European Guidelines for Breast Cancer Screening and Diagnosis

Cecily Quinn MD, FRCPath, FRCPI, FFPath

Clinical Professor, School of Medicine, University College Dublin & Consultant Histopathologist, Irish National Breast Screening Programme, St. Vincent's University Hospital, Dublin, Ireland Chair, European Working Group for Breast Screening Pathology ECIBC GDG member and Clinical Vice-Chair







European Commission Initiative on Breast Cancer

Origin and aims The working groups The pathway to a recommendation The recommendations

2008

"Due to the recognition of substantial & persistent inequalities in breast cancer incidence, mortality, prevalence and survival that existed within and between countries"

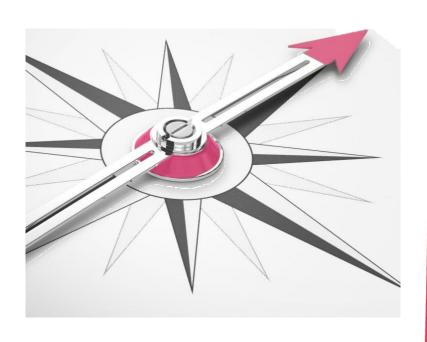


Asked the EC to establish the European Commission Initiative on Breast Cancer (ECIBC)

88 million women 35 countries

Objectives

1. Evidence based
Breast Cancer
Recommendations
New European Guidelines





2. European Quality
Assurance (QA) Scheme
for breast cancer services

Previous guidelines editions

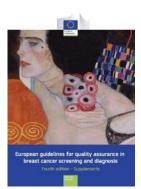












- Specialty and system orientated each section produced by relevant professionals
- Combination of best practice statements and guidelines
- Not always evidence based
- Paper / book format

New European Guidelines

- Key recommendations for screening and diagnosis and related activities
- Panel with broad representation of expertise, women, patients and patient advocates
- Evidence based and transparent
- Informed by systematic reviews
- Consider outcomes that are important to women
- Web based and tailored for three profiles
- Citizens and patients
- Health professionals
- Policy makers

Creation of Working Groups

- □ 2014: the EC was requested to create two working groups based on a public call
- ☐ Call open from 24 October to 11 December 2014
- Professionals (epidemiology, physics, public health, radiology, histopathology, breast care nurses etc)
- Methodologists
- Individuals with an interest in breast cancer
- Detailed application process
- ☐ Selection based on validity, eligibility, competence and independence

Results announced July 2015

Guidelines Development Group (GDG)

Quality Assurance Development Group (QASDG)

Project co-ordinated by the Joint Research Centre (JRC)

Science and knowledge service of the EC

Kick off meeting
JRC premises in Ispra
September 2015



Kick off meeting JRC Ispra September 2015



- Agreed rules of procedure
- Four physical meetings per annum at JRC premises / locality & online collaboration
- Re-inforced the aims of the project
- Elected
 Chairs (Holger Schunemann and Axel Graewingholt)
 Vice-chairs (Markus Follmann and Cecily Quinn)

