A voluntary accreditation scheme for Breast Cancer Services & the further development of European Breast Cancer Guidelines: project workshops report

Workshop for Experts:
From 21 to 22 February 2013

Workshop for Countries Delegates:
From 13 to 14 March 2013

Donata LERDA, Silvia DEANDREA, Crystal FREEMAN, Ciarán NICHOLL, Nicholas NICHOLSON, Jerica ZUPAN
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Authors:
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Joint Research Centre – Institute for Health and Consume Protection - Public Health Policy Support Unit
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Foreword

In 1987 the European Commission initiated the Europe Against Cancer Programme. The programme was instrumental in funding the actions to develop the European Quality Assurance (QA) guidelines for breast cancer screening.

Thereafter in 2003, the European Council issued a recommendation to the European Member States to offer evidence-based cancer screening through a systematic population-based approach with quality assurance at all appropriate levels, in particular in accordance with the European QA guidelines (now in their 4th edition since 2006). This was followed by the Council’s conclusions in 2008 inviting the European Commission to explore the potential for developing a European pilot accreditation scheme for breast cancer screening and follow-up, also based on the European QA guidelines.

The practical task of developing a single quality assurance scheme across Europe able to adapt to widely different health-care service infrastructures is a complex one. Following extensive discussions with a wide range of stakeholders involved in breast cancer health-care services as well as with the European Cooperation for Accreditation in view of the European legal framework for accreditation, the Commission drafted a proposal as to how such a European quality assurance scheme might look. Many of the elements of this proposal were discussed with stakeholders in the two workshops summarised in this report.

The Joint Research Centre’s Institute for Health and Consumer Protection is coordinating this task for the European Commission. I therefore follow with particular interest the further development of this highly important project, the success of which is likely to have a profound impact on health-care services – even beyond those dedicated solely to breast cancer. My sincere hope is that this ambitious goal will serve to catalyse the full cooperation of the wide range of stakeholders across the EU to contribute to its success, providing women across Europe with the confidence, trust, and assurance in all the processes directly concerning them in relation to breast cancer health-care.

Krzysztof MARUSZEWSKI

Director of Institute for Health and Consumer Protection of the Joint Research Centre
Executive Summary

In November 2012, the Joint Research Centre, which is the European Commission’s in-house science service, was assigned with the tasks of (i) updating the 4th edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis and of (ii) developing a quality assurance scheme for Breast Cancer Services based on the European legislative framework on accreditation (defined in Regulation (EC) No 765/2008).

Taking the view to develop both tasks in a coordinated, consensus-based and sustainable way, the JRC first embarked on setting up a series of targeted meetings with a wide range of stakeholders, experts and concerned authorities at the national level.

Following these bi-lateral meetings, the JRC organised two workshops in order to consolidate consensus on the project – particularly in view of the planned deliverables and the proposed working modalities.

The first workshop took place on 21-22 February 2013 and was primarily addressed to clinical experts and stakeholders whilst the second, on 13-14 March 2013, was aimed at delegates from concerned countries (EU Member States plus Croatia, Norway and Switzerland) responsible in some way for the provision of breast cancer screening and treatment programmes.

This report is a summary of the two workshops.
1 Introduction to the project

This project, underway at JRC’s Institute for Health and Consumer Protection (JRC-IHCP), is aimed at establishing a minimum set of quality requirements for breast cancer health-care across the EU. The project has two main pillars:

1. development of a Quality Assurance (QA) scheme for breast cancer services underpinned by accreditation1;
2. updating, integrating, and restructuring the European Guidelines for Quality Assurance of Breast Cancer Screening and Diagnosis (hereafter referred to as the European QA Guidelines).

This project responds to the Council of the European Union’s conclusions on reducing the burden of cancer2 and it aims to mitigate the risks connected to inadequate quality of prevention and care.

Its concept foresees that all aspects of breast cancer prevention and care, screening, diagnosis, treatment, survivorship - support - palliative care, and management of recurrence (follow-up) are covered. It also foresees that the requirement of a multi-disciplinary approach will be ensured and focuses on putting the patient at the centre of the process.

