Position Statement on the use of fine needle aspiration and core biopsy of the breast in the BreastScreen Australia program

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BreastScreen Australia is Australia's national population-based screening program for breast cancer. BreastScreen Australia services are delivered by state and territory governments, through dedicated, accredited Screening and Assessment Services (SAS).

The BreastScreen Australia Program aims to reduce morbidity and mortality from breast cancer through an organised systematic approach to the early detection of breast cancer using screening mammography.

Provision of a high-quality service to women is of great importance to BreastScreen Australia. For this reason, services accredited under BreastScreen Australia are expected to operate according to the BreastScreen Australia National Accreditation Standards (NAS), along with national policies and protocols.

Purpose and scope

The purpose of this Position Statement is to provide guidance on the use of fine needle aspiration (FNA)* and core biopsy for the assessment of abnormalities identified through population screening for breast cancer. The Position Statement will establish national BreastScreen Australia policy on breast biopsy and support best practice care in the BreastScreen Australia program.

Best practice care for women with screen-detected lesions identified through the BreastScreen Australia program is dependent on accurate and comprehensive needle biopsy information, so that women and their health professionals can make informed decisions about their treatment with minimal need for further investigations.

The intended audience of this Position Statement is health professionals within the BreastScreen Australia program. Accordingly, the language and terminology used in this Position Statement is based on the BreastScreen Australia data dictionary† https://www.aihw.gov.au/reports/cancer-screening/breastscreen-australia-data-dictionary-version-1/contents/table-of-contents.

* Fine needle aspiration and core biopsy may be referred to in a number of ways or abbreviations. These include fine needle aspiration (FNA), fine needle aspiration cytology (FNAC), fine needle aspiration biopsy (FNAB), core biopsy (CB), core needle biopsy (CNB), vacuum-assisted core biopsy (VACB) or vacuum-assisted core needle biopsy (VACNB) or mechanical biopsy. As the language and terminology used in this Position Statement is consistent with that used in the BreastScreen data dictionary, fine needle aspiration will be referred to as FNA and core biopsy will be referred to as core biopsy.

† Australian Institute of Health and Welfare 2015. BreastScreen Australia data dictionary: version 1.1. Cancer series no. 92. Cat. no. CAN 90. Canberra: AIHW.

This Position Statement is based on:

- a review of high-level clinical evidence[‡] relating to the use of FNA and core biopsy in the context of mammographically-detected breast abnormalities;
- a review of national and international guidelines on the use of FNA and core biopsy for mammographically-detected breast abnormalities in breast cancer screening;
- an analysis of National Accreditation Standard (NAS) data from the BreastScreen Australia program (2004-2015); and
- the clinical expertise of a multidisciplinary, Expert Advisory Group established by Cancer Australia to provide input into the development of the Position Statement, including representatives from medical colleges, and peak bodies and organisations including consumers.

This Position Statement sets out evidence-based recommendations (EBRs) and consensus-based recommendations (CBRs) regarding the use of FNA and core biopsy in the BreastScreen Australia program.

This Position Statement is not intended to provide guidance on the use of biopsy techniques outside of the BreastScreen Australia program and applies only to the assessment of screen-detected abnormalities.

For guidance on the investigation of new breast symptoms please refer to Cancer Australia's *Investigation of a new breast symptom – a guide for general practitioners* (https://canceraustralia.gov.au/publications-and-resources/cancer-australia-publications/investigation-new-breast-symptom-guide-general-practitioners). This guide indicates steps to be taken in investigating symptoms that could be breast cancer, and provides information about the triple test approach to diagnosis.

This Position Statement has been endorsed by BreastScreen Australia Program Management Group (BSA PMG), BreastScreen Australia National Quality Management Committee (BSA NQMC), Breast Cancer Network Australia (BCNA), Breast Surgeons of Australia and New Zealand (BreastSurgANZ), the Royal Australian and New Zealand College of Radiologists (RANZCR), and the Australian Health Ministers' Advisory Council's Standing Committee on Screening (AHMAC SCoS).

BreastScreen AUSTRALIA
A joint Australian, State and Territory Government Program

The Royal Australian and New Zealand College of Radiologists

Breast Cancer Network Australia

BreastSurgANZ

[‡] Search period for evidence review: 01 January 2000 – 31 July 2018.