GDG

28 members





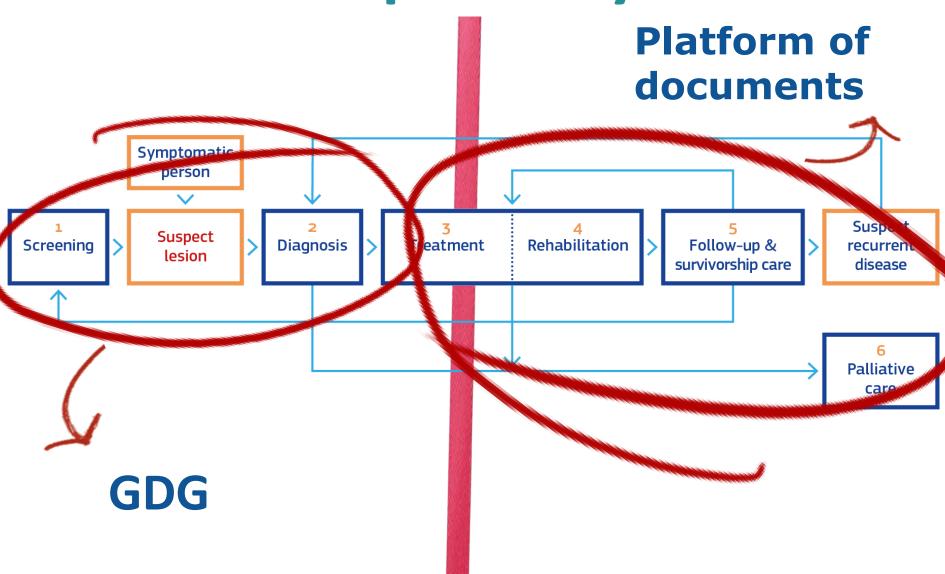


The Team

- ☐ GDG (Guideline Development Group)
- JRC (Joint Research Centre) ECIBC Coordination Team and Secretariat
- Systematic Review Team (SRT) at the Iberoamerican Cochrane Centre in Barcelona

- National contacts and stakeholders
- Scientific advisors and external experts
- Calls for feedback at regular intervals

Care pathway



New Guidelines Content

- Screening
- Diagnosis
- Communication
- ☐ Interventions to reduce inequalities
- Training of professionals
- Monitoring and evaluation

Guideline: document containing recommendations that are intended to optimise healthcare

A guideline is a statement by which to determine a course of action.

A guideline aims to streamline particular processes according to sound practice.

By definition, following a guideline is never mandatory.

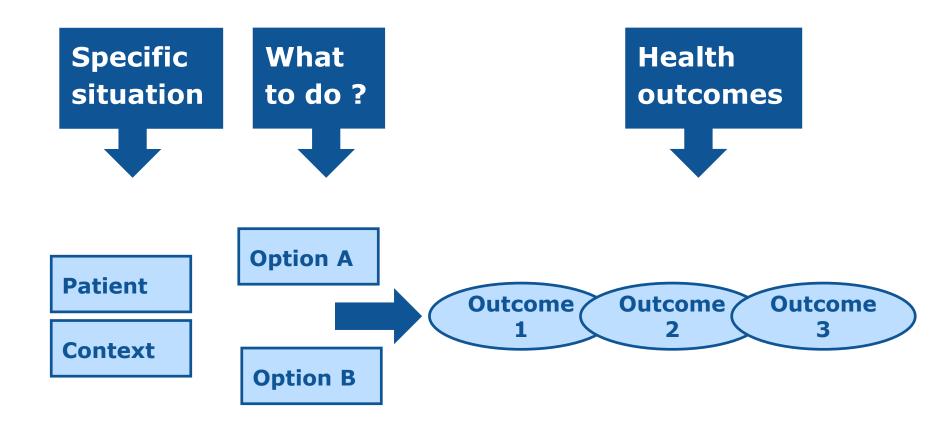
Guidelines are not binding and are not enforced.

Guidelines may be issued by and used by any organization (governmental or private) to make the actions of its employees or divisions more predictable, and presumably of higher quality. *From Wikipedia, the free encyclopedia*

Examples of guidelines are:

- •EASE Guidelines for Authors and Translators of Scientific Articles
- Federal Sentencing Guidelines
- •Guidelines for Examination in the European Patent Office
- •The Guidelines for Japan-U.S. Defense Cooperation
- Medical guidelines
- •<u>Human interface guidelines</u>
- Programming style guidelines
- <u>UNGEGN Toponymic Guidelines</u>

Recommendation: statement that tells the user of the guideline what to do in a specific situation to achieve the best health outcomes



The pathway to a recommendation

Prioritization of the European Breast Guidelines questions

Actors: GDG, JRC Framing the questions:

P - Population

I - Intervention C - Comparators

O - Outcomes

Actors: GDG, JRC

Systematic review of the evidence for each question and development of evidence profiles

Actors: SRT, GDG, JRC Going from the evidence to the recommendation (Evidence-to-Decision frameworks)

