as either the proportion or area of the breast that is dichotomously dense, or through categories such as the BI-RADS breast density categories that combine quantitative and qualitative aspects of the breast density.
BSA	BreastScreen Australia
BSAMR	BreastScreen Australia Monitoring Reports (published regularly by the AIHW).
BSAPMG	BreastScreen Australia Program Management Group
BSV	BreastScreen Victoria
Calibration	As used in this report, describes the agreement between predictions from a risk assessment tool and observed outcomes.
CCA	Cancer Council Australia
CEM	Contrast Enhanced Mammography

Community-detected cancer	Cancer diagnosed outside the screening program, including interval cancers.
Cumulus	Image processing software used to assist a reader measuring breast density from mammograms through adjustment of greyscale thresholds to partition the dense versus non-dense tissue.
Daffodil Centre (DC)	A joint venture between the Cancer Council NSW and the University of Sydney.
DBT	Digital breast tomosynthesis.
DCIS	Ductal carcinoma in situ.
Discrimination	As used in this report, refers to how well a risk assessment tool differentiates those at higher risk of having an event from those at lower risk.
DM	Digital Mammography
EAG	The ROSA project Expert Advisory Group
EBPAS-36	Evidence-based Practice Attitude Scale-36 - used to measure individual attitudes towards evidence-based practices.
External validation	As used in this report, refers to studies that aim to assess the predictive performance of existing risk assessment tools using data external to the development sample (i.e. using data from different participants).
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. Refer to context for specific definitions.
FCC	Family Cancer Centre or Family Cancer Clinic.
Higher-risk groups	As used in this report, groups of women estimated to be at higher risk of breast cancer. The definition and size of this group depends on the risk assessment tool and/or guidelines used. Refer to context for specific definitions.
HRT	Hormone Replacement Therapy.
Hypothetical screening tests	A term used in in the ROSA modelling evaluation describing screening tests modelled for a range of specified sensitivity and specificity values.
ICER	Incremental Cost Effectiveness Ratios; calculated by dividing the difference in costs by the difference in effectiveness.
Intention-to-treat analysis (ITT)	A method for analyzing results in a prospective randomized study where all participants who are randomized are included in the statistical analysis and analyzed according to the group they were originally assigned, regardless of what treatment (if any) they received.
Internal validation	As used in this report, using the same population sample to develop and validated a risk assessment tool.
Interval cancer	Cancer diagnosed following a negative screening episode, within a defined period of the screen (usually 12 or 24 months).
LCIS	Lobular Carcinoma *In Situ.*
LYG	Life-years gained.

LYS	Life-years saved.
MD	Mammographic Density. Another term for breast density, confined to breast density assessed from mammograms.
MHT	Menopausal Hormone Therapy (also known as HRT (hormone replacement therapy)).
Missed cancers	A term used in the ROSA modelling evaluation, defined as cancers at least 1mm in diameter but not detected at screening.
Mode of detection	Categorical description of how cancers were diagnosed e.g. screen-detected, interval cancer or other (i.e. cancers diagnosed outside the program including cancers in women previously screened but after the usual screening interval period).
MRI	Magnetic Resonance Imaging
Negative screening episode	A screening round not recalled for further assessment.
Nodal involvement	Breast cancers that involve the lymph nodes.
Non-inferiority trials	Trials assessing whether an intervention is no worse than the comparator (usually current practices). This includes, for example, trials or trial arms assessing less intensive breast screening for lower-risk groups.
OOP	Out of pocket (costs)
ORCA	Organizational Readiness to Change Assessment. A study instrument used to measure organisational readiness to implement evidence-based practices.
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).
Policy1-Breast Model	The simulation modelling platform used for ROSA modelling evaluation.
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. Can be reported for a period and/or a cohort.
Program specificity	The proportion of non-recalled screening episodes not followed by an interval cancer diagnosis.
Prospective study design	A study that follows outcomes subsequent to a specific intervention or exposure. Most often applied to prospective cohort studies, where outcomes in a cohort are followed over time.
QALY	Quality-adjusted life year. A composite measure of quality of life and quantity of life; QALYs are the number of life years saved adjusted for any reduction in quality of life (including morbidity), such as a temporary decrease after receiving a false positive screening result, or a prolonged decrease due to a breast cancer diagnosis.
QALYS	Quality-adjusted life-year saved.
Recall rates	The proportion of screening episodes requiring recall for further assessment.

Recall to assessment	Recall for further investigation by BreastScreen assessment services, following a screening mammogram.
Rescreening rates	In this report 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.
Risk assessment tool	As used in this report, a tool for estimating the risk of breast cancer in the future, sometimes to specific cancer types (e.g. invasive breast cancers) or modes of detection (e.g. interval cancers).
Risk categories	Ranges of estimates of risk for a future event as predicted by a risk assessment tool.
Risk predictor	As used in this report, a risk factor included in a risk prediction tool such as age, height, body mass index, mammographic density, etc
Risk-based surveillance	Breast cancer surveillance services provided outside BSA through such as primary care, high risk clinics, family cancer centres and specialist breast clinics. This includes breast imaging directed at asymptomatic women on the basis of their breast cancer risk.
Screen-detected cancer	Cancer detected by a population screening program.
Screening test sensitivity	The estimated proportion of cancers present at the time of the screening test that are detected.
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).
Superiority trials	Trials assessing whether an intervention is better than the comparator (usually current practices). This includes, for example, trials or trial arms assessing more intensive breast screening for higher-risk groups.
Type I error	Falsely rejecting a null hypothesis that is actually true. For example, finding a difference between interventions on outcomes when there is no difference.
Type II error	Failing to reject a null hypothesis that is actually false. For example, finding no difference between interventions on outcomes when there is, in truth, a difference.
US	Ultrasound
Worse prognosis cancers	A term used in in the ROSA modelling evaluation to describe invasive breast cancers that are high grade (grade 3), large (at least 15mm in diameter) and involving the lymph nodes at diagnosis.

2 ROSA project overview

The content below is complementary to the Executive Summary, providing further detail about the project background, stages, scope, governance and stakeholder engagement, and a full list of the key findings.

2.1 Project phases

The ROSA project has conducted an unprecedented evidence review and analysis, environmental scans of clinical services and stakeholder perspectives, and various stakeholder consultations and surveys. In addition to the information provided in the executive summary, we now provide additional detail about the project activities, methods and findings.

The ROSA project has followed three broad phases: scoping, technical and advisory (Table 3).

Table 3. Steps and phases in producing the ROSA recommendations. Approximate periods shown.

Step	Phase
1. Establish key questions and methods	*Scoping* May 2018 – Dec 2019
2. Review existing relevant guidelines, policies, and practices	
3. Review stakeholder perspectives	
4. Perform evidence reviews and/or generate high-priority evidence	*Technical* August 2019 – December 2022
5. Assess the body of evidence and formulate recommendations	
6. Write content narrative	
7. Expert review and endorsement of draft recommendations	*Advisory* November 2021 – December 2022
8. Consult stakeholders	
9. Finalise recommendations and Roadmap	

In addition to the current report, this work has generated a series of reports to the Australian Government Department of Health and Aged Care over 2019-2021 (Appendix 2.9.1, page 42), and research publications and strategic communications with key stakeholders across the sector as described in Appendix 2.9.2 (page 43).

2.2 Contracted activities

A detailed table of the correspondence between report chapters and contracted activities is shown in Appendix 2.9.3 (page 50), noting that the current report incorporates earlier reports where these have been directly used to help form the 2022 key findings, recommendations and updated Roadmap.

As noted, two activities done in collaboration with the Australian Institute Health and Welfare (AIHW) (linked data analyses and an analysis of annual screening) were originally specified to be provided in a separate joint report. However, the collaborators agreed that this report would be best provided

directly by the ROSA project due to the distinctly separate roles of data provision (AIHW) and analysis (ROSA), as required by each entity's data access terms (see Chapter 2 for more detail).

2.3 Considerations and frameworks

2.3.1 Health services under consideration

To consider options for risk-based breast screening in Australia, it is essential to understand both the BreastScreen program and risk-based surveillance outside the program. Any risk-based screening scenario should recognise the integrity of the current screening program including its high-quality monitoring and evaluation.

As described in the Population Based Screening Framework (2018)[7], screening program policies and protocols must be evidence-based, and follow a framework to:

- 'Develop a detailed national policy framework that includes the screening age range, screening interval, follow-up tests for those with a positive screening test result, clinical guidelines for treatment and management, ongoing surveillance processes, and identification and management of high-risk groups
- Define the screening pathway for the program, based on the best available evidence. The pathway must be efficient and cost-effective and make the best use of resources
- Enable the delivery of screening to diagnosis in a timely manner, minimising potential harms of delayed diagnosis and treatment
- Identify the resources required for the program, including funding allocation, workforce and facilities. Establish how these resources can be developed or established and used efficiently
- Define the roles and responsibilities of each level of government
- Define the governance, organisation and coordination of the program at each level of government. This includes the establishment of a register, invitation protocols, and follow-up protocols and how quality management processes will be built into the program.'

These principles hold for consideration of risk-based screening and highlight the need for a strong foundation across BreastScreen in terms of policies, governance, and resource allocation. The goal to balance outcomes in favour of benefits over harms should hold for women at all levels of risk; while aiming for an overall improved balance than the current approach.

Outside the BreastScreen program, as described in the August 2019 ROSA Clinical Services report (included in the appendix to Chapter 2 in the current report), Australian women without breast cancer symptoms currently access risk assessment, advice and risk-based management through a range of services. The related guidelines, policies and practices differ so that women will receive varying advice and management depending on where they live and the health setting within which they are referred. Such issues do need to be considered in relation to risk-based breast screening. This is especially important for options where services outside the program might complement services provided directly by the screening program (e.g., potential referral in low-resource or remote settings to imaging services for high-risk screening clients, assuming results would be reported back to the screening program for assessment and management).

2.3.2 Measuring benefits, harms and costs

7 Commonwealth of Australia, Department of Health, Population Based Screening Framework, updated 2018.

The ROSA project aims to assess the expected benefits, harms and costs of risk-based breast cancer screening in Australia. This aim is reflected throughout the project activities. To establish a framework for these concepts, in 2019 the project established a set of primary and secondary metrics as shown in Table 4, as refined through discussion with the project Expert Management Group.

Table 4. ROSA metrics, established in 2019, to assess the relative benefits, harms and costs of risk-based breast screening protocols in Australia.

Category	Primary metrics	Secondary metrics
Benefits	Deaths prevented Reduced treatment requirements (intensity) Reduced longer-term sequelae of treatment	Reduced interval cancers Potential reduction in disparities around participation/service access Potential to sustain/enhance appeal of population screening Moral right to breast density information and/or risk assessment Workforce retention
Harms	Increased overdiagnosis Increased false positive recalls False reassurance for low-risk women leading to reduced participation	Potential to deter some women from screening Potential increase in disparities around participation/service access Multiple sources of risk information and advice for women Additional requirements for service providers Discordance between service providers (BreastScreen, primary care, risk-based surveillance services)
Costs	Cost per QALY saved Consideration of scope of cost estimates (e.g. reduced treatment costs, prevented Medicare claims, OOP costs)	Options according to assumed budget envelopes

These metrics provided a valuable reference point for the project activities that followed.

2.3.3 Breast density

Mammographic breast density is an important consideration throughout the ROSA project, given its significance as a risk factor for both breast cancer and reduced screening test accuracy. On 18 September 2019, the project provided an additional report ‘Focus on breast density’, as requested by DHAC . This document summarised the breast density components within the two major reports previously delivered and highlighted the proposed breast density components within the agreed 2019/2020 work plan (Table 5).

