

Testing for Breast Cancer:

Will the real breast screening test please stand up?



Department of
Health



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1. Introduction

Breast cancer is a major health concern in the community and an important cause of cancer death in women. While men can also get breast cancer, it is much more common in women. In 2006, in Australia, 12,614 women and 102 men were diagnosed with invasive breast cancer.¹ Substantial effort has been invested in improving the diagnosis and treatment of breast cancer. One component of this has been the introduction of an effective and reliable screening program by mammography, which aims to increase the number of cases of breast cancer which are found at a stage early enough to maximise the chances of successful treatment.

Recently an increase in the aggressive promotion and marketing of commercial technologies purported to assess women for early signs of breast cancer has been observed in Western Australia and we believe elsewhere in Australia. This trend has raised concern among health professionals that women may be undergoing what they believe to be legitimate and scientifically based 'testing' for breast cancer, while the commercial operator selling the service may have little or no scientific evidence to demonstrate that these techniques reduce deaths from breast cancer.

This report presents the current evidence on breast cancer screening by mammography, and identifies new technologies for screening which are currently being promoted in Western Australia. It reports on what is known about these imaging technologies, and what is not known.

The organisations endorsing this summary cannot and do not claim that these technologies are ineffective. Their concerns are based on the fact that - for the most part - there is no, or insufficient, evidence of their effectiveness or potential harms. Until this evidence becomes available, women are advised to use proven strategies for the detection of breast cancer.

Women considering commercial forms of imaging or breast checks should therefore be made fully aware of the extent to their effectiveness and potential harms is supported by independent research.

2. Why screen for breast cancer?

Screening involves testing for breast cancer in women who do not have any obvious symptoms of the disease. The aim is to find breast cancer early, when it is easier to treat and cure.

Breast cancer meets the following 10 criteria for screening as adopted by the World Health Organisation:²

- The condition is an important health problem
- There is an accepted treatment or useful intervention for the disease
- The natural history of the disease is adequately understood
- There is a latent/early symptomatic stage
- There is a suitable/acceptable screening test
- There are facilities available for diagnosis and treatment
- There is an agreed policy on who should be treated as patients
- Treatment started at an early stage of the disease is more beneficial than treatment started at a later stage
- The cost is economically balanced in relation to possible expenditure on medical care as a whole
- Case finding is a continuing process rather than a once off project

3. BreastScreen Australia

BreastScreen Australia is the national breast cancer screening program. The screening test used is a mammogram, which is a low dose X-ray of a woman's breast. BreastScreen WA, a state component of BreastScreen Australia, provides free screening mammograms to Western Australian women aged 40 years or over with no breast symptoms every two years. Because research shows that they are most likely to benefit from screening mammography, women aged 50 to 69 years are especially encouraged to attend.

Do breast cancer screening mammograms save lives?

BreastScreen was established after a number of randomised controlled trials demonstrated that systematic mammographic screening successfully reduced the number of deaths from breast cancer by approximately 25% among those invited to participate in screening, and by approximately 35% among those who actually participated in screening.³

There is a substantial quality control program underpinning all components of the BreastScreen program, as well as an ongoing system to analyse and evaluate the results of the Program. A major national review conducted into the Program in 2009 found that for the target age group (women aged 50-69 years), participation in screening once every two years is associated with a 21-28% relative reduction in breast cancer deaths at the current national participation rate of 56%.⁴ If the participation rate for the target group were 70%, the estimated relative reduction in breast cancer deaths would be 34-45%.

Modelling of Australian data has shown that, in absolute terms, for every 1,000 women screened over 10 years, 167 to 251 women (depending on her age) will receive an abnormal result.⁵ Of these women, 56 to 64 will undergo at least one biopsy and 12 to 32 will have cancers detected by screening.⁵ For every 1,000 women aged 40 who chose to be screened, there are about 0.5 fewer deaths over 10 years compared to women who don't screen. For every 1,000 women aged 50 who chose to be screened, there are about 2 fewer deaths. For every 1,000 women aged 60 who chose to be screened, there are about 3 fewer deaths, and for every 1,000 women aged 70 who chose to be screened, there are about 2 fewer deaths.⁵