The processes involved in the development of this QA scheme will rely on information gathered through a survey of EU health systems, and will seek, as far as possible, not to duplicate existing national and private schemes. Also foreseen is the updating the 4th edition of the European QA Guidelines. The QA scheme will be based on the revised European QA Guidelines (in the following indicated as NEW European Guidelines) and, if necessary, on the selection of existing guidelines recommendations for other stages and aspects of care not covered in the NEW European Guidelines.

The first draft of the concept of this European Commission initiative was presented to the audiences at both workshops and the updated version was derived after incorporating the conclusions of the two workshops, feed-back from participants and further reflection and, after internal approval within the European Commission, will be made available to all project

1 Regulation (EC) 765/2008
2 COUNCIL OF THE EUROPEAN UNION - Council Conclusions on reducing the burden of cancer
2876th EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS Council meeting - Luxembourg, 10 June 2008
The links to the first and final version of the project concept is available at chapter 6. Hyperlinks to JRC public health webpages are provided in ANNEX I.

2 Scope of the workshops

During 2012 an intensive web search was conducted and in collaboration with DG SANCO; several networks, projects and stakeholders of potential interest for this project were identified. Twenty five bi-lateral meetings were held and the JRC team members participated in several workshops and conferences in order to deepen their knowledge of existing projects on breast cancer guidelines and quality assurance schemes, with particular attention to those based in Europe.

Besides the many expert groups, patients’ organisations were considered to be of major importance in order to launch this project on the right foot. Additionally, the major focus was to involve the concerned national authorities in defining the present situation and in representing the main engine for ensuring implementation and dissemination of the project outcomes. It should not be forgotten that, without implementation, even a perfectly designed accreditation scheme (based on very high quality guidelines), will not have any impact on the situation of women affected by breast cancer.

The JRC-IHCP will apply a consultation-consensus process for all relevant stages of this project, keeping it open to all main stakeholders, like experts, patients associations, screening programme managers, policy makers and general practitioners. The first step in this direction was to present the main project pillars to the concerned groups at both workshops. The first one was dedicated to patients' associations, to the experts involved in developing the previous editions of European QA Guidelines, to experts in areas linked with guidelines development and with accreditation, and to experts in stages of cancer care other than screening and diagnosis. For the second workshop countries delegates involved in breast cancer prevention and care were invited from the European Union plus Croatia, Norway and Switzerland.
3 Organisation and participants

3.1. Workshop for experts 21-22 February 2013

The workshop dates were announced to invitees via email, describing the event's scope, on 4 December 2012. A reminder requesting confirmation to join the workshop was sent out on 9 January 2013 and the official invitations to those interested were sent out on 15 January 2013. Participants were invited to register and the registration page was open from 15 January 2013 till 15 February 2013.

Agenda and project concept were made available on the webpage of the event Workshop for experts' webpage and after the event, and upon written consent, presentations and the list of participants were posted on the same webpage.

In ANNEX II - Table 1 contains the list of the 41 (non JRC-IHCP) participants.

3.2. Workshop for Countries delegates 13–14 March 2013

On 4 December 2012, the workshop dates were announced to European Partnership for Action Against Cancer (EPAAC) National contacts via email, describing the event’s scope. In addition, individual thank you letters for contributors to the survey were sent out to EPAAC National contacts and to Health Attaches. Information regarding the workshop dates and the confirmation deadline was included as well.

Individual reminders were sent out on 10 January 2013.

Official invitations to those interested were sent out on 7 February 2013. Participants were invited to register from 7 February 2013 until 4 March 2013.

Agenda and project concept were made available on the Workshop for countries’ delegates webpage and after the event, and upon written consent, presentations and the list of participants were posted on the same webpage.

In ANNEX II - Table 2 contains the list of the 35 (non JRC-IHCP) participants.
4 Agendas and presentations

4.1. Workshop for experts 21-22 February 2013

The workshop agenda foresaw plenary sessions, mostly dedicated to inform participants about background and main project pillars and to host open discussion on the various aspects presented. Parallel sessions (break-out sessions - BOSs) were organised to focus discussions on four main topics:

1. Accreditation
2. Guidelines and Research
3. Patients (in Accreditation and in Guidelines)
4. Databases and Cancer Registries

Before the workshop an expert from each topic was invited to lead their respective BOS. Explanations on BOSs organisation and open questions to be addressed during these sessions were defined and proposed to BOS leaders; they were given the opportunity to modify the proposal according to their experience and to prepare the purpose and design of their respective BOS.

