



EUROPEAN COMMISSION  
JOINT RESEARCH CENTRE

Directorate F - Health, Consumers & Reference Materials (Ispra)  
**Health in Society**

## European Commission Initiative on Breast Cancer (ECIBC): European guidelines on breast cancer screening and diagnosis

# Question

Should **stereotactic-guided needle core biopsy or stereotactic-guided vacuum assisted needle core biopsy** vs. **ultrasound-guided needle core biopsy or ultrasound-guided vacuum assisted needle core biopsy** be used to diagnose **the presence of breast cancer** in **individuals presenting with breast calcifications**?

<b>POPULATION:</b>	Women with a suspected breast cancer, defined by the presence of calcifications in a recent mammography	<b>BACKGROUND:</b> Calcifications (microcalcifications in previous Breast Imaging Reporting and Data System- BIRADS) constitute about one third of the lesions sampled for cyto/histological examination from patients with screen detected abnormalities (Farshid 2014). In women with calcifications, tissue sampling may be challenging because the suspicious area may not be well demarcated on imaging; calcifications are often not visible on ultrasound (US) and the associated histological change is usually impalpable. These considerations suggest that stereotactic-guided needle core biopsy (NCB) and, in particular, vacuum assisted needle core biopsy (VANCB) should be the preferred modality for sampling these lesions. Ultrasound-guided biopsy is easier and less time consuming so, it is important to assess if ultrasound-guided or stereotactic-guided biopsy is preferable for sampling calcifications. Ductal carcinoma in situ (DCIS) typically presents with calcifications and may be accompanied by invasive carcinoma. Detection of invasion in DCIS predominant cases is important as it may influence the choice of primary surgical treatment, particularly with regards to sentinel node sampling. It is, therefore, important that the area of calcification be adequately
<b>INTERVENTION:</b>	stereotactic-guided needle core biopsy or stereotactic-guided vacuum assisted needle core biopsy	
<b>COMPARISON:</b>	ultrasound-guided needle core biopsy or ultrasound-guided vacuum assisted needle core biopsy	
<b>PURPOSE OF THE TEST:</b>	Diagnosis of breast cancer	
<b>LINKED TREATMENTS:</b>		
<b>ANTICIPATED OUTCOMES:</b>	1) Specificity; 2) Sensitivity; 3) Adverse events: report of pain scores, bleeding, biopsy site infection, risk of metastasis and accelerated tumour growth; 4) Number of re-biopsies: number of additional biopsies that have to be done to make a diagnosis; 5) Wrong planning of surgical interventions: reports of misclassification of DCIS to invasive carcinoma or vice versa; 6) Quality of	

life scores.

**SETTING:**

European Union

**PERSPECTIVE:**

Population (National Health System)

sampled to maximise the chance of detecting invasion on the biopsy specimen. Although approximately two thirds of biopsies performed for assessment of calcifications do not show malignancy, DCIS or invasive carcinoma, a percentage of these biopsies show changes that are of uncertain malignant potential. In particular lesions such as flat epithelial atypia may be accompanied by DCIS. Similarly, some intrinsically benign lesions such as radial scar and papilloma that may, on occasion, present as calcification may be associated with a malignant change. Adequate sampling is imperative to permit a thorough histological examination of the abnormal area and to assess the need for further investigations, treatment or follow up. Another recommendation in the *European Breast Guidelines*, examining the sampling method in suspicious imaging lesions, recommended using needle core biopsy over fine needle aspiration cytology (FNAC). Taking into account this recommendation, in this comparison between US-guidance and stereotactic-guidance the literature search has been limited to NCB and VANCB, excluding FNAC.

Description of the technology

Ultrasound-guided biopsy (NCB or VANCB): sampling of the suspected lesion with a needle ranging from 11 to 18 Gauge in case of NCB and from 8 to 11 Gauge in case of VANCB. The sampling can be assisted by vacuum (VANCB) or not (NCB). A histological sample is obtained. The needle is guided by ultrasound. If the

results are not conclusive, VANCb (in case the first sampling was done using NCB) and then open biopsy are considered.

