European Commission

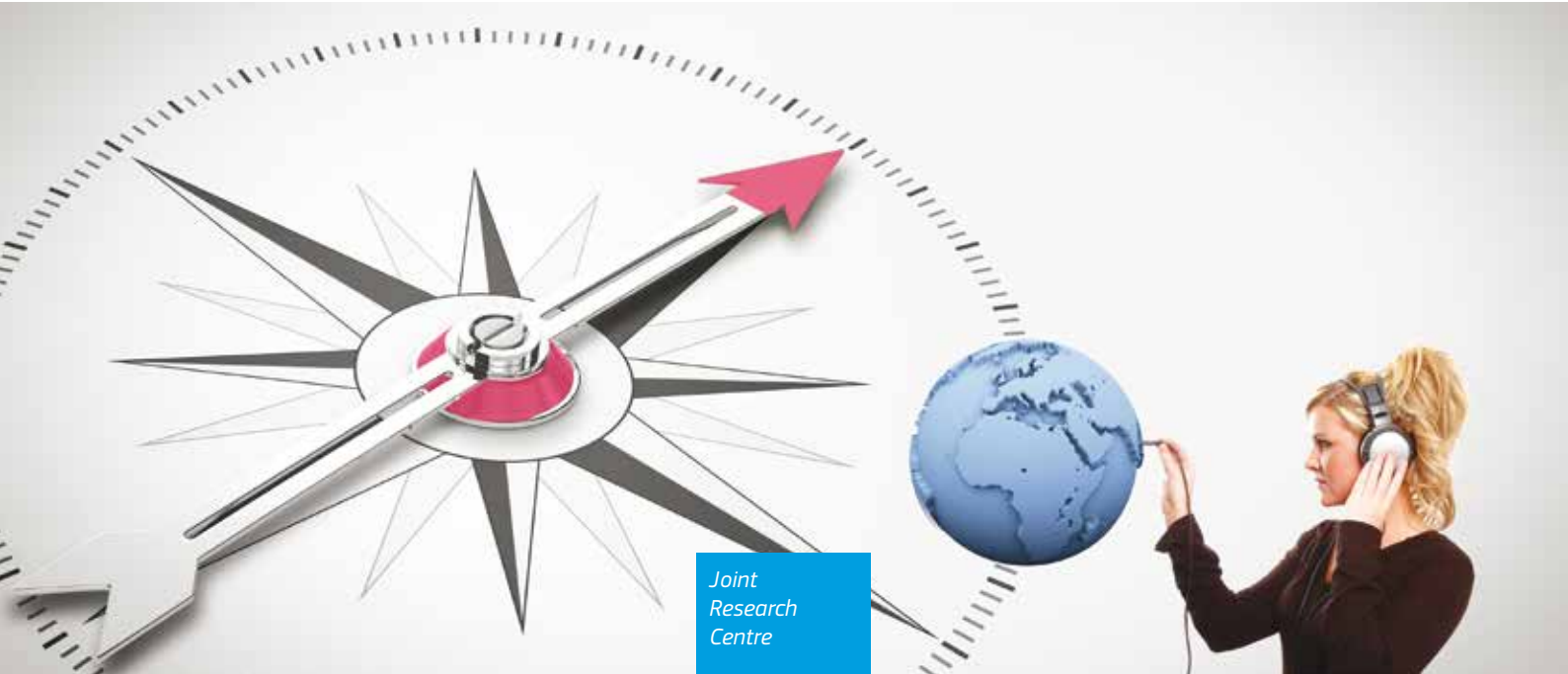
JRC TECHNICAL REPORT

Report on the call for feedback about The Scope of the European guidelines for breast cancer screening and diagnosis

European Commission Initiative on Breast Cancer

Saz-Parkinson Zuleika, Neamțiu Luciana, Pylkkanen Liisa, Deandrea Silvia, Dimitrova Nadya, Ambrosio Massimo, Bocchi Giulia, Bramesfeld Anke, Ulutürk Aslı, Lerda Donata and the Guidelines Development Group

2017



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The ECIBC as a whole is certainly enriched and its implementability enhanced thanks to the feedback received from stakeholders: we wish to thank all respondents for the time, dedication and competence they invested in providing their feedback to *The Scope* of the European guidelines for breast cancer screening and diagnosis (*European Breast Guidelines*).

Abstract

In 2015, the European Commission Initiative on Breast Cancer (ECIBC) started the development of the European guidelines for breast cancer screening and diagnosis (henceforth the *European Breast Guidelines*) under the auspices of the Directorate-General for Health and Food Safety (DG SANTE) and the technical and scientific coordination of the Directorate-General Joint Research Centre (JRC). To support the JRC in this task, a Guidelines Development Group (GDG), consisting of independent experts and individuals, was established.

The *European Breast Guidelines*' scope (*The Scope*) represented the first output of the development process of the *European Breast Guidelines*. Via a public call for feedback, stakeholders and individual citizens were invited to provide their feedback on *The Scope*.

The call for feedback was open from 18 December 2015 to 17 January 2016 and an online questionnaire was made available on the ECIBC web hub via the EU Survey platform. The JRC received a total of 82 valid responses, from 40 individuals from 18 different countries and from 42 organisations from 20 different countries.

During a meeting held in Varese (Italy) in March 2016, the GDG discussed the new version of *The Scope* which was prepared taking into account the results of the call for feedback. *The Scope* was finalised and approved by the GDG after some minor editing on 6 September 2016 and was later made publicly available together with this report.

1. Introduction

In December 2012, the Directorate-General for Health and Consumers (now the Directorate-General for Health and Food Safety – DG SANTE) assigned the task of coordinating the European Commission Initiative on Breast Cancer (ECIBC) to the Joint Research Centre (JRC).

The ECIBC's main tasks, as defined in the DG SANTE published document, are:

- To develop the European guidelines for breast cancer screening and diagnosis (*European Breast Guidelines*) based on updated evidence.
- To develop a voluntary European Quality Assurance scheme for Breast Cancer Services (*European QA scheme*) covering all care processes and based on the EU legislative framework on accreditation and underpinned by the evidence provided by the guidelines.

For recommendations on care processes other than screening and diagnosis (treatment, rehabilitation, follow-up and survivorship care, palliative care, and all relevant horizontal aspects), it is envisaged that an ECIBC platform for breast cancer guidelines (the *Guidelines Platform*) will host existing evidence-based, high-quality guidelines. In addition, Reference documents will be collected to support the implementation of evidence-based recommendations included in the existing guidelines for those aspects, e.g. related to diagnosis, where best practice guidance would be useful.

The ECIBC project also includes the definition of a concept for training professionals in breast cancer screening and the development of a dedicated web hub. It is foreseen that the ECIBC web hub will host all the tools developed (including the guidelines) and to make them available to and usable by all interested parties.

All these tasks are coordinated at the JRC level by a dedicated team, the ECIBC coordination team. The *European Breast Guidelines* are being developed in a web-based format and structured along PICO[1] questions/recommendations adopting GRADE[2] methodology for evaluating the available evidence and using it to support recommendations (1). To support the EC in the development of the *European Breast Guidelines*, a Guidelines Development Group (GDG) was established in 2015 following a Call for Expression of Interest[3] organised by DG SANTE and works under the JRC's technical and scientific coordination.

The *European Breast Guidelines´* scope (*The Scope*) represents the GDG's first output and defines the topics, considered important to the target audience, that the guidelines will cover within the ECIBC mandate limits and alongside what was agreed with the GDG regarding the purpose of the *European Breast Guidelines*, target population, healthcare setting, types of interventions, and key stakeholders and users.

To ensure that from this early stage of development the scope proposed for the *European Breast Guidelines* would be inclusive and feasible for different health systems, countries and contexts, stakeholders and individual citizens were invited via a call for feedback to provide their opinion on *The Scope*. This report is about the results of this exercise.

1 PICO stands for: Population under study (for example, women of a certain age); Intervention (for example, a medical examination); Comparator (other main options such as an alternative medical examination); and Outcomes (results).

2 GRADE (Grading of Recommendations Assessment, Development and Evaluation) – provides a system for rating quality of evidence and strength of recommendations that is structured and explicit.

3 http://ec.europa.eu/health/major_chronic_diseases/diseases/cancer/call_ecibc_en.htm

2. Methodology of the call for feedback

2.1 The questionnaire

The ECIBC coordination team drafted *The Scope* and submitted it to the GDG for approval in December 2015. The version approved by the GDG was submitted to the call for feedback, and participants in the call were also asked to propose questions relevant for inclusion in the *European Breast Guidelines*.

The public call for feedback took place from 18 December 2015 to 17 January 2016 (four weeks) in the form of an online questionnaire, using the EU Survey tool, published on the ECIBC web hub. This online consultation was open to all interested parties. To ensure that all relevant stakeholders were informed, several information channels were used, including the ECIBC web hub, DG SANTE's newsletter and the European Public Health Association's (EUPHA) newsletter. In addition, all the entities (including those reported in past ECIBC publications (2-4)) and individuals (including also the officially nominated ECIBC National Contacts) identified as ECIBC stakeholders received a targeted communication before and just after the publication of the public call for feedback.

To maximise the response rate, a reminder was sent on 11 January 2016 and, finally, an e-mail was sent to thank all participants following the closure of the survey.

The online questionnaire comprised four main sections:

The first section concerned general information about the respondents. They had to identify themselves and indicate whether they were replying as an 'individual' or 'on behalf of an organisation'. The responses from the ECIBC National Contacts were considered as 'on behalf of an organisation' because it was implied that they had responded on behalf of the corresponding country. Respondents could indicate how their contribution would appear: under the name supplied (and consent to publication of all the information contributed), anonymously (and consent to publication of all the information contributed excluding the name of the respondent and/or organisation), or ask that the contribution be treated confidentially, allowing for internal use within the European Commission only.

The second section included questions on the different parts of *The Scope*:

- Purpose of the guidelines;
- Target population;
- Healthcare settings;
- Types of interventions;
- Key stakeholders and users;
- Existing documents.

The third section gave the respondents an opportunity to provide general comments regarding *The Scope*.

In the fourth section, the respondents were asked to suggest questions that should be addressed by the *European Breast Guidelines* for each of the agreed chapters:

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

The full questionnaire is available as Annex I to this report.

A functional mailbox (JRC-ECIBC@ec.europa.eu), managed by the ECIBC coordination team based at the JRC's Ispra site (Italy), was available for requests for technical support.

2.2 Data collection and processing

Responses were collected and processed by the ECIBC coordination team. In particular, all personal data were treated pursuant to Regulation 45/2001/EC on the protection of individuals with regards to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

Only comments submitted before the deadline and relating to the content of the documents were considered. Comments were excluded if they included complaints against institutions, personal accusations, irrelevant or offensive statements or material, or content not related to policy aspects relevant for the ECIBC or outside the scope of ECIBC's activity.

A draft feedback report, including descriptive statistics about the distribution of responses and the list of comments, was shared with the GDG along with their input as to how each section of *The Scope* could be modified according to the comments received. GDG replies to respondents' inputs were integrated accordingly to produce the final version of *The Scope*.

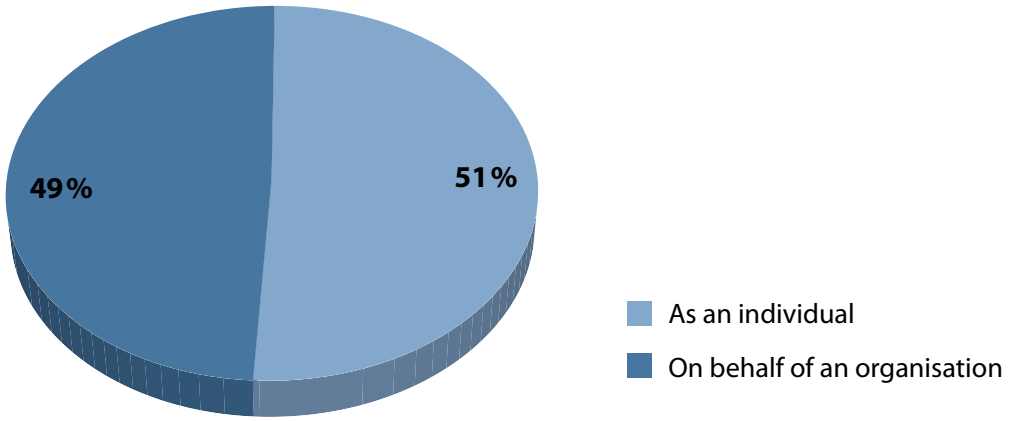
In this report, aggregated data are displayed for all the responses received. Comments from individuals and entities requiring anonymity are reported without the contributor's name, whilst comments from individuals and entities asking for confidential treatment of the contribution are not reported at all. The full database of responses received, with the exception of confidential ones, is available upon request.

3. Results

3.1. Information about respondents

The JRC received a total of 82 valid responses, from 40 individuals (49 % of total) and 42 organisations (51 %). Please note that affiliation is based on self-identification by respondents and has not been validated.

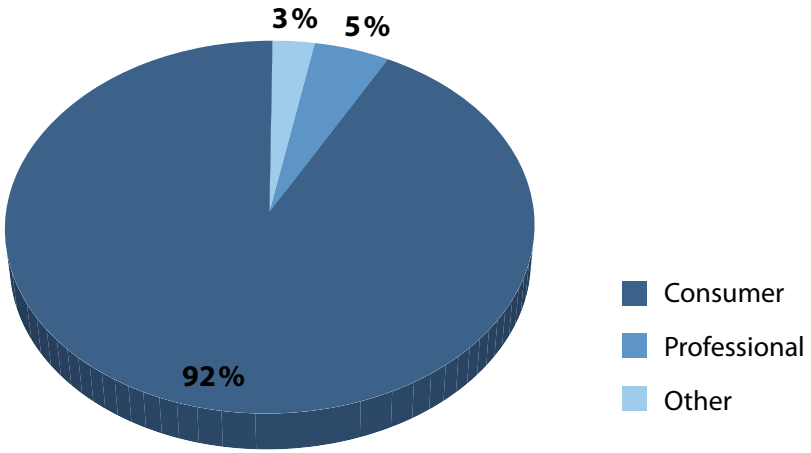
Figure 1: Distribution of survey responses to the public call for feedback (n=82)



Individuals

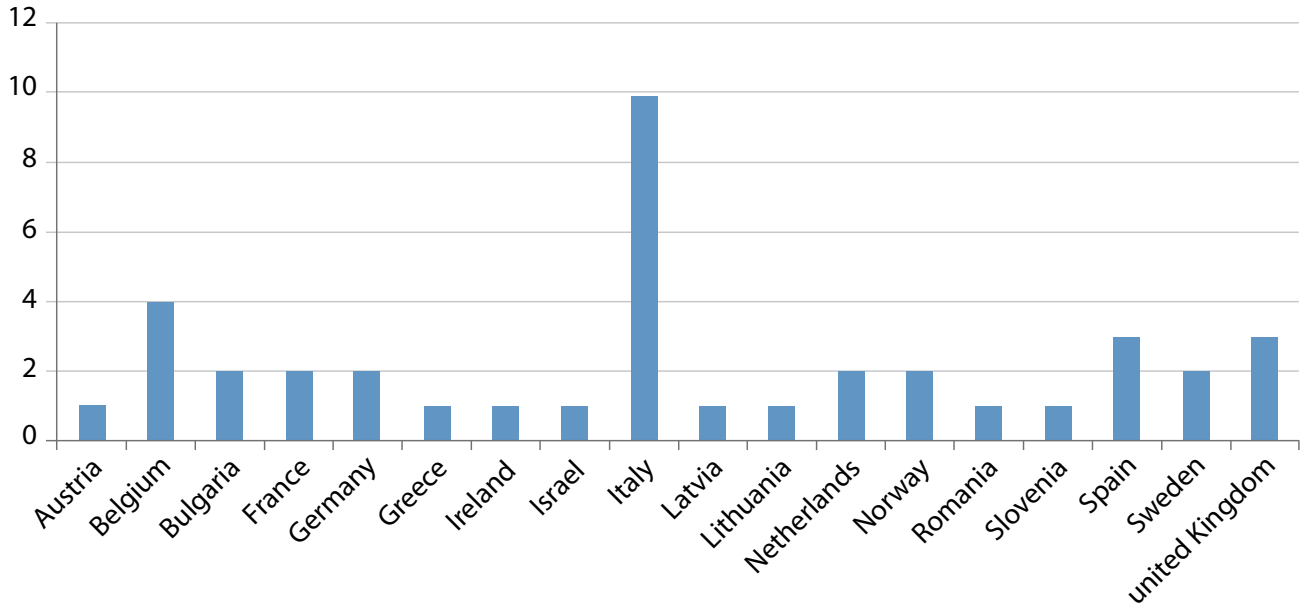
The vast majority of individuals, 37 out of 40 (92 %), identified themselves as professionals working in an area related to breast cancer. Five percent identified him/herself as a patient/ consumer and another 3 % as 'other'. Three of the respondents asked for their comments to be treated confidentially. The participation of patients/consumers as individuals was relatively small, although they also contributed on behalf of patient advocacy organisations (see table 1 below).

Figure 2: Survey responses from individuals, according to their background (n=40)



Individuals' responses came from 18 different countries, with the largest number of respondents (ten) from Italy. All but three of the responses (one from Israel and two from Norway) came from EU individuals, representing 16 (57 %) of the 28 Member States.

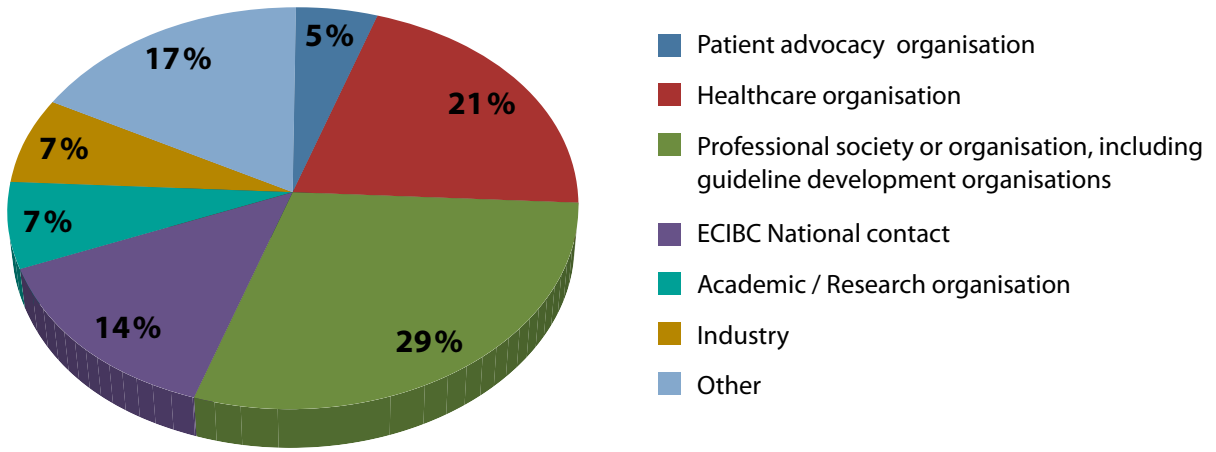
Figure 3: Geographical distribution of survey responses from individuals (n=40)



Organisations

Forty-two contributions were received from organisations, corresponding to seven different main types of entities. The majority of responses (29 %) were from professional societies or organisations, including guidelines development organisations. Another substantial contribution (21 %) came from healthcare organisations. The proportion of responses from the rest of the main entities varied from 5 % for the patient advocacy organisation to 14 % for the ECIBC National Contacts. In addition, there was a group of seven (17 %) respondents who identified themselves as other types of entity. One contributor responding on behalf of an organisation asked for confidential treatment of his/her comments.

Figure 4: Survey responses from organisations, according to the type of entity (n=42)



Responses came from organisations from 20 countries. Sixteen of the 28 EU Member States participated, as well as three European countries outside the EU (Serbia, Switzerland and Turkey) and one non-European country (Canada). The highest number of contributors came from Italy (seven), Belgium (four) and Netherlands (four).

Figure 5: Geographical distribution of survey responses from organisations (n=42)

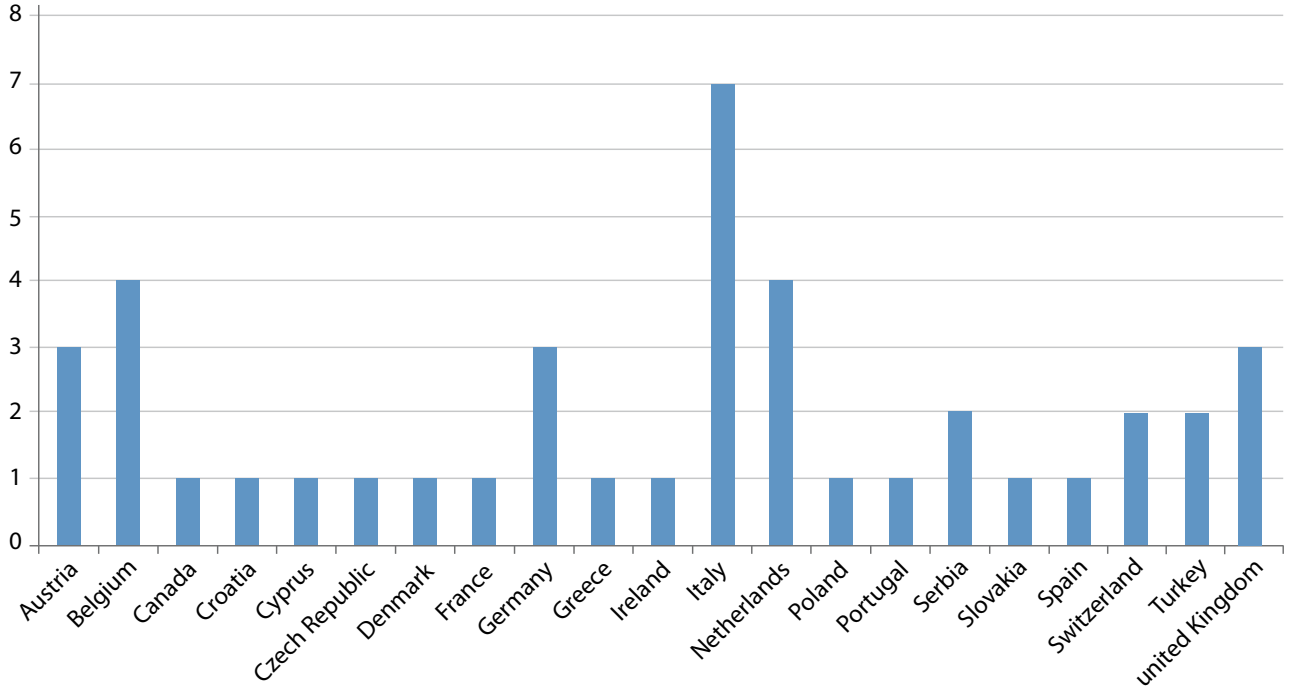


Table 1: List of organisations contributing to the call for feedback and not asking for anonymity or confidentiality, arranged by type of organisation

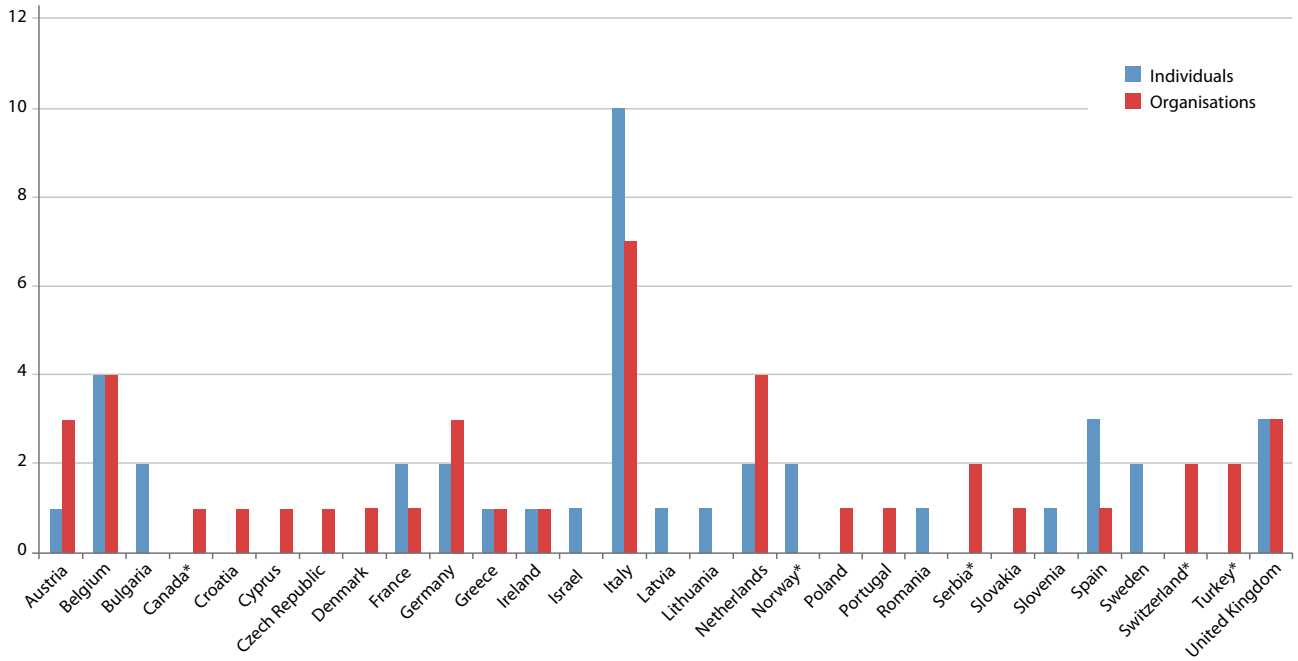
*Acronyms not reported by respondents are listed in Annex 5

NAME*	TYPE	COUNTRY
Europa Donna - The European Breast Cancer Coalition	Patient advocacy organisation	Italy
Borstkanker Actie	Patient advocacy organisation	Netherlands
Turkish Cancer Control Department of MoH	Healthcare organisation	Turkey
Croatian Institute of Public Health	Healthcare organisation	Croatia
Ministry of Health	Healthcare organisation	Republic of Cyprus
Ministry of Health	Healthcare organisation	Italy
Department of Health, Ireland	Healthcare organisation	Ireland
Kooperationsgemeinschaft Mammographie (mammography cooperative), Berlin	Healthcare organisation	Germany
CPO-Piemonte, AOU Città della salute e della scienza, Torino	Healthcare organisation	Italy
Istituto per lo studio e la prevenzione oncologica, Regione Toscana	Healthcare organisation	Italy
Danish Health Authority	Healthcare organisation	Denmark
Hellenic Society of Breast Surgeons	Professional society or organisation, including guidelines development organisations	Greece
European Reference Organisation for Quality Assured Breast Screening and Diagnostic	Professional society or organisation, including guidelines development organisations	Netherlands
BCCERT	Professional society or organisation, including guidelines development organisations	Italy
National Institute for Public Health and the Environment/ Centre for Population Screening	Professional society or organisation, including guidelines development organisations	Netherlands

NAME*	TYPE	COUNTRY
ESTRO, European Society for Radiotherapy & Oncology	Professional society or organisation, including guidelines development organisations	Belgium
EUSOMA	Professional society or organisation, including guidelines development organisations	Italy
Austrian Federal Ministry of Health	Professional society or organisation, including guidelines development organisations	Austria
Bundesverband Deutscher Pathologen e.V.	Professional society or organisation, including guidelines development organisations	Germany
Europrev	Professional society or organisation, including guidelines development organisations	Belgium
Centre Communautaire de Référence pour le dépistage des cancers (CCR asbl)	Professional society or organisation, including guidelines development organisations	Belgium
EFOMP	Professional society or organisation, including guidelines development organisations	United Kingdom
EUSOBI	Professional society or organisation, including guidelines development organisations	Netherlands
The Breast Clinical Reference Group, NHS England	ECIBC national contact	United Kingdom
Ministry of Health	ECIBC national contact	Slovakia
Accreditation Body of Serbia	ECIBC national contact	Serbia
Institute of Public Health of Republic of Serbia	ECIBC national contact	Serbia
Swiss Federal Office of Public Health FOPH, Health and Accident Insurance Directorate	ECIBC national contact	Switzerland
SENATURK	Academic/Research institution	Turkey
EORTC	Academic/Research institution	Portugal
Österreichische Röntgengesellschaft ÖRG, Chair of Breast Imaging Work Group	Academic/Research institution	Austria
GE Healthcare	Industry	France
Roche	Industry	Switzerland
COCIR	Industry	Belgium
United Kingdom Accreditation Service	Other	United Kingdom
Czech Accreditation Institute	Other	Czech Republic
Hamburg Cancer Registry	Other	Germany
ITALCERT Srl	Other	Italy
Badai	Other	Austria
Cancer Screening Programmes. Catalan Cancer Plan	Other	Spain
Canadian Breast Cancer Screening Network	Other	Canada

In total, 29 countries participated in the survey, including six non-EU countries. Twenty-three (82 %) out of 28 EU Member states sent responses – only as an individual (six countries), only on behalf of an organisation (seven countries) or both (ten countries).

Figure 6: Number of responses from individuals and organisations from all countries which participated in the survey (*non-EU countries)



3.2. Results concerning the different parts of *The Scope*

In the following paragraphs, the results of the call for feedback will be reported question by question. Thereby, the relevant section from the survey will be presented first, followed by a figure, showing the distribution of responses, a summary of the comments and the final text in *The Scope* with the parts which were modified according to the comments highlighted in yellow. Annex II contains the comments received from the respondents, and the reasoning provided by GDG/JRC for each comment, for modification of *The Scope*.

3.2.1 Purpose of the guidelines

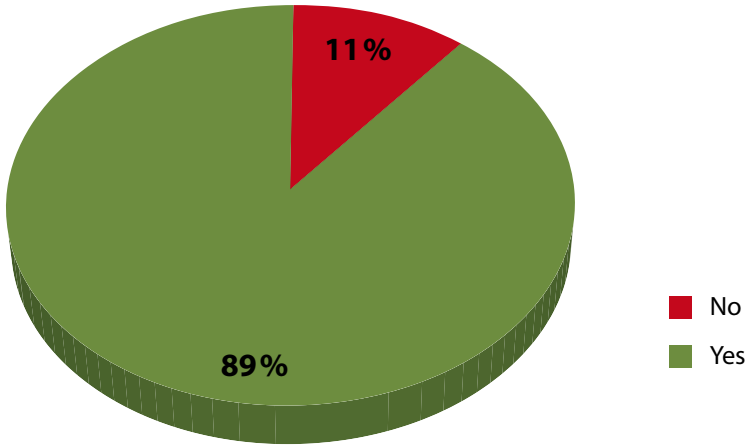
Clarity of objectives in the *European Breast Guidelines*

The first question related to the clarity of the Objectives section in *The Scope*:

> The primary objectives of the *European Breast Guidelines* are: (1) to provide users of breast cancer screening and diagnosis services (citizens and patients) and healthcare providers with clear, objective and independent guidance on breast cancer screening and diagnosis in order to promote informed decisions; and (2) to guide healthcare managers and policy-makers when planning, commissioning and organising services for breast cancer screening and diagnosis. This includes the development of evidence-based recommendations supporting quality assurance of breast cancer screening and diagnosis. According to these objectives, it can be anticipated that some questions of the *European Breast Guidelines* will take more than one perspective, e.g. an individual and a population perspective (see section '3b. Perspective of the *European Breast Guidelines*').

The majority of the respondents (89 %) said that the objectives are clear.

