Abstract

The European Commission Initiative on Breast Cancer (ECIBC) is aimed at ensuring and harmonising breast cancer services quality across European countries. It is coordinated by Commission’s Joint Research Centre, under the supervision of the Directorate-General Health and Food Safety. This document describes the background of the initiative, its general goals and objectives, and its foreseen outcomes.
European Commission

Initiative on Breast Cancer:
Concept document

2015
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What is the European Commission Initiative on Breast Cancer?

The European Commission Initiative on Breast Cancer (ECIBC) is an initiative of the European Commission (‘the Commission’). The initiative is taken forward with a focus on long term sustainability, building upon a platform bringing together a wide range of actors at EU level in a transparent way. The ECIBC is taken forward by the Commission’s Joint Research Centre (JRC) based on an agreement with the Commission’s Directorate-General Health and Food Safety (DG SANTE).

Its aim is to ensure and harmonise quality of breast cancer services across European countries.¹

DG SANTE has the policy leadership as regards the implementation of EU health policy on cancer. The Commission expert group on Cancer Control, which is a forum for Member States and stakeholders to provide input into cancer policy development at EU level, will regularly review the development of the ECIBC in order to guarantee the full compatibility and coordination of the initiative with the overall EU policy on cancer.²

JRC has the scientific and technical responsibility for the ECIBC and coordinates its implementation, ensuring synchronisation of all ECIBC objectives, the delivery of quality outputs and that deadlines are met. Owing to the inter-dependence of the different working groups of the ECIBC, close coordination and collaboration is essential for the success of the initiative. JRC also ensures appropriate linkages with other Commission services and EU projects in areas relevant for the project (for example, with the EU Joint Action on Cancer Control – CANCON).

¹. The ECIBC’s impact is foreseen to spread beyond the EU as it is expected to be implemented in the 28 EU Member States, EU candidate countries (Albania, Iceland, Montenegro, The Former Yugoslav Republic of Macedonia, Serbia and Turkey), EU potential candidates (Bosnia and Herzegovina and Kosovo), and EFTA members (Iceland, Liechtenstein, Norway and Switzerland).
². The Commission expert group on Cancer Control, created by Commission decision of 3 June 2014 and repealing Decision 96/469/EC, assists DG SANTE in its policy responsibility in the cancer domain in the drawing up of legal instruments and policy documents, guidelines and recommendations on cancer control at the request of the Commission.
Rationale: why is the ECIBC necessary?

Breast cancer, the most common cancer in Europe

According to WHO 2012 estimates, each year there are 2.6 million new cases of cancer in Europe (excluding non-melanoma skin cancers). Breast cancer is the most frequent one with 364,000 new cases. This represents 13.8% of all new cancer cases detected, followed by prostate (360,000), colorectal (342,000), and lung (310,000) cancer.

Among women, breast cancer is by far the most frequently diagnosed cancer in Europe each year, representing 28.8% of the diagnosed cancers.

Breast cancer, the leading cause of death from cancer in women in Europe

It is estimated that breast cancer causes 91,000 deaths each year in Europe. This represents the third most common cause of death from cancer in the overall population (7.2% of the total deaths by cancer), after lung cancer (20.9%) and colorectal cancer (11.9%).

Among women, breast cancer is the first cause of death from cancer, accounting for 16.3% of all cancer deaths.

Health inequalities in Europe related to breast cancer

There are substantial differences in breast cancer incidence, mortality, prevalence and survival within and among countries in Europe. For example, the estimated

3. Ferlay et al. 2013. WHO estimations for the EU-27 in 2012 are presented, as they are the most recent aggregated estimations which best apply to the geographical area covered by the ECIBC (http://www.sciencedirect.com/science/article/pii/S0959804913000073).
age-standardised mortality rate in EU-27 was 22.4 in 2012. Those estimations suggest that in a population of 100,000 women, about 22 died due to breast cancer that year. However, the mortality rates ranged from 15 to 29 across the countries, implying that age-standardised mortality in countries ranking the worst doubled those ranking the best. Although the higher mortality rates in some countries may reflect the higher incidence of breast cancer, in others they can be due to the lower survival of women with breast cancer.