Table 5. Breast density components within the project work plan, as described in September 2019.

Activity		Breast density components
1. Summaries of evidence	a) Update the summaries of evidence prepared for current project (overdiagnosis by risk group, BreastScreen outcomes by risk group, risk-based screening modalities and modelled estimates) with an updated sweep and scoping review of the literature	Updated summaries of evidence on breast density and: • Overdiagnosis by risk group • BreastScreen outcomes by risk group • Risk-based screening modalities • Modelled estimates
	b) Extend two topics to literature reviews, namely (i) risk assessment tools and (ii) mammographic density assessment tools.	• A literature review on mammographic density assessment tools

Activity		Breast density components
		• A literature review on risk assessment tools including tools that incorporate mammographic density
2. Review and evaluation of population-level trials	a) Summarise population trials of risk-based population breast cancer screening and critically compile interim and final trial results	• An updated summary of trials including mammographic density within a risk strata • A critical compilation of interim and final trials results for trials including mammographic density within a risk strata
	b) Scoping from an implementation science perspective current international risk-based breast cancer screening trials in terms of potential translation to the Australian setting	• Scoping from an implementation science perspective of risk assessment and stratification as done in trials, where breast density was part of the risk assessment and management (e.g. if/how breast density could be assessed in a similar way in Australia).
3. Clinical and health economics modelling	a) Select feasible and promising risk-based screening protocols for review	• Inclusion of screening protocols incorporating breast density assessment
	b) Collect and assemble clinical and health economics data	• Reporting and analysis of clinical data according to breast density (e.g. estimated screening test sensitivity and specificity for alternative screening tests).
	c) Model selected screening protocols	• Modelling of screening protocols incorporating breast density
	d) Report generated estimates of the benefits, harms and costs of various screening protocols	• Estimated benefits, harms and costs of screening protocols incorporating breast density
4. Analysis of current risk-based screening	a) Collect updated information on BreastScreen jurisdiction-level risk-based screening practices, policies	• Updated information on BreastScreen jurisdiction-level risk-based screening practices and policies, including breast density assessment and advice
	b) Collect and review peer-reviewed and grey literature about the performance of current jurisdiction-level risk-based screening practices.	• High quality summaries of peer-reviewed and grey literature about the performance of current jurisdiction-level risk-based screening practices according to breast density
5. Publication of updated summary information as appropriate	Pending approval from the Expert Advisory Group and the Department of Health and Aged Care, the Project would produce updated information (e.g. fact sheets, consensus statements) for consumers, health professionals and policy makers.	• Pending approval from the Expert Advisory Group and the Department of Health and Aged Care, updated information (e.g. fact sheets, consensus statements) for consumers, health professionals and policy makers in terms of breast density and the potential for more risk-based breast cancer screening.
6. Updated roadmap	Project deliverables outlined above would be developed and presented against key indicators on the optimising early detection of breast cancer roadmap; the roadmap would be updated based on evidence submitted as part of phase two. The roadmap would as a matter of course include recommendations for scaled-up activity and a longer-term plan.	• A roadmap to help achieve consensus among policy-makers, key professional, consumer and other stakeholder entities about optimal approaches to breast density assessment and management as part of optimising early detection of breast cancer in Australia.

2.3.4 Women aged 40-49 years

Most established population breast screening programs either include or target women aged 40-49.[1] In Australia, women aged 40-49 are eligible for but not targetted for screening, accessing around 11% of BreastScreen screens, yielding 6% of all screen-detected cancers and 19% of all interval cancers.[2] The ROSA project has included this age group in various analysis including the overview of routinely reported BreastScreen outcomes reported in Chapter 2, the modelled evaluation reported in Chapter 4, and the survey of health service providers reported in Chapter 5, noting that key project advisors requested consideration of risk-based screening protocols extended to this age group,

including that specific scenarios including women aged 40-49 be evaluated in the ROSA clinical and health economics modelling.

2.3.5 Scoping reviews versus systematic reviews

The ROSA project evidence reviews include a mix of scoping reviews and systematic reviews. As described by Munn et. al.[3], scoping reviews 'are useful for examining emerging evidence when it is still unclear what other, more specific questions can be posed and valuably addressed by a more precise systematic review', while systematic reviews are 'a type of research synthesis that are conducted by review groups with specialized skills, who set out to identify and retrieve international evidence that is relevant to a particular question or questions and to appraise and synthesize the results of this search to inform practice, policy and in some cases, further research'. According to the Cochrane handbook a systematic review 'uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusions can be drawn and decisions made'[4]. Systematic reviews can be considered 'the pillar of evidence-based healthcare' and are used widely to inform the development of trustworthy clinical guidelines.[5]

All topics within our various evidence summaries were first approached using scoping reviews, included in earlier ROSA reports. Two topics were subsequently adapted to systematic reviews. This is not a light decision, as systematic reviews are extremely resource-intensive and need to be produced within a fixed period of conducting literature searches. However, based on our scoping reviews we considered this to be essential to accurately assess the performance of assessment tools for breast cancer risk and mammographic density in terms of outcomes relevant to risk-based screening. In mid-2021 the work required for the systematic review on risk assessment tools expanded beyond our available capacity through the exponential rate of relevant publications on this topic over 2020. In response, we narrowed the scope and instead produced a systematic review of studies that compare tools on a single population (this being a higher standard of comparison than comparisons on different populations), reverting the remaining scope (studies that validate a single tool on one population) to a scoping review. This change in approach was supported by the project funder.

2.3.6 COVID impacts

Despite the impacts of the COVID pandemic, the project maintained its trajectory, with some delays to original timeframes. In addition, the COVID pandemic impacted capacity and participation in some BSA services, disrupted usual screening intervals in specific jurisdictions during lockdown and recovery periods. The adaptation required fast-tracked some elements of operational systems that would also be required to support risk-stratified screening protocols, such as directing available screens to particular sub-groups of BreastScreen clients.

2.4 Governance and personnel

The project has assembled or referred to various groups and panels to provide governance, advice and feedback. Summarised below, the membership for groups assembled by the ROSA project is provided in Appendix 2.9.4 (from page 54). The project also provided regular updates to the BreastScreen Australia Program Management Group (BSAPMG) and the earlier BreastScreen Australia Technical Reference Group.

2.4.1 Project Coordinating Group

The project was guided by a Project Coordinating Group which provided high-level feedback and guidance for the project direction and management, implemented by technical lead A/Prof Carolyn Nickson.

2.4.2 Expert Management Group

In the scoping phase, the project was supported by a large (approximately 30 member) Expert Management Group with a broad, multidisciplinary understanding of the key issues and representatives of key professional groups and stakeholders.

2.4.3 Expert Advisory Group

For the technical and advisory phases, this group was changed to a smaller Expert Advisory Group, who have provided detailed feedback on extensive technical materials, with various meetings held throughout the project. Membership is subject to *conflict-of-interest* clearance.

2.4.4 Co-opted expert panel

The project is also supported by a multidisciplinary panel of independent co-opted experts including many members from the initial Expert Management Group, plus additional experts suited to the more technical phase of work. Membership is not publicly distributed. Membership is subject to conflict-of-interest clearance.

2.4.5 ROSA BreastScreen Australia reference groups

The project established its first BreastScreen Australia Program Managers Reference Group in 2018, and this group provided updated data about BreastScreen policies and practices for the Environmental Scan – Clinical Practices. A second ROSA BreastScreen Reference Group was established in 2021, to provide operational input to ROSA project activities relates to translation of international trials to Australia. With the support of the BSAPMG, this group was established to bring together BreastScreen personnel from a range of professions to provide input and feedback as required, with communication primarily via email. Membership includes but is not limited to (i) BreastScreen state and territory service representative/s on the BSAPMG, invited to self-nominate or nominate a representative from their state/territory program and (ii) existing BreastScreen Australia representatives on the ROSA Expert Advisory Group and co-opted expert panel who elected to join the group.

2.4.6 Personnel

The ROSA project is led by A/Prof Carolyn Nickson, Stream Lead, Breast Cancer Policy and Evaluation, The Daffodil Centre (DC; a joint venture between the University of Sydney and Cancer Council NSW). Over the project period a majority of the project activities have been completed or coordinated by Cancer Council NSW personnel. Contributing personnel are listed in Appendix 2.9.5 (page 60).

2.5 Key findings

Key findings were derived from the report chapters, and further reviewed and refined through consultation with the ROSA project Expert Advisory Group in May-July 2022. The findings are collated Appendix 2.9.6 (page 61), categorised as either key evidence, considerations for implementation or priority evidence gaps. These findings address following questions:

Current health services (chapter 2)

1. How does BreastScreen Australia currently use risk information for risk assessment, advice and risk-based management?
2. How does BreastScreen Australia participation vary by factors of interest for risk-based screening?
3. How do BreastScreen Australia outcomes vary by factors of interest for risk-based screening?
4. How effective are current BreastScreen policies for annual screening?
5. Does overdiagnosis among women undergoing image-based screening vary by risk group?
6. How can national linked BreastScreen, cancer registry and mortality data inform risk-based screening?
7. What Australian breast cancer surveillance services and guidelines are in place outside the BreastScreen Australia program?
8. What are the current pathways between different Australian risk-based breast screeng and surveillance services?

Risk assessment (chapter 3)

1. For asymptomatic women, how do different breast cancer risk assessment tools compare in their ability to predict breast cancer risk across the risk groups determined by each of the tools?
2. For asymptomatic women, how does a given breast cancer risk assessment tool perform in predicting breast cancer risk across the risk groups determined by the tool?
3. For BreastScreen participants, how does risk assessment using age, family history and breast density compare to risk assessment using age and family history alone?
4. How accurately does a given mammographic density measurement tool stratify women according to their risk of a subsequent interval cancer and other screening outcomes?
5. How do different mammographic density measurement tools compare in their ability to stratify women according to their risk of a subsequent interval breast cancer and other screening outcomes?

Risk-based screening protocols (chapter 4)

1. How do alternative or supplemental breast imaging technologies/modalities perform for different breast cancer risk groups, compared to digital mammography?
2. What are the relative benefits, harms and costs of risk-based breast cancer screening as estimated by population-level modelling studies relevant to the Australian health setting, and how would their clinical and health economics estimates translate to an Australian setting?
3. What are the likely benefits, harms and costs of various risk-based population screening protocols in the Australian setting, compared to the current BreastScreen program?

Implementation (chapter 5)

1. Are Australian health services personnel working in screening and surveillance likely to support the introduction of risk-based breast screening, and do they think their organisations are ready?
2. What are the current registered ongoing randomised controlled trials (RCTs) of risk-based breast cancer screening, and what is the quality of these studies?
3. How could BreastScreen routine data collection and reporting be enhanced to support risk-based screening?
4. How does the COVID pandemic impact on consideration of risk-based breast screening?
5. What are stakeholder perspectives on risk-based breast screening?

2.6 Development of the recommendations

2.6.1 The development process

Drawing from the project findings and the broader program of technical and stakeholder engagement activities over 2018-2022, the ROSA project has developed a set of recommended actions to address known evidence and information gaps, prepare health services for potential risk-based breast screening in the future, and maintain connections with stakeholders and consumers.

The recommendations are based on evidence review and analysis, with review and advice from a diverse, multidisciplinary and multisectoral stakeholder group, developed and refined through a consensus-based approach, as shown in Table 6.

Table 6. Development of ROSA Recommendations.