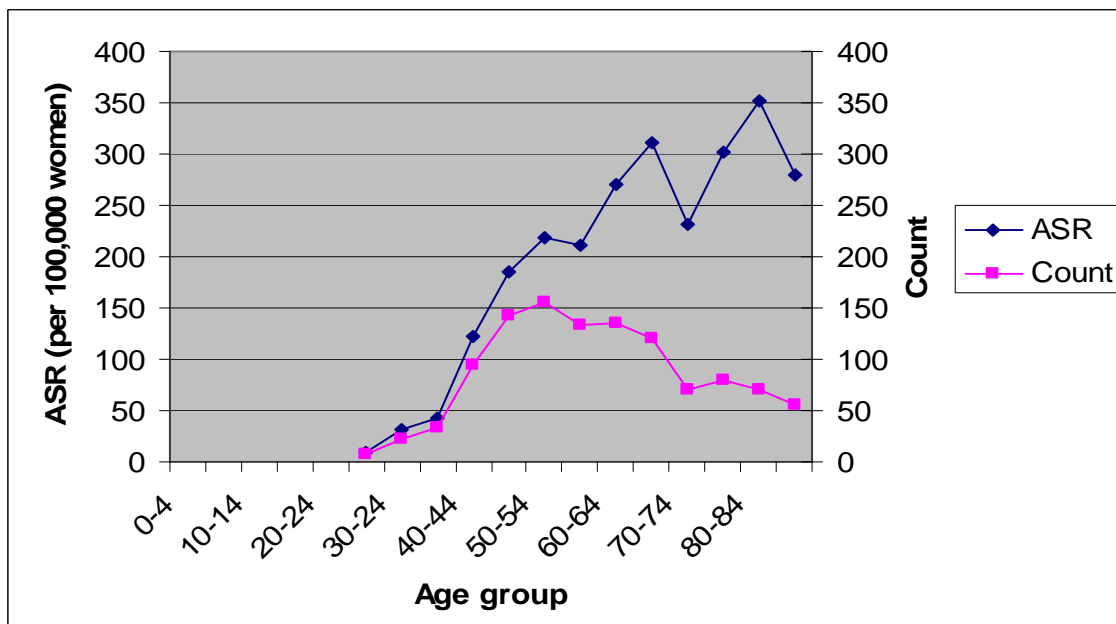
Like other screening tests, mammography is not 100% accurate in identifying those women who have breast cancer. Therefore there is the potential for false positives (when a woman with a positive screening test result does not have cancer), which may lead to unnecessary diagnostic procedures and anxiety, and false negatives (when a woman who has cancer has a negative screening test result), which may result in false reassurance and delayed treatment. Other potential costs include anxiety associated with recall to assessment, and overdiagnosis (treatment of cancers that, if left untreated, would not have otherwise caused death). While the overall harms are considered moderate across all age groups, the risk of false-positives is greatest for women aged 40-49 and the risk of overdiagnosis is greatest for women in the older age groups.⁶ To minimise potential harms associated with screening, BreastScreen aims to maximise sensitivity (by minimising the number of false-positive results) and maximise specificity (by minimising the number of false-negative results). In 2000-03, the Program sensitivity rate for women aged 50-69 years was 90.5% at 0-12 months after the first screening round. Specificity is more difficult to determine, however Program performance data indicate that specificity is maximised. Estimates of overdiagnosis of breast cancer as a result of screening vary, but are likely to be around 5-13%.³

Why aren't women under 40 years eligible for a screening mammogram?

There is inadequate research evidence to indicate that screening mammography reduces mortality from breast cancer in women under the age of 40, or that the benefits of screening mammography are greater than the potential costs in this age group.³

Breast cancer incidence is relatively low among women under 40 years, and increases markedly for women over 50 years. For screening to be useful, it needs to occur in a population where the disease is relatively common. In Figure 1, the pink line shows the total number of new cases diagnosed in each age group in 2007.⁷ The blue line represents the age-standardised rate (ASR), or the number of new cases per 100,000 women in that age group. The increasing ASR indicates that the *risk* of being diagnosed with breast cancer increases with age, even though the actual number of cases is falling due to lower numbers of women in older age groups.

Figure 1. Incidence of breast cancer among women in WA by 5-year age groups (2007)



Source: Threlfall T, Thompson J. Cancer incidence and mortality in Western Australia, 2007. Statistical Series No. 86. Perth: Western Australia; 2009

Screening mammography is less accurate in women under 40. Breast tissue in younger women is more dense than in older women. As dense breast tissue and tumours both appear opaque on an X-ray, detection of tumours using mammogram in younger women is less likely to be accurate.

Given its reduced effectiveness in women under 40, the costs of breast cancer screening in this age group (eg undergoing unnecessary procedures, anxiety, discomfort during screening, exposure to low-dose radiation) is currently thought to outweigh the benefits.

