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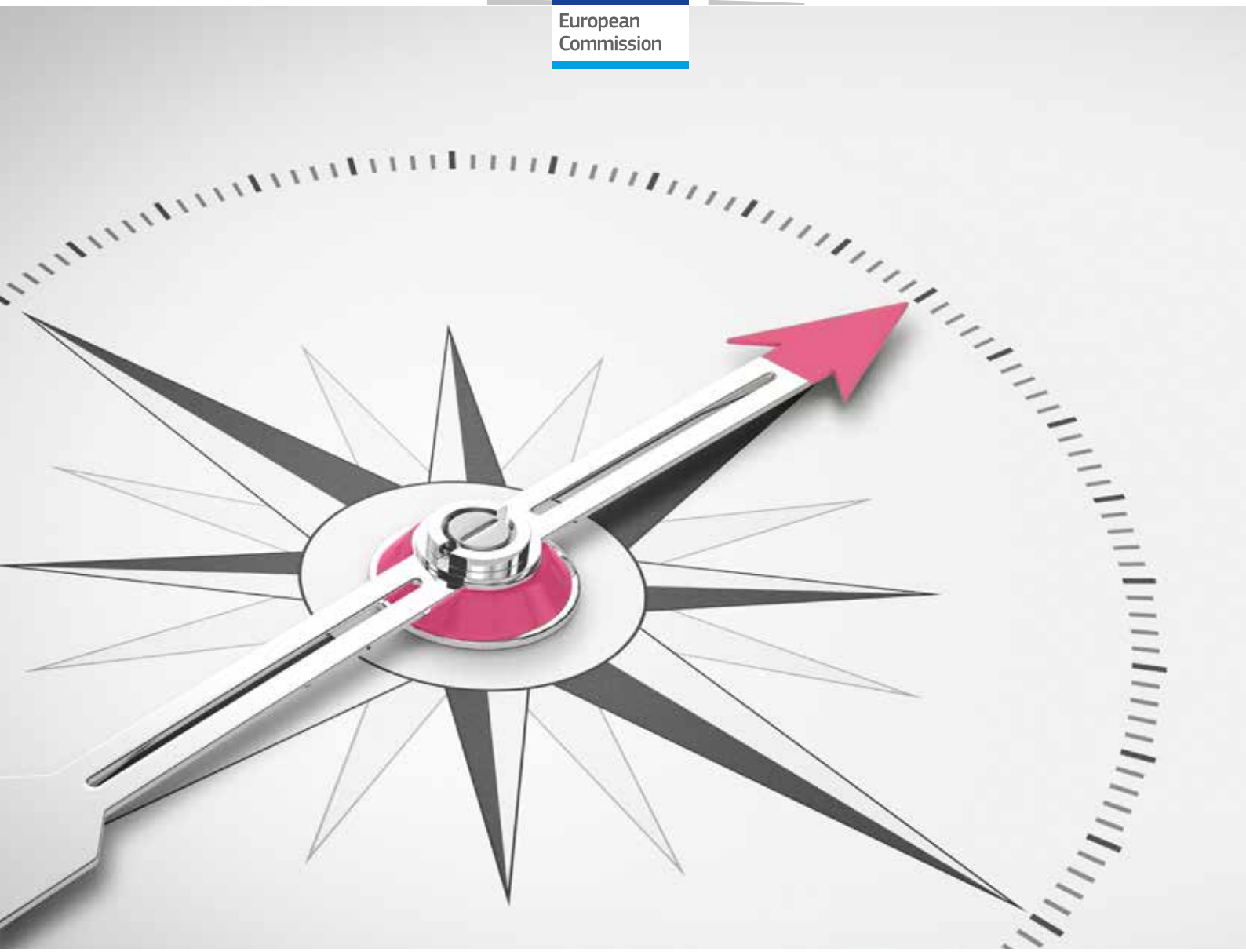

European guidelines for breast cancer screening and diagnosis

Scope

European Commission Initiative on Breast Cancer

Guidelines Development Group

Healthcare Quality Team

2017

Joint Research Centre

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Contents

This document concerns the scope of the **European guidelines for breast cancer screening and diagnosis** – in short, the ***European Breast Guidelines.***

The scope of guidelines defines the topics that they cover, such as whether diagnosis and/or treatment processes of a disease are included, or whether areas where there is a great uncertainty or variation in clinical practice are covered. Thus, the scope outlines those topics, considered important to the target audience, which the guidelines address.

