EUROPA DONNA
The European Breast Cancer Coalition

EUROPA DONNA

Advocates Guide to the

ECIBC

European Commission Initiative on Breast Cancer

Part 1

About
EUROPA DONNA

EUROPA DONNA – The European Breast Cancer Coalition is an independent non-profit organisation whose members are affiliated groups from countries throughout Europe. The Coalition works to raise awareness of breast cancer and to mobilise the support of European women in pressing for improved breast cancer education, appropriate screening, optimal treatment and increased funding for research. EUROPA DONNA has national groups in 47 member countries.

About
this Booklet

EUROPA DONNA has created this booklet to provide breast cancer advocates with the knowledge required to advocate for the implementation of European Commission-supported guidelines and a quality assurance scheme for breast health as a means to achieve high-quality breast cancer services across all countries. It is designed as an interactive training tool for advocates in order to prepare them to advocate for quality breast care both today and tomorrow. Part 1 covers the European Commission Initiative on Breast Cancer (ECIBC), the work of the Guidelines Development Group and an introduction to the Guidelines Platform and the Quality Assurance Scheme. Part 2, describing the work of the Quality Assurance Scheme Development Group (QASDG) in more detail will follow in 2019.

Participant
Learning Objectives

After completing this booklet EUROPA DONNA advocates should be able to describe:

- The ECIBC, as a European Commission initiative, and its importance in developing breast cancer care guidelines
- The ECIBC's Guidelines Development Group and the methods it is using to create Guidelines for Breast Cancer Screening and Diagnosis
- Those guideline recommendations that have been designated a "*strong*" and "*conditional*" recommendation, the meaning of "*strong*" and "*conditional*" and why these recommendations are a priority for advocacy work
- The purpose and nature of the online Guidelines Platform
- The aims and development process for the Quality Assurance Scheme

Contents

About the European Commission Initiative on Breast Cancer – ECIBC

- The ECIBC is a European Commission initiative to develop evidence-based recommendations and a quality assurance scheme for the entire pathway of breast cancer care, including screening, diagnosis and treatment through to end-of-life care.
- The European Commission Directorate-General for Health and Food Safety (DG SANTÉ), which is responsible for European Union (EU) policies that improve and protect public health, has given the task of coordinating the scientific and technical aspects of the ECIBC to the European Commission's Joint Research Centre based in Ispra, Italy.
- The ECIBC has convened two external expert groups that meet regularly to steer content, assess evidence and vote on recommendations.
- The first ECIBC recommendations are now published and available on a web hub that houses all the information and recommendations (**http://ecibc.jrc.ec.europa.eu/home**).

Why the ECIBC is important and its recommendations should be implemented

- As a European Commission initiative, the ECIBC provides guidance for all EU Member States, but also collaborates with non-EU countries. There are 35 countries actively collaborating in the ECIBC, including EU Member States, European Free Trade Association (EFTA) members, and Associated and Acceding countries.
- All screening and diagnosis recommendations are based on evidence gathered using a rigorous research method and on the input of leading experts in all fields of breast cancer care from many different countries.
- Patients are equal participants and voting members of these expert groups.
- Independence of all national, private and commercial interests has been applied in providing all ECIBC recommendations.

Advocacy tip:

The ECIBC web hub contains fact sheets on current breast services for 35 countries, which could serve as useful advocacy tools.

Why the
European Commission established the ECIBC

The delivery of health care is within the remit of EU Member States, and not of the European Union; the EU/European Commission's role is to promote health policies that protect the health of its citizens, and to reduce inequalities across the EU. Primary and secondary cancer prevention (eg, through screening), encouraging Member States to have integrated cancer strategies and sharing best practice fall within the scope of this goal.