These differences suggest the presence of health inequalities among countries.

**Figure 1:** Age-standardised incidence and mortality rates in Europe 2012: breast cancer.

Differences in a number of factors might give rise to health inequalities, such as differences in the socio-economic status, in exposure to risk factors, in health system policies (e.g. presence/absence of screening programmes), or in the effective delivery of cancer control measures. The heterogeneous quality of breast cancer services is, therefore, a relevant cause of health inequality.
Differences in the quality of breast cancer services in Europe

There are differences in the quality of healthcare services across European countries. Moreover, at least ten different quality schemes coexist in Europe with a specific target on breast cancer. This confirms that there is no common set of benchmarking quality requirements in Europe.

In summary, there is substantial potential for reducing inequalities in cancer amenable to healthcare in Europe. Therefore, a coordinated action at European level is needed to ensure that all European citizens have access to healthcare services with an essential level of quality and safety.

Legislative framework

According to the *Treaty of Lisbon* (Title XIV, Article 168), the Commission may promote cooperative actions particularly ‘to combat the major cross-border health scourges’ and take ‘initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation’ and adopt incentive measures.

In December 2003, the Council adopted the *Council Recommendation on cancer screening* and recommended population-based screening for breast, cervical and colorectal cancers in accordance with European guidelines. Adoption of European guidelines on best practice was identified as key for ensuring the development of high quality cancer-screening programmes, and the European Commission (‘the Commission’) coordinated the production of such guidelines. For breast cancer screening, the latest is the 4th edition of the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis,* which aims at promoting best practices identified via a consensus-based approach.

As regards the follow-up of lesions detected via screening, in 2008, both the *European Parliament Resolution,* which acknowledged the differences in ‘the quality of cancer treatment facilities, screening programmes and evidence-based best-practice guidelines…’, and the *Council Conclusions on reducing the burden of cancer,* called on the Commission ‘to support the development of European accreditation/certification programmes in cancer screening, diagnosis and treatment based on European quality-assurance guidelines’ and ‘to explore the potential for the development of voluntary European accreditation schemes for cancer screening.

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and appropriate follow-up of lesions detected by screening, such as a European pilot accreditation scheme for breast cancer screening and follow-up based on the European guidelines for quality assurance (QA) in breast cancer screening and diagnosis.

Other acts are as well relevant for the framing of the ECIBC project.

The Council Recommendation on Patient Safety:14 the minimum requirements set by the Recommendation will have to be included among the requirements of the ‘European accreditation/certification programmes’ mentioned by the Council Conclusions of 2008.

The Directive on the application of patients’ rights in cross-border healthcare:15 relevant both for patients’ safety aspects and as far as the rights of patients to transparent information on certain performance indicators for healthcare services.

The legislation on accreditation: the Regulation for Accreditation and Market Surveillance16 and its implementation acts are the legal basis for ensuring an officially recognised peer reviewing system for the ‘European accreditation/certification programmes’ developed upon the Council Conclusions.

General goal and objectives

General goal

Within the European Commission policies for chronic diseases, ECIBC’s overall goal is to contribute to improve health and to reduce health inequalities in Europe by ensuring the quality of breast cancer services.

Specific objectives

In order to contribute to the overall goal, ECIBC aims to achieve the following specific objectives:

Objective 1. To propose evidence-based recommendations for breast cancer services in Europe.

Objective 1.1. To develop a new version of the European Guidelines for Breast Cancer Screening and Diagnosis based on new knowledge and evidence (the new European guidelines).

Coordinated by the JRC, the new European Guidelines will continue the work of the 4th edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (published in 2006).

The ECIBC considers five stages along the breast cancer care pathway:

- screening
- diagnosis
- treatment
- rehabilitation
- follow-up.
The *new European Guidelines* will provide evidence-based recommendations for the screening and diagnosis stages of breast cancer services. When possible and appropriate, an evidence-based approach rather than a consensus-based one will be applied. Moreover, the *new European Guidelines* will have a web-based format.

