The European Commission Initiative on Breast Cancer (ECIBC): 2015 working groups’ meetings

Guidelines Development Group and Quality Assurance Scheme Development Group

Silvia Deandrea, Jesús López Alcalde, Anke Bramesfeld, Cristiano Gusmeroli, Luciana Neamțiu, Liisa Pylkkänen, Zuleika Saz-Parkinson, Aslı Ulutürk, Donata Lerda

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The two main goals of the European Commission Initiative on Breast Cancer (ECIBC) are to develop the *European guidelines for breast cancer screening and diagnosis* (European Breast Guidelines) and the voluntary *European Quality Assurance scheme for Breast Cancer Services* (the European QA scheme). The present report describes the kick-off and the second meeting of the two working groups established within the initiative to develop the *European Breast Guidelines* and the *European QA scheme*: the Guidelines Development Group (GDG) and the Quality Assurance Scheme Development Group (QASDG), respectively.

The two working groups were set up based on a Call for Expression of Interest organised by the Directorate-General for Health and Food Safety (DG SANTE). Thirty-four members for each working group were nominated in July 2015. The GDG includes individual citizens and patients, clinicians and methodology experts; the QASDG includes individual citizens and patients, clinicians and healthcare quality and safety experts. This is to ensure that a person-centred, while scientifically robust, process is followed for developing the *European Breast Guidelines* and the *European QA scheme*.

The kick-off meetings were held at the Joint Research Centre (JRC) premises in Ispra (Italy), on 7-9 September, 2015 for the GDG and 9-11 September, 2015 for the QASDG. The second set of meetings were held in Baveno (Italy) on 9-11 December 2015, back-to-back with the ECIBC 2015 Plenary. The meetings were dedicated to the introduction to the ECIBC project, the definition of the groups’ working modalities and the draft scope of the *European Breast Guidelines* and of the *European QA scheme*. The first recommendations from the *European Breast Guidelines* and the draft *European QA scheme* are expected to be available starting from 2017.
1. **Introduction**

According to World Health Organization (WHO) 2012 estimates [1], each year there are 2.6 million new cases of cancer in Europe (excluding non-melanoma skin cancers). Breast cancer is the most frequent one with 13.8% of all new cancer cases detected, followed by prostate, colorectal, and lung cancer. Among women, breast cancer is by far the most frequently diagnosed cancer in Europe each year. It is estimated that breast cancer is the third most common cause of death from cancer in the overall European population, after lung cancer and colorectal cancer. Among women, breast cancer is the first cause of death from cancer, accounting for 16.3% of all cancer deaths in Europe.

There are substantial differences in breast cancer incidence, mortality, prevalence and survival within and among countries in Europe [1] [2] [3]. While the estimated age-standardised mortality rate in EU-27 was 22.4 in 2012, it varied from approximately 15 to 29 across the countries, implying that age-standardised mortality in countries ranking the lowest was double that found in those ranking the highest. Although the higher mortality rates in some countries reflect the higher incidence of breast cancer, in others they can be due to the lower survival of women with breast cancer. These differences may suggest the presence of unacceptable variations leading to inequalities in health.

Differences in a number of factors might result in health inequalities, such as differences in the socio-economic status, in exposure to risk factors, in health system policies (e.g. presence/absence of screening programmes), or in the effective delivery of cancer control measures, as already highlighted in the Joint Research Centre (JRC) *Report of a European survey on the organisation of breast cancer care services* [4]. The heterogeneous quality of breast cancer services is, therefore, a relevant cause of health inequalities. There are differences in the quality of healthcare services across European countries. Moreover, more than fifteen different quality schemes coexist in Europe with a specific target on breast cancer, as described in the JRC Report entitled *External quality assessment of breast cancer care in Europe* [5]. This confirms that there is no common set of benchmarking quality requirements in Europe.
In summary, there is substantial potential for reducing inequalities in cancer amenable to healthcare services in Europe. Therefore, a coordinated action at European level to ensure that all European citizens have access to healthcare services with an essential level of quality and safety is very much needed.

Within the European Commission (EC) policies for chronic diseases, in 2012, the Directorate-General for Health and Food Safety (DG SANTE) allocated to JRC, in consideration of its independence and experience in carrying out large scientific projects with a strong cooperative dimension, the ECIBC. Its overall goal is to contribute to improve health and reduce health inequalities in Europe by ensuring a harmonised benchmarking for the quality of breast cancer services.