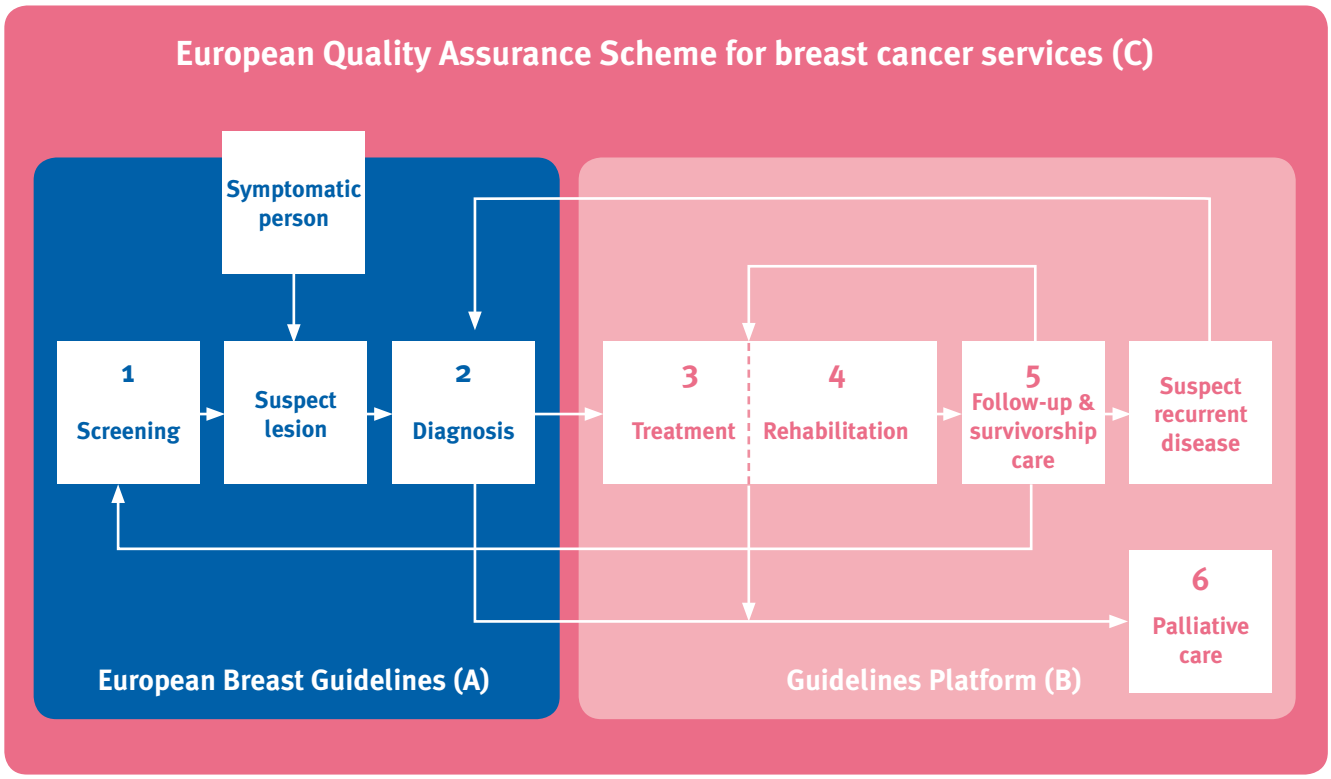
What
the ECIBC does

The ECIBC quest for quality standards is divided into three main areas:

A) Developing evidence-based *European Breast Guidelines* for screening and diagnosis of breast cancer. This task is performed by the Guidelines Development Group (GDG).

B) Developing a *Guidelines Platform,* for those processes not covered by the European Breast Guidelines, by initially searching and evaluating guidelines published worldwide.

C) Designing and implementing a *European Quality Assurance Scheme* that will guarantee that breast cancer services offer women the most up-to-date procedures for breast cancer screening and care. The requirements and indicators in the quality assurance scheme will cover the entire continuum of care, from treatment to survivorship and palliative care. This task is performed by the Quality Assurance Scheme Development Group (QASDG).