**Objective 1.2.** To create a platform of guidelines for breast cancer treatment, rehabilitation and follow-up.

The *new European guidelines* will cover breast cancer screening and diagnosis. For the remaining stages of the breast cancer pathway (treatment, rehabilitation and follow-up, and all relevant horizontal aspects), JRC will coordinate the development of a platform of trustworthy guidelines. This platform will provide evidence-based recommendations on those stages.

**Figure 2:** Stages of breast cancer care covered by the new European Guidelines and the platform of guidelines.

**Objective 1.3.** To propose a procedure to maintain the evidence-based recommendations for breast cancer services up-to-date in the long term.

The JRC will define the approach to assess the need to update guidelines and will apply this approach to warrant that the *new European Guidelines* and the recommendations collected in the platform are based on the best available and most updated evidence.
Objective 2. To develop a voluntary European QA scheme for Breast Cancer Services based on the EU legislative framework on accreditation, as defined in the Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance.

The *European QA scheme* will define a common set of quality and safety requirements for breast cancer services in Europe. It will be based on the European legal framework for accreditation, and hence will be under harmonised peer supervision across all involved countries under the co-ordination of the European co-operation for Accreditation (EA); it would be potentially usable by all countries associated to EA. The scheme will cover all the relevant areas of healthcare provision for breast cancer and all stages of breast cancer care (screening, diagnosis, treatment, rehabilitation and follow-up). Once finished, it will be piloted among participant services in Europe.

In order to respect the diversity of healthcare organisation settings across European countries, the *European QA scheme* will have a modular structure following the

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pattern of care as identified in Figure 4 below, where blocks represent the stages of care and the arrows the communication and traceability that has to be granted among stages and services.

**Figure 4**: Modular and sequential model for the European QA scheme.

![Diagram of care stages](image)

The *European QA scheme* will focus on requirements that are relevant to citizens. On the other hand, it will be voluntary and respectful of the autonomy of European countries while steering towards the harmonisation and coordination of existing quality schemes, in order to reduce duplication of efforts.

The *European QA scheme* will define its requirements considering evidence-based recommendations arising from high-quality guidelines whenever possible. Therefore, it will be underpinned by the relevant evidence collected via the first objective of the ECIBC.

**Objective 3.** To develop a European template of training on digital mammography.

The objective is to develop a concept for digital mammography training directed at health professionals involved in screening programmes. It will include the minimum requirements for professionals working for services adhering to the *European QA scheme*. It will be carried out in coordination with the European key stakeholders and, if successful, the model can be applied to other professional profiles covered by the *European QA scheme*.

**Objective 4.** To develop a long-term web hub hosting all the deliverables.

The web hub will be the communication interface of the ECIBC with the stakeholders. It will be the gateway to all the information, outputs and tools produced. Its deployment will be coordinated by the JRC, including stakeholders’ input on the desirable features.
The web hub will be user-friendly, adapted to the user (for example, to patients or professionals), and will comply with the standards for trustworthy health information. It will also offer the interface for the necessary collaboration of the stakeholders involved in the ECIBC, for example for the different working groups and for open consultations.

Moreover, it will be expandable to other cancer types and health problems.
Expected benefits

1. Greater confidence in breast cancer services

Citizens will receive clear information about what they can expect to receive at breast cancer services adhering to the European QA scheme, and this will help them developing confidence in the quality of breast cancer services in Europe, irrespective of the country they live in. This is relevant for the Cross-border Healthcare Directive and is particularly important because many citizens live and receive breast cancer care abroad.

2. Reduction of health inequalities in Europe

By improving the quality of breast cancer services in Europe, the ECIBC aims at contributing to reduce the burden of cancer and decrease the differences in incidence, mortality, prevalence and survival that exist between and within involved countries.

3. Effective implementation and updating of the evidence

The ECIBC model, where the European QA scheme assesses adherence to guidelines and may, in the long term, be standardised, is designed to facilitate the implementation of the evidence-based recommendations provided by guidelines. This will reduce unwanted variability in healthcare. In addition, the continuous implementation of the European QA scheme will be an effective way of maintaining guidelines up-to-date.

