

Position statement addressing the harms of population breast screening



September 2014 HP 6003

Position

The National Screening Unit (NSU) of the Ministry of Health recommends eligible women participate in the BreastScreen Aotearoa (BSA) programme. Screening mammography is the only proven public health intervention for reducing mortality from breast cancer. For most women the benefits of participation in the national breast screening programme will outweigh the harms.

The NSU requires that all women participating in the national breast screening programme are appropriately informed about the harms and benefits of screening, so that they can make an informed decision about participation in the screening programme.

The benefits of breast screening are frequently discussed more than the harms, yet understanding both is important. In the context of recent major reviews of breast screening, the known harms are described below. These harms are not new, or greater than previously considered by the BSA programme.

The intended audience of this statement is primary care practitioners who discuss breast screening with their patients.

Background

BreastScreen Aotearoa provides publicly funded, two-yearly mammographic screening for eligible¹ women aged 45–69, with the aim of reducing mortality from breast cancer in this population. In addition, women diagnosed with breast cancer through BSA's programme tend to be diagnosed at an earlier stage compared with those diagnosed outside the programme. As a result, women diagnosed in BreastScreen Aotearoa are more likely to have breast-conserving surgery, are less likely to require extensive axillary surgery

¹ Women are eligible for free mammography every two years through the BSA programme if they are aged 45–69 years, have not had mammography within the previous 12 months, are not pregnant or breastfeeding, are free from breast cancer (at least five years after a previous diagnosis), are asymptomatic and are eligible for public health services in New Zealand.

and are less likely to require chemotherapy and radiotherapy (Royal Australasian College of Surgeons 2013).

Informed decision-making

The NSU recognises the importance of each woman making an informed decision about participation. This choice will be based on their personal preferences given the current evidence. BreastScreen Aotearoa and its providers acknowledge their responsibility to provide accessible, appropriate and accurate information to eligible women and their whānau.

The pamphlet provided to all women before their mammograms – *Having a mammogram every two years improves a woman's chances of surviving breast cancer* – was updated in 2013 to include more information about the harms of screening.

Further information is available to women who would like more detail about breast screening, including on the BSA website. The booklet *More about breast screening and BreastScreen Aotearoa* discusses overdiagnosis and other risks. BreastScreen Aotearoa's quality standards require all BSA providers to ensure that women are provided with information about the benefits and harms of breast screening and have the opportunity to have any questions answered before consenting to a procedure.

Recent international reviews

The debate around the benefits versus harms of breast cancer screening dates back decades and has been regularly monitored and reviewed by all national breast screening programmes, including that of New Zealand. Many of the differences in research outcomes appear to be due to differences in study design and methodology.

In response to ongoing controversy about breast screening, an independent review was commissioned by Cancer Research UK and the Department of Health (England) and reported in 2012 (Marmot et al 2012). The review was based on both literature review and expert testimony. The review concluded that breast screening

programmes confer significant benefit, and the report recommended that the United Kingdom breast screening programme should continue. It estimated that screening reduces breast cancer mortality by 20 percent among women invited to screening.

A Cochrane Review on the benefits and harms of breast screening was released in 2013. This review is an update of one published in 2006 (Gøtzsche and Nielsen 2006) and updated in 2009 (Gøtzsche and Nielsen 2009). It estimates that screening reduces breast cancer mortality by 15 percent for women invited to screening. However, the findings of the Cochrane Review have been challenged by various expert groups.

Both the Cochrane Review and the United Kingdom expert review have been criticised due to being largely based on potentially outdated randomised controlled trials (Baum 2013). They thus do not fully incorporate the effect of advances in treatment of breast cancer, which may reduce the relative effectiveness of screening. Advances in technology and improved screening technique and experience are also not accounted for.

When considering the benefits and harms of population-based screening in practice, outside the trial setting, recent observational studies of programmes similar to New Zealand's provide more relevant evidence. EUROSCREEN has carried out a comprehensive analysis of observational data from European screening programmes (Broeders et al 2012; Paci and EUROSCREEN Working Group 2012). It concludes that breast cancer screening reduces mortality rates by 25–30 percent among invited women and approximately 40 percent among screened women.