Period	Step
May 2022	Recommendations drafted by the project team and Project Coordinating Group, drawing from key findings from ROSA technical reports and stakeholder input over 2018-2022.
June-August 2022	The ROSA Expert Advisory Group provided written review of summaries of evidence, draft key findings and recommendations, followed by an online discussion.
October 2022	Written feedback was invited from the following groups: ROSA co-opted expert panel, ROSA BreastScreen Reference Group, and the BSAPMG.
November 2022	Recommendations were further refined to the final recommendations shown below.

This approach to developing and refining the recommendations means that they are a synthesis of key findings and input from ROSA project advisory panels. Recommendations were drafted by the ROSA project team based on the key findings, and then further refined through engagement with the ROSA Expert Advisory Group over three months followed by feedback from three additional advisory groups over two months. Feedback included advice on ways to improve data collection, clarifying the sequence of activities to inform prospective policy reform, the function and potential role of mechanisms such as Medicare, and considerations regarding next steps such as optimal approaches to a prospective Australian trial of risk-based breast cancer screening. The final, consensus-based recommendations are provided in detail below.

Recommendations vary widely in scope, subject, scalability, and prospective timelines. Some further evidence reviews are recommended; this is not done lightly, as some stakeholders have indicated a frustration with resources being directed to evidence reviews rather than implementing risk-based breast screening. However, some critical evidence gaps remain.

2.6.2 An example of recommendation development

One example of how the ROSA recommendations synthesise evidence and stakeholder input is our recommendation related to risk assessment tools:

> *6.1. That evidence on the accuracy of breast cancer risk assessment tools incorporating breast density be regularly reviewed with consideration of tools that also incorporate polygenic*

> *risk scores, clinical histories, and AI methods to combine information, with consideration given to the feasibility implementing risk assessment tools in terms of resourcing, staff capacity and the impost on screening clients.*

(Refer to Section 1.9.2 (page 15) for the full list of recommendations.)

The ROSA systematic review of questionnaire-based risk assessment tools (with or without breast density or genetic risks) that have been validated on screening populations found that, while numerous risk assessment tools are available, no tool showed a consistently good overall fit between predicted and observed cancer rates in multiple studies. Some risk assessment tools based on self-reported information usually including family history and prior breast biopsies could identify groups of women at higher or lower risk, but the utility of any single tool for risk-based screening protocols tailored to both higher risk and lower risk women appears to be limited because tools tended to perform well either for higher risk or lower risk women but never for both groups. Tools were compared largely based on cancer diagnosis rates, with insufficient evidence available to compare interval cancers (i.e. cancers diagnosed following a negative population screening test), breast cancer mortality, nor incidence of breast cancer defined by different tumour characteristics (e.g. sub-type, size, grade, nodal involvement).

Additionally, breast density or polygenic risk scores did not improve the fit of tools relying on questionnaire data.

Based on these findings and noting that the development and validation breast cancer risk assessment tools is a very active research area, our recommendations include regular review of evidence on the accuracy of breast cancer risk assessment tools incorporating breast density, with consideration of tools that also utilise polygenic risk scores (Recommendation 6.1). Incorporating feedback from ROSA project advisory panels and stakeholders, this recommendation also includes review of tools that incorporate clinical histories and AI methods to combine information, with consideration given to the feasibility implementing risk assessment tools in terms of resourcing, staff capacity and the impost on screening clients.

2.6.3 Relationship to the Roadmap

All recommendations recognise that further evidence and stakeholder engagement are required before any changes in breast cancer screening policy and practice can be introduced at a population level. Implementing the recommendations would require significant investment and buy-in from multiple partners and stakeholders. The Roadmap provides a high-level framework for their prioritisation.

2.7 Development of the Roadmap

2.7.1 Roadmap purpose

The 2023-2037 ROSA Roadmap (Section 1.6.2, page 10) incorporates a complementary program of activities that align with the ROSA recommendations in relation to policy review, enhanced routine data collection, linkage and analysis, targeted evidence reviews, priority research projects to address priority evidence gaps, and consumer and stakeholder engagement. Together, these activities will support the trialling of risk-based breast screening and help prepare health services and the population for routine risk-based screening in the future.

The updated Roadmap factors in various activities and system changes that have evolved since the 2019 ROSA Roadmap was produced. For example:

- The COVID pandemic led to a pause of most BreastScreen services, followed by ongoing restricted throughput and the need for 'catch up' strategies including prioritising specific client groups for available screens.
- The COVID-19 pandemic has impacted current international trials, delaying or stopping the generation of evidence.
- BreastScreen South Australia has commenced piloting of routine mammographic breast density assessment and advice using an automated breast density assessment tool.
- BreastScreen Victoria is commencing a trial of digital breast tomosynthesis as the routine screening test, and development and validation of Artificial Intelligence algorithms to support reading of screening mammograms and improve breast cancer risk assessment.
- The NHMRC has funded a Centre of Research Excellence aiming to improve breast cancer risk classification and associated decision tools in the Australian screening population (APP2006899).
- The Medicare Benefits Schedule item for MRI (item 63434) recently expanded eligibility including to asymptomatic women assessed as higher risk using a 'clinically relevant risk evaluation algorithm'.[6]

These activities add to the capability and impetus in Australia to commence a well-planned and coordinated translational program of risk-based breast cancer screening.

2.7.2 Roadmap governance and resourcing

Governance and resourcing would be critical to the introduction of risk-based breast screening in Australia. This is clearly indicated by our own analysis and strongly supported by advice and feedback from ROSA advisory groups, the BSAPMG, and stakeholders within and outside the BreastScreen program.

Specifically, that the ROSA technical activities and stakeholder consultation as documented in detail in this report consistently show that any transition to risk-based breast screening in Australia would require:

- Strengthened national governance and coordination of BreastScreen state and territory programs, including mechanisms for independent, expert, evidence-based policy advice.
- Increased resourcing to support direct and indirect costs, tailored to suit the various funding and service delivery models of BreastScreen state and territory programs.
- Improved capacity in the breast imaging workforce to provide any alternative or supplemental risk-targetted screening tests.

- Capacity, training and support for client-facing staff to enable routine risk assessment and advice within the BSA program.

On this basis, the above items are included in the updated Roadmap.

2.7.3 Health service policy development and coordination

The ROSA project recommendations include specific areas for policy and practice review in the short-term (management of women at moderately increased risk outside BSA and sharing health records between BSA and risk-based surveillance outside the program). The 2023-2027 ROSA Roadmap includes developing a strategy for improved coordination between services and the potential development of national guidelines for the early detection of breast cancer in asymptomatic women. This longer-term activity would bring together representatives from the various health services likely to be involved in or impacted by a transition to risk-based breast screening and, ideally, reduce inconsistencies between the various guidelines and policy documents currently in use across the health sector (see Chapter 2. Current Health Services).

2.7.4 Trial program and complementary activities

In the 30-year history of cancer screening programs in Australia, despite significant advances in technologies and our capacity to identify groups of people at high, moderate or low risk of various cancers, there have only been three substantive changes to national policy:

- The introduction of bowel cancer screening, with the program completed in 2020 and broadly consistent with randomised control trial evidence published in 1997.
- An extension of the BreastScreen upper target age range from 69 to 74 from 2013 in view of increased life expectancy and to capture significant ad hoc screening.
- A change in primary screening test, cervical screening interval, age range, and management pathways from 2017, following documentation of substantial HPV vaccine effect on cervical precancer in younger women, a major evidence review (Medical Services Advisory Committee) of accrued evidence to support primary HPV screening, and development of new Clinical Management Guidelines for the renewed program.

This highlights the challenges of translating evidence into practice. For breast cancer, there is growing interest in risk-based screening, with significant research investment particularly in terms of risk assessment, breast density, alternative screening tests and Artificial Intelligence methods. While none of these research programs are expected to yield a major disruptor comparable to the human papillomavirus vaccine coupled with emergent randomised controlled trial (RCT) evidence on the protective effect of HPV screening against invasive cervical cancer, their findings can – and should – be translated into practice through a unified, policy-driven program of work.

Several international trials of risk-based breast cancer screening are underway (Table 7). As discussed in Chapter 5 of this report, Australia would require its own trial of risk-based breast cancer screening that would provide a rigorous, independent and accountable framework to develop, test and evaluate:

- integration of different screening technologies in BreastScreen clinical pathways
- routine risk assessment and advice
- information systems and reporting
- staff training programs
- communication tools and acceptability to women
- costs, within a rigorous and accountable framework

- risk-group level performance indicators.

The 2023-2027 ROSA Roadmap includes a staged trial program to enable a full-scale trial of risk-based breast screening in Australia, commencing with smaller, preliminary trials and pilot studies in various BreastScreen state and territory sites. This program-level approach would help ensure the large-scale trial is safe, successful and effective, non-disruptive for related health services, and provides insights so that a large-scale trial is adequately resourced and governed and minimises harms such as increased false-positive screens, negative psycho-social or cost impacts for Australian women, and health budget cost-shifts to services outside BreastScreen Australia.

Additionally, based on stakeholder perspectives and advice provided throughout the ROSA project, commencing smaller, preliminary trials and pilot studies in various BreastScreen state and territory sites would provide timely reassurance to many stakeholders and consumers that there is a national, material commitment to addressing the current limitations of breast screening in Australia, particularly in relation to harnessing the opportunity to provide routine assessment and advice about breast density and breast cancer risk, and relying solely on mammography as the screening test despite its known limitations for women with particularly extensive and opaque breast density. The large-scale trial would then evaluate, to the highest level of evidence, the benefits, harms and costs of breast cancer screening protocols tailored to breast cancer risk incorporating breast density.

Table 7. The six population level trials of risk-based breast cancer screening included in the ROSA quality appraisal of international trials and discussed in relation to potential Australian implementation in Chapter 5.

Acronym and age range	Full name and trial reference*	Location	Trial period	Risk groups	Comparator	Intervention	
						Intervals	Screening tests
MyPeBS (40-70)	Randomized, Comparison of Risk-Stratified versus Standard Breast Cancer Screening in European Women Aged 40-70 (MyPEBS), NCT03672331	France, Italy, UK, Belgium and Israel	2019 - 2025	BCSC/T-C scores (4 groups)	Various (Annual/biennial/triennial screening, with mammography/DBT± supp US)	1-4 years	Supp US/ABUS, supp MRI
WISDOM (40-74)	Women Informed to Screen Depending on Measures of Risk (Wisdom Study) (WISDOM), NCT02620852	US (California)	2016 - 2020	BCSC (4 groups)	Annual mammography	1-2 years None <50y	Supp MRI
TBST (45-50)	Tailored Screening for Breast Cancer in Premenopausal Women (TBST), NCT02619123	Italy	2013 - 2022	BI-RADS 1/2 vs 3/4	Annual mammography	1-2 years	No
DENSE (50-75)	Breast Cancer Screening with MRI in Women Aged 50-75 Years with Extremely Dense Breast Tissue: the DENSE Trial (DENSE), NCT01315015	Netherlands	2011 - 2019	Extremely dense (Volpara D)	Biennial mammography	No change	Supp MRI
BRAID (50-70)	Breast Screening – Risk Adaptive Imaging for Density (BRAID), NCT04097366	UK	2019 - 2026	BI-RADS C/D	Triennial mammography	18 months	Abbreviated MRI, ABUS, CEM
MISS (45-49 and 70-74)	What is the Best Interval to Screen Women 45-49 and 70-74 for Breast Cancer? (MISS), NCT04590560	Italy	2020 - 2026	BI-RADS A-C versus D.	Uncertain (most likely annual tomosynthesis)	2 years for BI-RADS A-C	N/A

.*Trial protocols are described at https://clinicaltrials.gov/ct2/show/[NCT#, using the NCT trial numbers shown.