Stereotactic-guided biopsy (NCB or VANCb): The sampling can be assisted by vacuum (VANCb) or not (NCB). Sampling of the suspected lesion with a needle ranging from 11 to 18 Gauge in case of NCB and from 8 to 11 Gauge in case of VANCb. A histological sample is obtained. The needle is positioned under stereotactic radiographic guidance. It can be performed either in a sitting or lying in prone position, on a special table, and using either mammography or tomosynthesis as a guiding device. If the results are not conclusive, VANCb (in case the first sampling was done using NCB) and then open biopsy are considered.

Management of Conflicts of Interest (Col): Col for all Guideline Development Group (GDG) members were assessed and managed by the Joint Research Centre (JRC) following an established procedure in line with European Commission rules. GDG member participation in the development of the recommendations was restricted, according to Col disclosure. Consequently, for this particular question, the following GDG members were recused from voting: Jan Danes, Lydia Ioannidou-Mouzaka, and Elsa

Pérez. Miranda Langendam was not allowed to vote due to the established rules for external experts.

## Assessment

	JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
PROBLEM	<b>Is the problem a priority?</b> <ul style="list-style-type: none"> <li>○ No</li> <li>○ Probably no</li> <li>○ Probably yes</li> <li>● Yes</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	<p>Calcifications (microcalcifications in previous BIRADS) account for 30-40% of the screen detected lesions with a probability of being malignant of around 13% pending on the type of calcification (1)(2). Calcifications are a typical sign of DCIS, but DCIS might be associated with invasive cancer. Nevertheless, the majority of the lesions that are biopsied because of suspicious calcifications are benign. However, some of these have uncertain malignant potential, like flat epithelial atypia (FEA) or atypical ductal hyperplasia (ADH). Therefore, the clinical consequences are quite variable and depend on the histological diagnosis. It is crucial that the calcifications have been adequately sampled to ensure that women are offered adequate treatment based on the histologically detected lesion that is associated with the calcification. Inadequate sampling of the calcifications could result in false-negative primary biopsies and additionally require further biopsies or surgical interventions.</p>	<p>The GDG selected this question as a priority for ECIBC. As agreement within the GDG could not be reached, voting among the members without CoI resulted in the following: 16 members voted "yes", 1 member voted "probably yes".</p>
TEST ACCURACY	<b>How accurate is the test?</b> <ul style="list-style-type: none"> <li>○ Very inaccurate</li> <li>○ Inaccurate</li> <li>○ Accurate</li> <li>● Very accurate</li> </ul>		<p>The GDG noted that both tests, compared to the reference standard, are very accurate as both have a sensitivity and specificity above 90%. The</p>