In the following the agenda is reported together with a summary of the respective presentations. Points raised during discussion time are summarised in the conclusions' documents reported in ANNEX III and merged with the conclusions from the second workshop at paragraph 6.1.
Purpose of the Workshop

(JRC - Ciarán NICHOLL)

Background
European Parliament Resolution of 10 April 2008 calls on the European Commission to “support the development of European accreditation/certification programmes in cancer screening, diagnosis and treatment based on European quality-assurance guidelines, which could also serve as an example for other areas of health care”. The European Council issues conclusions shortly thereafter (10 June, 2008) reiterating this request to the Commission.

Methods
In 2012, the JRC established a new Public Health Policy Support unit and its Cancer group launched a project entitled “A voluntary EU accreditation scheme for breast cancer services and the further development of the European Breast Cancer Guidelines”

Over 50 stakeholder events, a survey among 30 countries and literature research initiatives were all conducted in 2012 to help conceive the structure of the project. This has culminated
in various working documents which were analysed, leading to the draft concept (which participants received before the Workshop).

Results and Conclusions
The purpose of this workshop is to bring Europe's experts and stakeholders together so they can objectively contribute to discussions, Q&A sessions, break out sessions, etc. in pursuit of consensus and agreement on the best way forward for this important EU project which will be steered and coordinated by the European Commission's Joint Research Centre.

European quality assurance guidelines, a historical overview

(Swiss cancer screening, Fédération suisse des programmes de dépistage du cancer - Chris DE WOLF)

The development of comprehensive standards and recommendations for best practice in cancer screening and their publication by the European Commission in European QA guidelines for mammography screening has been a prime motor for the implementation of breast screening services of high quality in the EU.

The European breast Cancer Screening network, a project under the EAC programme served as a testing ground for the development of these guidelines. Full recognition arrived when in December 2003 the Council of the European Union made specific recommendations to the Member States to implement organised breast cancer screening programmes following the European QA guidelines.

Updating and expansion of the scope of the European QA guidelines was a primary objective of the network. With completion of the 4th edition, an important foundation has been laid for continued improvement in breast cancer care in Europe.

It is almost 7 years ago that the 4th edition appeared. Developments in breast cancer screening have accelerated and the need for more precise and universal quality parameters is often heard. The 5th edition should be an all-embracing, comprehensive update reflecting the latest evidence on breast cancer screening including assessment of screen detected cases. The certification process for breast units does not belong in these screening guidelines and should be developed separately.
Guidelines and Accreditation: the two main tasks to tackle

(JRC - Donata LERDA)

Background
The Commission Implementing Decision regarding the Health Programme 2008-2013 allocates to JRC the following needs:

A. to update cancer screening guidelines (to be extended to all other stages of BC care)
B. to develop a Voluntary European Accreditation Scheme for Breast Cancer Services

So the project and this workshop have two connecting pillars: the guidelines and the associated accreditation scheme.

Methods
A literature search and targeted studies, like the survey on the situation of breast cancer services in EU and the comparison of existing schemes, allowed to define the project frame and to map the complexity of the environment.

Results
A project concept was prepared and distributed to participants. The survey outcomes and the comparison of existing schemes provided essential information for designing a fit-for-purpose proposal for the protocol. From bilateral meetings and literature searches, the centrality of Guidelines content, structure and their lifecycle was highlighted together with the importance of evidence grading methodology. A proposal is presented to participants.

Conclusions
Base documents and proposals are presented for further discussion. Agreement of participants will be sought both on project content and future working modalities.
Framework for an accreditation scheme appropriate for a tapestry of public health services

CO-CHAIRS:

Robin WILSON - Clinical Radiology Department - The Royal Marsden

Jane BEAUMONT – United Kingdom Accreditation Service (UKAS)

Rolf STRAUB – Swiss Accreditation Service (SAS)

Ciarán NICHOLL – JRC

Picture 2 – Thomas Facklam presents the European co-operation for Accreditation

Presentation of EA

European co-operation for Accreditation – EA – Thomas FACKLAM)

Thomas Facklam gave a short introduction on the organisation and tasks of EA. The presentation was posted on the web at the conclusion of the workshop and includes an overview of the members of EA (the National Accreditation Bodies) and of the standards
applied in the accreditation frame according to EU legislation (see presentation of Nike BOENNEN below).