According to the scope the Guidelines Development Group (GDG) of the *European Breast Guidelines* has defined the following six chapters:

1. screening
2. diagnosis
3. communication
4. training
5. interventions to reduce inequalities
6. monitoring and evaluation of screening and diagnosis.

Each chapter is foreseen to include specific recommendations prioritised by the GDG, based on PICO[1] questions, relevant to the target audience.

1 P=population, I=intervention, C=comparator, O=outcome

1. Title

Full title: European guidelines for breast cancer screening and diagnosis
Short title: *European Breast Guidelines*

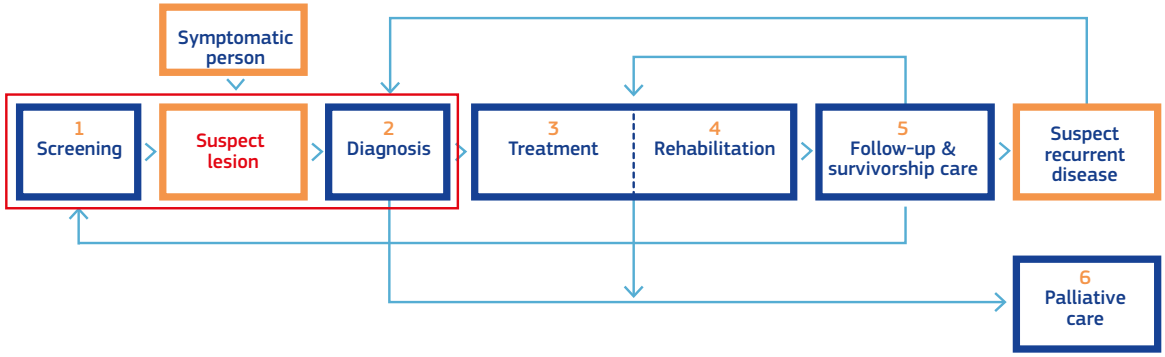
2. Purpose

2.1 Remit

The Directorate General for Health and Food Safety (DG SANTE) asked the European Commission's Joint Research Centre (JRC) to coordinate the European Commission Initiative on Breast Cancer (ECIBC). The ECIBC aims to ensure and harmonise the quality of breast cancer services across European countries via a quality assurance scheme for breast cancer services (in short, the *European QA scheme*) underpinned by evidence-based guidelines.

One objective of the ECIBC is to develop the *European Breast Guidelines* for the screening and diagnosis processes of breast cancer care (see boxes 1 and 2 in Figure 1 below). For the remaining processes (boxes 3-6 in Figure 1) evidence-based recommendations are being collected in a platform of evidence-based guidelines (the ECIBC *Guidelines Platform*). This platform, covering breast cancer treatment, rehabilitation, follow-up and survivorship care, and palliative care, as well is meant to support the *European QA scheme*. More information about the ECIBC is available in the concept document (2).

Figure 1: Breast cancer care pathway (red square signifies the processes within the scope of the *European Breast Guidelines*)



2.2 Objectives

The primary objectives of the *European Breast Guidelines* are:

1. to provide both **healthcare users** and **healthcare providers** with clear, objective and independent guidance on breast cancer screening and diagnostic services to enable them to take informed decisions; and
2. to guide **healthcare providers** and **policymakers** when planning, (de)commissioning and organising services for breast cancer screening and diagnosis. This is done by developing evidence-based recommendations to support the quality assurance of breast cancer screening and diagnosis, **with an emphasis on improvement of outcomes and quality of the processes.**

In accordance with these objectives, it is anticipated that some recommendations of the *European Breast Guidelines* include more than one perspective, *e.g.*, an individual and a population perspective (see section '3.2 Perspective of the *European Breast Guidelines*').

2.3 Expected outcomes

An '**outcome**' is the impact that a test, treatment, policy, programme or other intervention has on a person, group or population (1, 3). The importance of outcomes is likely to vary within and across cultures, and depending on the perspective, of the citizens, patients, clinicians or policymakers, considered. Cultural diversity often influences the relative importance of outcomes, particularly when developing recommendations for an international audience (4).