	<ul style="list-style-type: none"><li>◦ Varies</li><li>◦ Don't know</li></ul>		reference standard in both comparisons was open biopsy after surgery or follow-up.																																															
DESIRABLE EFFECTS	<p><b>How substantial are the desirable anticipated effects?</b></p> <ul style="list-style-type: none"><li>◦ Trivial</li><li>◦ Small</li><li>● Moderate</li><li>◦ Large</li><li>◦ Varies</li><li>◦ Don't know</li></ul>	<p><b>Part A. Stereotactic-guided needle core biopsy versus reference standard</b></p> <p>Stereotactic-guided needle core biopsy</p> <table><tr><td>Sensitivity</td><td>98 (95 to 99)-pooled</td></tr><tr><td>Specificity</td><td>98 (94 to 99)- pooled</td></tr></table> <table><tr><th rowspan="2">Outcome</th><th rowspan="2">№ of studies (№ of patients)</th><th rowspan="2">Study design</th><th colspan="5">Factors that may decrease quality of evidence</th><th colspan="2">Effect per 1.000 patients tested</th></tr><tr><th>Risk of bias</th><th>Indirectness</th><th>Inconsistency</th><th>Imprecision</th><th>Publication bias</th><th>pre-test probability of 34% <sup>b</sup></th><th>pre-test proba 50% <sup>b</sup></th></tr><tr><td><b>True positives</b> (patients with breast cancer)</td><td rowspan="2">23 studies 5349 patients</td><td rowspan="2">cross-sectional (cohort type accuracy study)</td><td rowspan="2">not serious</td><td rowspan="2">serious <sup>a</sup></td><td rowspan="2">not serious</td><td rowspan="2">not serious</td><td rowspan="2">none</td><td>333 (323 to 337)</td><td>490 (475 to 495)</td></tr><tr><td><b>False negatives</b> (patients incorrectly classified as not having breast cancer)</td><td>7 (3 to 17)</td><td>10 (5 to 25)</td></tr><tr><td><b>True negatives</b> (patients without breast cancer)</td><td rowspan="2">23 studies 5349 patients</td><td rowspan="2">cross-sectional (cohort type accuracy study)</td><td rowspan="2">not serious</td><td rowspan="2">serious <sup>a</sup></td><td rowspan="2">not serious</td><td rowspan="2">not serious</td><td rowspan="2">none</td><td>647 (620 to 653)</td><td>490 (470 to 495)</td></tr><tr><td><b>False positives</b> (patients incorrectly classified as having breast cancer)</td><td>13 (7 to 40)</td><td>10 (5 to 30)</td></tr></table> <p>a. Indirect comparisons. Stereotactic-guided biopsy was compared with a reference standard and accuracy estimates do not represent the effect of the guided method.</p> <p>b. Median prevalence extracted from Dahabreh 2014.</p>	Sensitivity	98 (95 to 99)-pooled	Specificity	98 (94 to 99)- pooled	Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease quality of evidence					Effect per 1.000 patients tested		Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of 34% <sup>b</sup>	pre-test proba 50% <sup>b</sup>	<b>True positives</b> (patients with breast cancer)	23 studies 5349 patients	cross-sectional (cohort type accuracy study)	not serious	serious <sup>a</sup>	not serious	not serious	none	333 (323 to 337)	490 (475 to 495)	<b>False negatives</b> (patients incorrectly classified as not having breast cancer)	7 (3 to 17)	10 (5 to 25)	<b>True negatives</b> (patients without breast cancer)	23 studies 5349 patients	cross-sectional (cohort type accuracy study)	not serious	serious <sup>a</sup>	not serious	not serious	none	647 (620 to 653)	490 (470 to 495)	<b>False positives</b> (patients incorrectly classified as having breast cancer)	13 (7 to 40)	10 (5 to 30)	<p>There is a paucity of studies reporting the use of US guidance for evaluating breast calcifications (microcalcifications in previous BIRADS). This is likely to be due to the limitations of ultrasound in visualising calcifications.</p> <p>For several years, it has been debated in the literature the potential of US to detect mammary calcifications.</p> <p>To date, no imaging modality other than x-ray mammography has an accepted role in the</p>
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## Part B. Ultrasound-guided needle core biopsy versus reference standard

	Ultrasound-guided needle core biopsy <sup>d</sup>
Sensitivity	0.90 to 1.00-range
Specificity	1.00 to 1.00-range

Outcome	No of studies (No of patients)	Study design	Factors that may decrease quality of evidence					Effect per 1.000 patients tested		Test accuracy QoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of 34% <sup>c</sup>	pre-test probability of 50% <sup>c</sup>	
<b>True positives</b> (patients with breast cancer)	2 studies 135 patients	cross-sectional (cohort type accuracy study)	not serious	serious <sup>a</sup>	not serious	Serious <sup>b</sup>	none	306 to 340	450	⊕⊕⊕ LOW
<b>False negatives</b> (patients incorrectly classified as not having breast cancer)								0 to 34	50	
<b>True negatives</b> (patients without breast cancer)	2 studies 135 patients	cross-sectional (cohort type accuracy study)	not serious	serious <sup>a</sup>	not serious	Serious <sup>b</sup>	none	660	500	⊕⊕⊕ LOW
<b>False positives</b> (patients incorrectly classified as having breast cancer)								0	0	