Figure 7: Clarity of *European Breast Guidelines* objectives (n=82)



In addition to YES/NO responses, nine comments were received: two from individuals and seven on behalf of an organisation, which are presented in Annex II, table 1.

As regards the first objective, it was suggested it should be rephrased to make it clearer that both healthcare users and healthcare providers will be provided with guidance to enable them to take informed decisions regarding breast cancer screening and diagnosis. One of the comments was related to the guidance for healthcare professionals and managers on how to ensure the participation of women in the screening: this will be considered in the communications section in the *European Breast Guidelines* and no further change was made in *The Scope*.

One comment, linked to the second objective, suggested an emphasis on quality of processes, as well as on improvement of outcomes. Another comment, relating to the use of 'common practice' for diagnostic procedures where no evidence-based recommendations are available, was not implemented in the objectives section of *The Scope*, although it will be considered in general within the ECIBC project, via Reference Documents. These documents are meant to support the implementation of evidence-based recommendations included in the existing guidelines for those aspects, e.g. related to diagnosis, where best practice guidance would be useful.

The explanation that 'some recommendations of the *European Breast Guidelines* include more than one perspective, *e.g.* an individual and a population perspective' was already in the Objectives section of *The Scope*, so no further modifications were made following this comment by an individual.

The modified text according to the comments is:

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

1. to provide both **healthcare users** and **healthcare providers** with clear, objective and independent guidance on breast cancer screening and diagnostic services to enable them to take informed decisions; and

2. to guide **healthcare providers** and policymakers when planning, (de)commissioning and organising services for breast cancer screening and diagnosis. This is done by developing evidence-based recommendations to support the quality assurance of breast cancer screening and diagnosis, **with an emphasis on improvement of outcomes and quality of the processes.**

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

Expected outcomes

This question investigated whether the proposed expected outcomes were considered relevant. Respondents were asked to reply if they agreed or had concerns and to provide comments regarding the following paragraph in *The Scope*:

Expected outcomes influenced by the guidelines

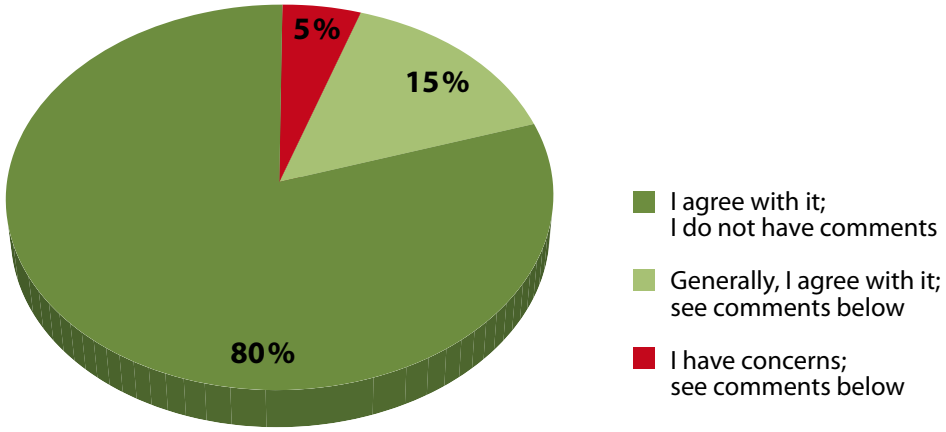
An 'outcome' is the impact that a test, treatment, policy, program or other intervention has on a person, group or population. The importance of outcomes is likely to vary within and across cultures or when considered from the perspectives of the citizens, patients, clinicians or policy-makers. Cultural diversity will often influence the relative importance of outcomes, particularly when developing recommendations for an international audience.

It is anticipated that the *European Breast Guidelines* will impact on outcomes important for the citizens and the health systems, such as:

- Mortality due to breast cancer
- Quality of life
- Patient safety
- Equity in healthcare
- Unnecessary variability in clinical practice

Eighty percent of the respondents replied that they agreed with the proposed expected outcomes and did not have comments, 15% agreed in general but also provided comments, and 5% had concerns for which they provided comments.

Figure 8: Relevance of proposed expected outcomes influenced by the *European Breast Guidelines* (n=82)



Twelve comments (five from individuals and seven on behalf of an organisation) were received from the respondents who replied with '**generally, I agree**' – Annex II, table 2. The comments suggested addressing additional outcomes such as:

- over-diagnosis and over-treatment;
- inequalities because of insufficient resources, healthcare organisation or cultural background;
- survivorship;
- patient satisfaction;
- cost effectiveness.

A modification of *The Scope* was not considered because these and other relevant outcomes will be taken into account when selecting outcomes for the specific PICO (Population, Intervention, Comparator, Outcomes) questions.

Comments related to unnecessary variability in clinical practice, target groups that have different needs, different cultural backgrounds and health systems, issues concerning communication and quality of services were not considered for modification of *The Scope*. However, some of them will be addressed in PICOs or by the *European QA scheme*, while others are considered in view of implementation aspects for each recommendation that will be issued.

There were four comments on behalf of an organisation from those who replied '**I have concerns**' – Annex II, table 3. They mainly suggested additional outcomes, which will be considered in the definition of the relevant and specific PICOs, so no changes were made in *The Scope*. One comment related to the inclusion of 'treatment and organisation of breast care', but no modification was made to this section of *The Scope* because a footnote was added to the target population section, explaining that the '*Guidelines Platform*, a collection of existing evidence-based guidelines, can include recommendations on treatment for all breast cancer patients'.

No changes were implemented to *The Scope* regarding the expected outcomes. However, the suggested additional outcomes will be considered in the definition of the relevant and specific PICOs.

3.2.2 Target population

This question investigated whether the proposed population groups, which will be addressed by the *European Breast Guidelines*, are adequate. Respondents were asked to reply if they agreed or had concerns and to provide comments regarding the relevant paragraphs in *The Scope* about: 1) groups that will be covered, and 2) groups that will not be covered.

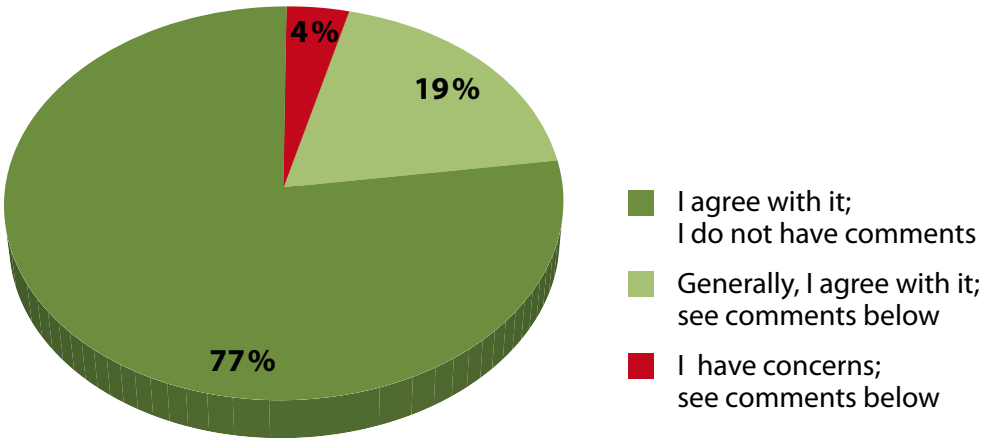
Groups that will be covered

Women eligible for breast cancer screening.

Women attending breast diagnostic services because of symptoms or because of a recall on the basis of their screening examination.

Seventy-seven percent of the respondents replied that they agreed with the proposed groups and did not have comments, 19% agreed in general but also provided comments, and 4% had concerns for which they provided comments.

Figure 9: Adequacy of proposed population groups which will be covered by the *European Breast Guidelines* (n=82)



There were 15 comments received by respondents who replied with '**generally, I agree**' – ten from individuals and five on behalf of an organisation – Annex II, table 4.

Five of the comments concerned the screening age groups. These comments will be considered in the definition of the relevant PICOs, so no modifications were made in *The Scope*.

Several comments related to addressing women at high risk (BRCA1/2, positive family history and other). No change was made in *The Scope*, but some PICO questions may relate to varying the screening regimen depending on certain risk factors.

Two of the comments related to opportunistic screening and target population. These will be taken into account when formulating the relevant specific PICOs, so no modifications were made in *The Scope*.

Three comments suggested clarification about groups covered and not covered – namely about women with symptoms or a previous diagnosis of breast cancer, and men. Modifications of *The Scope* were made to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*. In addition, 'women' has been substituted with 'persons', because the screening chapter will not cover men; however, the diagnostic procedures will cover any person with breast cancer (women and men).

Three comments were received from those who replied '**I have concerns**' – two as an individual and one on behalf of an organisation – Annex II, table 5. They concerned male breast cancer, high-risk groups, and women with a previous diagnosis of breast cancer. Following these comments, relevant modifications were made in *The Scope*, as described in the previous paragraph.

After considering all the comments, the final text in *The Scope* is the following:

Groups covered:

- persons eligible for breast cancer screening;
- persons accessing breast diagnostic services because of symptoms, referral

(e.g. following a risk assessment) or a recall on the basis of their screening examination.

Regarding the groups that will not be covered by the *European Breast Guidelines*, the respondents were asked to provide feedback on the following text:

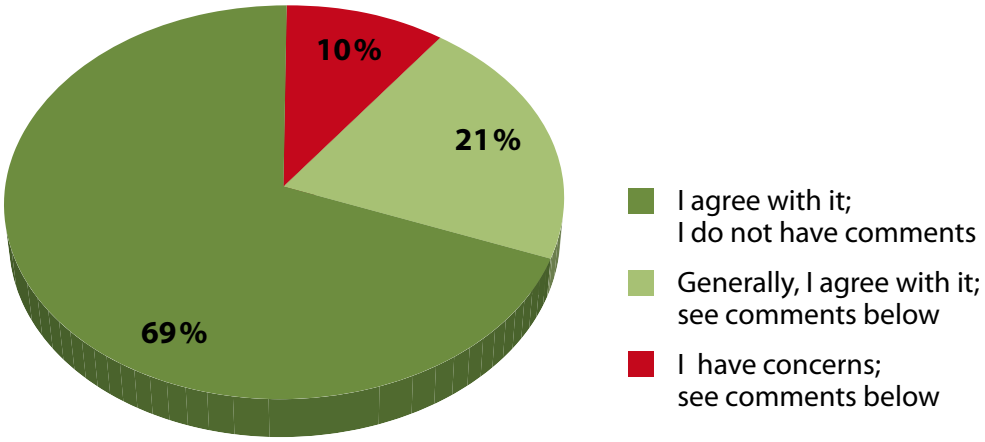
Groups that will not be covered

The following populations will not be specifically addressed by the guidelines:

- Males
- Women with loco-regional recurrences
- Women with metastatic breast cancer

Almost 70 % of the respondents replied that they agreed with the proposed groups and did not have comments, about 20 % agreed in general but also provided comments, and 10 % had concerns on which they provided comments.

Figure 10: Adequacy of proposed groups which will not be covered by the *European Breast Guidelines* (n=82)



There were 17 comments received from those who replied '**Generally I agree**' – 11 as an individual and six on behalf of an organisation – Annex II, table 6.

Comments relating to the inclusion of males in the diagnostic part of the guidelines were considered and *The Scope* was modified – 'women' has been substituted with 'persons'.

There were several suggestions to include all patients in *The Scope*, also covering loco-regional recurrences, metastatic breast cancer, and second primary tumour. *The Scope* was modified (interventions not covered) to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines* but are part of the *Guidelines Platform*.

Three of the comments were on follow-up (surveillance) of women with breast cancer (screen- or non-screen-detected). Since this topic will be covered by the *Guidelines Platform*, *The Scope* was not modified.

Following the comments on high-risk patients and hereditary breast cancer, *The Scope* was modified to clarify that breast cancer risk assessment is among the interventions not covered by the *European Breast Guidelines*, but the groups covered include those accessing breast diagnostic services because of symptoms, referral (e.g. following a risk assessment) or a recall on the basis of their screening examination. Some PICO question may be related to varying the screening regimen depending on certain risk factors.

Seven comments were received from those who replied '**I have concerns**' – one as an individual and six on behalf of an organisation – Annex II, table 7.

Four of the comments related to the inclusion of males in the diagnostic part of the guidelines and *The Scope* was modified accordingly – 'women' has been substituted with 'persons'.

Regarding the comments relating to the inclusion of patients with recurrences and metastases, and high-risk individuals, *The Scope* was modified accordingly, as described above for the comments received from those who replied '**Generally I agree**'.

After considering all the comments, the final text in *The Scope* is the following:

Groups NOT covered:

The *European Breast Guidelines* will not address questions concerning issues in these specific populations:

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

A note was added: 'Treatment regimens and surveillance for patients are regularly updated in international treatment guidelines. The *Guidelines Platform*, a collection of existing evidence-based guidelines, can include recommendations on treatment for all breast cancer patients.'

Perspective

This question related to the clarity of the perspective section in *The Scope*:

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

The first purpose of the *European Breast Guidelines*, in particular from its European legal background, should be to give policy makers and healthcare administrators evidence-based recommendations on the implementation of cancer screening programmes and on the organisation of diagnostic procedures for breast cancer.

However, one main conclusion of the two workshops held at JRC-Ispra in 2013 was that the *European Breast Guidelines* should be 'women-centred'. This implies that the perspective of users of breast cancer services (citizens and patients) should be taken into consideration during all stages of the guidelines development.

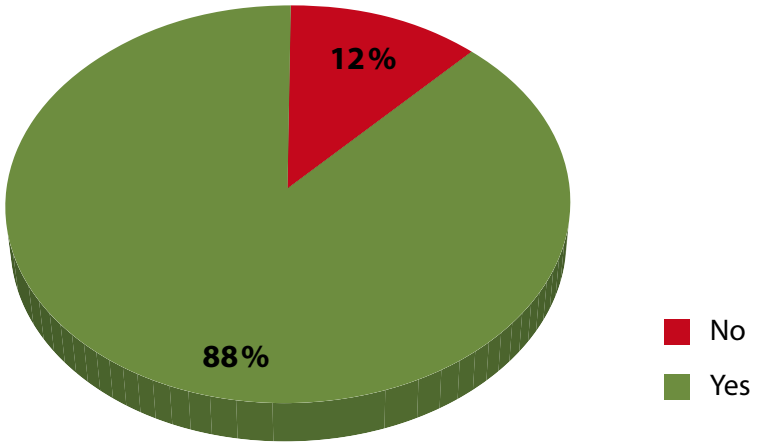
On the other hand, for questions related to diagnosis, especially when it happens outside of a screening programme, the patients' and clinicians' perspective will be prioritised. This means that the focus will be on the views of the individual user of the healthcare service (citizens and patients) and the healthcare professional that provides that service.

When developing the recommendations of the *European Breast Guidelines*, a balance between different perspectives (e.g., women vs. public health vs. policy support) shall be sought. This will be taken into account when choosing the outcomes for each question.

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

Eighty-eight percent of the respondents replied positively that the section is clear.

Figure 11: Clarity of perspective of the *European Breast Guidelines* (n=82)



For 12 % of the respondents the perspective was not clear and they provided nine comments – three as an individual and six on behalf of an organisation – Annex II, table 8.

Three of the comments suggested clarification regarding different perspectives, which was taken into account in the wording of the final text of *The Scope*.

Four of the comments pointed out the importance of education about symptoms, explanation about over-diagnosis and harm, considering the socio-economic situation, legal and ethical frameworks, as well as addressing all settings for cancer screening. All of these will be taken into account in the formulation of relevant and specific PICOs and no further changes were made in *The Scope*.

Two of the comments concerned the clarity of the text and complementing the second paragraph with an 'adequate evaluation' of programmes and services, which was taken into account and *The Scope* was modified accordingly.

After considering all comments, the final version of the text regarding 'Perspective' is the following:

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

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

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

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

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

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

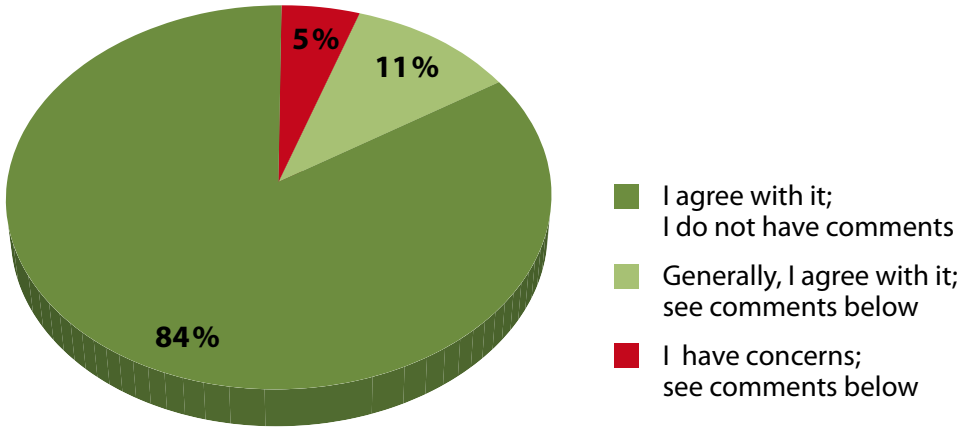
3.2.3 Healthcare settings

This question investigated whether the proposed healthcare settings, which will be covered by the *European Breast Guidelines*, are adequate. Respondents were asked to reply if they agreed or had concerns and to provide comments regarding the following paragraph in *The Scope*:

> The *European Breast Guidelines* will cover all healthcare settings where services for breast cancer screening and diagnosis are delivered.

Eighty-four percent of the respondents said they agreed with the proposed groups and did not have comments, 11% agreed in general but also made comments, and 5% had concerns for which they provided comments.

Figure 12: Adequacy of healthcare settings covered by the *European Breast Guidelines* (n=82)



There were seven comments provided by those who replied '**Generally I agree**' – four as an individual and three on behalf of an organisation – Annex II, table 9.

The comments underlined the importance of including both private and public healthcare services, for screening and for diagnostic services, which were taken into account and *The Scope* was modified accordingly. The quality assurance aspects will be addressed by the *European QA scheme*. Therefore, this comment, which was provided on behalf of an organisation, was not considered for modification of *The Scope*. The title of the guidelines had already been agreed on as the *European Breast Guidelines*, so the comment on this topic was not considered for modification of *The Scope*.

Two of the comments related to issues regarding implementation of the recommendations in different healthcare systems. The *European Breast Guidelines* will include evidence-based recommendations. It may be difficult for some countries to implement them, but since this issue has to be addressed in the proper way at country level no change was made to *The Scope*.

One comment on behalf of an organisation suggested inclusion of a 'policy-making setting'. Since the *European Breast Guidelines* are being developed as a web-based application and one of the profiles foreseen on the web page is that of policymakers, which will include information adapted to their needs, no further modification was made to *The Scope*.

Two comments were received from those who replied '**I have concerns**' – Annex II, table 10. One suggested including treatment, but since this topic will be covered by the *Guidelines Platform* it was not considered for modification in *The Scope*. The other comment concerned the role of a primary care team, which will be considered in the formulation of PICOs related to communication; thus, no further modification to *The Scope* was required.

After considering all comments, the final text in *The Scope*, regarding Healthcare settings, is the following:

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

3.2.4 Types of interventions

Definitions
This question investigated whether or not the proposed definitions are clear. Respondents were asked to reply if they agreed or had concerns and to provide comments regarding the following paragraph in *The Scope*:

Definitions
The following classification and definitions are proposed for screening and screening programmes (7, 8).

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

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

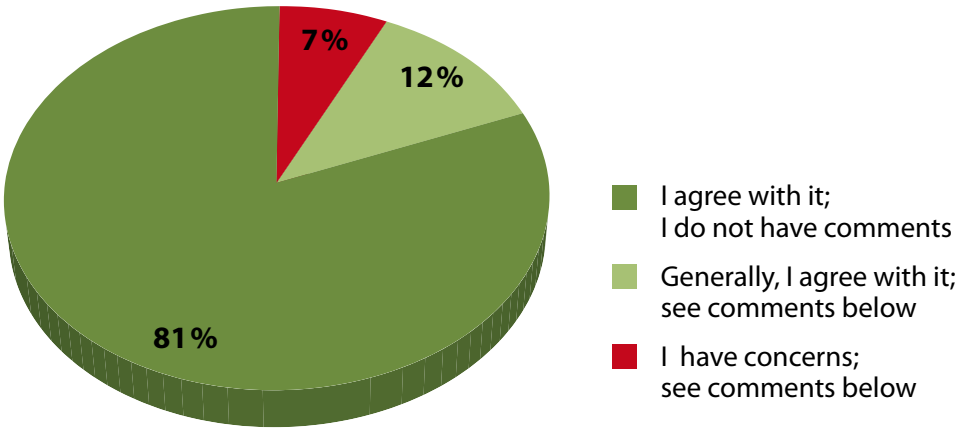
SCREENING PROGRAMME: examinations financed by public sources performed in the context of a public screening policy documented in a law, or an official regulation, decision, directive or recommendation, and where the policy defines, at minimum: the screening test, the examination intervals, group of persons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

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

POPULATION-BASED SCREENING: screening programme where in each round of the screening the persons in the eligible target area served by the programme are individually identified and personally invited. A diagnostic assessment may stem from referral for symptoms or palpable mass, or as further investigation of women with a screening mammography abnormality suggestive of breast cancer.

Eighty-one percent of the respondents replied that they agreed with the proposed definitions and did not have any comments, 12 % agreed in general but also made comments, and the rest had concerns for which they provided comments.

Figure 13: Agreement with proposed definitions in *The Scope* (n=82)



There were eight comments received from those who replied '**Generally I agree**' – three as an individual and five on behalf of an organisation – Annex II, table 11. Most of the comments suggested clarification of the definitions used. *The Scope* was modified to present the definitions as described in the reference provided, e.g. WHO and IARC (International Agency for Research on Cancer). All comments provided by respondents regarding these definitions will be made available to IARC for possible consideration when an update of the definitions is envisaged.

A suggestion from an individual to substitute the phrase 'screening mammography abnormality' with 'screening abnormality' was considered because there will be PICO questions about different modalities used for screening, and *The Scope* was modified accordingly.

Six comments were received from those who replied '**I have concerns**' – five on behalf of an organisation and one as an individual – Annex II, table 12. They had remarks on the definitions – not really matching the main aspect of screening, not being intuitive/logical, presented without the context or quite punitive. *The Scope* was modified to present the definitions as described in the reference provided. All comments provided by respondents regarding these definitions will be made available to IARC for possible consideration when an update of the definitions is envisaged.

Since topics relating to referral for further investigation, coordination and invitations, suggested in a comment on behalf of an organisation, will be covered by some PICOs and the *Guidelines Platform*, no further modifications were made to *The Scope*.

After considering all the comments, the final text in *The Scope* regarding definitions is the following:

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

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

NON-PROGRAMME SCREENING (commonly referred also as opportunistic screening):

examinations for early detection of cancer performed in a diagnostic or clinical setting, independent from the public screening policy (if existing).

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

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

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

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

Interventions that will be covered

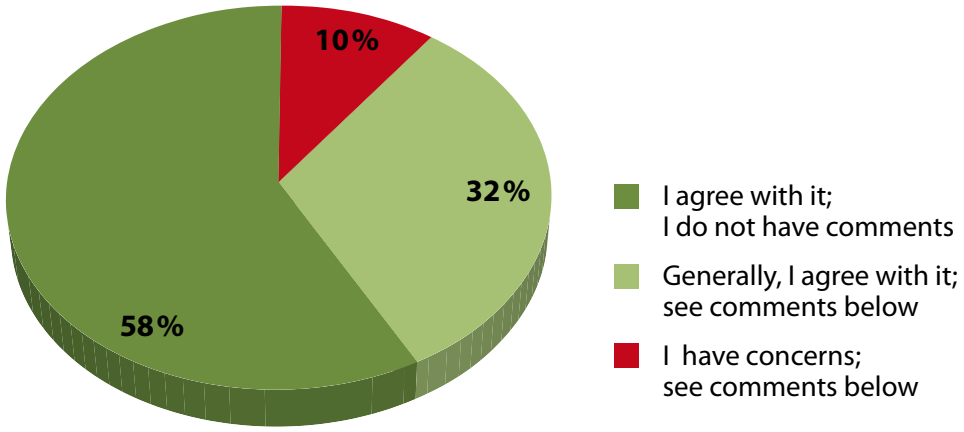
This question asked the participants in the survey about their opinion regarding the interventions that will be covered. Respondents could reply that they agreed or had concerns and were asked to provide comments on the following paragraph in *The Scope*:

The *European Breast Guidelines* will cover screening and diagnosis of breast cancer. In particular, the desirable and undesirable effects of the following interventions will be assessed:

- **Breast cancer screening policies and programmes:**
  - Different modalities of organised population-based screening programmes according to women's age, screening intervals and tests
  - Opportunistic screening
- **Breast cancer diagnostic steps and preoperative staging procedures** (that is, the examinations undertaken after referral and before surgery):
  - Criteria for referral of symptomatic patients
  - The diagnostic procedures for benign lesions
  - Evaluation of different methods for diagnosis and preoperative staging (and, more in general, breast imaging techniques)
  - All biopsy procedures and their pathological examination (including fine needle aspiration, core biopsy and surgical biopsy). Surgical treatment as such will not be covered. However, diagnostic procedures during the surgery, such as lymph node excision by sentinel node biopsy and pathological evaluation of the lymph node evacuation specimens will be covered.
- **Breast cancer surveillance for high-risk women.**
- **Interventions for primary prevention of breast cancer** provided as co-interventions nested in organised screening programmes.
- **Interventions to reduce harms** due to breast cancer screening or diagnosis, such as overdiagnosis or discomfort with screening procedures.
- **Interventions to improve communication in breast cancer screening and diagnosis.**
- **Interventions to improve organisational aspects** of breast cancer screening and diagnosis (such as multidisciplinary team meetings).
- The *European Breast Guidelines* will cover the following types of recommendations related to breast cancer screening and diagnosis:
- Clinical recommendations about interventions and diagnostic tests
- Health systems and public health recommendations (such as recommendations about population-based screening programmes or recommendations focusing on quality assurance aspects).

Among the respondents, 58 % said they agreed with the interventions that will be covered and did not have any comments, 32 % agreed in general but also made comments, and the remaining 10 % had concerns for which they provided comments.

Figure 14: Agreement with interventions covered by the *European Breast Guidelines* (n=82)



Twenty-three comments were received from those who replied '**Generally I agree**' – Ten as an individual and 13 on behalf of an organisation – Annex II, table 13.

Some comments related to diagnostic procedures for benign lesions, suggesting not to differentiate them from diagnostic procedures for malignant lesions. No change was made in *The Scope* because it was considered that there are some differences in the malignant lesions in the diagnostic process which are important to point out.

Different biopsy procedures were also discussed in the context of diagnostic process. Since all biopsy procedures and their pathological examination have already been considered in *The Scope*, no further change was made.

Two comments pointed out the importance of the neoadjuvant treatment and *The Scope* was modified accordingly to clarify that 'examinations undertaken following referral and prior to treatment' are included.

The Scope was also modified following comments on familial predisposition and screening for asymptomatic high-risk women, in order to clarify that breast cancer risk assessment is among the interventions not covered in *The Scope*. However, some PICO questions may relate to varying the screening regimen depending on certain risk factors.

Two comments related to harm and undesirable effects. Harm is included in each PICO question among the outcomes. Desirable and undesirable effects are examined using Evidence-to-Decision Frameworks[4] for each PICO in order to decide where the balance lies, which might influence the direction of the corresponding recommendation, thus no further change was made in *The Scope*.

4 Evidence to Decision (EtD) frameworks – an explicit and transparent system for decision-making, provide a systematic and transparent approach for going from the evidence to the healthcare decision. EtD frameworks inform users about the judgments that were made and the evidence supporting those judgments by making the basis for decisions transparent to target audiences. EtD frameworks also include detailed justification (undesirable effects, values, certainty of the evidence), sub-group considerations, implementation considerations, monitoring and evaluation considerations and research priorities.

Regarding a comment for inclusion of metastatic disease, *The Scope* was modified (in the interventions section not covered) to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*.

The Scope was also modified following a comment to include not only women – the word 'women' has been substituted with 'persons' because the screening chapter will not cover men, although the diagnostic procedures will cover any person with breast cancer (women and men).

The link between screening, diagnosis and other care procedures was pointed out in several comments. Therefore, *The Scope* was modified to include (in the purpose section) a figure about the breast cancer care pathway.

There were eight comments received from those who replied '**I have concerns**' – four as an individual and four on behalf of an organisation – Annex II, table 14. Two of these related to evaluation of pathological parameters, which may be covered by some PICO questions in the diagnosis chapter or by reference documents that will be provided to support ECIBC implementation, so no further change was made in *The Scope*.

The Scope was modified to include examinations prior to treatment and pre-treatment staging, instead of 'pre-operative staging', as suggested in several comments.

Comments relating to high-risk women were followed by a relevant modification of *The Scope*, as already described in the paragraph regarding comments from those who replied '**Generally I agree**'.

After considering all comments, the final text of *The Scope* regarding interventions that will be covered is the following:

The *European Breast Guidelines* cover the screening and diagnosis of breast cancer.

The desirable and undesirable effects of the following interventions are being assessed in order to produce clinical recommendations, as well as health systems and public health recommendations:

- Breast cancer screening policies and programmes:
  - different modalities of organised population-based screening programmes according to women's age, screening intervals and tests
  - opportunistic screening.
- Breast cancer diagnostic processes – these include examinations undertaken following referral and prior to treatment processes, considering:
  - criteria for referral of symptomatic persons
  - diagnostic procedures for benign lesions
  - evaluation of different methods for diagnosis and pre-treatment staging (and, more in general, breast imaging techniques)

- all biopsy procedures and their pathological examination (such as fine-needle aspiration, core biopsy and surgical biopsy).

- Interventions for primary prevention of breast cancer provided as co-interventions nested in organised screening programmes (e.g. information, counselling).
- Interventions to reduce harms due to breast cancer screening or diagnosis.
- Interventions to improve communication on breast cancer screening and diagnosis.
- Interventions to improve the organisational aspects of breast cancer screening and diagnosis (such as multi-disciplinary team meetings).

Interventions that will not be covered

This survey question asked the participants for their opinion regarding the interventions that will not be covered. Respondents could reply that they agreed or had concerns and were asked to provide comments on the following paragraph in *The Scope*:

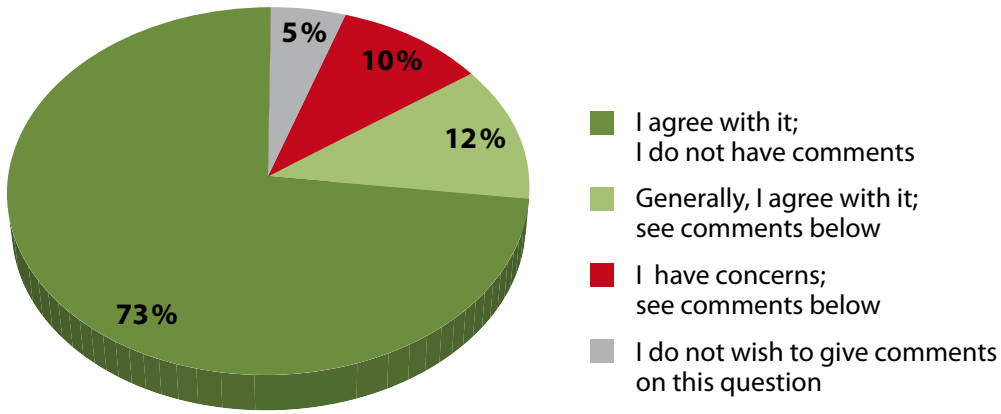
Aspects out of The Scope of breast cancer screening and diagnosis. Breast cancer treatment, rehabilitation, follow-up or palliative care will not be covered. For example, surgical management of lesions detected with mammography will not be covered.

