European Guidelines
for Breast Cancer Screening and Diagnosis–
the European Breast Guidelines

Nadya Dimitrova, Zuleika Saz Parkinson, Anke Bramesfeld, Aslı Ulutürk, Giulia Bocchi, Jesús López-Alcalde, Liisa Pylkkanen, Luciana Neamţiu, Massimo Ambrosio, Silvia Deandrea, Donata Lerda

2016
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Foreword

Cancer is the second most common cause of death in the EU and breast cancer, in particular, is the most common cancer among females in the European Union.

The European Commission Initiative on Breast Cancer is the tangible demonstration of what Europe can achieve working in synergy with Member States, the scientific community, civil society and patient organisations.

The European Commission Initiative on Breast Cancer today boasts the most inclusive expert groups within the EU, and they have been given the mandate to develop and deliver guidelines and a quality assurance scheme on breast cancer screening, diagnosis and care.

Under the European Commission’s Joint Research Centre coordination, the group of experts dedicated to the development of European Guidelines for Breast Cancer Screening and Diagnosis are now publishing the first four European Breast Guidelines’ recommendations. This publication will ensure that any organisation, programme or authority in the Member States, as well as every European citizen, can gain access to the recommended standards and procedures, with the view of reaching our shared European objective of promoting health and preventing human illness and diseases.

The recommendations and information about their development will be easy to access online through a user-friendly interface, and easily understandable by everyone thanks to a clear and comprehensible wording.

It is my hope that these recommendations will improve and strengthen breast cancer care and will help save countless lives in the future.

John F. Ryan
Director
European Commission, DG Health and Food Safety, Directorate C–Public Health
Acknowledgements

The authors would like to acknowledge the valuable work of the Guidelines Development Group (GDG\(^1\)) and the CCIb (Iberoamerican Cochrane Centre\(^2\)) team for the development of *European Breast Guidelines* recommendations.

2. http://es.cochrane.org/home
EXECUTIVE SUMMARY

Policy context

The Written Declaration of the European Parliament on the fight against breast cancer in the European Union (2007-2015) states that in order to reduce the breast cancer mortality rate, it is important to implement nationwide mammography screening programmes and provide comprehensive breast cancer care, as called for in the European Parliament resolutions of 2003 and 2006 and foreseen to be facilitated by the development of the European guidelines for breast cancer screening and diagnosis (European Breast Guidelines) and the European quality assurance scheme for breast cancer services (European QA Scheme).

This report intends to inform stakeholders, policy makers in particular, about the methods used and outcomes delivered in the European Breast Guidelines within the European Commission Initiative on Breast Cancer (ECIBC). As a result of a complex process, involving a wide range of experts and patients, evidence-based recommendations on screening and diagnosis are being formulated to support the countries in defining relevant policies and strategies.

Key conclusions

The major impact of the European Breast Guidelines on EU policy is foreseen in the screening area, possible leading to updating needs for the Council Recommendations of 2003 on cancer screening. Screening is a population based intervention and, for instance, screening recommendations concerning the different age-ranges of women to be invited/covered by screening and/or the different techniques to be used may have a great impact on health policies across the EU, and beyond.

The recommendations related to diagnosis, where costly investments may or may not be required will be of interest to policy makers, as well. In addition, the development of European Breast Guidelines will also contribute to several EU initiatives, summarised in the following figure.
Main findings

The *European Breast Guidelines* will contain six chapters: Screening, Diagnosis, Communication, Training, Interventions to reduce inequalities, Monitoring and evaluation of screening and diagnosis.

These chapters have been defined by the ‘Guidelines Development Group’ (GDG), created in July 2015 following a call for expression of interest organised by DG SANTE. Each chapter will include specific recommendations, based on the questions, relevant to the target audience, that are prioritised by the GDG. The whole work of the dedicated subgroups is coordinated by the JRC. The workflow for production of the evidence-based recommendations, applying the GRADE (Grading of Recommendations Assessment, Development and Evaluation) system, is presented in *Fig. 2*. Other related activities and processes complementing the workflow include calls for feedback (on the scope of the *European Breast Guidelines*, on the final recommendations), management of conflict of interests, organisation of meetings and on-line voting, collaboration with other ongoing projects.
Fig. 2. The workflow for production of evidence-based recommendations, included in the European Breast Guidelines.