- a. Indirect comparisons. Ultrasound-guided needle core biopsy was compared with a reference standard and accuracy estimates do not represent the effect over stereotactic-guided method.
- b. Based on 2 studies with limited sample size and number of events. Percentage of calcifications: Hahn 2011= 100%; Kim 2008= 100%
- c. Median prevalence extracted from Dahabreh 2014.
- d. Due to scarcity of data, we were unable to perform a meta-analysis for Ultrasound-guided biopsy studies.

detection of mammary calcifications. Despite this, since the implementation and improvement of high-frequency US equipment, the quality of breast US has markedly improved. However, the capability and reliability of this improved US equipment in detecting calcifications has not been adequately studied yet. The GDG noted that with the lower test accuracy estimate,, when using stereotactic-guided biopsy there were 27 more true positives and 27 fewer false negatives per 1000 women with calcifications compared to using ultrasound-guided biopsy (See table labelled part C).

**How substantial are the undesirable anticipated effects?**

- Large
- Moderate
- Small
- Trivial
- Varies
- Don't know

### Part C: Stereotactic-guided needle core biopsy versus ultrasound-guided needle core biopsy

	Stereotactic-guided needle core biopsy	Ultrasound-guided needle core biopsy
Sensitivity	98 (CI 95% = 95 to 99)	Range: 0.90 to 0.99
Specificity	98 (CI 95% = 94 to 99)	Range: 0.99 to 0.99

Outcome	Effect per 1.000 patients tested		Effect per 1.000 patients tested		Test accuracy QoE
	pre-test probability of 34%		pre-test probability of 50%		
	Stereotactic-guided needle core biopsy	Ultrasound-guided needle core biopsy	Stereotactic-guided needle core biopsy	Ultrasound-guided needle core biopsy	
True positives (patients with breast cancer)	333	High sensitivity: 337 Low sensitivity: 306	490	High sensitivity: 495 Low sensitivity: 450	⊕⊕○○ LOW
	4 fewer to 27 more TP in stereotactic-guided needle core biopsy		40 more to 5 fewer TP in stereotactic-guided needle core biopsy		
False negatives (patients incorrectly classified as not having breast cancer)	7	High sensitivity: 3 Low sensitivity: 34	10	High sensitivity: 5 Low sensitivity: 50	
	4 more to 27 fewer FN in stereotactic-guided needle core biopsy		5 more to 40 fewer FN in stereotactic-guided needle core biopsy		
True negatives (patients without breast cancer)	647	653	490	495	⊕⊕○○ LOW
	6 fewer TN in stereotactic-guided needle core biopsy		5 fewer TN in stereotactic-guided needle core biopsy		
False positives (patients incorrectly classified as having breast cancer)	13	7	10	5	
	6 more FP in stereotactic-guided needle core biopsy		5 more FP in stereotactic-guided needle core biopsy		

The GDG noted that with the lower test accuracy estimate,,when using stereotactic-guided biopsy there were 6 fewer true negatives and 6 more false positives per 1000 women with calcifications compared to using ultrasound-guided biopsy.

As agreement within the GDG for the undesirable effects could not be reached, voting among the members without CoI resulted in the following: 1 member voted "moderate", 8 members voted "small" and 8 members voted "trivial". The GDG agrees that the undesirable effects tend to be small.