Background

The assessment of screen-detected abnormalities in the BreastScreen Australia program is based on assessing breast lesions using the "triple test", comprising clinical assessment (medical history and clinical breast examination), radiological assessment (mammography and/or ultrasound) and pathological assessment (needle biopsy).

Needle biopsy plays a key role in the pathological assessment of screen-detected lesions. FNA and core biopsy (including vacuum-assisted core biopsy) are the two needle biopsy methods available, each with their own benefits and limitations, and varying degrees of sensitivity and specificity depending upon the clinical circumstance. A summary of specific advice on the use of FNA or core biopsy based on lesion type in the BreastScreen Australia program is provided in Table 1. A summary of the benefits and limitations of each technique is provided in Table 2.

Guidance

1. All needle biopsies performed as part of the BreastScreen Australia program should be reviewed and documented in the context of a multidisciplinary team meeting. [CBR§]

2. It is recommended that needle biopsy be performed using image guidance (either ultrasound or mammography). As per the BreastScreen Australia data dictionary, the guidance method should be recorded.** [CBR§]

Core Biopsy

3. Core biopsy (including vacuum-assisted core biopsy) is the procedure of choice for the assessment of the majority of screen-detected breast abnormalities. Core biopsy provides histological confirmation of invasive status of malignant breast lesions, tumour subtype, and an indication of tumour grade in breast malignancies, which cannot be reliably obtained from FNA. In addition, it is recommended that assessment of receptor/biomarker status (ER/PR and HER2 status) be performed on core biopsy specimens (The Royal College of Pathologists of Australasia 2018). This information is important in guiding pre-operative treatment planning and informing patient decision-making. Core biopsy also aids in the definitive diagnosis of benign lesions and, in the context of a screening program, reduces the need for repeat procedures compared with FNA. [EBR††]

FNA

4. The use of FNA in the screening setting is appropriate for simple cysts, some complex cystic lesions, axillary lymph nodes‡‡ and rare situations where a core biopsy is not possible (for example in women with lesions close to a breast implant capsule or in some women on anticoagulation therapy). [CBR§]

§ Consensus-based recommendation (CBR) – a recommendation formulated in the absence of systematically reviewed evidence, based on expert opinion and formulated via a deliberative process that sought to achieve consensus.

** Australian Institute of Health and Welfare 2015. BreastScreen Australia data dictionary: version 1.1. Cancer series no. 92. Cat. no. CAN 90. Canberra: AIHW

†† Evidence-based recommendation (EBR) – a recommendation formulated after a systematic review of the evidence, with a clear linkage from the evidence base to the recommendation.

‡‡ Core biopsy may be appropriate, where technically feasible, for the investigation of axillary lymph nodes in situations where there is a large asymmetrical axillary lymph node and no known primary lesion in the breast.

Table 1: Circumstances where FNA and/or core biopsy are appropriate in the BreastScreen Australia program (see Guidance for further details and exceptional circumstances)[§§]

Lesion type on imaging (identified through the BreastScreen Australia program)	Recommended pathological investigation[***]	
	Fine needle aspiration (FNA)	**Core biopsy (including vacuum assisted core biopsy; VACB)**
1. Simple cyst	Asymptomatic simple cysts generally do not require needle biopsy.	
	If fluid from a simple cyst is aspirated for diagnostic purposes, a sample of the fluid should be sent for cytopathological assessment for confirmation of imaging findings.	Core biopsy is not recommended.
2. Complex cystic lesion	FNA is appropriate. If fluid is aspirated, it should be sent for cytopathological assessment. However, core biopsy is required if: • no material is aspirated, • no definitive benign diagnosis is provided, • there is a residual mass.	Core biopsy is appropriate.
3. Circumscribed solid mass lesion	FNA is not recommended.	Core biopsy is recommended.
4. Spiculated lesion	FNA is not recommended.	Core biopsy is recommended.
5. Architectural distortion	FNA is not recommended.	Core biopsy is recommended.
6. Calcifications with no mass lesion	FNA is not recommended.	Core biopsy is recommended with a strong preference for VACB.
7. Lymph node	FNA or core biopsy is appropriate.	
8. Multiple cystic lesions	Manage as per single simple cyst and complex cystic lesion.	
9. Multiple circumscribed solid mass lesions	Manage as per single circumscribed solid mass lesion, noting that not every lesion may need to be biopsied.	
10. Multiple suspicious solid lesions	FNA is not recommended.	Multiple suspicious solid lesions require a definitive diagnosis by core biopsy, of more than one lesion. At least the two furthest apart lesions or the two most suspicious lesions on imaging, should be sampled by core biopsy.

