



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 **needle core biopsy** vs. **fine needle aspiration cytology** be used to diagnose **breast cancer** in **women with suspicious breast lesions in mammography**?

POPULATION: women with suspicious breast lesions in mammography

INTERVENTION: needle core biopsy

COMPARISON: fine needle aspiration cytology

PURPOSE OF THE TEST: Replacement

LINKED TREATMENTS: Breast cancer treatments

ANTICIPATED OUTCOMES: Sensitivity, specificity, adverse events, number of re-biopsies, wrong planning of surgical interventions, and quality of life.

SETTING: European Union

PERSPECTIVE: Population (National Health System)

BACKGROUND In the assessment of women who have a screening mammography showing suspicious findings, the aim is to minimise the need for surgical removal of non-clinically relevant lesions and, at the same time, to minimise the risk of missing a clinically relevant lesion. The only way to significantly reduce both risks is to perform pre-surgical cytology or histopathology assessment of suspicious lesions. Currently, there are two non-operative methods to obtain samples of a breast lesion: fine needle aspiration cytology involves the removal of cells which does not conserve the architectural structure of the lesion and needle core biopsy which removes tissue from the lesion. Depending on the type of lesion the needle core biopsy may

be carried out under ultrasound or stereotactic guidance, utilising needles of varying calibre and vacuum assisted technology where indicated.

Mass lesions and asymmetric densities represent about 30-40% of the suspicious breast lesions that are sampled for cytological/histological assessment in the mammographic screening population and about 70% of the sampled lesions in symptomatic women (1). Sampling of these lesions is usually less challenging than that of other radiological findings such as calcifications (microcalcifications in previous BIRADS) because these changes are usually visible on ultrasound.

Architectural distortions comprise about 7% of the lesions undergoing cytological/histological sampling in screening. In this population, sampling may be more challenging than in mass lesions, because the limits of the lesions are not clearly defined and the changes may not be visible on ultrasound.

Calcifications constitute about 30% of the lesions undergoing cytological/histological sampling in screening. Representative sampling tends to be more difficult and more expensive because calcifications are impalpable and are rarely visible on ultrasound. Despite this calcification may be associated with in situ and invasive carcinoma. The overall risk for each diagnosis in a woman with calcifications is approximately 6%.

Fine needle aspiration cytology (FNAC) is a minimally invasive diagnostic method performed with a 20-25 gauge needle. This procedure can provide rapid diagnosis (less than 30 minutes) and reduce biopsy related pain due to the use of a smaller needle size. Factors such as tumour size (small lesions), the type of suspicious mammographic lesion (in particular in case of calcifications) and the use of freehand method without any radiological guidance have been documented to affect the rate of inconclusive results (50). Since the architectural pattern of a lesion is not preserved in FNAC, it is not possible to accurately distinguish in situ from invasive carcinoma. In view of this, FNAC samples are not suitable for assessment of histological tumour type, grade and biomarker profile. It is important to have access to this information pre-operatively to make decisions regarding type of surgery and in the consideration of recommendations regarding neoadjuvant chemotherapy for the treatment of invasive breast cancer.

Needle core biopsy (NCB) involves sampling of the suspicious lesion with a needle ranging in size from 8G to 11G for the vacuum assisted systems and 12G to 18G for other types of needle core biopsy (50). At the time of writing, NCB is considered a standard procedure for the evaluation of most breast lesions. In some countries, FNAC is still used as the first line of sampling due to ease of access and lower cost. The pathological analysis of the tissue sample taken by NCB or

vacuum assisted NCB (VANCB) permits evaluation of cellular and architectural features of a lesion. This enables distinction of in situ from invasive carcinoma and determination of prognostic and predictive biological information including histological type, grade and biomarker receptor status. This greatly improves the pre-surgical decision-making and management process. The use of tissue biopsy has been related to mildly increased pain, risk of haematoma due to larger needle size and, on rare occasions, an increased risk of infection compared with FNAC.

Although the role of FNAC is questionable due to rates of inadequacy and limitations in characterising and profiling a tumour as outlined above, it may be useful in the assessment of some types of abnormality. In deciding to utilise FNAC or NCB it is important to consider the clinical and imaging characteristics of the lesion and ability or not to visualise the lesion on ultrasound.