Actors: GDG, SRT, JRC Formulation of recommendations

Actors: GDG, JRC

Annals of Internal Medicine RESEARCH AND REPORTING METHODS

Methods for Development of the European Commission Initiative on Breast Cancer Guidelines

Recommendations in the Era of Guideline Transparency

Holger J. Schünemann, MD, PhD, MSc; Donata Lerda, PhD; Nadya Dimitrova, PhD; Pablo Alonso-Coello, MD, PhD; Axel Gräwingholt, MD; Cecily Quinn, MD; Markus Follmann, MD, MPH, MSc; Robert Mansel, MD; Francesco Sardanelli, MD; Paolo Giorgi Rossi, PhD; Annette Lebeau, MD; Lennarth Nyström, PhD; Mireille Broeders, PhD; Lydia Ioannidou-Mouzaka, MD; Stephen W. Duffy, BSc, MSc, CStat; Bettina Borisch, MD; Patricia Fitzpatrick, MD; Solveig Hofvind, PhD; Xavier Castells, MD, PhD; Livia Giordano, MD; Sue Warman, MEd; and Zuleika Saz-Parkinson, PhD; for the European Commission Initiative on Breast Cancer Contributor Group*



Create bank of key questions

Prioritise questions

Carried out by entire GDG

PICO format

is a technique used in **evidence based practice**

to frame and answer a clinical or health care related question

to develop the relevant literature search strategies

Should organised mammography screening versus no mammography screening be used for early detection of breast cancer in women aged 50 to 69?

Population: women aged 50 -69

Intervention: mammography screening

Comparison: no mammography screening

Outcomes: breast cancer diagnosis, breast cancer mortality, overdiagnosis, anxiety

Systematic Review Team (SRT)

Literature search and analysis of randomized control trials, observational studies etc to assess suitability for inclusion



PICO Responsible Unit (PRU)

- Take responsibility for a specific question
- Develop background explanatory document
- Liaise with and advise SRT
- Present the evidence at the GDG meeting







GDG assess the evidence

GRADE (Grading of Recommendations Assessment, Development and Evaluation) Evidence to Decision (EtD) framework

Guidelines development tool: the official tool of GRADE and DECIDE to develop guidelines and recommendations http://www.guidelinedevelopment.org/



GRADE EtD framework to formulate a recommendation

Assesses 12 criteria

Benefits and harms
Certainty of the evidence
Values, Equity, Costs
Acceptability, Feasibility

For



Against

Assessment of 12 criteria

Online prior to the GDG meeting



In person by whole GDG at the meeting



CRITERIA	SUMMARY OF JUDGMENTS								
FEASIBILITY	No		Probably no		Probably yes		Yes	Varies	Don't know
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	
ACCEPTABILITY	No		Probably no		Probably yes		Yes	Varies	Don't know
RESOURCES REQUIRED	Large Model costs cost		3.3			Moderate savings	Large savings	Varies	Don't know
EQUITY	Reduced	ced Proba		Probabl impa	,	Probably increased	Increased	Varies	Don't know
UNDESIRABLE EFFECTS	Large		Moderate		Small		Trivial	Varies	Don't know
DESIRABLE EFFECTS	Trivial		Small		Moderate		Large	Varies	Don't know
BALANCE OF EFFECTS			bably Does not far ors the the intervent			Probably favors the	Favors the intervention	Varies	Don't know
COST EFFECTIVENESS	comparison favo		obably ors the parison	rs the the intervent		Probably favors the intervention	Favors the intervention	Varies	No included studies
CERTAINTY OF EVIDENCE	Very low		Low		Moderate		High	No included studies	
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low		Low		Moderate		High	No included studies	
PROBLEM	No		Probably no		Probably yes		Yes	Varies	Don't know

C1

100

Annals of Internal Medicine®

LATEST

ISSUES

CHANNELS

CME/MOC

IN THE CLINIC

JOURNAL CLUB

WEB EXCLUSIVES

AUTHOR INFO

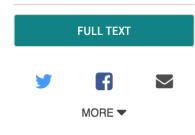
PREV ARTICLE | THIS ISSUE | NEXT ARTICLE >