How much do you know **about the ECIBC?**

1. What does ECIBC stand for?

a) European Community Institute for Breast Cancer

b) European Committee for Investigational Breast Care

c) European Commission Institute for Breast Care

d) European Commission Initiative on Breast Cancer

2. Which one of the following best reflects the overall aim of the ECIBC?

a) To develop evidence-based recommendations on screening and diagnosis and a quality assurance scheme for the full breast care pathway

b) To develop evidence-based recommendations and quality assurance for breast cancer screening and diagnosis

c) To develop evidence-based recommendations for treatment through to end of life care

d) To develop a quality assurance scheme for breast centres

3. Who decides what breast cancer screening and diagnosis recommendations are made for the ECIBC?

a) European Commission Directorate-General Health and Food Safety

b) Joint Research Centre

c) The Guidelines Development Group

d) European Free Trade Association

4. Which of the following is NOT among the ECIBC's three main projects?

a) European Breast Cancer Guidelines

b) European Health Technology Assessment Scheme

c) European Guidelines Platform

d) European Quality Assurance Scheme

The correct answers and their explanations are on page 12.

About the Guidelines Development Group

What
the GDG does

The *Guidelines Development Group* (GDG) is developing evidence-based European guidelines for breast cancer screening and diagnosis (also known as the *European Breast Guidelines*). The GDG uses a strict methodology to identify a health care question to address (eg, what age group of women benefits from population-based mammography screening), synthesise the data gathered from the scientific literature, and develop recommendations.

Members of the GDG

The GDG has an international and European membership. It comprises 28 experts in all areas, with vast experience in implementing screening programmes in different countries, including epidemiologists, radiologists, radiographers, nuclear physicists, pathologists, physicians, statisticians, and patients, among others. Members of this group were selected transparently via a public call and their participation is voluntary. More about the members, their experience and where they come from is available here: http://ecibc.jrc.ec.europa.eu/guidelines-team

Advocacy tip:

A key point to remember is that the European Breast Guidelines are based on scientific evidence and developed by a highly skilled group of individuals, with vast experience gleaned from successful screening programmes in different countries.

How the
GDG decides what recommendations to make

The GDG uses a currently widely-accepted guideline development system called Grading of Recommendations Assessment, Development and Evaluation (GRADE). The GRADE approach helps to rate the quality or certainty of evidence and strength of recommendations.

Using this approach, the GDG compiled a list of research questions that would need to be answered to develop new breast guidelines and to ensure that these guidelines are based on carefully researched evidence. Each of the resulting questions addressed a specific angle of a research topic with a view to making a recommendation. Examples of questions they sought to address include: “In what age ranges should women undergo breast cancer screening?” and “What additional screening techniques, if any, should be used in women with dense breast tissue?”

How the
GDG structures questions to be answered in a comparative format: PICO

The GDG formulates questions according to a structured format used extensively in guideline development today called “PICO”; this stands for **P**opulation under study (eg, women aged 50-69); **I**ntervention (eg, mammography); **C**omparator (eg, no mammography, or an alternative medical examination such as tomosynthesis); and **O**utcomes (eg, how the women in the age group fare after the intervention vs. the comparison).

Example: Should screening using **tomosynthesis** (including synthesised 2D images) vs. **digital mammography** be used for **early detection of breast cancer** in **asymptomatic women**?

P	I	C	O
Asymptomatic women **Population**	Tomosynthesis **Intervention**	Digital mammography **Comparator**	Early detection of breast cancer **Outcome**

The GDG defines the PICO elements of each question and defines whether the "Outcomes" are "critical" or "important" for decision making. The "outcome" is the impact that a treatment, policy or test, for example, will have on a person or group (eg, breast cancer mortality, quality of life or patient safety).

How the
GDG finds evidence to answer the questions

The system for gathering evidence is rigorous and involves searching existing systematic reviews (an analysis and summary of research articles on the same subject) or conducting new ones. The European Commission outsources this gathering of data to the Iberoamerican Cochrane Centre. The evidence for each PICO is presented using a tool called GRADE Evidence to Decision (EtD) framework.

How the
GDG uses the evidence to answer the question and then make a recommendation

The GDG members use the Evidence to Decision framework to guide their decision about the final recommendation. EtDs include criteria, such as the quality of the evidence, desirable or undesirable effects and the values and preferences of patients, that help the GDG formulate recommendations as "strong" or "conditional", after balancing out all the criteria.