**Presentation of Accreditation frame, examples and audit description**

(UKAS – Jane BEAUMONT)

Consumers demand confidence in the reliability of health-care services, the safety and quality of products they use, the environment they live in, and many other aspects of daily life. It is important for businesses and regulators to have confidence in the integrity and quality of the services supplied by laboratories, inspection bodies, certification bodies, diagnostic services and other organisations. Accreditation by national accreditation bodies (NABs) provides such confidence.

Accreditation is a formal, third party recognition of the competence, impartiality and performance capability of organisations to perform specific activities. When an organisation has achieved accreditation, it means that it has been assessed and can demonstrate to users of services that it has been successful at meeting the requirements of international accreditation standards.

Within the European cooperation for Accreditation (EA), NABs provide accreditation services in accordance with an international standard EN ISO/IEC 17011. EA ensures consistency and transparency of accreditation services throughout Europe.

Confidence in breast cancer services is essential and this presentation aims to provide information about the important role that the accreditation process can play in helping to improve and maintaining the quality of care at different stages in the breast cancer pathway.

**Presentation of comparison of quality assurance schemes for Breast Cancer Services in Europe**

(JRC – Silvia DEANDREA)

**Background**

In order to draft a proposal for an EU accreditation protocol for breast cancer services, a description and an analysis of existing schemes was needed.

**Methods**

Existing quality assurance schemes for breast cancer care were identified through different sources: searches in PubMed, results from the 2012 Survey on the organisation of breast cancer services in Europe and contacts with relevant stakeholders.
Results
At least 20 different quality assurance schemes are operating in Europe. Some are public and country-specific, others are led by private organisations and cover more than one country. In some cases, there is a general quality assurance scheme for the whole health institution plus an additional set of standards for cancer (breast or any kind of cancer). In other cases there is a specific scheme for breast cancer, independent of the general quality management system. Every stage of breast cancer can be covered, in isolation or in connection with others (i.e. screening, diagnosis, treatment, and follow-up).

Conclusions
Many different quality assurance schemes are present in Europe at the moment, showing a great effort played by different actors in order to improve the quality of care provided to women. A more integrated approach is now needed.

Presentation of legal background of accreditation, differences accreditation / certification
(DG ENTR – Nike BOENNEN)

Regulation (EC) 765/2008 on accreditation and market surveillance sets out a comprehensive legal framework for accreditation for the first time. Accreditation is to serve as the last level of public control in the conformity assessment chain. While certification bodies and laboratories check whether certain products and services comply with the necessary requirements, accreditation is to ensure that these bodies have the necessary technical competence to perform their duties.

The Regulation sets out a number of requirements for accreditation, namely one single national accreditation body acting as public authority. Accreditation is to be performed as a non-commercial, non-competitive activity and the national accreditation bodies have to undergo peer evaluation to ensure the continuous quality of their work.

Furthermore, national accreditation bodies have to be members of the European co-operation for Accreditation which organises the peer evaluation process and which may be requested by the Commission to develop specific schemes, such as a scheme for breast cancer units.

Cancer registries & cancer screening programmes: an important interface
(Mass Screening Registry/Finnish Cancer Registry - Ahti ANTTILA)

Background
Systematic quality assurance, monitoring and evaluation are prerequisites for the organised
population-based cancer screening programmes for cervical, breast and colorectal cancers as recommended by the Council of the EU. Evaluation of benefits and harms requires regular linkages between screening and cancer registry as well as with mortality records and other files within health-care. Consideration of cancer screening programmes for any other primary site necessitates rigorous evaluation of the efficacy and adverse effects, using randomised trials and integrated analyses of quality-of-life and health economical aspects.