RESEARCH AND REPORTING METHODS | 20 AUGUST 2019

Methods for Development of the European Commission Initiative on Breast Cancer Guidelines: Recommendations in the Era of Guideline Transparency

Holger J. Schünemann, MD, PhD, MSc; Donata Lerda, PhD; Nadya Dimitrova, PhD; Pablo Alonso-Coello, MD, PhD; Axel Gräwingholt, MD; Cecily Quinn, MD; Markus Follmann, MD, MPH, MSc; Robert Mansel, MD; Francesco Sardanelli, MD; Paolo Giorgi Rossi, PhD; Annette Lebeau, MD; Lennarth Nyström, PhD; Mireille Broeders, PhD; Lydia Ioannidou-Mouzaka, MD; Stephen W. Duffy, BSc, MSc, CStat; Bettina Borisch, MD; Patricia Fitzpatrick, MD; Solveig Hofvind, PhD; Xavier Castells, MD, PhD; Livia Giordano, MD; Sue Warman, MEd; Zuleika Saz-Parkinson, PhD; for the European Commission Initiative on Breast Cancer Contributor Group

Article, Author, and Disclosure Information



Abstract

Neither breast cancer prevention and early-detection programs, nor their outcomes, are uniform across Europe. This article describes the rationale, methods, and

November 2016

Working groups meetings

QASDG | GDG

Discussion and voting on recommendations and thematic meetings on testing and imaging

September 2016

QASDG | GDG

Subgroups meetings

June 2016

QASDG | GDG

Set-up of methodological fran

March 2016

QASDG | GDG

Approval of the scopes

December 2015

QASDG | GDG

Organisations of thematic su

September 2015

QASDG | GDG

Kick-off meeting

November 2017

QASDG | GDG

Discussion and voting on recommendations requirements and indicators

September 2017

QASDG | GDG

Discussion and voting on recommendations

May 2017

GDG

Discussion and voting on recommendations

February 2017

QASDG | GDG

Discussion and voting on recommendations requirements and indicators

November 2018

QASDG | GDG

Discussion on recommendations. Data-set for computing indicators and requirements for training of auditors and auditees

September 2018

GDG

Discussion and voting on breast cancer screening and diagnosis recommendations

June 2018

QASDG | GDG

Discussion and voting on recommendations and quality assurance requirements and indicators

April 2018

QASDG

Discussion and voting on quality assurance requirements and indicators.

Working groups meetings

January 2020

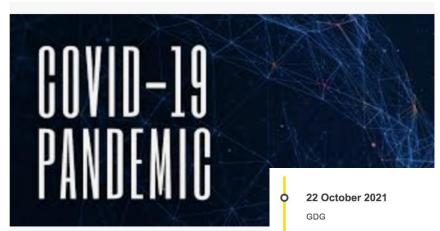
GDG

First update of the European guidelines on breast cancer screening and diagnosis

May 2019

QASDG | GDG

Discussion and voting on breast cancer recommendations. Discussion on requir diagnosis



Update of the European guidelines on breast cancer screening and diagnosis: third virtual meeting.

16-17 September 2021

GDG

Update of the European guidelines on breast cancer screening and diagnosis: second virtual meeting.

10-11 June 2021

GDG

Update of the European guidelines on breast cancer screening and diagnosis: first virtual meeting.



European Commission Initiative on Breast Cancer (ECIBC)

European Commission Initiative on Breast Cancer (ECIBC)

European Commission Initiative on Breast Cancer (ECIBC)

ECIBC is a person-centred initiative to improve breast cancer care. The JRC, with ECIBC, is developing the most up-to-date evidence-based recommendations on screening and diagnosis, with a platform of trustworthy guidelines for the whole care pathway.



