The ECIBC Guidelines Platform for all breast care processes

- With specific reference on sustainability and stakeholder involvement

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Abstract

Breast cancer is the most frequent cancer in Europe and accounts for 16.3% of female cancer deaths in Europe, being thus a major health problem. Improvements in the quality of care, in particular increasing the adherence to evidence-based guidelines/recommendations, are therefore welcome.

Within the European Commission’s Initiative on Breast Cancer (ECIBC), guidelines addressing breast cancer screening and diagnosis, henceforth mentioned as the *European Breast Guidelines*, are being developed by the Guidelines Development Group (GDG) under the coordination of the JRC Healthcare Quality Team. However, in order to cover all care processes, the guidelines developed by the GDG need to be complemented by the ECIBC *Guidelines Platform* (later referred to as the *Guidelines Platform* or platform) that will contain guidelines and recommendations for all breast care processes with main focus on those on treatment, rehabilitation, follow-up and palliative care.

For the *Guidelines Platform*, breast cancer guidelines produced by different entities and stakeholder organisations, such as professional societies, have been searched from all publicly available sources. To be as inclusive as possible, also a public call for guidelines was organised. The identified evidence-based guidelines and those submitted by different stakeholder organizations (altogether around 280) are to be evaluated for their quality, clinical impact, geographical coverage and sustainability.

Only those trustworthy guidelines fulfilling the carefully defined eligibility criteria (AGREE II requirements plus others) will be included in the *Guidelines Platform* to be hosted in the ECIBC website. These guidelines - in addition to the *European Breast Guidelines* - will also become reference documents for the voluntary European Quality Assurance scheme for Breast Cancer Services, henceforth mentioned as *European QA scheme*.

Besides supporting the *European QA scheme*, the *Guidelines Platform* can be foreseen as a valuable resource of guidelines for professionals, policy makers, researchers, guidelines developers, as well as for citizens and patients. The ultimate impact of the *Guidelines Platform* would be to reduce unnecessary variability in healthcare services and hence contribute to improve the outcomes of breast cancer patients in terms of morbidity, mortality, and quality of life.
1. Introduction

1.1 Breast cancer trends in Europe

Breast cancer incidence and mortality

According to WHO 2012 estimates, each year there will be approximately 2.6 million new cancer cases in Europe (excluding non-melanoma skin cancers). Breast cancer is the most frequent cancer with around 364,000 new cases each year in Europe. Among women, breast cancer is clearly the most frequently diagnosed malignancy in Europe, representing almost 30% of all diagnosed cancers. It is estimated that breast cancer causes almost 91,000 deaths each year in Europe and is the most common cause of death from cancer among women, accounting for 16.3% of all female 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, in 2012 the estimated age-standardised mortality rate in EU-27 was approximately 22 per 100,000 with great variations, ranging from 15 to 29 per 100,000. Although the higher mortality rates in some countries may reflect the higher incidence of breast cancer, in others it may be due to the poor survival of women diagnosed with the disease.

A number of factors may give rise to health inequalities, such as differences in the socio-economic status, exposure to risk factors, health system policies (e.g. presence or absence of screening programmes), effective delivery of cancer control measures, availability of early detection, and appropriate and timely treatment. The heterogeneous quality of breast cancer services is, therefore, a relevant cause of health inequalities.

References:
There is substantial potential for reducing inequalities in cancer related to the varying provision of healthcare services in Europe.\(^6\) A coordinated action is needed to ensure that all citizens have access to healthcare services with an essential level of quality and safety across Europe. A wider implementation of high-quality evidence-based guidelines, via quality assurance schemes assessing their application, is proposed as an efficient way to improve care and reduce inequalities in cancer, including breast cancer.

### 1.2. ECIBC objectives

The European Commission's Initiative on Breast Cancer (ECIBC), taken forward by the Commission's Joint Research Centre (JRC) under the auspices of Directorate-General Health and Food Safety (DG SANTE), aims at ensuring and harmonising quality of breast cancer services across European countries.\(^7\) Within the European Commission policies for chronic diseases, the ECIBC's overall goal is to contribute to improve health while reducing health inequalities in Europe by enhancing the quality of breast cancer services.

