European Commission

ECIBC at a Glance

EUROPEAN COMMISSION INITIATIVE ON BREAST CANCER

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Tackling cancer is of fundamental importance for our future. If we join forces at EU level we can make a difference and reduce the suffering of cancer in Europe.

Stella Kyriakides,
European Commissioner
for Health and Food Safety

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AN INITIATIVE TO TACKLE BREAST CANCER

WHAT IS ECIBC?

In 2008 the European Parliament and Council gave strategic directions to future European activities on combatting cancer, and sought to further support Member States in their efforts to reduce the burden of this disease. Particular attention was given to the most frequent cancers. This led, among other things, to the **European Commission Initiative on Breast Cancer (ECIBC)**.

ECIBC addresses the need to improve the quality of breast cancer care across Europe, from screening and diagnosis to treatment and palliative care.

This is achieved through developing and providing evidence-based recommendations for breast cancer screening and diagnosis (European Guidelines) and a voluntary quality assurance scheme (QA Scheme) for breast cancer early detection and care. In addition, useful information and tools for breast cancer services, healthcare professionals and women will be made available.

All ECIBC products are publicly available and free to access on the ECIBC website.[1]

1 ECIBC Internet address: healthcare-quality.jrc.ec.europa.eu

WHY IS THERE A NEED FOR THIS INITIATIVE?

Breast cancer is a cross-border issue that affects women of all ages, and inequalities in healthcare delivery in this area persist. Every woman in Europe should have the right to access quality breast cancer services, regardless of where she lives or her financial resources.

Coordinated action at the European level for the quality assurance of breast cancer care will contribute towards ensuring that women across Europe have access to optimal healthcare based on the latest available evidence.

WHO WILL BENEFIT?

ECIBC activities will ultimately benefit women. By ensuring an essential level of quality of breast cancer services with a person-centred perspective, the initiative aims to help reduce inequalities in healthcare delivery, empowering women and improving their quality of life and survival.

Women, patients and their families can access the latest European Guidelines on breast cancer screening and diagnosis developed by the ECIBC initiative also in plain language formulated for non-professional public. Additionally, specific tools are being developed to help make decisions that are more informed.

HOW IS THE INITIATIVE IMPLEMENTED?

The ECIBC quality assurance scheme defines a common set of requirements for breast cancer services covering all stages of care. It is for voluntary application but those services seeking certification must meet all the requirements outlined in the QA Scheme.

The European Guidelines provide evidence-based recommendations for screening and diagnosis, and inform the development of the ECIBC quality assurance scheme.

Healthcare authorities and professionals can adopt the European Guidelines as they are provided, or adapt them to their local context through a transparent process made available by ECIBC.

EUROPEAN GUIDELINES

KEY FEATURES

- Evidence-based recommendations for screening and diagnosis
- Available online and regularly updated
- Targeted to address professionals, women and policy makers

ECIBC has developed evidence-based practice guidelines for breast cancer screening and diagnosis including recommendations intended to optimise patient care. Each recommendation, publicly available on the ECIBC website, contains information specifically tailored to women and healthcare professionals, as well as decision-makers.

The recommendations in the European Guidelines:

- are based on systematic reviews of existing evidence conducted by an independent team;
- have been developed by a knowledgeable, multidisciplinary panel of experts, namely the Guideline Development Group (GDG);
- take into account patient needs;
- follow a transparent process that minimises conflicts of interest;
- provide a clear explanation of care options, including their benefits and harms;

- rate both the quality of the evidence and the strength of the recommendation;
- are revised when important new evidence comes to light.

The recommendations, freely accessible from the ECIBC website, are grouped into three main topics (see table below).

Each sub-topic includes one or more recommendations presented in a *question and answer format*. The strength of each recommendation is qualified as 'strong' or 'conditional' based on an analysis of the evidence available.

- A strong recommendation means that most people in this situation would want and should receive the recommended course of action and only a small proportion would not, and that the recommendation can be adapted as a policy in most situations.
- A conditional recommendation means that the majority of people in this situation would want the recommended course of action, but many would not. Clinicians should be prepared to help patients make a decision that is consistent with their own values, and for policy makers, a substantial debate is needed that involves stakeholders.