- Recommendations from European Breast Guidelines http://ecibc.irc.ec.europa.eu/recommendations/
- 2. Invitation to express preliminary interest in a future European Breast QA scheme Piloting for Breast Cancer Services and stakeholders http://ecibc.jrc.ec.europa.eu/-/invitation-to-express-preliminary-interest-in-a-future-european-qa-scheme-piloting-for-breast-cancer-services-and-stakeholders

. Recommendations from European Breast Guidelines <u>http://ecibc.jrc.ec.europa.eu/recommendations/</u>

European guidelines on breast cancer screening and diagnosis

The guidelines present the latest evidence available in the form of recommendations and good practice statements intended to optimise patient care. These are developed starting from relevant 'healthcare questions' that below are grouped into main topics and presented in a question-and-answer format.

More about the European guidelines

How the guidelines have been developed and the topics selected >

What the strength of the recommendations implies >

Screening programme performance indicators >

How the guidelines have been developed and the topics selected

1

The European guidelines have been developed in the context of **population-based organised mammography screening**, although some may also apply in contexts where organised screening programmes are not in place.

2

The recommendations contained in the guidelines primarily address women at **average risk of breast cancer** without increased risk due to genetic predisposition (mutations in BRCA1 and BRCA2), reproductive history or race and ethnicity. They also inform decision-making for women who are recalled for suspicious lesions or women with high breast density.

3

Healthcare authorities and professionals can adopt the European guidelines as they are provided, or adapt them to their local context.

4

The European guidelines are complemented with a <u>collection of</u> <u>international guidelines</u> on breast cancer care, which cover the rest of the care pathway, from treatment to end-of-life care.

RELATED LINKS

Guidelines Development working Group (GDG)

Methodology of the European guidelines

European guidelines on breast cancer screening and diagnosis

Breast cancer screening

Screening ages and frequencies

Use of tomosynthesis

Women with high breast density

Inviting and informing women about screening

Organising breast cancer screening programmes

Screening ages and frequencies

These recommendations are for women who do not have symptoms of breast cancer, are not at high risk of breast cancer and want to know when they should attend screening and with which frequency.

PAGE CONTENTS

Women aged 40-44

Women aged 45-49

Women aged 50-69

Women aged 70-74

Screening for women aged 50-69

PAGE CONTENTS

Healthcare question

Recommendation

Recommendation strength

Subgroup considerations

Considerations for implementation and policy making

Monitoring and evaluation

Supporting documents

RELATED LINKS

Summary information for women

Healthcare question

Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged 50 to 69?

Recommendation

For asymptomatic women aged 50 to 69 with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) recommends mammography screening over no mammography screening, in the context of an organised screening programme.

Recommendation strength (1)

- Strong recommendation for the intervention
- ✓ Moderate certainty of the evidence

What the strength of the recommendation implies

When a recommendation is strong:

- For patients*: most individuals in this situation would want the recommended course of action, and only a small proportion would not.
- For clinicians: most individuals should follow the recommended course of action. Formal decision aids are not likely to be needed to help individual patients make decisions consistent with their values and preferences.
- For policy makers: the recommendation can be adopted as policy in most situations. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator.
- For researchers: the recommendation is supported by credible research or other convincing judgments that make additional research unlikely to alter the recommendation. On occasion, a strong recommendation is based on low or very low certainty in the evidence. In such instances, further research may provide important information that alters the recommendations

When wording recommendations, those that are strong are worded as "the ECIBC's Guidelines Development Group **recommends...**".

When a recommendation is conditional:

- For patients*: the majority of individuals in this situation would want the suggested course of action, but many would not. Decision aids may be useful in helping patients to make decisions consistent with their individual risks, values, and preferences.
- For clinicians: different choices will be appropriate for individual
 patients, and clinicians must help each patient arrive at a management
 decision consistent with the patient's values and preferences. Decision
 aids may be useful in helping individuals to make decisions consistent
 with their individual risks, values, and preferences.
- For policy makers: policy making will require substantial debate and involvement of various stakeholders. Performance measures about the suggested course of action should focus on whether an appropriate decision-making process is duly documented.
- For researchers: this recommendation is likely to be strengthened (for future updates or adaptation) by additional research. An evaluation of the conditions and criteria (and the related judgments, research evidence, and additional considerations) that determined the conditional (rather than strong) recommendation will help to identify possible research gaps.