ECIBC responds to 2008 Council Conclusions calling on the Commission "to explore the potential for the development of voluntary European accreditation schemes for cancer screening and appropriate follow-up of lesions detected by screening, [...]" with four main pillars:

1. **To establish a European QA scheme**: a voluntary European quality assurance scheme for breast cancer services addressing all care processes including screening, diagnosis, treatment, rehabilitation, follow-up and survivorship, and end-of-life care.

2. **To develop evidence-based recommendations supporting the European QA scheme**:
   - **European Breast Guidelines**: the European guidelines for breast cancer screening and diagnosis;
   - **Guidelines Platform**: a platform of existing evidence-based guidelines covering all breast care processes.

3. **To support professional training** via a European training template on digital breast screening.

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\(^6\) Commission communication on action against cancer 2009

4. **To launch and manage the ECIBC web hub**: a web interface offering complete information since the ECIBC development phase. It hosts ECIBC deliverables, their life-cycle processes, and in future also the list of certified breast cancer services and respective indicators. Key-information will be available in all EU official languages.

For details of the project, please refer to the ECIBC concept document and web hub⁷.

This report focuses on the needs of evidence-based recommendations for those breast care processes which are not covered by the *European Breast Guidelines*. 
2. Overall goals of the Guidelines Platform

2.1. Evidence needs for the European QA scheme

One of the four ECIBC pillars, 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, hence under harmonised peer supervision across all involved countries co-ordinated by the European co-operation for Accreditation (EA). It would be potentially usable by all countries associated to EA and can in future also inspire non-EA coordinated QA schemes.

The European QA scheme will focus on requirements that are relevant to citizens and patients, and will cover all the relevant breast cancer care processes from screening until the end-of-life care. At present there are at least ten quality schemes coexisting in Europe with a specific target on breast cancer, with different requirements (see the JRC report on the quality schemes for breast cancer in Europe).\(^8\) There is thus no common European set of benchmarking quality requirements.

The European QA scheme will define its requirements considering evidence-based recommendations arising from high-quality guidelines, whenever possible, rather than using a consensus-based approach. The European QA scheme will be underpinned by relevant evidence provide both by the European Breast Guidelines and by the Guidelines Platform.

2.2. Evidence provided by the guidelines

The European Breast Guidelines, based on new knowledge and evidence on breast cancer screening and diagnosis, are to be developed by an expert group nominated by the European Commission and coordinated by the JRC, the Guidelines Development Group (GDG). However, JRC does not have the mandate to develop guidelines for other processes of breast cancer care, and therefore other sources of evidence will be needed. The different breast care processes covered by these two sources of guidelines can be seen in the figure below (in the blue area those that are covered by the platform).

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The **Guidelines Platform** aims to provide guidance for all processes of breast cancer care pathway including all treatment processes, rehabilitation, follow-up and survivorship care, and palliative/end-or-life care. It will include recommendations based on evidence from existing high-quality guidelines. Besides its role in underpinning the *European QA scheme* with evidence, the general aim of the **Guidelines Platform** is to promote the timely and effective dissemination and implementation of evidence-based guidelines for breast cancer.

Any process related to breast cancer services (from prevention to end-of-life care) will be included. Different processes may be provided by different services, such as screening services or breast centres, or those service providers offering, *e.g.* palliative care services.

Owing to substantial clinical practice variations and health inequalities described above, there is a clear need to identify and collect those breast cancer guidelines that are rigorously developed, sustainable (*e.g.* existence of an updating plan, a reference organisation, a contact person, etc.), and currently up-to-date.

**The overall goals of the Guidelines Platform are:**

- **To build a public platform of evidence-based guidelines for breast cancer.** High-quality evidence-based guidelines for breast cancer care processes will be collected in a single, web-based platform. The platform is focusing, but not limited to, the European context.