The ECIBC was started in 2012 with some mapping and research activities carried out by the JRC [4-6], in order to prepare the ground for the main ECIBC task (the breakdown of tasks is detailed in paragraph 3.1 below).

A Guidelines Development Group (GDG) and a Quality Assurance Scheme Development Group (QASDG) were established in 2015 following a Call for Expression of Interest¹ organised by DG SANTE to support the EC for the main ECIBC objectives. Under the JRC technical and scientific coordination, the two working groups regularly meet and contribute substantially to the development of the European guidelines for breast cancer screening and diagnosis (henceforth the European Breast Guidelines) and the European Quality Assurance scheme for Breast Cancer Services (henceforth the European QA scheme). This series of reports will provide an overview of the GDG and QASDG meetings that have taken place each year and their respective main outcomes.

In December 2003, the Council adopted the Council Recommendation on cancer screening and recommended population-based screening for breast, cervical and colorectal cancers in accordance with European guidelines. Adoption of European guidelines on best practice was identified as key for ensuring the development of high quality cancer-screening programmes, and the EC coordinated the production of such guidelines. For breast cancer screening, the latest is the 4th edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis and its 2013 supplements, which aim to promote best practices identified via a consensus-based approach.

As regards the follow-up of lesions detected via screening, in 2008, both the European Parliament Resolution which acknowledged the differences in ‘the quality of cancer treatment facilities, screening programmes and evidence-based best-practice guidelines…’ and the Council Conclusions on reducing the burden of cancer, called on the EC to ‘facilitate the development and updating of, and/or publish, web-based quality assurance and evidence-based guidelines on cancer (breast, cervical and colorectal) in the official languages of the EU’, ‘to support the development of European accreditation/certification programmes in cancer screening, diagnosis and treatment based on European quality-assurance guidelines’ and ‘to explore the potential for the development of voluntary European accreditation schemes for cancer screening and appropriate follow-up of lesions detected by screening, such as a European pilot accreditation scheme for breast cancer screening and follow-up based on the European guidelines for quality assurance in breast cancer screening and diagnosis’.

3. **The European Commission Initiative on Breast Cancer**

3.1. **ECIBC’s objectives**

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

- **Objective 1.1.** To develop the *European Breast Guidelines* based on new knowledge and evidence. – Coordinated by the JRC and supported by the GDG, the *European Breast Guidelines* will continue the work of the 4th edition of the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis* (published in 2006) [7]. They will provide evidence-based recommendations for the screening and diagnosis processes of breast cancer services. An outsourced systematic review team, *Centre Cochrane Iberoamericà* (CCIb), will support the GDG in performing the systematic reviews and providing the best available evidence on which the recommendations of the *European Breast Guidelines* will be based.

- **Objective 1.2.** To create a platform of guidelines for breast cancer treatment, rehabilitation and follow-up. – The *European Breast Guidelines* will cover breast cancer screening and diagnosis. For the remaining processes of the breast cancer pathway (such as treatment, rehabilitation, follow-up, and palliative care, together with all relevant horizontal aspects), the JRC will coordinate the development of a platform of trustworthy guidelines (the *Guidelines Platform*). This platform will provide evidence-based recommendations on those processes. Both GDG and QASDG members will be kept informed and potentially contribute to the *Guidelines Platform*.

- **Objective 1.3.** To propose a procedure to maintain the evidence-based recommendations for breast cancer services up-to-date in the long term. – The JRC will define the approach to assess the need to update guidelines and will apply this approach to warrant that the *European Breast Guidelines* and the recommendations collected in the *Guidelines Platform* are based on the best available and most updated evidence.
• **Objective 2.** To develop the voluntary *European QA scheme* based on the EU legislative framework on accreditation, as defined in the Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance. The QASDG is mainly involved in this objective. – The *European QA scheme* will define a common set of quality and safety requirements for breast cancer services in Europe, under harmonised peer supervision across all involved countries under the co-ordination of the European co-operation for Accreditation (EA); it would be potentially usable by all countries associated to EA. The scheme will cover all the relevant areas of healthcare provision for breast cancer and all processes of breast cancer care. It will define its requirements considering evidence-based recommendations arising from high-quality guidelines whenever possible, best professional practices and the relevant legislation. Once the scheme has been finalised, it will be piloted among participant services in Europe.

