

## BreastScreen Australia Clinical Advisory Group (CAG) Role of bilateral tomosynthesis in BreastScreen Australia assessment

Version  Advice requested by	Date of completed advice: 12 November 2025 Review due: November 2030 Version number: 1 BreastScreen Australia Program Management Group
Category	Best practice guidance
Recommendations	<ul> <li>Bilateral tomosynthesis is considered best practice for all women recalled for BreastScreen Assessment.</li> <li>BreastScreen Assessment provides the opportunity to further evaluate both breasts for the presence of cancer. There is a duty of care to perform as thorough an evaluation of both breasts as possible at the time.</li> <li>It is critical that the BreastScreen service makes it clear in the assessment report and in any subsequent communications, exactly what imaging has been performed, including whether unilateral or bilateral, and the findings, preferably in a synoptic report format.</li> </ul>
Discussion	<ul> <li>Tomosynthesis, where available, has been shown to be the standard of care at BreastScreen Australia assessment clinics for mammographic work-up of screen-recalled abnormalities, with improved diagnostic performance of tomosynthesis when compared with conventional 2D workup (1,2).</li> <li>Published research on the role of tomosynthesis in screening is mostly directed at the detection of cancer at the earliest possible stage, rather than the utility of bilateral tomosynthesis at assessment.</li> <li>One published study of the use of bilateral tomosynthesis at assessment has shown a reduction of one third in the rate of benign breast biopsies, without compromise in cancer detection (3).</li> <li>Anecdotally, BreastScreen services routinely performing bilateral tomosynthesis at assessment have detected contralateral cancers on tomosynthesis alone, as well as</li> </ul>

- unsuspected cancers in the recalled breast, independent of mammographic density.
- It is the standard of care in diagnostic breast imaging to evaluate both breasts, and increasingly this is being done with bilateral tomosynthesis. Screen readers can have satisfaction bias, i.e., decreased vigilance or awareness of abnormalities after recalling one lesion (4). It is therefore the responsibility of the assessing radiologist to scrutinise the mammograms of both breasts to ensure there is no overlooked lesion, particularly in the context of malignant assessment findings in the recalled breast.
- It is the standard of care in assessment clinics for the current screening images and relevant prior films of both breasts to be reviewed by the assessing radiologist, with additional workup views determined by this review and the reasons for recall.
- Workflow is also a consideration in busy clinics. The extent
  to which bilateral imaging is performed depends on
  abnormalities detected on radiological assessment and
  clinical breast examination, the client's risk factors for breast
  cancer, and the human and equipment resources available
  in the clinic at the time of assessment.
- If a contralateral abnormality is detected at assessment, the usual workup is recommended. This workup would include bilateral two-view tomosynthesis, if it has not already been performed.
- The detection of additional malignant lesions is higher with tomosynthesis, with one study showing the sensitivity of preoperative tumour assessment to be higher with tomosynthesis compared with 2D full field digital mammograms (90.7% vs 85.2%) (6).
- A study evaluating the performance of bilateral tomosynthesis versus additional workup views for noncalcified lesions demonstrated that radiologists on average increased the frequency of category 5 assessment for malignant lesions with tomosynthesis, without increasing the frequency of false-positive results (7).
- Potential disadvantages attributed to bilateral tomosynthesis include:
  - Concerns about radiation dose, however the radiation dose of four-view tomosynthesis is not disproportionate to the standard mammographic (minimum three-view) workup.
  - Additional radiologist and radiographer time, particularly if an abnormality is found. However, it should be noted that the impact of the introduction of bilateral tomosynthesis needs to be factored into workflow, and resourcing.
  - The likelihood of detecting a non-harmful abnormality (overdiagnosis) is greater if bilateral imaging is performed, however this is less with tomosynthesis

## than ultrasound (8). Assessment practices across BreastScreen services vary, and are managed at the individual service level, with outcomes monitored at a jurisdictional and national level. This is largely dependent on resourcing and workflow in individual clinics. Similar constraints apply to tomosynthesis. Routinely performing a bilateral tomosynthesis examination on all women at assessment may provide a more efficient workflow and equity of service. Background Large international population-based studies on breast tomosynthesis performance have concentrated on mammographic screening trials comparing tomosynthesis with digital mammography. These studies have repeatedly demonstrated increased breast cancer detection and reduced recall rates with tomosynthesis (9,10). A 2020 article demonstrated improved cancer detection and fewer false positive recalls with tomosynthesis, which was sustained over multiple years and multiple screening rounds (i.e. prevalence and incidence screening rounds) and showed tomosynthesis to be associated with detection of a higher proportion of poor prognosis cancers than digital mammography, with detection of these clinically significant cancers also sustained over multiple screening rounds (11). Stakeholder The BreastScreen Australia CAG is grateful to stakeholders who provided input, including: consultation Australasian Society of Breast Physicians Australian College of Rural and Remote Medicine **Breast Cancer Network Australia BreastScreen Clinical Directors** Breast Surgeons of Australia and New Zealand Royal Australian and New Zealand College of Radiologists Royal Australian College of General Practitioners Royal College of Pathologists of Australasia Mall S, Noakes J, Kossoff M, et al. Can digital breast References tomosynthesis perform better than standard digital mammography work-up in breast cancer assessment clinic? Eur Radiol 2018; 28(12):5182-5194. 2. Lockie D, Nickson C, Aitken Z. J Med Radiat Sci. Evaluation of digital breast tomosynthesis (DBT) in an Australian BreastScreen assessment service (an abstract). 2014; 61:63-112. 3. Sharma N, McMahon M, Haigh I, et al. The Potential Impact of Digital Breast Tomosynthesis on the Benign Biopsy Rate in Women Recalled within the UK Breast Screening Programme. Radiology 2019; 00:1-8.

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- 5. Hooley R, Durand M, and Philpotts L. Advances in Digital Breast Tomosynthesis. AJR 2017; 208: 256-266.
- 6. Mariscotti G, Houssami N, Durando M, et al. Accuracy of mammography, digital breast tomosynthesis, ultrasound and MR imaging in preoperative assessment of breast cancer. Anticancer Res 2014;34:1219-1225.
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- 8. Tagliafico AS, Mariscotti G, Valdora F, et al. A prospective comparative trial of adjunct screening with tomosynthesis or ultrasound in women with mammography-negative dense breasts (ASTOUND-2). Eur J Cancer. 2018;104:39-46.
- Ciatto S, Houssami N, Bernardi D et al. Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study. Lancet Onc 2013; 14(7):583-589.
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- 11. Conant E, Zuckerman S, McDonald E et al. Five Consecutive Years of Screening with Digital Breast Tomosynthesis: Outcomes by Screening Year and Round. Radiol 2020; 00:1-9.

## 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.

The final decision on categorisation of clinical advice is by the <u>Cancer and Population Screening</u> (<u>CAPS</u>) <u>Committee</u>.