- **To build a platform of evidence-based recommendations derived from evidence-based guidelines.** This objective will underpin the evidence needs (*e.g.* for clinical requirements) of the *European QA scheme.*

Through ECIBC, the European Commission continues to support the development, dissemination and implementation of guidelines. According to the Treaty of Lisbon (Title
XIV, Article 168) 'The Commission may take [...] in particular 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.' Hence, the development of a Guidelines Platform would not only be necessary for the European QA scheme and useful to the professionals involved in breast cancer care, but also a useful support for countries along the lines of the Treaty of Lisbon.
3. The expected benefits of the Guidelines Platform in breast cancer

3.1. The benefits of high-quality guidelines

A guideline is a document that focuses on a disease or condition and includes recommendations for appropriate management of patients with that disease or condition. The guideline should be based on the best available evidence and should help healthcare providers by supplementing their knowledge and skills. Guidelines may also aim at directing health policy makers’ decisions. They can be tailored to clinical, health policy, health systems or public health settings, among others.9

Guidelines have evolved from opinion-based guidelines to consensus-based guidelines – and, currently, to evidence-based guidelines. Both opinion-based and consensus-based guidelines are usually created by small non-representative groups of professionals in a non-standardised format that may be liable to many types of bias.10 Research has shown that expert opinion does not always reflect the state of current medical knowledge.11 According to the most recent definition, clinical practice guidelines can be defined as “statements that include recommendations intended to optimise patient care that are informed by systematic review of evidence and an assessment of the benefits and harms of alternative care options”.12

Clinical practice variations occur when patients with similar diagnosis, prognosis and demographic status receive different levels of care depending on when, where and by whom they are treated, despite agreed and documented evidence on the clinical practice to be applied. This can occur at individual, facility, professional and organisational levels. Reasons underlying clinical practice variation are numerous. Although difficult to quantify with accuracy, there is clear evidence that gaps exist between what is known to be effective according to the best available evidence, and what happens in practice.13, 14

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In addition, physicians tend to rely on their rather “old” knowledge, varying opinions, and personal experiences with certain interventions in their daily practice.¹⁰

Guidelines aim at improving patients’ outcomes and the quality and appropriateness of care. Their implementation may also increase cost-effectiveness of healthcare. Furthermore, guidelines are educational tools and instruments to reduce unjustified variations in clinical practice.

3.2. The expected benefits of the Guidelines Platform

At present, many breast cancer guidelines are published by different institutions and organisations. As a consequence, it is getting more and more difficult for healthcare professionals to know, select and implement guidelines for different breast cancer care processes. Further, not all the guidelines published fulfil the minimum criteria to be considered as evidence-based and some of them are poorly formulated.¹⁵, ¹⁶ Moreover, many of them require updating. For being considered of high quality and sustainable, guidelines should be produced within a structured and coordinated programme.

Therefore, collection of high-quality evidence-based breast cancer guidelines in a single platform is urgently needed.

Within ECIBC, breast cancer guidelines aim at:

• supporting the European QA scheme with the necessary evidence
• providing users of breast cancer services (citizens and patients) and healthcare providers with clear, objective and independent guidance on all breast cancer processes via evidence-based trustworthy guidelines. This will promote informed decisions, and hence contribute to reduce unnecessary variability in healthcare and ultimately to improve patient outcomes in terms of morbidity, mortality, and quality of life.
• guiding healthcare managers and policy-makers on planning, commissioning and organising breast cancer services; and
• supporting auditors and auditees through the conformity assessment, certification and accreditation of breast cancer services along the European QA scheme requirements.