Open biopsy is a surgical procedure that is diagnostic and frequently therapeutic at the same time. It is the most invasive method to obtain a diagnosis and is performed only when it has not been possible to reach a diagnosis using the non-invasive techniques described above.

Some authors have hypothesised that cell or tissue sampling may increase the risk of metastases due to displacement of cancer cells. Although there is a large consensus regarding the benefits of cytological and/or histological assessment prior to surgery, this issue has been addressed in the systematic review with evaluation of any indirect evidence or related research.

Management of Conflicts of Interest (Col): Col for all Guidelines 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: Roberto d'Amico, Jan Danes and Miranda Langendam. Lydia Mouzaka was restricted from voting, as a preventive measure, as the Col information was not provided, but after its provision it was assessed and no Col were found.

Assessment

	JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
PROBLEM	<p>Is the problem a priority?</p> <ul style="list-style-type: none"> ○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know 	<p>In the assessment of women who have a screening mammography showing suspicious findings, the aim is to minimise the risk of surgery for non-clinically relevant lesions and, at the same time, minimise the risk of missing a clinically relevant lesion. The only way to significantly reduce both risks is to have a pre-surgical cytology or histopathology assessment of suspicious lesion.</p>	<p>The GDG prioritised this question for the ECIBC.</p>
TEST ACCURACY	<p>How accurate is the test?</p> <ul style="list-style-type: none"> ○ Very inaccurate ○ Inaccurate ● Accurate ○ Very accurate ○ Varies ○ Don't know 	<p>From a total of 9 studies directly comparing the accuracy of NCB to FNAC in a population of 1498 women with suspicious lesions in mammography, the pooled estimates were:</p> <p>Test accuracy</p> <p>Fine needle aspiration cytology</p> <p>Sensitivity: 0.83 (95% CI: 0.71 to 0.91) Specificity: 0.96 (95% CI: 0.92 to 0.98)</p> <p>Needle core biopsy</p> <p>Sensitivity: 0.92 (95% CI: 0.87 to 0.95) Specificity: 0.99 (95% CI: 0.66 to 1.00)</p>	<p>The GDG discussed the surprisingly high specificity for FNAC; the variation observed may be due to the reference standard that was used in these studies.</p> <p>The GDG notes that the data involved for the decision is primarily test accuracy outcomes as no evidence was found for patient-important outcomes and there is no direct evidence as to how test accuracy relates to the effect on health outcomes.</p> <p>Wang et al in</p>

			<p>January 2017 published a similar review that compares the sensitivity and specificity of NCB and FNAC in women with suspicious lesions. Authors estimated that the pooled sensitivity of NCB was 87% (95% CI = 84- 88) versus 74% for FNAC (95% CI = 72%-77%, and the pooled specificity of NCB was 98% (95% CI= 96-99) versus 96% for FNAC (95% CI= 94-98).</p> <p>The GDG expressed their concern with the reference standard used in the systematic review of Wang 2017. In fact, they used as gold standard: 1) Final pathological results by open surgical biopsy or frozen Section 2) A definitive diagnosis reported on core biopsy specimens was considered as gold standard if it</p>
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									correlated with the radiological findings. 3) For patients with lesions with a benign result after the biopsy and not undergoing operations, Wang 2017 used long-term follow-up information as an indirect assessment of the presence of breast cancer. The second criterion has a strong rationale, since the NCB may have ablated all the malignancy, but it makes difficult to have a fair comparison between FNAC and NCB specificity.	
DESIRABLE EFFECTS	How substantial are the desirable anticipated effects? ○ Trivial ○ Small ○ Moderate ● Large ○ Varies ○ Don't know									Overall, the GDG judged that the greater number of true positives and negatives as well as the lower number of false positives and negatives with NCB, compared to FNAC, were large desirable anticipated effects. The GDG agreed by
		Outcome	Study design	Test accuracy QoE	Effect per 1000 patients/year for pre-test probability of 34%		Effect per 1000 patients/year for pre-test probability of 50%		Importance	
					Needle core biopsy	fine needle aspiration cytology	Needle core biopsy	fine needle aspiration cytology		

Outcome	Study design	Test accuracy QoE	Effect per 1000 patients/year for pre-test probability of 34%		Effect per 1000 patients/year for pre-test probability of 50%		Importance
			Needle core biopsy	fine needle aspiration cytology	Needle core biopsy	fine needle aspiration cytology	