Related and future JRC work

The JRC will define a methodology to assess the need and periodicity for updating the European Breast Guidelines. The lifecycle of this process will include identification of research gaps and search for the best available evidence, which might contribute to the revision of recommendations. Moreover, the process of development of the recommendations can be used as an example for an appropriate approach to be applied also for other types of cancers or other diseases.

Quick guide

In order to reduce the breast cancer mortality rate, it is important for European countries to implement nationwide mammography screening and provide comprehensive breast cancer care. To facilitate these activities, the European Breast Guidelines are under development, which will include evidence-based recommendations, formulated as a result of a complex process, involving a wide range of experts and patients, applying the GRADE (Grading of Recommendations Assessment, Development and Evaluation) system. The recommendations will support relevant EU and country-specific policy decisions and strategies.
1. Introduction

The European Commission Directorate-General Health and Food Safety (DG SANTE) has the policy leadership on the EU health-related policies. Cancer control activities are prioritised within these policies, among other reasons, due to the impact on population health and the inequalities in quality of care across Member States.

On the one hand, Europe carries a significant load of the global cancer burden, while on the other hand there are evidence-based strategies proven to be successful to reduce this burden, such as prevention and early-detection programmes, including screening. The implementation of these programmes is not uniform across Europe and depends very much on the policies in place in the different countries and the organisation of healthcare and available resources, among other reasons. As a result, outcomes for people with cancer vary and this inequality has to be addressed in a proper way. Therefore, in order to support national policies on cancer control, DG SANTE has taken forward several initiatives on cancer—the European Commission Initiative on Breast Cancer (ECIBC) being one of them.

The ECIBC started in December 2012 and is coordinated by the Commission’s Joint Research Centre (JRC).
2. Background

2.1. Breast cancer incidence, mortality and survival

An estimated 464,000 women were diagnosed with breast cancer in Europe in 2012. Breast cancer (BC) was the leading cancer site among women in all European countries, accounting for 29% of all new female cases that year. In the same year, 131,000 women were estimated to die from BC, accounting for 17% of all female cancer deaths in Europe and making it the most common cause of female cancer death [1]. The incidence of BC has continued to increase in almost all European countries in recent decades, while mortality rates have fallen in many countries since the mid-1990s, but not in all European regions [2]. Five-year survival of women with BC is 82% with variations from 74% in Eastern Europe to 85% in Northern Europe [3], indicating possible inequalities in BC care for European women.

2.2. Legal framework

While it is up to national governments to organise healthcare and ensure that it is provided, the European Commission (EC) supports national policies coordinating development of guidelines and recommendations. Thus, following the Council Recommendation on cancer screening3 from December 2003, the 4th edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis4 was produced, including best practices defined by consensus of experts. Moreover, the Consolidated Treaty of the EU5 (2007), the European Parliament Resolution6 (2008) the Council Conclusions on reducing the burden of cancer7 (2008) and several other official documents [4] [5] [6] [7] also contributed to emphasise the strong determination

to tackle these issues at European level—recognising breast cancer screening as an effective strategy for reducing cancer risk and mortality, and underlying the need for comprehensive strategies for breast cancer control.
The main objectives of the ECIBC project are two: 1) to propose evidence-based recommendations on screening and care for breast cancer services in Europe and 2) to develop a voluntary European quality assurance (QA) scheme for Breast Cancer Services. In order to achieve these objectives, two working groups, the ‘Guidelines Development Group’ (GDG) and the ‘Quality Assurance Scheme Development Group’ (QASDG), were created in July 2015 following a call for expression of interest organised by DG SANTE. The selection process was according to the rules for establishing scientific and consultative groups in the European Union. The GDG and QASDG contribute to the development of the European Guidelines for Breast Cancer Screening and Diagnosis (European Breast Guidelines) and the European QA scheme, respectively.