There is currently no screening technology that is proven to reduce deaths from breast cancer in women under the age of 40. For women who are younger than 50 years of age or have dense breast tissue, detection of breast cancer is somewhat higher using digital mammography, a newer mammographic technique that uses less radiation than the traditional film mammography.⁶ Overall, however, detection of breast cancers using film mammography and digital mammography is similar for most women. The false-positive rate is similar for film and digital mammography, but it is not certain whether overdiagnosis more common using digital mammography. Whether digital mammography screening reduces breast cancer mortality is yet to be studied, and more evidence is needed to assess whether the benefits outweigh potential harms.⁶ Within the Australian context there is a move towards digital mammography.

Can women with breast implants receive a mammogram?

Yes, most can, but before making an appointment they may wish to discuss their suitability with their GP or a breast specialist. Mammography for women with implants often requires more X-rays and may be less effective because the implant can obscure some of the breast tissue.

Mammograms are generally safe for women with breast implants; the risk of damage to the implant is very small.

4. What new commercial technologies are on the market?

This section provides information on companies in Western Australia that offer breast imaging services other than mammography. These breast imaging techniques will be referred to as 'commercial technologies' in this document. Information on how the commercial technologies work is also provided.

There is at least one device for each commercial technology which has received approval from the Therapeutic Goods Administration (TGA) and is entered on the Australian Register of Therapeutic Goods (ARTG). All medical devices must be entered on the ARTG before they can be supplied in Australia. TGA approval ensures that these technologies are safe in terms of immediate harm. However, it does not necessarily mean that they are proven as effective screening tools for breast cancer or that the risk of other undesirable outcomes, such as risk of missed cancer and false reassurance from false positive test results or unnecessary investigations from false positive tests, is low.

There are legitimate research programs that could determine whether new breast screening technologies might perform better than the current 'gold standard' of mammography. To our knowledge, none of the commercial technologies reported here have been or are currently being researched in this manner. Edith Cowan University however have commenced a research project examining the prospect of one technology being of some benefit (see page 8).

Commercial technologies currently available in Perth

Breast Check (Mosman Park)

<http://www.breastcheck.com.au/>

BreastCheck is promoted as a 'medical breast health imaging centre' that uses 'safe, non-invasive, radiation-free devices'. The word screening is not explicitly used. They suggest their services are suitable for women under 50 years, with implants, on hormone replacement therapy (HRT) or with dense breast tissue. While BreastCheck claims to support and recommend mammography, they also assert that 'BreastCheck is picking up clinically confirmed cancers down to 3mm (including those who have had a negative mammogram or ultrasound)'. Their website states that BreastCheck is currently involved in a scientific clinical trial at the University of Western Australia, but details of this trial could not be found.

Commercial technologies used by this company are electrical impedance, thermal radiometry and infrared thermography. More information on each of these techniques is outlined below.

Electrical Impedance

Electrical impedance measures how fast electricity travels through a given material (conductivity).⁸ The electrical conductivity of tumours may differ from that of surrounding normal tissue due to

changes in cell structure and function. Electrical conductivity of breast cancer cells is suggested to be higher, and therefore has lower electrical impedance. The technology is promoted as being non-invasive and does not use radiation.

While it is not known exactly which devices are used by BreastCheck or Safe Breast Imaging (see below), there is an electrical impedance scanner listed on the ARTG. The ARTG public summary for the scanner states its intended purpose is to detect, record and map differences in the electrical conductivity of cancerous and surrounding normal tissue. The device is described as an adjunct to other imaging modalities (that is, it is used to assist other imaging devices). No mention is made of breast cancer screening.

Digital Infrared Thermal Imaging/Thermography

This technology uses infrared imaging to detect changes in skin temperature.⁸ Tumours are areas of high cell growth and metabolism, which may generate more heat. The infrared camera detects these warmer areas. People undergoing infrared imaging are advised to avoid physical activity, alcohol and cigarettes 20 minutes prior to imaging as they may affect body temperature. Thermography is non-invasive and does not use radiation.

It is not known exactly which devices are being used by all providers offering thermography. However, an ARTG entry was found for the device distributed by Meditherm (see below). The intended purpose of the device, as outlined in the ARTG public summary, is to record human body thermal (temperature) variations. Breast cancer screening is not mentioned.

Thermal Radiometry (also known as microwave radiometry)

Thermal radiometry measures the temperature of surface and internal breast tissue.⁹ Like infrared thermography, it operates on the principle that 'hotter' areas may indicate areas of possible abnormality. Thermal radiometry is different from infrared thermography in that it measures the surface and internal temperature of the breast, while thermography measures only surface temperature.

It is not known exactly which device is used by BreastCheck. There is however at least one ARTG entry for a microwave radiometer. Its intended purpose is described as 'microwave thermography for early breast cancer detection and screening'. It is important to note that this does not mean that the device's efficacy in achieving its intended purpose has been adequately evaluated.