UNDESIRABLE EFFECTS		True positives	cross-sectional (cohort type accuracy study)	⊕⊕⊕⊕ HIGH ^{a,b}	313 (296 to 323)	282 (241 to 309)	460 (435 to 475)	415 (355 to 455)		voting that the desirable effects were 'large' with 18 members voting; no other options were voted.	
	TP absolute difference	31 more TP in needle core biopsy			45 more TP in needle core biopsy						
	How substantial are the undesirable anticipated effects? ○ Large ○ Moderate ○ Small ● Trivial ○ Varies ○ Don't know	False negatives			27 (17 to 44)	58 (31 to 99)	40 (25 to 65)	85 (45 to 145)		Inconclusive results were lower in NCB than in FNAC. Risk of local recurrence was similar between NCB and excisional biopsy.	
		FN absolute difference			31 fewer FN in needle core biopsy		45 fewer FN in needle core biopsy				
		True negatives	cross-sectional (cohort type accuracy study)	⊕⊕⊕⊕ HIGH ^{a,b}	653 (436 to 660)	634 (607 to 647)	495 (330 to 500)	480 (460 to 490)		The main direct adverse effects and complications of both FNAC and NCB is pain during the biopsy procedure. It seems obvious that larger needles would cause more biopsy-related pain. Haematoma formation can be expected after any needle biopsy, but haematomas requiring intervention are uncommon.	
		TN absolute difference			19 more TN in needle core biopsy		15 more TN in needle core biopsy				
		False positives	7 (0 to 224)	26 (13 to 53)	5 (0 to 170)	20 (10 to 40)					
		FP absolute difference	19 fewer FP in needle core biopsy		15 fewer FP in needle core biopsy						
		a. Most studies do not clearly report details on patient selection, index test or intervention. The panel considers that unclear risk of bias does not affect the overall confidence in the accuracy estimates. b. Most studies include a heterogeneous population with suspected lesions in the mammography, being mass lesions the most frequent. This directly applies to the question whether biopsy or cytology should be used.									
		Baseline prevalence assumptions: The prevalence of malignant disease from a systematic review of indirect comparisons between NCB and FNAC was 34% (median estimation; range from 1% to 94%) (Dahabreh 2009). The prevalence of malignant disease from direct comparisons between NCB and FNAC also varied. In those studies which included patients with suspicious mass lesions, the prevalence of malignancy ranged from 56% to 83%. In those studies which included heterogeneous lesions, the prevalence of malignancy ranged from 13% to 29%. Rate of inconclusive results was higher for FNAC compared to NCB in all studies except in one (Tikku 2015). Inconclusive									
Overall, the GDG considered these undesirable anticipated effects											

		<p>results using FNAC ranged from 2.8% to 51% whereas inconclusive results using NCB ranges from 2% to 14%.</p> <p>Local recurrence: four retrospective studies in a total of 1885 women found no significant difference with respect to the local recurrence rate between patients who had undergone a preoperative diagnostic needle core biopsy (863 women) or an excisional biopsy (1022 women). The local recurrence rates varied between 1.1 and 3.7% for the needle core biopsy group and between 2.1 and 10.3% for the excisional biopsy group</p> <p>Adverse events: the most frequent adverse event is pain although pain leading to test discontinuation is occasional. The absolute incidence of adverse events such as bleeding or infection is low and the incidence of severe complications is less than 1%.</p>	as trivial.
<p>CERTAINTY OF THE EVIDENCE OF TEST ACCURACY</p>	<p>What is the overall certainty of the evidence of test accuracy?</p> <ul style="list-style-type: none"> ○ Very low ○ Low ○ Moderate ● High ○ No included studies 		<p>The overall certainty of the evidence of test accuracy was considered high. Although most of the included studies underreported some items of QUADAS II tool, consistency was seen across studies with very similar sensitivity and specificity. Only one small study had a high risk of bias but it did not appear to affect the results. Therefore, the GDG did not lower for risk of bias and considered that this limitation did not affect the overall certainty of the results.</p> <p>The GDG considered</p>

			that, although the studies did not have a homogeneous population (they included a mixture of findings in mammography: mass lesions, calcifications, etc.) there was no reason to suspect that the already good accuracy results would improve if there was a high proportion of calcification lesions in the study population. Therefore, they did not lower the certainty in the evidence due to indirectness.
CERTAINTY OF THE EVIDENCE OF TEST'S EFFECTS	<p>What is the overall certainty of the evidence for any critical or important direct benefits, adverse effects or burden of the test?</p> <ul style="list-style-type: none"> ○ Very low ○ Low ● Moderate ○ High ○ No included studies 		Observational accuracy type studies with a proper design provided information about the rate of inconclusive results for NCB and FNAC. A large number of observational accuracy type studies with indirect comparisons between NCB and FNAC provided