[§§] This Position Statement is not intended to provide guidance on the use of biopsy techniques outside of the BreastScreen Australia program and applies only to the assessment of screen-detected abnormalities.

[***] Needle biopsy is recommended to be performed under image guidance (either ultrasound or mammography). As per the BreastScreen Australia data dictionary, the guidance method should be recorded.

Table 2: Summary of benefits and limitations of fine needle aspiration and core biopsy*

	Fine needle aspiration	Core biopsy
Sensitivity and specificity		
Sensitivity (95% CI)†††	74% (72-77)‡‡‡	87% (84-88) ‡‡‡
Specificity (95% CI)§§§	96% (94-98) ‡‡‡	98% (96-99) ‡‡‡
Procedural advantages and disadvantages		
Ability to distinguish between *in situ* and invasive cancer	Low	High
Degree of invasiveness of technique	Low	Low to moderate
Success rate (rate of sufficient sampling)	Moderate	High
Complication rate	Very low	Low
Use of local anaesthetic	Optional	Required
Time taken to perform biopsy	Short duration (5-10 mins)	Moderate duration (15-20 mins)
Assessment of prognostic and predictive biomarkers		
Ability to assess tumour grade****	Low	Moderate to High
Ability to assess HER2 and ER/PR receptors	Receptor testing is recommended on core biopsies of the primary tumour††††	

Source: *Willems 2012: Table 1, page 290; supplemented by Mitra 2016: Table 1, page 2.

††† The sensitivity of a diagnostic test quantifies its ability to correctly identify subjects with the disease. It is the proportion of true positives that are correctly identified by the test.

‡‡‡ Wang 2017 – the limitations of this review are discussed within the text of the Position Statement including that Ultrasound guidance was used in 5 of the 12 studies included in Wang.

§§§ The specificity of a diagnostic test is the ability of a test to correctly identify subjects without the disease. It is the proportion of true negatives that are correctly identified by the test.

**** Using Nottingham histological score (Elston, CW; Ellis, IO. Pathologic prognostic factors in breast cancer. I. The value of histological grades in breast cancer. Experience from a large study with long-term follow-up. Histopathology 19(5):403–10. Republished Histopathology 41:154–161. 2002).

†††† Royal College of Pathologists of Australasia 2018

Abbreviations: ER, oestrogen receptor; HER2, human epidermal growth factor receptor 2; PR, progesterone receptor;

Context

The use of biopsy techniques for the assessment of suspicious lesions detected by screening mammograms varies across Screening and Assessment Services (SAS) within the BreastScreen Australia program. Accurate biopsy information is essential as women with screen-detected lesions and their health professionals make decisions on their management options using this information.

As part of the development of this Position Statement, a high-level review was undertaken to identify and evaluate up-to-date clinical evidence and current national and international guidelines on the use of FNA and core biopsy techniques in the screening setting. In addition, an analysis of available BreastScreen Australia data was undertaken to provide contextual information regarding trends between 2004 and 2015 in the use of FNA and core biopsy, and the extent to which National Accreditation Standards (NAS) have been met by FNA and core biopsy (albeit for the differing circumstances in which they are used).

Methodology and Scope

This Position Statement is based on:

- a review of high-level published peer-reviewed, clinical evidence (01 January 2000 to 31 July 2018) relating to the use of FNA and core biopsy in the context of mammographically-detected breast abnormalities;
- a review of recent national and international guidelines on the use of FNA and core biopsy for mammographically-detected breast abnormalities;
- an analysis of National Accreditation Standard (NAS) data from the BreastScreen Australia program (2004-2015); and
- the clinical expertise of a multidisciplinary, Expert Advisory Group established by Cancer Australia to provide expert input into the development of the Position Statement.

The scope of this Position Statement encompasses the use of FNA and core biopsy in the BreastScreen Australia Program.