• Diagnostic procedures in breast cancer patients with suspected recurrences or metastases.

For example: staging procedures in women with suspected recurrences or metastases during follow-up will be excluded.

Seventy-three percent of the respondents replied that they agreed with the interventions that will be covered and did not have comments, 12% agreed in general but also provided comments, 10% had concerns for which they provided comments, and 5% did not want to comment on this question.

Figure 15: Agreement with interventions not covered by the *European Breast Guidelines* (n=82)



Ten comments were received from those who replied '**Generally I agree**' – seven as an individual and three on behalf of an organisation – Annex II, table 15.

Several comments related to diagnostic procedures for metastatic disease and suspected recurrences, and to follow-up and surveillance. *The Scope* was modified to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, as well as follow-up and survivorship, but are part of the *Guidelines Platform*.

Some comments related to the link between diagnosis and treatment and suggested including surgical management and the pathological parameters evaluated in the surgical specimen. Since this will be covered by the *Guidelines Platform*, no further modification was made to *The Scope*.

Eight comments were received from those who replied '**I have concerns**' – four as an individual and 4 on behalf of an organisation – Annex II, table 16. Most related to metastatic and recurrent disease, as well as to treatment and follow-up. *The Scope* was modified to clarify these issues, as described above regarding similar comments received from those who replied '**Generally I agree**'.

After considering all comments, the final text regarding interventions that will not be covered is the following:

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

- **Diagnostic procedures in breast cancer patients with suspected recurrences or metastases,** such as the staging procedures in persons with suspected recurrences or metastases during follow-up are not covered (but are part of the *Guidelines Platform*).
- **Breast cancer risk assessment.** The *European Breast Guidelines* do not cover questions specifically addressing breast cancer surveillance in women with hereditary breast cancer.

3.2.5 Key stakeholders and users

This question asked the call's participants about their opinion regarding the relevant key stakeholders and users whose views will be considered. Respondents could reply that they agreed or had concerns and were asked to provide comments on the following paragraph in *The Scope*:

The following are the relevant groups whose views will be sought:

1. Users of breast screening and diagnostic services (women attending breast cancer screening services or women who undergo diagnostic assessment because of symptoms / recall from screening), their families and carers, and the general public who need to be informed in a clear and constructive way on this topic. The *European Breast Guidelines* will be 'women-centred'. This implies that the perspective of users of breast cancer services (citizens and patients) will be taken into consideration during all stages of the development of the guidelines.

2. Healthcare providers directly responsible for providing breast cancer services, such as primary care physicians, radiologists, nurses, etc.

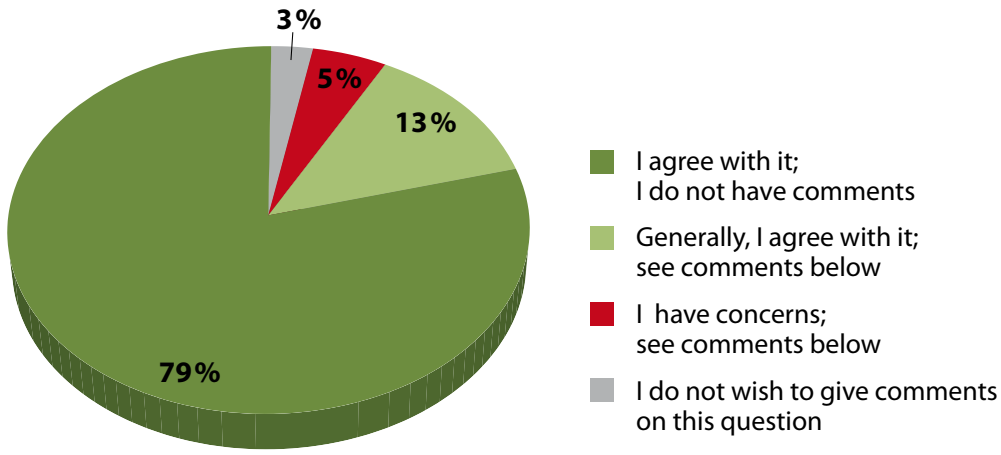
3. Managers of breast screening and diagnosis services.

4. Public health officers.

5. Policy-makers, such as those involved in the development of national screening programmes.

Seventy-nine percent of the respondents replied that they agreed with the proposed key stakeholders and users and did not have any comments, 13% agreed in general but also provided comments, 5% had concerns for which they provided comments, and 3% did not want to comment on this question.

Figure 16: Agreement with stakeholders and users proposed (n=82)



There were 11 comments from those who replied '**Generally I agree**' – four as an individual and seven on behalf of an organisation – Annex II, table 17. All of them suggested including additional groups of stakeholders and users. These additional groups were taken into account and *The Scope* was modified accordingly.

There were three comments from those who replied '**I have concerns**' – all on behalf of an organisation – Annex II, table 18. They suggested including additional groups of stakeholders and users, which were taken into account and *The Scope* was modified accordingly.

After considering all comments, the final text about stakeholders and users is the following:

The following are the relevant groups whose views are considered:

1. **Users of breast screening and diagnostic services** (persons attending breast cancer screening services or those who undergo diagnostic assessment because of symptoms/ recall from screening/referral), their families and carers, and the general public need to be informed in a clear and constructive way on this topic. The *European Breast Guidelines* are 'person-centred'. This implies that the perspective of users of breast cancer services is taken into consideration during all stages of the development of the *European Breast Guidelines*.

2. **Healthcare providers** directly responsible for providing breast cancer services, such as general practitioners/family doctors, gynaecologists, radiologists, histopathologists, surgeons, medical oncologists, radiation oncologists, reconstructive surgeons, palliative care physicians, breast care nurses, psychologists, genetic counsellors, etc.

3. **Managers** of breast screening and diagnosis services.

4. **Public health officers.**

5. **Policymakers.**

6. **Professional bodies/associations/academic societies.**

7. **Epidemiologists and other researchers.**

8. **Non-governmental organisations.**

9. **Patients organisations, breast cancer support groups, other voluntary organisations and charities.**

10. **Industry** linked to breast cancer screening and diagnosis.

11. **Families** of persons with breast cancer.

3.2.6 Existing documents

This question asked the call's participants about their opinion on the existing documents relevant to the *European Breast Guidelines*. Respondents could reply that they agreed with the proposed list or had concerns, and provide comments on the following paragraph in *The Scope*:

Existing guidelines on breast cancer screening and diagnosis which are likely to be currently used in practice:

- World Health Organization. WHO position paper on mammography screening Switzerland 2014 [cited 2015 Nov 5]; Available from: http://www.who.int/cancer/publications/mammography_screening/en/.

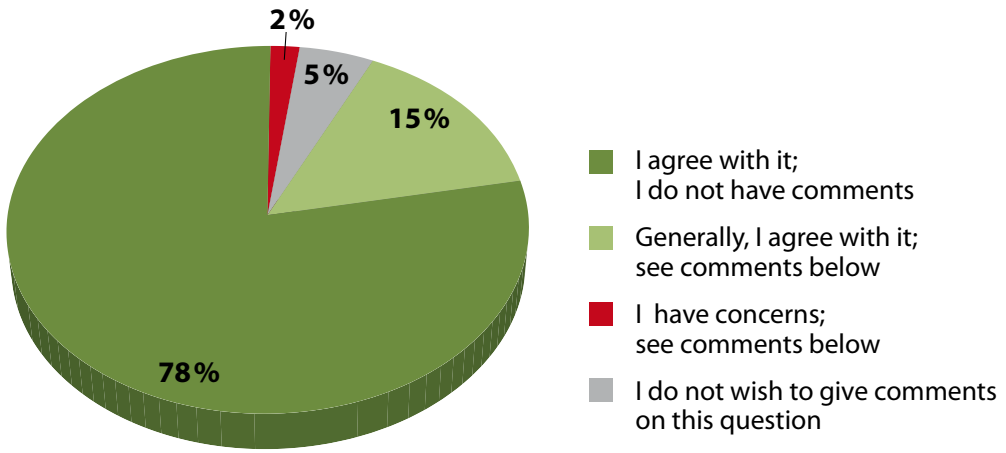
- European Commission. European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth ed. Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L, et al., editors. Luxembourg: Office for Official Publications of the European Communities; 2006. 416 p.

- European Commission. European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition, supplements. Fourth ed. Perry N, Broeders M, de Wolf C, Törnberg S,Holland R, von Karsa L, editors. Luxembourg: Office for Official Publications of the European Communities; 2013. 160 p.

This is not an exhaustive list. The JRC is running a systematic search to identify guidelines and recommendations on breast cancer screening and diagnosis published after 2005.

Seventy-eight percent of respondents replied that they agreed with the proposed list of documents and did not have any comments, 15% agreed in general but also provided comments, 2% had concerns for which they provided comments, and 5% did not want to comment on this question.

Figure 17: Agreement with proposed list of existing documents relevant to the *European Breast Guidelines* (n=82)



There were 12 comments from those who replied '**Generally I agree**' – six as an individual and six on behalf of an organisation – Annex II, table 19. Most of them suggested the inclusion of additional research papers and reports from screening programmes. A note was added in *The Scope* to clarify that the bibliography presented is a brief list of documents used to prepare *The Scope*. All the literature which will be used to make the recommendations will be included in the ECIBC's web hub. For the *European Breast Guidelines*, the literature review team has been

externalised to ensure an independent approach and minimise potential conflict of interest. The Iberoamerican Cochrane Centre, Barcelona, will carry out the literature reviews for each specific PICO and will consider systematic reviews (if already available) or will carry out de-novo ones.

Two comments related to the use of other international and national guidelines. Since the *Guidelines Platform* will include recommendations from evidence-based existing guidelines on all breast cancer care processes, no additional changes were made in *The Scope*.

Two comments were received from those who replied '**I have concerns**' – on behalf of an organisation – Annex II, table 20. They suggested including additional documents as well as taking different opinions into account. This will be considered during the literature review, as described above for similar comments from those who replied '**Generally I agree**'.

After considering all comments, the final bibliography in *The Scope* is the following:

1. Guidelines International Network (G-I-N), *Guideline Development Checklist – Glossary of Terms. Version* 16 December 2013. McMaster University, Hamilton, 2013. Available from: http://cebgrade.mcmaster.ca/checklistglossaryprintable.pdf

2. European Commission, *European Commission Initiative on Breast Cancer*: Concept document, Publications Office of the European Union, Luxembourg, 2015. Available from: https://ec.europa.eu/jrc/sites/jrcsh/files/ecibc_concept_document.pdf

3. National Institute for Health and Care Excellence (NICE). Glossary, 2013. Available from: http://www.nice.org.uk/website/glossary/glossary.jsp

4. Schunemann, H., Brożek, J., Guyatt, G., Oxman, A., editors, *GRADE handbook for grading quality of evidence and strength of recommendations*, UpdatedOctober 2013. The GRADE Working Group 2013. Available from: http://gdt.guidelinedevelopment.org/app/handbook/handbook.html

5. Perry, N., Broeders, M., de Wolf, C., Törnberg, S., Holland, R., von Karsa, L., et al., editors, European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth ed., Office for Official Publications of the European Communities, Luxembourg, 2006.

6. Moberg, J., Alonso-Coello, P., Oxman, A.D., *GRADE Evidence to Decision (EtD) Frameworks Guidance*, Version 1.1 [updated May 2015], The GRADE Working Group, 2015. Available from: http://ietd.epistemonikos.org/#/help/guidance

7. Von Karsa, L., Anttila, A., Ronco, G., Ponti, A., Arbyn, M., Segnan, N., et al., editors, *Cancer screening in the European Union. Report on the implementation of the Council Recommendation on cancer screening. First Report*, Office for Official Publications of the European Communities, Luxembourg, 2008, p. 14-15.

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

A footnote was added for clarification: 'This is a brief list of documents used to prepare *The Scope*. All literature used to make the recommendations that the *European Breast Guidelines* will provide will be included in the ECIBC's web hub.

3.3 General comments regarding *The Scope*

There were 32 general comments – 13 as an individual and 19 on behalf of an organisation – Annex II, table 21. They addressed the following main topics:

- Quality assurance – definition of targets/thresholds for indicators, performance indicators, evaluation of outcome, availability of data, use of ISO standards, training and licensing of specialists.

- Differences among countries – organisation of healthcare systems, cultural background, socio-economic status, legal background and ethical concepts.

- Appropriate language of the guidelines – it has to be clear and plain for patients/ individuals, but must also provide the necessary information for professionals.

- Process of formulating recommendations – evidence-based, using the available scientific literature, transparent procedures for selecting experts.

- Diagnosis and treatment – including different groups of patients (with metastatic disease, males, high-risk patients), evaluation of breast cancer specimen, molecular diagnosis, over-diagnosis and over-treatment.

Some of the suggestions were considered for modifications to *The Scope*, while others will be covered by different chapters of the *European Breast Guidelines* or by the *Guidelines Platform* and the *European QA scheme*, as described previously in this report.

3.4 Questions that should be addressed by the *European Breast Guidelines*

In this part of the survey the respondents were given the opportunity to suggest questions that should be addressed by the *European Breast Guidelines*. In total, 217 proposals were received – 124 (57%) from an individual and 93 (43%) on behalf of an organisation. The distribution of the number of questions by *European Breast Guidelines* chapter and profile of the respondents is presented in table 2.

Table 2: Number of questions proposed by the respondents that should be addressed by the *European Breast Guidelines

Chapter of the European *Breast Guidelines*	As an individual	On behalf of an organisation	Total
Screening	25	23	**48**
Diagnosis	20	14	**34**
Communication	19	13	**32**
Training	24	14	**38**
Interventions to reduce inequalities	19	11	**30**
Monitoring and evaluation of screening and diagnosis	17	18	**35**
Total	**124**	**93**	**217**

*Numbers in this table include all responses, but are not equal to those listed in the tables in Annex III as some some duplicates or comments, which were not relevant, were excluded.

All questions suggested by the respondents and considered relevant to be addressed by the *European Breast Guidelines* were modified accordingly to PICO model and added to a list prepared in advance by the GDG members. This combined list contained more than 200 questions (Annex IV) which were then prioritised by GDG members voting for the top questions for each chapter of the *European Breast Guidelines*. The questions that were not prioritised may be considered in future updates of the *European Breast Guidelines*. The list of both included and excluded questions along with the rationale for the decision is provided in Annex III.

4. Conclusions

Overall, the results of this public call for feedback indicate that respondents appreciated the openness of the procedure and, on JRC side, the usefulness of this kind of process. For these reasons, this same degree of transparency will be applied throughout the ECIBC.

In general, respondents represented the main categories of stakeholders (see Figure 4, Table 1) and expressed acceptance and positive consideration of the main features of the *European Breast Guidelines* as presented in *The Scope*. The percentage of respondents agreeing with the items proposed in *The Scope* varied between 85 % and 96 %, while the negative responses were usually below 10 %. These general figures suggest that no major changes to *The Scope* were required.

The JRC and GDG carefully evaluated the feedback, in particular the two points commented on most by the respondents:

- Interventions that will or will not be covered;
- Target populations – groups that will or will not be covered.

Regarding the first point, *The Scope* was amended to allow for the inclusion of examinations undertaken during the breast cancer diagnostic processes following referral and prior-to-treatment examinations, considering different methods for diagnosis (also including benign lesions) and pre-treatment staging, and all biopsy procedures and their pathological examination. Interventions that will not be covered were better detailed and it was clarified that, even though the *European Breast Guidelines* will not provide specific recommendations about them, they will be part of the *Guidelines Platform*.

With reference to the target populations, *The Scope* was modified to include males in the diagnostic part of the *European Breast Guidelines*. Furthermore, a note was added explaining that although specific recommendations will not be provided for patients with loco-regional breast cancer recurrence or metastatic breast cancer, guidelines for diagnostic work-up and treatment regimens for these cases will be collected by the *Guidelines Platform*.

The large number of suggestions received for questions that should be addressed by the *European Breast Guidelines* demonstrated the interest in this activity, both from individuals and organisations.

Although seven countries (Estonia, Finland, Hungary, Iceland, Luxembourg, Montenegro and Malta) of the 34 invited did not contribute to the call for feedback, it can be considered that the responses and comments received represent the main categories of stakeholders and users of these guidelines, and thus the *European Breast Guidelines* will take them into account.

The new version of *The Scope*, published together with this report, integrates a significant number of the inputs received; where feedback is not integrated, the reasons are clearly expressed in this report.

The call for feedback has led to an enriched document, thanks to the diversity and meaningfulness of contributions. Thus, it can be considered a success and hopefully will contribute to enhancing the future implementation of the *European Breast Guidelines* across Europe.

References

1) Guyatt, G.H., Oxman, A.D., Vist, G.E., Kunz, R., Falck-Ytter, Y., Alonso-Coello, P., et al., GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ (2008); 336(7650):924-6.

2) Neamtiu, L., Deandrea, S., Lerda, D, Lopez-Alcalde, J., Uluturk, A., European Commission initiative on breast cancer – ECIBC. Organisation of project guiding and support meetings 2011-2013. Luxembourg: European Commission, Office for Official Publications of the European Communities, 2014.

3) Neamtiu, L., Bramesfeld, A., Deandrea, S., Lerda, D., Lopez-Alcalde, J., Pylkkanen, L., Saz-Parkinson, Z., Uluturk, A., European Commission initiative on breast cancer – ECIBC. Organisation of project guiding and support meetings – 2014. Luxembourg: European Commission, Office for Official Publications of the European Communities, 2015.

4) Neamtiu, L., Bramesfeld, A., Deandrea, S., Lerda, D., Lopez-Alcalde, J., Pylkkanen, L., Saz-Parkinson, Z., Uluturk, A., European Commission initiative on breast cancer – ECIBC. Organisation of project guiding and support meetings – 2015. Luxembourg: European Commission, Office for Official Publications of the European Communities, 2016.

List of abbreviations

CESM: Contrast Enchanced Spectral Mammography

DG SANTE: Directorate-General for Health and Food Safety

EC: European Commission

ECIBC: European Commission Initiative on Breast Cancer

EU: European Union

EUPHA: European Public Health Association

EUROPEAN QA SCHEME: voluntary European quality assurance scheme for breast cancer services, covering all care processes, based on the EU legislative framework on accreditation and underpinned by the evidence provided by the guidelines

GDG: Guidelines Development Group

GRADE: Grading of Recommendations Assessment, Development and Evaluation

JRC: Joint Research Centre

MRI: Magnetic Resonance Imaging

PICO: Population; Intervention; Comparator; Outcome

WHO: World Health Organization

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Annex 1

Call for feedback on the scope of the European guidelines for breast cancer screening and diagnosis

Call for feedback on the scope of the European guidelines for breast cancer screening and diagnosis

Fields marked with * are mandatory.

From 18 December 2015 to 17 January 2016, the European Commission Initiative on Breast Cancer (ECIBC) is asking stakeholders for comments on the scope of the European guidelines for breast cancer screening and diagnosis.

The Guidelines Development Group (GDG) is a working group supporting the European Commission in developing the *European guidelines for breast cancer screening and diagnosis* (in short, the *European Breast Guidelines*). More information is available in the Concept document of the ECIBC and in the Call for feedback.

The GDG has drafted the general scope of the *European Breast Guidelines*. **This draft document tries to define the topics that the guideline will and will not cover.**

The ECIBC coordination team has launched a call for feedback on this draft document.

Interested parties are invited to submit written comments by **17 January 2016**.

Comments will not be considered if they:

- are submitted after the deadline of the feedback call;
- are not related to the contents of the document;
- contain complaints against institutions, personal accusations, irrelevant or offensive statements or material;
- are related to policy aspects outside the scope of ECIBC's activity.

In addition, **we invite you to provide questions you think would need to be addressed** by the *European guidelines for breast cancer screening and diagnosis*.

ECIBC coordination team shall process personal data pursuant to Regulation 45/2001/EC on the protection of individuals with regards to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

Published:

18 December 2015

Privacy statement

Privacy statement

* I confirm that I read and agree with the Privacy statement.

- ○ Yes
- ○ No

Respondent's information

* Your full name

250 character(s) maximum

* Your e-mail address for correspondence only (the e-mail address will not be disclosed under any circumstances, please refer to the privacy statement)

* I am replying:

- As an individual
- On behalf of an organisation (including any association, authority, company or body)

* Please select the category that you identify with best.

- Consumer or patient
- Family member or carer of a patient
- Professional working in areas related to breast cancer screening or diagnosis, such as radiologists, pathologists, epidemiologists, clinicians, policymakers, researchers, guideline developers
- Other

* Name of the organisation

250 character(s) maximum

* Please select the category that you identify with best.

- 1. Patient advocacy organisation
- 2. Healthcare organisation
- 3. Professional society or organisation, including guidelines development organisations
- 4. ECIBC National contact
- 5. Academic / Research institution
- 6. Trade union
- 7. Industry
- 8. Other

* Your country

- EU country
- Non EU country

* EU country

- Austria
- Belgium
- Bulgaria
- Croatia
- Republic of Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- UK

Non EU country (please specify)

40 character(s) maximum

* Do you agree to the publication of your contribution?

- Yes (I consent to the publication of my contribution together with my name, and I declare that none is subject to copyright restrictions that would prevent publication)
- Yes (I consent to the publication of my contribution in an anonymous manner, and I declare that none is subject to copyright restrictions that would prevent publication)
- No (the contribution cannot be published, but the contribution may be used internally within the Commission)

Part 1. General scope of the *European guidelines for breast cancer screening and diagnosis*

DRAFT General scope of the guidelines

All references indicated with numbers in brackets in the different sections can be found in the bibliography section of the pdf version of the DRAFT General scope of the guidelines.

Purpose of the guidelines

* **Objectives**

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

(1) to provide users of breast cancer screening and diagnosis services (citizens and patients) and healthcare providers with clear, objective and independent guidance on breast cancer screening and diagnosis in order to promote informed decisions; and

(2) to guide healthcare managers and policy-makers when planning, commissioning and organising services for breast cancer screening and diagnosis. This includes the development of evidence-based recommendations supporting quality assurance of breast cancer screening and diagnosis.

According to these objectives, it can be anticipated that some questions of the *European Breast Guidelines* will take more than one perspective, *e.g.*, an individual and a population perspective (see section '3b. Perspective of the *European Breast Guidelines*').

Is this section clear?

- ○ Yes
- ○ No

* Please include your comments.

250 character(s) maximum

*** Expected outcomes influenced by the guidelines**

An 'outcome' is the impact that a test, treatment, policy, program or other intervention has on a person, group or population (1,3). The importance of outcomes is likely to vary within and across cultures or when considered from the perspectives of the citizens, patients, clinicians or policy-makers. Cultural diversity will often influence the relative importance of outcomes, particularly when developing recommendations for an international audience (4).
It is anticipated that the *European Breast Guidelines* will impact on outcomes important for the citizens and the health systems, such as:
• Mortality due to breast cancer
• Quality of life
• Patient safety
• Equity in healthcare
• Unnecessary variability in clinical practice

- ○ I agree with it, I do not have comments
- ○ Generally, I agree with it; see comments below
- ○ I have concerns; see comments below
- ○ I do not wish to answer this question

Please include your comments.

250 character(s) maximum

Target population

*** Population addressed by these guidelines**
Groups that will be covered
• Women eligible for breast cancer screening.
• Women attending breast diagnostic services because of symptoms or because of a recall on the basis of their screening examination.

- ○ I agree with it, I do not have comments
- ○ Generally, I agree with it; see comments below
- ○ I have concerns; see comments below
- ○ I do not wish to answer this question

* Please include your comments.

250 character(s) maximum

* **Groups that will not be covered**

The following populations will not be specifically addressed by the guidelines:

- Males
- Women with loco-regional recurrences
- Women with metastatic breast cancer

- I agree with it, I do not have comments
- Generally, I agree with it; see comments below
- I have concerns; see comments below
- I do not wish to give comments on this question

Please include your comments.

250 character(s) maximum

* **Perspective**

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

The first purpose of the *European Breast Guidelines*, in particular from its European legal background, should be to give policy makers and healthcare administrators evidence-based recommendations on the implementation of cancer screening programmes and on the organisation of diagnostic procedures for breast cancer.

However, one main conclusion of the two workshops held at JRC-Ispra in 2013 was that the *European Breast Guidelines* should be 'women-centred'. This implies that the perspective of users of breast cancer services (citizens and patients) should be taken into consideration during all stages of the guidelines development.

On the other hand, for questions related to diagnosis, especially when it happens outside of a screening programme, the patients' and clinicians' perspective will be prioritised. This means that the focus will be on the views of the individual user of the healthcare service (citizens and patients) and the healthcare professional that provides that service.

When developing the recommendations of the *European Breast Guidelines*, a balance between different perspectives (*e.g.*, women vs. public health vs. policy support) shall be sought. This will be taken into account when choosing the outcomes for each question (6).

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

Is this section clear?

- ○ Yes
- ○ No

* Please include your comments.

250 character(s) maximum

Healthcare setting

* **Healthcare setting**

The *European Breast Guidelines* will cover all healthcare settings where services for breast cancer screening and diagnosis are delivered.

- ○ I agree with it, I do not have comments
- ○ Generally, I agree with it; see comments below
- ○ I have concerns; see comments below
- ○ I do not wish to give comments on this question

* Please include your comments.

Types of interventions

* **Definitions**

The following classification and definitions are proposed for screening and screening programmes (7, 8).

SCREENING: the systematic application of a screening test in a presumably asymptomatic population. In cancer screening, it aims to identify individuals with an abnormality suggestive of a specific cancer. These individuals require further investigation.
NON-PROGRAMME SCREENING (commonly referred also as opportunistic screening): examinations for early detection of cancer performed in a diagnostic or clinical setting, independent from the public screening policy (if existing).
SCREENING PROGRAMME: examinations financed by public sources performed in the context of a public screening policy documented in a law, or an official regulation, decision, directive or recommendation, and where the policy defines, at minimum: the screening test, the examination intervals, group of persons eligible to be screened.
ORGANISED SCREENING: screening programme where other procedures (e.g. standard operating procedures) are specified and where a team at national or regional level is responsible for implementing the policy, *i.e.*, for coordinating the delivery of screening services, quality requirements, and reporting on performances and results.
POPULATION-BASED SCREENING: screening programme where in each round of the screening the persons in the eligible target area served by the programme are individually identified and personally invited.

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

Is this section clear?

- ○ I agree with it, I do not have comments
- ○ Generally, I agree with it; see comments below
- ○ I have concerns; see comments below
- ○ I do not wish to give comments on this question

* Please include your comments.

250 character(s) maximum

* **Interventions that will be covered**

The *European Breast Guidelines* will cover screening and diagnosis of breast cancer. In particular, the desirable and undesirable effects of the following interventions will be assessed:

• **Breast cancer screening policies and programmes:**

- Different modalities of organised population-based screening programmes according to women's age, screening intervals and tests

- Opportunistic screening

• **Breast cancer diagnostic steps and preoperative staging procedures** (that is, the examinations undertaken after referral and before surgery):

- Criteria for referral of symptomatic patients

- The diagnostic procedures for benign lesions

- Evaluation of different methods for diagnosis and preoperative staging (and, more in general, breast imaging techniques)

- All biopsy procedures and their pathological examination (including fine needle aspiration, core biopsy and surgical biopsy). Surgical treatment as such will not be covered. However, diagnostic procedures during the surgery, such as lymph node excision by sentinel node biopsy and pathological evaluation of the lymph node evacuation specimens will be covered.

• **Breast cancer surveillance for high-risk women**[1].

• **Interventions for primary prevention of breast cancer** provided as co-interventions nested in organised screening programmes.

• **Interventions to reduce harms** due to breast cancer screening or diagnosis, such as overdiagnosis or discomfort with screening procedures.

• **Interventions to improve communication in breast cancer screening and diagnosis**

• **Interventions to improve organisational aspects** of breast cancer screening and diagnosis (such as multidisciplinary team meetings).

The *European Breast Guidelines* will cover the following types of recommendations related to breast cancer screening and diagnosis:

• Clinical recommendations about interventions and diagnostic tests

• Health systems and public health recommendations (such as recommendations about population-based screening programmes or recommendations focusing on quality assurance aspects).

- ○ I agree with it, I do not have comments
- ○ Generally, I agree with it; see comments below
- ○ I have concerns; see comments below
- ○ I do not wish to give comments on this question

250 character(s) maximum

*** Interventions that will not be covered**

• **Aspects out of the scope of breast cancer screening and diagnosis.** Breast cancer treatment, rehabilitation, follow-up or palliative care will not be covered. For example, surgical management of lesions detected with mammography will not be covered.
• **Diagnostic procedures in breast cancer patients with suspected recurrences or metastases.** For example: staging procedures in women with suspected recurrences or metastases during follow-up will be excluded

- ○ I agree with it, I do not have comments
- ○ Generally, I agree with it; see comments below
- ○ I have concerns; see comments below
- ○ I do not wish to give comments on this question

Please include your comments.

250 character(s) maximum

*** Key stakeholders and users**

The following are the relevant groups whose views will be sought:

1. Users of breast screening and diagnostic services (women attending breast cancer screening services or women who undergo diagnostic assessment because of symptoms / recall from screening), their families and carers, and the general public who need to be informed in a clear and constructive way on this topic. The *European Breast Guidelines* will be 'women-centred'. This implies that the perspective of users of breast cancer services (citizens and patients) will be taken into consideration during all stages of the development of the guidelines.
2. Healthcare providers directly responsible for providing breast cancer services, such as primary care physicians, radiologists, nurses, etc.
3. Managers of breast screening and diagnosis services.

4. Public health officers.
5. Policy-makers, such as those involved in the development of national screening programmes.

- I agree with it, I do not have comments
- Generally, I agree with it; see comments below
- I have concerns; see comments below
- I do not wish to give comments on this question

Please include your comments.

250 character(s) maximum

*** Existing documents**

Existing guidelines on breast cancer screening and diagnosis which are likely to be currently used in practice:

• World Health Organization. WHO position paper on mammography screening Switzerland 2014 [cited 2015 Nov 5]; Available from: http://www.who.int/cancer/publications/mammography_screening/en/.

• European Commission. European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth ed. Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L, et al., editors. Luxembourg: Office for Official Publications of the European Communities; 2006. 416 p.

•European Commission. European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition, supplements. Fourth ed. Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L, editors. Luxembourg: Office for Official Publications of the European Communities; 2013. 160 p.

This is not an exhaustive list. The JRC is running a systematic search to identify guidelines and recommendations on breast cancer screening and diagnosis published after 2005.

- I agree with it, I do not have comments
- Generally, I agree with it; see comments below
- I have concerns; see comments below
- I do not wish to give comments on this question

Please include your comments.

250 character(s) maximum

General comments regarding the document

Please insert here comments related to the content of the document which were not addressed in the above questions.

500 character(s) maximum

Part 2. Questions that should be addressed by the *European Breast Guidelines*

Chapter 1: Screening

Please add questions

1000 character(s) maximum

Chapter 2: Diagnosis

Please add questions

1000 character(s) maximum

Chapter 3: Communication

Please add questions

1000 character(s) maximum

Chapter 4: Training

Please add questions

1000 character(s) maximum

Chapter 5: Interventions to reduce inequalities

Please add questions

1000 character(s) maximum

Chapter 6: Monitoring and evaluation of screening and diagnosis

Please add questions

1000 character(s) maximum

Thank you for your feedback!