• **Objective 3.** To develop a European template of training on digital mammography. – The objective is to develop a concept for digital mammography training directed at health professionals involved in screening programmes. It will include the minimum requirements for professionals working for services adhering to the *European QA scheme*.

• **Objective 4.** To develop a long-term web hub hosting all the deliverables. – The web hub is the communication interface of the ECIBC with the stakeholders. It will be the gateway to all information, outputs and tools produced, once they are made available. Its deployment will be coordinated by JRC, including stakeholders’ inputs on the desirable features and contents.

3.2. **ECIBC’s actors**

The EC, DG SANTE and the JRC, coordinates the ECIBC to ensure that deadlines are met and actions implemented. The EC is a suitable institution to coordinate this initiative as it can steer it in the long-term (sustainability), represents a neutral platform (neutrality) for bringing together a wide range of actors at EU

level and foresees transparent procedures for taking into account stakeholders’ inputs, such as open consultations (transparency).

**DG SANTE** has the policy leadership as regards the implementation of the EU public health policy on cancer. In addition, the Commission expert group on Cancer Control, created by Commission Decision of 3 June 2014 and repealing Decision 96/469/EC, should guarantee the full compatibility and coordination of the ECIBC with the overall EU policy on cancer.

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

Moreover, two external contractors were recruited via the tendering procedures of the Commission: 8 the **CCIb** as the systematic review team mainly supporting the development of the guidelines, and **EA** mainly supporting the development of the *European QA scheme*.

The JRC has asked 34 European countries (including the 28 EU Member States) to nominate an **ECIBC National Contact** as a focal point to represent each participating country during the project. Delegates are required to provide their contribution at various stages. The continuous communication with the National Contacts will provide essential inputs on respecting the countries’ own healthcare set-up throughout the project and providing a basis for the successful implementation of the scheme.

The selection procedure of members for the **GDG** and **QASDG** was based on specific qualification criteria and adhered to the principles of transparency regularly applied to scientific and consultative groups in the EC, to help safeguard against potential conflict of interests. The members were chosen on the basis of

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skills, experience and knowledge appropriate to carry out the tasks assigned to them. The list of fields of competence and profiles searched in the call is reported in Annex I.

Out of the 125 applications received for the GDG and the 63 for the QASDG, an EC panel selected 34 members for each working group, plus 12 reserve list members. The working groups’ members are appointed in their personal capacity, not representing any institution or organisation.

The list of GDG and QASDG members, with the profile and declaration of interest for each of them is available on the ECIBC web hub: http://ecibc.jrc.ec.europa.eu/guidelines-team for GDG and http://ecibc.jrc.ec.europa.eu/qa-team for the QASDG.

More working groups may be set up on demand to accomplish the remainder objectives of the initiative.
4. GDG and QASDG meetings in 2015

4.1. Kick-off meeting’s scope

They were held at the JRC premises in Ispra (Italy), on 7-9 September, 2015 for the GDG and 9-11 September, 2015 for the QASDG.

The first meeting of the GDG was dedicated to the introduction to the ECIBC project, the GDG working modalities and the draft scope of the guidelines was presented. A short training on methods in guidelines development was also provided.

The first meeting of the QASDG was dedicated to the introduction to the ECIBC project, the QASDG working modalities and the draft scope of the scheme was also presented.

Figure 1: GDG kick-off group picture.
Figure 2: GDG kick-off meeting picture.

Figure 3: QASDG kick-off group picture.
4. GDG and QASDG meetings in 2015

4.2. Kick-off agendas and presentations

Both meetings foresaw an introductory session to the following topics:

- the JRC, the Institute for Health and Consumer Protection (IHCP) and the Public Health Policy Support Unit (PHPS), by Krzysztof Maruszewski (IHCP Director, JRC, EC) and Ciarán Nicholl (PHPS Head of Unit, IHCP, JRC, EC);
- the ECIBC project and its policy context, by Michael Hübel (DG SANTE, EC) and Donata Lerda (Healthcare Quality Team, PHPS, IHCP, JRC, EC).

They were chaired by the EC (Michael Hübel, Ciarán Nicholl, and Donata Lerda) while waiting for election of chairs and co-chairs.