How the
GDG ranks its recommendations

Based on the balance of all the different criteria considered in the Evidence to Decision framework, the GDG votes in favour or against a specific recommendation. They then qualify the strength of their recommendation as "strong" or "conditional" based on their analysis of the evidence. For a strong recommendation, 80% of votes in favour are needed. They use the following ranking:

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

How much do you know **about the ECIBC recommendation process?**

1. The GDG stands for which one of the following?

a) Guidelines Direction Group

b) Guidance Dialogue Group

c) Guidelines Development Group

d) Group for Development of Guidelines

2. What is the aim of the GDG?

a) To develop evidence-based breast cancer recommendations for screening and diagnosis

b) To develop breast cancer guidelines from screening through to palliative care

c) To develop guidelines to implement in the EU only

d) To develop a quality assessment scheme

3. Why are all the recommendations written in a question and comparison format?

a) The GDG considers answering questions as the most efficient working method

b) The methodology follows a widely used structured format called PICO

c) Because the questions are answered in systemic reviews known as GRADE

d) The methodology ensures that all options within a question are considered

4. Which one of the following systems, known as PICO, was used to develop the guidelines questions?

a) Priority Initiative Control Objectives

b) Population Intervention Comparator Outcomes

c) Personnel Interest Capability Outreach

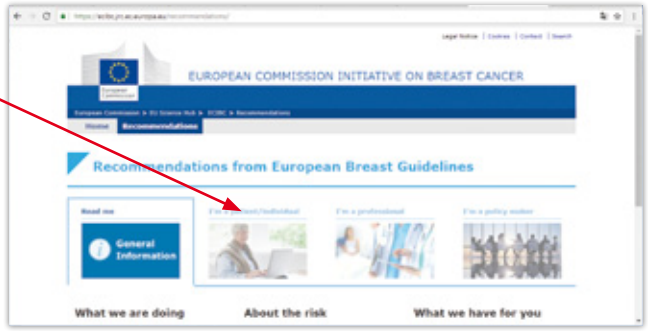
d) Perspective Insight Consistency Outcomes

The correct answers and their explanations are on page 12.

The Recommendations on Breast Cancer Screening and Diagnosis and where to find them

The ECIBC is developing a maximum of 90 evidenced-based recommendations regarding screening and diagnosis, based on women at "average risk" or "low risk" of breast cancer. These are being published on the web hub dedicated to this purpose as they become available. Supplemental recommendations will be developed and updated as new evidence and priorities emerge.

On the web hub, each recommendation includes a section tailored to the needs of citizens and patients, healthcare professionals, and policy makers.



Advocacy tip:

In addition to the patient section of the web hub, advocates can consult the section for policy makers so that they are familiar with the information tailored for them.

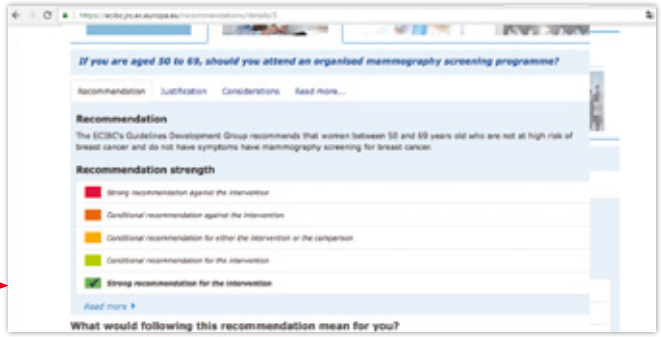
The recommendations available so far

At the time of writing, 11 different recommendations in the form of questions/answers had been published on the ECIBC web hub. These focus on four main areas: suitable age for participation in an organised screening programme, suitability of tomosynthesis for early detection, suitable imaging method for screening in women with dense breast tissue, and suitable biopsy method for breast calcifications.

