



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 Evidence profile

<b>Healthcare question</b>	Should tailored screening with digital breast tomosynthesis (including synthesised 2D images) vs. digital mammography be used for early detection of breast cancer in asymptomatic women with high mammographic breast density in organised screening programmes?
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<b>Abbreviations</b>	<b>CI:</b> Confidence interval <b>RR:</b> Risk ratio

Certainty assessment							Nº of patients		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Tailored screening with digital breast tomosynthesis (DBT) (including synthesised 2D images)	Digital mammography alone	Relative (95% CI)	Absolute (95% CI)		
Breast cancer detection												
1 <sup>1</sup>	observational studies <sup>a</sup>	serious <sup>b</sup>	not serious	not serious	serious <sup>c</sup>	none	36/2592 (1.4%)	20/2592 (0.8%)	RR 1.80 (1.04 to 3.10)	617 more per 100,000 (from 31 more to 1,620 more)	⊕⊕○○ LOW	CRITICAL
Adverse effects (false positive)												
1 <sup>1</sup>	observational studies <sup>a</sup>	serious <sup>b</sup>	not serious	not serious	serious <sup>d</sup>	none	155/2555 (6.1%)	101/2555 (4.0%)	RR 1.53 (1.20 to 1.96)	2,095 more per 100,000 (from 791 more to 3,795 more)	⊕⊕○○ LOW	CRITICAL
Breast cancer mortality - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	
Breast cancer stage - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	
Interval breast cancer - not reported - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	
Mastectomy - not reported - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	
Provision of chemotherapy - not reported - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	
Adverse effects - not reported - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	

## Explanations

- a. Cohort studies provided partial diagnostic information from paired analysis. The risk of bias was assessed using an ad-hoc modified QUADAS-2 tool.
- b. Concerns for risk of bias due to reference standard was not blinded to the index tests. Additionally, there was variability in the number of readings, readers' experience, and the number of readers (i.e. single or double) across studies.
- c. The results show imprecise estimates going from relevant decrease to increase in the breast cancer detection rate.
- d. The results show imprecise estimates going from relevant decrease to increase on the false positive rate.
- e. The results show imprecise estimates.
- f. One diagnostic accuracy-test study with random allocation of participants reported a lower, but imprecise, risk for recall for assessment with DBT (RR 1.08; 95% CI 0.82 to 1.43). However, no data was reported in breast cancer detection, which precludes the interpretation of this estimate.

## References

1. Bernardi, D., Gentilini, M. A., De Nisi, M., Pellegrini, M., Fanto, C., Valentini, M., Sabatino, V., Luparia, A., Houssami, N.. Effect of implementing digital breast tomosynthesis (DBT) instead of mammography on population screening outcomes including interval cancer rates: Results of the Trento DBT pilot evaluation. Breast; 2019.