The research questions guiding the high-level review of recent evidence were:

1. *In women with suspicious lesions detected by breast cancer screening programs[‡‡‡‡], what is the diagnostic accuracy, reliability and reproducibility of FNA compared with core biopsy for the detection of (a) DCIS or (b) invasive breast cancer?*

2. *In women with suspicious lesions detected by breast cancer screening programs[§§§§], what are the clinical consequences of FNA compared with core biopsy for the detection of (a) DCIS or (b) invasive breast cancer?*

Searches were undertaken in EMBASE and Medline, the Cochrane Library, the websites of peak cancer and health technology assessment agencies, and scanning of the reference lists of included studies for additional relevant studies that might not have been identified in the formal literature search. The search cut-off date was 31 July 2018.

‡‡‡‡ Breast cancer screening includes routine and population-based breast cancer screening
§§§§ Breast cancer screening includes routine and population-based breast cancer screening

Recent Australian and international guidelines and Position Statements were also sourced.

An analysis of BreastScreen Australia data was undertaken to provide local context. The data analysis is seen as ancillary to the evidence from the high-level review of clinical evidence. The data analysis addressed the following questions:

> Question 1: What are the trends in use of FNA and core biopsy in the BreastScreen Australia program?
>
> Question 2: How have FNA and core biopsy performed, as related to their respective National Accreditation Standard (NAS)?
>
> Question 3: What are the differences in BreastScreen Australia Screening and Assessment Service (SAS) performance outcomes as related to their use of FNA and core biopsy?

A multidisciplinary Expert Advisory Group was established by Cancer Australia to oversee the development of the Position Statement, provide expert opinion into the development of evidence-based content, and provide advice on the recommendations of the Position Statement. The Expert Advisory Group included representatives who work within the BreastScreen Australia program from the Royal College of Pathologists of Australasia, the Royal Australian and New Zealand College of Radiologists, Breast Surgeons of Australia and New Zealand, and the Australasian Society of Breast Physicians. The Expert Advisory Group also included consumer representatives from the Breast Cancer Network Australia, a BreastScreen Australia jurisdictional Program Manager representative from the BreastScreen Australia National Quality Management Committee, an epidemiologist, as well as observers from the Department of Health and Cancer Australia.

For further information refer to the *Technical Report: Position Statement on the use of fine needle aspiration (FNA) and core biopsy of the breast in the BreastScreen Australia program: High level review of recent evidence and existing national and international guidelines*.

Interpretation of the evidence

A focused evidence review was conducted which included studies that compared FNA and core biopsy in women with breast lesions (where the women had both FNA and core biopsy procedures) and that had assessed at least one outcome of interest (as defined by the Expert Advisory Group). This was to ensure that the evidence was from a direct comparison of FNA and core biopsy, but the review included women with symptomatic lesions as well as lesions found in mammographic screening programs. The aim was to limit the impact of potential bias due to differences in characteristics of women or lesions if only one type of biopsy is performed on a lesion.

Sensitivity and specificity of FNA and core biopsy (including vacuum-assisted core biopsy)

Results from a published systematic review and meta-analysis of twelve diagnostic accuracy studies by Wang 2017 showed that core biopsy had significantly higher sensitivity, and similar specificity to FNA. Wang 2017 reported a pooled sensitivity for core biopsy of 87% (95% CI, 84%-88%, I^2 = 88.5%) and for FNA of 74% (95% CI, 72-77%, I^2 = 88.3%). The pooled specificity for core biopsy was 98% (95% CI, 96%-99%, I^2 = 76.2%) and for FNA was 96% (95% CI, 94%-98%, I^2 = 39.0%). Ultrasound guidance was only used in 5 of the 12 studies included in Wang 2017, whereas ultrasound guidance for breast FNA has been standard practice in Australia since 1986.

Similar observations regarding the relative sensitivity and specificity of core biopsy, VACB and FNA were made in two prospective cohort studies (Lieske 2006 and Bonifacino 2005). Results from Bonifacino 2005 revealed that absolute sensitivity was higher for VACB than FNA (97% versus 77%, respectively when all categories of lesion types were included). VACB samples a greater tissue volume than conventional core biopsy. VACB is generally used to sample very small or very diffuse lesions, particularly those presenting with microcalcifications. VACB can be used under ultrasound, mammography or Magnetic Resonance Imaging (MRI) guidance.

When assessing non-palpable lesions (which are likely to make up a substantial proportion of lesions identified via mammographic screening), sensitivity was substantially higher for core biopsy (84% (95% CI, 81%-87%, I^2 =94.6)) compared with FNA (68%; (95% CI, 64%-72%, I^2 = 86.8)) (Wang 2017). In similar circumstances, the sensitivity of core biopsy was better than that of FNA, while their specificities were similar.