Breast cancer screening
Screening ages and frequencies
Tomosynthesis use in screening
Additional tests for dense breast screening
How to invite and inform women about screening
How to organise breast cancer screening programmes

Breast cancer diagnosis
How to inform women about their results
Further assessment after the mammogram
Staging of breast cancer
Towards the treatment of invasive breast cancer

Training of the staff
Mammography readers
Communication training for the staff

WHAT DO THE EUROPEAN GUIDELINES LOOK LIKE?

Each recommendation in the European Guidelines is organised, for example, as follows:

1. **Healthcare question**
   Should organised mammography screening versus no mammography screening be used for early detection of breast cancer in women aged 40 to 44?

2. **Final recommendation**
   For asymptomatic women aged 40 to 44 with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests not implementing mammography screening.

3. **Strength of the recommendation**
   - Conditional recommendation against the intervention.
   - Moderate certainty of the evidence.

4. **Considerations on specific population sub-groups**
   This recommendation does not apply to high-risk women.

5. **Considerations for implementation and policy making**
   GDG members agreed on the need for additional imaging techniques in this age group, as well as the need for shared decision making.

6. **Monitoring and evaluation of the recommendation**
   Future monitoring and evaluation of screening services should consider benefits and risks in the context of evolving treatment and management protocols.

7. **Research priorities, if identified:**
   - Carry out evaluations of the efficacy of the intervention, time intervals, risk factors and stratification of women, as well as context specific cost-effectiveness in this age group.
   - Carry out studies addressing the role of other screening modalities (such as magnetic resonance imaging – MRI) in this population.

8. Supporting documents

- **Evidence to Decision:** recommendation justifications, considerations and assessments.
- **Evidence Profile:** Quality assessments of the evidence from literature reviews and a summary of findings.
- **Bibliography**.

9. Summary information for women

This section includes the recommendation itself; what following this recommendation means; who the recommendation is for; as well as definitions and additional considerations for further clarification.

UPDATING STRATEGY

The European Guidelines are regularly monitored and updated as and when new scientific evidence becomes available. This makes the process time- and cost-efficient. Some recommendations are likely to need more frequent updates than others, such as those related to new innovative technologies or rapidly evolving scientific fields.

The updating process allows the consideration of new evidence, which may impact recommendations. The process is modular and subdivided into phases, to assess specific updating needs for each recommendation.

The four phases of the updating strategy consist of:
i) prioritisation;
ii) surveillance;
iii) updating; and
iv) publication.

Each recommendation can go through one or more of these phases depending on the new evidence available.

REPOSITORY OF INTERNATIONAL GUIDELINES

KEY FEATURES

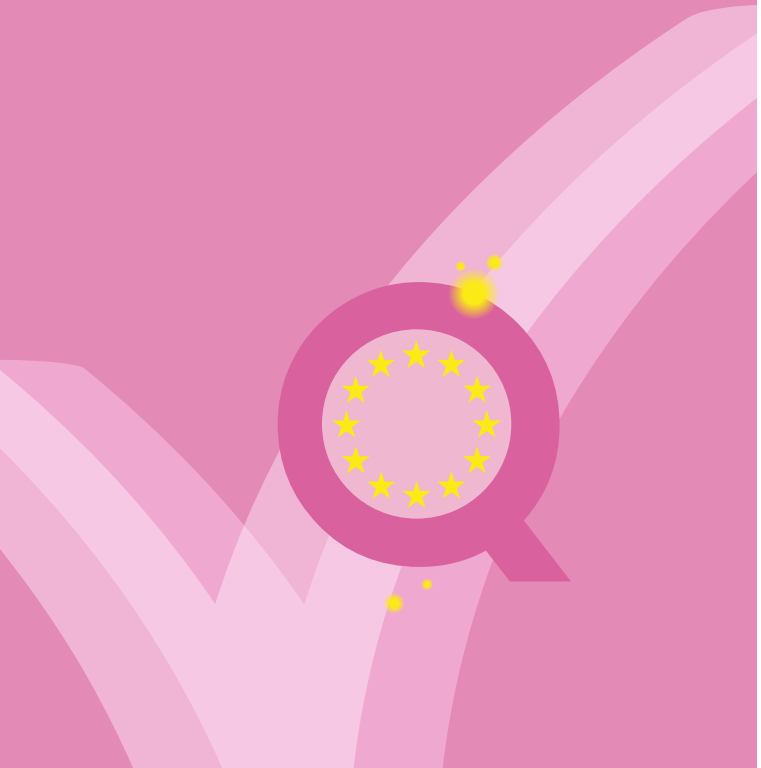
- Library of guidelines from around the world
- Includes treatment, rehabilitation, follow-up and palliative care
- Inform the ECIBC quality assurance scheme