When wording recommendations, those that are conditional are worded as "the ECIBC's Guidelines Development Group **suggests...**".

Subgroup considerations

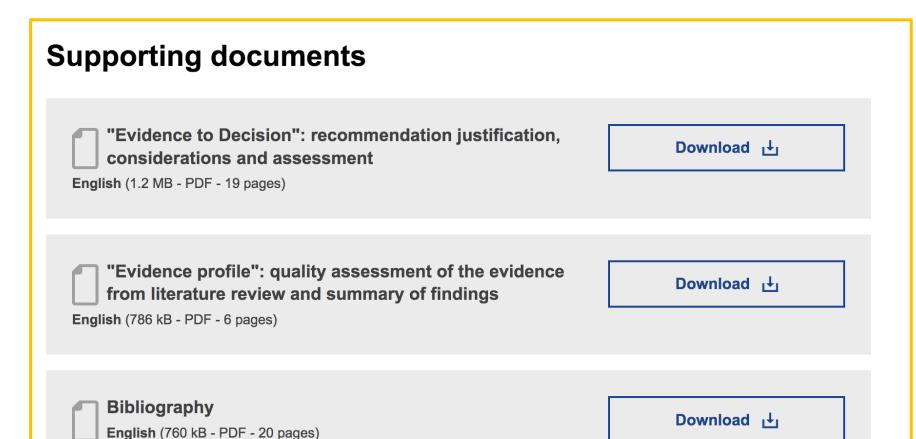
This recommendation does not apply to high-risk women (see recommendations for women with high breast density).

Considerations for implementation of policies

Despite being a strong recommendation, women should be provided with the information regarding benefits and harms of screening.

Monitoring and evaluation

Future monitoring and evaluation of screening services should consider risks and benefits in the context of evolving treatment and management protocols. Monitoring and evaluation criteria are being developed within the ECIBC initiative.



Screening for women between 50-69 (summary information for women)

Who are these recommendations for?

- You are between 50 and 69 years old
- You do not have a high risk of breast cancer
- You do not have symptoms of breast cancer

What would following these recommendations mean for you?

You may wish to speak with your healthcare professional to determine if you are at high, average or low risk of breast cancer, or if you want to discuss the balance of benefits and harms further.

Additional considerations

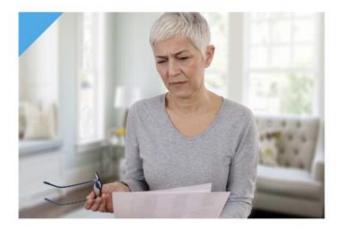
Having mammography to screen for breast cancer when you are between 50 and 69 years old, is strongly recommended because there are greater benefits than harms.

The risk of dying from breast cancer is reduced and your risk of developing breast cancer stage III or greater may be reduced. There would be little or no effect on your risk of death from other causes.

Annual screening, compared to screening every 2 or 3 years, may reduce your risk of dying from breast cancer but might increase your chance of being overdiagnosed.

Annual screening may also increase the chance of you receiving a false positive mammography result, which means that you would have further tests after screening, including biopsy. These tests will confirm that you do not have cancer, but you may have suffered unnecessary anxiety and distress.

When having a mammogram every 2 years compared to 3, there are fewer breast cancers diagnosed with symptoms in the interval between the scheduled screening appointments.



Definitions

Overdiagnosis: An overdiagnosed cancer is a cancer diagnosed by screening which is so slow-growing that it would never have been diagnosed in a person's lifetime if the person had not been screened. We cannot tell which cancers are of this type, however, so, treatment is the same as if it was not overdiagnosed. Therefore, you will be advised to have treatment, possibly including mastectomy (removal of the breast).

Use of tomosynthesis

Digital breast tomosynthesis (DBT)

In the context of an organised screening programme, for asymptomatic women with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests:

- using either DBT or digital mammography
 (conditional recommendation, very low certainty of the evidence)
- not using both DBT and digital mammography
 (conditional recommendation, very low certainty of the evidence)

Since the GDG made a strong recommendation for <u>screening at ages</u> <u>50-69</u>, these apply specifically to this age group.