4.3. **Kick-off’s evaluation**

Participants’ feedback was collected and evaluated in order to determine satisfaction with the event and to identify areas for improvement. The feedback form covered the event’s preparation, delivery, organisation, logistics as well as an overall evaluation. The general evaluation of the meetings was positive: 81% of GDG respondents and 83% of QASDG respondents declared that the kick-off meeting ‘met expectations’ and for 19% and 17% it was ‘above expectations’ respectively. As regards the contents’ aspect, a general suggestion from both GDG and QASDG members was towards an improvement of the interactions between the two groups. Details on the feedback received are available upon request.

4.4. **Second meeting’s scope**

The second meetings were held in parallel in Baveno (Italy) on 9-11 December 2015, back-to-back with the ECIBC 2015 Plenary. A common GDG-QASDG session was devoted to the explanation of the common working modalities of the two groups. Then, independent GDG and QASDG sessions were organised, as well as a preliminary meeting of the joint GDG/QASDG subgroup for testing and examination activities.

4.5. **Second meeting’s agendas and presentations**


A specific evaluation process for the second meeting was not foreseen as it was incorporated in the overall evaluation of 2015 edition of the ECIBC Plenary (included in the respective report).
4. GDG and QASDG meetings in 2015

**Figure 5:** GDG second meeting picture.

**Figure 6:** QASDG second meeting picture.
5. Topics addressed by GDG and QASDG in 2015

5.1. GDG and QASDG rules

The rules of procedure of the two working groups are inspired by the rules for EC expert groups; each GDG and QASDG member was asked to sign a confidentiality form and to commit to the respective working group mandate which can be found at the following websites: http://ecibc.jrc.ec.europa.eu/gdg-documents for GDG and http://ecibc.jrc.ec.europa.eu/qa-documents for QASDG.

Briefly, the two mandates included the following items:

- Develop the *European Breast Guidelines* (GDG) and the ‘service/process requirements’ for the *European QA scheme* (QASDG).
- Support JRC on addressing the comments on the *European Breast Guidelines* (GDG) and the *European QA scheme* (QASDG) submitted by the public through consultation or other means.
- Support JRC with the dissemination and implementation of the *European Breast Guidelines*, as well as defining a long-term strategy for updating (GDG).
- Support JRC during the pilot stage of the *European QA scheme* and on integrating changes that may be necessary after the piloting (QASDG).
- Support other groups of the ECIBC (e.g. the group that will develop the Guidelines Platform, and other working groups that may be set up on demand).
- Support JRC on conducting studies underpinning the ECIBC’s main tasks (e.g. surveys, methodological studies, etc.).

11. ‘Service/process requirements’: clinical and organisational requirements as well as quality performance and results indicators that the breast cancer service shall demonstrate to fulfil in its provision of breast cancer prevention, diagnosis and care (with reference to guidelines and other sets of evidence, such as best professional practices).
5.2. GDG and QASDG working modalities

The two working groups approved a document describing the team that will develop the European Breast Guidelines and the European QA scheme, and how it will work. Briefly, this group will include:

• ECIBC Coordination Team and Secretariat, represented by the Healthcare Quality Team and other personnel from the PHPS.
• Some GDG members were appointed for the following roles:
  • co-chair of methodology and clinical co-chair (the first an expert guideline methodologist, and the other an expert on the guideline topic);
  • vice-chair of methodology and clinical vice-chair;
  • steering group (a maximum of eight members: the co-chairs, the vice-chairs, and a maximum of four members with a citizen/patient profile to be proposed by the GDG, of which two will participate in the meetings at the same time);
  • chapter co-editors (see paragraph 5.5 for description of chapters).
• Some QASDG members were appointed for the following roles:
  • chair;
  • vice-chair;
  • steering group (the chair, the vice-chair, the coordinator of the certification subgroup, the coordinator of the testing subgroup, the coordinator of the quality domain – see paragraph 5.8 – active in the moment and two members with a citizen/patient profile).
  • subgroup coordinators (see paragraph 5.5 for description of subgroups).

Other people contributing to the development of the European Breast Guidelines and the European QA scheme may be: associated members and scientific advisors (experts chosen from the reserve lists), external experts (not part of the GDG and QASDG reserve lists, appointed based on the suggestion of the working groups or on a call for experts), National Contacts, stakeholders (individuals and organisations), external reviewers, editors.

For the role of external contractors, currently only CCIb and EA, within the ECIBC, are involved. See paragraph 3.2.