Breast cancer guidelines are published by numerous institutions and organisations across the world. Healthcare professionals can find it challenging to identify and implement guidelines for specific breast cancer care processes.

This repository of current international guidelines on breast cancer complements the European Guidelines on screening and diagnosis. These guidelines were assessed for their quality, clinical impact, geographical coverage and sustainability, and have been published within the past 10 years.

They cover prevention of breast cancer, treatment, rehabilitation, follow-up and survivorship, palliative care and end-of-life care. Additionally, they provide underpinning evidence for the European quality assurance scheme, addressed in the next chapter.

THE QUALITY ASSURANCE SCHEME



KEY FEATURES

- Quality, safety and training requirements for breast cancer services and professionals
- From organised population-based screening to end-of-life care
- Voluntary, flexible and modular implementation

The ECIBC quality assurance scheme (QA Scheme) defines a common set of quality and safety requirements for breast cancer services in Europe, as well as training requirements for professionals involved in breast cancer care. It focuses on aspects that are relevant to citizens and patients, and covers all the relevant care processes from screening until the end-of-life care.

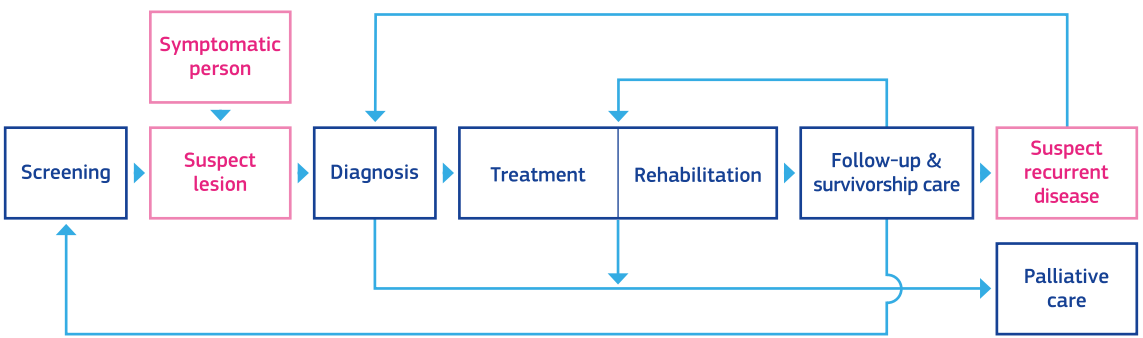
The QA scheme will be freely available to all interested breast cancer services (e.g. hospitals, clinics, diagnostic centres, etc.) worldwide.

The requirements contained in the scheme are definable, measurable and actionable. They relate directly to the maintenance, restoration or improvement of health, and relate to one or more of the following quality domains:

- clinical effectiveness;
- facilities, resources and workforce;
- personal empowerment and experience;
- safety.

Breast cancer screening and care involves different healthcare services, depending on the individual course of the disease. The breast cancer pathway defined and covered by the scheme shows the journey followed by a patient, including possible entry and end points and the services involved.

Breast cancer care pathway covered by the QA Scheme



REQUIREMENTS

The scheme includes a list of requirements for breast cancer services addressing the quality of care. Each requirement comprises: i) a statement, ii) detailed information on what is measured and how, and iii) provides the corresponding supporting evidence and references. Breast cancer services that fulfil the QA Scheme requirements will obtain a recognised certificate.

The QA Scheme is based on evidence coming from recommendations from the European Guidelines on screening and diagnosis, as well as the repository of international guidelines.