Core biopsy – Advantages and disadvantages

Core biopsy is a common breast biopsy technique performed by pathologists, radiologists, breast physicians or surgeons. The patient receives local anaesthetic and a small incision is made in the breast. A hollow needle between 10 and 16 gauge is then inserted into the breast through this incision and is guided to the lesion with an imaging test or by palpation.

VACB is another core biopsy technique that is also used to diagnose breast lesions. Through a small incision or cut in the skin, a biopsy needle is inserted into the breast and, using a vacuum-assisted instrument, several tissue samples are taken. The vacuum draws tissue into the centre of the needle and a rotating internal trocar then cuts the tissue and the sample is retrieved.

The core biopsy method removes a cylindrical (core) sample of the lesion that is later histologically analysed. As a result, more intact tissue is removed with architectural preservation during a core biopsy than with FNA biopsy, enabling core biopsy to distinguish between *in situ* and invasive cancer. Both tests are a sampling procedure. Multiple core biopsies can be performed through the same incision, while multiple FNA can be performed of a lesion from different angles. Standard tissue processing and preparation of core biopsy samples takes longer than for FNA samples. Histological analysis of core biopsy samples may take one to three days. Core biopsy can be performed on palpable or non-palpable lesions and a range of imaging guidance techniques can be utilised, including ultrasound, mammography and MRI.

From the evidence review, the published data showed that the advantages of core biopsy are that it has a lower rate of inadequate sampling and requires fewer repeat tests (Willems 2012). The accuracy of core biopsy is not impacted as heavily by the level of operator experience as FNA and consequently is associated with a substantially higher success rate in terms of specimen adequacy and definitive diagnosis (Willems 2012). The histological result of core biopsy has a moderate to high ability to grade tumours and is recommended for the assessment of ER/PR, HER2 and Ki67 proliferation rates (Lukasiewicz 2017, Mitra 2016, Willems 2012 and The Royal College of Pathologists of Australasia 2018). The accurate assessment of biomarkers/receptor status is important for consideration of neoadjuvant systemic therapy. The scar resulting from the core biopsy track can aid correlation of biopsy site with the open surgical biopsy specimen.

Consideration should be given to placing a clip or a marker at the completion of the core biopsy, particularly in situations where a substantial proportion of the lesion may be removed

by the biopsy process. Lesion marker clips are also used when multiple lesions are biopsied, and to assist multimodality lesion correlation.

FNA – Advantages and disadvantages

FNA is a commonly used breast biopsy procedure undertaken by radiologists, pathologists, breast physicians or surgeons. A 22-25 gauge needle is inserted into the breast and used to remove some fluid or cells from the breast lesion of interest. Single or multiple samples are taken from the breast lesion and these are then cytologically assessed on smear preparations.

The performance of FNA is operator-dependent. In Lieske 2006 it is noted that FNA is more operator-dependent than core biopsy, and that an adequately trained and experienced cytopathologist skilled in the interpretation of FNA and an experienced aspirator is necessary to reduce the number of non-diagnostic and inadequate FNA samples. FNA requires specific expertise which is likely to diminish with the reduced use of FNA within the BreastScreen Australia program.

Depending on the experience and expertise of the operator and on the staining process used, rapid provisional FNA results can be available within 5 minutes to one hour (utilising rapid on-site reporting - if a cytopathologist is available on site). If rapid on-site reporting is not available, it can take a few hours to one day to receive an FNA result, depending on the speed of delivery to the laboratory.

FNA is regarded as minimally-invasive, with a lower chance of complications and no requirement for local anaesthesia (although local anaesthesia is used by some facilities). FNA is undertaken with ultrasound guidance for palpable and non-palpable lesions. FNA is not able to distinguish *in situ* and invasive cancers and is less specific when diagnosing pre-invasive lesions and borderline lesions such as papillary lesions.

While FNA is minimally invasive and provides a rapid diagnosis, it does not demonstrate histological architecture, which can make distinguishing *in situ* and invasive lesions and the interpretation of borderline lesions difficult. FNA is not suitable for tumour grading. Whilst ER/PR and HER2 receptor assessment may be undertaken using a cell block preparation, national guidelines for receptor testing recommend these are done on core biopsy specimens (The Royal College of Pathologists of Australasia 2018).