It is anticipated that the *European Breast Guidelines* are meant to have an impact on outcomes important to citizens and health systems, such as:

- breast cancer mortality;
- quality of life;
- patient safety;
- equity in healthcare;
- unnecessary variability in clinical practice.

3. Target population

3.1 Population addressed

Groups covered:

- persons eligible for breast cancer screening;
- persons accessing breast diagnostic services because of symptoms, referral (*e.g.* following a risk assessment) or a recall on the basis of their screening examination.

Groups NOT covered:

The *European Breast Guidelines* will not address questions concerning issues of these specific populations[2]:

- patients with loco-regional breast cancer recurrence;
- patients with metastatic breast cancer.

3.2 Perspective

The legal basis for the *European Breast Guidelines* and the previous European guidelines for quality assurance in breast cancer screening and diagnosis (5) is the 2003 Council Recommendations. It states that 'the Council [...] hereby recommend the Member States to [...] implement cancer screening programmes in accordance with European guidelines on best practice where they exist and facilitate the further development of best practice for high quality cancer screening programmes on a national and, where appropriate, regional level'.

The primary purpose of the *European Breast Guidelines*, in particular as stated in the aforementioned Council Recommendations, should be to give policymakers, as well as healthcare users and providers, guidance, through evidence-based recommendations, on the implementation of population-based breast cancer screening programmes and on the organisation of diagnostic procedures for breast cancer, as well as on the adequate evaluation of these programmes and services (See chapter 6 **Monitoring and evaluation of screening and diagnosis**).

2 Treatment regimens and surveillance for patients are regularly updated in international treatment guidelines. The *Guidelines Platform*, as collection of existing evidence-based guidelines, can include recommendations on treatment for all breast cancer patients.

The perspective of users of these breast cancer services (healthcare users) are being taken into consideration during all stages of the *European Breast Guidelines* development.

For diagnostic services, especially when provided outside of a screening programme, the perspectives of healthcare users and clinicians are prioritised. This means that the focus is on the views of the individual healthcare user of the breast cancer service and the healthcare professional that provides that service.

When developing the recommendations of the *European Breast Guidelines*, a balance between these different perspectives (*e.g.*, healthcare users vs. public health vs. policy support) is being sought. This is also taken into account when choosing the outcomes for these recommendations (6).

Finally, quality assurance of all breast cancer care processes is a key aspect to be addressed by the ECIBC. Although it is anticipated that most quality assurance aspects are covered by the *European QA scheme*, some questions of the *European Breast Guidelines* may focus on the quality assurance aspects of breast cancer screening and diagnosis.

4. Healthcare setting

4.1 Healthcare setting

The *European Breast Guidelines* cover all healthcare settings, both private and public, where services for systematic breast cancer screening and breast cancer diagnostic services are delivered.

4.2 Geographical context

The *European Breast Guidelines* aim to have an impact beyond the EU, so the European Commission asked the 28 EU Member States plus Iceland, Montenegro, Norway, Serbia, Switzerland, Liechtenstein, the former Yugoslav Republic of Macedonia and Turkey to each nominate a National Contact as a focal point to represent each participating country during the ECIBC project (see full list of National Contacts of the ECIBC) (2).

Other countries outside Europe may also implement the *European Breast Guidelines* once they are published. The *European Breast Guidelines* consider the geographical context, socioeconomic factors, and the strength of the health systems in which the recommendations are implemented. Therefore, the resources used and cost-effectiveness of the interventions are taken into account when developing the recommendations.

5. Types of interventions

5.1 Definitions

The following definitions of a commonly used terminology, based on the European Commission's Report on the implementation of the Council Recommendation on cancer screening and on the WHO guide for effective programmes (7, 8) are adopted for use in the *European Breast Guidelines*.

SCREENING: the systematic application of a screening test in a presumably asymptomatic population. In cancer screening, it aims to identify individuals with an abnormality suggestive of a specific cancer. These individuals require further investigation.

NON-PROGRAMME SCREENING (commonly referred also as opportunistic screening): examinations for early detection of cancer performed in a diagnostic or clinical setting, independent from the public screening policy (if existing).