For both groups a transparent policy for management of potential Conflict of Interests was put in place and is applied to minimise the risk that voting/decisions would be biased. A more detailed overview on how independence is granted within ECIBC is given in chapter 4.1 below.

The European Breast Guidelines are developed applying GRADE (Grading of Recommendations Assessment, Development and Evaluation). Increasingly being adopted by organisations worldwide, GRADE provides a system for rating quality of evidence and strength of recommendations that is structured and explicit [8].

The process of formulating the recommendations includes the following steps:

1) Prioritisation of the European Breast Guidelines questions – The JRC compiles an extensive list of potential questions, which is completed by the GDG and after a public consultation and relevant modifications, the list is submitted for rating

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by the GDG members. The GDG agrees on the final list of prioritised questions at a physical meeting.

2) Framing the questions – The GDG formulates the questions according to a standard structured format, generally called PICO format, which stands for: Population under study; Intervention; Comparator: other main options; and Outcomes that are important to consumers and relevant stakeholders. The GDG defines the components of each question. In the case of the outcomes, the JRC prepares a dedicated prioritisation exercise that is then completed online by the GDG, and only those outcomes rated as ‘critical’ or ‘important’ for decision making are included in the question.

3) Quality of the evidence related to each question – The JRC has outsourced a systematic review team according to the usual tendering procedures of the Commission [9]. It is a multidisciplinary group of methodologists, information specialists, health economists, and qualitative researchers based at the Iberoamerican Cochrane Centre – CCIb (GRADE centre, Barcelona, Spain). Each guideline recommendation is based on the best available body of evidence obtained through systematic reviews, which are based on exhaustive search strategies allowing the identification of relevant evidence related to each critical or important outcome [10] [11] [12] [13]. For each question, the contractor CCIb (systematic review team) seeks evidence related to the patient-important outcomes prioritised by the GDG as well as the value patients place on those outcomes. In order to do so, already existing high quality systematic reviews can be used or de novo systematic reviews are conducted, depending on availability of updated and targeted systematic reviews. CCIb follows a two-step process for rating the quality of evidence: 1) rates the overall quality of evidence for each outcome across studies; 2) rates the overall quality of evidence for each recommendation across all outcomes. Finally, the systematic review team produces ‘evidence tables’ summarising the body of evidence for each recommendation. The JRC interacts with the GDG and CCIb in order to ensure the experts’ inputs are taken into consideration in the evidence findings.

4) Going from the evidence to the recommendation – CCIb, in coordination with the JRC, provides evidence-to-decision frameworks (EtDs) to help the GDG making recommendations. EtDs include criteria and judgements informed by re-
3. Methods

Search evidence and additional considerations. The EtD frameworks are used to vote or achieve consensus within the GDG meetings on the criteria that influence a recommendation or decision. Then CCIib proposes a neutral draft recommendation. Based on this draft (and on the final EtD framework) the GDG agrees on the direction of each recommendation (for or against the particular intervention under study) and its strength (strong or weak-conditional). GRADE defines the strength of a recommendation as ‘the extent to which one can be confident that the desirable effects of an intervention outweigh its undesirable effects’ [14]. Weak-conditional recommendations can be accompanied by a recommendation for research in case it should be clear that stronger evidence can be achieved via additional/more solid research results.

5) Approval and publication of the European Breast Guidelines recommendations – All the recommendations and underpinning work, once approved, will be made publicly available on the ECIBC web hub. The approval process foresees as first step the approval of the recommendation and its framework by the GDG. The language of each recommendation is then revised to ensure that the recommendations are clear and understandable to all users, and a specific patient-adapted version of the recommendation is also prepared. The JRC has also the responsibility to approve the CCIib deliverables (in short, systematic reviews, participation to meetings and formulation of the draft recommendation) both as owner of the contract and in view of publication of the recommendations on the ECIBC web hub (and, when appropriate, on peer reviewed journals).