			<p>information about adverse effects (see table of the included studies).</p> <p>To estimate the risk of local and distant recurrence, presumably due to displacement of tumour cells, an observational study compared the local recurrence up to 5 years after diagnosis in women who had biopsy and in women who had only surgical assessment, adjusting for all the known prognostic factors (Taxin 1997). Despite the inherent design limitation of retrospective studies, the risk was similar in women who received either of the two types of biopsy.</p>
<p>EVIDENCE OF MANAGEMENT'S EFFECTS</p>	<p>What is the overall certainty of the evidence of effects of the management that is guided by the test results?</p> <p>○ Very low</p>		<p>The GDG considered the certainty of the information for health outcomes as being moderate due to some uncertainty regarding the management for</p>

	<ul style="list-style-type: none"> ○ Low ● Moderate ○ High ○ No included studies 		some lesions of intermediate malignancy potential.
CERTAINTY OF THE EVIDENCE OF TEST RESULT/MANAGEMENT	<p>How certain is the link between test results and management decisions?</p> <ul style="list-style-type: none"> ○ Very low ○ Low ● Moderate ○ High ○ No included studies 		<p>The GDG considered the impact of false negatives. The GDG noted the uncertainty concerning 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 false negatives may have additional biopsies but in other cases they may go undetected for an unknown amount of time. The impact will vary depending on the biology of the tumour that has not been diagnosed.</p> <p>The GDG acknowledges that there is less uncertainty in what happens to persons</p>

			who are false positive due to a clearer pathway for their management, as all positive biopsies undergo surgery.
CERTAINTY OF EFFECTS	<p>What is the overall certainty of the evidence of effects of the test?</p> <ul style="list-style-type: none"> ○ Very low ○ Low ● Moderate ○ High ○ No included studies 		<p>The GDG acknowledged that results from test accuracy studies provide indirect estimations of effects (downstream consequences) of the tests on health outcomes.</p> <p>The GDGs final judgement on the certainty of the evidence was based on the assumption that there will always be more desirable health effects than undesirable ones based on better typification of breast lesions with NCB.</p>
VALUES	<p>Is there important uncertainty about or variability in how much people value</p>	No systematic review was conducted.	A few people may prefer surgical/ excisional biopsy instead of either of the tests proposed,

	<p>the main outcomes?</p> <ul style="list-style-type: none"> ○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability ○ No known undesirable outcomes 		<p>due to anxiety towards pain as an adverse effect or because they can choose to remove completely the lesion as soon as possible. The GDG felt that once a person has made the decision to have a biopsy, they would place great value on the accuracy of the test and there would not be much variability. The GDG noted this judgement on value may not apply to people who do not choose to have a biopsy. The GDG, therefore, judged that there is probably no important uncertainty in the value women place on the main outcomes once they have chosen to have a biopsy.</p>
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BALANCE OF EFFECTS	<p>Does the balance between desirable and undesirable effects favor the intervention or the comparison?</p> <ul style="list-style-type: none"> ○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ● Favors the intervention ○ Varies ○ Don't know 		<p>The GDG judged that it favours the intervention for the reasons discussed (more desirable than undesirable effects on health)</p>
RESOURCES REQUIRED	<p>How large are the resource requirements (costs)?</p> <ul style="list-style-type: none"> ○ Large costs ○ Moderate costs ● Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know 		<p>The GDG judged that the cost of the intervention is negligible.</p> <p>The GDG noted that with inconclusive results a repeat biopsy is required. Therefore, the average cost per case in FNAC, that has a greater number of inconclusive results, would be higher.</p>

Study ID	Country (year value)	Test	Average cost per breast lesion case
Hukkinen 2008	Finland (2005)	US-guided FNAC ¹	150 €
		US-guided NCB ¹	176 €
Study ID	Country (year value)	Test	Average cost per biopsy
Vimpeli 2008	Finland (2005, except for the technicians' fees at 2004)	- US-guided FNAB ²	45 €
		- Palpation guided FNAB ²	37 €
		- US-guided NCB ²	83 €
		- Palpation guided NCB ²	70 €

€: Euros. **US**: ultrasound. **FNAC/B**: fine needle aspiration biopsy. **NCB**: needle core biopsy.