Safe Breast Imaging (North Perth - conducted at various places throughout Perth on demand)

<http://www.safebreastimaging.com.au/>

Safe Breast Imaging uses electrical impedance (see above for more information on this technology).

This company describes their services as a 'safe and comfortable option' for women of all ages, with 'no squeezing'. They promote their service as the 'safe breast imaging choice for young women'. Safe Breast Imaging indicates that they support BreastScreen Australia, but go on to state that 'Safe Breast Imaging believes there is an ethical obligation to offer women of all ages another option for monitoring their breast health. Safe Breast Imaging therefore offers breast health screening for women who can not or will not have a mammogram and want another option'. The FAQs section of their website states that 'for most women, the MEM (multi-frequency electrical impedance mammograph) is sufficient', and it is described as a screening tool. There is no evidence that MEM is an effective screening tool and we are concerned that these statements may lead

women to believe that the effectiveness of electrical impedance is equivalent to that of mammography.

Ultra Health Centre (Floreat)

<http://www.ultrahealthcentre.com/>

<http://www.meditherm.com/>

This centre uses Digital Infrared Thermal Imaging (thermography) for the breast and body (see above for more information on this technique).

Ultra Health Centre promotes their service as completely painless, radiation-free, and involving no contact with the body. They mention the service is suitable for all ages, particularly those under 50 years. Their website refers viewers to the manufacturer's (Meditherm) website, which describes thermography as being part of an early detection program. While their early detection guidelines do include regular mammography for those over 50, they also claim that thermography 'provides women with detection of any breast disease earlier than has previously been possible either by self-examination, doctor examination or mammography alone'. We are not aware of any evidence that this is so.

Breast Logic (Leederville)

<http://www.breastlogic.com.au/>

<http://www.suretouch.com.au/>

Breast Logic use computerised/mechanical breast imaging. The technique is promoted as being radiation and pain-free, and suitable for women of all ages and breast types, including those with implants. On their website, Breast Logic refers to a number of papers, but they are not peer-reviewed scientific reports. The website also refers viewers to the manufacturer's (SureTouch) website, which claims that the technology is particularly beneficial to women aged 25-40 years. It also states that the technology is up to four times more sensitive than human touch and can scan areas that mammograms cannot reach.

Computerised/mechanical breast imaging

This technique involves applying mechanical pressure to the breast tissue with a hand-held probe and recording reaction to this force by sensors in probe.¹⁰ The theory is that tissues of different types within the breast have different mechanical properties (eg hardness of tissue, elastic composition, mobility and boundaries) that can be assessed from the skin's surface, and a 'visual map' of a clinical breast examination that would normally be done by hand is created.

The computerised/mechanical breast imaging device used by Breast Logic is listed on the ARTG. The ARTG public summary states that 'The device should not be used for clinical decision-making' and that identified changes to lesions should continue to be monitored using clinical breast examination, mammography or ultrasound.

Breast Sense (self-examination kit that can be purchased online)

<http://www.breastsense.net.au/>

The Breast Sense self-examination kit contains an instructional DVD and booklet, a glove claimed to make self-examination easier and more comfortable, and a carrier pouch.

On the homepage of the Breast Sense website, it is stated that 'self examining one's own breasts every month is the best method for detecting the early stages of breast cancer'. However, there is currently no evidence from randomised trials that breast self-examination actually reduces risk of death from breast cancer.¹¹ On the page 'Breast Awareness & Self-Examination' (found under the drop-down menu 'Breast Cancer') it states 'mammography is the most effective way to find breast cancer early, often before a lump is even large enough to be felt'; this, while correct, contradicts the statement on their homepage.

Jainsons (Ballajura)

<http://www.jainsons.com.au/>

Jainsons are suppliers of Computed Tomography Laser Mammography (CTLM) devices. It is not known whether any clinics in Perth currently offer CTLM. The technology is promoted as radiation-free, not requiring breast compression, and suitable for women with dense breast tissue or implants. It is claimed that CTLM has the capacity to diagnose very small malignant tumours before they are detectable using mammography or ultrasound. Jainsons state that CTLM is used in combination with ultrasound, which provides further confirmation once CTLM identifies whether an abnormality is cancerous or not.

The CTLM device supplied by Jainsons is listed on the ARTG. It is described as an adjunctive (assisting) tool to *aid* in the detection of female breast cancer.

The following section includes more information on how CTLM works.