Women with high breast density

PAGE CONTENTS

Digital breast tomosynthesis (DBT)

Magnetic resonance imaging and ultrasound

These recommendations aim to provide advice about the most suitable test for women with high breast density attending a screening programme.

These new recommendations have been issued during the latest Guidelines Development Group meeting, considering available evidence until 3 August 2021. They include a more detailed description of the target population as compared to previous recommendations.

Digital breast tomosynthesis (DBT)

In the context of an organised screening programme, the ECIBC's Guidelines Development Group (GDG) suggests:

- not implementing tailored screening with both DBT and digital mammography for women with high mammographic breast density detected for the first time with digital mammography (conditional recommendation, very low certainty of the evidence)
- using DBT for women with high mammographic breast density detected in previous screening exams
 (conditional recommendation, very low certainty of the evidence)

Recommendation details

Tailored screening with DBT

Screening with DBT vs. DM

Magnetic resonance imaging and ultrasound

In the context of an organised screening programme, for asymptomatic women with high mammographic breast density, the ECIBC's Guidelines Development Group (GDG) suggests:

 not implementing tailored screening with magnetic resonance imaging (MRI)

(conditional recommendation, very low certainty of the evidence)

 not implementing tailored screening with automated breast ultrasound system (ABUS)

(conditional recommendation, very low certainty of the evidence)

 not implementing tailored screening with hand-held ultrasound (HHUS)

(conditional recommendation, low certainty of the evidence)

Recommendation details

Tailored screening with MRI

Tailored screening with ABUS

Tailored screening with HHUS

Summary information for women

What you need to know

Inviting and informing women about screening

These recommendations aim to determine the best way to invite women to organised breast cancer screening programmes and to explain the benefits and harms attending.

PAGE CONTENTS

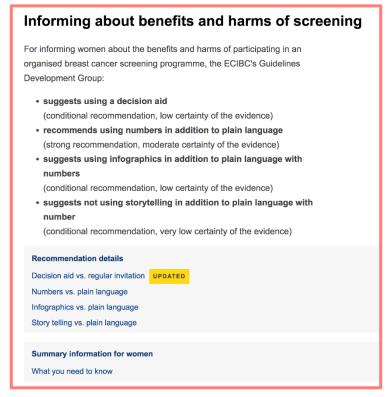
Women aged 50-69

Informing about benefits and harms of screening

Socially disadvantaged women

Women with an intellectual disability

Non-native speaking women



Organising breast cancer screening programmes

PAGE CONTENTS

Implementing mammography screening

Reading mammograms

Training of healthcare professionals

Reading mammograms

In the context of an organised screening programme, the ECIBC's Guidelines Development Group (GDG) **suggests:**

- using double reading (with consensus or arbitration for discordant readings) to screen mammograms for early detection of breast cancer (conditional recommendation, moderate certainty of the evidence)
- mammography readers read between 3 500 and 11 000 mammograms annually (conditional recommendation, very low certainty of the evidence)

Recommendation details

Single vs. double reading

Optimal number of readings

Summary information for women

What you need to know

European guidelines on breast cancer screening and diagnosis

Breast cancer diagnosis

Informing women about their results

Further assessment after the mammogram

Staging of breast cancer

Planning surgical treatment

Towards the treatment of invasive breast cancer

Informing women about their results

PAGE CONTENTS

Informing women who have a negative result

Inviting women for further diagnostic assessment

The different phases of screening should correspond to different communication modalities and information needs. These recommendations aim to determine the optimal strategies to inform women about screening results such as negative results and recall for further assessment.

Informing women who have a negative result

To inform women who have negative screening result, the ECIBC's Guidelines Development Group (GDG) suggests:

- using a letter
 (conditional recommendation, very low certainty of the evidence)
- not using a phone call (conditional recommendation, very low quality of the evidence)
- not using a face to face interview
 (conditional recommendation, very low certainty of the evidence)

Further assessment after the mammogram

PAGE CONTENTS

Women recalled due to suspicious lesions

Obtaining a sample from a suspicious breast lesion

Type of guidance for needle core biopsy

When a suspicious lesion is detected in mammography screening, the woman is recalled for further assessment.