Purpose
In the EUROCOURSE WP on the Interfaces between cancer registries and cancer screening programmes, recommendations and priorities were developed on the domain.

Results
The recommendations developed by the work group deal with the cancer registry practices (coding structures, inclusion of pre-cancers, and utilisation of the diagnostic and management processes); developing standards on the data items and key indicators for cancer screening registries and for linking processes between registers. A proposal on research priorities and collaborative projects within the European setting was developed.

Conclusions
Standardisation of data items and indicators is essential to develop appropriate monitoring at the regional, national and European level. Data linking processes need to be extended to new programmes, in order to obtain a comprehensive and systematic evaluation system for the programmes. To enable linkage procedures, adoption of the legal frameworks is required in the MSs. It is also crucial that the new European data safety regulation under development would enable appropriate register-based evaluation and quality assurance.

Presentations of results from a survey on Breast Cancer Services in European Countries

(JRC – Donata LERDA)

Background
The objective of the survey was to collect information from the countries concerned by the project (Member States, plus Iceland and Norway) on the organisation of Breast Cancer services (BCSs) and on other aspects of interest for the project (e.g. screening programmes, training requirements for professionals, quality and safety aspects, QA schemes, etc.).

Methods
The survey included a questionnaire and a data protection form. PDF forms (Adobe LiveCycle designer) were prepared and distributed by email. DG SANCO informed EPAAC national
contacts that the survey was going to be launched and they were asked to nominate a person responsible for it. A functional mailbox address and a list of telephone numbers were provided to participants.

Results
Twenty-five of the 30 contacted countries responded, corresponding to a response rate of 83%. Aggregated results on organisation and quality assurance of BCSs are presented. A full report will be published upon validation of participants' individual responses.

Conclusions
1. Health-care systems are diverse across Europe
2. QA systems for BCSs are in place in less than 50% of countries
A European wide harmonised (evidence-based and flexible) scheme is needed to grant equal and quality benchmarked treatment to patients.

Presentation of protocol concepts
(JRC – Silvia DEANDREA)

Background
European Parliament Resolution of 10 April 2008 calls on the European Commission to "support the development of European accreditation/certification programmes in cancer screening, diagnosis and treatment based on European QA guidelines, which could also serve as an example for other areas of health-care".

Methods
General characteristics and key concepts of existing quality assurance schemes for breast cancer have been compared and analysed. Stakeholders have been met in several bi-lateral meetings.

Results
The general concept of the proposed scheme will be developed taking into account accreditation requirements (e.g. ISO 15189:2007) and including a list of specific items linked to the future 5th edition of the European guidelines for quality assurance in breast cancer screening and diagnosis. The processes covered will be: screening, diagnosis, treatment (surgery, chemotherapy/hormone therapy, and radiotherapy), post treatment surveillance and management of recurrence (including palliative and psychosocial care). Specific attention will be paid to: patient-centred care, evidence-based indicators, quality of data and interface with other databases and cancer registries.
Conclusions
The main project pillars should be agreed among stakeholders and concerned countries, in order to meet the needs of professional communities and citizens towards a European harmonisation of breast cancer care.
DAY 1 AFTERNOON

Revision of the European Breast Cancer Guidelines - a scalable approach

CO-CHAIRS:

Lawrence VON KARSA – IARC

Ahti ANTTILA - Mass Screening Registry/Finnish Cancer Registry

Donata LERDA - JRC

Fourth edition of the European Guidelines

(Editorial board of the 4th Edition of the European QA Guidelines - Nicholas PERRY)

Objectives
Describe current status and future importance of the European QA Guidelines.

Methods
Outline progression from the 3rd to 4th editions and subsequent annexes.

Results
The 3rd edition raised political and professional awareness of the Guidelines, and was used as a basis for National guidelines by several Member States.
For the 4th edition the European Commission required inclusion of symptomatic activity, also promotion of Specialist Breast Units and the setting out of accreditation/certification mechanisms and protocols.