6) Impact on Policies – Vis-à-vis DG SANTE, JRC holds also the responsibility to provide evidence that can potentially modify Health Policies in the area of breast cancer care, for instance as regards the age-range to be targeted by a population-based intervention like breast cancer screening. For this reason, DG SANTE is promptly informed in case a policy change may be triggered by the recommendations, and the Expert Group on Cancer Control, supporting the Commission for cancer-related policies, is involved as well.
The GDG has defined the following six chapters within the *European Breast Guidelines*:

- Screening
- Diagnosis
- Communication
- Training
- Interventions to reduce inequalities
- Monitoring and evaluation of screening and diagnosis.

Each chapter will include specific recommendations, based on the questions, relevant to the target audience, that are prioritised by the GDG. Each chapter is produced by dedicated subgroups, all coordinated by the JRC.

JRC drafted the scope of the *European Breast Guidelines* and after discussion it was approved by the GDG. Next, a call for feedback was carried out asking stakeholders for their approval and suggestions for improvements of this first draft scope. Taking into account all the comments received, a final version of the scope was issued and, once again, approved by the GDG.

In parallel, and according to the process described in the *Methods* section, the JRC prepared a list of possible PICOs to be prioritised that included questions generated by the GDG as well as those suggested by stakeholders, and fitting with the GDG scope, during the above mentioned call for feedback. This prioritised list includes a maximum of 90 questions for the complete *European Breast Guidelines*.

During the next step, under JRC coordination, the prioritised PICOs are again discussed within the subgroups, working on the corresponding chapters of the *European Breast Guidelines*, as many questions were given similar ratings during
the first GDG prioritisation exercise, were not clearly understood by the entire GDG or are, in reality, equivalent to more than one PICO question (because the question included more than one intervention or more than one population). Therefore, a second prioritisation step was needed. After the adequately framed questions are agreed on, the outcomes for each of those questions are able to be prioritised and CCIb is able to search for the evidence for each of the questions. This evidence is presented to the GDG for discussion and agreement on the evidence-to-decision frameworks (EtDs).

Other related activities and processes complementing the workflow include calls for feedback (on the scope of the European Breast Guidelines, on the final recommendations), management of conflict of interests, organisation of meetings and on-line voting, collaboration with other ongoing projects.

As a result of this complex process, which involves a wide range of experts, patients and policy makers, final recommendations are formulated.

The recommendations will be issued in significant groups of questions—the first set to be published are on the relevant screening ages, which will be followed by recommendations on other interventions in screening diagnosis, communication, etc.

The recommendations will be also adapted to be informative not only for clinicians, but for patients/citizens and for policy makers, as well. All of these recommendations will be made publicly available on a dedicated web page, and in the future will be translated into all European languages.

4.1. Overview of transparency and independence in the European Breast Guidelines (and ECIBC) context

Identifying and managing conflict of interest (Col) of contributors is a key attribute and requirement for trustworthy guidelines and reduces the risk of bias in the development of recommendations [8]. Preventive actions were taken to ensure independence of the GDG: (i) GDG members and contributors are nominated through a transparent and open process; (ii) GDG members and contributors act
upon their personal capacity and do not represent any entity or affiliation; (iii) GDG members and contributors, have to sign a confidentiality and a commitment form, implying that the content of the meetings’ discussions and decisions taken in the context of the ECIBC cannot be disclosed during the mandate and in the future—this helps protecting them from possible pressures from external groups of interest.

The outsourcing of systematic reviews can as well be considered as part of the preventive actions contributing to improve the independence of the work done by the GDG under the coordination of the JRC.

As corrective measures, CoI of all GDG members and other contributors are assessed and managed by the JRC following an established procedure in line with the EC rules [15] and their participation in the development/approval of the respective recommendations is limited accordingly.

4.2. Procedure to maintain the evidence-based recommendations for breast cancer services up-to-date in the long term

The JRC will define a methodology to assess the need and frequency for updating the European Breast Guidelines in order to ensure that they are based on the best available and up-to-date evidence. Fig. 3 shows the lifecycle of this process.

4.3. Impact of the recommendations on the EU policy regarding cancer

The fight against cancer, in this case breast cancer, requires cooperation at EU-level, which has proven to be of added value in the past.