Harms of breast screening

Though at a population level the benefits of screening exceed the harms, harms are an important ongoing consideration. All screening has limitations. As no screening test is 100 percent accurate, well women may be subjected to unnecessary interventions as a result of screening.

Anxiety, inconvenience, discomfort, radiation exposure, false positive and false negative results, and overdiagnosis are all recognised harms of breast screening programmes.

BreastScreen Aotearoa and external organisations regularly monitor the New Zealand programme against a set of programme targets and quality standards, many of which ensure that harms are minimised.

Overdiagnosis

Overdiagnosis is defined as diagnosis of a breast cancer through screening that would not have been identified clinically in the woman's lifetime without screening (Cancer Australia 2014). This can lead to unnecessary treatment, including surgery and radiotherapy. There is currently no test that can differentiate these cancers from cancers that would have become clinically significant if left untreated.

Estimates of overdiagnosis vary with methodology used. The Cochrane Review estimated that the number of women overdiagnosed as a result of screening outnumbers the number of breast cancer deaths averted by a factor of 10:1, while the United Kingdom report provided an estimate of 3:1. However, the EUROSCREEN analysis showed that when background breast cancer risk and lead time² are appropriately adjusted for, rates of overdiagnosis are lower than previously reported; this analysis estimated that only one case of overdiagnosis will occur for every two breast cancer deaths averted by screening (Puliti et al 2012).

Ductal carcinoma-in-situ (DCIS) is the pre-invasive stage of breast cancer, although not all DCIS will progress to invasive breast cancer. Because DCIS rarely presents as a palpable lump, it is less likely to be diagnosed clinically, but may be detected by mammographic screening. Therefore, detection of DCIS may contribute to overdiagnosis in breast screening programmes. It is not possible to differentiate which women diagnosed with DCIS will or will not progress to invasive breast cancer without treatment.

2 Screening causes an initial increase in breast cancer incidence in the screened group – the so-called 'lead time effect' – because cancers are detected earlier. However, this is compensated for by a decrease in breast cancer incidence after cessation of screening, when the group is older (ie, if more cancers are diagnosed when the group is younger, fewer will be diagnosed when the group is older). Studies that have inadequate follow-up time or that do not adjust for this lead-time will overestimate the incidence of overdiagnosis.

However, low-grade DCIS is less likely to progress to invasive cancer than high-grade DCIS. Reassuringly, in New Zealand, low-grade DCIS is not overrepresented as a proportion of all DCIS diagnoses within the BSA programme compared with non-BSA diagnoses (Royal Australasian College of Surgeons 2013).

False positive and false negative tests

A screening mammogram by itself does not diagnose cancer but indicates if further investigations are needed. Most women recalled to assessment will not have breast cancer diagnosed. For every 1000 women who have a mammogram in the BSA programme, 42 (4%) will be recalled to have further assessment. Of the 42 women recalled to assessment out of every 1000 women screened, 35 will not have breast cancer (Robson et al 2014). The screening mammogram result for these 35 women is a false positive.

Interval cancers

Screening mammography will not detect all breast cancers and this is a known limitation of screening. Some breast cancers will become clinically apparent between screens when the result of the previous screen was normal: these are referred to as interval cancers. A potential harm is that women who have been reassured by a normal screen may not present for investigation of symptoms. Most interval cancers (>70%) are true interval cancers and were not visible on the previous mammogram. The remaining interval cancers include those with false negative results, where in retrospect an abnormality was detectable on the screening mammogram. BSA interval cancer rates are similar to comparable screening programmes internationally (Taylor 2012).

Radiation exposure

Women are exposed to a very low dose of radiation during a mammogram. Digital mammography has been shown to use lower doses of radiation than film-based mammography (Hendrick et al 2010). Estimates of the actual dose associated with a mammogram vary widely, but the benefit of early detection of breast cancer is believed to outweigh the risk of the small dose of radiation (Marmot et al 2012).

BSA has always achieved a low radiation dose, by international standards, while maintaining image quality (Nicoll 2014).

Anxiety, inconvenience and discomfort

The compression associated with a mammogram can cause discomfort or pain for some women. International evidence shows that compression force is lower with digital mammography (Hendrick et al 2010), which is now routinely used in New Zealand.