5.3. Assessment and management of interests

Declaration of interests will follow the implementation of the provisions on independence and transparency of Commission Decision 2012/C 198/06. EC will provide clear guidance about how to declare interests with explicit definitions of the different types of interests, including ‘strong personal views on a particular topic addressed in the guidelines’ (such as intellectual interests or previous public statements or positions). The declaration of interest from each working group member is made available on the ECIBC web hub together with their photos and profiles.

5.4. Nomination of (co-)chair(s) and vice-(co-)chair(s)

Nominations took place the last day of the two kick-off meetings.

The GDG members expressed their interest for the positions of clinical and methodological co-chairs and vice-chairs. Holger Schünemann was elected as co-chair of methodology and Markus Follmann as vice-chair of methodology. Chris De Wolf was elected as clinical co-chair and Cecily Quinn as clinical vice-chair.

The QASDG members also expressed their interest for the positions of chair and vice-chair. Robert Mansell was elected as chair and Francesco Sardanelli as vice-chair.

5.5. Creation of subgroups

For the GDG, the subgroups were formulated based on the structure of the guidelines. All members of the GDG were invited to express their interest and also clarify whether they were interested in being chapter co-editors or just members of the different chapters. The following themes were agreed:
• Chapters:
  1. Screening.
  2. Diagnosis.
  3. Communication.
  4. Training.
  5. Interventions to reduce inequalities.
  6. Monitoring and evaluation of screening and diagnosis.
  7. Glossary (task force).

Screening and diagnosis will form the basis for the guidelines. The other chapters will be more horizontal: they will be independent chapters but these topics may be addressed within other chapters as well.

All members of the QASDG were invited to express their interest in different subgroups and also clarify whether they were interested in being subgroup coordinator. The following subgroups and respective coordinators were nominated:

• Testing (Imaging, Pathology, Medical Physics, Molecular/Genetic Testing).
• Competence.
• Quality concepts and keywords (glossary).
• Organisation, Scope and Modules.
• Certification Processes.
• Indicators.
• Research.

Collaboration between the GDG and the QASDG is foreseen for the following tasks:

• screening and diagnosis (GDG) vs. testing activities, such as medical imaging, clinical pathology, medical physics, molecular/genetic testing (in QASDG);
• training (GDG) vs. competence (QASDG);
• monitoring (GDG) vs. indicators (QASDG);
• glossary (GDG) vs. quality concepts and keywords (QASDG).
5.6. Methods for the development of the European Breast Guidelines

The European Breast Guidelines will be developed using the GRADE method.

GRADE stands for Grading of Recommendations Assessment, Development and Evaluation. It is a system used to assess the quality of evidence and decide whether or not to recommend an intervention [9] [10] [11]. GRADE was developed by the GRADE working group, an international group which began in 2000 as an informal collaboration of people with an interest in addressing the shortcomings of present grading systems in healthcare interventions. Their aim was to develop a common, sensible approach to grading quality of evidence and strength of recommendations.

The question formulation is a crucial stage of the guideline development process because, among other reasons, it allows for patients and relevant stakeholders’ interests to be taken into consideration.

The guideline panel will agree each guideline question in terms of the following components:

- the population (P),
- the alternative management strategies (that is an intervention (I) and a comparator (C)), and
- all outcomes that are important to patients and relevant stakeholders (O).

GRADE requires the panel to classify the selected outcomes as ‘critical’, ‘important but not critical’ (important) or ‘not important’ for those that will be affected by the recommendation, that is, citizens/patients and other relevant stakeholders. On the other hand, GRADE recommendations will be based only on ‘critical’ or ‘important’ outcomes, therefore, promoting that the decision making process is based on information meaningful to those that will be affected by the recommendation. To go from the evidence to the recommendation the GDG will consider the evidence for several domains, such as resources, patients’ values and preferences, and feasibility. This evidence can be obtained with systematic reviews or with more pragmatic reviews, depending on the relevance of the questions and
on the resources available. There are some PICO questions for which a formal systematic review is not needed. In these occasions the evidence can be summarised based on best clinical practice and consensus.

A key contribution of the working group begins when the evidence that has been collected by the systematic review team is provided in evidence tables. Based on this evidence, the group will formulate the recommendations.

The GDG will generate a list of potential questions for the European Breast Guidelines. The GDG will implement an explicit prioritisation process in order to choose the most relevant PICO questions.