<p>CERTAINTY OF THE EVIDENCE OF TEST ACCURACY</p>	<p><b>What is the overall certainty of the evidence of test accuracy?</b></p> <ul style="list-style-type: none"> <li>○ Very low</li> <li>● Low</li> <li>○ Moderate</li> <li>○ High</li>   <li>○ No included studies</li> </ul>		<p>The GDG agrees that the overall certainty of the evidence is low, due to the quality of the studies for the ultrasound body of evidence, which only has two studies.</p>
<p>CERTAINTY OF THE EVIDENCE OF TEST'S EFFECTS</p>	<p><b>What is the overall certainty of the evidence for any critical or important direct benefits, adverse effects or burden of the test?</b></p> <ul style="list-style-type: none"> <li>○ Very low</li> <li>○ Low</li> <li>○ Moderate</li> <li>○ High</li>   <li>● No included studies</li> </ul>		<p>No studies were included. No evidence was reviewed on the downstream consequences of the false negatives, etc.</p> <p>The GDG noted the uncertainty concerning the cases that are false negatives on biopsy. What happens to a person who is false negative is very variable. It is possible that in multidisciplinary conferences,</p>

CERTAINTY OF THE EVIDENCE OF MANAGEMENT'S EFFECTS			<p>false negatives are identified due to discordance between imaging and pathology results, and as a result, additional biopsies are recommended. However, other cases might stay undetected for an unknown period of time.</p> <p>Finally, if the lesion remains undetected, the impact will vary depending on the biology of the tumour that has not been diagnosed and on the magnitude of the delay in the diagnosis.</p>
	<b>What is the overall certainty of the evidence of effects of the management that is guided by the test</b>		<p>No studies were included, but the GDG felt there was very little doubt that the histopathology positive breast cancers would be managed appropriately.</p>

	<b>results?</b> <ul style="list-style-type: none"> <li>○ Very low</li> <li>○ Low</li> <li>○ Moderate</li> <li>○ High</li> <li>● No included studies</li> </ul>		
CERTAINTY OF THE EVIDENCE OF TEST RESULT/MANAGEMENT	<b>How certain is the link between test results and management decisions?</b> <ul style="list-style-type: none"> <li>○ Very low</li> <li>○ Low</li> <li>○ Moderate</li> <li>○ High</li> <li>● No included studies</li> </ul>		<p>No studies were included. However, the GDG discussed the certainty that the women receiving the test would move to the next management step.</p> <p>The GDG noted that false positives are referred to surgery; hence, the GDG felt that it was quite certain that this individual would be managed appropriately. When there is a false negative, the GDG had less certainty on whether the</p>

			individual would receive appropriate management during the follow-up.
CERTAINTY OF EFFECTS	<p><b>What is the overall certainty of the evidence of effects of the test?</b></p> <ul style="list-style-type: none"> <li>○ Very low</li> <li>○ Low</li> <li>○ Moderate</li> <li>○ High</li> <li>● No included studies</li> </ul>	We have low certainty to perform a comparison between the two assessed techniques, due to one of them having more information (and better quality) than the other.	No studies were included for the overall certainty as, on one hand, there is low certainty of the two assessed techniques in terms of the accuracy of the data and on the other, there are no included studies for the rest of the aspects.
VALUES	<p><b>Is there important uncertainty about or variability in how much people value the main outcomes?</b></p> <ul style="list-style-type: none"> <li>○ Important uncertainty or variability</li> <li>● Possibly important</li> </ul>	No systematic review was conducted.	The GDG judged that possibly there would be important variability in how women would value the outcomes.