¹The cost of the initial biopsy was 150 € per lesion for FNAC and 176 € per lesion for CNB. These costs included costs of radiology, pathology and surgery costs of interventions needed for one detected cancer. With the expenses caused by the additional needle biopsies included, the need for surgical biopsies and the unnecessary axillary operations due to false-positive findings corresponding costs per lesion were 294€ with FNAC and 223€ with NCB.

²The average biopsy cost per case, regardless the method used to guide the needle to the lesion, were 66 € in the FNAB group and 221 € in the NCB group. All calculations covered the costs of professionals (technicians, radiologists), cytological/ histological analysis of biopsies, radiological and other equipment, disposable supplies, and social security and administrative costs.

Indirect evidence:

Two studies conducted in the USA (Masood2015 and Nagar2012) reported that biopsy with NCB was more expensive than FNAC. However, due to the greater number of inconclusive results with FNAC, the initial biopsy with FNAC may require additional biopsies, and surgeries, thus raising the costs per case as compared to cost per case in NCB.

CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	<p>What is the certainty of the evidence of resource requirements (costs)?</p> <ul style="list-style-type: none"> ○ Very low ● Low ○ Moderate ○ High ○ No included studies 		<p>Low certainty 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>Does the cost-effectiveness of the intervention favor the intervention or the comparison?</p> <ul style="list-style-type: none"> ○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ● Favors the intervention ○ Varies ○ No included studies 		<p>The GDG notes that NCB is more costly but there would be 29% more non-operative malignant diagnosis prior to surgery with NCB compared to FNAC which would be advantageous as less additional biopsies due to inconclusive results are needed and surgical planning is improved. No intraoperative frozen sections are needed to clarify if the lesion is benign or malignant; less re-excisions are required to achieve complete removal of the tumour. As the increased costs are</p>

Nº. of studies	Study design	Nº. of women	Incremental costs	Incremental effects	ICER (NCB vs. FNAC)	Quality
Cost per changes in the proportion of pre-surgical malignant diagnoses						
1	Cost-consequences study	572	26 € (2005 value) per biopsy	29% of pre-surgical malignant diagnoses	NCB is more costly and has higher proportion of pre-surgical malignant diagnoses	⊕○○○ VERY LOW*
Cost per changes in the proportion false-positives and false-negatives						
1	Cost-consequences study	688	155 € (2005 value) per biopsy	-8% of false-positives -8% of false-negatives	NCB is more costly and has higher proportion of false-positives and false-negatives	⊕○○○ VERY LOW*

ICER: Incremental cost-effectiveness ratio. **QALY:** Quality adjusted life years. **€:** Euros.

*Cost-consequence analysis was based on observational data. Both studies were conducted in Finland. The costs, resources used, and cost-effectiveness results may not be applicable to other European settings. The authors did not reported the ICER.

negligible, compared with the increased benefits, the GDG judged that the cost-effectiveness favours the intervention.

EQUITY	<p>What would be the impact on health equity?</p> <ul style="list-style-type: none"> ○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ● Varies ○ Don't know 	No systematic review was conducted.	<p>The GDG agreed the impact on health equity would vary. On the one hand the GDG noted that a recommendation for the use of NCB would result in increased equity within countries that currently do not routinely use NCB in all healthcare centres.</p> <p>On the other hand, in some countries FNAC is still used, so in those countries it may result in inequity.</p>
ACCEPTABILITY	<p>Is the intervention acceptable to key stakeholders?</p> <ul style="list-style-type: none"> ○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know 	No systematic review was conducted.	<p>The GDG noted that FNAC requires less time and inconvenience for the woman; as such they may find NCB less acceptable. However, the GDG judged that acceptability overall will likely be greater because there is more reliable diagnostic information provided with NCB than FNAC. The GDG noted that individual clinicians in healthcare centres</p>

			where they are currently using FNAC may not find NCB so acceptable.
FEASIBILITY	Is the intervention feasible to implement? <ul style="list-style-type: none"> ○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know 	No systematic review was conducted.	<p>The GDG judged that this intervention would be feasible to implement.</p> <p>The GDG agreed that clinicians performing FNAC should be able to perform NCB without significant additional human resources or training.</p>