Where to find the recommendations

On the web hub, these appear in the section for patients as follows:

Clicking on a question leads to a recommendation page like this:



Each recommendation page describes the strength of the recommendation. It also includes a **Justification** section explaining the evidence and reason for the decision, and how many GDG members voted for or against it. There is a **Considerations** section with a summary of the GDG's recommendation for implementing the decision, along with sections for monitoring and evaluation, and research priorities. A **Read more** section with a bibliography and an assessment section listing the Evidence to Decision framework (the questions addressed) so that users can see how each criterion was discussed in the GDG and a decision was reached.

Summary of the current recommendations: What to advocate for

Below we have synthesised the recommendations available to date.

As a reminder, a recommendation can be strong or conditional. When a recommendation for an intervention is **strong**, most women will want to follow it**. Advocates should advocate for the implementation of strong recommendations.** When a recommendation is **conditional for** an intervention, the majority of women will want to follow it but may need more discussion with their healthcare professional first**. Advocates may want to advocate for these;** they should consider if there is a need for such an intervention in their country, based on the needs of women, the health system and available resources.

Advocacy tip:

Advocates need to ensure that the national screening programme in their countries includes women aged 50-69 and meets quality standards; at that point they may consider advocating for screening to be available for women aged 45-49 and 70-74 years, based on a thorough assessment of needs and resources in the country. At that point women can then make individual decisions regarding their participation.

Recommendation 1: Ensure availability of nationwide screening for all women aged 50-69

GDG recommendation:

Women aged 50-69 years (strong recommendation for)

Women aged 45-49 and 70-74 years (conditional recommendation for)

Not recommended for women aged 40-44 years (conditional recommendation against)

Recommendation 2: Ensure that screening programmes use digital mammography or tomosynthesis

GDG recommendation:

Screening should be carried out with either digital mammography OR tomosynthesis (conditional recommendation for either one)

Recommendation 3: Women with dense breasts should attend population-based screening with digital mammography like women without dense breasts

GDG recommendation:

Regarding additional screening after a negative mammogram in women with dense breasts the GDG recommends:

Either to have tomosynthesis after a negative mammogram or to have only the mammogram (Conditional recommendation for either)

Not to have automated whole breast ultrasound (ABUS), hand-held ultrasound (HHUS) or magnetic resonance imaging (MRI) after a negative mammogram but rather to have only the mammogram (Conditional recommendations against each)

Recommendation 4: Women with breast calcifications should undergo stereotactic-guided needle core biopsy to diagnose breast cancer

GDG recommendation:

Stereotactic-guided needle core biopsy should be used over ultrasound-guided needle core biopsy to diagnose breast cancer when there are breast calcifications (strong recommendation for)

How much do you know about the European Breast Guidelines?

1. Where can people find the ECIBC recommendations?

a) On a European Commission web hub

b) In a printed brochure

c) In the Short Guide to the 4th Edition of the EU Guidelines

d) On the WHO website

2. Where can I find an explanation for the evidence and reason for a specific recommendation?

a) On the EUROPA DONNA website

b) In the Cochrane Database

c) In the Professional section of the ECIBC website

d) In the Justification section for each individual recommendation on the ECIBC web hub

3. What does it mean if there is a strong recommendation for an intervention?

a) There is ample evidence supporting it and advocates should advocate for it

b) There is sufficient evidence, but advocates should decide if it is feasible for their health system

c) Evidence is reasonable, but most women would not want to follow it

d) There is ample evidence that it should not be used, and advocates should advocate against it

4. What does it mean if there is a conditional recommendation for an intervention?

a) There is insufficient evidence and advocates should advocate for more studies on the topic

b) There is definitive evidence and advocates should advocate for it

c) There is sufficient but not definitive evidence; advocates may want to advocate for it but should consider the specific needs and resources in their country

d) There is sufficient evidence and advocates should advocate against its use, depending on the specific needs of their country

The correct answers and their explanations are on page 12.

What to expect from the ECIBC in the future

Guidelines Platform: a platform of existing evidence-based guidelines covering all aspects of breast cancer

The European Breast Guidelines developed by the GDG are to be complemented by the ECIBC Guidelines Platform. This is to be a public web-based platform that will compile evidence-based guidelines recommendations for all breast care processes with a focus on treatment, rehabilitation, follow-up, survivorship and palliative care.