Political and professional concordance was achieved with multinational input from over 200 professionals from 18 Member States and other non-EU countries. Pragmatic combination of existing National guidelines with wide experience of best practice produced a document of achievable standards whilst prioritising the need for mortality reduction and benefit over harm.
Despite recent publication of further annexes, much of the 2006 edition requires updating with additional sections to be discussed. Scientific references supporting an evidence-based approach should be employed in the interests of conformity.
Conclusion
The pre-requisite of a drive towards a robust and defensible accreditation/certification process must be the existence of an up to date and acceptable reference document which a revised edition of the European QA Guidelines would provide.

A proposal for a generic structure of health-care Guidelines

(JRC – Nicholas NICHOLSON)

Background
The European Guidelines for quality assurance in breast cancer screening and diagnosis is in its 4th edition (2006). The revision of the European QA Guidelines will be undertaken in parallel with the development of the EU voluntary accreditation scheme for breast cancer services.

Methods
A structure should be conceived that provides a scalable concept for the development of European health-care guidelines and places individual guidelines at their correct level of abstraction. Such a structure will encourage reuse of guidelines and limit duplication of effort. Moreover, the “information space” associated with each guideline can be amplified using relational database methodology. A possible means for a generic structure of guidelines is presented which could find application to the 5th edition of the European guidelines for quality assurance in breast cancer screening and diagnosis.
Organisation and open questions for Break-out sessions

(JRC – Crystal FREEMAN)

BOS leaders received information regarding the functioning of BOSs before the workshop. Concepts were clarified and participants were informed of their roles and expected duties. Prior to the workshop BOS leaders received a list of open questions to be discussed and they were also asked to prepare a report of the main session's conclusions to be shared with other BOS participants during a "poster" session. BOS leaders were asked also to give a short presentation during DAY 2.

The links to the respective lists of points of discussion are given below

1 - Accreditation

2 - Guidelines and Research

3 - Patients

4 - Databases and Cancer Registries
DAY 2

Day 2 presentations were prepared during the workshop. Therefore, no abstracts are available.

Reportage of Break-out-sessions

**BOS 1 - Accreditation**

BOS Leader: Jane BEAUMONT - UKAS

**BOS 2 - Guidelines and Research**

BOS Leader: Nereo SEGNAN – CPO Turin

**BOS 3 - Patients**

BOS Leader: Susan KNOX – Europa Donna

**BOS 4 - Databases and Cancer Registries**

BOS Leader: Stefano ROSSO - ENCR
Final agreement

CHAIR: Ciarán NICHOLL - JRC

Interface Guidelines versus Accreditation

(Centro Cochrane Iberoamericano - Jesús LÓPEZ ALCADE)

The possibility of referring requirements of the quality assurance scheme to evidence based guidelines, as well as on the basis of conclusions from break-out sessions was investigated. In addition, information about guidelines life-cycle, literature reviewing and grading of evidence was provided.

Organisation of future work and agreement on project fundamentals and next steps

(JRC – Donata LERDA)

Based on BOSs conclusions and on plenary sessions’ discussions, the presentation was prepared and posted on the webpage after the workshop. It summarises the main conclusions from the workshop (which were also included in a document circulated for approval among participants - see ANNEX III).

Picture 4 – Second day lunch
4.2. **Workshop for Countries delegates 13–14 March 2013**

The workshop agenda foresaw some plenary sessions dedicated to inform participants on the background and main project pillars and to host open discussion on the various aspects presented, and one very important plenary session where some countries’ delegates were invited to present the situation of Breast Cancer Services in their own country. As most of the JRC presentations were similar to those given at the previous workshop, the corresponding abstracts can be found in paragraph 4.1 above.

The following sections include the agenda and a summary of the respective presentations given by JRC and non-JRC speakers when made available. Points raised during discussion time were summarised in the last presentation but also in the conclusions’ document reported at ANNEX III.

**Picture 5 – Group picture from the second workshop**
DAY 1

Introduction and background

CHAIR: Krzysztof MARUSZEWSKI - JRC

Introduction and background

(JRC - Krzysztof MARUSZEWSKI)

The organisation of the Joint Research Centre (JRC) – the research hub of the European Commission – is reported, focussing on the policy support profile characterising research carried-out at the JRC. The many activities on-going at the Institute of Health and Consumers Protection (IHCP) are described and the link with human health is detailed. The background for the constitution of a group dedicated to Public Health was given as introduction to the agenda and speakers for the two days event.