The guidelines should consider the geographical context, socioeconomic factors, and the strength of the health systems in which the recommendations will be implemented. Therefore, the resource use and the cost-effectiveness should be taken into account when developing the recommendations. A balance between different perspectives (e.g., women vs. public health, policy support) should be found and should be taken into account when choosing the outcomes of the PICO question.

5.7. European QA scheme legal background

The voluntary European QA scheme will be developed, piloted, and in the future run, under the Regulation (EC) No 765/2008. In this respect, EA, within its coordination role of NABs, supports the development and piloting of the European QA scheme.

In order to achieve consistency in the accreditation of conformity assessment bodies, NABs utilise harmonised standards. Considering that, the European QA scheme will cover many healthcare processes, some of them being testing and examination activities, two main harmonised standards have been chosen: the ISO 15189:2012 (Medical laboratories—Requirements for quality and competence) for

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the testing activities and the ISO/IEC 17065:2012 (Conformity assessment–Requirements for bodies certifying products, processes and services). Both standards will be directly used by the NABs: the first for accrediting testing activities (e.g. laboratories) associated to breast cancer services aiming to adhere to the European QA scheme, and the second, for accrediting certification bodies (CB)\textsuperscript{14} that certify that the breast cancer service fulfils all the specific requirements of the scheme.

- ISO/IEC 17065:2012 Conformity assessment–Requirements for bodies certifying products, processes and services. – This standard specifies general requirements for certification bodies operating service or process certification schemes. ISO/IEC 17065 does not set out the requirements for a scheme as this is the role of the scheme owner. This is the standard that NABs will use to accredit CBs that will perform the certification of the breast cancer services, excluding medical laboratories and diagnostic imaging centres (see next item).

- ISO 15189:2012 Medical laboratories–Requirements for quality and competence. – This standard describes the requirements for competence and quality specific to medical laboratories. Medical laboratory services include arrangements for examination requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work. It also declares that other services and disciplines such as clinical physiology, medical imaging and medical physics could find the standard useful.

5.8. European QA scheme’s methods

The first activity of the QASDG was the mapping of the breast cancer treatment pathway, intended as the flow chart that the person goes through in her journey from screening to (when applicable) end of life care. Working on this pathway allowed the QASDG to identify six main processes of breast cancer care, plus several sub-processes either at person or system level. The processes identified are:

\textsuperscript{14} According to the definition included in EA press kit for government ‘A Certification Body is an organisation that will carry out an assessment to determine if your management system conforms to the requirements of, for example, the ISO 9000 standard’ (http://www.european-accreditation.org/publications).
1. Screening.
2. Diagnosis.
3. Treatment.
4. Rehabilitation.\textsuperscript{15}
5. Follow-up and survivorship.
6. Palliative care.\textsuperscript{16}

For each process, quality requirements, reference documents and indicators will be identified in the following QASDG meetings. Requirements and indicators will be mainly selected by the QASDG orienting towards methods such as RAND/UCLA [8]. This implies that experts of the working group will select requirements and indicators by rating them for relevance and feasibility in Delphi-like rounds. Both requirements and indicators will have a reasoning attached that provide the evidence and reference documents which justify them. Requirements directly related to clinical practice will derive from the \textit{European Breast Guidelines} and from the platform of trustworthy guidelines for the other processes of care, which will be developed in the context of the ECIBC.

Requirements will address the following quality domains:

a) Clinical effectiveness.
b) Facilities, resources and workforce.
c) Personal empowerment and experience.
d) Safety.

Those derive from the three key quality domains that have been identified in the Reflection Paper entitled \textit{Quality of Health care: policy actions at EU level} \textsuperscript{17} with the further inclusion of a domain for structures and workforce. Furthermore, the inclusion of additional transversal items may also be discussed by the QASDG. These transversal items refer to concepts that can be adopted from other existing classifications for different aspects of quality in healthcare, such as efficiency,

\textsuperscript{15} See WHO: http://www.who.int/topics/rehabilitation/en/ (last accessed 11/2015) for definition.
\textsuperscript{17} http://ec.europa.eu/health/patient_safety/docs/ps_qc_cons2013_background_en.pdf.
access, equity, appropriateness, timeliness, acceptability, satisfaction, health improvement and continuity of care [11].

