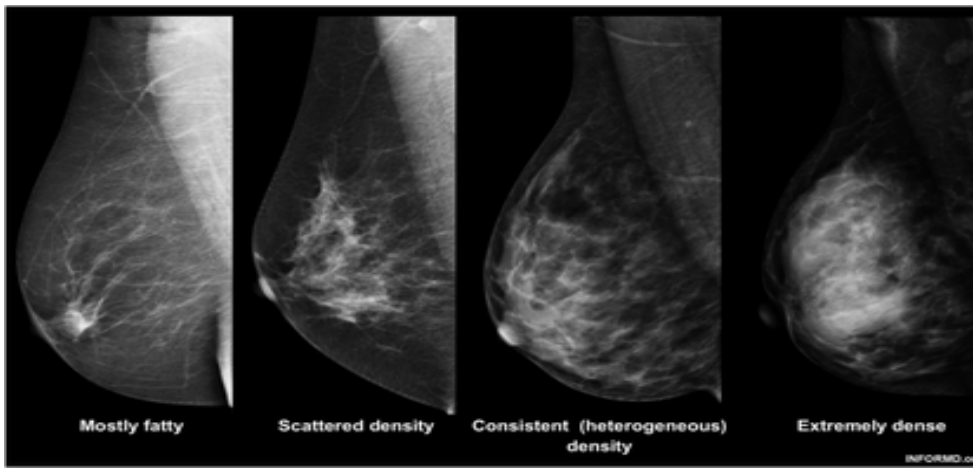
BreastScreen AUSTRALIA
A joint Australian, State and Territory Government Program

BreastScreen Australia Clinical Advisory Group

BreastScreen Australia Position Statement on Mammographic (Breast) Density and Screening

Version	Date of advice: 6 November 2024 Review date: November 2029, or earlier as required Version number: 2.0
Advice requested by	Department of Health, Disability and Ageing
Category	National policy for BreastScreen Australia services
Recommendations	• **Women are informed in writing of their mammographic (breast) density as measured on their screening mammogram.** • **BreastScreen Australia clients may seek advice from their General Practitioner (GP) or breast cancer specialist regarding whether or how their breast density affects their choice of approach to breast cancer early detection, in the context of their other risk factors, personal circumstances, and preferences.**
Key points	• There are demonstrated benefits of mammography screening for women of all breast densities, including a reduction in the risk of death due to breast cancer. • High mammographic (breast) density is associated with an increased risk of breast cancer (although this may be small in absolute terms).[1] • High mammographic (breast) density should be considered in the context of the woman's overall risk for breast cancer and can be used to inform decisions about breast cancer prevention and detection. • Mammograms are less sensitive in women with dense breasts, as dense breast tissue can mask the appearance of breast tumors on a mammogram. • There is currently no consensus on the optimal supplemental screening test(s) for women with dense breasts. • Whilst supplemental screening (including magnetic resonance imaging (MRI), ultrasound, tomosynthesis and contrast-enhanced mammography) improves cancer detection in women with dense breasts, it is associated with an increase in false positive results, with more follow-up tests and increased costs. • Although there is a randomised controlled trial (RCT) that shows MRI identifies more cancers in those with very high density,2 there are no RCTs that show supplemental screening saves additional lives in asymptomatic women with no other risk factors for breast cancer.

	• It will be important that all clients have access to the care and diagnostic support they need. Further research to address uncertainty in supplemental diagnostic and management pathways for clients with dense breasts, will assist in driving equity of access to evidence-based care.

Introduction	• 'Mammographic density' is a term that refers to the relative amount of dense breast tissue (glandular and connective tissue), which appears white on a mammogram, compared with non-dense fatty tissue, which appears dark. Mammographic density is also commonly referred to as 'breast density'.[3]
	• High mammographic density is associated with an increased risk of breast cancer. It also has an impact on screening mammography as it can lead to a lower accuracy or 'sensitivity' for cancer detection.[4-6]
	• Whilst mammographic density can be estimated by the radiologist reading the mammogram, there are validated, reproducible, automated tools available to measure mammographic density.
	• The Breast Imaging Reporting and Data System (BI-RADS)[7] for mammography (fifth edition) is used to describe four categories of density:
	  • **BI-RADS category-a**: the breasts are almost entirely fatty;
	  • **BI-RADS category-b**: there are scattered areas of fibroglandular density;
	  • **BI-RADS category-c**: the breasts are heterogeneously dense, which may obscure small masses;
	  • **BI-RADS category-d**: the breasts are extremely dense, which lowers the sensitivity of mammography.
	• The BI-RADS-c and -d categories are often combined and referred to as 'dense breasts'. BI-RADS category-d is referred to as 'extremely dense'.
	• Breast density generally reduces with age.
	• The following mammogram images (courtesy of InforMD)[8] show normal breasts with varying amounts of dense breast tissue.
	 