Annex 3

List of comments on different parts of *The Scope*

Table 1. Comments on **Clarity of objectives of the** *European Breast Guidelines*

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	Objective 1 is not clear to me. What is meant with 'guidance on breast cancer screening and diagnosis' for patients and healthcare providers? This can only mean whether to go to screening or not, as there is usually only one system.	Yes	*The Scope* was modified to clarify that the *European Breast Guidelines* will provide guidance on breast cancer screening and diagnostic services to enable healthcare users and healthcare providers to make informed decisions.
2	On behalf of an organisation	To promote informed decisions through continuous and regular education.	Yes	*The Scope* was modified to clarify that the *European Breast Guidelines* will provide guidance on breast cancer screening and diagnostic services to enable (instead of promote) healthcare users and healthcare providers to make informed decisions. The Training chapter of the *European Breast Guidelines* will address training issues.
3	On behalf of an organisation	With users and health care providers in the same paragraph, it is not clear to me to what kind of decision on health are you talking about. I suggest to separate users (decision to participate) and health care providers (how to organize).	Yes	*The Scope* was modified to clarify that the *European Breast Guidelines* will provide guidance on breast cancer screening and diagnostic services to enable healthcare users and healthcare providers to make informed decisions (regarding breast cancer screening and diagnosis). Several PICO questions, particularly in the Communication chapter, will address as an outcome informed decision making.
4	On behalf of an organisation	The objective should include guidance for healthcare professionals and managers on how to ensure women participate in the screening, as this is not always the case. See: http://bit.ly/1SkdvXW	No	No change in *The Scope*. The Communication chapter of the *European Breast Guidelines* will address the issue regarding the relevant information that has to be provided to women.
5	On behalf of an organisation	Evidence based recommendations and information from broad scale EU screening programs.	No	No change in *The Scope*. The *European Breast Guidelines* will include evidence based recommendations. However, when needed, Reference documents[1] will be provided to support ECIBC[2] implementation.
6	As an individual	In: 'evidence-based recommendations will be used', but for some of the diagnostic procedures no evidence-based recommendations are available, only a 'common practice' or an 'experienced panel recommendations'. This should be included.		

1 Reference documents - Reference documents will be collected in support to implementation of evidence-based recommendations included in the existing guidelines for those aspects, e.g. related to diagnosis, where best practice guidance would be useful.

2 ECIBC – European Commission Initiative on Breast Cancer

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	**Reasoning**
7	On behalf of an organisation	The main objective of population-based breast cancer screening is to reduce cancer related mortality. Therefore we suggest complementing the 2nd sentence of (2) by 'particularly regarding outcomes' quality besides structural and procedural quality'.	Yes	*The Scope* was modified to clarify that there is 'an emphasis on improvement of outcomes and quality of the processes'. Quality of structure and procedures will be addressed by the *European QA scheme*[3].
8	On behalf of an organisation	To centralize the user perspective does not mean the objective should be to address the women. Therefore the objective should not be to 'provide women with…'. It should be the objective to guide policy makers, healthcare providers etc. and as a consequence they should provide women with the best screening (i.e. ideally a fully quality assured screening programme) they can deliver (within their budget and in accordance with social and cultural background and values).	Yes	*The Scope* was modified to clarify that 'both healthcare users and healthcare providers' will be provided with guidance to 'enable them to make informed decisions'. It was added to the second objective that there is 'an emphasis on improvement of outcomes and quality of the processes'.
9	As an individual	The guidelines should take a population perspective. Screening programs are public health services.	No	No change in *The Scope*. It was already included in the Objectives section of the draft scope that 'some recommendations of the *European Breast Guidelines* include more than one perspective, e.g., an individual and a population perspective'. In addition, in the Perspective section it was specified that 'a balance between these different perspectives is being sought'.

3 European QA scheme - voluntary European quality assurance scheme for breast cancer services, covering all care processes, based on the EU legislative framework on accreditation and underpinned by the evidence provided by the guidelines.

Table 2. Comments on **Expected outcomes:** by respondents who replied with 'Generally, I agree'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	As an individual	There is a very clear potential for overdiagnosis and overtreatment. This needs to be addressed as an outcome.	No	No change in *The Scope*. Not explicitly stated in *The Scope*, but will be covered when selecting outcomes for the PICO[4] questions.
2	As an individual	I am concerned that specific harms such as overdiagnosis are addressed and that information will be provided in formats such as Number needed to treat/screen and number needed to harm.		
3	On behalf of an organisation	I acknowledge the purpose of the EU to eliminate inequalities between healthcare systems within the EU, but this should not mean that a well-established system lowers its standards to enable equality. Some countries will not have necessary resources.	No	No change in *The Scope*. The *European Breast Guidelines* will not propose lowering of standards for any country. Some countries may not have the appropriate resources to implement the evidence-based recommendations, but this issue has to be addressed in a proper way at a country level.
4	On behalf of an organisation	Add additional outcomes: survivorship, participation rates, cost effectiveness, patient satisfaction, downstaging of the disease, numbers needed to screen to detect one cancer, overdiagnosis, radiation-dose exposure to patients.	No	No change in *The Scope*. Not all of the suggested outcomes are listed in *The Scope*, but these and other relevant ones will be taken into account when selecting outcomes for the PICO questions. In addition, cost effectiveness is part of the Evidence to Decision (EtD) frameworks[5] that will be used to develop the recommendations.
5	On behalf of an organisation	Suggestion to add additional outcomes expected: cost-effectiveness optimization, data governance, survivorship, participation rates, patient satisfaction, disease downstaging, overdiagnosis; radiation-dose exposure to patients.		
6	On behalf of an organisation	Ensure that clear indications are included in the guidelines so that all those who need screening participate in screening programmes: http://bit.ly/1SkdvXW	No	No change in *The Scope*. Recommendations about effective communication will be included in the *European Breast Guidelines*. In addition, the recommendations are formulated in lay-person language in order to be understandable by all.

4 PICO format stands for: **P**opulation under study (for example women of certain age); Intervention (for example a medical examination); **C**omparator (other main options such as an alternative medical examination); and **O**utcomes (results).

5 Evidence to Decision (EtD) frameworks – an explicit and transparent system for decision making, provide a systematic and transparent approach for going from the evidence to the healthcare decision. EtD frameworks inform users about the judgments that were made and the evidence supporting those judgments by making the basis for decisions transparent to target audiences. EtD frameworks include also detailed justification (undesirable effects, values, certainty of the evidence), subgroup considerations, implementation considerations, monitoring and evaluation considerations and research priorities.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
7	On behalf of an organisation	A minor point: Scope would use Irrational or Non-rational instead of Unnecessary. Or, 'Variability….' not supported by evidence or best practice. Or delete it, as it belongs in fact to the previous subject, 'Equity in healthcare'.	No	No change in *The Scope*. It was agreed to keep 'unnecessary variability', because it is slightly different than 'equity in healthcare'.
8	On behalf of an organisation	The objectives are very ambitious. The objectives focus on different target groups that have different needs in terms of content, detailing and language use. It will be difficult to provide the different target groups with adequate information simultaneously, and taking the differences between countries into account. For this reason, I also have concerns to realizing the outcomes. Besides the guideline aims to target different cultural backgrounds and has to deal with different health systems.	No	No change in *The Scope*. The *European Breast Guidelines* will include evidence-based recommendations, also considering different population subgroups, such as socially disadvantaged, illiterate, etc. In addition, the recommendations will be translated into lay-person language, in order to be understandable by all. Because of the differences in healthcare systems, it might be difficult for some countries to implement the recommendations, but this issue has to be addressed in a proper way at a country level.
9	As an individual	The bullet list is not meant to be exhaustive but I do think it would be good to emphasise in this list that the guidelines also aim to support more (evidence-) informed decision making between patients and their health professionals.	No	No change in *The Scope*. These issues will be covered when selecting outcomes for the PICO questions (in particular for the Communication chapter).
10	As an individual	I agree as long as not all outcome measurements have to be impacted and as long as the overall balance remains positive.	No	No change in *The Scope*. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
11	On behalf of an organisation	I suggest to add: Quality of breast health care services	No	No change in *The Scope*. Quality of breast healthcare services will be covered by the *European QA scheme*.
12	As an individual	Consider that the same information presented in terms of mortality or of survival has a strongly different impact on perception (see D. Kahneman, 'prospect theory'). I propose to write 'mortality and survival associated with breast cancer'.	No	No change in *The Scope*. Traditionally, for an intervention that is done in healthy individuals, population mortality is the more appropriate metric, rather than survival, so it will be kept throughout the whole document.

Table 3. Comments on **Expected outcomes:** by respondents who replied with 'I have concerns'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	The expected outcomes influenced by the guidelines are listed without stating the desirable effect. We suggest to complete the list as follows: 1. Reduction of mortality... 2.-4. Improvement of ... 5. Minimisation of unnecessary ...	No	No change in *The Scope*. This will be covered when selecting outcomes for the PICO questions. Desirable and undesirable effects are examined using EtD frameworks for each PICO question. In addition, the Monitoring and evaluation chapter of the *European Breast Guidelines* will contain recommended thresholds of relevant indicators.
2	On behalf of an organisation	Define what are primary and secondary outcomes as well as proxies for outcomes. E.g. mortality should be a primary outcome. 'Unnecessary variability…' is a secondary outcome and is a proxy for … (what?) If 'Unnecessary variability' is one of the outcomes, there should probably be many, many more outcomes than that.		
3	On behalf of an organisation	Outcomes in terms of harm have to be included: Overdiagnosis, overtreatment and false positive and false negative rates.		
4	On behalf of an organisation	Impact of interventions exclusively in screening is likely to be minimal in EU (most countries already have screening). To really have an impact, especially in mortality, this project should include treatment & organization of breast care.	Yes	*The Scope* was modified – a footnote was added to the Target population section of *The Scope* to clarify that 'the *Guidelines Platform*[6], as collection of existing evidence-based guidelines, can include recommendations on treatment for all breast cancer patients'. Organisation of breast healthcare services will be covered by the *European QA scheme*.

6 For recommendations on processes of care other than screening and diagnosis (treatment, rehabilitation, follow-up and survivorship care, palliative care, and all relevant horizontal aspects), an ECIBC platform for breast cancer guidelines (the *Guidelines Platform*) is envisaged to host existing evidence-based, high-quality guidelines.

Table 4. Comments on **Target population, groups that will be covered:** by respondents who replied with 'Generally, I agree'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	As an individual	Is there an agreement on which women are eligible for breast cancer screening? Particular age groups? Across Europe, there are major differences in lower and upper age limits for screening.	No	No change in *The Scope*. This will be covered when selecting the PICO questions to be addressed.
2	As an individual	Women's screening age – starts at 40? 45? 50? Ends at 70? 75?		
3	As an individual	In my country screening population roughly covers 50% of all diagnosed breast cancers. More than 30% of women are older the age of 69 and quite often we hear that the age limit should be extended to at least the age of 75.		
4	On behalf of an organisation	It is important to explain the age for the target group to all women.		
5	As an individual	It seems important for the European Guidelines to offer clear indications on the controversial theme of the mammographic screening and its optimal timing for women aged from 40 to 49 years and for the ones with 70 or more years.		
6	As an individual	It must be made clear how women on High risk (BRCA1/2 and other) will get access to screening. Usually it starts earlier and is done with mammography and MRI.	No	No change in *The Scope*. Some PICO questions may be related to varying the screening regimen depending on certain risk factors.
7	On behalf of an organisation	Groups to be covered: Since the guideline will not encompass women with hereditary breast cancer is it possible to insert if even a very short recommendation related to this issue necessary for better implementation of the screening program?		
8	On behalf of an organisation	Suggestion to add women with positive family history and also women under active surveillance who are eligible to come back into the screening cycle.		
9	On behalf of an organisation	Also high-risk groups who are eligible for surveillance should be pointed out as a group that will be covered.		

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
10	On behalf of an organisation	Surveillance for high-risk women (not hereditary) is included and here it is not clear where they fit: is this screening?	Yes	Relevant modifications in *The Scope* were made in order to clarify this issue: 1) surveillance for high-risk women is included in the section 'Interventions not covered'; 2) the groups covered include 'persons eligible for breast cancer screening and persons accessing breast diagnostic services because of symptoms, referral (e.g. following a risk assessment) or a recall on the basis of their screening examination'.
11	As an individual	What about opportunistic screening in women not eligible for breast cancer screening (I assume within a screening programme)? It is not necessarily done based on symptoms or a recall from a previous screening as far as I understand it.	No	No change in *The Scope*. Opportunistic screening has been already included in the draft scope sent for feedback, in the section 'Interventions covered'. In addition there is a PICO question proposed about comparison of organised vs. non organised screening.
12	As an individual	Eligibility for breast cancer screening varies according to different policies and guidelines. The target population should be better specified or a note added to refer to subsequent definitions.	No	No change in *The Scope*. The target population will be clarified for each specific PICO (P=Population).
13	As an individual	I am not sure whether women attending diagnostic services because of symptoms/ signs should be in the target population.	No	No change in *The Scope*. Persons with symptoms are not in the screening process; however, they will be covered by the Diagnosis chapter questions.
14	As an individual	I suggest that a section ('Women followed-up for breast cancer') be devoted to the option of offering (or continue screening) to women with a prior diagnosis of breast cancer, either screen-detected and/or detected outside the screening setting.	Yes	*The Scope* was modified (Interventions not covered) to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*.
15	As an individual	I am not an expert in breast cancer management (my expertise is in research methods) so I cannot comment on the focus. I will however mention that excluding males does somewhat go against the aim of improving equity. Men do get breast cancer.	Yes	*The Scope* was modified – 'women' has been substituted with 'persons', because the Screening chapter will not cover men; however, the diagnostic procedures will cover any person with breast cancer (women and men).

Table 5. Comments on **Target population, groups that will be covered:** by respondents who replied with 'I have concerns'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	As an individual	Please do not forget that there are also male breast cancer patients in the world. I am a male breast cancer survivor since 1999.	Yes	*The Scope* was modified – 'women' has been substituted with 'persons', because the Screening chapter will not cover men; however, the diagnostic procedures will cover any person with breast cancer (women and men).
2	On behalf of an organisation	Missing population with high (!!!) risk of breast cancer due to BRCA mutation, PTEN, CDH1, CHEK2, Lynch or women Hodgkin/chest radiation	Yes	*The Scope* was modified to clarify that breast cancer risk assessment is among the interventions not covered by the *European Breast Guidelines*, but the groups covered include 'persons accessing breast diagnostic services because of symptoms, referral (e.g. following a risk assessment) or a recall on the basis of their screening examination'. Some PICO questions may be related to varying the screening regimen depending on certain risk factors.
3	As an individual	Women eligible for breast cancer screening. Screening participants with breast cancer, regardless when they were diagnosed: during the screening process or following a negative screening episode and prior to the next screening examination.	Yes	*The Scope* was modified (Interventions not covered) to clarify that: -Diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*. - The groups covered include 'persons accessing breast diagnostic services because of symptoms, referral (e.g. following a risk assessment) or a recall on the basis of their screening examination'.

Table 6. Comments on **Target population, groups that will not be covered:** by respondents who replied with 'Generally, I agree'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	As an individual	Males should be included in the diagnostic phase	Yes	*The Scope* was modified – 'women' has been substituted with 'persons', because the Screening chapter will not cover men; however, the diagnostic procedures will cover any person with breast cancer (women and men).
2	As an individual	Although breast cancer in men is rare, I feel there should be some guidelines for male breast cancer as well.		
3	As an individual	I am not an expert in breast cancer management (my expertise is in research methods) so I cannot comment on the focus. I will however mention that excluding males does somewhat go against the aim of improving equity. Men do get breast cancer.		
4	On behalf of an organisation	As male breast cancer is such rare disease frequently there is uncertainty about diagnostic procedures and male patients tend to have delayed diagnoses. I wonder if the ECIBC wants to reconsider the exclusion of male citizen from the project.		
5	As an individual	If the guidelines involve both breast cancer screening and diagnosis, maybe also diagnosis in males could be considered although breast cancer in males is quite a peculiar and rare condition.		
6	On behalf of an organisation	If the program should be complex all patients afflicted by BC should be covered.	Yes	*The Scope* was modified (Interventions not covered) to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*. In addition, 'women' has been substituted with 'persons', because the Screening chapter will not cover men; however, the diagnostic procedures will cover any person with breast cancer (women and men).
7	On behalf of an organisation	You will cover metastatic disease in sentinel node. Modify first sentence: Women with loco-regional and/or distant recurrences. Delete second sentence.		
8	As an individual	Women with logo-regional recurrences can be included in the guidelines, because they present diagnostic problem and it is a local disease, requiring special approach.		

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
9	As an individual	The diagnosis of loco-regional recurrences needs also to be included certainly when first cancer was detected more than ten years earlier: whether it is a recurrence or not is not known by the first symptoms.		
10	As an individual	There could be links included what guidelines or recommendations should be followed in EU in case of loco-regional or metastatic breast cancer (NCCN guidelines, Australian guidelines etc).		
11	As an individual	How can we manage with women with second primary tumour (contralateral breast)?		
12	As an individual	I would prefer including a short section focusing on the differences in diagnosing and treating patients belonging to these three categories [males, loco-regional recurrences, metastatic breast cancer] as compared with those having screen-detected cancers.		
13	As an individual	I suppose that women with early stage breast cancer after 5 years of follow-up may follow routine screening thereafter.	No	No change in *The Scope*. Follow-up procedures and survivorship care will be covered by the *Guidelines Platform*.
14	As an individual	It is not clear if the issue of follow up of women with breast cancer (BC) is included in the guidelines. In my opinion that is an argument of crucial importance either from women's or health care system perspective.		
15	On behalf of an organisation	It might be unclear where diagnosis ends and this should probably be defined early on. Not every reader will be able to understand that there is a distinction between diagnosis and surveillance after diagnosis and treatment. Especially because surveillance of high-risk groups is within the focus.		

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
16	On behalf of an organisation	The guideline must exclude the 'high risk patient' group also, because after risk assessment the patient may have to get involved in a high risk screening programme.	Yes	*The Scope* was modified to clarify that breast cancer risk assessment is among the interventions not covered by the *European Breast Guidelines*, but the groups covered include 'persons accessing breast diagnostic services because of symptoms, referral (e.g. following a risk assessment) or a recall on the basis of their screening examination'. Some PICO questions may be related to varying the screening regimen depending on certain risk factors.
17	On behalf of an organisation	Add: hereditary breast cancer		

Table 7. Comments on **Target population, groups that will not be covered:** by respondents who replied with 'I have concerns'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	Men also get breast cancer, I am not sure why they would not be included? There are many patients with metastatic breast cancer who need support, and appropriate facilities and services for their care; an area that is currently lacking.	Yes	*The Scope* was modified – 'women' has been substituted with 'persons', because the Screening chapter will not cover men; however, the diagnostic procedures will cover any person with breast cancer (women and men).
2	As an individual	Why exclude male patients? There is no screening for men, but the diagnosis and treatment of male patients is almost the same as female patients. In Belgium the prognosis for male patients is worse than for women! Why discriminate?		
3	On behalf of an organisation	Males, while at a much lower risk of breast cancer, are not completely immune, and especially those with a strong family history of breast cancer should be covered by such programmes.		
4	On behalf of an organisation	Although screening does not apply to men perhaps a rationale could be given as to why men are excluded from the diagnostic piece.		
5	On behalf of an organisation	*The Scope* of the project is too limited to have a real impact. Unfortunately and as it is so common, metastatic patients are forgotten.	Yes	*The Scope* was modified (Interventions not covered) to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*.
6	On behalf of an organisation	Women with loco-regional recurrences should be added as they are often already back in the screening cycle after active surveillance. Guidelines should also be issued to specifically address the management of metastatic cancer.		
7	On behalf of an organisation	Risk persons should be covered (BRCA).	Yes	*The Scope* was modified to clarify that breast cancer risk assessment is among the interventions not covered by the *European Breast Guidelines*, but the groups covered include 'persons accessing breast diagnostic services because of symptoms, referral (e.g. following a risk assessment) or a recall on the basis of their screening examination'. Some PICO questions may be related to varying the screening regimen depending on certain risk factors.

Table 8. Comments on clarity of **perspective** of the *European Breast Guidelines*

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	It is complicated to handle different perspectives in one document. Providing a good balance between these perspectives might not be the right solution to handle this problem as compromises might not lead to the most optimal outcomes.	No	No change in *The Scope*. Each specific PICO will include the perspective taken. Every recommendation will be formulated in a different manner depending on the profile chosen (patient/citizen, policy maker/ healthcare professional).
2	As an individual	Text: 'the patients' and clinicians' perspective will be prioritised. This means that the focus will be on the views of the individual user of the healthcare service (citizens and patients) and the healthcare professional' ==> why 'citizens and'?	Yes	*The Scope* was modified and the phrase 'citizens and patients' has been substituted with 'healthcare users'.
3	On behalf of an organisation	It is not clear to me why 'clinicians perspective' will be also prioritised in services outside the screening programme, but not inside the screening programme.	Yes	*The Scope* was modified to clarify that: 'For diagnostic services, especially when provided outside of a screening programme, the perspectives of healthcare users and clinicians are prioritised.' In addition, each specific PICO will include the perspective taken.
4	On behalf of an organisation	Missing honest information and explanation about overdiagnosis and harm. No overall mortality data. There is nothing wrong with not participating to screening. Give education about symptoms!!	No	No change in *The Scope*. Harms are included in each PICO question as outcomes. Desirable and undesirable effects are examined using EtD frameworks for each PICO in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
5	As an individual	As the socioeconomic (and geographical) situation impacts the use of the recommended Guidelines importantly, this must be added (for ex: guideline for Invasive lobular ca is MRI but without availability MRI, another recommendation needs to be described.	No	No change in *The Scope* This is part of the implementation considerations that will be taken into account for each individual PICO.
6	On behalf of an organisation	Will all settings for cancer screening, not only organized population-based programmes, be within *The Scope*? This is only made explicit for diagnostic procedures. Opportunistic screening and other interventions in chapter 5b should be included.	No	No change in *The Scope*. There is a proposal for a PICO question to compare organised vs. non- organised screening. In addition, each individual PICO specifies the setting.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
7	On behalf of an organisation	The legal framework and the centralized vision of users is not clear. Legal issues have a purpose as well as the fact that we screen and diagnose women for their well-being. Why do we do that or want to do that, because it's unethical not to. Therefore your focus should primarily be on the ethical framework of necessity, proportionality and subsidiarity, because from there a legal as well as a women-centered framework will almost logically follow.	No	No change in *The Scope*. The legal framework is defined by the Council Recommendations. Ethical issues will be considered in each PICO question.
8	On behalf of an organisation	We suggest to complement the 2nd paragraph after '...for breast cancer' (line 101) by 'as well as on adequate evaluation.'	Yes	Adequate evaluation of relevant programmes and services is now included in the Perspective section of *The Scope*.
9	As an individual	The text between the second and third paragraphs was rather unclear, particularly what distinction exactly was being drawn between these two paragraphs.	Yes	*The Scope* has been modified in order to clarify the Perspective section.

Table 9. Comments on adequacy of **healthcare settings** covered by the *European Breast Guidelines:* by respondents who replied with: 'Generally, I agree'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	As an individual	So, both private and public healthcare services?	Yes	*The Scope* was modified to clarify that 'both private and public' healthcare settings will be covered.
2	On behalf of an organisation	It is also important to describe the connection between screening and diagnostic services.	Yes	*The Scope* was modified to clarify that 'breast cancer screening and breast cancer diagnostic services' are covered. The *European Breast Guidelines* will include recommendations on screening and diagnosis, but the connection/interfaces between different services will be covered in the *European QA scheme*.
3	On behalf of an organisation	Please take our response letter to your feed-back call into consideration. The institutes within the healthcare settings should be not only meeting the minimal requirements of ISO15189 but the increase of quality assurance given by ISO17020 should be taken into account and mentioned.	No	No change in *The Scope*. This will be covered by the *European QA scheme*.
4	As an individual	It should read 'The European Breast CANCER Guidelines'	No	No change in *The Scope*. The word 'cancer' is part of the full version of the title (European Guidelines for breast cancer screening and diagnosis). The GDG discussed this point and agreed to keep the short version of the title as it is – *European Breast Guidelines*.
5	As an individual	In the guidelines themselves it would be useful to make it clear what impact contextual differences might have on the anticipated benefits of following a particular recommendation. Evidence generated in one context may, for example, show strong benefit but that benefit is heavily dependent on one or other contextual factor (e.g access to screening facilities). If those factors are not replicated in another context, then the anticipated benefit of following the recommendation may well be much less than the evidence would suggest. It would be good to be clear about this in the guidelines.	No	No change in *The Scope*. The *European Breast Guidelines* will include evidence-based recommendations. For some countries it may be difficult to implement them, but this issue has to be addressed in a proper way at a country level.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
6	As an individual	Has to acknowledge different health care systems in different member states – e.g. State Provider as per NHS and Private/ Insurance based system.		
7	On behalf of an organisation	Is it correct not to include the policy-making 'setting'?	No	No change in *The Scope*. The *European Breast Guidelines* are being developed as a web-based application and one of the profiles foreseen on the webpage is the policy maker, which will contain information, adapted to their needs.

Table 10. Comments on adequacy of **healthcare settings** covered by the *European Breast Guidelines*: by respondents who replied with: 'I have concerns'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	Treatment should be included, the real outcome of screening program is not evaluable if one doesn't consider treatment (above all: surgery) using the appropriate and already well established quality/performance indicators.	No	No change in *The Scope*. Treatment will be covered by the *Guidelines Platform*. Monitoring and evaluation chapter of the *European Breast Guidelines* will contain recommended thresholds of relevant indicators. In addition, quality will be covered by the *European QA scheme*.
2	On behalf of an organisation	The first European guidelines on breast cancer screening included a section indicating the role of primary health care in the provision of patient centered information and support; as in organised programs patients generally are directly invited the informative role of the primary care team might be neglected; the role the primary care team has covers phases before screening (motivation phase; information of on invited), during screening and after symptomatic presentations or positive screening tests; moreover the third phase in the EU breast cancer initiative, i.e. treatment, and eventually also end of life are also phases primary care plays a role. These aspects therefore need also to be clarified and guidance provided on the role of the primary care team and the GP.	No	No change in *The Scope*. There are PICOs proposed in the Communication chapter that cover this issue. The general aspects of the role of general practitioners and primary care team, also in relation to treatment and end of life care, will be covered by the *Guidelines Platform*. In addition, Reference documents will be provided to support ECIBC implementation.

Table 11. Comments on proposed **definitions** in *The Scope* regarding types of interventions: respondents who replied with 'Generally I agree'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	In some countries (usually with not existing public screening policy) screening is offered/ supported in private sector annually by private insurance policies or sponsored by companies to their eligible employees.	No	No change in *The Scope*. Such examinations are included in the definition provided in *The Scope* for non-programme screening.
2	On behalf of an organisation	Is it to be publicly financed a necessary condition for a screening programme?	No	No change in *The Scope*. The definition provided in *The Scope* for programme screening refers to 'examinations financed by public sources'.
3	On behalf of an organisation	Mammography, Contrast Enhanced Spectral Mammography (CESM), DBT, Automated Breast Ultrasound or MR are useful for further investigation. Clinical practice is moving more towards personalized screening.	No	No changes in *The Scope*. Some PICO questions have been proposed on different imaging techniques.
4	As an individual	Use the term 'Opportunistic screening' rather than 'non-programme screening'. Please add: 'it is more likely to result in variability in the definition criteria of the eligible individuals and in the quality of the screening process'.	No	No change in *The Scope*. Non-programme screening is commonly referred to as opportunistic screening, as described in the definition from the reference provided.
5	As an individual	For me it is not clear what is the difference between 'screening' and 'screening programme'.	Yes	*The Scope* was modified to present the definitions for screening, programme screening, organised screening and population-based screening, as described in the reference provided.
6	On behalf of an organisation	This section could be made clearer. For example the UK national breast cancer screening programme is organised, population based, financed from public sources and the primary test is defined. The programme appears to include most of the above.		
7	On behalf of an organisation	The Definitions of the population based screening program and organized screening program could be made more clear.		
8	As an individual	In the very last sentence I would prefer the term 'screening abnormality' and not 'screening mammography abnormality' as this solution would open for the possibility of screening with other methods.	Yes	*The Scope* was modified accordingly. In addition, there will be PICO questions about different modalities used for screening.

* All comments provided by respondents regarding these definitions will be made available to the International Agency for Research on Cancer for possible consideration when update of the definitions is envisaged.

Table 12. Comments on proposed **definitions** in *The Scope* regarding types of interventions: respondents who replied with 'I have concerns'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	The proposed definitions don't really match to the main aspect of a screening that is, firstly in the perspective of women and then in the health services' and the professionals ones, that of a pathway.	Yes	*The Scope* was modified to present the definitions for screening, non-programme screening, programme screening, organised screening and population-based screening as described in the reference provided. The different perspectives will be taken into account in the formulation of recommendations.
2	On behalf of an organisation	The definitions used are not intuitive logical. In de Dutch situation, a screening programme is also organized and population-based.		
3	As an individual	To define a non-programme screening as 'opportunistic' is quite punitive especially for those asymptomatic women that ask for a mammogram in country or a region where an organized screening is not available. I propose to use the word 'spontaneous'.		
4	On behalf of an organisation	It is difficult without the context to see how good these definitions are. For many readers the differences will probably seem only semantics without describing what the real differences are and why this is important.		
5	On behalf of an organisation	Line 140/143 need rewording – screening can be used to detect pre-malignant lesions, not just cancer.		
6	On behalf of an organisation	1. Women with unclear imaging also need further investigation 2. Screening programme can also be performed in a clinical setting 3. Please provide a clearer definition of coordination 4. Invitation should not be compulsory (e.g. invitation letter).	No	No change in *The Scope*. Topics related to referral for further investigation, coordination and invitations will be covered by some PICOs and also by the *Guidelines Platform*.

* All comments provided by respondents regarding these definitions will be made available to the International Agency for Research on Cancer for possible consideration when update of the definitions is envisaged.

Table 13. Comments on **interventions that will be covered** by the *European Breast Guidelines*: respondents who replied with 'Generally I agree'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	Delete: The diagnostic procedures for benign lesions. We do not know in beforehand if the lesion is benign. Procedures for malignant/benign are the same till the pathological examination and result.	No	No change in *The Scope*. All examinations undertaken following referral and prior to treatment have already been considered in *The Scope*, including also diagnostic procedures for benign lesions. Harms are included in each PICO question as outcomes. Desirable and undesirable effects are examined using EtD frameworks for each PICO in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
2	On behalf of an organisation	The diagnostic procedures for benign lesions. When to call a lesion benign, at clinical examination, at imaging or at pathology?		
3	On behalf of an organisation	Why diagnostic procedures for benign lesions only will be covered? What kind of procedures are you referring to: to diagnose?, to characterize? a benign lesion. Harms are a hot topic we need to address, but also interventions to improve benefit?		
4	As an individual	Why 'diagnostic... for benign lesions': just say all lesions. Add after 'clinical recommendations about interventions': related to the socioeconomic situation of the health care service in the country.	No	No change in *The Scope*. All examinations undertaken following referral and prior to treatment have already been considered in *The Scope*. Resource use and cost-effectiveness are examined using EtD frameworks for each PICO. In addition, socio-economic considerations will be some of the implementation considerations to be taken into account at a country level.
5	On behalf of an organisation	Evaluate both benign and suspicious lesions, communicate beyond the month of October to patients, educate physicians on new modalities, provide information on low dose screening with DBT and ABUS. Use CESM for cost effective diagnosis. Consider one breast stop units.	No	No change in *The Scope*. All examinations undertaken following referral and prior to treatment have already been considered in *The Scope*. Communication, training and imaging modalities will be addressed in some PICOs in the pertinent chapters. Organisation of breast cancer care (breast units) will be covered by the *European QA scheme*.
6	As an individual	Diagnostic procedures during the surgery should be considered within the surgical treatment.	No	No change in *The Scope*. These procedures will be covered by PICO questions in the Diagnosis chapter.
7	On behalf of an organisation	Diagnostic procedures during the surgery should be considered within the surgical treatment.		