DEVELOPING THE QUALITY ASSURANCE SCHEME

The QA Scheme is the result of cooperative work. The Quality Assurance Scheme Development Group (QASDG) brought together a panel of international professional experts in all areas of breast cancer care and quality assurance, as well as patients.

Requirements were developed based on reviewing existing literature, databases and other quality assurance schemes internationally. Additionally, new requirements were formulated in areas where the expert group identified a need for quality improvement.

Requirements were prioritised and first rated for: i) relevance and understandability, and then for ii) feasibility. Relevance relates to the significance of the requirements for a person-oriented care. Feasibility relates to the ability of the requirements to be implemented.

IMPLEMENTING THE QA SCHEME

The QA Scheme aims to support quality breast cancer care across Europe and to decrease inequalities in care and survival. Implementation of the QA Scheme is voluntary. The initiative has been developed in a flexible way, adaptable to national contexts.

The QA Scheme adheres to evidence-based guidelines, and this has been linked with achieving better health outcomes.

Certification

Breast cancer services that fulfil the quality assurance requirements can be certified. This certification covers the entire breast cancer care pathway as defined by ECIBC.

Services that outsource certain processes can also be certified. In these circumstances, legal agreements must be in place, and all outsourced processes have to comply with the requirements of the QA Scheme.

To demonstrate compliance, breast cancer services will be audited. Auditing is carried out by independent certification bodies accredited by National Accreditation Bodies. Accreditation ensures that all bodies can perform harmonised independent audits, across borders if required. It is envisaged therefore that the QA Scheme will follow ISO/IEC/17065 for accrediting certification bodies.

Auditors will assess whether the QA Scheme requirements are fulfilled by different means, including remote checking of documents/reports and on-site visits in the breast cancer services, the review of medical records, interviews with service staff, etc.

Breast cancer services can also follow the QA Scheme requirements to improve their current performance, without seeking certification, or in view to obtain it later on.

QA SCHEME MANUALS

Manuals have been developed for each main actor involved in the scheme implementation process. These manuals are freely available on the website.

- **Manual for breast cancer services**
  All requirements are listed and described in this manual. It provides details on how to meet the respective requirements, as well as on the calculation of indicators that will be used to verify quantitative requirements. The manual also specifies how compliance with a given requirement has to be demonstrated by the breast cancer services.

- **Scheme owner manual**
  This manual sets out how the QA Scheme is organised, managed and maintained and how the certification process is carried out. The aim is to provide full details of scheme owner requirements for breast cancer services and certification bodies participating in the scheme.

- **Manual for certification bodies**
  A section of the scheme owner manual is dedicated to certification bodies. This document contains everything auditors need to know in terms of scheme requirements, how to perform the audit, and when to give certification.

ADDITIONAL TOOLS SUPPORTING IMPLEMENTATION

KEY FEATURES

- Support implementation of the European Guidelines and the QA Scheme
- Freely available online
- Can be used independent of certification

Additional resources are available to support implementation of the ECIBC. All these are also freely accessible on the ECIBC website and serve a variety of functions.

These tools complement both the European Guidelines and the QA Scheme, and can also be independently used to monitor and improve the quality of breast cancer care.

EUROPEAN GUIDELINES

Decision support tools

In order to empower women to participate in the decision about what intervention is best, decision aids will be made available. They will provide information about the possible options women have and the consequences of each of those options, helping them to reach an informed decision which takes into account their personal values and risks.

Population-based screening indicators

A number of indicators to evaluate the effectiveness of population-based organised screening programmes have been developed. These indicators measure, for example, the coverage and participation in the screening programme, the number of screen-detected and interval cancers, or time to start treatment.

These indicators were chosen based on a set of criteria that include relevance, measurability, accuracy, ethical considerations and understandability.

QUALITY ASSURANCE SCHEME

Self-assessment tool

A self-assessment tool will help services to determine the preparedness of breast cancer services to comply with the requirements of the QA Scheme and to identify what they need to do to achieve compliance.

Services can then apply for formal recognition of compliance with the scheme, which will be assessed by independent bodies recognised by the scheme.

Quality indicators calculator

A calculator is available to help breast cancer services to compute indicators in a standardised manner, to measure compliance with the QA Scheme developed by ECIBC. Services not looking for certification can also use the tool to assess or improve their current performance.

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