	
	BI-RADS a BI-RADS b BI-RADS c BI-RADS d
	• A significant proportion of the BreastScreen Australia eligible population has high mammographic density. While figures for prevalence vary throughout the literature, Australian evidence notes:

	• about 33% of women 50-74 years have high breast density[9-10] (BI-RADS category-c or -d); • about 10% of women aged 50-74 years have extremely dense breasts (BI-RADS category-d); • about 25% of women under the age of 50 years have extremely dense breasts (BI-RADS category-d).[11] • Because breast tumours most often appear white on a mammogram, the presence of dense breast tissue can mask their appearance and affect the accuracy of interpretation of the mammogram. • The sensitivity of a mammography screening program (that is, its ability to correctly identify those with disease, or detection rate), is approximately: • 90% for women with BI-RADS category-a or -b • 84% for those in BIRADS category-c • 64% for those in BI-RADS category -d.[12] • However, it is important to recognise that irrespective of breast density, mammography is still the best breast cancer screening test in a population-based screening program for asymptomatic women aged 50 to 74 years.
Density as part of breast cancer risk assessment	• Increased mammographic density independently increases an individual's risk of breast cancer and the size of this risk increases with increasing density.[1] Compared with age and other risk factors however, the increased risk may be small in absolute terms. • As a group, women with BI-RADS category-a have around half the risk for breast cancer than women with BI-RADS category-b, while those with BI-RADS category-c and -d have 1.6-fold and 2.6-fold higher risk, respectively, than women with BI-RADS category-b.[12-13] • When assessing a woman's risk of breast cancer, it is important to consider breast density in the context of other common risk factors. These include non-modifiable risk factors such as increasing age, having a strong family history, and having a high-risk genetic variant; and modifiable factors such as drinking alcohol, increased weight, being physically inactive and taking menopausal hormone therapy.[14-17] • Using a validated risk assessment tool such as iPrevent™ [18-19] or the Tyrer-Cuzick Risk Assessment Calculator or CanRisk, before a woman decides to participate in breast cancer screening can provide the basis for discussions between women and their doctors about reducing risk of breast cancer and the benefits of participating in mammography screening.
Supplemental screening for women with dense breasts	• Because high mammographic density reduces the sensitivity of mammography, additional screening tests may be useful. This is referred to as 'supplemental screening'. • Presently, there is no consensus on the optimal supplemental screening pathway for those with increased mammographic density. This is partly because what is appropriate for any individual woman will depend on her age, other risk factors, personal circumstances, and preferences. • A range of technologies, in addition to mammography, may be of value for screening or follow-up assessment of women with high mammographic density. There is most evidence for the use of MRI, ultrasound and

	tomosynthesis.[20-26] There is also emerging evidence for the use of Contrast Enhanced Mammography (CEM).[27] • Supplemental screening can improve cancer detection and reduce interval cancer rates in women with dense breasts, suggesting an improvement in outcomes. • However, supplemental screening including ultrasound is also associated with an increase in false positive results.[28] False positive screening results mean that women may be called back for additional scans or needle biopsies that turn out to be benign (or normal). The impacts on a woman of this can be significant in terms of cost, anxiety, and willingness to continue to participate in screening. • Whilst it is recognised that supplemental screening may lead to additional cancer diagnoses in some women, evidence is still evolving about the most suitable supplemental screening modality. • RCTs (or prospective cohort studies) with a longer observation period are needed to assess the effects of supplemental screening on outcomes. Some of these are underway.[20] • Currently, supplemental screening is only available outside of the BreastScreen Australia program following a consultation and referral by a GP to a public or private diagnostic imaging service. This raises issues of equity of access. • Medicare rebates for services provided by a private diagnostic imaging service are only available in specific circumstances. • This complex area highlights the important role of the GP or a breast cancer specialist who may work with their patient to determine the most suitable management pathway for each individual woman with high breast density.
Reporting mammographic density in the BreastScreen Australia program	• There is growing awareness and interest in Australia in mammographic density and its role in breast cancer risk.[29-30] • Multiple BreastScreen services are measuring and reporting mammographic density or investigating doing so in the near future. A consistent approach across the BreastScreen Australia program is identified as an important goal.[12] • There is evidence that notification of mammographic density may be acceptable to and supported by Australian women.[31-35] • Reporting of mammographic density informs shared decision making about breast cancer screening between women and their healthcare teams. Clear and sensitive communication to women and their GPs is needed to support shared decision making on the best management option for each individual woman. • Reporting of mammographic density also facilitates further research and analysis of mammographic density, its measurement, and clinical implications.
Evidence gaps and unanswered questions	• There are important gaps in understanding the potential impacts on women of mammographic density measurement and notification. More evidence is required to inform current and future practice.[36-39]