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	**Reasoning**
8	On behalf of an organisation	I would not include surgical Sentinel Lymph Node Biopsy in this point. I would include only FNA or Core biopsy (+/- ultrasound guidance) of suspicious axillary nodes.	No	No change in *The Scope*. All biopsy procedures and their pathological examination have been already considered in *The Scope*, including Sentinel Lymph Node Biopsy (SNLB). Several PICO questions are proposed on different diagnostic procedures.
9	As an individual	It is not clear why it will be considered the 'lymph node excision by sentinel node biopsy and pathological evaluation of the lymph node evacuation specimens will be covered'? This is part of breast cancer treatment.		
10	As an individual	Whilst not routine there should also be availability of Vacuum Assisted Biopsy?		
11	On behalf of an organisation	This assumes the patient will have surgery as a first treatment. Patients may also have neoadjuvant chemotherapy may not have surgery at all or refuse any treatment. Suggest using 'after referral and before definitive management is recommended'.	Yes	*The Scope* is modified accordingly: 'following referral and prior to treatment'. The interfaces between different services will be covered by the *European QA scheme*.
12	On behalf of an organisation	Some patients will have as 1st treatment, systemic therapy and not surgery; imaging techniques for neoadjuvant approaches should be included. Crucial is also the link to treatment facilities; it must be included how and to whom refer patients.		
13	On behalf of an organisation	I would strongly encourage for an optimal time period for the mentioned keeping of mammograms to be concocted and made available to countries carrying out screening programs, as well as devoting a number of pages to evidence, data collection.	No	No change in *The Scope*. There are PICO questions on different imaging modalities and implementation considerations are considered in the EtD frameworks for each PICO. Issues on data management should be a part of Reference documents that will be provided to support ECIBC implementation.
14	As an individual	One of the main risk factors is familial predisposition. If gene testing is costly, at least the guidelines have to provide description of the familial breast cancer risk in the context of surveillance and screening.	Yes	*The Scope* was modified to clarify that breast cancer risk assessment is among the interventions not covered in *The Scope*. Some PICO questions may be related to varying the screening regimen depending on certain risk factors.
15	As an individual	For asymptomatic high-risk women a tailored screening should be considered. More frequent screening or additional screening test.		

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
16	As an individual	The section on interventions to reduce harms must include the reduction of psychological harm as the potential for this is very great.	No	No change in *The Scope*. Desirable and undesirable anticipated effects are examined using EtD frameworks for each PICO. However, benefits and harms are convenient terms for general use.
17	As an individual	I suggest considering 'undesired effects' or a similar expression, rather than 'harms' in relation to breast cancer screening. 'Harms' suggests the idea of something that is voluntarily wrong; also, I should not describe 'discomfort' as harm.		
18	On behalf of an organisation	I understand the legal basis for the guidelines, but inclusion of metastatic disease if at all possible would be good.	Yes	*The Scope* was modified (Interventions not covered) to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*.
19	On behalf of an organisation	We would like to add, again, that not only women should be covered by such programmes.	Yes	*The Scope* was modified – 'women' has been substituted with 'persons', because the Screening chapter will not cover men; however, the diagnostic procedures will cover any person with breast cancer (women and men).
20	As an individual	I was particularly pleased to see the interventions linked to communication in this list. I also think it would be useful to clarify what is meant by 'interventions'.	No	No change in *The Scope*. All specific interventions will be defined in each PICO (I=Intervention).
21	On behalf of an organisation	Please take our response letter to your feed-back call into consideration. The institutes carrying out such procedures should be not only meeting the requirements of ISO15189 but the increase of QA given by ISO17020 should be mentioned.	No	No change in *The Scope*. This will be covered by the *European QA scheme*.
22	On behalf of an organisation	Mainly the chain of care between the interventions is missing. This is underlined as well because the order in which the interventions are presented isn't logical. Why is surveillance put after diagnosis and primary prevention after that?	Yes	*The Scope* was modified to clarify that breast cancer risk assessment and surveillance in women with hereditary breast cancer is among the interventions not covered in *The Scope*. A pathway of care has been defined so each intervention is clearly referred to a particular step in the pathway – a figure about breast cancer care pathway is now included in the section Purpose of *The Scope*.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
23	As an individual	The question is whether the level of 'obligation' versus 'free advices' can be the same for all aspects. This should be made very clear.	No	No change in *The Scope*. The *European Breast Guidelines* will contain evidence-based recommendations and their implementation has to be addressed in a proper way at a country level.

Table 14. Comments on **interventions that will be covered** by the *European Breast Guidelines*: respondents who replied with 'I have concerns'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	As an individual	Preoperative prognostic and predictive evaluation besides diagnosis. Diagnostic evaluation must include also postoperative pathological aspects not covered preoperatively: margins, grading, pTNM, other immunohistochemical markers, molecular tests.	No	No change in *The Scope*. Some PICO questions in the Diagnosis chapter may cover this. This will be also covered by the *Guidelines Platform* or by Reference documents that will be provided to support ECIBC implementation.
2	As an individual	The pathological parameters as evaluated in the surgical specimen represent the most important feed-back for the radiologist. The guidelines should contain definitions of histological multifocality, tumor size, disease extent and heterogeneity.		
3	On behalf of an organisation	1) Criteria for referral of screening detected lesions (not symptomatic) is missing. 2) Purpose of 'diagnostic procedures for benign lesions' unclear. 3) Purpose of 'Evaluation of different methods for diagnosis and preoperative staging' unclear.	Yes	*The Scope* was modified to include 'pre-treatment staging', not only 'pre-operative staging'. Some PICO questions in the Diagnosis chapter may cover these issues, together with Reference documents that will be provided to support ECIBC implementation.
4	On behalf of an organisation (including any association, authority, company or body)	The 2nd definition is problematic as some pre-surgical 'examinations' are only done in the context of neo-adjuvant therapy. A definition around '... examinations undertaken after referral and before treatment initiation or surgery' is more appropriate.	Yes	*The Scope* was modified to include examinations prior to treatment.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	**Reasoning**
5	As an individual	I'd like to remind you the CESM examination as a valid alternative to MRI.In fact its diagnostic accuracy is recognized (see literature).CESM is also quick,simple,well tolerated and it has lower false positives than MRI (that is very expensive).	No	No change in *The Scope*. There are PICO questions on other imaging modalities in the Screening and Diagnosis chapter. S
6	On behalf of an organisation	Ignoring women with high risk of breast (and ovarian) cancer. (BRCA, CDH1, Cowden, Lynch, CHEK2, Ashkenazi Jewish roots and radiation after Hodgkin). A European approach to find high risk families is necessary. Here lives can be really saved.	Yes	*The Scope* was modified to clarify that breast cancer risk assessment and surveillance in women with hereditary breast cancer is among the interventions not covered in *The Scope*. Some PICO questions may be related to varying the screening regimen depending on certain risk factors.
7	On behalf of an organisation	High-risk women are not defined. Interventions for primary prevention are out of *The Scope* of 'screening and diagnosis'. As important topic they should have a place in the guideline platform. Add interventions increasing benefit?	Yes	*The Scope* was modified to clarify that breast cancer risk assessment and surveillance in women with hereditary breast cancer is among the interventions not covered in *The Scope*. Some PICO questions may be related to varying the screening regimen depending on certain risk factors. Interventions for primary prevention of breast cancer were already included in the draft scope sent for feedback as co-interventions nested in organised screening programmes. Desirable and undesirable anticipated effects are examined using EtD frameworks for each PICO in order to decide what the balance is.
8	As an individual	Also intermediate risk should be included. Why high-risk is included and women with hereditary predisposition are excluded? What's the difference between screening and surveillance? Also false positive recall may be an example of harm.		

Table 15. Comments on **interventions that will not be covered** by the *European Breast Guidelines*: respondents who replied with 'Generally I agree'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	It would be good to include the diagnosis of metastatic disease.	Yes	*The Scope* was modified to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*.
2	As an individual	Diagnostic procedures in women with suspected recurrences have to be included, because this is important for treatment decision.		
3	As an individual	As mentioned before the issue of follow up is crucial.		
4	On behalf of an organisation	Add Diagnostic procedures in breast cancer patients with suspected recurrences (Groups that will be covered specified above).		
5	As an individual	I agree. So the focus is only on first primary breast cancer: should this be specified somehow in the title of the guideline?		
6	On behalf of an organisation	Again here it should be pointed out that not everybody will understand the difference between surveillance of high-risk groups and the surveillance after diagnose and treatment.	Yes	*The Scope* was modified to clarify that: - aspects, related to follow-up and survivorship are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*. - surveillance of high-risk women will not be specifically addressed by the *European Breast Guidelines*. Some PICO questions may be related to varying the screening regimen depending on certain risk factors.
7	As an individual	I feel sorry some steps of breast cancer treatment are out of *The Scope* (e.g. surgical management of detected lesions). The initial EC guidelines highlighted the importance of the multi-step multidisciplinary procedures.	No	No change in *The Scope*. This will be covered by the *Guidelines Platform*, which will include recommendations from evidence-based existing guidelines on all breast cancer care processes, including treatment regimens.
8	As an individual	Today the process of diagnostics and the one of treatment are closely related, especially for molecular diagnostics (we use the term 'theranostics').		

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	**Reasoning**
9	As an individual	The pathological parameters as evaluated in the surgical specimen represent the most important feed-back for the radiologist. The guidelines should contain a definitions of histological multifocality, tumor size, disease extent and heterogeneity.	No	No change in *The Scope*. Some PICO questions in the Diagnosis chapter may cover this. In addition, Reference documents will be provided to support ECIBC implementation.
10	As an individual	There could be links included what guidelines or recommendations should be followed in EU	No	No change in *The Scope*. For screening and diagnosis the recommendations to be followed will be those included in the *European Breast Guidelines*. In addition, the *Guidelines Platform*, will include recommendations from evidence-based existing guidelines on all breast cancer care processes, including treatment regimens.

Table 16. Comments on **interventions that will not be covered** by the *European Breast Guidelines*: respondents who replied with 'I have concerns'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	As an individual	Pathological diagnostic evaluation of metastases and recurrences must be in *The Scope* once the samples are available.	Yes	*The Scope* was modified to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*.
2	On behalf of an organisation	Diagnostic procedures in breast cancer patients with suspected recurrences should be covered (Groups that will be covered specified above)		
3	As an individual	Screening of women who had a previous BC (the most relevant group of women at intermediate risk) should be included in *The Scope*. In other words, what is the limit between follow-up and (re-) screening women with a previous BC history?	Yes	*The Scope* was modified to clarify that: - aspects, related to follow-up and survivorship are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*. - surveillance of high-risk women will not be specifically addressed by the *European Breast Guidelines*. Some PICO questions may be related to varying the screening regimen depending on certain risk factors.
4	On behalf of an organisation	Treatment should be included. Otherwise we'll be able only to evaluate process and output indicators (for instance: adherence or the number of women referred to treatment).	Yes	*The Scope* was modified to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered in *The Scope* of the *European Breast Guidelines*, but are part of the *Guidelines Platform*. In addition, the *Guidelines Platform*, will include recommendations from evidence-based existing guidelines on all breast cancer care processes, including treatment regimens.
5	On behalf of an organisation	Please see above my deep concerns about the very small impact of this project if not tackling treatment and the whole breast cancer spectrum. Particularly worrisome is the continuous abandonment of metastatic patients.		
6	As an individual	Screen-detected breast cancer surgery should be covered, too. The existing EU guidelines have Quality assurance guidelines for surgery. The surgery of clinically occult breast cancers differs from symptomatic cancers surgery.		
7	As an individual	As noted above, I recommend to include follow-up among the topics to be covered; not in all its implications, but at least as far as may be dealt with in a screening/diagnostic unit: i.e., repeat mammography mainly		

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
8	On behalf of an organisation	Guidelines – Platform This seems to me a rather bureaucratic and irrational approach. Instead, you should call Guidelines A: Screening, Diagnostic… and Guidelines B: treatment, rehabilitation... Full text comment will be sent separately.	Yes	A pathway of care has been defined so each intervention is clearly referred to a particular step in the pathway – a figure about breast cancer care pathway is now included in the section Purpose of *The Scope*.

Table 17. Comments on the proposed list of **stakeholders and users**: respondents who replied with 'Generally I agree'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	Professional bodies/associations for example in the UK the Royal College of Pathologists; Royal College of Radiologists; The Society and College of Radiographers; The Royal College of Nursing.	Yes	*The Scope* was modified to include professional bodies, associations and academic societies.
2	As an individual	I do suppose that the 'Healthcare provider' do include the people involved in the treatment as well? If not, I have a concern.	Yes	*The Scope* was modified to include an extended list of healthcare providers.
3	As an individual	Patients' advocates could also be included as stakeholders.	Yes	*The Scope* was modified to include patients' organisations, breast cancer support groups, other voluntary organisations and charities.
4	On behalf of an organisation	I suggest the inclusion of patient advocacy groups, support groups and other voluntary organisations as stakeholder.		
5	As an individual	Not explicitly mentioned patient advocacy groups. This should be done.		
6	On behalf of an organisation	Psychological support should be useful.		
7	On behalf of an organisation	In an ageing population, it is important that all care givers, and in particular long term carers, are aware of options.	No	No change in *The Scope*. Carers were already included in the draft scope sent for feedback.
8	On behalf of an organisation	Add (1) Healthcare modalities and solutions suppliers (2) families of women with breast cancer (3) breast cancer charities (4) academic societies (5) manufacturers of imaging and interventional equipment.	Yes	*The Scope* was modified to include the suggested groups.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
9	On behalf of an organisation	Add breast cancer charities, academic societies, as well as manufacturers of imaging and interventional equipment and more importantly families of women with breast cancer.		
10	On behalf of an organisation	For diagnosis services also men should be considered; if the guidelines are only screening-centred, the focus on women is clear for us.	Yes	*The Scope* was modified – 'women' has been substituted with 'persons', because the Screening chapter will not cover men; however, the Diagnosis chapter will cover procedures for any person with breast cancer (women and men).
11	As an individual	Diffusion of the documents to the women and health care professionals were not so easy with the previous EC guidelines. This should be improved with the new working group.	No	No change in *The Scope*. Dissemination of the recommendations will be emphasised by the EC.

Table 18. Comments on the proposed list of **stakeholders and users**: respondents who replied with 'I have concerns'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	Genetic counsellors (for women with high risk) – Patient organizations – Epidemiologists (and not only the ones with conflicting interests concerning screening) – Oncologists and oncological researchers with more knowledge of 'early detection'.	Yes	*The Scope* was modified to include the suggested groups.
2	On behalf of an organisation	We presume it is important to highlight communication between oncology, gynaecology specialists and the primary care team; as such I would recommend to add specifically gynaecologists and oncologists in the list under 2.		
3	On behalf of an organisation	Guidelines are not focused at potential participants or patients, they are focused on healthcare workers and policy makers. Putting the users central means you seek their perspective when formulating a guideline, you e.g. don't look at the clinically best (screening or diagnostic) test but at the best test given the acceptability to the users.		

Table 19. Comments on the proposed list of **existing documents**: respondents who replied with 'Generally I agree'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	As an individual	In addition to a systematic research for guidelines and recommendations, I would like to add that research papers on the effect of screening and the excellent meta-analysis of the previously performed RCTs by Cochrane (Gotsche etal) should be used.	Yes	A note was added in *The Scope* clarifying that the presented bibliography is a brief list of documents, used to prepare *The Scope*. All literature, used to make the recommendations, will be included in the ECIBC's web-hub. For the *European Breast Guidelines*, the literature review team was externalised to ensure an independent approach and minimise potential conflict of interest. The Iberoamerican Cochrane Centre, Barcelona, will carry out the literature reviews for each specific PICO and will consider systematic reviews (if already available) or will carry out de-novo ones. In addition, the *Guidelines Platform*, will include recommendations from evidence-based existing guidelines on all breast
2	On behalf of an organisation	I would recommend to not only use EU oriented papers, but also local 'best practices' from different countries. You might want to consider the guidelines by the Health Council of the Netherlands (www.gezondheidsraad.nl/en) en de RIVM (www.RIVM.nl/en). You may ask me for these documents, but you could already have some of these documents as I sent them before.		
3	As an individual	Many other documents, especially at the national level, do exist.		
4	On behalf of an organisation	Publications from established national screening programmes in the UK and possibly other countries that also have similar documents.		
5	On behalf of an organisation	CESM in patients referred from the breast cancer screening programme by Lobbes M.B, et al, European radiology, July 2014, volume 24, Issue 7, pp 1668-1676. J-Star: Japan Strategic Anti-cancer Randomized Trial, Lancet. 2015 Nov 4.		
6	On behalf of an organisation	Consider CESM in patients referred from the breast cancer screening programme by Lobbes M.B, et al, European radiology, July 2014, volume 24, Issue 7, pp 1668-1676. J-Star: Japan Strategic Anti-cancer Randomized Trial, Lancet. 2015 Nov 4.		

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
7	As an individual	Perhaps the recommendation of The Breast Health Global Initiative (BHGI) in Cancer, Supplement: Guidelines for International Breast Health and Cancer Control–Implementation 15 October 2008 Volume 113, Issue S8 should be added to the documents.		
8	As an individual	Although the Marmot Report on Breast Screening referred only to the NHS Breast Screening Programme in England, the report is relevant to any review of guide panel did review all currently available evidence and is more recent and should be included.		
9	On behalf of an organisation	EUSOMA position paper: Quality indicators in breast cancer care. M. Rosselli Del Turco. European Journal of Cancer vol. 46, 2344 – 2356, 2010.		
10	On behalf of an organisation	Several other guidelines are missing. It will be important to see the full list after JRC search.	Yes	A note was added in *The Scope* clarifying that the presented bibliography is a brief list of documents, used to prepare *The Scope*. All literature, used to make the recommendations, will be included in the ECIBC's web-hub. In addition, the *Guidelines Platform*, will include recommendations from evidence-based existing guidelines on all breast cancer care processes.
11	As an individual	There are, of course, national guidelines in some countries and perhaps it would be good to refer to them where appropriate.		
12	As an individual	Performance indicators in 'European guidelines for... 2006' need to be adjusted with Supplement – reviewed with novelties in radiology, surgery and pathology, reviewed in the light of best clinical practice.	No	No change in *The Scope*. This will be part of the Monitoring and Evaluation chapter of the *European Breast Guidelines*.

Table 20. Comments on the proposed list of **existing documents**: respondents who replied with 'I have concerns'

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	Please refer to earlier documents as well highlighting role of primary care team.	Yes	A note was added in *The Scope* clarifying that the presented bibliography is a brief list of documents, used to prepare *The Scope*. All literature, used to make the recommendations, will be included in the ECIBC's web-hub. For the *European Breast Guidelines*, the literature review team was externalised to ensure an independent approach and minimise potential conflict of interest. The Iberoamerican Cochrane Centre, Barcelona, will carry out the literature reviews for each specific PICO and will consider systematic reviews (if already available) or will carry out de-novo ones.
2	On behalf of an organisation	The lists continues to use the old way of looking at early detection in breast cancer. At least ask Peter Gotzsche, Gilbert Welch, Luc Bonneux, Archie Bleyer etc etc for their opinion. Critics have been ignored for too long.		

Table 21. General comments regarding *The Scope*

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
1	On behalf of an organisation	As the EU guideline is addressed, EU must show its will and effort in lean quality management of screening programmes. As it is complicated it is harder to implement. The major targets for screening must be determined. The necessity and the recommended interval of the screening must be determined.	No	No change in *The Scope*. The Monitoring and Evaluation chapter of the *European Breast Guidelines* will cover this, together with the *European QA scheme*.
2	On behalf of an organisation	I have concerns about the quality assurance aspects such as performance indicators. It is mentioned that they will be addressed in both (EU guidelines and accreditation scheme). It will be difficult to avoid redundancy and ensure easy access and referral (what is written down in which document and why).		

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
3	On behalf of an organisation	Population-based breast cancer screening predominantly aims at a reduction of cancer related mortality. Therefore the evaluation of outcome, the importance of adequate and available data like regionalized participation rates and the requirement of population-based cancer registry data should be mentioned in *The Scope*, possibly in the context of expected outcomes.		
4	On behalf of an organisation	Please take our response letter to your call for feedback for *The Scope* of the European guidelines for breast cancer screening and diagnosis into consideration as it is our common goal to ensure the highest standard of care. Meeting the requirements of ISO15189 is the minimum but the increase of QA given by ISO17020 should be taken into account and mentioned. Any decision in such a leading area of expertise should be made with utmost care since it might set precedence for other cancer entities.	No	No change in *The Scope*. This will be covered by the *European QA scheme*.
5	On behalf of an organisation	Some chapters mentioned (training, monitoring and evaluation), mainly related to quality issues and quality assurance are not further specifically mentioned in this document. Quality assurance is crucial maximize benefits/ reduce harms. It is not clear to me at this point, with no detailed information on the EQA Scheme proposal, how EQAS and EBG will complement each other, and which of the 'missed' quality assurance topics (organization, interventions, etc.) will be finally addressed.	No	No change in *The Scope*. A text was already included in the draft scope that 'the ECIBC aims to ensure and harmonise the quality of breast cancer services across European countries via a quality assurance scheme for breast cancer services underpinned by evidence-based guidelines'.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	**Reasoning**
6	On behalf of an organisation	Keeping in mind that the guideline should and will focus on the quality assurance aspects of breast cancer screening and its diagnosis, it would also prove helpful to offer a scheme and/ or table explaining a minimal threshold for the quality of screening and tips on how to obtain it. The training and licensing of radiology specialists that are to be preforming screening mammography (first and second readers of mammograms, radiologists, supervisors), and training curricula for it.	No	No change in *The Scope*. The Monitoring and evaluation chapter of the *European Breast Guidelines* will provide a list of relevant performance indicators with their recommended thresholds. The Training chapter of the *European Breast Guidelines* will contain recommendations for radiologists. Licensing of specialists will be tackled by the *European QA scheme* and Reference documents that will be provided to support ECIBC implementation.
7	On behalf of an organisation	The project seems to be ambitious, however existing different health systems in EU countries should be respected.	No	No change in *The Scope*. The *European Breast Guidelines* will contain evidence-based recommendations and implementation considerations are considered in the EtD frameworks for each PICO. However, their implementation has to be addressed in a proper way at a country level.
8	On behalf of an organisation	The objectives are very ambitious. The objectives focus on different target groups that have different needs in terms of content, detailing and language use. It will be difficult to provide the different target groups with adequate information simultaneously, and taking the differences between countries into account. For this reason, I also have concerns to realizing the outcomes. Besides the guideline aims to target different cultural backgrounds and has to deal with different health systems.	No	No change in *The Scope*. The *European Breast Guidelines* will include evidence-based recommendations, also considering different population subgroups, such as socially disadvantaged, illiterate, etc. In addition, the recommendations will be translated into lay-person language, in order to be understandable by all. Implementation considerations, taking into account differences in healthcare systems, are considered in the EtD frameworks for each PICO. However, they have to be addressed in a proper way at a country level.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
9	As an individual	The Breast Health Global Initiative (BHGI) defines in Cancer, Supplement: Guidelines for International Breast Health and Cancer Control–Implementation 15 October 2008 Volume 113, Issue S8 different levels of screening for breast cancer according to the socio-economic status of the region/country. It is very important to consider the recommendations of this group into the European ones as for a lot of countries, not all diagnostic imaging and care (including breast nurses etc.) are available.		
10	On behalf of an organisation	In order for the document to be of a high quality, there is a need to include in the guidelines the differences that appear among European countries in terms of health care system as well as include the possible ways of creating legal tools that could allow making European countries to apply and implement guidelines into health care systems in these countries.		
11	On behalf of an organisation	Given that accreditation in the field of medicine is voluntary in the Republic of Serbia it is a good idea that it is mentioned under Perspective that the *European Breast Guidelines* took into consideration the EU legal background, whereas this will help the national policy-makers implement the cancer screening programmes.	No	No change in *The Scope*. Implementation considerations are considered in the EtD frameworks for each PICO. However, they have to be addressed in a proper way at a country level. In addition, the *European QA scheme* will tackle the issues related to accreditation.
12	On behalf of an organisation	Mainly a synopsis: use the ethical concepts of necessity, proportionality and subsidiarity as a framework and from there it will naturally follow that the users are put central. *The Scope* really is your basis and still needs work to become more focused.	Yes	*The Scope* was modified (Key stakeholders and users) to clarify that the *European Breast Guidelines* are 'person-centred'.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
13	As an individual	This new perspective is in the continuity of the efforts of the previous EC guidelines and working teams. Do not drop in the archives... In my opinion, better diffusion of the guidelines to the public and related professionals would be beneficial. I do not clearly see an item on the multidisciplinary breast unit and certification.	No	No change in *The Scope*. Dissemination of the recommendations will be emphasised by the EC. Organisation of breast cancer care (breast unit) and certification will be covered by the *European QA scheme*.
14	As an individual	This is a clear resumè of a potentially very important document. The role of breast cancer screening has received a lot of attention lately and to write a 'women-centred' document is innovative and timely. Care should be put in using plain language and clear definitions also for a lay audience, including citizens and carers. Nonetheless, evidence and controversies should be available for a specialized audience including primary care physicians, radiologists, oncologists, breast surgeons etc.	No	No change in *The Scope*. The recommendations will be issued in clear language understandable by all and a specific patient profile is envisaged in the web hub of the *European Breast Guidelines*. It was already included in the draft scope that more than one perspective will be taken into account – e.g. an individual and a population perspective and the views of all relevant groups of stakeholders and users are considered.
15	As an individual	I agree that the guidelines should be women-centred. Therefore, patients and citizens' concerns should be addressed in a clear, plain language. However, some sections should be specifically addressed to the professionals involved in the screening process (i.e. quality assurance issues: indicators, standards, etc.). Opportunistic screening is less efficient in terms of resources and harms & more costly than organized or population-based screening. Thus, guidelines should be population-oriented.		
16	As an individual	Important with a straightforward English language to pay attention to those who are not native English speakers.	No	No change in *The Scope*. The recommendations will be issued in clear language understandable by all.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
17	As an individual	I had problems completing the previous section as I was prevented from completing an edit of wording in second line In the Concept Document there are several instances of incomplete sentences – pages 7, 15 & 25 In *The Scope* Document. Existing documents – as in previous section, Marmot should be included.	Yes	The text of *The Scope* was revised to remove errors. For the *European Breast Guidelines*, the literature review team was externalised to ensure an independent approach and minimise potential conflict of interest. The Iberoamerican Cochrane Centre, Barcelona, will carry out the literature reviews for each specific PICO and will consider systematic reviews (if already available) or will carry out de-novo ones.
18	As an individual	The debate on screening for breast cancer has been long and strenuous. In breast cancer screening policy, emotional arguments are dominating the debate. However, evidence for the efficacy of breast cancer screening is scarce (see the Cochrane meta-analysis by Gotzsche et al). Therefore, I think that this guideline should be very critical and should mostly use rational arguments (i.e. evidence based medicine) instead of emotional arguments when creating this guideline.	No	No change in *The Scope*. The *European Breast Guidelines* will contain evidence-based recommendations. The literature review team was externalised so to ensure an independent approach and minimise potential conflict of interest. The Iberoamerican Cochrane Centre, Barcelona will carry out the literature reviews for each specific PICO and will consider systematic reviews (if already available) or will carry out de-novo ones.
19	As an individual	The document is really timely and it will serve both the patients and the oncologists.	No	No change in *The Scope*. Feedback was positively appreciated.
20	On behalf of an organisation	The GDG should consider to include/cover a 7th Chapter in their list: The Implementation of a Screening programme. Countries that are planning to set up a screening programme, centralized, population based, or decentralized, should receive advice how to do this based on the Guidelines and based also on the experience of established European screening programmes.	No	No change in *The Scope*. Implementation is not explicitly mentioned in *The Scope*, but implementation considerations are considered in the EtD frameworks for each PICO. Additional information might be provided through the Reference documents that will support ECIBC implementation.
21	On behalf of an organisation	Overall, the guidelines should promote further awareness around breast cancer screening to ensure patient participation http://bit.ly/1MbUxM8	No	No change in *The Scope*. This issue will be covered in the Communication chapter of the *European Breast Guidelines*.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	**Reasoning**
22	On behalf of an organisation	I suggest to include the knowledge, proposals and referrals of some scientific articles that are not included in the above mentioned guidelines, i.e. * SA Feig. Screening Mammography Benefit Controversies. Sorting the Evidence. Radiol Clin N Am 52 (2014) 455 -480	No	No change in *The Scope* For the *European Breast Guidelines*, the literature review team was externalised so to ensure an independent approach and minimise potential conflict of interest. The Iberoamerican Cochrane Centre, Barcelona, will carry out the literature reviews for each specific PICO and will consider systematic reviews (if already available) or will carry out de-novo ones, and all references will be adequately cited.
23	On behalf of an organisation	What criteria will be used to select who will be consulted? How will the consulting process occur? How to make sure it is complete and unbiased? Also the criteria for the choices of the working groups are not clear.	No	No change in *The Scope*. The European Commission rules have been followed and the details of the selection procedure are available on the ECIBC web-site.
24	As an individual	This document is missing important aspects of the diagnostic process of breast cancer samples and is biased to the screening and clinical aspects of diagnosis. If no other in depth document is being planned for consensus on breast cancer specimens' evaluation, the current scope should provide deeper instructions not only on diagnostic but also on prognostic and predictive aspect to be considered during the management of specimens of this cancer.	No	No change in *The Scope*. Not explicitly mentioned in *The Scope*, but some PICO questions in the Diagnosis chapter will cover this topic. Additional information might be provided through the Reference documents that will support ECIBC implementation.
25	As an individual	A general comment could be that today, as already reported, the diagnostic process is closely related and conditions treatment, especially if we consider molecular diagnostics. Separating diagnosis from therapy cannot really be done because a specific diagnosis drives the therapy. Thus it is a problem to divide diagnosis from treatment and it should be commented and justified.	No	No change in *The Scope*. The *Guidelines Platform* will include recommendations from evidence-based existing guidelines on all breast cancer care processes. In addition, Reference documents will be provided to support ECIBC implementation.
26	On behalf of an organisation	I would like to see metastatic disease included if at all possible	Yes	*The Scope* was modified to clarify that diagnostic procedures in breast cancer patients with suspected recurrences or metastases during follow-up are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	**Reasoning**
27	As an individual	Please do not forget the male breast cancer patients.	Yes	*The Scope* was modified – 'women' has been substituted with 'persons', because the Screening chapter will not cover men; however, the diagnostic procedures will cover any person with breast cancer (women and men).
28	On behalf of an organisation	Would welcome the opportunity to share our experience and new technology specifically designed for screening and diagnostic programs. Our technology is supported by a large number of publications from peer reviewed journals. We have also been involved in setting up screening programs and diagnostic clinics, happy to share our experience.	Yes	*The Scope* was modified (Key stakeholders and users) to include also industry, linked to breast cancer screening and diagnosis.
29	On behalf of an organisation	We would welcome the opportunity to share our members' experience and new technology specifically designed for screening and diagnostic programs. Our members' technology is supported by a large number of publications from peer reviewed journals. Our members have also been involved in setting up screening programs and diagnostic clinics.		
30	As an individual	This scope definition does not consider risk stratification as a key aspect for the future of BC screening. There is a logic contradiction between including in *The Scope* 'high-risk surveillance' and excluding 'surveillance in women with hereditary breast cancer' such as those with BRCA1/2, strong family history and not proven mutations, etc.. This exclusion, being in the note 1, is not visible when answering the survey. Intermediate risk, especially women with previous BC, should be included.	Yes	*The Scope* was modified to clarify that breast cancer risk assessment, surveillance in women with hereditary breast cancer and aspects, related to follow-up and survivorship are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*. Some PICO questions may be related to varying the screening regimen depending on certain risk factors.