Research conducted by Edith Cowan University (ECU)

Computed tomography laser mammography / near infrared breast scanner

The Vario Institute at ECU is currently researching the use of a near-infrared breast scanner (NIBS), which is said to be very similar to CTLM.

This technology measures the absorption of near infrared non-ionising (safe) radiation by haemoglobin (red blood cells) in breast tissue.¹² Tumours will absorb the radiation differently to normal breast tissue, as cancers have an increased blood supply (and therefore more haemoglobin). The procedure is painless and there are no harmful side effects.

The results of this research are not yet available.

5. What are the concerns and implications of these commercial technologies for public health/breast cancer outcomes for women in WA?

Screening has the potential to reduce the burden of breast cancer by preventing premature death from the disease and improving quality of life through early detection. However, there may also be costs to screening, for example, false positive tests leading to unnecessary diagnostic procedures and anxiety and false negatives resulting in false reassurance and delayed treatment. As screening has the potential to cause harm, screening programs should be based on good quality evidence which demonstrates that their benefits outweigh their potential costs, and should also be monitored by an effective quality assurance program.³

Like other screening tests, mammography is not 100% accurate in identifying those women who have breast cancer. However, the effectiveness of mammography screening in reducing the number of deaths from breast cancer has been investigated using long term high-quality research studies. This benefit of a reduction in mortality is then considered against potential costs of participation in screening. For women aged 50-69, it is considered that the benefits are greater than the potential harms of screening.³ Furthermore, BreastScreen Australia undergoes an accreditation process that ensures it provides high quality service.

Some women may believe that the commercial breast imaging technologies are equally effective as mammography in increasing early detection of and reducing death from breast cancer. However, these technologies, to the best of our knowledge, have not been evaluated using appropriate research studies. Therefore there currently is no reliable or accurate evidence showing that these technologies will have any benefit in the early detection of breast cancer, or whether they are better than mammography in reducing death from breast cancer. There is also the harm from investigation of 'abnormalities' detected by these tests. For example, women may have to undergo unnecessary breast ultrasounds or needle biopsies. So while participating in commercial forms of breast imaging instead of mammography may not cause any immediate harm, since the effectiveness of the commercial techniques is unproven, it may lead to delayed diagnosis and treatment of cancer.

6. What are the options for women who fall outside the BreastScreen target audience?

Women under 40 years of age

There is inadequate evidence that participation in screening mammography, or any other form of breast imaging technique, is effective in reducing death from breast cancer among women under 40 years of age.³

For women of all ages, breast self-awareness and prompt reporting of symptoms to a GP is extremely important. Women are encouraged to become aware of the normal look and feel of their breasts, so that they notice any new changes. A special technique does not have to be used. Changes to look out for include:

- A new lump or lumpiness
- A change in size or shape
- A change to the nipple eg an ulcer, redness, inversion or discharge
- A change in the skin of the breast, such as redness or dimpling
- Any unusual pain that doesn't go away

While most breast changes are NOT due to cancer, if any unusual changes are found it is important to see a GP to make sure.

What about women with a family history of breast cancer?

A woman's risk of breast cancer is increased if she has a family history of breast cancer. Although this risk is influenced by the number of women (and men) with breast cancer in her extended family of blood relatives, the most useful indicator is whether one or more first-degree relatives (mother, sister, daughter) are affected.¹³ The more relatives diagnosed the higher the risk. Similarly, the younger those relatives were at age of diagnosis, the higher the risk. Women concerned about their family history should speak to their GP, who will determine if a referral is necessary to a specialist agency - Genetic Services WA - for a full assessment, and if appropriate, ongoing surveillance.

Women who have not previously been diagnosed with breast or ovarian cancer can assess their risk for developing breast cancer using the online risk calculator developed by the National Breast and Ovarian Cancer Centre: <http://nbocc.org.au/risk/yourrisk.html>

Guidelines for the management of women who carry a BRCA mutation can be found at: http://www.genomics.health.wa.gov.au/publications/docs/Protocol_for_the_management_of_BRCA_mutation_carriers_in_WA.pdf

7. Conclusion

Breast cancer is a serious disease that caused more than 250 deaths in WA in 2007.⁷ Mammographic screening is a proven technology that contributes to a reduction in deaths from breast cancer. There are a range of unproven commercial technologies being promoted in the private marketplace. Women who purchase these services should be aware of the lack of evidence to demonstrate their effectiveness.

Our motivation in raising these concerns is to prevent a scenario where a woman may rely on one of these unproven technologies to detect early signs of breast cancer, and subsequently develops a tumour which is detected too late for successful treatment. We consider that this scenario may occur unless action is taken to ensure that these businesses can only make claims that are substantiated by peer reviewed research.

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