2.7.5 Health inequalities

A principle of the project, as agreed by all key stakeholders, is that any resulting reform must not lead to further inequities, for example by phasing in improved technologies and enhanced approaches to risk-based screening, which are accessed only by high socioeconomic status groups. This could have the dual impact of widening disparities, through inequitable access to new services and result in a diversion of resources to support those services away from interventions with potential to provide improved access for Indigenous and other disadvantaged women to appropriate interventions already supported by the evidence.

Indigenous women in Australia have poorer breast cancer outcomes than non-Indigenous women and, on current evidence, poorer overall access to services across the spectrum. Barriers to more equitable outcomes are complex and multifaceted. During the scoping phase of the ROSA project, an expert in Indigenous cancer control, Professor Jacinta Elston, was appointed to the Expert Management Group to help ensure the project included a focus on inequities faced by Indigenous women, and the manager of BreastScreen in the Northern Territory, Ms Kim Coulter, was also specifically invited on to the Expert Management Group to focus on inequities, given the high proportion of Indigenous women in the NT and the challenges of a dispersed and remote population. The summary report from the scoping phase advised that, while the technical focus on potential enhancements to risk-based breast screening would remain central to the work of the ROSA project, it was critical to continue monitoring progress on access to established services for Indigenous and other disadvantaged women and to consider further funding for parallel work in this area.

2.8 References

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5. Munn, Z., Peters, M.D.J., Stern, C. et al. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. BMC Med Res Methodol 18, 143 (2018). https://doi.org/10.1186/s12874-018-0611-x
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2.9 Appendices

2.9.1 ROSA project reports

Reports previously provided by the project to the Australian Government Department of Health and Aged Care (formerly the Department of Health) are shown below.

1. Nickson C, Campbell D, Carle C, Deij S, Egger S, Freeman V, Grogan P, Hughes S, Luo Q, Mann GB, O'Connell D, Petelin L, Procopio P, Smith A, Tattam A, Taylor N, Tiernan G, Vardon P, Varlow M, Velentzis L, Yuill S, Canfell K. for Cancer Council Australia. Roadmap to Optimising Screening in Australia: Draft Final Report. Report to Australian Government Department of Health. September 2021 (431 pages)
2. Nickson C, Grogan P, Tattam A. Optimising Early Detection of Breast Cancer in Australia Interim Report: COVID-19. Report to Australian Government Department of Health, 9 November 2020 (22 pages)
3. Nickson C, Procopio P, Deij S, Velentzis L. COVID-19 scenario modelling for cancer screening programs: The BreastScreen Australia Program. Report to Australian Government Department of Health. May 2020 (23 pages).
4. Nickson C. Hughes S, Campbell D, Freeman V, Carle C, Velentzis L, Procopio P, Deij S, Grogan P. Canfell K. for Cancer Council Australia. Optimising Early Detection of Breast Cancer in Australia: Phase II Interim Report. Report to Australian Government Department of Health. May 2020 (276 pages)
5. Nickson C. Morgan A, Hughes S, Freeman V, Carle C, Velentzis L. Grogan P. Canfell K. for Cancer Council Australia. Summaries of Evidence: Australian screening outcomes by risk groups; Risk assessment; Mammographic breast density and screening outcomes; Overdiagnosis by risk group; Alternative screening modalities by risk group; Costs, benefits and harms of risk-based breast cancer screening: modelling studies; Potentially valuable data reports. Optimising Early Detection of Breast Cancer in Australia. Report to Australian Government Department of Health. August 2019 (220 pages)
6. Nickson C. Morgan A, Velentzis L. Grogan P. Canfell K. for Cancer Council Australia. Environmental Scan - Clinical Services. Report to Australian Government Department of Health. Optimising Early Detection of Breast Cancer in Australia. August 2019 (130 pages)
7. Nickson C. Morgan A, Grogan P. Canfell K. for Cancer Council Australia. Stakeholder Report. Optimising Early Detection of Breast Cancer in Australia. Report to Australian Government Department of Health. November 2019 (111 pages)
8. Nickson C. Grogan P. Canfell K. for Cancer Council Australia Cancer Council Australia's roadmap to evaluate, and potentially implement, more risk-based, personalised approaches to breast cancer detection and screening. Optimising Early Detection of Breast Cancer in Australia. Report to Australian Government Department of Health. August 2019 (3 pages)

2.9.2 ROSA communications and stakeholder engagement

Stakeholder engagement over the course of the ROSA project has been comprehensive, extensive and varied, tailored for diverse audiences and an evolving project brief. It should be noted, however, that the project was not designed for public consultation but rather an independent review and analysis of the evidence, to inform steps towards wider consultation and community engagement.

While COVID-19 disrupted the workplan, as it did to many non-pandemic related public health research activities at times, there was nonetheless a steady flow of information and engagement with key stakeholder groups and individuals as research and environmental scans were conducted and project materials drafted.

Stakeholder input and interactions also varied, from the official project management and advisory roles of the project's expert management and advisory groups, interface with state and territory BreastScreen advisory groups through to invited feedback from co-opted experts. The project's communications and stakeholder engagement strategy, set out in project governance at the commencement of the work and refined as the project progressed, is summarised as follows.

As agreed with the project funder, the project recommendations and Roadmap will form the basis for fact sheets and consensus statements, subject to DHAC approval. Meanwhile, the project has produced a range of publications and undertaken public-facing dissemination of project information as summarised below.

Project publications

Project personnel have led or contributed to various papers related to the project as shown below. Various additional publications are under development.

1. Velentzis LS, Freeman V, Campbell D, Hughes S, Luo Q, Steinberg J, Egger S, Mann GB, Nickson C. Breast Cancer Risk Assessment Tools for Stratifying Women into Risk Groups: A Systematic Review. Cancers (Basel). 2023 Feb 9;15(4):1124.
2. Bulliard JL, Beau AB, Njor S, Wu WY, Procopio P, Nickson C, Lynge E. Breast cancer screening and overdiagnosis. Int J Cancer. 2021 Apr 19. Epub ahead of print. PMID: 33872390.
3. Feletto E, Grogan P, Nickson C, Smith M, Canfell K. How has COVID-19 impacted cancer screening? Adaptation of services and the future outlook in Australia. Public Health Res Pract. 2020 Dec 9;30(4):3042026.
4. Saxby K, Nickson C, Mann GB, Park A, Bromley H, Velentzis L, Procopio P, Canfell K, Petrie D. Moving beyond the stage: how characteristics at diagnosis dictate treatment and treatment-related quality of life year losses for women with early stage invasive breast cancer. Expert Rev Pharmacoecon Outcomes Res. 2021 Aug;21(4):847-857. Epub 2021 Jan 27.
5. Saxby K, Nickson C, Mann GB, Velentzis L, Bromley HL, Procopio P, Canfell K, Petrie D. The financial impact of a breast cancer detected within and outside of screening: lessons from the Australian Lifepool cohort. Aust N Z J Public Health. 2020 Jun;44(3):219-226. Epub 2020 Apr 20.
6. Lew JB, Feletto E, Wade S, Caruana M, Kang YJ, Nickson C, Simms KT, Procopio P, Taylor N, Worthington J, Smith D, Canfell K. Benefits, harms and cost-effectiveness of cancer screening in Australia: an overview of modelling estimates. Public Health Res Pract. 2019 Jul 31;29(2):29121913.
7. 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

Seminars and presentations

Presentations as at December 2022 are summarised in Table 8, noting a shift to online forums with the onset of the COVID pandemic.

Table 8. Overview of ROSA seminars and presentations.

Topic/paper	Presenter/s	Forum	Date
The estimated impact of targeted breast screening tests with improved test sensitivity for women with dense breasts	Dr Pietro Procopio	Why Study Mammographic Breast Density online conference,	12-15 October 2020
Rosa Breast Overview	A/Prof Carolyn Nickson	BreastScreen Australia research webinar	5 November 2020
The ROSA project—options for risk-based breast cancer screening	A/Prof Carolyn Nickson	University of Melbourne Centre for Cancer Research	16 June 2021
Summary of ROSA project	A/Prof Carolyn Nickson and Amanda Tattam	BreastScreen Victoria meeting – 50 participants,	28 August 2021
Overview of Risk based screening	A/Prof Carolyn Nickson and Dr Pietro Procopio	Victorian Comprehensive Cancer Centre *grand rounds*	25 August 2021
Can mammographic density add value to the Gail model in risk-stratifying women in BreastScreen Australia?	Dr Pietro Procopio, A/Pr of Carolyn Nickson	World Conference of Epidemiology	5 September 2021
Oral presentation: “Population-based genetic testing in Australia: A cost-effectiveness analysis”	Lara Petelin, Michelle Cunich, Pietro Procopio, Carolyn Nickson, Paul A James, Ian Campbell, Alison H Trainer	kConFab Familial Aspects of Cancer,	30 Aug – 3 Sept 2021 (virtual)
The estimated impact of targeted breast screening test with improved sensitivity for women with dense breasts	Procopio P, Velentzis L, Diej S, Nickson C	World Conference of Epidemiology oral presentation	Sept 2021
The estimated impact of COVID-19 on Australia's BreastScreen Program	Procopio P, Velentzis L, Diej S, Nickson C,	University of Sydney, Cancer conference	10 Sept 2021
ROSA Roadmap to Optimising Screening in Australia (Breast Cancer)	C Nickson	Canadian Breast Cancer Screening Network	27 October 2022
Risk adjusted screening: Considerations and lessons from COVID-19	C Nickson (invited Speaker)	Australasian International Breast Congress (AIBC)	14 October 2022

In addition, on 22 February 2022 the project helped to convene a forum on risk-based breast screening, jointed hosted by the Daffodil Centre and the Victorian Comprehensive Cancer Centre. The program aimed to provide technical updates about ROSA project activities, updates from other Australian research on risk-based breast screening, and an opportunity for networking and discussion. Professor Gareth Evans, a leading risk-based screening clinical researcher from the UK, was a guest speaker at the forum. The program is shown in Table 9.

Table 9. The program for the February 2023 risk-based breast screening forum

Session & Chair	**Topic**	**Speaker/*chair***
Arrival and registration 8:45 – 9:00		
Setting the scene Chair: Rita Butera 90 mins (1hr30) 9:00 – 10:30	Welcome and introduction	Bruce Mann
	Australian cancer policy development	Paul Grogan
	The ROSA Breast project	Carolyn Nickson
	Community perspectives (consumer surveys)	Jocelyn Lippey
	Community perspectives	BCNA representatives Leslie Gilham and Vicki Durston
	The UK experience	Gareth Evans
	Discussion	*Chair: Rita Butera*
Morning tea 10:30 – 10:50		
Risk assessment and advice Chair: Jocelyn Lippey 100 mins (1hr40) 10:50 – 12:30	Evaluating risk assessment tools for risk-based screening (ROSA)	Louiza Velentzis
	Genetic risks	Paul James
	Emerging risk assessment methods	John Hopper
	MD as a predictor of screening accuracy (ROSA)	Carolyn Nickson
	MD assessment and notification in BreastScreen Australia programs	Jennifer Stone and Nick Ormiston-Smith
	Web-based risk advice	Holly Keane
	Risk assessment and advice in primary care	Kelly Phillips
	Risk assessment to support prevention	Nehmat Houssami
	Discussion	*Chair: Jocelyn Lippey*
Grand round 12:30-1:30	Risk-based breast cancer screening: perspectives from the UK	Gareth Evans
Lunch 1:30-2:10		
Screening technologies and protocols Chair: Jill Evans 80 mins (1hr20) 2:10pm – 3:30pm	Population-level assessments of screening technologies (ROSA)	Carolyn Nickson
	Contrast imaging	Allison Rose
	AI to support the screening test	Helen Frazer
	Managing higher risk women	Alison Trainer
	Australian modelled estimates of risk-based screening scenarios (ROSA)	Pietro Procopio
	Discussion	*Chair: Jill Evans*
Afternoon tea 3:30 – 4:00pm		
Looking forward Chair: Bruce Mann 60 mins 4:00pm – 5:00pm	Australian cancer policy development	Paul Grogan
	International trials of risk-based screening (ROSA)	Carolyn Nickson
	Risk based breast screening activities in Canada	Jennifer Brooks
	Routine risk assessment and advice in BreastScreen (BRAVO)	Louiza Velentzis
	Discussion	*Chair: Bruce Mann*
Close 5:00pm		

Other dissemination of project activities

The project has also disseminated written content to a variety of audiences, as outlined in Table 10.