The comprehensive approach, promoted by EU [16], to tackling the chronic disease burden, including breast cancer, in Europe will benefit from the development of evidence-based recommendations in several different ways, corresponding to the main areas covered by the European Breast Guidelines, summarised in Table 1.

In the Commission Communication on Action Against Cancer: European Partnership [4], a goal was set to reduce the burden of cancer by achieving 100%
population coverage of screening for breast, cervical and colorectal cancer. In addition, the European Parliament Declaration on the fight against breast cancer in the European Union [6], emphasised the importance of reducing the breast cancer mortality rate.

Therefore, the major impact of the European Breast Guidelines on EU policy is foreseen to be seen in the screening area. Screening is a population-based intervention and, for instance, screening recommendations concerning the different age-ranges of women to be invited/covered by screening an or the different techniques to be used may have a great impact on health policies across Europe.

However, the recommendations related to diagnosis, where costly investments may or may not be required, will also be of interest for policy makers.

The development of European Breast Guidelines will also contribute to several EU initiatives [14] targeting the following issues:
Table 1. Potential impact of the European Breast Guidelines on EU cancer policy and initiatives.

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<tr>
<td>Reduce the burden of cancer by achieving 100% population coverage of screening for breast cancer [4]</td>
<td>The Communication chapter of the European Breast Guidelines will include evidence-based recommendations about the appropriate approach for informing society, individuals and high-risk groups about the benefits and harms of screening. In addition, the Monitoring and evaluation chapter will include indicators for measuring the effectiveness of the screening programme. The recommendations regarding reducing inequalities will also contribute to increasing the population coverage of screening.</td>
<td>Communication; Monitoring and evaluation of screening and diagnosis; Interventions to reduce inequalities</td>
</tr>
<tr>
<td>Systematically integrating policy and action to reduce inequalities in health [11]</td>
<td>A dedicated chapter of the European Breast Guidelines will include evidence-based recommendations to reduce inequalities in screening and diagnosis</td>
<td>Interventions to reduce inequalities</td>
</tr>
<tr>
<td>Making national statistics [12] as reliable and comparable as possible, so they can serve as a good guide to policy effectiveness</td>
<td>The experts, contributing to Monitoring and evaluation chapter of the European Breast Guidelines will define process and outcome indicators, which will be comparable between countries and will be potentially monitored at population level in order to measure the effectiveness of the relevant interventions regarding screening and diagnosis.</td>
<td>Monitoring and evaluation of screening and diagnosis</td>
</tr>
<tr>
<td>Supporting public-awareness-raising and disease-prevention campaigns that actively target high-risk groups and individuals</td>
<td>The Communication chapter of the European Breast Guidelines will include evidence-based recommendations about the appropriate approach for informing society, individuals and high-risk groups about benefits and harms of screening.</td>
<td>Communication</td>
</tr>
<tr>
<td>Expert Group on Cancer Control [13]</td>
<td>Updated regularly on the status of the process of development of the European Breast Guidelines and are expected to facilitate the implementation of recommendations at national level.</td>
<td>All chapters</td>
</tr>
<tr>
<td>European Code Against Cancers [14]</td>
<td>The development and the constant update of the European Breast Guidelines may facilitate the implementation of the screening recommendations.</td>
<td>Screening</td>
</tr>
</tbody>
</table>

• **Inequalities** in health\(^{15}\) – a dedicated chapter of the *European Breast Guidelines* will include evidence-based recommendations to reduce inequalities in screening and diagnosis.

• Making national **statistics**\(^{16}\) as reliable and comparable as possible, so they can serve as a good guide to policy effectiveness – the experts, contributing to Monitoring and evaluation chapter of the *European Breast Guidelines* will define process and outcome indicators, which will be comparable between countries and will be potentially monitored at population level in order to measure the effectiveness of the relevant interventions regarding screening and diagnosis.

• Supporting **public-awareness**-raising campaigns that actively **target high-risk groups and individuals** – the Communication chapter of the *European Breast Guidelines* will include evidence-based recommendations about the appropriate approach for informing society, individuals and high-risk groups about benefits and harms of screening.