Having a mammogram is associated with anxiety for some women, particularly if they are recalled for further assessment. In BSA's programme, 4 percent of women will be recalled to have further assessment (Robson et al 2014). This also means that 96 percent of women are advised there is no evidence of breast cancer and will return to routine screening.

Breast screening programmes try to minimise the inconvenience of attending for screening by the use of local clinics and mobile units. However, for the 4 percent of women who are recalled for further assessment, the assessment clinics in New Zealand are only performed at larger centres, and women are required to travel and attend for part or all of a day.

Conclusions

The importance of clear communication of potential benefits and harms to women eligible for breast screening has been highlighted recently in many parts of the world. Ensuring women have full, fair and balanced information is an important part of BSA's programme. Primary care providers can be a valuable part of the decision-making process.

The NSU recommends eligible women participate in the national breast screening programme as the benefits exceed the harms for most women. The decision to participate remains an individual decision.

References

- Baum M. 2013. The Marmot report: accepting the poisoned chalice. *British Journal of Cancer* 108(11): 2198–9.
- Broeders M, Moss S, Nystom L, et al. 2012. The impact of mammographic screening on breast cancer mortality in Europe: a review of observational studies. *Journal of Medical Screening* 19 (Suppl 1): 14–25.
- Cancer Australia. 2014. *Overdiagnosis from mammographic screening*. URL: <http://canceraustralia.gov.au/publications-and-resources/position-statements/overdiagnosis-mammographic-screening> (accessed 28 March 2014).
- Gøtzsche PC, Jørgensen K. Screening for breast cancer with mammography. *Cochrane Database Syst Rev* 2013, Issue 6, Art. No. CD001877. DOI: 10.1002/14651858.CD001877.pub5 (accessed 27 August 2014).
- Gøtzsche PC, Nielsen M. Screening for breast cancer with mammography. *Cochrane Database Syst Rev* 2006, Issue 4, Art. No. CD001877. DOI: 10.1002/14651858.CD001877.pub2 (accessed 27 August 2014).
- Gøtzsche PC, Nielsen M. Screening for breast cancer with mammography. *Cochrane Database Syst Rev* 2009, Issue 4, Art. No. CD001877. DOI: 10.1002/14651858.CD001877.pub3 (accessed 27 August 2014).
- Hendrick RE, Pisano ED, Averbukh A, et al. 2010. Comparison of acquisition parameters and breast dose in digital mammography and screen-film mammography in the American College of Radiology Imaging Network digital mammographic imaging screening trial. *American Journal of Roentgenology* 194(2): 362–9.
- Marmot MG, Altman D, Cameron D, et al. 2012. *The Benefits and Harms of Breast Cancer Screening: An Independent Review*. URL: www.cancerresearchuk.org/about-us/we-develop-policy/our-policy-on-early-diagnosis/our-policy-on-breast-cancer-screening (accessed 7 May 2014).
- Nicoll J. 2014. *BreastScreen Aotearoa Report on Medical Physics Testing in 2012*. Dunedin. (Unpublished.)
- Paci E, EUROSCREEN Working Group. 2012. Summary of the evidence of breast screening service screening outcomes in Europe and first estimate of the benefit and harm balance sheet. *Journal of Medical Screening* 19 (Suppl 1): 5–13.
- Puliti D, Duffy SW, Miccinesi G, et al. 2012. Overdiagnosis in mammographic screening for breast cancer in Europe: a literature review. *Journal of Medical Screening* 19 (Suppl 1): 42–56.
- Robson B, Stanley J, Ikeda T, et al. 2014. *BreastScreen Aotearoa Independent Māori Monitoring Report 4: Screening and Assessment July 2010 to June 2012*. Wellington: Te Rōpū Rangahau Hauora a Eru Pōmare.
- Royal Australasian College of Surgeons. 2013. *BreastSurgANZ Quality Audit: Report on early and locally advanced breast cancers diagnosed in New Zealand patients in 2011*. Adelaide: Breast Surgeons of Australia and New Zealand.
- Taylor R, Wall M, Morrell S. 2012. *Interval cancers in BreastScreen Aotearoa 1999–2007*. Sydney: University of New South Wales.



www.nsu.govt.nz

[New Zealand Government](http://www.govt.nz)