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.

Women recalled due to suspicious lesions

The ECIBC's Guidelines Development Group (GDG) suggests using digital breast tomosynthesis (DBT) over diagnostic mammography projections in women at average risk for breast cancer recalled for suspicious lesions at mammography screening (conditional recommendation, moderate certainty of the test accuracy data).

Staging of breast cancer

PAGE CONTENTS

Stage 1

Stage 2

Stage 3

The main cause of death from breast cancer is distant metastases. The detection of distant metastases in patients with breast cancer alters treatment and prognosis. The staging interventions aim to avoid overtreatment. The risk for metastases is lower in stage 1 and stage 2.

Stage 1

For breast cancer patients without symptoms suggestive of metastases at **clinical stage 1**, the ECIBC's Guidelines Development Group (GDG)

- suggest against using conventional staging exams (conditional recommendation, low certainty of the evidence)
- recommends against using positron emission tomographycomputed tomography (PET-CT) (strong recommendation, very low certainty of the evidence)

Planning surgical treatment

PAGE CONTENTS

Use of clip-marking

Additional magnetic resonance imaging

Contrast-enhanced mammography

Use of clip-marking

The ECIBC's Guidelines Development Group suggests using clipmarking after needle core biopsy (NCB)/vacuum assisted needle core biopsy (VANCB) for surgical therapy planning in patients with breast cancer lesions (conditional recommendation, very low certainty of the evidence).

Recommendation details

Clip-marking vs. no clip-marking

Summary information for women

What you need to know

Towards the treatment of invasive breast cancer

PAGE CONTENTS

Threshold of oestrogen and progesterone for endocrine therapy

Multigene testing to guide the use of chemotherapy

Threshold of oestrogen and progesterone for endocrine therapy

In women with invasive breast cancer, the ECIBC's Guidelines Development Group (GDG) **suggests**:

- administration of adjuvant endocrine therapy if 1% or greater of tumour cells show oestrogen receptor positivity rather than applying a threshold of 10% tumour cell oestrogen receptor positivity (conditional recommendation, very low certainty of the evidence)
- administration of adjuvant endocrine therapy if 1% or greater of tumour cells show progesterone receptor positivity rather than applying a threshold of 10% tumour cell progesterone receptor positivity (conditional recommendation, very low certainty of the evidence)

Multigene testing to guide the use of chemotherapy

To guide the use of chemotherapy in women with hormone receptor positive, HER2-negative, and lymph node negative or up to 3 lymph nodes positive invasive breast cancer, the ECIBC's Guidelines Development Group (GDG):

- recommends not using the 70 gene signature test when women are at <u>low clinical risk</u> (strong recommendation, low certainty of the evidence)
- suggests using the 70 gene signature test when women are at <u>high</u>
 <u>clinical risk</u> (conditional recommendation, low certainty of the
 evidence)
- suggests using the 21 gene recurrence score (conditional recommendation, very low certainty of the evidence)

Recommendation details

70 gene signature at low clinical risk

70 gene signature at high clinical risk

21 gene recurrence

ECIBC GDG process limitations

- Linear process and time consuming
- Individual specific expertise applicable to small number of recommendations
- Do not replace traditional 'manual of instructions' guidelines
- Re-affirm already good practice in some countries

ECIBC GDG achievements

- Evidence based recommendations
- Developed by an international GDG, that includes patients and women, in collaboration with JRC and SR team
- Focus on outcomes that matter to women with emphasis on benefits and harms
- ☐ Consider cost, feasibility and need for further research
- Living document that can be updated as new evidence emerges

Implementation of recommendations
commenced or being considered in
Bulgaria, Estonia, Czech Republic,
Slovakia, Denmark, Germany, Italy, Norway,
Chile, Bahrain & Tunisia