Diagnostic performance of FNA and core biopsy

While it is important to note that there are limitations to the published evidence (e.g. concerns regarding the level of bias and applicability of international studies to Australian settings), there did not seem to be a statistically significant difference between experienced pain levels, overall survival or tumour recurrence when comparing FNA and core biopsy (Wong 2009). Most data for clinical impact outcomes were at high risk of bias (unadjusted findings from cohort studies).

There is a difference between FNA and core biopsy in rates of inadequate/unsatisfactory sampling; that is, the inability of an initial biopsy (FNA or core biopsy) to obtain a diagnostic sample for testing. Inadequate sampling often results in the need for a repeat needle biopsy, incurring additional costs and exposure to the risks associated with the procedure (Mak 2012). This may cause the patient anxiety, discomfort and inconvenience, especially when required to return on another day. Inadequate FNA samples can be rectified by immediate repeat FNA if a cytopathologist is available to assess the initial sample adequacy.

Rapid on-site reporting of the FNA sample allows for triage of breast lesions. A benign diagnosis by FNA as part of the triple test assessment requires no further biopsy, saving the cost and the potential risk of increased complications of a core biopsy, while with rapid on-site reporting, an atypical, suspicious of malignancy or malignant diagnosis can go on to immediate core biopsy. A rapid provisional diagnosis by rapid on-site reporting performed by a cytopathologist can also reduce patient anxiety and facilitate immediate management planning and discussion.

Core biopsy may be associated with more frequent and more pronounced haematomas. Pain is typically a complication associated with both biopsy techniques. Additionally, Lukasiewicz 2017 noted that haematoma and discomfort may occur following either biopsy procedure, but is more common following core biopsy than FNA. Mitra 2016 and Willems 2012 also include infection and pneumothorax as possible complications associated with FNA and core biopsy. However, both reviews note that pneumothorax is very rare for either biopsy procedure.

Use of local anaesthesia

As noted above, due to the invasive nature of breast biopsy, local anaesthesia is sometimes used to decrease patient discomfort and pain during the procedure. Local anaesthesia is used occasionally for FNA, mostly in cases when the patient is anxious about the procedure, and always for core biopsy procedures.

Analysis of data from the BreastScreen Australia program

As part of the development of this Position Statement, an analysis was undertaken of aggregated data from the BreastScreen Australia program collected during 2004-2015. These data were submitted by state and territory BreastScreen Australia services as part of data reporting in the National Accreditation program. This data analysis was undertaken to provide contextual information regarding:

- any changes in the use of FNA and core biopsy in the BreastScreen Australia program over time,
- the extent to which individual BreastScreen Australia National Accreditation Standards (NAS) have been met by FNA and core biopsy (albeit for the differing clinical circumstances in which they are used),
- relevant BreastScreen Australia Screening and Assessment Services (SAS) performance outcomes according to their use of these procedures within the BreastScreen Australia program. Performance outcomes included: detection rates for invasive cancers and DCIS; small invasive cancer detection rates; diagnosis made without need for open biopsy; interval cancer rates; assessment time to gain a definitive outcome; and recommendations for early review for further assessment.

In relation to the service performance outcomes, the findings of this study of data routinely collected by BreastScreen Australia are regarded as ancillary to the published evidence which included more appropriately designed research studies and data that cover the broader range of outcomes required to more fully compare the performance of core biopsy and FNA. Results of these analyses warrant cautious interpretation due to the observational nature of the study. This introduces potential confounding. Also, the limited routine data that are available are inadequate to control for confounding. Controlling for confounding would require linking biopsy method with outcomes for individual women.

Outcomes

Data were extracted from routine BreastScreen Australia accreditation data reports for 2004-2015. Little use of core biopsy was made prior to 2004 and the central collection of data on outcomes of FNA and core biopsy specifically was phased out circa 2015. Relevant SAS performance outcomes according to FNA and core biopsy were reviewed. FNA and core biopsy results were also compared with their respective FNA and core biopsy NAS, although due to non-equivalence of women receiving these procedures, results were used to provide a context only and not to provide a comparative assessment of the technical performance of FNA and core biopsy.

Overall the data analysis found the following:

- The proportion of needle biopsies that were FNAs as opposed to core biopsies reduced from approximately 55% in 2004-2006 to 30% in 2013-2015, with marked variation across BreastScreen Australia services at both time points.
- In general, both FNA and core biopsy met their NAS while recognising that the clinical circumstances in which they were used, and the type of lesion being assessed are non-equivalent. A continuing improvement over time in meeting the NAS for both methods was observed.