5.9. Call for feedback for the European Breast Guidelines and the European QA scheme’s scope

To keep the process as transparent as possible, a call for feedback concerning the scope of the guidelines was planned. The call for feedback was launched after the two working groups had finalised the draft scope for consultation. After the consultation period the GDG and QASDG will provide input regarding the acceptance or non-acceptance of comments received. This process is still ongoing.

The two documents that were sent for the call are available at this link: http://ecibc.jrc.ec.europa.eu/calls-for-feedback.
Conclusion

The two working groups’ meetings conveyed more than 50 experts and individuals from 14 Member States, US, Canada and Israel for a successful step forward for the ECIBC and launch of its two working groups. The high level of expertise of the working group members, the variety of professional profiles involved, and the presence of experts with a methodology profile is an innovative approach in the implementation of a European cancer policy. In fact, this is the first time that the GRADE method is applied in EU cancer screening guidelines and that the accreditation legal framework is used for a scheme including clinical practice. The clear focus on evidence-based methodology in the development of the *European Breast Guidelines* and the innovative approach used to apply healthcare accreditation and certification to improve the quality of the services while developing the *European QA scheme* will form the basis of the future work of the working groups.

Both the GDG and the QASDG members expressed the need to be more informed on the activities of the other working group and to be involved in cross-cutting activities. Issuing a common proceedings’ report represents a first step towards this goal. Sharing of documents when needed, joint meetings (instead of back to back ones) as from 2016, joint meetings of the two steering groups, and common subgroups across the GDG and QASDG, are the additional actions planned and ongoing to facilitate collaboration between the two groups. In particular, future meetings will include both common and parallel sessions to facilitate the work, increase synergy and guarantee the flow of information between the groups.

In conclusion, the first milestone of the ECIBC to establish the two working groups, and present a draft scope for the *European Breast Guidelines* and the *European QA scheme* has been achieved. The submission of the scope for consultation to external stakeholders, the planning of the first tasks for the subgroups and the collection of existing requirements are the steps foreseen for early 2016 meetings.


References


## List of abbreviations and definitions

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<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>CB</td>
<td>Certification Body</td>
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<td>DG GROWTH</td>
<td>Directorate General Internal Market, Industry, Entrepreneurship and SMEs</td>
</tr>
<tr>
<td>DG RTD</td>
<td>Directorate General Research &amp; Innovation</td>
</tr>
<tr>
<td>DG SANTE</td>
<td>Directorate General for Health and Food Safety</td>
</tr>
<tr>
<td>EA</td>
<td>European co-operation for Accreditation</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>ECIBC</td>
<td>European Commission Initiative on Breast Cancer</td>
</tr>
<tr>
<td>GDG</td>
<td>Guidelines Development Group</td>
</tr>
<tr>
<td>GRADE</td>
<td>Grading of Recommendations Assessment, Development and Evaluation</td>
</tr>
<tr>
<td>IHCP</td>
<td>Institute for Health and Consumer Protection</td>
</tr>
<tr>
<td>JRC</td>
<td>Joint Research Centre</td>
</tr>
<tr>
<td>NAB</td>
<td>National Accreditation Body</td>
</tr>
<tr>
<td>PHPS</td>
<td>Public Health Policy Support</td>
</tr>
<tr>
<td>PICO</td>
<td>Patient-Intervention-Comparison-Outcome</td>
</tr>
<tr>
<td>QASDG</td>
<td>Quality Assurance Scheme Development Group</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
List of figures

Figure 1. GDG kick-off group picture.
Figure 2. GDG kick-off meeting picture.
Figure 3. QASDG kick-off group picture.
Figure 4. QASDG kick-off meeting picture.
Figure 5. GDG second meeting picture.
Figure 6. QASDG second meeting picture.
## Annex I: Fields of competence and profiles for the working groups