Table 10. Summary of ROSA content published 2021-22.

Stakeholder/ Channel	Date	Activity/content	Target audience
Cancer Nurses Society of Australia (content available to members only)	June 2021	Newsletter article	Cancer nurses
BreastScreen Victoria	July 2021	Online news story[8] + social media social media (LinkedIn and Facebook)	BreastScreen Victoria participants, stakeholders – general public (1413 views of online story at 13 July 2022)
Daffodil Centre (a joint venture between Cancer Council NSW and the University of Sydney)	July 2021	Blog and LinkedIn post	Researchers, cancer control stakeholders, policy makers
Oncology republic	August 2021	News story[9]	Medical oncologists
BreastScreen Queensland	Sept 2021	Newsletter content	BreastScreen Queensland personnel
Royal Australasian College of Radiolgists magazine 'Inside Radiology'	Sept 2021	Feature article[10]	Radiologists
BSA National Quality Management Committee update	September 2021	Newsletter content	BSA audience
Cancer Council Australia	October 2022	Blog article	General – consumer and professional. Cancer Control professionals
Australasian Society for Breast Disease	October 2021	Newsletter content[11]	ASBD membership includes broad range of health professionals
Breast Cancer Network Australia	April 2022	Newsletter content re online surveys	Health professional subscribers to BCNA communications
McGrath Foundation Australia	April 2022	News item re survey	McGrath nurses (note many work in roles outside the McGrath Foundation including in BSA and as breast care nurses).

[8] BreastScreen Victoria online news. 'ROSA - a Roadmap for individualised screening'. 15 July 2021

[9] Oncology Republic. 'Personal breast cancer screening'. August 2021
[10] Inside News, Royal Australian and New Zealand College of Radiologists magazine. 'On the Road to Personalised Breast Cancer Screening'. September 2021
[11] Australian Society for Breast Disease, 'Roadmap for Optimising Screening'. October 2021

An example of a published article is shown in Figure 5.

On the Road to Personalised Breast Cancer Screening

Dr Jill Evans

Associate Professor Michelle Reintals

Figure 5. A ROSA article published in Inside News, Quarterly magazine of the Royal Australian and New Zealand College of Radiologists, Vol 17: No 4, September 2021

Website

The Cancer Council Australia web pages (www.cancer.org.au/go/rosabreast) provide accessible, summary information about the ROSA project to the general public.

Stakeholder engagement

BreastScreen Australia

Since its inception, the ROSA project has engaged with BreastScreen Australia in various ways.

In the initial scoping phase (2018-19), the ROSA Project Coordinating Group appointed Ms Vicki Pridmore (CEO of BreastScreen Victoria and Chair of the BSAPMG as co-chair of the independent project advisory group). Following Ms Pridmore's retirement, this role was taken by Paul Vardon (Director, Cancer Screening Unit, Queensland Health and 2020-2021 BSAPMG Chair).

During the scoping period of this project, project staff consulted extensively with its 30-member Expert Management Group, jointly chaired by Ms Pridmore and Professor Bruce Mann. The project also provided brief updates to the BreastScreen Australia Program Management Group. The current Expert Advisory Group is jointly chaired by Mr Vardon and Professor Mann.

In October 2019 A/Prof Nickson presented to the BSAPMG a requested overview of the project activities and the proposed role for the BSAPMG in supporting or advising on those activities. Feedback was invited following this presentation; the project summarised this feedback and provided responses in a report provided to the BSAPMG on 17 Feb 2020 and also shared with the project sponsor.

In addition to providing project updates at each BSAPMG meeting, under the current phase the project has engaged with the BSAPMG in various ways, for example:

- In March 2020 the project held a half-day workshop with the BSAPMG on the population modelling activity. This is summarised in the 'Clinical and health economics modelling' activity report provided in this draft report.
- In April/May 2021 the project provided the BSAPMG with two protocols for ROSA activities for their input and review, and an interim modelling update report for feedback and input. The resulting feedback helped guide these activities, and led to the establishment of a dedicated ROSA BreastScreen Reference Group to guide work related to scoping potential translation of international trials to an Australian setting (Activity 2). The group provided input to the survey of health service personnel within and outside the BreastScreen program reported in Chapter 5.
- In June 2021 the BSAPMG held an extended meeting dedicated to the ROSA project, where the project technical lead A/Prof Nickson provided a general overview and update and responded to various queries about the project.
- In 2022, draft project recommendations were submitted to the ROSA BreastScreen Reference Group for feedback, and the recommendations were refined using this feedback. These recommendations were also reviewed by the project Expert Advisory Group and co-opted expert panel, which include various BreastScreen Australia personnel.

Other stakeholders

Despite COVID-19 restrictions and subsequent changes to ways of working, the project has continued to communicate and engage with stakeholders by:

- successfully engaging with stakeholders in small virtual meetings
- sharing project development at online events and seminars
- publishing stories about the project to key stakeholders in industry publications
- publishing peer-reviewed papers; and
- building on existing communications to create accessible website content and updates on the project.

There are a large number and wide range of stakeholders involved in the early detection of breast cancer in Australia, each with specific interests, information requirements and prior knowledge.

The ROSA project has used a staged framework for communications about consideration of risk-based breast screening, tailored to stakeholder roles in relation to the activities:

- Awareness raising – starting point – unaware or knows little and needs to know 'what', 'who,' 'where,' 'why'? For example, the project has engaged with Breast Cancer

Network Australia (BCNA), through regular meetings with its coordinating staff. The BCNA is now actively engaged with the project, promoting the project and its activities through its own communication channels.

- Passive engagement – taking an interest and prepared to attend online seminar or another event. For example, over 100 participants have attended webinars featuring ROSA personnel and this has paved the way for more active engagement.
- Active engagement – actively supportive, sharing information, taking part in interviews, surveys or supplying other input more than once (e.g., Program managers group, BreastScreen Reference Group). For example, the Royal Australian and New Zealand College of Radiologists and the Australian Society of Breast Disease published articles about the project in their September 2021 editions. Additionally, some BreastScreen jurisdictions have published content about ROSA to all staff, and A/Prof Nickson provided an invited overview about the project to a group of 40 BreastScreen Victoria client-facing personnel.
- Taking action – become a champion, join a panel, support an evaluation or trial. The project has engaged numerous stakeholders as members of its advisory groups, with members providing substantial productive feedback throughout the project.

The disruption created by COVID-19 altered stakeholder engagement for this project. In place of longer face-to-face forums which were highly effective in the earlier project stages (the project hosted several all-day national meetings), since the COVID pandemic meetings have by necessity been shorter and conducted online, with fewer opportunities for incidental information sharing. To ensure that stakeholders have opportunity to respond to information presented at meetings, it is now part of routine practice to accommodate email or telephone feedback and information sharing. This was greatly assisted by the appointment of a dedicated stakeholder engagement and communications staff member over 2020-2022.

Stakeholder engagement insights

Stakeholder engagement continues to be a critical part of considering risk-based breast screening in Australia. Stakeholder engagement over the course of the ROSA project has changed considerably, driven by a shift towards more open communication, restrictions and competing demands imposed by the COVID pandemic, and the engagement of specialist personnel from 2020.

Ongoing engagement across BreastScreen services and with personnel from a range of BreastScreen roles and jurisdictions is essential to inform and support any implementation to risk-based breast cancer screening in Australia. Our earlier surveys of stakeholder groups and ongoing online engagement through the COVID pandemic confirm that Australian stakeholder groups prefer face-to-face engagement, and this should be a priority in the future.

Priority areas for stakeholder engagement are managing the risk of misinformation and improving the coordination of multiple scientific disciplines involved in optimal early detection of breast cancer. In particular, any changes to breast screening intervals (longer or shorter intervals) would require a consistent and balanced communication strategy for consumers and health services personnel.

2.9.3 Contracted activities and chapters in the current report

Table 11. Contracted activities (2020-2022) and their corresponding chapters in the current report.

Contracted activity	1. Current health services	2. Risk assessment	3. Risk-based screening protocols	4. Implementation
1. Summaries of evidence				
a) 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.	✓	✓	✓	
b) Extend two topics to systematic reviews, namely (1) risk assessment tools and (ii) mammographic density assessment tools.		✓	✓	
c) Expert Advisory Group to review protocols and findings.	✓	✓	✓	
2. Review and evaluation of population-level trials				
a) Summarise population trials of risk-based population breast cancer screening and critically compile interim and final results.				✓
b) Scope from an implementation science perspective current international risk-based breast cancer screening trials in terms of potential translation to the Australian setting.				✓
c) Expert Advisory Group to review protocols and findings, and provide information about relevant health services (including BreastScreen Australia Services) to support the evaluation of how findings from current trials would translate to the Australian setting				✓
3. Clinical and health economics modelling				
a) Select feasible and promising risk-based screening protocols for review.			✓	
b) Include work on improved precision of tumour subtypes and expected treatment costs, burden and prognosis.			✓	
c) Collect and assemble clinical and health economic data.			✓	
d) Model selected screening protocols.			✓	
e) Report generated estimates of the benefits, harms and costs of various screening protocols.			✓	
f) Expert Advisory Group to advise on which risk-based screening protocols to evaluate through clinical and health economics modelling.			✓	
g) Expert Advisory Group to provide model input data where feasible/possible.			✓	
h) Expert Advisory Group to review and discuss modelled costs, benefits and harms of various screening protocols.			✓	

Contracted activity	1. Current health services	2. Risk assessment	3. Risk-based screening protocols	4. Implementation
4. Analysis of current risk-based screening				
a) Collect updated information on BreastScreen jurisdiction-level risk-based screening practices and policies.	✓			
b) Collect and review peer-reviewed and grey literature about the performance of current jurisdiction-level risk-based screening practices.	✓			
c) Expert Advisory Group to provide advice on data sources.	✓			
d) Expert Advisory Group to share data and information to support analyses, as feasible.	✓			
e) Expert Advisory Group to review design and findings of any data analyses.	✓			
5. Epidemiological comparison of current and feasible BreastScreen risk assessments on the lifepool cohort.				
a) Undertake an epidemiological comparison of current and feasible BreastScreen risk assessments on the lifepool cohort.		✓		
b) Expert Advisory Group to review protocols and findings.		✓		
6. BreastScreen risk-related data project (in collaboration with the AIHW).				
a) Undertake enhanced data collection and reporting:				
a. Develop a protocol for BreastScreen jurisdictions to routinely report policies and practices related to risk assessment and risk-based management and advice to the AIHW. The Cancer Council Australia and AIHW will both provide input, assistance and advice to this project element.	See separate report			
b. Develop a protocol for the AIHW to routinely collect and report enhanced BreastScreen outcomes by risk group. The Cancer Council Australia and AIHW will both provide input assistance and advice to this project element.				
c. Assemble BreastScreen jurisdiction-level policies and practices related to risk assessment and risk-based management and advice into an unpublished report. The Cancer Council Australia will provide input, assistance and advice to this project element; collection and reporting of data will be undertaken by the AIHW.				
b) Focus on annual screening				
a. Analyse lifepool cohort data, generating example tables and outputs to guide selection of scaled-up analyses from nationally collected data held by the AIHW. The Cancer Council Australia will lead this project element, with the AIHW providing input, assistance and advice.	✓			
b. Using results from the lifepool cohort data analysis, devise an analysis plan for annual screening from nationally collected data held by the AIHW. The Cancer Council Australia and AIHW will both provide input, assistance and advice to this project element.	✓			