Sequence number	Type of response	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
			Decision	Reasoning
31	As an individual	The shared document appears to be clear and thorough. An introductive chapter in which the materials and methods used for data analysis are described, accompanied by an Evidence Based Recommendations scale supporting all the guidelines and representing in a balanced way the necessity to be Evidence based, women centred and usable in the different participating European countries, would be desirable. It seems important for the European Guidelines to offer clear indications on the controversial theme of the mammographic screening and its optimal timing for women aged from 40 to 49 years and for the ones with 70 or more years. For further information it could be useful that the treatise about the 'Breast Cancer Surveillance for High risk Women' theme should not consider only the BRCA1 and/ or BRCA2 mutation bearers but also women with high risk for breast cancer linked to a relevant breast cancer family history.	Yes	*The Scope* was modified to clarify that breast cancer risk assessment and surveillance in women with hereditary breast cancer are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*. *The Scope* includes only a short introduction, because most of the details mentioned in the comment are presented in the ECIBC Concept document[7], available on the web site. Different age groups will be addressed by the recommendations for screening. Some PICO questions may be related to varying the screening regimen depending on certain risk factors.
32	On behalf of an organisation	Overevaluating ´early detection breast cancer´. No information of biogenetic diversity of all breast cancers. Small can be lethal. Big can be curable. Focusing on size and early detection of oversimplifying. This means harm to breast cancer patients. Ignoring women with high risk pf breast (and ovarian) cancer. (BRCA, CDH1, Cowden, Lynch, CHEK2, Ashkenazi jewish roots and radiation after Hodgkin). A European approach to find high risk families is necessary. Here lives can be really saved. Not a word of honest information and helping women to decide after years of promoting only the 'benefits' of screening, this will need more effort. Normal women don't understand overdiagnosis, overtreatment.	Yes	*The Scope* was modified to clarify that breast cancer risk assessment and surveillance in women with hereditary breast cancer are not covered by the *European Breast Guidelines*, but are part of the *Guidelines Platform*. Breast cancer subtypes are not explicitly mentioned in *The Scope*, but some PICO questions in the Diagnosis chapter will cover this topic. Recommendations about effective communication regarding harms and benefits of the intervention will be included in the *European Breast Guidelines*. The recommendations will be issued in clear language understandable by all and specific patient, healthcare professional and policy maker profiles are envisaged in the web hub of the *European Breast Guidelines*.

7 Concept document – a document describing the background of the ECIBC, it's general goals and objectives, and its foreseen outcomes (http://ecibc.jrc.ec.europa.eu/-/ecibc-concept-document)

Annex 3

List of suggested topics/questions for inclusion in the different chapters of the *European Breast Guidelines*

Table 1. List of questions suggested for inclusion in the **Screening chapter** of the *European Breast Guidelines*

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
1	Because of the very real risk of overdiagnosing and treating women with DCIS the question must be addressed as to whether screening causes more harm than good.	Yes	Questions addressing women with DCIS[1] were included in the prioritisation exercise[2]. Overdiagnosis and potential harms associated with screening are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using Evidence to Decision (EtD) frameworks[3] for each PICO[4] question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
2	What age range should undergo screening? How does family history influence the start of screening for some patients?	Yes	Questions addressing different age groups and varying the screening regimen depending on certain risk factors were included in the prioritisation exercise.
3	Age of screening. Frequency of screening stratification of screening by risk.		
4	Breast cancer related mortality is a poor outcome measurement for evaluating the efficacy of breast cancer screening. Over the years, treatment has improved and led to improved outcomes as well and therefore the increase in survival could not be explained by screening policy alone. Only well performed RCTs could provide you with an accurate answer for this questions. A better question to assess the efficacy of cancer could be: Does breast cancer screening lead to a decline in incidence of late stage tumors and increase or stabilization in incidence of early stage tumors (as you expect to happen, see Rethinking Screening for Breast Cancer and Prostate Cancer, Esserman et al, JAMA 2009)? What is the estimate of overdiagnosis in breast cancer due to screening? Which methods to quantify overdiagnosis are used?	Yes	Questions addressing monitoring and evaluation of screening were included in the prioritisation exercise. Overdiagnosis and breast cancer mortality are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.

1 DCIS – ductal carcinoma in situ

2 Prioritisation exercise - All questions suggested by the respondents and considered relevant to be addressed by the European Breast Guidelines were modified accordingly and added to a list, prepared in advance by the GDG members. This combined list contained more than 200 questions (Annex IV), which then had to be prioritised by voting among the GDG members in order to identify the top questions for each chapter of the European Breast Guidelines. The questions that were not prioritised may be considered in the future update of the European Breast Guidelines recommendations.

3 Evidence to Decision (EtD) frameworks – an explicit and transparent system for decision making, provide a systematic and transparent approach for going from the evidence to the healthcare decision. EtD frameworks inform users about the judgments that were made and the evidence supporting those judgments by making the basis for decisions transparent to target audiences. EtD frameworks include also detailed justification (undesirable effects, values, certainty of the evidence), subgroup considerations, implementation considerations, monitoring and evaluation considerations and research priorities.

4 PICO format stands for: Population under study (for example women of certain age); Intervention (for example a medical examination); Comparator (other main options such as an alternative medical examination); and Outcomes (results).

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
5	What is the optimal screening interval? 12 months? 18 months? 24 month? Longer? Is the interval depending on the woman's breast density and/or age? How to manage women with BIRADS density 3 and 4? Is it possible to implement a good strategy for these women in a screening setting? Offer Ultrasound (automatic (ABUS) or hand-held), MRI? Offer frequent mammography? What is enough breast compression pressure? Is it possible to reduce the compression pressure without reducing image quality? Is the compression force depending on vendor and/or radiographers? How to implement tomosynthesis in screening? How to optimize the examination for women with breast implants? Included or excluded these women in screening?	Yes	Questions addressing the topics suggested – screening intervals, imaging techniques, age groups, identifying women at high risk of breast cancer and varying the screening regimen depending on certain risk factors were included in the prioritisation exercise.
6	Clearly define the target population (age) and the medium and high risk women (out of the standard screening) Define the screening procedures for these patients (tools, screening frequencies, ...).		
7	What is the common technology recommended by EU for screening mammogram? Digital or analogue mammogram or tomosynthesis?		
8	Personalised screening by age with related procedures (MRI, MX, US, clinical) and by individual risk (based on mathematical model).		
9	If the target population could be extended to the age of 75?		
10	What is the age group that should be included for screening programmes? What should the frequency of examination be? Should screening consist of full field digital mammography, tomosynthesis or both?		
11	Consider including chapter/section screening by new emerging methodologies e.g. tomosynthesis.		
12	The guidelines should be clear in providing as much information as possible in answer to the following questions: What are the harms associated with taking part in a screening program? What will happen to me if I do not take part in screening?	Yes	Questions addressing the topics suggested were included in the prioritisation exercise. Potential harms associated with screening are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
13	1) In the context of individual informed choice for or against screening (and lower participation rates), how can the impact and benefit-harm-ratio of a screening program be evaluated? How can the gap between the public health (and economic) interest and the individual interest (choice) be addressed? 2) recommendation for recall rates in first-time participants (usually among the youngest age group) in an established program 3) exclusion (permanently or temporarily) of breast cancer patients from screening (how long)? 4) definition of high risk women 5) relevance of radiation induced cancer (in the benefit-harm context) 6) clear minimal documentation record (set of parameters: screening, diagnoses, post-operative outcome – therapy and prognostic factors).	Yes	Questions addressing varying the screening regimen depending on certain risk factors and identifying women at high risk of breast cancer were included in the prioritisation exercise. Informed decision making and potential harms associated with screening are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. Data management will be addressed within the *European QA scheme*[5]. In addition, Reference documents[6] will be provided to support ECIBC[7] implementation.
14	I think that the problem of evaluation of new technology (as digital mammography or tomosynthesis) in screening programme (as well in opportunistic screening) should be carefully addressed, at least as general recommendations in facing such a problem	Yes	Questions addressing imaging techniques were included in the prioritisation exercise.
15	Is it recommended to be screened regularly with a mammography for an average-risk women? Balance benefit-harms [critical appraisal of literature] Personalized risk-based screening programs. Are we there yet? How to get started? How to assess risk? How to establish/define target population and screening intervals according to risk criteria? How to ensure continued monitoring of changes to risk? Efforts needed to identify predictive factors of slow-growing tumors. What for? Could be useful to reduce the risk of overdiagnosis?	Yes	Questions addressing varying the screening regimen depending on certain risk factors, identifying women at high risk of breast cancer, imaging techniques and predictive factors assessed in a standard pathologic assessment were included in the prioritisation exercise. Overdiagnosis and potential harms associated with screening are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
16	Evidence for improved benefits or reduced harms for individualized screening based on, other than age, women factors (risk factors, breast density...). Evidence for new technologies: tomosynthesis.		

5 *European QA scheme* - voluntary European quality assurance scheme for breast cancer services, covering all care processes, based on the EU legislative framework on accreditation and underpinned by the evidence provided by the guidelines.

6 Reference documents - Reference documents will be collected in support to implementation of evidence-based recommendations included in the existing guidelines for those aspects, e.g. related to diagnosis, where best practice guidance would be useful.

7 ECIBC – European Commission Initiative on Breast Cancer.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
17	Question 1.1: Should Digital Breast Tomosynthesis be introduced by the *European Breast Guidelines* as a breast cancer screening tool? Is the expert panel planning to consider the stratification of screening in to sub-sets defined by risk factors such as breast density, and the risk evaluation models. We would like you to take into consideration the following publications which support the use of ABUS in breast cancer screening. J-Star: Japan Strategic Anti-cancer Randomized Trial, Lancet. 2015 Nov 4. pii: S0140-6736(15)00774-6. doi: 10.1016/S0140-6736(15)00774-6 The SomoInsight Study. Radiology. 2015 Mar; 274(3): 663-73 ACRIN 6666. JAMA. 2008; 299(18):2151-2163. doi:10.1001/jama.299.18.2151. EASY Study: European Asymptomatic Screening Study (Submitted).		
18	Is personalized screening (in some circumstances, like dense breast) preferred instead of population based screening? Is Digital Breast Tomosynthesis to be considered as the new screening modality (if financial situation is OK)?		
19	Women in which age groups do have a net benefit from screening? Do certain groups of women (according to determinants such as age, education or health related factors) have an elevated risk for harms? Does adapting screening intervals to the individual risk of breast cancer decrease risk of harms? Which screening steps (identification/invitation, information/decision, radiologic examination – reading, diagnostic steps) have most importance for a balance of benefits and harms and for reduction of inequalities. This could lead to identification of screening steps also amenable to improvement in settings outside of organised population-based screening programmes.	Yes	Questions addressing age groups, identifying women at high risk of breast cancer and varying the screening regimen depending on certain risk factors were included in the prioritisation exercise. Potential harms associated with screening are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
20	Digital as routine? Double Reporting on Mammograms – could be aspirational?	Yes	Questions addressing imaging techniques were included in the prioritisation exercise.
21	Will the guidelines address the gaps in screening and diagnosis for senior women? About 50 percent of breast cancer cases are found in women over age 65, http://bit.ly/1SQ8dmy A recent study published in the journal Radiology suggests that early detection with mammography reduces the risk of late-stage breast cancer diagnosis in women over 75, requiring less treatment and improving survival rates. http://1.usa.gov/1Q89kgv How will the guidelines promote the bridging from screening and diagnosis to treatment?	Yes	Questions addressing age groups were included in the prioritisation exercise. The interfaces between different services will be covered by the *European QA scheme*.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
22	In addition to habitual questions: In the light of improving diagnosis do the age group specifications for mammographic screening still hold? In the light of increased life-expectancy what should be the provisions made for non-programmatic or opportunistic screening at 70 and above?		
23	What is/are the appropriate test(s) to screen for breast cancer? Is there a place for tomosynthesis or syntheisized mammography in organized breast cancer screening? To whom should breast cancer screening programs be offered to? At what age should average risk women commence screening? What is the appropriate interval for screening? How are risk stratification and personaled screening recommendation based on risk profile incorporated into organized screening programs?	Yes	Questions addressing age groups, imaging techniques, identifying women at high risk of breast cancer and varying the screening regimen depending on certain risk factors were included in the prioritisation exercise. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
24	Does the benefit for patients with cancer outweighs the risk to which it is subjected to the healthy population? Why is not recommended screening in other groups of age? Why are not recommended another test as tomosynthesis?		
25	1.1. Should Digital Breast Tomosynthesis be introduced by the *European Breast Guidelines* as a breast cancer screening tool? 1.2. Is the expert panel planning to consider the stratification of screening in to sub-sets defined by risk factors such as breast density, and the risk evaluation models? COCIR suggests to take into consideration the following publications which support the use of ABUS in breast cancer screening: • J-Star: Japan Strategic Anti-cancer Randomized Trial, Lancet. 2015 Nov 4. pii: S0140-6736(15)00774-6. doi: 10.1016/S0140-6736(15)00774-6 • The SomoInsight Study. Radiology. 2015 Mar; 274(3): 663-73 • ACRIN 6666. JAMA. 2008;299(18):2151-2163. doi:10.1001/jama.299.18.2151. • EASY Study: European Asymptomatic Screening Study (Submitted)		
26	Role of new diagnostic techniques (tomosynthesis/DBT, automated ultrasound/ AUS, ...) with emphasis on evidence of benefits vs negative effects vs costs/ feasibility. Possible alternative screening protocols based on variations in diagnostic modalities and/or intervals and/or risk factors (tailoring) etc. All the above should be analysed with the strongest emphasis on feasibility (in strictly financial terms as well as staffing/personnel considerations). Possible role of CAD in mammography, DBT, AUS	Yes	Questions addressing imaging techniques, identifying women at high risk of breast cancer and varying the screening regimen depending on certain risk factors were included in the prioritisation exercise.
27	Should we also include a focus of developing new technologies to reduce potential risks of ionising radiation		

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
28	Generally speaking, could the mammographic screening be integrated/carried out according to different risk profiles? Are the new polygene tests available able to integrate the mammographic screening in order to select different risk groups? Would they be cost-effective? Could the mammographic density be routinely used to enable a differential screening according to the breast density at different ages?		
29	Contrast-enhanced spectral mammography (CESM) is a relatively recently introduced imaging technique that uses an intravascular contrast agent to identify breast cancer on the basis of iodine signal enhancement from tumor angiogenesis. Contrast enhanced digital mammography (CESM) has been shown to have a higher sensitivity and specificity than standard mammography and similar diagnostic accuracy compared to breast MRI. Two questions should now be addressed: – Is CESM could be used in alternative to MRI in the screening of high risk women? – Is CESM could be used in alternative to mammography in the screening of intermediate risk population?		
30	The *European Breast Guidelines* should address the age groups of women suggested for mammography screening. It is important as there is no general consensus and the practice is different even in countries having a nation-wide mammography screening program. The *European Breast Guidelines* should address the specific issues of guidelines for screening high-risk women (e.g. for women with family history of breast/ovarian cancer or BRCA1-2 positive women).	Yes	Questions addressing age groups, identifying women at high risk of breast cancer and varying the screening regimen depending on certain risk factors were included in the prioritisation exercise.
31	Best interval of screening. Best method including new technologies: a) to include US or not; b) to use tomosintesis or not; c) use of MRI for BRCA carriers or not. Screening and following BRCA carriers as well as women with strong family history. Classification of lesions. Why and when to call back women. Criteria for biopsy and for referral. Quality assurance criteria for evaluation of the screening process and of the screening units. Provide list of adequate places for women to go, in each country. Links to Treatment Units.	Yes	Questions addressing imaging techniques, identifying women at high risk of breast cancer and varying the screening regimen depending on certain risk factors were included in the prioritisation exercise. Quality of breast healthcare services will be covered by the *European QA scheme*, as well as the interfaces between different
32	Screening of high risk groups have to be defined. Gene carriers etc....	Yes	Questions on identifying women at high risk of breast cancer and varying the screening regimen depending on certain risk factors were included in the prioritisation exercise.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
33	Age interval of women at average risk to be screened (from 40, 45, 50 to 70-75?). What to do over 75? Screening intervals (1, 2, 3 years?) Recommend preference for direct digital (not phosphor plates) mammography instead of film-screen mammography. Recommend for using standardized descriptors and diagnostic categories (e.g., BI-RADS, R1-R5) Discuss the perspective for implementation of digital breast tomosynthesis for screening (ro be ready for this). Define facility minimal volume limits (mammograms/year; needle biopsies/ year). Define minimal and maximal individual volume limits for radiologists Define minimal individual volume limits for pathologists Define the need of individual proficiency test for radiologists and pathologists Define individual minimal volume limits for technicians.	Yes	Questions addressing age groups, imaging techniques, volumes and training requirements were included in the prioritisation exercise.
34	In general, the guidelines should allow modifications of screening parameters such as the age of the women and the intervals of screening exams to individual circumstances and requirements	Yes	Questions addressing age groups, screening intervals and varying the screening regimen depending on certain risk factors were included in the prioritisation exercise.
35	High risk screening groups, age groups, screening after breast reconstruction and breast cancer.	Yes	Questions on identifying women at high risk of breast cancer, varying the screening regimen depending on certain risk factors and imaging techniques (addressing also different subgroups) were included in the prioritisation exercise.
36	How to implement an effective breast cancer screening. Risk adapted screening strategies. Appropriate use of technology in special patient population (e.g. genetic predisposition carriers or Hodgkin lymphoma survivors). How to integrate genomics, proteomics and liquid biopsies in breast cancer screening. Are we using the appropriate endpoints to evaluate efficacy and appropriateness of screening programs?	Yes	Questions on identifying women at high risk of breast cancer, varying the screening regimen depending on certain risk factors, imaging techniques, diagnostic methods and monitoring and evaluation of screening were included in the prioritisation exercise. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
37	Age of women undergoing the screening, frequency of screening examinations, organisation structure for covering screening in individual countries – the same for all or individual per country.	Yes	Questions on age groups and screening intervals were included in the prioritisation exercise. The *European Breast Guidelines* will include evidence-based recommendations. Their implementation has to be addressed in a proper way at a country level[8].

8 Lisbon Treaty art. 168 foresees that 'Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.'

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
38	Timely innovation of screening programmes is important. Innovation should also be evidence based. It can be complicated to unite these two objectives. It is necessary to pay attention to this problem.	Yes	Questions on imaging techniques and diagnostic methods were included in the prioritisation exercise. In addition, Reference documents will be provided to support ECIBC implementation.
39	How will women be helped to understand overdiagnosis bias, lead time bias and other harm? After years of emphasizing only the benefits, it is hard to explain women that not going to screening without symptoms is not wrong at all. What will be done to explain this to women? Will women with high risk due to a genetic mutation be approached on a different way? Will women get psychological support after false positive or false negative results?	Yes	Questions addressing optimal strategy to communicate results and identifying women at high risk of breast cancer were included in the prioritisation exercise. Informed decision making, overdiagnosis and potential harms associated with screening are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. In addition, the recommendations are formulated in lay-person language in order to be understandable by all.
40	1. To what extent should they made obligatory? 2. How to cope with variation in outcome/results based on social, demographic, cultural and other differences? 3. How to follow the results over time: population based studies coupled to the screening programme? 4. Who should organise it: privately; existing primary/ second line health care/dedicated services/ ...? 5. Who should pay for it: health insurance companies/government/patients/ employers/...? 6. How to prevent over-use of "opportunistic" screening? Who pays in that case? 7. How to set up, fund, maintain and evaluate/publish quality assurance.	Yes	Questions addressing the topics suggested were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. The *European Breast Guidelines* will include evidence-based recommendations. Their implementation has to be addressed in a proper way at a country level. The economic aspects will be covered in the EtD frameworks. Questions addressing monitoring and evaluation of screening were included in the prioritisation exercise. Quality of breast healthcare services will be covered by the *European QA scheme*.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
41	1) evidence, data collection, medical records and documentation. 2) proposal of optimal time period for the keeping of mammograms to be concocted and made available to countries carrying out screening programs 3) to offer a scheme and/or table explaining a minimal threshold for the quality of screening and tips on how to obtain it 4) The training and licensing of radiology specialists that are to be preforming screening mammography within the screening program (first and second readers of mammograms, radiologists, supervisors) and training curricula for said training programs	Yes	Questions addressing monitoring and evaluation of screening and training of professionals were included in the prioritisation exercise. Data management will be addressed within the *European QA scheme*. In addition, Reference documents will be provided to support ECIBC implementation.
42	Please highlight the role of technicians in the screening and suggest required numbers of screens per year.	Yes	Questions addressing training requirements for professionals were included in the prioritisation exercise.

Table 2. List of questions suggested for inclusion in the **Diagnosis chapter** of the *European Breast Guidelines*

1	What histopathological techical procedures must preferentially be used in the initial diagnosis of breast cancer (cytology, needle biopsy, tumorectomy? in what situation each? what are the prognostic and predictive pathological markers to be evaluated in breast samples and in which type of breast samples? will there be an european consensus in the criteria for the evaluation of the above markers? what and when must molecular studies be used in the prognosis and prediction of breast cancers?	Yes	Questions on histopathological procedures and parameters, prognostic and predictive pathological markers, and training requirements for radiologists were included in the prioritisation exercise. In addition, Reference documents will be provided to support ECIBC implementation.
2	Already defined in the previous versions of the EC guidelines but need to update with next diagnostic tools (e.g. molecular and gene).		

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
3	Histopathological parameters that only can be assessed during examination of the surgical (operative) specimen should be included. They are tumor size, lesion distribution (unifocal, multifocal and diffuse, both for the invasive and in situ components of the tumor), disease extent, and intratumoral / intertumoral heterogeneity. The document should include consensus definitions of each of these parameters, guidelines to their adequate histological assessment, suggestions for the way of their reporting, and first of all, quality assurance schemes for radiological – pathological correlation with regard of these parameters. As these parameters are preoperatively assessed with radiology methods (histological evaluation of the biopsy specimens is not sufficient in this aspect), the radiologists need this feed-back as confirmation or modification of their preoperative assessment results.		
4	Is it worth it? The risk of overdiagnosis, MRI guided biopsies.	Yes	Questions addressing imaging techniques were included in the prioritisation exercise. Informed decision making and overdiagnosis are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
5	What is the golden standard to achieve breast cancer diagnosis? Core biopsy or fine needle? (between Sweden and other EU countries)	Yes	Questions on diagnostic procedures were included in the prioritisation exercise.
6	Minimal diagnostic procedures to be done		
7	Contrast-enhanced spectral mammography (CESM) is a relatively recently introduced imaging technique that uses an intravascular contrast agent to identify breast cancer on the basis of iodine signal enhancement from tumor angiogenesis. Contrast enhanced digital mammography (CESM) has been shown to have a higher sensitivity and specificity than standard mammography and similar diagnostic accuracy compared to breast MRI. Two questions should now be addressed: – Is CESM could replace mammography in symptomatic breast patient? – Is CESM could be used as a case solver in diagnostic setting in case of inconclusive mammography and ultrasonography as an alternative to breast MRI?	Yes	Questions on imaging techniques were included in the prioritisation exercise.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
8	Personalised procedure for the diagnosis with regards to the biology of the tumors as new drug are now available, thus better diagnostic methods are required to understand how to proper use the drug (ex: neoadjuvant model).	Yes	Questions on histopathological procedures and parameters, prognostic and predictive pathological markers were included in the prioritisation exercise. In addition, Reference documents will be provided to support ECIBC implementation.
9	Can we name the indications for certain postscreening examinations (another MG or US)?	Yes	Questions on imaging techniques were included in the prioritisation exercise.
10	Is there a role for new diagnostic techniques such as CESM in the diagnosis of breast cancer?		
11	I would like to bring to your attention the growing importance of mammography with contrast medium (CESM-Contrast Enhanced Spectral Mammography) in the diagnostic presurgical breast cancer. In particular, this examination, based on our experience and that of many breast centers in Europe and other parts of the world, has a diagnostic accuracy comparable to breast MRI. CESM also has advantages: useful, rapid execution, immediate interpretation, display similar to a standard mammography (easier interpretation by other specialists: surgeons, oncologists) a lower number of false positive than MRI and above a lower cost. Because of the well documented validity of the method as an alternative to breast MRI (see scientific literature regarding this matter), where it is indicated as an examination of the second level, I think it is appropriate to consider the CESM between one of the methods useful in diagnostic breast imaging protocol.		
12	Criteria for classification of lesions. Criteria for biopsy, clear criteria for FNA, criteria for referral. What to include in the Pathology report from biopsies, surgical specimens and sentinel lymph node examination; should include traditional pathology assessment but also needed biomarkers such as ER, PR, HER-2, ki67. For the biomarkers describe best antibodies to use, cut-offs, quality assurance programs to implement in Pathology Laboratories. For surgical specimens define how to assess margins, what are clear margins. For SLNB how to examine LNs, define micro and macro metastases as well as isolated cells, and their impact in prognosis and treatment. Mandatory marking and how to mark lesions both pre-surgery and pre-neoadjuvant systemic therapy (use of clips, use of carbon). Quality assurance criteria and programs for Screening Units. Multidisciplinary approach and discussions between radiologists, surgeons, medical oncologists and pathologists. Links to Treatment Units.	Yes	Questions on histopathological procedures and parameters, prognostic and predictive pathological markers were included in the prioritisation exercise. In addition, Reference documents will be provided to support ECIBC implementation. Quality of breast healthcare services will be covered by the *European QA scheme*, as well as interfaces between different services.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
13	1) clear recommendations for diagnostic workup (imaging and invasive techniques and workflow) 2) clear minimal documentation record (set of parameters: screening, diagnoses, post-operative outcome – therapy and prognostic factors).	Yes	Questions on histopathological procedures and parameters, prognostic and predictive pathological markers were included in the prioritisation exercise. Data management will be addressed within the *European QA scheme*. In addition, Reference documents will be provided to support ECIBC implementation.
14	How useful is it to reclassify cancers based on their molecular profile vs. traditional classification based on tissue of origin (i.e. connections between basal-like breast cancer tumors and some ovarian and lung tumors)?		
15	Interventions that will be covered: Breast cancer diagnostic steps and preoperative staging procedures I would add: Is there a role of molecular gene signatures, applied to pre-operative diagnostic samples, to guide treatment?		
16	Question 2.1: Will the expert panel consider creating specific guidelines related to the use of 2D synthetic images for diagnostic use? Question 2.2: Will the expert panel consider creating new guidelines related to the use of CESM to support breast cancer diagnosis?	Yes	Questions on imaging techniques were included in the prioritisation exercise. In addition, cost effectiveness is part of the EtD frameworks for each recommendation.
17	What is the recommendation for breast imaging in breast cancer diagnosis if MRI is not available (due to geogrpahical or economic reasons) for the women? What is the recommendation for breast diagnosis in breast cancer diagnosis if vacuum assisted large needle biopsy is not available (due to economic reasons) for the women?		
18	Role of new diagnostic techniques (tomosynthesis/DBT, automated ultrasound/ AUS, ...) with emphasis on evidence of benefits vs negative effects vs costs/ feasibility.		
19	Recommend for preference for continuity of care between screening and diagnosis. Screening reading radiologists should be also involved in the diagnosis of suspected case (supplemental views, ultrasound, needle biopsy, communication of diagnosis). Define indications for different biopsy systems, from fine needle aspiration cytology to core biopsy, to vacuum assisted biopsy under different guiding systems (stereotactic unit, tomo-guide, ultrasound, magnetic resonance imaging). Recommend for using cyto-pathologic standardized descriptors and diagnostic categories. Define how to manage non malignant cases such as "lesions with uncertain malignant potential" (B3 lesions) for which a tumor board discussion may be useful for decision-making.	Yes	Questions on diagnostic procedures (relevant to all lesions), histopathological parameters, prognostic and predictive pathological markers and discussion of the patient cases at the multidisciplinary team meeting (tumour board) were included in the prioritisation exercise. In addition, Reference documents will be provided to support ECIBC implementation. Quality of breast healthcare services will be covered by the *European QA scheme*, as well as interfaces between different services.
20	The management of benign lesions such as atypical ductal hyperplasia. The management of low risk lesions such as lobular carcinoma in situ and low grade ductal carcinoma in situ.		

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
21	Effective management and integration of records to ensure efficient transition across the pathway particularly where there is a private/public interface; to ensure equitable care of patients in different healthcare set ups across the EU (and elsewhere).	Yes	Questions about addressing inequalities were included in the prioritisation exercise. Quality of breast healthcare services will be covered by the *European QA scheme*, as well as interfaces between different services. In addition, Reference documents will be provided to support ECIBC implementation.
22	As already reported, diagnosis is closely related to treatment and the separation should be justified. How can it be justified?		
23	The use of MRI of the breast in the screening of high-risk groups is of importance and should be mentioned.	Yes	Questions about imaging techniques, varying the screening regimen depending on certain risk factors, identifying women at high risk of cancer and procedures to be used to diagnose breast cancer in women with familiar hereditary risk of cancer were included in the prioritisation exercise.
24	Finding these families with HIGH risk of breast cancer (BRCA: 60-80%) is very useful. What will be done to find these families?		
25	1. How to cope with variation in outcome/ results based on social, demographic, cultural and other differences? 2. How to define, organise and monitor timing and time lines; what if this is not respected; quality assurance; ... 3. How to follow the results over time: population based studies coupled to the screening programme? 4. How to avoid over diagnosis? 5. Who pays when diagnosis is based on patient-demand only?	Yes	Questions about addressing inequalities and monitoring and evaluation of screening were included in the prioritisation exercise. Quality of breast healthcare services will be covered by the *European QA scheme*. Overdiagnosis is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. The economic aspects will be covered in the EtD frameworks.
26	Patients need to be given their diagnosis together with explanation of type of tumour in a manner suitable to the individual person and preferably in presence of relative. Time should be given and any questions answered. A summary of the diagnosis, discussion and next appointment should be given to the patient.	Yes	Questions addressing and optimal strategy to communicate results were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
27	The physician should take enough time during the diagnosis to answer questions the patient might have and ensure a smooth and timely transition into treatment. Will this be part of the guideline? http://bit.ly/1ZxyFq1 Will there is a recommendation for appropriate patient support during the course of the treatment starting at the point of diagnosis? The psychological aspect of a breast cancer diagnosis is not always recognised by health professionals http://1.usa.gov/1URJBIl	Yes	Questions about optimal strategy to communicate results were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. Follow-up procedures and survivorship care will be covered by the *Guidelines Platform*[9].
28	In addition to habitual questions: In the view of risk of over diagnosis and unavoidable additional work up examinations without existence of cancer, what information should be provided to women joined to the invitation letters and in information provided by the primary care team?		
29	Although men are excluded, maybe one paragraph could be addressed to male breast cancer. It gives a recognition of exciting and can make policy makers aware of this problem (although small) as well.	Yes	Questions about diagnostic procedures were included in the prioritisation exercise and they will cover any person with breast cancer (women and men).

