

BreastScreen Australia Information for *General Practitioners* on Breast Tomosynthesis

Key Messages

- Breast tomosynthesis (3D mammography) has been approved by the Australian Therapeutic Goods Administration for screening and diagnosis of breast cancer.
- Evidence indicates 3D mammography may improve diagnostic accuracy in the early detection of breast cancer. However, there is limited data on the impact of 3D mammography when used prospectively in population screening environments.
- In 2014 BreastScreen Australia reviewed the current evidence and published a position statement of the use of Tomosynthesis in the BreastScreen Australia program stating that:
 - The use of tomosynthesis as a screening technology be confined to a clinical trial setting;
 - Two view mammography remains the most effective screening test at the time; and
 - Tomosynthesis can be of benefit in an assessment setting.
- More evidence would be needed before 3D mammography could be considered for possible implementation in the BreastScreen Australia program for screening purposes.
- The Standing Committee on Screening will continue to monitor and analyse the emerging evidence.

Background Information

Therapeutic Goods

The Australian Therapeutic Goods Administration (TGA) has approved a mammography device capable of tomosynthesis, on the Australian Register of Therapeutic Goods.

The TGA has not yet approved marketing of breast tomosynthesis to consumers. Certain standards of evidence must be met before such marketing can be approved. However, Hologic, a developer and manufacturer of medical imaging has commenced advertising their Genius 3D mammography (breast tomosynthesis) device directly to General Practitioners.

Hologic Advertising

Hologic claims that Genius 3D Mammography is “41% more effective in detecting invasive breast cancer”; however the study referenced did not assess tomosynthesis as a standalone medical device. Furthermore, the study was conducted within a

hybrid environment; therefore results may not be applicable to the entire population. The study concluded that further studies are needed to assess the relationship to clinical conclusions.

Research

Tomosynthesis is a promising technology which may be able to improve diagnostic accuracy in the early detection of breast cancer. However, further evidence is required before the consideration of any widespread implementation of tomosynthesis in population based screening.

New Technologies in Population Based Screening

Any new technology needs to demonstrate a benefit at least equivalent to mammography in the population based screening context. New technologies for breast cancer screening must meet the Australian criteria for the assessment of population screening as outlined in the Population Based Screening Framework. In particular, any new test needs to be highly sensitive and specific, validated, safe, have a high positive and negative predictive value, be acceptable to the target population and be cost-effective.

Questions remain on issues such as radiation dose, cost, efficiency, and benefit that need to be addressed before consideration of any widespread implementation of tomosynthesis into a population based screening program. It is not clear at this stage if there is a future role of tomosynthesis in a screening setting.

In October 2014, the Standing Committee on Screening (SCoS) endorsed a *Position Statement on the use of Tomosynthesis within BreastScreen Australia services* which recommends that, based on current evidence, the use of tomosynthesis as a screening technology in BreastScreen Australia be confined to clinical trial settings. Two-view mammography remains the most effective screening test at this time. Tomosynthesis can be of benefit in an assessment setting.

The position statement was endorsed by the Community Care and Population Health Principal Committee of the Australian Health Ministers' Advisory Council on 13 November 2014 and is available at: www.cancerscreening.gov.au

Q&As

What is breast tomosynthesis?

Breast tomosynthesis (3D mammography) is a new digital mammography technology that is in the testing and clinical evaluation stages for its possible benefits in screening and assessment.

Currently, BreastScreen Australia uses two-view (2D) digital mammography as the primary test to screen women for breast cancer.

What are the benefits of 3D mammography/breast tomosynthesis?

3D mammography (or breast tomosynthesis) gives a series of images to identify tissue at different depths within the breast. This gives clinical confidence to reach a diagnosis earlier meaning a woman may go through fewer invasive tests to reach a firm diagnosis.

It is important to note that the benefits of tomosynthesis have only been trialled in an Australian setting for the **assessment** of women recalled for further tests after their initial screening.

The results provide good reason to believe that tomosynthesis can give a definitive result earlier in the assessment of breast cancers and reduces the risk of missing cancers.

Why doesn't BreastScreen Australia use breast tomosynthesis in the routine screening process?

There is evidence that tomosynthesis may be of benefit in an **assessment setting**. There is currently insufficient evidence for the benefit of tomosynthesis as the screening test for **population screening** of well women.

We do not yet have a clear picture of the benefits and costs of using tomosynthesis for population screening generally within the BreastScreen Australia service.

The results of further Australian clinical trials are needed before the technology could be considered for routine population screening.

A Victorian study is currently underway to further understand the costs and benefits associated with implementation of tomosynthesis in breast cancer assessment.

At this time, 2D mammography remains the only proven technology for screening healthy women aged 50-74 years for breast cancer in Australia.

Are women getting a second rate service with 2D mammography now that 3D mammography/tomosynthesis is a proven technology?

Women should continue to feel confident that having a free mammogram every two years with BreastScreen as recommended, will give them the best chance of detecting and surviving breast cancer.

BreastScreen Australia notes research from a Lund University major screening [study](#) in Sweden that tomosynthesis detects 40% more breast cancers than traditional two-view (2D) mammography in a screening population.

The results look promising, however the study has also raised important considerations such as a reported increase in recall rates, meaning healthy women with non-cancerous conditions were recalled for further testing – which is widely debated as over-diagnosis.

Any potential increase in radiation dosage and further testing (over-diagnosis) to healthy women in Australia needs further exploration to ensure the benefits for women far outweigh the harms.

We do not yet have a clear picture of the benefits, harms and costs of using tomosynthesis for population screening generally in the BreastScreen Australia service.

Currently, 2D mammography remains the only proven technology for screening healthy women aged 50-74 years for breast cancer in Australia.

Haven't some states and territories already licensed the use of tomosynthesis as part of BreastScreen Australia services?

Jurisdictions are gathering evidence on tomosynthesis for breast screening but BreastScreen Australia will make a national decision on its use for screening in the BreastScreen program.

The next step is to understand the impact of introducing tomosynthesis as the *only* form of breast screening technology, instead of as an adjunct to the existing 2D mammography.

Have other countries rolled out tomosynthesis for population screening?

Australia is aware of one other country that has recently begun the use of tomosynthesis for population screening.

However, population screening programs differ between countries and we need to be confident that it is appropriate in an Australian population screening setting.

The results of further Australian clinical trials are needed before the technology could be recommended for routine population screening.

What kind of radiation does tomosynthesis deliver?

The radiation exposure is safely below the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) guidelines. However, the radiation dose with tomosynthesis may be higher compared to 2D mammography; the evidence remains unclear.^{i,ii} A higher radiation dose will occur when using 2D mammography and tomosynthesis in conjunction. This risk needs to be weighed carefully against the potential benefits to healthy people with no signs or symptoms of breast cancer who undergo population screening.

ⁱ Dance DR, Strudley CJ, Young KC, et al. Comparison of breast doses for digital tomosynthesis estimated from patient exposures and using PMMA breast phantoms. In: Maidment AD, Bakic PR, Gavenonis S (eds) *Proceedings of the 11th international conference on breast imaging (IWDM 2012)*. Berlin: Springer; 2012, 316-321.

ⁱⁱ Skaane P, Bandos A & Gullien R. Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program. *Radiology*: Published online before print & January 2013.