Contracted activity	**1. Current health services**	**2. Risk assessment**	**3. Risk-based screening protocols**	**4. Implementation**
c. Conduct agreed analyses, as feasible within the time and resources available. The Cancer Council Australia will support data analysis and reporting, dependent on data governance and access arrangements as determined after project commencement. The AIHW will implement and/or support data analysis and reporting, dependent on data governance and access arrangements as determined after project commencement.	✓			
c) Linked data analyses:				
a. Design additional analyses on the AIHW linked dataset to further investigate screening behaviour for screening women. The Cancer Council Australia and AIHW will both provide input assistance and advice to this project element.	✓			
b. Conduct agreed analyses, as feasible within the time and resources available. The Cancer Council Australia will support data analysis and reporting, dependent on data governance and access arrangements as determined after project commencement. The AIHW will implement and/or support data analysis and reporting, dependent on data governance and access arrangements as determined after project commencement.	✓			
d) Produce a combined Cancer Council/AIHW report for the Australian Department of Health and Aged Care:				
a. Jointly prepare a combined Cancer Council/AIHW report for the Australian Department of Health and Aged Care, including:	See separate report			
i. A protocol for routine centralised collection and reporting on BreastScreen jurisdiction-level practices related to risk assessment and risk-based management and advice, and an unpublished report of that information.				
ii. A protocol for AIHW to routinely collect and report enhanced BreastScreen outcomes by risk group.				
iii. An assessment of current annual BreastScreen screening, and recommendations for further analyses.^	✓			
iv. A report of additional analyses of linked AIHW data, and recommendations for further analyses. ^	✓			
e) Expert Advisory Group to review protocols and findings.	✓			
f) Expert Advisory Group to provide feedback on priority analyses of AIHW linked data	✓			
7. Publication of updated summary information as appropriate				
Pending approval from the Expert Advisory Group and the Australian Department of Health and Aged Care, the Project would publish updated information (fact sheets, consensus statements) for consumers, health professionals and policy makers.	Described in Section 2.9.2.			
8. Updated roadmap				
Project deliverables outlined above would be developed and presented against key indicators on the optimising early detection of breast cancer roadmap; the roadmap	See Chapter 1			

Contracted activity	1. Current health services	2. Risk assessment	3. Risk-based screening protocols	4. Implementation
would be updated based on evidence submitted as part of Phase Two of the Optimising Early Detection of Breast Cancer in Australia project. The roadmap would include recommendations for scaled-up activity and a longer-term plan.				
9. Interim Report				
a) Prepare an Interim Report focused on project elements that can help provide guidance about optimal screening response and recovery related to the COVID-19 pandemic.	See separate report			
b) Expert Advisory Group to provide feedback to the Interim Report				
10. Draft Report				
Produce a draft report on all activities undertaken for Phase Two of the Optimising Early Detection of Breast Cancer in Australia.	✓			
11. Final report.				
Produce a final report on all activities undertaken for Phase Two of the Optimising Early Detection of Breast Cancer in Australia.	✓			

Table footnote: Provided directly by the ROSA project due to terms of data access and analysis.

2.9.4 Governance and advisory group membership

Project Coordinating Group

Membership of the Project Coordinating Group is shown in Table 12. The project also acknowledges the significant contribution by Vicki Pridmore over 2018-2019 in her roles as joint chair of the Expert Management Group and member of the Project Coordinating Group.

Table 12. ROSA Project Coordination Group membership.

Member	Affiliation/s
Professor Bruce Mann	Professor of Surgery, University of Melbourne Director of Breast Services at Royal Women's and Royal Melbourne Hospitals
Mr Paul Vardon	Director Cancer Screening Unit, Queensland Heath Chair, BreastScreen Australia Program Management Group.
A/Prof Carolyn Nickson	Stream Lead, Breast Cancer Policy and Evaluation, Daffodil Centre, University of Sydney Associate Professor, University of Melbourne Adjunct Associate Professor, University of Sydney
Professor Karen Canfell	Director, The Daffodil Centre, Professor & NHMRC Leadership Fellow, Faculty of Medicine and Health, The University of Sydney
Ms Megan Varlow	Director, Cancer Control Policy, Cancer Council Australia,
Mr Paul Grogan	Senior Strategic Adviser, Pathways The Daffodil Centre,
Ms Amanda Tattam	Project Coordinator – communications and stakeholder engagement (to September 2022)

Expert Advisory Group (2020-2022)

ROSA Expert Advisory Group membership as at December 2022 is shown in Table 13Table 16. The group is jointly chaired by Prof Bruce Mann and Mr Paul Vardon. Ms Terri Smith (CEO BreastScreen Victoria 2021-2022) was a member until she resigned from her BSV position in April 2022 with advice that her role did not need to be filled by the new BSV CEO for the remaining period of the project.

Table 13. ROSA Expert Advisory Group membership (December 2022)

Member	Affiliation/s
Prof Bruce Mann (Chair)	Professor of Surgery, University of Melbourne Director of Breast Tumour Stream, Victoria Comprehensive Cancer Centre
Mr Paul Vardon (Chair)	Director Cancer Screening Unit, Queensland Heath Chair, BreastScreen Australia Program Management Group
Ms Alison Lang	Acting Director, Screening Policy Section, Cancer Policy and Services Branch, Australian Government Department of Health and Aged Care
Ms Harj Bariana	Director Clinical Services and BreastScreen Operations, Westmead Breast Cancer Institute, BreastScreen NSW Sydney West Service
Dr Jill Evans	Clinical Director and Chief Radiologist, Monash BreastScreen
Ms Anny Friis	Consumer Representative, Cancer Voices Australia (until June 2022)
Ms Leslie Gilham	Consumer Representative, Breast Cancer Network of Australia
Dr Mandy Henningham	First Nations Fellow, Cancer Council Australia and Postdoctoral Research Fellow in Indigenous Social Sciences, University of Sydney.
Ms Sarah McGill	Director – Screening and Prevention, Cancer Institute NSW
Associate Professor Vivienne Milch	Director Cancer Care, Cancer Australia Medical Advisor to the Department of Health and Aged Care on cancer screening policy
Associate Professor Michelle Reintals	Head of RANZCR Breast Imaging Group, Clinical Director, BreastScreen South Australia.
Prof David Roder	Chair, Cancer Epidemiology and Population Health, School of Health Sciences, University of South Australia Principal Research Fellow, SA Health and Medical Research Institute
Prof Christobel Saunders	James Stewart Chair of Surgery Royal Melbourne Hospital University Department of Surgery | School of Medicine

Expert Management Group (2018-2019)

ROSA Expert Management Group membership as at September 2019 is shown in Table 14. This group was replaced by the smaller Expert Advisory Group and co-opted expert panel from 2020.

Table 14. ROSA Expert Management Group membership as reported in September 2019.

Member	Affiliation/s
Bronwyn Adams	Acting Director, Screening Policy Section (in place of Caroline Arthur), Cancer Policy and Services Branch, Department of Health
Prof Patrick Brennan	Faculty of Health Sciences, University of Sydney, Co-Director BreastScreen Reader Assessment Strategy, MIOPeG Researcher
Dr Alison Budd	Screening Analysis and Monitoring Unit, AIHW
Dr David Clouston	Anatomical Pathologist, Tissupath Melbourne
Ms Kim Coulter	Manager of Cancer Screening Services, BreastScreen NT
Prof Jacinta Elston	Pro-Vice Chancellor (Indigenous), Monash University
Prof Jon Emery	Professor of Primary Care Cancer Research, Uni Melbourne and Director, Cancer Australia Primary Care Collaborative Cancer Clinical Trials Group (PC4)
Dr Jill Evans	Clinical Director, BreastScreen VIC and Clinical Director and Chief Radiologist, Monash BreastScreen
Dr Susan Fraser	Chair, Breast Group, COSA. Australasian Society of Breast Physicians
A/Prof Helen Frazer	Clinical Director, BreastScreen St Vincent's Hospital, Breast Imaging Reference Group, RANZCR
Ms Anny Friis	Consumer Representative, Cancer Voices Australia
Ms Leslie Gilham	Consumer Representative, BCNA
Prof Nehmat Houssami	Professor of Public Health, NBCF Breast Cancer Research Leadership Fellow Sydney School of Public Health | Faculty of Medicine and Health
Dr Gemma Jacklyn	Senior Consultant, Quantium and Academic Fellow, Epidemiology, School of Public Health, University of Sydney (on long term leave)
A/Prof Paul James	University of Melbourne and Sir Peter MacCallum Department of Oncology
A/Prof Louise Keogh	Associate Professor Health Sociology, Centre for Health Equity, Melbourne School of Population and Global Health. Uni Melbourne
Prof Bruce Mann	Co-Chair of EMG, Professor Surgery, Uni Melbourne Director of Breast Tumour Stream, Victoria Comprehensive Cancer Centre
Ms Sarah McGill	Director – Screening and Prevention, Cancer Institute NSW
Ms Vicki Pridmore	Co-Chair of EMG, CEO BreastScreen VIC
Prof Nicole Rankin	Senior Research Fellow – Lung Cancer, Cancer Council NSW Senior Lecturer, Implementation Science, Sydney Health Partners, University of Sydney
Prof Mary Rickard	Consultant radiologist to BreastScreen NSW. Adjunct Professor, Discipline of Medical Radiation Sciences, Faculty of Health Sciences, University of Sydney
Prof David Roder	Chair Cancer Epidemiology and Population health, School of health Sciences, University of South Australia, Senior Research fellow SA Health and Medical Research Institute
Prof Christobel Saunders	Consultant Surgeon, Royal Perth Hospital and St John of God Hospital Head of Surgery/Professor of Surgical Oncology, UWA Medical School

Member	Affiliation/s
Dr Jennifer Stone	Centre for Genetic Origins of Health and Disease, and School of Biomedical Sciences, University of Western Australia, Honorary Appointment, Centre for Epidemiology and Biostatistics, The University of Melbourne
Mr Dylan Sutton	Data Manager, BreastScreen Tasmania
Prof Rik Thompson	Professor of Breast Cancer Research, School of Biomedical Sciences, QUT, COSA, Honorary Professor, Department of Surgery, University of Melbourne, Adjunct Group Leader, Invasion and Metastasis Unit, St Vincent's Institute of Medical Research
Dr Haitham Tuffaha	Senior Research Fellow Health Economics, NHMRC Early Career Fellow, Chair - COSA Epidemiology Group, Centre for Applied Health Economics, School of Medicine, Griffith University, Menzies Health Institute Queensland
Mr Paul Vardon	Director Cancer Screening Unit, Queensland Heath BreastScreen Australia Program Management Group, BreastScreen Queensland

Co-opted Panel of Experts

The ROSA co-opted expert panel as at December 2022 is shown in Table 15.

Table 15. ROSA Expert Management Group membership as reported in September 2019.