9 For recommendations on processes of care other than screening and diagnosis (treatment, rehabilitation, follow-up and survivorship care, palliative care, and all relevant horizontal aspects), an ECIBC platform for breast cancer guidelines (the *Guidelines Platform*) is envisaged to host existing evidence-based, high-quality guidelines.

Table 3. List of questions suggested for inclusion in the **Communication chapter** of the *European Breast Guidelines*

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
1	Will the section on communication include who is available to support women through this process, especially those who are recalled, either where the outcome is benign or malignant? Will communication include training on both verbal communication and the way that written information is provided?	Yes	Questions addressing optimal strategy to communicate results and training of professionals were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
2	Recommend to regularly update website. Endeavour to have communication and to collaborate with national and/or local breast screening organizations.	No	This was not included in the prioritisation exercise, because it is a comment, not a question, but it is however appreciated.
3	The effectiveness of the communication with the female population to assist in their understanding of the benefits and risks.	Yes	Questions about optimal strategy to communicate results were included in the prioritisation exercise. In addition, the recommendations will be translated into lay-person language, in order to be understandable by all. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
4	How to communicate the concept of risk and risk reduction to citizens. They found something: how to communicate to patients a suspicious finding. Mortality zero: an unrealistic target?		
5	It is important to pay attention to the problem of informed choice with special attention for the lower social class. Perhaps decision aids could be helpful.		
6	Availability of list of Screening Units with a good quality assurance in each country, where women should go. Availability of list of Treating Units with a good quality assurance in each country, where women should go. Educational tools, in lay language, explaining importance of screening, what it is, who should do it, how and where. Education tools to lobby and inform politicians and policy makers about the need for screening, quality criteria, importance of Breast Units/Services, need to include Breast Units in the law of each country. Widespread distribution of the final product of this project, in conjunction with the main European Societies and Organizations dealing with Breast Cancer.	Yes	Questions about monitoring and evaluation of screening, and optimal strategy to communicate results were included in the prioritisation exercise. In addition, the recommendations will be translated into lay-person language, in order to be understandable by all. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. Quality of breast healthcare services will be covered by the *European QA scheme*.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
7	The guidelines should be clear in providing as much information as possible to organisations implementing the guidelines in answer to the following questions: How should we best communicate the benefits and harms of taking part in screening programs? How should health professionals ensure that patient preference as part of the decision-making with regard to screening and the subsequent actions that come from the results of that screening?	Yes	Questions about decision aids that explain pros and cons of screening, patient experience/satisfaction, optimal strategy to communicate results and use of social media for implementation of a screening programme were included in the prioritisation exercise. Informed decision making and potential harms associated with screening are considered looking at the different outcomes. Desirable and undesirable effects of outcomes, as well as women´s values and preferences, are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. The recommendations will be issued in clear language understandable by all and specific patient, healthcare professional and policy maker profiles are envisaged in the web hub of the *European Breast Guidelines*.
8	Include section on Benefits and Risks Include section on using social media		
9	Addressing the differences between the individual view and the public health view in the communication with the women.		
10	Decision-making How do we need to help the women taking part in breast cancer screening to make an informed decision? What are the best ways (examples) in delivering clear and balanced information? Are there examples or studies on the impact of the participation in function to the information delivered? Are there decision-making aid tools validated? Provide a list of resources. Add a Q&A section for women diagnosed with breast cancer concerning prognosis, treatment and follow-up.		
11	1. How to avoid a screening and diagnosis related unwarranted stress/anxiety? 2. How to communicate from the screening service to the care system for further diagnosis and treatment? 3. How to involve the primary line including general practitioners?	Yes	Questions about optimal strategy to communicate results and involving primary health providers in communication strategies were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
12	Define levels of communication related to levels of education of the women.	Yes	Questions about the use of targeted communication in particular subpopulations of women were included in the prioritisation exercise.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
13	How do women prefer receiving information regarding benefits, harms and further aspects of screening (which information, written/oral, by whom, which form of communication of risks)? How do women in different European countries prefer receiving an appointment for screening (invitation with fixed appointment, invitation to contact and make an appointment?	Yes	Questions about optimal strategy for communication with women were included in the prioritisation exercise. Informed decision making and potential harms associated with screening are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
14	All Health Care Professionals in contact with screening patients should have current accreditation in communication skills. High quality, easily accessed pre-screening information is essential Patient's comprehension of the information received should be assessed at the end of consultation.	Yes	Questions about training and strategies for educating or supporting healthcare professionals for providing information were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
15	How will the target audience be identified to ensure awareness among all people? While the European guidelines for quality assurance in breast cancer screening and diagnosis of 2006 mention the possible development of a communication strategy for breast cancer screening, the updated guidelines of 2013 and the concept document of the European Commission Initiative on Breast Cancer of 2015 don't address the communication aspect in detail. The guidelines should provide a comprehensive communication strategy on this matter. – http://bit.ly/1ORdUig – http://bit.ly/1PhPL3b – http://bit.ly/1JMyZKx.	Yes	Questions about optimal strategy for communication with women were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
16	A model invite for women to participate in screening mammography Communication strategy for organised screening program		

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
17	How is informed consent to participate in organized screening achieved? What is the necessary information that should be included in an invitation to participate in screening? How are the results of the screening intervention communicated to women and their primary care provider? How can decision aids and decision tools become incorporated into the process of informing women of the benefits and harms of screening?	Yes	Questions about optimal strategy to communicate results, use of decision aids, and involving primary health providers in communication strategies were included in the prioritisation exercise. Informed decision making and potential harms associated with screening are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
18	Should it be the communication on the screening equal in all countries?	Yes	Questions about optimal strategy to communicate with women and strategies for educating or supporting healthcare professionals for providing information were included in the prioritisation exercise.
19	A dedicated nurse or a health visitor should be mandatory for communication. EU should address prepare a statement on this.		
20	In addition to habitual questions on communicating results: How to assure good communication about the invitation process between the organised program management, the primary care team , the diagnostic workup team and the target population in case of high risk, in case of normal or suspect results.	Yes	Questions about optimal strategy to communicate results in particular subpopulations of women and involving primary health providers in communication strategies were included in the prioritisation exercise.
21	Define how information about advantage and disadvantages of screening should be delivered (balance sheet, etc.) to women with different risk level. Discuss the possibility of a direct interaction with a physician at the first screening event, also but not only to verify that women have understood the crucial information about pros and cons of screening. Define how to verify that clinicians have real skills in communication to women. Importantly, consider the new approaches to the theory of risk and opportunity perception which demonstrated that human choices are not "rational" and that how data are presented strongly determines preferences (see: Verna et al. Understanding choice. Why physicians should learn prospect theory. JAMA 2014). As mentioned before, in some analyses, mortality and survival are mathematically equivalent but their impact on perception is completely different.	Yes	Questions about optimal strategy to communicate results, strategies for educating or supporting health professionals for providing information and use of targeted communication in particular subpopulations of women were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
22	How will women be helped to understand overdiagnosis bias, lead time bias and other harm? After years of emphasizing only the benefits, it is hard to explain women that not going to screening without symptoms is not wrong at all. What will be done to explain this to women? Will women with high risk due to a genetic mutation be approached on a different way? Will women get psychological support after false positive or false negative results?	Yes	Questions on identifying women at high risk of breast cancer, optimal strategy to communicate results and use of targeted communication in particular subpopulations of women were included in the prioritisation exercise. Informed decision making, overdiagnosis and potential harms associated with screening are considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
23	Since the use of CESM imaging modality is rapidly growing in the field of breast disease, there is clearly a need to provide a consensus among experts to standardize CESM examinations reporting and to reconcile terms used to describe features on both LE image and subtracted images. The question is: – Is a new CESM lexicon of standardized terminology designed to standardize CESM reporting should be elaborated?	Yes	Questions on imaging techniques were included in the prioritisation exercise.
24	What lines of communication should exist between patient and health care professionals?	Yes	Questions about optimal strategy for communication with women and strategies for educating or supporting health professionals for providing information were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
25	Fundamental. How to diffuse the EC guidelines and recommendations (and updates) to the women, the patients, the doctors, the breast units and the para-medics on an efficient way.	Yes	Questions about optimal strategy for communication with women were included in the prioritisation exercise. In addition, the recommendations will be issued in clear language understandable by all and specific patient, healthcare professional and policy maker profiles are envisaged in the web hub of the *European Breast Guidelines*. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
26	Will there be and unified document with recommendations? will there be obligation to follow the consensus of the EU in this matter?	No	These are not questions that can be addressed in the prioritisation exercise and were hence not included. However, the recommendations will be issued in clear language understandable by all and specific patient, healthcare professional and policy maker profiles are envisaged in the web hub of the *European Breast Guidelines*. The *European Breast Guidelines* will include evidence-based recommendations. Their implementation has to be addressed in a proper way at a country level.

Table 4. List of questions suggested for inclusion in the **Training chapter** of the *European Breast Guidelines*

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
1	Will training include communication skills?	Yes	Questions about strategies for educating or supporting healthcare professionals for providing information were included in the prioritisation exercise.
2	Will there be any kind of unified recommendations or obligations in the national training programs for pathologist related to breast cancer diagnosis? Will there be EU international programs for exchange of trainees in breast pathology?	Yes	Questions on histopathological procedures, specialisation and training of pathologists were included in the prioritisation exercise. In addition, Reference documents will be provided to support ECIBC implementation.
3	The role of advanced nurse practitioners, and advanced practise radiographers. The training of sufficient numbers of radiologists etc.	Yes	Questions addressing imaging techniques, volumes and training requirements of different healthcare professionals were included in the prioritisation exercise. The economic aspects will be covered in the EtD frameworks.
4	The presence of an appropriate skill mix based on defined competencies to enable efficient, flexible and cost effective reporting of images.		
5	What kind of training should professionals have (i.e. radiologists, surgeons, oncologists etc). Should there be a distinction between regular breast cancer specialist or super specialized doctors?		
6	Should the different types of training that are necessary for screening and diagnosis be defined?		
7	Training courses with quality certificates for people working in Screening Units. Training courses on how to communicate a diagnosis of a suspicious lesion and of a cancer.		
8	Competencies should be defined to ensure the development of evidence-based practices and the provision of comprehensive, personalized care and quality practices. Core Competencies for Inter professional Collaborative Practice should be defined as well their assurance and assessment. Training plan to achieve core competencies by type of professional (epidemiologist, nurses, radiologists, pathologists, biologists,...) should be elaborated.	Yes	Questions addressing training requirements and strategies for educating or supporting health professionals for providing information were included in the prioritisation exercise. Quality of breast healthcare services will be covered by the *European QA scheme*.
9	Should include recommendations for training for staff e.g. in reading of mammograms, taking biopsies, communication skills.		
10	The training and licensing of radiology specialists that are to be preforming screening mammography within the screening program (first and second readers of mammograms, radiologists, supervisors) and training curricula for said training programs. Licensing procedure for radiographers (technicians) for screening mammography.		

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
11	This means 2 different things: 1. training curriculum for radiologists and pathologists (post-graduation schools) and graduation course (or equivalent) for technicians. This is not exactly the same across the 28 EU member states. Which suggestion to harmonize? 2. Specific training for radiologists, pathologists, and technicians, including proficiency tests (as already mentioned above).	Yes	Questions addressing training requirements of healthcare professionals were included in the prioritisation exercise.
12	It is worth mention the value of additional training for radiologist before entering a screening program. Please try to find out if there is enough evidence to make it an obligatory requirement for radiologist before reading screens		
13	What qualifications and training required of the radiologist who interprets mammography? What are the minimum number of mammograms a radiologist should interpret on an annual basis to maintain proficiency in screening mammography? What are the qualifications and training required of the technologist who acquires the image?	Yes	Questions addressing imaging techniques, volumes and training requirements were included in the prioritisation exercise. In addition, the *European QA scheme* will also address the question on radiologist volumes.
14	Training program and certification or exam form for radiologists, technologists, med. physicists training for screening program managers?		
15	1) Role of digital systems/databases/ training sets in order to build up and maintain the best performance in film reading 2) Role of double reading in various formats (arbitration, consensus, etc.) 3) Emphasis on positioning 4) Emphasis on specific screening reading skills 5) Emphasis on imaging-guided biopsy training. I should stress the importance of Reference Training Centre (RTC) at different levels (Regional, National, European). It should be emphasized the importance of setting up RTC/ or cooperate/or make use of the most skilled Units and experts for training and education.		
16	Radiographers continuing education: needs for updating the certification? How to handle updating and certification after long-time sick leave and maternity leave? And the radiologists after long-time sick leave and maternity leave? Recommend Internal refreshers courses?		
17	Quality control for technicians. Minimal standards for a qualified breast cancer screening and diagnosis healthcare center. Digital pathology for breast biopsies after breast cancer screening.	No	Quality of breast healthcare services will be covered by the *European QA scheme*.
18	What must be the duration of learning curve assigned in the guideline for: reporting a screening mammogram, ultrasound, core biopsy, vacuum biopsy... etc.	Yes	Questions addressing training requirements were included in the prioritisation exercise.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
19	Dedicated professional to breast: EU agency should receive a statement from EU hospital about breast program and dedicated person requiring a document stating that the dedicated professional are involved at 80% of their time.	Yes	Questions on minimal requirements for professionals involved in breast cancer screening and diagnosis were included in the prioritisation exercise.
20	In addition to habitual questions on screening professionals' specific training: What basis training should be provided to all medical and paramedical professions even if not directly involved? How to assure proper understanding of age limits for screening invitations (i.e. knowledge and updates on results of screening pilot studies and further evaluations of ongoing programs)? What information should be provided in secondary level schools to prepare right attitude and knowledge for later years among female population?	Yes	Questions addressing training requirements and optimal strategy for communicating information about breast cancer screening to the general public were included in the prioritisation exercise. However, questions addressing what training should be provided to all medical and paramedical professional concerning screening were not specifically included in the prioritisation exercise. Neither were questions on what information should be provided in secondary level schools.
21	Question linked to chapters 4, 5 and 6. If monitoring of diagnostic, treatment procedures and training via certified breast units are still ongoing (IQA and EQA, audit), identifying inadequate interventions could be identified and discouraged.	Yes	Questions addressing training requirements, monitoring and evaluation of screening and diagnosis were included in the prioritisation exercise. Quality of breast healthcare services will be covered by the *European QA scheme*.
22	Since the use of CESM imaging modality is rapidly growing in the field of breast disease, there is clearly a need to provide a consensus among experts to standardize CESM examinations reporting and to reconcile terms used to describe features on both LE image and subtracted images. The question is: Is a new CESM lexicon of standardized terminology designed to standardize CESM reporting should be elaborated?	Yes	Questions addressing imaging techniques were included in the prioritisation exercise.
23	Could there be a training programme or at least suggestion for screening registrars?	Yes	Questions on minimal requirements for professionals involved in breast cancer screening and diagnosis were included in the prioritisation exercise. Data management will be addressed within the *European QA scheme*.
24	1) quality assurance measures such as: – minimum reading/case numbers; training (courses and individual); internal quality management with certain individual statistics – reading tests, peer reviewing; multidisciplinary approach and training – sampling tests (image quality, diagnostic workup).	Yes	Questions addressing training requirements and volumes for professionals involved in breast cancer screening and diagnosis were included in the prioritisation exercise.
25	Will new European guidelines for breast cancer screening and diagnosis propose European reference training centers for all EU screening programmes personel?	Yes	Questions addressing training were included in the prioritisation exercise.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
26	Shared decision making with honest information and no pressure of doing screening without symptoms.	Yes	Questions about optimal strategy to communicate with women were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.
27	1. Accreditation/training/...: who pays? Why manages? 2. Separate new group of professionals or a second activity of current healthcare professionals?	Yes	Questions on training and minimal requirements for professionals involved in breast cancer screening and diagnosis were included in the prioritisation exercise. The economic aspects will be included in the EtD frameworks of PICO questions. Accreditations/certification will be covered by the *European QA scheme*.
28	Definition of Training Center Duties of a Training Center		
29	Availability of training and follow up programs of quality on all stages of screening (readings, positionning) and dianogstics including biopsy techniques Should all radiologists specialised in breast cancer diagnosis succed the EDBI exam organised by the European Society of Breast Imaging (different options here can be discussed).		
30	Regarding training of pathologists, the initiatives of the European Society of Pathology, like the European School of Pathology – breast pathology arm, as well as training centers in the Giordano fellowship program may be explored.		
31	How will the guidelines ensure that all healthcare providers are trained in adequate and effective communication around the need for timely treatment following diagnosis?	Yes	Questions addressing training requirements and strategies for educating or supporting health professionals for providing information were included in the prioritisation exercise.
32	Should you create a system of accreditation of professionals included in population screening programs common for Europe?	No	Accreditation/certification will be covered by the *European QA scheme*.

Table 5. List of questions suggested for inclusion in the **Interventions to reduce inequalities chapter** of the *European Breast Guidelines*

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
1	Will the panel recommend on research findings that describe how risk is best presented to those with low literacy levels?	Yes	Questions addressing optimal strategy to communicate with women and the use of targeted communication in particular subpopulations of women were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. In addition, the recommendations will be translated into lay-person language, in order to be understandable by all.
2	Reimbursement of screening not just from public services but also insurance companies; explain companies the crucial role of screening and early diagnosis. Establish ways to quickly refer women with suspicious lesions to high quality Treatment Units, where care is covered either by public system or insurance companies.	Yes	Questions addressing optimal strategy to communicate information about breast cancer screening to the general public and minimal requirements for professionals involved in breast cancer screening and diagnosis were included in the prioritisation exercise. The economic aspects will be covered in the EtD frameworks. In addition, quality of breast healthcare services will be covered by the *European QA scheme*.
3	The guidelines should be clear in providing as much information for those implementing the guidelines as possible the following questions: What are the most evidence-based strategies for ensuring that underserved populations gain the health benefits offered by the recommendations?	Yes	Questions about optimal strategy to communicate with women and the use of targeted communication in particular subpopulations of women were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. In addition, the recommendations will be translated into lay-person language, in order to be understandable by all.
4	1. How to support public and open communication? 2. How to prevent unwarranted marketing?	Yes	Questions about optimal strategy to communicate information about breast cancer screening to the general public were included in the prioritisation exercise.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
5	Define different levels of recommendations, according to the socioeconomic status of the country, as suggested by the Breast Health Global Inithiative (Cancer, Supplement: Guidelines for International Breast Health and Cancer Control–Implementation 15 October 2008 Volume 113, Issue S8 Pages i–ix, 2215-2371)	Yes	Questions about optimal strategy to communicate with women were included in the prioritisation exercise. Informed decision making is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. In addition, the recommendations will be translated into lay-person language, in order to be understandable by all. Socio-economic considerations will be some of the implementation considerations to be taken into account at a country level. In addition, the economic aspects will be covered in the EtD frameworks.
6	How will the guidelines ensure that all women who are offered a screening, regardless of factors such as socio economic status and other factors, will accept the invitation and understand the importance of receiving a screening?		
7	In addition to habitual questions on assuring access: How to involve local communities and primary care teal to motivate participation of non-attenders in organised screening programs?	Yes	Questions about optimal strategy to communicate with women and involving primary health providers in communication strategies were included in the prioritisation exercise.
8	Preference for organized population-based screening programs instead of spontaneous screening access to breast diagnostic services. Important points and priorities: 1. Total screening coverage (invitation) of the target population aged from 50 to 70 with 2 or 3 (UK) interval 2. Usage of mobile units to cover rural zones 3. Extension from 40 or 45 (1-year interval) or to 73 or 75 (2- or 3-year interval) 3. General transition to direct digital mammography for all women 4. Strategies for supporting the screening attendance and referral to diagnostic services of low-income women 5. Strategies for supporting the screening attendance and referral to diagnostic services of women coming from extra-EU countries with potential cultural or religious barriers (e.g., female technicians are essential for this issue).	Yes	Questions about age groups, screening intervals, organised vs. non-organised screening, imaging techniques, optimal strategy for communicating information about breast cancer screening to socially disadvantaged women were included in the prioritisation exercise.
9	The diagnosis and treatment of breast cancer in those over 70 years.	Yes	Questions about diagnostic procedures were included in the prioritisation exercise. The *Guidelines Platform*, as collection of existing evidence-based guidelines, can include recommendations on treatment for all breast cancer patients.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
10	Encourage cooperation across borders, centres. Exchange cases to review both for diagnosis and for images quality.	Yes	Questions on training and minimal requirements for professionals involved in breast cancer screening and diagnosis were included in the prioritisation exercise.
11	The presence of an appropriate skill mix based on defined competences to enable efficient, flexible and cost effective reporting of images.		
12	Question linked to chapters 4, 5 and 6. If monitoring of diagnostic, treatment procedures and training via certified breast units are still ongoing (IQA and EQA, audit), inadequate interventions could be identified and discouraged.	Yes	Questions addressing training requirements, monitoring and evaluation of screening and diagnosis were included in the prioritisation exercise. Quality of breast healthcare services will be covered by the *European QA scheme*.
13	Breast cancer screening in low-middle income countries: time for a reappraisal? Reimbursement policies to favour universal access to breast cancer screening. Opportunistic screening for relatives of hospitalized patients.	Yes	Questions addressing barriers and facilitators to screening participation were included in the prioritisation exercise. Socio-economic and organisational considerations will be some of the implementation considerations to be taken into account at a country level. In addition, the economic aspects will be covered in the EtD frameworks.
14	Breast US and clinical examination for low income countries?		
15	Are there any regulations about how many screening units should be on certain amount of population?		
16	Should be addressed without lowering already established high standards in individual countries.		
17	What are the most effective methods to increase participation in hard to reach group? Tailored recruitment: Are different strategies for recruitment used for different groups in the population? Is this effective?	Yes	Questions addressing barriers and facilitators to screening participation were included in the prioritisation exercise.
18	Would the expert panel consider the use of CESM as an alternative to MRI especially considering the case of patients with MRI contra indications, patients with limited access to MRI or regional areas with limited availability of MRI.	Yes	Questions about imaging techniques were included in the prioritisation exercise.
19	This is difficult with the differences in availability of screening and in quality of screening in different countries. Is it possible to have recommended minimum standards re availability of screening and the quality of imaging technology, reading, unit appearance/ comfort etc.	Yes	Questions about training, minimal requirements for professionals involved in breast cancer screening and diagnosis, monitoring and evaluation of screening and optimal strategy for communicating information about breast cancer screening to socially disadvantaged women were included in the prioritisation exercise. Quality of breast healthcare services will be covered by the *European QA scheme*.
20	Try to define the minimum quality criteria for mammography equipment used in screening as well as reading stations.		
21	Basic screening benchmarks data base creation and spread in the EU countries for evaluation of programs, data collection and inequalities reduction.		

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	Reasoning
22	Would the expert panel consider the use of CESM as an alternative to MRI especially considering the case of patients with MRI contra-indications, patients with limited access to MRI or regional areas with limited availability of MRI?	Yes	Questions on imaging techniques were included in the prioritisation exercise.

Table 6. List of questions suggested for inclusion in the **chapter about Monitoring and evaluation of screening and diagnosis** of the *European Breast Guidelines*

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	Reasoning
1	Will monitoring and evaluation include questions around the patient experience of screening, from call, through testing, the manner of recall and final delivery of screening findings?	Yes	Questions about appropriate indicators for monitoring informed choice, diagnostic process and standardized reporting in diagnosis in a population-based screening program with mammography were included in the prioritisation exercise.
2	Which are the requirements for an independent and adequate evaluation of outcome that enables both the public and the policy makers to decide on participation or continuation?	Yes	Questions about the most relevant process and performance indicators of an efficient population-based screening programme and appropriate indicators to be reviewed in an external audit were included in the prioritisation exercise.
3	One of the outcomes of the screening in an initial phase could be modification of breast cancer incidence, modification of the type of tumour diagnosed (intraductal carcinomas), different stages of tumours. Should also this be taken into consideration?		
4	It is important to describe the differences between monitoring and evaluation. It would also be helpful to describe a minimal set of relevant indicators (for example based on the ECHI method) to facilitate international comparison of screening programmes.		
5	Will new European guidelines for breast cancer screening and diagnosis provide new acceptable levels of breast screening performance indicators? Will the provide clarifications / exact definitions about methodology how to calculate those indicators? This is necessary for reporting and comparisons.	Yes	Questions about the most relevant process and performance indicators of an efficient population-based screening programme were included in the prioritisation exercise. In addition, the Monitoring and evaluation chapter of the *European Breast Guidelines* will contain recommended thresholds of relevant indicators.
6	Quality indicators for evaluation of screening with a scheme and/or table explaining a minimal threshold for the quality of screening and tips on how to obtain it.		

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
7	I think the evaluation of the impact of screening programme on general population should be encouraged and properly carried out. Experiences as Euroscreen working group on this issue should be encouraged to continue.	Yes	Questions about the most appropriate study design to evaluate the impact of a population-based screening program with mammography and the relevant indicators were included in the prioritisation exercise.
8	There should be recommendations re audit – especially of recalls and of interval cancers – false negatives should be assessed and explained to patients as well as commissioners & primary care doctors. Patient assessment of the screening unit should also be sought and suggestions for improvement welcomed.	Yes	Questions about the most appropriate indicators to be reviewed in an external audit were included in the prioritisation exercise.
9	Will the monitoring and evaluation of screening and diagnosis also take into account how many patients receive appropriate and adequate care in a timely manner? One in 10 women waited ≥ 60 days to initiate treatment after a diagnosis of breast cancer. Waiting ≥ 60 days to initiate treatment was associated with a significant 66% and 85% increased risk of overall and breast cancer-related death. Source http://1.usa.gov/1P2GI9C How will the guidelines connect and complement the development of national cancer registries and their coordination via the European Network of Cancer Registries to allow monitoring the effectiveness of the fight against breast cancer? Source http://bit.ly/1nl7v4D	Yes	Questions about the most relevant process and performance indicators of an efficient diagnostic process and an efficient population-based screening programme were included in the prioritisation exercise. Data management will be addressed within the *European QA scheme*.
10	In addition to habitual questions; How to evaluate communication process, over diagnosis and risk of overtreatment.	Yes	Questions about the appropriate indicators for monitoring informed choice in a population-based screening program with mammography were included in the prioritisation exercise. Overdiagnosis is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
11	1/ How to take into account neoadjuvant chemotherapy in the reporting of cancer stages? 2/ How to take into account the molecular signatures (basal type / luminal type)? 3/ Set criteria for identifying the risk of overdiagnosis (see IDLE condition (Indolent Lesion of Epithelial origin), Dr. Laura Esserman) Thank you.	Yes	Questions on histopathological procedures and parameters, prognostic and predictive pathological markers were included in the prioritisation exercise. Overdiagnosis is considered looking at the different outcomes. Desirable and undesirable effects of outcomes are examined using EtD frameworks for each PICO question in order to decide what the balance is, which might influence the direction of the corresponding recommendation. In addition, Reference documents will be provided to support ECIBC implementation. Data management and the quality of breast healthcare services (including neoadjuvant chemotherapy) will be addressed within the *European QA scheme*.
12	The new guidelines should define the relevance of screening performance analysis, not only in terms of attendance rate, detection rate, recall rate, benign/malignant biopsy rate, tumor size and stage of detected cancers, etc, but also in terms of interval cancers and T2-stage screen-detected cancers for each local screening program. This analysis should be strongly suggested to all screening programs as one of the best indicators of performance, also because the open discussion of all the cases among the radiologists enhances diagnostic skills.	Yes	Questions about the most relevant process and performance indicators of an efficient diagnostic process and an efficient population-based screening programme were included in the prioritisation exercise.
13	Registration of interval cancers should be included as part of a nationwide screening program.		
14	What is an appropriate population particapation rate for organzied population bases breast cancer screening? What is an appropriate abnormal call rate for initial screens and for subsequent screens? What is an appropriate PPV for the screening test? What is the appropriate length of the screening episode? (ie. amount of time from an abnormal screening to definitive diagnosis of benign or cancer). What proportion of cancers, that are screen detected, have a tumour size of 15 mm or less? What proportion of cancers, that are screen detected, have node negative? What is an appropriate non-malignant biopsy rate?	Yes	Questions about the most relevant process and performance indicators of an efficient population-based screening programme were included in the prioritisation exercise. In addition, the Monitoring and evaluation chapter of the *European Breast Guidelines* will contain recommended thresholds of relevant indicators.
15	Would the expert panel please share their evaluation of digital breast tomosynthesis equipment and the acceptance criteria for screening and diagnosis?	Yes	Questions about imaging techniques, the most relevant process and performance indicators of an efficient diagnostic process and an efficient population-based screening programme were included in the prioritisation exercise.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
16	1) I suggest that a minimum set of indicators should be used for quick check-up, based on results at subsequent examinations (incidence screening indicators) 2) The utmost importance should be given to the absolute rate of Stage T2+ advanced cancers in the population, regardless of their mode of detection as Interval Cancers or as Screen-Detected Cancer. 3) These T2+ cases should form the main basis for radiological revision as a means of internal audit and external evaluation and training. 4) Monitoring should be aimed to get as far as to the individual operator level 5) Clear recommendations as to the steps to implement should be given in cases of insufficient or critically low indicators of performance 6) Special funds should be reserved for setting up not only the monitoring system; Reference Training Centres should be adequately funded and maintained.	Yes	Questions about the most relevant process and performance indicators of an efficient diagnostic process and an efficient population-based screening programme were included in the prioritisation exercise. Socio-economic and organisational considerations will be some of the implementation considerations to be taken into account at a country level. In addition, the economic aspects will be covered in the EtD frameworks.
17	How can the quality of a breast cancer screening programme be assured on a long term? What are good examples of how quality assurance (QA) activity is implemented in the breast cancer screening programme? How to assure the quality of the mammography production and reading process chain? What are the threats to quality assurance in BC screening programs (i.e. regression towards the mean, insufficient statistical power)?	Yes	Questions about the most relevant process and performance indicators of an efficient diagnostic process and an efficient population-based screening programme, the appropriate timescale for each (surrogate) impact indicator of evaluation of a population-based screening programme with respect to precision in the estimates (statistical power) were included in the prioritisation exercise. Quality of breast healthcare services will be covered within the *European QA scheme*.
18	The guidelines should be clear in providing as much information as possible the following questions: How will our health system show that its management of breast cancer screening and diagnosis is achieving important health outcomes for citizens?	Yes	Questions about the requirements for an independent and adequate evaluation of outcomes that enables both the public and the policy makers to decide on participation or continuation of a screening programme were included in the prioritisation exercise.
19	Dose limitations? Regularly feedback to radiographers on image quality? Regularly feedback to radiologists on recall rate?	Yes	Questions about the process and performance indicators that will be communicated to professionals were included in the prioritisation exercise.