	<p>uncertainty or variability</p> <ul style="list-style-type: none"> <li>○ Probably no important uncertainty or variability</li> <li>○ No important uncertainty or variability</li> <li>○ No known undesirable outcomes</li> </ul>		
<p><b>BALANCE OF EFFECTS</b></p>	<p><b>Does the balance between desirable and undesirable effects favor the intervention or the comparison ?</b></p> <ul style="list-style-type: none"> <li>○ Favors the comparison</li> <li>○ Probably favors the comparison</li> <li>○ Does not favor either the intervention or the comparison</li> <li>● Probably favors the intervention</li> </ul>	<p>No systematic review was conducted.</p>	<p>The GDG judged that probably the balance favours stereotactic-guided needle core biopsy over ultrasound-guided needle core biopsy.</p>

	<ul style="list-style-type: none"> <li>○ Favors the intervention</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>																
RESOURCES REQUIRED	<p><b>How large are the resource requirements (costs)?</b></p> <ul style="list-style-type: none"> <li>○ Large costs</li> <li>○ Moderate costs</li> <li>● Negligible costs and savings</li> <li>○ Moderate savings</li> <li>○ Large savings</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	<table> <tr> <th>Study ID</th><th>Country (year value)</th><th>Test</th><th>Average cost per breast lesion</th></tr> <tr> <td>Hukkinen 2008</td><td>Finland (2005)</td><td>Ultrasound-guided needle core biopsy <sup>a</sup></td><td>176 €</td></tr> <tr> <td rowspan="2">Vimpeli 2008</td><td rowspan="2">Finland (2005)</td><td>Ultrasound-guided needle core biopsy <sup>b</sup></td><td>83 €</td></tr> <tr> <td>Stereotactic-guided needle core biopsy <sup>c</sup></td><td>246 €</td></tr> </table> <p><b>C:</b> Euros. <b>NCB:</b> needle core biopsy.</p> <p>a) The cost of the initial biopsy was 176 € per lesion for US NCB. This cost included costs of radiology and pathology needed for one detected cancer. With the expenses caused by the additional needle biopsies, the need for surgical biopsies and the unnecessary axillary operations due to false-positive findings, the corresponding cost per lesion was 223 € with US NCB.</p> <p>b) The cost of the biopsy was 83 € and included costs of radiology (radiologists, technicians, equipment, disposable supplies), pathology analysis and administrative costs. Ultrasound equipment cost was 3 €.</p> <p>c) The cost of the biopsy was 246 € and included costs of radiology (radiologists, technicians, equipment, disposable supplies), pathology analysis and administrative costs. Stereotaxis equipment cost was 152 €.</p>	Study ID	Country (year value)	Test	Average cost per breast lesion	Hukkinen 2008	Finland (2005)	Ultrasound-guided needle core biopsy <sup>a</sup>	176 €	Vimpeli 2008	Finland (2005)	Ultrasound-guided needle core biopsy <sup>b</sup>	83 €	Stereotactic-guided needle core biopsy <sup>c</sup>	246 €	<p>Regarding ultrasound-guided NCB, differences between Hukkinen and Vimpeli are because Vimpeli did not include surgery costs and, therefore the amount of 83€ was lower than the 176€. Regarding the difference between the 83€ for ultrasound-guided NCB and the 246€ for stereotactic-guided NCB, this was due to the equipment costs, which was 3 € for the ultrasound and 152 € for the stereotaxy.</p> <p>The GDG noted that the costs</p>
Study ID	Country (year value)	Test	Average cost per breast lesion														
Hukkinen 2008	Finland (2005)	Ultrasound-guided needle core biopsy <sup>a</sup>	176 €														
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		Stereotactic-guided needle core biopsy <sup>c</sup>	246 €														

			may be higher with US-NCB than those reported in the Vimpeli and Hukkinen studies, because you may have to re-biopsy more frequently.
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	<p><b>What is the certainty of the evidence of resource requirements (costs)?</b></p> <ul style="list-style-type: none"> <li>○ Very low</li> <li>● Low</li> <li>○ Moderate</li> <li>○ High</li> <li>○ No included studies</li> </ul>		<p><b>Low certainty</b> due to indirectness. Both studies were conducted in Finland and were 10 years old. Costs and resources used may not be applicable to other European settings.</p>
COST EFFECTIVENESS	<p><b>Does the cost-effectiveness of the intervention favor the intervention or the comparison?</b></p> <ul style="list-style-type: none"> <li>○ Favors the comparison</li> </ul>	No relevant economic evaluations were identified.	