4. Model exportable to other health problems

If this approach proves to be successful, the JRC will, upon request, provide support for its application to other diseases, such as colorectal and cervical cancer, as well as other healthcare areas.
ECIBC structure

Figure 5: Policy responsibility and endorsement of Guidelines and QA scheme.\(^{18}\)

1. The coordination role

The European Commission, in particular DG SANTE\(^{19}\) and the JRC,\(^{20}\) will coordinate the ECIBC to ensure that deadlines are met and actions implemented.

The Commission is a suitable institution to coordinate this initiative as it can steer the initiative in the long-term (sustainability), it represents a neutral platform (neutrality) for bringing together a wide range of actors at EU level and foresees transparent procedures for taking into account stakeholders’ input, like open consultations (transparency).

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2. The policy responsibility

DG SANTE has the policy leadership as regards the implementation of the EU public health policy on cancer. In addition, the Commission expert group on Cancer Control should guarantee the full compatibility and coordination of the ECIBC with the overall EU policy on cancer.

The Commission expert group on Cancer Control, created by the Commission Decision of 3 June 2014 and repealing Decision 96/469/EC, will assist DG SANTE in its policy responsibility in the cancer domain in the drawing up of legal instruments and policy documents, guidelines and recommendations on cancer control at the request of the Commission.

3. The technical role

3.1. Technical coordination

JRC coordinates the technical aspects of the work ensuring synchronisation of all the initiative’s objectives. JRC also provides the outsourced supports, the collaborating tools and logistics for the ECIBC working groups and other involved stakeholders. JRC also ensures appropriate communication with other Commission services or working/expert groups in areas relevant for the project.

3.2. The working groups

For the first two objectives of the initiative, two working groups, the ‘Guidelines Development Group’ (GDG) and the ‘Quality Assurance Scheme Development Group’ (QASDG), will be established by Autumn 2015 following a call for expression of interest organised by DG SANTE. The selection process followed the rules for establishing scientific and consultative groups in the European Union.

The new European Guidelines and the European QA scheme will be developed with the support of the GDG and QASDG, respectively. More working groups will be set up on demand to accomplish the remainder objectives of the initiative.

3.3. The outsourced technical teams

The JRC will outsource any necessary service according to the usual tendering procedures of the Commission.

In this line, an outsourced systematic review team, the Asociación Colaboración Cochrane Iberoamericana, will support the GDG in performing the systematic reviews and developing the evidence-based recommendations. Moreover, the EA has been contracted for providing support to the QASDG both in the development and in the piloting phase of the European QA scheme (and to ensure that all National Accreditation Bodies will be ready to run it once approved).

3.4. Non-working group members attending the working group meetings

Interested individuals may also attend the meetings, as either expert advisers or observers.

3.5. Input of Member States, other European countries and stakeholders

Member States, interested EFTA or candidate countries and other relevant stakeholders will be invited to express their opinion and suggestions on activities performed by the different working groups at various stages of the ECIBC project.

3.5.1. The group of ECIBC National Contacts

The JRC has asked the 28 EU Member States plus other European Countries to nominate a national contact as a focal point to represent each participating country during the project. Delegates are required to provide their contribution at various stages. The continuous communication with the National Contacts will provide essential inputs on respecting the countries’ own set-up throughout the project and providing a basis for the successful implementation of the scheme.
3.5.2. Other stakeholders

The JRC will invite other relevant parties or individuals affected by the project (experts, patient’s organisations, professional societies, industry, etc.) to register their interest to participate. In particular, they will contribute during the consultation stages planned for the key outputs of the initiative.

4. External peer review

The JRC will arrange peer review from external experts for the publication of the key deliverables of the project; for example, for the final version of the new European guidelines.
Working methods

Person-centred

The ECIBC will promote an approach that is respectful of the needs and preferences of citizens and takes into account all the aspects that can have an impact on quality of life. The citizens will be involved in the development through all stages of the initiative (e.g. actively as members of GDG and QASDG, during open consultations and in the piloting and implementation phases).