To create the Guidelines Platform, the ECIBC has searched all publicly available sources for breast cancer guidelines produced by different entities and organisations, such as professional societies. Based on this and a public call for submission of guidelines, more than 250 guidelines have been received and are being evaluated for their quality, clinical impact, geographical coverage and sustainability.

- Only those meeting clear quality criteria will be included in the Guidelines Platform

Main Aim of the Guidelines Platform

Among the various aims of the Guidelines Platform is to provide citizens, patients and health care providers with clear, objective, independent, evidence-based guidance on all breast care processes.

- This would help to reduce unnecessary variability in healthcare services and to improve the outcomes of breast cancer patients in terms of morbidity, mortality, and quality of life.

The European Quality Assurance Scheme for Breast Cancer Services (European QA Scheme)

The *Quality Assurance Scheme Development Group* (QASDG) is developing the European Quality Assurance Scheme for Breast Cancer Services (the *European QA scheme*) to set common quality and safety requirements for person-centred breast cancer services in Europe. The scheme will cover all the processes of breast cancer care (screening, diagnosis, treatment, rehabilitation and supportive care, follow-up and survivorship care, and palliative care). It will use the *European Breast Guidelines* created by the ECIBC, along with other quality indicators, to provide requirements for the functioning of breast cancer services.

The aim of the European QA scheme

The European QA scheme is a collection of requirements and indicators. Its voluntary implementation will guarantee that compliant breast cancer services can offer to users (women, patients and carers) top quality and the most up-to-date procedures for breast cancer screening and care. The requirements focus on the person's needs and are based on the most current evidence-based guidelines. Compliance with these requirements and their impact on outcomes will be evaluated, whenever appropriate, via quality indicators.

Questions

that advocates should be prepared to answer about the ECIBC

Why should my country or health system implement the ECIBC?

The EU/European Commission role is to promote health policies that protect the health of its citizens, and to reduce inequalities across the EU. Primary and secondary cancer prevention (eg, through screening), encouraging Member States to have integrated cancer strategies and sharing best practice fall within the scope of this goal. The European Commission's Joint Research Centre (JRC) is steering the ECIBC process that defines the entire pathway of breast services to which women in Europe should have access. Therefore, the implementation of the ECIBC should improve the level of breast cancer care provided across Europe as a whole.

What is the ECIBC and why is it important to my country?

The ECIBC is a European Commission initiative that is developing evidence-based guidelines and a quality assurance scheme for voluntary implementation in all countries across Europe. It aims to ensure that women receive high quality breast services that cover the entire pathway from screening through diagnosis, treatment, follow-up and palliative care.

What makes the ECIBC's new European Breast Guidelines different from other guidelines available and why should we implement its recommendations in our country?

All recommendations made by the Guidelines Development Group are based on international evidence gathered using a rigorous research method, including tailor-made systematic reviews of evidence, and on the input of leading experts in all fields of breast cancer care from many different countries. Citizens and patients are also part of the Guidelines Development Group. The European Breast Guidelines are also to be updated regularly on the web hub as new evidence becomes available.

Why should we implement the strong recommendations in the European Breast Guidelines?

Strong recommendations are recommendations that most women would want to follow. These are recommendations for which the Guidelines Development Group have rigorously weighed the evidence and determined that they have great confidence that the desirable effects of adherence to a recommendation outweigh the undesirable effects.

What is the purpose of the Quality Assurance Scheme Development Group and how is it relevant to my country?

The *Quality Assurance Scheme Development Group* (QASDG) is developing the European Quality Assurance Scheme for Breast Cancer Services (the *European QA scheme*) to set common quality and safety requirements for person-centred breast cancer services in Europe. The scheme will cover all the processes of breast cancer care (screening, diagnosis, treatment, rehabilitation and supportive care, follow-up and survivorship care and palliative care). It will use the *European Breast Guidelines* created by the ECIBC, along with other guidelines, to provide requirements for the functioning of breast cancer services.