Member	Affiliation/s
Prof. Patrick Brennan	Faculty of Health Sciences, University of Sydney, Co-Director BreastScreen Reader Assessment Strategy, MIOPeG Researcher.
Dr David Clouston	Anatomical Pathologist, Tissupath Melbourne.
Prof. Jon Emery	Professor of Primary Care Cancer Research, Uni Melbourne and Director, Cancer Australia Primary Care Collaborative Cancer Clinical Trials Group (PC4)
Dr Susan Frazer	Chair, Breast Group, Clinical Oncology Society of Australia, Australasian Society of Breast Physicians.
A/ Prof Haitham Tuffaha	Health Technology Assessment Leader NHMRC Research Fellow, Centre for the Business and Economics of Health, UQ.
Prof. Nehmat Houssami	Professor of Public Health, NBCF Breast Cancer Research Leadership Fellow, Sydney School of Public Health | Faculty of Medicine and Health.
Prof. Louise Keogh	Associate Professor Health Sociology, Centre for Health Equity, Melbourne School of Population and Global Health, The University of Melbourne.
Prof. John Hopper	NHMRC senior principal research fellow, Director (Research) of the Centre for Epidemiology and Biostatistics, The University of Melbourne School of Population and Global Health.
Dr Darren Lockie	Clinical Director, Maroondah BreastScreen Reading and Assessment Service.
A/Prof Nicole Rankin	A/Prof In Evaluation & Implementation Science, School of Population and Global Health, University of Melbourne
A/Prof Jennifer Stone	Centre for Genetic Origins of Health and Disease, and School of Biomedical Sciences, University of Western Australia, Honorary Appointment, Centre for Epidemiology and Biostatistics, The University of Melbourne.
Dylan Sutton	Data Manager, BreastScreen Tasmania. (also acting Program Manager, BreastScreen Tasmania until December 2022)
Prof. Rik Thompson	Professor of Breast Cancer Research, School of Biomedical Sciences, QUT, COSA, Adjunct Group Leader, Invasion and Metastasis Unit, St Vincent's Institute of Medical Research.
A/Prof Alison Trainer	Consultant Clinical Geneticist, Peter Macallum Cancer Centre.

BreastScreen Reference Groups

ROSA BreastScreen Reference Group membership as at December 2022 is shown in Table 16. Additionally, Doris Whitmore (Director of Client Services, BSV) was a member until she resigned from her BSV position in May 2022.

Table 16. ROSA BreastScreen Reference Group membership, 2022.

Member	Affiliation/s
Niamh Wade	Program Manager, BSSA
Dr Liz Wylie	Program Manager, BSWA
Dr Zoe McInally	Breast Physician, BSQ
Gail Ward	Program Manager, BSTAS (on secondment for 2022)
Mr Dylan Sutton	Information Systems and Data Manager, BreastScreen Tasmania, and acting Program Manager, BSTAS
Dr Darren Lockie	Clinical Director, Maroondah BreastScreen Reading and Assessment Service, BSV
Harj Bariana	Director Clinical Services and BreastScreen Operations, Westmead Breast Cancer Institute / Sydney West Service, BSNSW
Dr Jill Evans	Clinical Director and Chief Radiologist, Monash BreastScreen, BSV
Assoc. Prof Michelle Reintals	Clinical Director, BSSA

2.9.5 Project personnel

The following personnel have contributed directly to the ROSA project technical activities under the technical leadership of A/Prof Carolyn Nickson (in alphabetical order):

- Dr Denise Campbell – Systematic Reviewer
- Chelsea Carle – Systematic Reviewer
- Dr Jennifer Cauchi – Research support and document review
- Dr Sabine Deij – Economist/Analyst
- Sam Egger – Statistician
- Victoria Freeman – Systematic Reviewer
- Suzanne Hughes – Systematic Reviewer
- Dr Saima Islam – Statistician
- Dr Qingwei Luo – Statistician
- Prof Dianne O'Connell – Statistician and Epidemiologist
- Dr Lara Petelin - Modeller
- Dr Pietro Procopio – Modeller/Analyst
- Dr Andrea Smith - Implementation Research and Evaluation
- Elijah Tyeders – Research Assistant
- Dr Andrea Smith – Implementation Scientist
- Dr Julia Steinberg – Statistician and Epidemiologist
- Amanda Tattam – Communications and stakeholder engagement
- A/Prof Natalie Taylor – Implementation Research and Evaluation
- Gabrielle Tiernan – Research Assistant
- Paige Todd – Project Support (Cancer Council Australia)
- Mr Elijah Tyedmers – Research Assistant
- Dr Louiza Velentzis – Epidemiologist
- Ms Emily Websdale – Project Support
- Dr Susan Yuill – Systematic Reviewer

The project also acknowledges regular contributions from Project Coordinating Group members and a significant contribution in the first phase of this project by Dr Adelaide Morgan from Cancer Council Australia, from which many elements of the current project have evolved.

2.9.6 List of key findings

The key findings from each technical chapter are shown below. Refer to the chapters for detailed reports supporting these findings. These findings were reviewed by the ROSA project Expert Advisory Group in May-July 2022.

Current health services (chapter 2)

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 self-reporting known high-risk genetic mutations at 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

Abridgement note: Detailed statements are withheld as the data analysed was not for public distribution. In summary, we described various epidemiological trends in breast cancer screening and diagnosis using analytic models that would enhance monitoring and evaluation of any introduction of risk-based breast screening in Australia.

[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.

Risk assessment (chapter 3)

Q1. Breast cancer risk tools (between tool comparisons). For asymptomatic women, how do different breast cancer risk assessment tools compare in their ability to predict breast cancer risk across the risk groups determined by each of the tools?

Key evidence

1. For breast screening populations, some risk assessment tools based on self-reported information usually including family history and prior breast biopsies can identify groups of women at higher or lower risk.

2a. The precision of breast cancer risk assessment tools depends on the population and setting.

2b. The precision of breast cancer risk assessment tools can be improved with calibration to the target population.

3. Mammographic breast density assessments have not been demonstrated in the reviewed external validation cohort studies to improve the accuracy of breast cancer risk assessment tools based on self-reported information usually including family history and prior breast biopsies.

4. Polygenic risk scores have not been demonstrated in external validation cohort studies to improve the accuracy of breast cancer risk assessment tools based on self-reported information usually including family history and prior breast biopsies.

Considerations for implementation

1. Breast cancer risk assessment tools are expected to improve over time due to advances in technologies, image analysis and incorporation of AI systems.

2. Breast cancer risk assessment incorporating genetic test results may have ethico-legal consequences for individual women. These consequences should be well-understood before any introduction of population-level risk assessment incorporating genetic testing, with any implementation being on an opt-in basis and supported by an informed decision-making process.

3. While the contribution of breast density assessment to breast cancer risk assessment tools was not demonstrated in this review, breast density remains an important tool for assessing risk of reduced sensitivity and specificity of mammographic screening tests.

4. Breast cancer risk assessment tools of equal accuracy that rely on limited or no self-reported information may be more reliable and easier to implement than more detailed questionnaire-based tools, once suitable information systems are established.

Priority evidence gaps

1. The accuracy of breast cancer risk assessment tools where input data is missing, compared to risk assessment with complete information.
2. The accuracy of breast density alone as a risk assessment tool, with an assessment of whether other risk factors improve the accuracy of risk assessment when added to breast density.
3. The accuracy of risk assessment tools for predicting breast cancer incidence according to prognostic indicators (e.g. tumour subtype, grade, size, nodal) and in situ breast cancer incidence.
4. Further information on the performance of breast cancer risk assessment tools in the Australian breast screening population, noting that risk assessment tools can perform differently in different settings and populations.

Q2. Breast cancer risk tools (within tool comparisons): For asymptomatic women, how does a given breast cancer risk assessment tool perform in predicting breast cancer risk across the risk groups determined by the tool?

Key evidence

1. In the Australian setting, the Gail risk assessment tool (version 2), which does not include breast density, can identify groups of BreastScreen Australia participants at higher or lower risk of breast cancer.

Q3. Simplified risk assessment using breast density: For BreastScreen participants, how does risk assessment using family history and breast density compare to risk assessment using family history alone?

Key evidence

1. For women aged 50-69 attending subsequent round screening, combinations of family history and breast density may be comparable to the BCRAT questionnaire-based risk assessment tool in terms of estimating risk of future invasive breast cancer, screen-detected invasive breast cancer or interval cancer.

Considerations for implementation

1. More simplified approaches to risk assessment should be included in consideration of options for risk-based breast screening in Australia, mindful of the resources and imposts involved in undertaking detailed risk assessment, and stakeholder interest in informing women about their breast density.

Priority evidence gap

1. Larger studies to validate the finding of our analysis.

Q4. Breast density as a risk tool (within tool comparisons): How accurately does a given mammographic density measurement tool stratify women according to their risk of a subsequent interval cancer and other screening outcomes?

Key evidence

1. Breast screening populations can be stratified into groups according to interval cancer rates, program sensitivity, and false positive rates [SOME DETAIL WITHHELD – PUBLICATION IN PROCESS]
2. For each breast density assessment tool assessed, the accuracy of this risk stratification varied between studies (which varied in terms of settings and screening program design).

3. For each breast density assessment tool assessed, interval cancer risk stratification is often accurate either for higher risk groups or lower risk groups, but rarely both.

4a. For population mammographic screening, while breast density does not universally improve breast cancer risk assessment tools, it is a critical risk factor for estimating expected program sensitivity, program specificity, interval cancer rates and false positive rates.

4b. Breast density assessment tools and other potential tools to identify groups of women according to BreastScreen Australia program sensitivity, program specificity, interval cancer rates and false positive rates are expected to improve over time due to advances in technologies, image analysis and incorporation of AI systems.

Q5. Breast density as a risk tool (between tool comparisons). How do different mammographic density measurement tools compare in their ability to stratify women according to their risk of a subsequent interval breast cancer and other screening outcomes?

Key evidence

1. There is some evidence that the performance of different breast density assessment tools in the same population is very similar.

Priority evidence gaps

1. Further evaluation of how different approaches to breast density as a risk tool compare on the same population, in an Australian screening setting.

Risk-based screening protocols (chapter 4)

Q1. How do alternative or supplemental breast imaging technologies/modalities perform for different breast cancer risk groups, compared to digital mammography?

Digital breast tomosynthesis

Key evidence

1a. For digital breast tomosynthesis (DBT) when used in a population screening setting, all reviewed studies [randomised controlled trials (RCTs), fully paired or cohort studies] assessed DBT used in conjunction with 2D imaging (as either digital mammography or a synthetic 2D image), rather than DBT alone, with outcomes compared to screening using digital mammography.

1b. Following from (1a):

a) These studies showed that DBT combined with 2D imaging increased cancer detection rates across all risk groups based on age.
b) Findings on interval cancer outcomes were mixed. DBT with 2D imaging may decrease interval cancer rates in women with higher breast density and increase interval cancer rates in women with lower breast density, but the evidence is not consistent.
c) Findings on screening program sensitivity are mixed, with some studies finding no differences and others finding increased program sensitivity for some age groups with inconsistent outcomes according to breast density.
d) Program specificity was increased similarly across risk groups based on age and breast density.
e) All outcomes vary markedly between populations and settings, particularly in terms of false positive recall rates.

Ultrasound (US)

Key evidence

2a. For supplemental US used in population breast screening, adding US to mammography (whether hand-held; HHUS or automated breast ultrasound; ABUS), compared to digital mammography alone can increase cancer detection rates and false positive rates for women with dense breasts and/or women at very high risk of breast cancer.

2b. For supplemental US used in population breast screening, adding US to mammography (whether hand-held; HHUS or automated breast ultrasound; ABUS) compared to digital mammography alone, the increases in cancer detection rates and false positive rates appeared consistently greater for women with denser breasts.