Summary of judgements

	JUDGEMENT							IMPLICATIONS
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know	
TEST ACCURACY	Very inaccurate	Inaccurate	Accurate	Very accurate		Varies	Don't know	
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know	
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know	

	JUDGEMENT							IMPLICATIONS
CERTAINTY OF THE EVIDENCE OF TEST ACCURACY	Very low	Low	Moderate	High			No included studies	
CERTAINTY OF THE EVIDENCE OF TEST'S EFFECTS	Very low	Low	Moderate	High			No included studies	
CERTAINTY OF THE EVIDENCE OF MANAGEMENT'S EFFECTS	Very low	Low	Moderate	High			No included studies	
CERTAINTY OF THE EVIDENCE OF TEST RESULT/MANAGEMENT	Very low	Low	Moderate	High			No included studies	
CERTAINTY OF EFFECTS	Very low	Low	Moderate	High			No included studies	
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			No known undesirable outcomes	
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know	
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and	Moderate savings	Large savings	Varies	Don't know	

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

Conclusions

Should needle core biopsy vs. fine needle aspiration cytology be used to diagnose breast cancer in women with suspicious breast lesions in mammography?

TYPE OF RECOMMENDATION	Strong recommendation against the	Conditional recommendation against the	Conditional recommendation for either the intervention or the	Conditional recommendation for the intervention	Strong recommendation for the intervention

	<div>intervention</div> <div>○</div>	<div>intervention</div> <div>○</div>	<div>comparison</div> <div>○</div>	<div></div> <div>○</div>	<div></div> <div>●</div>
RECOMMENDATION	<p>In individuals with suspicious breast lesions (including mass lesions, asymmetric breast density, calcifications and/or architectural distortions) in mammography, the ECIBC's Guidelines Development Group recommends needle core biopsy over fine needle aspiration cytology to diagnose breast cancer (strong recommendation, moderate certainty in the evidence).</p>				
JUSTIFICATION	<p>Overall justification</p> <p>The GDG agreed that NCB is recommended over FNAC for the following reasons:</p> <p>Detailed justification</p> <p><i>Desirable Effects</i></p> <p>The GDG judged that there are large desirable effects of the intervention (NCB) due to the increased number of true positives and true negatives and less false positives and false negatives.</p> <p><i>Undesirable Effects</i></p> <p>The GDG judged that the undesirable effects of the intervention, including bleeding and pain, are trivial.</p> <p><i>Balance of effects</i></p> <p>The GDG judged that the balance of effects favours NCB because the desirable health effects considerably outweigh the undesirable ones.</p> <p><i>Resources required</i></p> <p>The GDG judged that the additional resources required for NCB are negligible in view of its increased effectiveness.</p> <p><i>Equity</i></p> <p>The GDG judged that the strong recommendation for the use of NCB would result in increased equity within countries that</p>				

	currently do not routinely use NCB in all healthcare centres.
SUBGROUP CONSIDERATIONS	Initially, the GDG had divided this question in three according to different types of subpopulations (i. mass lesions and/or asymmetric density, ii. architectural distortions and iii. calcifications) but as the literature search did not find studies giving information for the relevant outcomes separately for the two subpopulations, it was merged.
IMPLEMENTATION CONSIDERATIONS	The GDG noted that FNAC may have utility in other medical conditions or contexts (e.g. FNAC of axilla lymph nodes) and as such reinforces that this recommendation applies only to the population addressed in this question; the GDG did not consider other populations. The GDG noted that there may be resistance to implementation in certain settings where providers are using FNAC over NCB. The concomitant issue is that if we are monitoring the move to NCB you should also monitor other histopathology tests that are implemented in parallel to NCB.
MONITORING AND EVALUATION	<p>The GDG notes that the Quality Assurance Development Group should be alerted to this recommendation and consider monitoring and evaluation issues for this question. Monitoring the positive predictive value of the intervention may be helpful for quality assurance.</p> <p>The GDG notes that centres currently performing FNAC instead of NCB (for the population in this question) should be monitored for the implementation of this intervention.</p>
RESEARCH PRIORITIES	Research on how to communicate more effectively with women so they can make an informed choice, in this assessment stage of breast cancer, for NCB vs FNAC, based on this recommendation. This is particularly important in settings where FNAC is still used.