	<ul style="list-style-type: none"> <li>○ Probably favors the comparison</li> <li>○ Does not favor either the intervention or the comparison</li> <li>○ Probably favors the intervention</li> <li>○ Favors the intervention</li> <li>○ Varies</li> <li>● No included studies</li> </ul>		
EQUITY	<p><b>What would be the impact on health equity?</b></p> <ul style="list-style-type: none"> <li>○ Reduced</li> <li>● Probably reduced</li> <li>○ Probably no impact</li> <li>○ Probably increased</li> <li>○ Increased</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	No systematic review was conducted.	The GDG reasoned that as the availability of stereotactic-guided NCB is quite low, recommending its use would probably increase inequity regarding its accessibility, therefore probably reducing equity.



ACCEPTABILITY	<p><b>Is the intervention acceptable to key stakeholders?</b></p> <ul style="list-style-type: none"> <li>○ No</li> <li>○ Probably no</li> <li>● Probably yes</li> <li>○ Yes</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	<p>No systematic review was conducted.</p>	<p>The GDG judged that the acceptability for key stakeholders would be as follows.</p> <p><u>For women:</u> US, where women are lying down, may be more comfortable than stereotaxy where there may be more compression and it may be more traumatic for women. Nonetheless, overall the GDG felt that the majority of women would find the intervention acceptable.</p> <p><u>For radiologists:</u> they may be more comfortable with US-guided procedure and may prefer to perform this over stereotaxy.</p> <p>Panel members were concerned about acceptability. Therefore, as agreement within</p>
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			the GDG for the acceptability could not be reached, voting among the members without CoI resulted in the following: <b>11 members voted "probably yes", one member voted "probably no"; three members voted "varies"; and one member voted "yes".</b>
FEASIBILITY	<p><b>Is the intervention feasible to implement?</b></p> <ul style="list-style-type: none"> <li>○ No</li> <li>○ Probably no</li> <li>○ Probably yes</li> <li>● Yes</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	No systematic review was conducted.	The GDG agreed the intervention would be feasible.

## Summary of judgements

	JUDGEMENT							IMPLICATIONS
<b>PROBLEM</b>	No	Probably no	Probably yes	<b>Yes</b>		Varies	Don't know	
<b>TEST ACCURACY</b>	Very inaccurate	Inaccurate	Accurate	<b>Very accurate</b>		Varies	Don't know	
<b>DESIRABLE EFFECTS</b>	Trivial	Small	<b>Moderate</b>	Large		Varies	Don't know	
<b>UNDESIRABLE EFFECTS</b>	Large	Moderate	<b>Small</b>	Trivial		Varies	Don't know	
<b>CERTAINTY OF THE EVIDENCE OF TEST ACCURACY</b>	Very low	<b>Low</b>	Moderate	High			No included studies	
<b>CERTAINTY OF THE EVIDENCE OF TEST'S EFFECTS</b>	Very low	Low	Moderate	High			<b>No included studies</b>	
<b>CERTAINTY OF THE EVIDENCE OF MANAGEMENT'S EFFECTS</b>	Very low	Low	Moderate	High			<b>No included studies</b>	
<b>CERTAINTY OF THE EVIDENCE OF TEST RESULT/MANAGEMENT</b>	Very low	Low	Moderate	High			<b>No included studies</b>	
<b>CERTAINTY OF EFFECTS</b>	Very low	Low	Moderate	High			<b>No included studies</b>	
<b>VALUES</b>	Important uncertainty or variability	<b>Possibly important uncertainty or variability</b>	Probably no important uncertainty or variability	No important uncertainty or variability			No known undesirable outcomes	