PROGRAMME SCREENING: screening examinations financed by public sources performed in the context of a public screening policy documented in a law, or an official regulation, decision, directive or recommendation, and where the policy defines, at minimum: the screening test, the examination intervals, groups of persons eligible to be screened.

ORGANISED SCREENING: programme screening where additional procedures (*e.g.* standard operating procedures) are specified and where a team at national or regional level is responsible for implementing the policy, *i.e.* for coordinating the delivery of screening services, maintaining requisite quality, and reporting on performances and results.

POPULATION-BASED SCREENING: organised screening programme where in each round of the screening, the persons in the eligible target population in the area served by the programme are individually identified and personally invited to attend screening.

A diagnostic assessment may stem from referral for symptoms or palpable mass, or as further investigation of women with a screening abnormality suggestive of breast cancer.

5.2 Interventions covered

The *European Breast Guidelines* cover the **screening and diagnosis of breast cancer**. The desirable and undesirable effects of the following interventions are being assessed, in order to produce clinical recommendations, as well as health systems and public health recommendations:

- **Breast cancer screening policies and programmes:**
  - different modalities of organised population-based screening programmes according to women's age, screening intervals and tests
  - opportunistic screening.
- **Breast cancer diagnostic processes** — these include examinations undertaken following referral and prior to treatment processes, considering:
  - criteria for referral of symptomatic persons
  - diagnostic procedures for benign lesions
  - evaluation of different methods for diagnosis and pre-treatment staging (and, more in general, breast imaging techniques)
  - all biopsy procedures and their pathological examination (such as fine needle aspiration, core biopsy and surgical biopsy).
- **Interventions for primary prevention of breast cancer** provided as co-interventions nested in organised screening programmes (*e.g.* information, counselling).
- **Interventions to reduce harms due to breast cancer screening or diagnosis.**
- **Interventions to improve communication on breast cancer screening and diagnosis.**
- **Interventions to improve the organisational aspects** of breast cancer screening and diagnosis (such as multidisciplinary team meetings).

5.3 Interventions NOT covered

- **Aspects outside the scope of breast cancer screening and diagnosis care processes**. Breast cancer treatment, rehabilitation, follow-up and survivorship care and palliative care are not covered (but are part of the *Guidelines Platform*).

- **Diagnostic procedures in breast cancer patients with suspected recurrences or metastases**, such as the staging procedures in persons with suspected recurrences or metastases during follow-up are not covered (but are part of the *Guidelines Platform*).

- **Breast cancer risk assessment**. The *European Breast Guidelines* do not cover questions specifically addressing breast cancer surveillance in women with hereditary breast cancer.

6. Key stakeholders and users

The following are the relevant groups whose views are considered:

1. **Users of breast screening and diagnostic services** (persons attending breast cancer screening services or those who undergo diagnostic assessment because of symptoms/recall from screening/referral), their families and carers, and the general public need to be informed in a clear and constructive way on this topic. The *European Breast Guidelines* are 'person-centred'. This implies that the perspective of users of breast cancer services is taken into consideration during all stages of the development of the *European Breast Guidelines*.
2. **Healthcare providers** directly responsible for providing breast cancer services, such as general practitioners/family doctors, gynaecologists, radiologists, histopathologists, surgeons, medical oncologists, radiation oncologists, reconstructive surgeons, palliative care physicians, breast care nurses, psychologists, genetic counsellors, etc.
3. **Managers** of breast screening and diagnosis services.
4. **Public health officers**.
5. **Policymakers**.
6. **Professional bodies/associations/academic societies**.
7. **Epidemiologists** and other **researchers**.
8. **Non-governmental organisations**.
9. **Patients organisations, breast cancer support groups, other voluntary organisations and charities**.
10. **Industry** linked to breast cancer screening and diagnosis.
11. **Families** of persons with breast cancer.

7. Bibliography[3]

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8. WHO (2007). *Cancer control: knowledge into action: WHO guide for effective programmes: early detection,* p. 3.

3 This is a brief list of documents used to prepare the scope. All literature used to make the recommendations that the *European Breast Guidelines* will provide will be included in the ECIBC's web-hub.

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The European Commission's in-house science service

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