### Fields of competence represented in the GDG

<table>
<thead>
<tr>
<th>Fields of competence</th>
<th>I. Professionals</th>
<th>II. Individual citizens or patients</th>
<th>III. Methodologists</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Health care systems administration</td>
<td></td>
<td>25. Evaluation of diagnostic tests</td>
<td></td>
</tr>
<tr>
<td>6. Health promotion, such as community nursing or other disciplines</td>
<td></td>
<td>26. Evidence-based guidelines development</td>
<td></td>
</tr>
<tr>
<td>7. Information technology</td>
<td></td>
<td>27. Guidelines implementation</td>
<td></td>
</tr>
<tr>
<td>9. Nursing</td>
<td></td>
<td>29. Integration of patient values in guidelines</td>
<td></td>
</tr>
<tr>
<td>10. Pathology</td>
<td></td>
<td>30. Prevention and management of conflicts of interests in guidelines</td>
<td></td>
</tr>
<tr>
<td>11. Medical physics</td>
<td></td>
<td>31. Quality assurance guidelines</td>
<td></td>
</tr>
<tr>
<td>12. Policymaking</td>
<td></td>
<td>32. Synthesis of qualitative evidence</td>
<td></td>
</tr>
<tr>
<td>13. Psycho-oncology</td>
<td></td>
<td>33. Systematic reviews of diagnostic tests</td>
<td></td>
</tr>
<tr>
<td>14. Public Health</td>
<td></td>
<td>34. Systematic reviews of public health interventions</td>
<td></td>
</tr>
<tr>
<td>15. Quality and patient safety</td>
<td></td>
<td></td>
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<tr>
<td>16. Radiography</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>17. Radiology</td>
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</tbody>
</table>
Fields of competence represented in the QASDG

<table>
<thead>
<tr>
<th>Profiles</th>
<th>I. Professionals</th>
<th>II. Individual citizens or patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Breast cancer quality assurance schemes</td>
<td>35. Carers and family members</td>
</tr>
<tr>
<td>2.</td>
<td>Breast surgery</td>
<td>36. Patients diagnosed with breast cancer</td>
</tr>
<tr>
<td>3.</td>
<td>Cancer epidemiology</td>
<td>37. Users of screening programmes</td>
</tr>
<tr>
<td>4.</td>
<td>Cancer registries and databases</td>
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<tr>
<td>5.</td>
<td>Communication in cancer</td>
<td></td>
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<tr>
<td>6.</td>
<td>Conformity assessment/inspection/certification bodies (healthcare area)</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Evidence-based complementary and alternative medicine</td>
<td></td>
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<tr>
<td>8.</td>
<td>General practice</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Genetics</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Healthcare accreditation systems</td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Healthcare systems administration</td>
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</tr>
<tr>
<td>12.</td>
<td>Hospital management</td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Information technology</td>
<td></td>
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<tr>
<td>14.</td>
<td>Management of breast cancer screening programmes</td>
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<tr>
<td>15.</td>
<td>Medical Oncology</td>
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</tr>
<tr>
<td>16.</td>
<td>Medical Physics</td>
<td></td>
</tr>
<tr>
<td>17.</td>
<td>Nursing (both community and hospital)</td>
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<tr>
<td>18.</td>
<td>Nutrition</td>
<td></td>
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<tr>
<td>19.</td>
<td>Palliative Care</td>
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<tr>
<td>20.</td>
<td>Pathology</td>
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<tr>
<td>21.</td>
<td>Patient safety</td>
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<tr>
<td>22.</td>
<td>Patient-centered care</td>
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<tr>
<td>23.</td>
<td>Pharmacy</td>
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<tr>
<td>24.</td>
<td>Policymaking</td>
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<tr>
<td>25.</td>
<td>Psycho-oncology</td>
<td></td>
</tr>
<tr>
<td>26.</td>
<td>Public Health</td>
<td></td>
</tr>
<tr>
<td>27.</td>
<td>Quality assurance schemes for chronic diseases</td>
<td></td>
</tr>
<tr>
<td>28.</td>
<td>Development of quality indicators</td>
<td></td>
</tr>
<tr>
<td>29.</td>
<td>Radiography</td>
<td></td>
</tr>
<tr>
<td>30.</td>
<td>Radiology</td>
<td></td>
</tr>
<tr>
<td>31.</td>
<td>Radiotherapy</td>
<td></td>
</tr>
<tr>
<td>32.</td>
<td>Reconstructive breast surgery</td>
<td></td>
</tr>
<tr>
<td>33.</td>
<td>Rehabilitation</td>
<td></td>
</tr>
<tr>
<td>34.</td>
<td>Social assistance</td>
<td></td>
</tr>
</tbody>
</table>

18. Here ‘accreditation’ is intended as any evaluation mechanism aimed at assessing the performance of a healthcare institution through investigating its compliance with a series of pre-defined standards.
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