In addition, the *Guidelines Platform* is expected to deliver several other benefits:

- It will allow guideline developers to identify those areas of practice that need further evidence (*e.g.* research/evidence/guidelines).
- It will allow the identification of those guidelines and topics that require updating.
- As a consequence, it will support researchers in prioritising research topics.
- It will allow those attempting to adapt guidelines produced by others to easily identify high quality guidelines that would be suitable for adaptation. This will be useful for all, but particularly for low resource countries, where adaptation of high quality guidelines is considered to be a potentially effective way forward.
- Via the *European QA scheme*, the dissemination, implementation and uptake of the guidelines collected in the platform will be facilitated.
4. Collection and evaluation of the guidelines for the *Guidelines Platform*

4.1. Criteria for inclusion of guidelines in the platform

For the *Guidelines Platform*, only those guidelines fulfilling the following criteria, and thus considered trustworthy, sustainable and of high-quality, will be considered:17

- be based on a systematic review of the existing evidence;
- be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups;
- consider important patient subgroups and patient preferences, as appropriate;
- be based on an explicit and transparent process that minimises distortions, biases, and conflicts of interest;
- provide a clear explanation of the logical relationships between alternative care options and health outcomes; and
- provide ratings of both the quality of evidence and the strength of the recommendations.

In addition some sustainability requirements will have to be fulfilled, such as:

- a clear identification of a contact person; and
- inclusion of a plan for revision as appropriate when important new evidence warrants modifications of recommendations.

These criteria provide a clear distinction between trustworthy clinical practice guidelines and other forms of clinical guidance, such as consensus statements and expert advice. Guidelines concerning those having (or suspected to have, or have a potential to have) breast cancer will be included.

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The following types of guidelines will be included in the *Guidelines Platform*:

- clinical practice guidelines/recommendations about preventive, therapeutic, or rehabilitative interventions;
- clinical practice guidelines/recommendations about tests used for diagnostic, screening, monitoring or other purposes;
- guidelines providing decisions made on behalf of a population about which clinical interventions are paid for by a third party (i.e., coverage decisions); and
- guidelines providing recommendations and decisions, made on behalf of a population, about health systems and public health interventions.

### 4.2. Search methods and data collection processes

Searches have been performed in health-related bibliographic databases, including MEDLINE, EMBASE and CINHAL, and guidelines repositories, including GIN’s International Guidelines Library, AHRQ’s Guidelines Clearinghouse, NICE Guidance, Canadian Medical Association Infobase and Australian NHMRC Guidelines portal. In addition, the websites on professional societies and national professional breast cancer associations have been searched. The search was outsourced to the Iberoamerican Cochrane Centre (CCIb), through an open tendering process.

Guidelines or recommendations published since 01.01.2006 i.e., during the last 10 years, have been included. The key inclusion criterion is that the guideline or recommendation shall be based on a systematic review of the evidence.\(^\text{18}\)

To be as transparent and inclusive as possible, also a call for guidelines was organised by the JRC during Q2/2016. The call was published in the ECIBC website and announced through direct e-mail to all ECIBC National Contacts, guideline developers and professional societies, and all ECIBC stakeholders included in the ECIBC contact list.

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For each guideline, detailed information has been collected, including:

- objective(s);
- target population(s);
- interventions and practices considered;
- type of the guideline;
- methodology used to develop the guideline/recommendation.
- developer/owner of the guideline/recommendation;
- updating plan; and
- geographical context where the guideline applies (country, and region, if applicable).

From the originally 2551 records obtained from the searches, a total of 230 documents with breast cancer recommendations were considered by CCIb eligible for being assessed for possible inclusion into the Guidelines Platform. Through the call altogether 50 guidelines were proposed to be included in the platform.

**4.3. Assessment of the quality of guidelines and updating the evidence**

The assessment of the quality of the guidelines, those found via a search and those collected via the call, was outsourced via a tendering procedure. In September 2016 the contract was awarded to CCIb (the same contractor that performed the search); they are proceeding evaluating all the guidelines, collected via the search and the call, for their quality, clinical impact, geographical coverage, and sustainability. The quality of the guidelines will be evaluated separately by two appraisers (possibly with different profiles, *i.e.* a methodologist and a content expert).

A publicly available tool, **AGREE II -tool**, will be used in the quality evaluation process, in particular for the methodological aspects.\(^\text{19}\) For the content-related aspects, although content-specific expertise is not necessary, this kind of expertise may improve the ease of interpretation of the findings.\(^\text{20}\) As content is concerned, members of GDG and

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QASDG may also be consulted during the evaluation process in line with the remit of the working groups described in the governance document\textsuperscript{21} and with respect to their clinical competence. Even though the majority of the guidelines are published in English, translation of some guidelines not published in English is foreseen.