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
20	Monitoring and release an EU statement on the indicators to be followed as Indicator Number of screens, Number of 1 screens, Number of cancers, Participation Rate, Retention Rate, 1 screen, Re-screen, Abnormal Screen Rate,1 screen, Re-screen, Invasive Cancer Rate,1 screen, Re-screen, In Situ cancer Rate,1 screen, Re-screen, Diagnostic Interval, No open biopsy, With open biopsy, Positive Predictive Rate 1 screen, Re-screen, B : M open biopsy ratio, Invasive ca tumor size, Node negative cancers, Indicator Post Screen Detected, Invasive Cancer Rate 2, within 12 months, within 24 months).	Yes	Questions about the most relevant process and performance indicators of an efficient population-based screening programme were included in the prioritisation exercise. In addition, the Monitoring and evaluation chapter of the *European Breast Guidelines* will contain recommended thresholds of relevant indicators.
21	The shape and detail of the quality assurance programme.	Yes	Questions addressing training requirements, monitoring and evaluation of screening and diagnosis were included in the prioritisation exercise. Quality of breast healthcare services will be covered by the *European QA scheme*. Socio-economic and organisational considerations will be some of the implementation considerations to be taken into account at a country level. In addition, the economic aspects will be covered in the EtD frameworks.
22	Essential that funding is available to ensure that any breast cancer screening programme is routinely and objectively evaluated.		
23	Question linked to chapters 4 and 6. If monitoring of diagnostic, treatment procedures and training via certified breast units are still ongoing (IQA and EQA, audit), identifying inadequate interventions could be identified and discouraged.		
24	What is the actual effectiveness of mammographic screening (according to different selected outcomes) in Europe performed according to the current EU recommendations? How does it differ if mammography is performed every year in the same age groups? What is the comparative cost-effectiveness across different countries? What is the rate of interval cancer in the screened population when screening is performed according to the current EU recommendations? What is the rate of over-diagnosis? What is the combination of timing (e.g., once a year, once every two years), test/s (e.g., mammography, ultrasound, polygene testing) and age/risk profile (e.g., age group, mammographic density, genetic profile) that could optimize these outcomes?	Yes	Questions about the most relevant process and performance indicators of an efficient population-based screening programme, age groups, screening intervals, imaging techniques and varying the screening regimen depending on certain risk factors were included in the prioritisation exercise. In addition, cost effectiveness is part of the EtD frameworks for each recommendation.
25	Will the guidelines include a recommended minimum data set for monitoring and evaluation of the program?	Yes	Questions about the most relevant process and performance indicators of an efficient population-based screening programme were included in the prioritisation exercise. Data management and the quality of breast healthcare services will be addressed within the *European QA scheme*. In addition, Reference documents will be provided to support ECIBC

Sequence number	Comments	Consideration for modification of *The Scope* of the *European Breast Guidelines*	
		Decision	**Reasoning**
26	Consider defining minimum dataset and data formats for facilitating EU-wide comparisons of evaluation.		
27	Screening data must be published in each country and centrally in EU. There must be proof that the screening is being effective, for example, through the decrease in the median size of the tumor at diagnosis, from the decrease of late diagnosis. The submission of data should be mandatory to an independent body, preferably at a EU level, that analysis the data and verifies the quality of the screening. This is lacking and in many countries too much money is wasted in bad quality screening programs that have no independent verification.		
28	1) clear minimal documentation record (set of parameters: screening, diagnoses, post-operative outcome – therapy and prognostic factors) 2) review and update of existing and established performance indicators.	Yes	Questions on minimal requirements for standardised reporting in diagnosis and the most relevant process and performance indicators of an efficient population-based screening programme were included in the prioritisation exercise.
29	Evaluation population based screening is impossible. Let's stop to pay money for useless research.	Yes	Questions about the most appropriate study design to evaluate the impact of a population-based screening programme were included in the prioritisation exercise. The economic aspects will be covered in the EtD frameworks.
30	1. Accreditation/training/...: who pays? Why manages? 2. Separate new group of professionals or a second activity of current healthcare professionals?	Yes	Questions about training and minimal requirements for professionals involved in breast cancer screening and diagnosis were included in the prioritisation exercise. Accreditation/certification will be covered by the *European QA scheme*. The economic aspects will be covered in the EtD frameworks.
31	Should the results of the evaluation of the professionals involved in screening and diagnostic unit's programmes be public?	Yes	Questions about the requirements for an independent and adequate evaluation of outcome that enables both the public and the policy makers to decide on participation or continuation of a screening programme were included in the prioritisation exercise.

Annex 4

List of questions for prioritisation for inclusion in the *European Breast Guidelines*

LIST OF QUESTION FOR PRIORITISATION

(The number before each question refers to inclusion in the relevant chapter of the European Breast Guidelines – 1. Screening, 2. Diagnosis, 3. Communication, 4. Training, 5. Inequalities, 6. Monitoring and evaluation; RD – Reference document)

1.1 Which is the optimal age range in which to carry out mammography screening?

1.1.1 Is breast cancer screening effective in reducing breast cancer mortality?

1.1.2 Does breast cancer screening affect deaths from other causes than breast cancer?

1.2 Should mammography screening once a year vs other screening frequencies be used for early detection of breast cancer in asymptomatic women?

1.3 Should BIRADS system vs R-type system or others be used to report readings in a screening programme for asymptomatic women?

1.4 Should Screening with reader recall triggering vs single reading be used for screening asymptomatic women with breast cancer risk

1.5 Should Screening with double reading with consensus or arbitration vs single reading be used for screening asymptomatic women with breast cancer risk

1.6 Should Screening using digital breast tomosynthesis vs single reading mammography be used for screening asymptomatic women with breast cancer risk

1.7 Should Screening with breast MRI vs single reading mammography be used for screening asymptomatic women with breast cancer risk

1.8 Should Screening with breast MRI and mammography vs single reading mammography be used for screening asymptomatic women with breast cancer risk

1.9 Should a high number of mammographic views vs a low number of mammographic views be used for screening women eligible for BC screening?

1.10 Should ultrasound plus mammography vs mammography by itself be used for screening breast cancer in women with dense breasts?

1.11 Should ultrasound plus mammography vs mammography by itself be used for screening breast cancer in women eligible for BC screening?

1.12 Should physical examination together with mammography vs. mammography alone be used for screening for BC in women eligible for BC screening?

1.13 Should screening using digital breast tomosynthesis together with mammography vs mammography alone be used for screening for BC in women eligible for BC screening?

1.14 Should screening using digital breast tomosynthesis together with mammography vs mammography alone be used for screening for BC in women eligible for BC screening?

1.15 Should screening using MRI vs mammography be used for screening for BC in women eligible for BC screening?

1.16 Should screening using MRI together with mammography vs mammography alone be used for screening for BC in women eligible for BC screening?

1.17 Should organised screening vs non-organised screening be used for screening asymptomatic women with breast cancer risk

1.18 Which risk factors are necessary to assign women to screening protocols different from the strategy used for average risk populations?

2.1 Should standardized reporting versus no standardized reporting be used in the reporting of imaging results?

2.2 Which classification system should be used for the different imaging techniques (Mx; Ultrasound; MRI; Tomosynthesis/synthetized 2D mammogram; CESM)?

2.3 In women with screening detected abnormalities ("Mx positive": mass lesion, microcalcification, asymmetric density or architectural distortion), what are the effects of each technique (Breast examination?; Mx magnification (with and without spot compression)?; Ultrasound?; Tomosynthesis/synthetized 2D mammogram?; MRI?; CESM (contrast enhanced spectral mammography) depending on the lesion?

2.4 Should contralateral ultrasound vs clinical breast examination or no intervention on contralateral breast be used in women with suspect of breast cancer (screening mx positive)

2.5 In symptomatic women >=40yo with suspicion of breast cancer, what are the effects of the different imaging techniques (Should Mx, Ultrasound, Tomosynthesis/synthetized 2D mammogram, MRI, CESM) depending on the symptoms (swelling of all or part of the breast, skin irritation or dimpling, unilateral breast pain, nipple pain or the nipple turning inward, redness, scaliness, or thickening of the nipple or breast skin, a nipple discharge other than breast milk, a lump in the underarm area)

2.6 Should Mx, Ultrasound, Tomosynthesis/synthetized 2D mammogram, MRI, or CESM be used to diagnose breast cancer in symptomatic women aged <40?

2.7 Should Mx, Ultrasound, Tomosynthesis/synthetized 2D mammogram, MRI, or CESM be used to diagnose breast cancer in symptomatic pregnant or breast-feeding women?

2.8 Should MRI or other imaging techniques be used to diagnose breast cancer in patients with clinical symptoms who have normal Mx and ultrasound?

2.9 Should Mx, Ultrasound, Tomosynthesis/synthetized 2D mammogram, MRI, or CESM be used to diagnose breast cancer in women with augmentation implants, either symptomatic or asymptomatic?

2.10 Should any additional assessment procedure vs standard assessment procedure be used to diagnose breast cancer in women with familiar hereditary risk of cancer?

2.11 Should a particular algorithm vs any comparison be used for identifying women at high risk of cancer?

2.12 Should US guided FNAC; US guided CNB; Mx guided VAB; Tomosynthesis guided CNB/VAB; MRI guided CNB; or Surgical biopsy after localization vs. any comparison be used in women (screening and symptomatic) with suspect lesions (BI-RADS IV/V: mass lesion, microcalcification, architectural distortion)?

2.13 Should cyto/histological sampling and pathological analysis vs no further analysis be used in women with symptoms suggestive of cancer but with negative Mx and US?

2.14 Should an increased length of biopsy (up to 22 mm) versus the minimal length (15 mm) be used in women positive after imaging second level assessment for breast cancer using Tru-cut CNB?

2.15 Should an increased length of biopsy (up to 7G) versus the minimal thickness (from 16G) be used in women positive after imaging second level assessment for breast cancer using Tru-cut CNB?

2.16 Should a one use system versus reusable body be used in women positive after imaging second level assessment for breast cancer using Tru-cut CNB?

2.17 Should standard anaesthetic protocol versus alternative protocols be used in women positive after imaging second level assessment for breast cancer using Tru-cut CNB?

2.18 Should standard sterilization protocol versus using alternative sterilization protocols be used in women positive after imaging second level assessment for breast cancer using Tru-cut CNB?

2.19 Should increasing length of biopsy versus the minimal length be used in women positive after imaging second level assessment for breast cancer using Vacuum Assisted Biopsy (VAB)?

2.20 Should increasing thickness of biopsy versus the minimal thickness be used in women positive after imaging second level assessment for breast cancer using Vacuum Assisted Biopsy (VAB)?

2.21 Should a one use system versus reusable body be used in women positive after imaging second level assessment for breast cancer using Vacuum Assisted Biopsy (VAB)?

2.22 Should standard anaesthetic protocol versus alternative protocols be used in women positive after imaging second level assessment for breast cancer using Vacuum Assisted Biopsy (VAB)?

2.23 Should standard sterilization protocol versus alternative sterilization protocols be used in women positive after imaging second level assessment for breast cancer using Vacuum Assisted Biopsy (VAB)?

2.24 Should more than one core sampled versus one core sampled be used in women positive after imaging second level assessment for breast cancer and undergoing core-biopsy?

2.25 Should clip marking of the biopsy site versus no clip marking be used in women positive after imaging second level assessment for breast cancer and undergoing core-biopsy?

2.26 Should imaging control after biopsy versus no imaging control be used in women positive after imaging second level assessment for breast cancer and undergoing core-biopsy, by sub groups

2.27 Should immediate imaging control after biopsy versus delayed imaging control after biopsy be used in women positive after imaging second level assessment for breast cancer and undergoing core-biopsy needing imaging control after biopsy

RD 2.1 Which criteria indicate that a biopsy has been performed properly?

2.28 Should pretreatment ultrasound of the axilla and/or of the fossa supraclavicularis versus no pretreatment be used in patients with breast cancer to determine node status and treatment options?

2.29 In patients with breast cancer who have had ultrasound of the axilla performed, what features on ultrasound indicate that fine needle aspiration or core biopsy are required?

2.30 Should sentinel lymph node versus no sentinel lymph node be used in women with ascertained DCIS (by sub groups of risk available according to data from assessment (diameter; grading; morphology)?

2.31 Should sentinel lymph node versus no sentinel lymph node be used in women with ascertained invasive cancer, by sub groups of risk available according to data from assessment (clinical T; grading; morphology)?

2.32 In women with ascertained invasive cancer or DCIS that should undergo to SLN, which is the adequate detection technique (Radioactive tracer, Blue dye, or both)

2.33 In women with ascertained invasive cancer or DCIS that should undergo to SLN, which is the recommended needle size?

2.34 In women with ascertained invasive cancer or DCIS that should undergo to SLN, which is the recommended injection site?

RD 2.2 When should the injection be considered non-satisfactory?

2.35 Should a minimal number of sentinel lymph node sampling strategy (i.e. mostly 1 or 2) versus multiple SLN sampling strategy be used in women with ascertained invasive cancer or DCIS?

2.36 In women with ascertained invasive or DCIS undergoing surgery, which lesions are candidates for localization?

2.37 Should imaging localization with blue dye or ROLL versus imaging localization with wire be used in women with ascertained invasive or DCIS undergoing surgery and needing imaging guided localization?

2.38 Should trans tumoral localization or intratumoral localization versus peritumoral localization be used in women with ascertained invasive or DCIS undergoing surgery and needing imaging guided localization?

2.39 Which mammographic projections must be performed after wire marking in women with ascertained invasive or DCIS undergoing surgery and needing imaging guided localization?

RD 2.3 When is the wire marking non-satisfactory? (QA question)

2.40 Should post surgery imaging versus no post surgery imaging be used in women with ascertained invasive or DCIS undergoing surgery, by subgroup of risk (needing or not needing pre-surgery localization according to Q1; diameter; clinical characteristics?

RD 2.4 How should post-operative sample imaging be done? (time, piece orientation, disposal..)

2.41 Should same imaging as preoperatory versus any imaging method be used in women with ascertained invasive or DCIS undergoing surgery and needing imaging guided localization pre and after surgery?

RD 2.5 What are the minimum requirements for standardized workup of the specimens?

2.42 Should step section versus standard sectioning be used to diagnose DCIS/invasive carcinomas in women?

2.43 How many step sections are needed to diagnose DCIS/invasive carcinomas in women with calcifications sampled by VAB?

RD 2.6 What are the minimum requirements for standardized reporting the results of cyto-/ histological assessment?

RD 2.7 In case of DCIS and invasive breast carcinoma: What are the minimum parameters that have to be assessed?

2.44 In women with A) DCIS or B) invasive breast cancer in breast biopsy for suspect of cancer, which are the known prognostic factors and predictive that can be assessed in a standard pathologic assessment?

RD 2.8 Which are the prognostic factors needed to be defined pre-surgery therapeutic plan?

RD 2.9 What are the minimum requirements for standardized workup of the specimens?

RD 2.10 What are the indications for intra-operative frozen sectioning?[1][1] Now it is recommended: Women with a palpable suspect mass lesion > 1,0 cm: a) without pre-operative diagnosis (i. e. because of pre-pectoral localization) for definite surgery within one intervention; b) for margin assessment. SLN: If positive SLN results in axillary dissection. Since ACOSOG Z0011 in Germany most patients with breast conserving therapy have no axillary dissection if one or two SLNs are histologically positive. Only those women with mastectomy who will not be irradiated are candidates for axillary dissection if SLN are positive. In consequence we perform frozen sections of the SLNs only in these patients.

RD 2.11 What are the minimum requirements for standardized reporting the results of histological assessment?

RD 2.12 In case of DCIS and invasive breast carcinoma: What are the minimum parameters that have to be assessed?

2.45 Which are the known prognostic and predictive factors that can be assessed in a standard pathologic assessment?

RD 2.13 Which are the prognostic factors to define post-surgery therapeutic plan?

2.46 In patients with invasive breast cancer, which ER and/or PR cut-offs (1% or 10%) indicate responsiveness to endocrine therapy?

2.47 In patients with invasive breast cancer, which parameter ((a) Ki67 and (b) Multiparameter molecular test) helps to differentiate ER-positive carcinomas (luminal A- and B-like) with regard to responsiveness to cytotoxic therapies

2.48 In patients with invasive breast cancer, which are the most useful multiparameter molecular tests to differentiate ER-positive carcinomas (luminal A- and B-like) with regard to responsiveness to cytotoxic therapies?

2.49 Should HER2 testing be repeated on surgical specimen versus no repetition of HER2 testing on surgical specimen be used in patients with invasive breast cancer with negative HER2-status on CNB/VAB and histological grade 3?

2.50 Should HER2 testing be repeated on surgical specimen versus no repetition of HER2 testing on surgical specimen be used in invasive breast cancer with borderline HER2-status on CNB/VAB (IHC Score 2+ and HER2/CEP17 Ratio <2,0, HER2 copy number > 4 and < 6/cell)?

2.51 In women with breast cancer, who/what subgroups should have staging investigations performed to detect metastases?

2.52 In women with breast cancer who are being staged, what investigations should be performed?

2.53 Should all women have quantification of breast density and how should it be done and reported?

RD 2.14 What are the minimum quality requirements for the breast imaging techniques: Mx (compression, doses, quality of imaging etc.)?; Ultrasound (MHz, transducer, room lighting..)?; Tomosynthesis?; MRI?; CESM?

RD 2.15 Should there be a uniform system for radiographic image quality assessment?

2.54 What are adequate quality assurance schemes for radiological-pathological correlation?

2.55 Should imaging follow-up versus not performing imaging follow-up be used in patients with benign histopathology (B2) after suspect imaging (BIRADS IV/V) (and when?)?

2.56 Which safety issues must be taken into account when injecting radioisotopes in an ultrasound/XR setting?.

2.57 Which is the recommended time period between assessment and diagnosis?

2.58 Which is the recommended time period between diagnosis and intervention?

2.59 Should discussion of the patient's case at the multidisciplinary team meetings versus any comparison be used in breast cancer to improve patient's outcomes?

RD 2.16 How can we optimize the process between a positive mammography result and diagnostic verification (i.e., to minimize delay without losing quality of the services)?

RD 2.17 What are the most effective strategies to develop integrated cancer care during the screening and diagnostic processes of breast cancer (for example, by using common clinical guidelines, management protocols and strategies of care etc.)?

2.60 Should standard mammography views vs other views be used to diagnose breast cancer in women?

3.1. What is the optimal strategy used for communicating information about breast cancer Screening programmes to the general public?

3.2 Should a multimodal intervention in addition to written information vs only written information be used for communicating information about BC screening to the general public?

3.3 What are the currently available strategies for educating or supporting health professionals for providing information about BC screening to the general public?

3.4 What is the optimal strategy for providing the information needed to increase informed participation in breast cancer Screening programmes to the general public?

RD 3.1 What are the key steps in developing and testing BC messages and materials? Which characteristics should the written communication tools have in order to be understandable ?

3.5 Should targeted communication vs general communication be used in particular subpopulations of women in order to increase informed participation in breast cancer screening programmes?

RD 3.2 Which kind of tailored strategies for informing women in screening could be recommended?

RD 3.3 What are the benefits and harms of tailored strategies for informing women in screening in different population groups?

RD 3.4 What communication aids should be introduced in BC screening to enhance women's understanding about harms and benefits of BC screening?

3.6 Should primary health providers be involved in communication strategies vs not involving them be used for providing information to women invited for screening on BC screening

RD 3.5 How can we ensure appropriate communication skills training for all health care professionals engaged in a screening?

3.7 Should social media or electronic communication vs other interventions be used to implement a BC screening programme?

3.8 Should a community based-intervention vs no intervention be used to implement BC screening programmes?

RD 3.6 What characteristics should have the BC screening programme website?

3.9 Should advocacy groups and other relevant stakeholders vs not involving them be used for providing information to the general public on BC screening?

3.10 What quality indicators are currently used to evaluate the effectiveness of communicating information to the general public concerning BC screening?

3.11 Which active invitation strategy is more effective in improving participation in breast cancer screening among women?

RD 3.7 What are the effects of an individual invitation letter on participation to screening as compared to invitation by phone in women aged 50 – 69 years (potentially also in women aged 40 – 49 years and 70 – 75 years, if the data exist)?

RD 3.8 What are the effects of sending a flyer on breast cancer along with the invitation letter on participation to screening?

RD 3.9 What are the effects of sending a pre-invitation letter before the invitation letter on screening participation?

3.12 Should a telephone or text message reminder vs nothing be used to increase participation in breast cancer screening programmes?

3.13 Should a re-invitation letter vs nothing be used to increase participation of non-responders to first invitation in breast cancer screening programmes?

RD 3.10 What information should be included in the invitation letter (in case of invitation letter+ leaflet) ?

RD 3.11 What information should be included in the leaflet (in case of invitation letter+ leaflet) ?

RD 3.12 Who, how and when should communicate benefits and harms of mammography screening. a. How the concept of BC development risk and risk reduction should be communicated to women invited to screening

3.14 Should providing information about benefits and harms vs not providing it be used in women invited to participate in screening?

3.15 Should the GP vs other strategies be used to invite women eligible for screening in order to increase well-informed participation of women in breast cancer screening programmes?

3.16 Should public campaigns vs nothing be used to increase participation of women in breast cancer screening programmes

RD 3.13 What information should be included in the letter and leaflet used to notify results?

3.17 What is the optimal and timely strategy to inform women who have a negative result in order to decrease their anxiety

3.18 What is the optimal and timely strategy to invite women for further assessment?

RD 3.14 If further investigations are needed, what is the maximum time limit (in days) for those to be performed to avoid mental burden and anxiety?

RD 3.15 How the need of further investigations should be communicated to women to reduce the mental burden and anxiety?

3.19 Should a contacting strategy vs no strategy be used in non-responders to further assessment to improve BC detection rate?

3.20 What is the optimal and timely strategy to communicate results to women who were positive to screening?

RD 3.16 If further investigation results in a diagnosis of breast cancer, what type of health care professionals should this be and what type of communication skills training should be mandatory for this person?

RD 3.17 What is the most effective way to ensure proper referral or transition from the screening program to treatment in a breast unit.

RD 3.18 How should this referral be communicated to the woman to minimise anxiety?

RD 3.19 What methods should be employed to ensure that a smooth transition has taken place?

RD 3.20 What are the most effective methods for maintaining clear lines of communication between hospital breast units and primary care teams?

3.21 What is the optimal and timely strategy to invite women who tested negative in the previous screening round for the next screening round?

RD 3.21 How and how often BC screening outcomes should be communicated to the relevant stake holders and to the general population? a. Specifically for what concerns QA protocols and QA outcomes

RD 3.22 What kind of interventions intended to promote informed decisions by women in breast cancer screening are the most effective?

RD 3.23 Does giving the patient balanced information decrease anxiety and reduce decisional conflict?

3.22 Should an intervention where the radiographer explains the screening procedure vs one where he does not explain the procedure be used to increase patient experience/ satisfaction with BC screening programmes

RD 3.24 How does the explanation of the screening procedure by the radiographer affect the patient experience and patient satisfaction?

RD 3.25 What communication methods have been shown to be most effective in improving women's satisfaction and/or reducing anxiety?

3.23 Should a decision aid that explains pros and cons of screening vs a normal invitation letter be used to inform patients about the benefits and harms of BC screening

RD 3.26 What are the best ways (examples) in delivering clear and balanced information concerning screening?

RD 3.27 How does the information delivered (quality, quantity and means of information) affect the participation in screening

RD 3.28 How will the new BC screening Guidelines and updates be disseminated to the public, Breast Units, patients and professionals?

4.1 Should a minimum academic background versus any comparison be used to allow radiologist readers to start in a mammography screening program?

4.1.1 What should be the minimum requirements for a reader to start in a mammography screening program

4.2 Should a minimum number of readings versus any comparison be used to allow radiologist readers to start in a mammography screening program?

4.3 Should a minimum weeks of readings versus any comparison be used to allow radiologist readers to start in a mammography screening program?

4.4 Should a minimum threshold in sensitivity and specificity for radiologist readers versus any comparison be used to allow readers to start in a mammography screening program?

4.5 Should a minimum number of readings versus any comparison be used to maintain the license as a radiologist reader in a mammography screening program?

4.5.1 What should be the minimum requirements for a reader to maintain the license in a mammography screening program

4.6 Should a minimum weeks of readings versus any comparison be used to maintain the license as a radiologist reader in a mammography screening program?

4.7 Should a minimum threshold in sensitivity and specificity for readers versus not requiring any threshold be used to maintain the license as a reader in a mammography screening program?

4.8 Should a minimum training versus any comparison be used to maintain the license as a reader in a mammography screening program?

RD 4.1 What are the passing thresholds in a yearly reading regarding the sensitivity and the specificity?

4.9 Should a maximum number of readings per day versus any comparison be used for radiologists working in breast cancer screening?

4.10 Should radiologists specialized in breast cancer imaging versus not being specialized be used in breast cancer screening?

4.10.1 Does the specialization on breast imaging (diagnostic and/or screening) have any impact?

4.11 Should radiologists specialized in breast cancer imaging versus not being specialized be used in diagnosis of breast cancer?

4.12 Should a minimum number of mammograms versus any comparison be used to maintain the license as a radiologist in diagnostic mammography?

4.12.1 What should be the minimum requirements for a radiologist to maintain the license in diagnostic mammography

4.13 Should continuous medical education versus any comparison be used to maintain the license as a radiologist in diagnostic mammography?

4.14 Should continuing exams versus any comparison be used to maintain the license as a radiologist in diagnostic mammography?

RD 4.2 Which courses are mandatory for a radiologist in diagnostic mammography

RD 4.3 What are the rules for maintaining his/her licenses as a radiologist in a diagnostic mammography?

RD 4.4 What are the minimum requirements for a radiologist/senologist doing assessment in a woman with mammographic abnormalities in the context of a screening program or diagnostic procedure?

RD 4.5 What are the minimum requirements for a radiologist/senologist doing assessment in a mammography screening program/diagnostic procedure to maintain his/her licence?

4.15 Should a minimum number of readings of mammograms versus any comparison be used in mammography diagnosis

4.16 Should a specialisation on breast diagnostic imaging vs no specialisation on breast diagnostic imaging be used for radiologists or senologists working in breast cancer diagnostic services?

RD 4.6 Are all these requirements mandatory for radiologist doing diagnostic mammography?

RD 4.7 What are the minimum standards and requirements for continuous professional development (CPD), to ensure that practinioners remain up to date on contemporary studies/issues in their field of specialty?

RD 4.8 What are the minimum standards and requirements for continuous professional development (CPD), to ensure that practitioners understand links to other disciplines?

4.17 Should a minimum training versus any comparison be used to participate as a radiographer in a mammography screening program?

4.18 Should a minimum training versus any comparison be used to participate as a radiographer in a diagnostic mammography service

RD 4.9 What are the minimum requirements for a radiographer in a screening program regarding quality measured as in performing mammography?

RD 4.10 What are the rules for maintaining a licenseas a radiographer in a screening program/ diagnostic mammography?

RD 4.11 What are the minimimun requirements in respect of academics and test readings for a radiographer to start as a reader in a mammography screening program

4.20 Should a minimum training versus any comparison be used to participate as a pathologist in a mammography screening program?

4.21 Should a minimum training versus any comparison be used to participate as a pathologist in a diagnostic mammography service

RD 4.12 Which are the minimum requirements for a pathologist, in breast pathology diagnostic experience, in a screening program?

RD 4.13 What are the rules for maintaining a licence as a pathologist in a screening program?

4.19 Should a specialisation on breast diagnostic imaging vs no specialisation on breast diagnostic imaging be used for pathologists working in breast cancer diagnostic services?

4.20 Should a minimum training versus any comparison be used to participate as a specialized nurse in a mammography screening program?

RD 4.14 What are the contents of : Multidisciplinary trunk/basic course; Mammography course; readers course; biopsy course; Ultrasound course; and MRI course

RD 4.15 How is the quality of the teaching courses evaluated?

RD 4.16 How can the effects of the teaching courses be evaluated?

5.1. What are the barriers and facilitators to screening participation?

5.2. What is the optimal strategy for communicating information about breast cancer Screening programmes to socially disadvantaged women?

RD 5.1 What are the effects of ethnicity, education, general health, co-morbidities and life style on adherence to breast cancer screening?

5.3. What is the knowledge, attitudes and perceptions of women towards participating in screening programmes?

5.4. Should effective communication techniques on harms and benefits of screening versus any comparison be used in hard to reach population groupsto increase their participation in screening programmes

RD 5.2 What has been the impact of these interventions on increasing participation in screening

5.5 Should guidelines be used in hard to reach population groups to increase their education and communication with regards to screening programmes

5.6 What is the impact of the healthcare system (type of reimbursement,etc..) on information and participation in screening programmes

6.1 What are the most relevant process indicators of an efficient population-based screening program with mammography?

6.2 What are the most relevant performance indicators of an efficient population-based screening program with mammography?

6.3 Does an external audit group, i.e. a group independent of the organization and execution of the program, improve the quality and/or increase the trustworthiness of the monitoring of a population-based screening program with mammography?

6.4 What are the most relevant indicators to be reviewed in an external audit?

6.5 What is the appropriate timeliness and data level, e.g. national, regional, screening centre, of the monitoring cycle for process and performance indicators with respect to precision in the estimates (statistical power)?

6.6 Which, if any, of the process and performance indicators will, if communicated to professionals, improve the awareness among the professionals?

6.7 What are appropriate indicators for monitoring a population-based screening program with mammography from an equity point of view?

6.8 What are appropriate indicators for monitoring informed choice in a population-based screening program with mammography?

6.9 What are the threats to monitoring quality assurance in population-based screening program with mammography?

6.10 What are the most appropriate impact indicators of an effective population-based screening program with mammography?

6.11 What are the most appropriate surrogate impact indicators of an effective population-based screening program with mammography?

6.12 What are the most appropriate indicators to measure indirect impacts of an effective population-based screening program with mammography

6.13 What is the appropriate timescale for each (surrogate) impact indicator of evaluation of a population-based screening program with mammography with respect to precision in the estimates (statistical power)?

6.14 What are appropriate indicators for evaluating a population-based screening program with mammography from an equity point of view?

6.15 What is the most appropriate study design to evaluate the impact of a population-based screening program with mammography?

6.16 What is the most appropriate method to weigh benefits versus harms of a population-based screening program with mammography?

6.17 Does an external audit group, i.e. a group independent of the organization and execution of the program, improve the quality and/or increase the trustworthiness of the evaluation of a population-based screening program with mammography?

6.18 Which are the requirements for an independent and adequate evaluation of outcome that enables both the public and the policy makers to decide on participation or continuation?

6.19 What are the most relevant process and performance indicators of an efficient diagnostic process?

6.20 What are minimal requirements for standardized reporting in diagnosis (radiology, pathology, etc)?

6.21 Does an external audit group, i.e. a group independent of the organization and execution of the program, improve the quality and/or increase the trustworthiness of the diagnostic process

6.22 What are appropriate indicators for monitoring the diagnostic process from an equity point of view

6.23 What are the necessary requirements on diagnostic procedures to minimise overdiagnosis?

6.24 What are the most appropriate impact indicators of an effective diagnostic process?

6.25 Does an external audit group, i.e. a group independent of the organisation and execution of the program, improve the quality and/or increase the trustworthiness of the evaluation of the diagnostic process?

6.26 What are appropriate indicators for evaluating the diagnostic process from an equity point of view?

Annex 5

List of acronyms

- MoH: Ministry of Health
- CPO: Centro di Riferimento per l'Epidemiologia e la Prevenzione Oncologica in Piemonte
- AOU: Azienda Ospedaliero-Universitaria
- EUREF: European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services
- BCCERT: Breast Centres Certification
- EUSOMA: European Society of Breast Cancer Specialists
- Europrev: European Network for Prevention and Health Promotion in Family Medicine and General Practice
- EFOMP: European Federation of Organisations For Medical Physics
- EUSOBI: European Society of Breast Imaging
- NHS: National Health Service
- SENATURK: Senoloji Akademisi
- EORTC: European Organisation for Research and Treatment of Cancer
- GE: General Electric
- COCIR: European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
- ITALCERT: Organismo di Certificazione Italiano

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