The recommendations, included in the *European Breast Guidelines*, will complement also other outputs, resulting from EU-level cooperation, such as:

• the *European Guide on Quality Improvement in Comprehensive Cancer Control*, developed by the CANCON Joint Action 2014-2017 \(^{17}\).

• the EPAAC – European Partnership for Action Against Cancer (2009-2013) \(^{18}\), aiming to help Member States and other stakeholders to tackle cancer more efficiently.

In 2014, the Commission established the Expert Group on Cancer Control \(^{19}\), which includes representatives of the Member states. They have been updated regularly on the status of the development of the *European Breast Guidelines* and are expected to facilitate the implementation of recommendations at national level.


\(^{19}\) [http://ec.europa.eu/health/major_chronic_diseases/diseases/cancer/index_en.htm#fragment2](http://ec.europa.eu/health/major_chronic_diseases/diseases/cancer/index_en.htm#fragment2).
As a result from another international collaboration— with IARC, the European Code Against Cancer [20] was developed, based on the latest scientific evidence. Among the set of 12 recommendations on how people can take action to reduce their cancer risk is the one about participation in organised breast cancer screening programmes. Therefore, the development and the constant update of the European Breast Guidelines may contribute to the successful implementation of this recommendation.

To summarise, the European Breast Guidelines, and the ECIBC as a whole, are expected to impact on breast cancer care and on policies aiming to reduce the burden of the disease. An overall view of the expected impacting modalities is provided in Table 1.

The GDG, under the JRC coordination, is developing recommendations relevant for screening and diagnosis in breast cancer along the six chapters foreseen for the European Breast Guidelines.

These recommendations together with all the supporting information (e.g. evidence tables, justification, subgroup considerations, implementation considerations, research priorities, references) will be published in a lay-person language on the ECIBC web hub.21 Publications in peer reviewed journals derived e.g. from systematic reviews executed for the development of the European Breast Guidelines are also planned in agreement with the contributing GDG members, CClb, and DG SANTE.

All this work will serve DG SANTE in their support to the national policies regarding breast cancer control and can be used as an example for an appropriate approach to be applied also for other types of cancers or other diseases.

References


[16] European Commission, DG Health and Food Safety, Public Health, Major and chronic diseases policy.30
[17] CANCON–Cancer Control Joint Action.31
[18] EPAAC–European Partnership for Action Against Cancer.32
[19] European Commission, Commission expert group on Cancer Control (E03203).33
[20] European Code Against Cancer–12 ways to reduce your cancer risk.34

**List of abbreviations and definitions**

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<th>Abbreviation</th>
<th>Definition</th>
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<td>CANCON</td>
<td>Cancer control joint action</td>
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<td>CCIb</td>
<td>Iberoamerican Cochrane Centre</td>
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<td>DG SANTE</td>
<td>European Commission Directorate-General Health and Food Safety</td>
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<td>EC</td>
<td>European Commission</td>
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<td>ECIBC</td>
<td>European Commission Initiative on Breast Cancer</td>
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<td>EPAAC</td>
<td>European Partnership for Action Against Cancer</td>
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<td>EtD</td>
<td>Evidence-to-decision framework</td>
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<td>EU</td>
<td>European Union</td>
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<td>GDG</td>
<td>Guidelines Development Group</td>
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<td>GRADE</td>
<td>Grading of Recommendations Assessment, Development and Evaluation—a system for rating quality of evidence and strength of recommendations that is structured and explicit</td>
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<td>JRC</td>
<td>Joint Research Centre</td>
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<td>QA Scheme</td>
<td>European Quality assurance scheme for breast cancer services</td>
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<td>QASDG</td>
<td>Quality assurance scheme development group</td>
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Fig. 1. Contribution of the European Breast Guidelines to EU initiatives.
Fig. 2. The workflow for production of evidence-based recommendations, included in the European Breast Guidelines.
Fig. 3. Guidelines lifecycle.

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Table 1. Potential impact of the European Breast Guidelines on EU cancer policy and initiatives.
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