The exact number of guidelines finally included in the Guidelines Platform can only be determined after the assessment phase has been completed by the contractor. This evaluation is expected to be finalized until Q1/2017.

4.4. Compilation of recommendations based on guidelines

A platform of recommendations, derived from existing guidelines, and from those developed by GDG on breast cancer diagnosis and screening will be established. Recommendations provided in the guidelines will be extracted and presented in an easily readable and understandable format. For each recommendation its direction (for or against an option) and its strength (strong or weak recommendation), using GRADE\textsuperscript{22} concept and rating will be presented.

The Guidelines Platform will be web-based as the European Breast Guidelines. The appearance and web structure can only be defined at a later stage and will have to be harmonised across the two ‘evidence pillars’ of the ECIBC. The harmonised format (taking into account possible restrictions due intellectual property rights) will facilitate the usability and readability of recommendations throughout the whole breast care pathway, even if screening and diagnosis will be covered by the European Breast Guidelines (developed under the direct coordination of the JRC) whilst the other processes are in the Guidelines Platform scope (including guidelines developed by other entities). The presentation of the recommendations in the platform will also take into account the evidence needs and requirements of the European QA scheme.

The recommendations derived from evidence-based guidelines will be formulated as clearly and precisely as possible, and will be written in a language understandable to all, including lay citizens. All recommendations will be linked to relevant guidelines and publications to provide professionals and other stakeholders the background information they may require. This part of the work, including re-wording and translation into all EU languages of at least the short version of the recommendation, may need to be outsourced as well, even though supervised by JRC.

\textsuperscript{21} http://ec.europa.eu/health/major_chronic_diseases/docs/eibc_structure_2014_en.pdf
\textsuperscript{22} http://www.gradeworkinggroup.org/
5. Resource use and timelines for the Guidelines and Recommendations Platforms

The development of the Guidelines Platform and the derived Recommendations Platform will be coordinated and partially performed by the JRC Healthcare Quality Team including professionals covering different clinical, health technology assessment, healthcare research and IT expertise. Some parts of the development work, e.g. search and evaluation of the quality of guidelines are being outsourced to reliable and knowledgeable service providers according to transparent tendering/recruitment procedures.

Expert group members of GDG and QASDG may also support the Guidelines Platform either as advisors on the activities linked to the development of the platform and/or as possible contributors, as indicated in the governance document of the working groups.

The collection of additional guidelines via a call was completed by Q2/2016. The collection via the search of available breast cancer guidelines according to pre-specified criteria, as well as structured data extraction from guidelines has been completed by Q3/2016. The evaluation of the quality of the collected guidelines will be performed during Q3 - Q4/2016 and Q1/2017.

The final set of the guidelines to be included in the Guidelines Platform will be available by Q2/2017. Already during that evaluation process the compilation of the recommendations in the platform may be started and continued in the following months with first recommendations expected to be published in Q3/2017.

The platform of recommendations based on all available guidelines (both those derived from the platform and from the guidelines to be developed by the GDG) is expected to be finalized by Q1/2018. All tasks should be completed in parallel with the publication of the recommendations of the guidelines on screening and diagnosis developed by the GDG (the European Breast Guidelines) so to ensure that the piloting of the European QA scheme can start.
6. Hosting of the *Guidelines Platform* in the ECIBC web hub

The ECIBC web hub is the first communication interface with stakeholders and the main sustainable tool to disseminate information on the initiative. The ECIBC web hub is envisaged as a platform containing all ECIBC deliverables, including the *Guidelines Platform* for all breast cancer care processes. This website ensures that the platform is sustainable, and will be regularly updated.

The *Guidelines Platform* will be a web-based platform, complemented by efficient and multi-dimensional (e.g. per professional profile, per care process, per quality dimension, per care service) search tools for identifying guidelines and recommendations for different breast cancer processes, addressing different quality aspects (e.g. patient safety, patient experience), and providing data for different patient and professional profiles.