Test your understanding: Answer key

How much do you know about the ECIBC? (from page 3)

1. **What does ECIBC stand for?** Correct answer (d): *European Commission Initiative on Breast Cancer. For more information please see the ECIBC web hub: http://ecibc.jrc.ec.europa.eu*
2. **Which one of the following best reflects the overall aim of ECIBC?** Correct answer (a): *The ECIBC is a European Commission initiative to develop evidence-based guideline recommendations and a quality assurance scheme for the full breast care pathway. The European Breast Guidelines will cover screening and diagnosis while the Quality Assurance Scheme will cover the entire continuum of breast cancer services from screening through to end-of-life care.*
3. **Who decides what breast cancer screening and diagnosis recommendations are made for the ECIBC?** Correct answer (c)*: The Guidelines Development Group. The European guidelines for breast cancer screening and diagnosis are part of the ECIBC, which is an initiative of the European Commission's Directorate-General for Health and Food Safety (DG SANTÉ). The Joint Research Centre is responsible for coordinating the scientific and technical aspects of the ECIBC. The Guidelines Development Group, made up of international experts including patients, radiologists, pathologists, radiographers, screening professionals, etc. makes the recommendations based on rigorous examination of evidence.*
4. **Which of the following is NOT among the ECIBC's three main projects?** Correct answer (b): *European Health Technology Assessment Scheme. The ECIBC comprises three main activities in development and that are to be complementary: European Breast Guidelines, European Guidelines Platform, European Quality Assurance Scheme.*

How much do you know about the ECIBC recommendation process? (from page 6)

1. **The GDG is**: Correct answer (c): *Guidelines Development Group.*
2. **What is the aim of the GDG?** Correct answer (a): *The Guidelines Development Group is developing evidence-based breast cancer recommendations for screening and diagnosis. This is a European Commission project, but the guidelines can be applied anywhere.*
3. **Why are all the recommendations written in a question and comparison format?** Correct answer (b): *The methodology follows a structured format that uses a question and comparison format called PICO (Population Intervention Comparator Outcomes). It is widely used to frame and answer healthcare questions and make recommendations based on the findings.*
4. **Which one of the following systems, known as PICO, was used to develop the guidelines questions?** Correct answer (b): *Population Intervention Comparator Outcomes*

How much do you know about the European Breast Guidelines? (from page 9)

1. **Where can people find the ECIBC recommendations?** Correct answer (a): *The recommendations are all published on the ECIBC web hub (http://ecibc.jrc.ec.europa.eu). This replaces the previous EU guidelines and EUROPA DONNA's Short Guide to the EU Guidelines.*
2. **Where can I find an explanation for the evidence and reason for a specific recommendation?** Correct answer (d): *A description of the evidence and reason for or against an intervention are found at the "justification" tab for each recommendation on the ECIBC web hub.*
3. **What does it mean if there is a strong recommendation for an intervention?** *Correct answer (a): When a recommendation **for** an intervention is strong, most women will want to follow it and advocates should advocate for it. When a recommendation **against** an intervention is strong, the evidence indicates that it should not be used.*
4. **What does it mean if there is a conditional recommendation for an intervention?** Correct answer (c): *When a recommendation is "conditional for" an intervention, a majority of women want to follow it but may need more discussion with their health care professional first. Advocates may want to consider if there is a need to advocate for such an intervention in their country, based on the needs of women, the health system and resources. A recommendation may be awaiting further data and may change as that becomes available.*

Where to find out more about the ECIBC, the recommendations, web hub and Quality Assurance Scheme

ECIBC

ECIBC web hub

https://ecibc.jrc.ec.europa.eu/home

National contacts

https://ecibc.jrc.ec.europa.eu/national-contacts

European Breast Guidelines

https://ecibc.jrc.ec.europa.eu/recommendations

The European Quality Assurance scheme

https://ecibc.jrc.ec.europa.eu/qa-scope

Europa Donna – The European Breast Cancer Coalition

www.europadonna.org

This EUROPA DONNA booklet is based on content from the ECIBC — European Commission Initiative on Breast Cancer and available at: https://ecibc.jrc.ec.europa.eu

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Views expressed in this booklet do not necessarily reflect those of EUROPA DONNA.

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