The clinical significance of these findings and causality attributable to the needle biopsy method ratio cannot be determined from these data in isolation, and should be interpreted in the context of the broader evidence available.

When service performance outcomes were used as program outcome indicators comparing groups of SAS rather than individual SAS:

- A difference was evident, indicating a higher 0 to <12 month interval cancer rate for SAS with a higher FNA to core biopsy ratio, which persisted after adjusting for time period.
- A difference was also evident, indicating a corresponding higher 12 to 24 month interval cancer rate for SAS with a higher FNA to core biopsy ratio, although the evidence was weaker.
- The percentage of women attending screening who were recommended for early review for further assessment tended to be higher for BreastScreen Australia services with a higher FNA to core biopsy ratio, which persisted after adjusting for time period.

Australian and International clinical guidance on the use of FNA or core biopsy

A search was carried out for national and international evidence-based clinical practice guidelines and position statements on the use of FNA and/or core biopsy after breast cancer screening[*****] (published from 2008 onwards). Eleven clinical guidance documents met the eligibility criteria for the review.

The search for Australian clinical guidance identified two documents. One was developed by BreastScreen Australia Clinical Advisory Committee (CAC) (BreastScreen Australia 2017) and the other by Cancer Australia, *Investigation of a new breast symptom: a guide for*

[*****] Breast cancer screening includes routine and population-based breast cancer screening

General Practitioners (INBS) (Cancer Australia 2017). Only the BreastScreen Australia 2017 guidance was specifically targeted to the screening setting. Both documents indicated a preference for the use of core biopsy, with BreastScreen Australia 2017 recommending "*the use of FNA in the screening setting should be limited to cysts, lymph nodes and the rare situations where core biopsy is not possible*. *Where possible core biopsy, including vacuum assisted biopsy, should be the procedure of choice*". Cancer Australia's 2017 clinical guidance advised "Core biopsy is preferable for the investigation of suspicious lesions or when additional information, such as tumour type, histological grade and receptor status of cancer is required". In addition, Cancer Australia's guidance stated that "*FNA cytology may be used to confirm the diagnosis of a cystic lesion or fibroadenoma identified by diagnostic imaging in centres with cytopathological expertise*".

The search for international clinical guidance documents identified nine documents (eight clinical practice guidelines and one position paper). Only one of the identified clinical practice guidelines (National Health Service (NHS) 2016; United Kingdom), and the Position Statement (European Society of Breast Imaging (EUSOBI) 2017 (Sardanelli 2017); Europe) specifically related to breast cancer screening with the remainder of articles making recommendations in the diagnostic setting.; There are also recommendations in the National Comprehensive Cancer Network (NCCN) 2018 guideline that are related to use of core biopsy following mammographic evaluation (which encompasses both screening and diagnostic settings) These international guidance documents are consistent with the BreastScreen Australia CAC 2017 recommendations; in both international guidance documents that relate to the use of testing in screening for breast cancer, one recommends the use of core biopsy over FNA (NHS 2016), and one presents a preference towards core biopsy (EUSOBI (Sardanelli 2017) 2017). The NCCN 2018 recommendations following mammographic evaluation (which may refer to the screening or diagnostic setting) suggest only the use of core biopsy.

Conclusion

Core biopsy and FNA are effective methods for the diagnosis of screen-detected breast lesions. Whilst FNA may offer rapid assessment and is a relatively non-invasive technique, it is less sensitive in comparison to core biopsy and requires specific expertise which is likely to diminish with the reduced use of FNA within the BreastScreen Australia program. Moreover, core biopsies are more suitable for the definitive assessment of borderline and *in situ* lesions, as well as prognostic features and receptor assessment in invasive lesions which is important to guide treatment decisions. FNA may be used under limited circumstances such as for the investigation of cysts or where a core biopsy may not be possible, particularly where rapid on-site reporting is available. In the BreastScreen Australia program, a limited number of services have access to rapid on-site reporting. For the investigation of the majority of screen-detected lesions in the context of the BreastScreen Australia program, core biopsy under image guidance is a sensitive and specific technique and is the procedure of choice for the assessment of the majority of screen-detected breast lesions.

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