The potential users for the web-based *Guidelines Platform* range from healthcare professionals to patients and citizens, but also to healthcare professional, healthcare and quality managers, researchers, academics, policy-makers and other stakeholders.

All information and recommendations provided in the *Guidelines Platform* will be presented in a user-friendly manner and will use clear language that is understandable to all potential users.
7. Plan for sustainability and stakeholder involvement

7.1. Sustainability

The Guidelines Platform is foreseen to be a sustainable source of guidelines. The accuracy of the evidence will be regularly reviewed and updated to include new guidelines and delete outdated information. At present it is estimated that updating is needed once a year.

In critical situations, e.g. in case of clinical breakthroughs or when severe safety concerns are raised, more frequent updating may be needed. In addition, the platform may also highlight needs for updating guidelines already included, and therefore the concerned guideline developers/owners will be contacted to verify whether a new version is in preparation or the old version has to be discharged from the platform.

To ensure that the care processes covered by ECIBC would not be impaired by the fact that the guidelines collected on the platform are under the responsibility of other entities than the JRC, on the medium term a process of inclusion of care processes in the European Breast Guidelines scope, additionally to screening and diagnosis, may be attempted. This would facilitate both the updating of the European QA scheme for the part related to clinical requirements and the searches of guidelines users across the various processes of care.

Even during the development of the Guidelines Platform updates may be foreseen. Between 2018 and 2019, when all ECIBC deliverables are expected to be finalized, a check of updating needs of the Guidelines Platform will be carried out.

7.2. Stakeholder involvement

The core principles of ECIBC include transparency and person-centredness. Various stakeholders, including guideline developers, health care professionals, and citizens and patients, are being informed on the progress of ECIBC and its core deliverables. This includes information provided in the web-site, ECIBC news and presentations at
conferences and meetings. Moreover, stakeholders have the opportunity to participate in the annual ECIBC Plenaries.

As regards the Guidelines Platform, stakeholders were already involved in its development through the call for guidelines, and provided more than 50 documents containing recommendations; they may be further involved, e.g., to provide feedback on searchability, readability, etc.

The potential users for the Guidelines Platform range from healthcare professionals to patients and citizens, but also to healthcare managers, quality managers, researchers, academics, policy-makers and others. They all have an opportunity to contribute at different phases of the development of the platform and also after that to ensure that information provided in the platform is sustainable and up-to-date.

In addition, after the launch of the platform, the stakeholders will be constantly encouraged to propose their new guidelines and updates of existing guidelines to be included. The inclusion of new guidelines and recommendations will be done either through the planned annual updates or in case of emerging information also ad hoc, but always applying the same initial strict criteria in order to grant a constant and consistent quality of the derived recommendations.

For optimal implementation of the Guidelines Platform, presentations at meetings and conferences at international and also national level will be arranged.
8. Summary and conclusions

High-quality evidence-based guidelines will be collected in the Guidelines Platform with the goal of providing (1) evidence to the European QA scheme, (2) objective and clear guidance to all potential users of breast cancer services, and (3) a tool for promoting informed decisions. The platform will be hosted in the ECIBC web hub that is the main sustainable tool to disseminate all ECIBC deliverables.

While GDG is developing European Breast Guidelines on screening and diagnosis of breast cancer, high-quality evidence-based guidelines on all breast cancer care processes will be collected in the Guidelines Platform. This will be done after a comprehensive search for guidelines, a call for guidelines, and a careful evaluation of the quality and applicability of the so collected guidelines.

The European Breast Guidelines and the Guidelines Platform together will form the evidence-base for the European QA scheme for all breast cancer services. On the other hand, the implementation of the recommendations will be guaranteed through the European QA scheme. In this way, the implementation of high-quality evidence-based guidelines in breast cancer will be enhanced and monitored and is expected to result in reduction of unnecessary variability in healthcare services. Within the whole ECIBC, the Guidelines Platform is foreseen to be a powerful tool to reduce morbidity and mortality, and to improve quality-of-life of the patients.
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