	JUDGEMENT							IMPLICATIONS
<b>BALANCE OF EFFECTS</b>	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	<b>Probably favors the intervention</b>	Favors the intervention	Varies	Don't know	
<b>RESOURCES REQUIRED</b>	Large costs	Moderate costs	<b>Negligible costs and savings</b>	Moderate savings	Large savings	Varies	Don't know	
<b>CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES</b>	Very low	<b>Low</b>	Moderate	High			No included studies	
<b>COST EFFECTIVENESS</b>	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	<b>No included studies</b>	
<b>EQUITY</b>	Reduced	<b>Probably reduced</b>	Probably no impact	Probably increased	Increased	Varies	Don't know	
<b>ACCEPTABILITY</b>	No	Probably no	<b>Probably yes</b>	Yes		Varies	Don't know	
<b>FEASIBILITY</b>	No	Probably no	Probably yes	<b>Yes</b>		Varies	Don't know	

## Conclusions

**Should stereotactic-guided needle core biopsy or stereotactic-guided vacuum assisted needle core biopsy vs. ultrasound-guided needle core biopsy or ultrasound-guided vacuum assisted needle core biopsy be used to diagnose breast cancer in individuals with breast calcifications?**

TYPE OF RECOMMENDATION	Strong recommendation against the intervention  ○	Conditional recommendation against the intervention  ○	Conditional recommendation for either the intervention or the comparison  ○	Conditional recommendation for the intervention  ○	Strong recommendation for the intervention  ●
<b>RECOMMENDATION</b>	In individuals presenting with breast calcifications, the ECIBC's Guidelines Development Group recommends the use of stereotactic-guided needle core biopsy over ultrasound-guided needle core biopsy to diagnose the presence of breast cancer (strong recommendation, low certainty evidence).				
<b>JUSTIFICATION</b>	The GDG noted that while stereotactic guidance is favourable, in practice there was low certainty in the evidence reviewed that compared stereotactic to ultrasound guidance. Despite this, the GDG agreed that, when comparing stereotactic-guided NCB with open biopsy, the recommendation was strong and the certainty of this evidence was high. However, when comparing stereotactic guidance to ultrasound guidance, as there were no studies directly comparing both interventions, the overall certainty of the evidence was low, due to the low quality of the evidence for ultrasound guidance compared to open biopsy, as well as the fact that only two studies were found on ultrasound guidance. The GDG agreed to issue a strong recommendation in favour of the use of stereotactic guidance for biopsy evaluation of breast calcification despite the low certainty of the evidence. The radiologist GDG members advised the group that this technique poses less risk for the individual and permits accurate visualisation and targeted biopsy of the calcification. The GDG histopathologists confirmed that their experience indicates that stereotactic-guided biopsy is far superior to ultrasound-guided biopsy in obtaining representative tissue samples of calcification for microscopic evaluation.				
<b>SUBGROUP CONSIDERATIONS</b>	None considered.				
<b>IMPLEMENTATION CONSIDERATIONS</b>	1. Training for radiologists who currently biopsy for calcifications using US-NCB.  2. The GDG noted that effective communication strategies are critical so that women can make informed-decisions throughout all phases of the screening process.  3. In settings where stereotactic equipment is not widely available there may be a need to consider how to refer patients to a reference setting where they can have access to stereotactic-guided biopsy.				
<b>MONITORING AND EVALUATION</b>					

**RESEARCH PRIORITIES**

1. Research was suggested to be done by the GDG on communication strategies for diagnostic tests that are used in different settings, in order to promote informed decision-making by women.

## References Summary

1. Farshid, G., Sullivan, T., Jones, S., Roder, D.. Performance indices of needle biopsy procedures for the assessment of screen detected abnormalities in services accredited by BreastScreen Australia. Asian Pac J Cancer Prev; 2014.
2. Rominger, M., Wisgickl, C., Timmesfeld, N.. Breast microcalcifications as type descriptors to stratify risk of malignancy: a systematic review and meta-analysis of 10665 cases with special focus on round/punctate microcalcifications. Rofo; Dec 2012.