Inclusive: multidisciplinary approach

The JRC is making a great effort to foster networking throughout the evolution of the project in order to involve in the ECIBC all the profiles that could be affected by the project. Individuals from the key areas for the project are involved in the working groups. Views of interested parties (entities and individuals) will be integrated via public consultations, contributing in this way to ECIBC’s successful implementation and to increase its impact.

Based on this cooperative approach, the ECIBC will bring together a wide range of actors at a European level, including lay citizens, patients, experts, professionals, NGOs, patient groups, civil society representatives, the industry, policy makers and involved countries (via ECIBC National Contacts).

Evidence-based

The ECIBC will apply rigorous methods based on the best available evidence. As an example, the requirements of the European QA scheme will be based on evidence-based recommendations. Moreover, the recommendations provided by the new European guidelines will be developed according to rigorous methods (e.g.

GRADE²⁵ when applicable), and therefore will be based on the systematic review of the evidence.

**Transparent and explicit**

The ECIBC working modality will promote transparency in different ways:

1. It will follow the rules implemented by the Commission to enhance transparency for its expert groups, for example, by publishing the profiles, declarations of interest and photos of GDG and QASDG members, the list of the ECIBC National Contacts, the minutes of GDG and QASDG (and other working groups) meetings, and JRC reports on the work carried out to support the ECIBC project (on the research conducted and on the organisation/participation to relevant events).

2. State-of-art of the ECIBC project will be communicated periodically; deliverables will be submitted to public consultations and peer reviewing, final versions will be made publicly available via the web hub and disseminated through publications.

3. The GRADE approach will be followed to develop the healthcare recommendations whenever applicable. It is a transparent and explicit approach to grading the quality of evidence and strength of recommendations in healthcare; similar methods will be applied when GRADE would not be appropriate. Delphi or other consolidated methods will be applied in all cases where consensus will constitute the only possible approach. Already developed and validated tools will be applied when needed.

4. Outsourcing of services functional to the objectives will always be organised via public tenders following the most transparent rules for contracting services. This outsourcing part is important both for ensuring a competent, independent and timely support to the ECIBC working groups.

Independent

The scientific advice will be independent of all commercial, private and national interests, it will be derived from the scientific assessment of topics evaluated.

Exportable model

The ECIBC model is being developed as a ‘blueprint’ so if/when it is successful, it will be easily exportable to other cancers or diseases. In particular, its extension to colorectal and cervical cancers is already envisaged, linked to the existence of European guidelines for screening for these types of cancer.

Monitoring

Annual implementation reports will be submitted to DG SANTE and made publicly available.
Life-cycle plan

The ECIBC framework model provides an optimised and potentially standardised way of:

• referring from recommendations (guidelines) to requirements (QA scheme)
• navigating across different guidelines/QA scheme requirements
• reducing duplication of effort and resources, and
• transparently involving stakeholders.

With the support of GDG and QASDG, a plan will be developed for the application of that model across the life-cycle of guidelines and QA scheme. This will ensure a timely update of the evidence and its swift inclusion into the QA scheme.

As well a long-term planning for monitoring ECIBC impact will be developed.

Budget and timeline

DG SANTE allocated a total of EUR 2,400,000 (two million four hundred thousand euros) to JRC for the ECIBC. JRC contributes at least double that amount out of its own budget and resources.

The first draft recommendations and the QA scheme framework will be available on the new ECIBC web hub by 2016.
Contact information

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(The link for the ECIBC web hub will be made available once the web hub is launched.)
Europe Direct is a service to help you find answers to your questions about the European Union.
Freephone number (*): 00 800 6 7 8 9 10 11

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JRC Mission

As the Commission’s in-house science service, the Joint Research Centre’s mission is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle.

Working in close cooperation with policy Directorates-General, the JRC addresses key societal challenges while stimulating innovation through developing new methods, tools and standards, and sharing its know-how with the Member States, the scientific community and international partners.

Serving society
Stimulating innovation
Supporting legislation