Magnetic Resonance imaging (MRI)

Key evidence

3a. For MRI compared to digital mammography in a population screening setting, all reviewed studies compared supplemental MRI for high-risk women, with outcomes compared to screening using digital mammography alone.

3b. Following from (3a), supplemental MRI increases cancer detection and false positive recall rates in high-risk women, compared to screening using digital mammography. The increase in cancer detection is lower for women who are mutation carriers compared to those who are negative or untested for any predisposing mutations and is possibly greater for younger women (40-49 years).

Contrast enhanced mammography

Key evidence

4. No studies of contrast-enhanced mammography (CEM) used in population breast screening were identified with risk-stratified results.

Considerations for implementation

1. Breast imaging technologies are rapidly evolving and expected to improve over time due to advances in technologies and incorporation of AI systems.

Priority evidence gaps

1. Evaluation of breast imaging technologies used in population screening in the Australian setting.

Q2. What are the relative benefits, harms and costs of risk-based breast cancer screening as estimated by population-level modelling studies relevant to the Australian health setting, and how would their clinical and health economics estimates translate to an Australian setting?

Key evidence

1. Published modelled evaluations of risk-based breast screening indicate that some risk-based scenarios may improve the balance of benefits, harms and cost-effectiveness compared to current approaches to population breast screening.
2. Assessing which modelled scenarios are optimal requires consensus about how to best balance benefits, harms and costs for different groups of women and in different health settings.

3. Clinical modelling components should include, at a minimum, current screening program protocols and participation rates as well as screening cancer detection rates, interval cancer rates and false positive rates.
4. Modelled estimates should include the benefits and harms for each risk group as well as the whole population.
5. Breast density is an important consideration for risk-based breast screening and should be incorporated into modelled evaluations.

What are the likely benefits, harms and costs of various risk-based population screening protocols in the Australian setting, compared to the current BreastScreen program?

Key evidence

1a. The ROSA modelled evaluation of risk-based screening (stratified to around 30% of women in a lower-risk group, 50% of women in an average risk group, and 20% of women in a higher risk group) indicates that risk-based screening could, in the first 10 years of implementation, reduce population level breast cancer mortality by up to 7%, saving up to 873 lives.

Following from (1a), this evaluation indicates that:

1b. Risk-based screening is expected to have a greater impact on mortality for the higher-risk group for scenarios where alternative screening technologies are used.

1c. Less frequent (triennial) screening of 30% of the population (women at lowest risk of breast cancer) may lead to small increases in breast cancer mortality in that risk group.

1d: Some outcomes, such as screen-detected cancers rates, could fluctuate markedly in the first 7-8 years of risk-based screening, while other outcomes, such as the stage of cancers at diagnosis, are expected to improve in the short-term and demonstrate sustained improvement over time.

1e. Estimated costs and cost-effectiveness of modelled scenarios indicate a cost-effectiveness frontier preferencing scenarios involving either (i) digital mammography for all women combined with targeted screening technologies for higher-risk women or (ii) screening technologies other than mammography for all screened women.

Following from (1a), this evaluation indicates that, depending on the scenario, risk-based screening could:

1f. Reduce interval cancer rates in the higher-risk group, with some scenarios leading to rates comparable to the current rates for the average-risk group.

1g. Decrease the proportion of large, nodal, grade 3 breast cancers at a population level by up to 25%.

1h. Increase the proportion of screen-detected cancers that are overdiagnosed by up to 50%, noting that overdiagnoses under the current program are estimated to be lowest in the higher-risk group, and some scenarios modelled would lead to this group having the highest rates of overdiagnosis.

1i. Reduce interval cancer rates in the higher-risk group, with some scenarios leading to rates comparable to the current rates for the average-risk group

1j. Reduce or increase DCIS diagnoses, recall rates, and ‘missed’ cancers.

1k. Reduce population-level treatment intensity in terms of extent of surgery (breast conserving vs mastectomy), chemotherapy and radiotherapy.

2a. The modelled evaluation of 156 scenarios identified a shortlist of 19 risk-based breast screening protocols which were most promising when compared to current practice in terms of reducing breast cancer deaths, finding more advanced breast cancers earlier when they have a better prognosis, and ensuring a balance of costs and impacts on quality of life at a population level.

2b. Following from 2(a), all shortlisted scenarios involve digital mammography for lower-risk and average-risk women, and a targeted screening technology for the higher-risk group.

2c. Following from 2©, 10 of the 19 shortlisted scenarios would be for the current target age range of 50-74 years, while three scenarios would target screening from age 45 and six scenarios from age 40.

2d. [FINDING WITHHELD DUE TO SENSITIVE CONTENT]

Considerations for implementation

1. The ROSA modelled evaluation indicates that some risk-based screening protocols are expected to improve the clinical effectiveness of population breast cancer screening for the Australian population.

2. Perspectives on potentially extending screening intervals for lower risk-women are highly varied between senior BreastScreen state and territory personnel.

3. Modelled estimates for life-years and quality-adjusted life-years incorporated the impacts of screening, diagnosis and treatment. This meant that some more intensive screening protocols that were expected to improve population-level life-years compared to the current screening program (through saving lives) could also reduce quality-adjusted life-years at a population level through factors such as increased population-level exposure to screening, increased overdiagnosis, and living longer with a breast cancer diagnosis.

Priority evidence gaps

1. Accurate estimates of the sensitivity and specificity of different screening technologies in the Australian screening setting, for different risk groups.

2. Modelled estimates of scenarios offering annual screening to the higher-risk group and biennial screening to the lower-risk and average-risk group, targetted use of digital breast tomosynthesis, and risk-based recruitment of women aged 40-49.

3. Modelled estimates of scenarios changing the eligibility of screening for women aged 75+

4. Modelled estimates of scenarios that incorporate risk assessment outside the program or repeated risk assessments.

5. Modelled estimates of outcomes for specific population groups (e.g. age groups, breast density groups, women who do or don’t attend screening).

Implementation (chapter 5)

Q1. Are Australian health services personnel working in screening and surveillance likely to support the introduction of risk-based breast screening, and do they think their organisations are ready?

Considerations for implementation

BreastScreen Australia

1. On average, BreastScreen personnel (representing a range of experience, roles and state/territory locations) consider BreastScreen to have good readiness for change to more risk-based screening in terms of leadership culture, staff culture, leadership, measurement (how well an organisation and its leadership motivates its aims and supports staff to understand what they should be doing and giving feedback on their performance within their role) and opinion leadership (the role influential people within the organisation play to influence the change processes), with some variation of views among respondents.
2. On average, BreastScreen personnel (representing a range of experience, roles and state/territory locations) have a wide range of attitudes towards adoption of new evidence-based guidelines, with greatest value placed on openness to new practices and the time and administrative burden with learning new evidence-based practices.
3. On average, in response to a range of scenarios involving risk-based breast screening, BreastScreen personnel (representing a range of experience, roles and state/territory locations) indicated a good likelihood of adopting specific risk-based screening guidelines, with mixed views on whether they should have a say in how guidelines should be put into practice.

Other health services

1. On average, health services personnel outside BreastScreen (representing a range of experience, roles and state/territory locations) have mixed views about whether their organisations are ready for change to more risk-based screening in terms of leadership culture, staff culture, leadership, measurement (how well an organisation and its leadership motivates its aims and supports staff to understand what they should be doing and giving feedback on their performance within their role) and opinion leadership (the role influential people within the organisation play to influence the change processes).
2. On average, health services personnel outside BreastScreen (representing a range of experience, roles and state/territory locations) have a wide range of attitudes towards adoption of new evidence-based guidelines, with greatest value placed on openness to new practices, feedback, monitoring and the time and administrative burden with learning new evidence-based practices.
3. On average, health services personnel outside BreastScreen (representing a range of experience, roles and state/territory locations) had mixed views about the likelihood of adopting specific risk-based screening guidelines, with greater value placed on the appeal (if the guidelines made sense, there was sufficient training and colleagues were happy using them) and fit (if the guidelines were the ‘right thing’ to do, they fitted with the respondent’s clinical approach and they had a say on how they were implemented) of guidelines rather than requirements (if the guidelines were required by their organisation, state/territory or supervisor).

Priority evidence gaps

1. More detailed analyses of ROSA survey data.
2. Qualitative research with health services personnel within and outside BreastScreen (such as follow-up interviews of ROSA online survey respondents).

3. Additional ROSA surveys targeted to health services providers working in remote and rural settings.

Q2. What are the current registered ongoing randomised controlled trials (RCTs) of risk-based breast cancer screening, and what is the quality of these studies?

Key evidence

1. Of the six trials outside Australia assessing various protocols for risk-based screening, all trials are methodologically valid

Considerations for implementation

1. Most current trials are awaiting primary outcomes.
2. Trials usually assess tumour stage as the primary outcome, as a surrogate for mortality.
3. Four current trials are assessing reduced screening intensity in lower risk groups, which requires a non-inferiority framework.
4. No trial evidence is expected to translate directly to Australia due to differences in health systems.
5. Various trials currently underway involve methods and instruments that are likely to be relevant to a trial in the Australian setting.

Priority evidence gaps

1. A trial conducted in the Australian setting

Q3. How could BreastScreen routine data collection and reporting be enhanced to support risk-based screening?

These findings refer to an activity described in the joint ROSA/AIHW report 'Enhanced BreastScreen data collection and reporting. An activity under the Roadmap for Optimising Screening in Australia (ROSA). Australian Institute of Health and Welfare & Cancer Council Australia. 21 December 2021', provided separately to the Australian Department of Health and Aged Care (unpublished). Considerations for implementation

1. Current BreastScreen data collection and reporting for women aged 50-74 includes some information by factors of interest for risk-based screening, but there are opportunities for this to be enhanced.
2. A suitable change management protocol to support enhanced BreastScreen data collection and reporting would incorporate a clear, evidence-based, reasonably independent and robust governance framework, well-defined decision-making bodies including representatives with operational expertise and advisors with scientific expertise about the items being considered, clear mechanisms for making decisions and careful consideration of national and state-level policies and guidelines, and resources to support the development, implementation and quality assurance of data collection and reporting processes.

Q4. How does the COVID pandemic impact on consideration of risk-based breast screening?

These findings refer to special report provided to the Australian Department of Health and Aged Care in 2020 (unpublished).Considerations for implementation

1. BreastScreen adaptations to providing services during the COVID pandemic included various approaches to prioritising which women should be screened first during recovery periods. This may provide insights about implementing more targeted approaches to screening invitations.

2. COVID impacts on observed BreastScreen participation and potential changes in the profile of screened women is expected to impact routinely reported outcomes for the BreastScreen program for some time, and this may impact evaluations of the effectiveness of risk-based screening protocols in the future.

Q5. What are stakeholder perspectives on risk-based breast screening?

These findings refer to ROSA Stakeholder Perspectives report provided to the Australian Department of Health and Aged Care in 2019 (unpublished).Considerations for implementation

1. Stakeholder groups consider mortality benefit, reduced treatment intensity, reduced interval cancers and minimised overdiagnoses to be priority considerations to build consensus on risk-based breast screening.
2. There is a lack of consensus among stakeholders about how breast cancer risk should be assessed, how breast density should be measured and if and how screening should be tailored according to breast cancer risk.
3. Stakeholder interest and advocacy for breast density notification is significant, with a range of views around whether women should be advised about their breast density, and whether breast density advice should be provided without policies and resources in place to provide screening and surveillance services tailored to their breast density.
4. There is increasing effort from commercial interests to promote new technologies to health services and consumers in relation to breast density and risk assessment, including add-ons to mammography machines currently used by BreastScreen services.