	• A consistent theme in the literature reviewed is the uncertainty of evidence and lack of consensus for recommendations regarding management pathways for women with dense breasts. • Whilst MRI, ultrasound, and tomosynthesis were the most assessed supplemental screening methods, several studies pointed to the need for more research, including the need for studies with longer observation periods to understand the impact of different supplemental screening methods on clinical outcomes. • The BreastScreen Australia Clinical Advisory Group acknowledges that using mortality as an endpoint in breast cancer screening trials is no longer feasible for determining changes in policy. This is because breast cancers, especially early cancers diagnosed on screening, are highly treatable and so improvements in mortality would not become apparent for many years, if not decades. It is now more appropriate to consider cancer detection rates, stage, morbidity, and interval cancer rates. • In addition, international evidence is based on different and varying population groups, settings, available technologies (e.g., in the context of specific screening programs), and measures of mammographic density, which may affect its applicability to the Australian screening context. • The ROSA project – 'Roadmap for Optimising Screening in Australia – Breast' noted that alternative screening modalities for women with high mammographic density should be considered in the context of risk-based screening. • Although the BreastScreen Victoria Pilot[9]of tomosynthesis screening showed that it significantly increased screening sensitivity in women with dense breasts (BI-RADS- c and BI-RADS- d), a larger study is underway using hybrid tomo technology which may be more scalable for BreastScreen.[40] • Studies are underway to explore combining mammographic density with other routinely collected information and also studies applying artificial intelligence to develop personalised risk assessment approaches.[41-42]
Implementation considerations	• The BreastScreen Australia Clinical Advisory Group acknowledges stakeholder feedback about the challenges of implementing mammographic density measurement and reporting in the BreastScreen Australia program. **Implementation considerations** • A nationally consistent approach to the measurement and reporting of mammographic density, potentially including the use of validated, automated software, is encouraged. This would have significant cost implications. • Nationally consistent information about mammographic density for BreastScreen clients, including guidance on following up with their GP or breast specialist if they have questions or concerns about their breast density or overall risk of breast cancer, should be developed. Client information should include the benefits and risks of supplemental screening in the context of individual breast cancer risk, personal circumstances, and preferences. This information should be tailored for priority population groups. • Nationally consistent information and guidance for GPs on the management of patients with dense breasts is required. The information should include

	current limitations of the evidence about supplementary screening. Decision aids to support shared decision making are required and may include determining the patient's overall breast cancer risk using a validated risk assessment tool. • Achieving equity in access to supplemental screening is important for a population screening program, particularly for priority population groups, including rural and remote communities, Aboriginal and Torres Strait Islander people, culturally and linguistically diverse communities, LGBTQ+ people, and people living with a disability. Further research to address uncertainty in supplemental diagnostic and management pathways for women with dense breasts will assist in driving equity of access to evidence-based care.

Stakeholder consultation	• The BreastScreen Australia Clinical Advisory Group is grateful to stakeholders who provided input during the Position Statement's development, including:
	  • Clinical Directors and other experts from state and territory BreastScreen services
	  • Breast Cancer Network Australia (BCNA)
	  • Australian College of Rural and Remote Medicine (ACRRM)
	  • Breast Surgeons of Australia and New Zealand (BreastSurgANZ)
	  • Medical Oncology Group of Australia (MOGA)
	  • Royal Australasian College of Physicians (RACP)
	  • Royal Australian College of General Practitioners (RACGP)
	  • Royal Australian and New Zealand College of Radiologists (RANZCR)
	  • Royal College of Pathologists of Australasia (RCPA)
	  • BreastScreen Australia Program Management Group
	  • BreastScreen Australia National Quality Management Committee
	  • Other stakeholders with expertise in breast cancer screening, diagnosis, and treatment.

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Appendix: Additional guidance for drafting

Category

Clinical Advisory Group advice needs to be categorised, selecting from the following 3 options:

- **National policy:** evidence-based best practice that is agreed to by all jurisdictions, is mandatory to implement nationwide, and is, or will be reflected in the BreastScreen Australia National Accreditation Standards (NAS) at the appropriate time.
- **Best practice guidance:** clinical advice that has a rigorous evidence base and should be encouraged as the care standard nationwide, however, is not mandated. For example, there may be jurisdictional constraints of an operational, budget or service delivery kind. Best practice guidance would not be included in the NAS, although over time there might be opportunity for it to become national policy.
- **Emerging evidence:** clinical evidence or operational trends that have not yet been rigorously verified or evidence that is conflicting, unclear, immature or requires further investigation. Jurisdictions may adopt emerging evidence or undertake trials or pilots to test, demonstrate or add to the evidence base (as they have done in examples to date). In this case, the clinical advice could be expressed as a position statement or a summary of evidence to inform jurisdictional decisions.