Purpose of the workshop

(JRC - Ciarán NICHOLL)

See paragraph 4.1

Aim of the initiative, legal and historical background

(DG SANCO C.1 – Michael HÜBEL on behalf of Antoni MONTSERRAT)

Since 1985, cancer has been a priority issue for EU public health policy. The first ‘European Action Plan Against Cancer’ was adopted in 1987. Nowadays, and in order to strength the cooperation between the European Commission and the Member States efforts are performed jointly, implementing the concrete actions set up by the Commission Communication on Action Against Cancer: European Partnership (2009) with the ambitious goal to reduce cancer incidence by 15% by 2020 and being now implemented via the joint action (2011-2013) ‘European Partnership for Action Against Cancer’ (EPAAC). The EU Health Programme supports the revision of the third version of the European Code Against Cancer (2003). The new version should be available by the end of the EPAAC joint action.
The European Commission is preparing the future, together with Member States, with a new Joint Action (2014-2016) to prepare a guide for comprehensive cancer control, which will be funded under the budget 2013 of the Health programme.

In December 2003, the Council adopted a Recommendation on cancer screening, which sets out principles of best practice in the early detection of cancer, and invites all Member States to take common action to implement national population-based screening programmes for breast, cervical and colorectal cancer, with appropriate quality assurance at all levels. Through its various actions, the EPAAC is supporting better implementation of the European cancer screening guidelines.

Based on the administrative agreement between SANCO and the Joint Research Centre, the in-house science service of the European Commission, a first European voluntary accreditation scheme for breast cancer services will be developed and, at the same time, the 4th edition of the European QA Guidelines will be revised.

The European Partnership is promoting the creation of a European Cancer Information System in cooperation with the JRC. Without more complete and reliable cancer data, the effects arising from any decision or implementation measures to reduce the cancer burden in the EU will remain the subject of debate. Harmonised data and agreed metadata standards are fundamental for accurate comparisons of data across regional and national boundaries.

The European Partnership for Action Against Cancer: [EPAAC](http://www.ezac.org)
The EU public health action on cancer: [EU public health-cancer](http://ec.europa.eu/health)

**Project pillars - Accreditation scheme and revision of European QA Guidelines**

(JRC – Donata LERDA)

See paragraph 4.1.
**Accreditation and certification**

**CHAIR: Ciarán NICHOLL - JRC**

**Presentation of legal background of accreditation, differences accreditation / certification**

(DG ENTR – Nike BOENNEN)

See paragraph 4.1.

**The European Cooperation for Accreditation**

(European co-operation for Accreditation - EA – Thomas FACKLAM)

The definition of accreditation as defined in regulation 765/2008 EU was explained and its possible application as a tool for a voluntary European scheme for breast cancer services underpinned by accreditation.

The European co-operation for Accreditation as the association of national European accreditation bodies was presented and the possible involvement of EA in the development of a scheme for breast cancer services has been provided with the following possible areas including standards to be used:

- **ISO 15189: 2012** - Medical laboratories. Accreditation of medical laboratories bodies to perform screening, medical testing and examinations based on procedures and guidelines (e.g. mammography, histopathology tests, etc.).

**Proprietary scheme especially designed for BCS activities.**

Accreditation of certification bodies for certifying products, processes and services against both the requirements of ISO/IEC 17065: 2012 and any additional measures prescribed by the scheme owner in regulations, operating manuals, directives and guidelines. Audit of management system including also a check of medical specifications (e.g. based on guidelines for the treatment of breast cancer).

**Procedures and installations.**

Accreditation of inspection bodies to inspect specific procedures and installations in the pathway of breast cancer treatment based on given specifications.
Presentation of Protocol concepts

(JRC – Silvia DEANDREA)

See paragraph 4.1.
**Guidelines within the accreditation scheme**

**CHAIR: Ciarán NICHOLL - JRC**

**Overview of existing breast cancer screening guidelines in EU and outside**

(Ministero della Salute Italiano – Antonio FEDERICI)

The presentation described the experience in Italy in reviewing the quality of guidelines (GLs) on cancer screening programmes (CSP) using the *Appraisal of Guidelines for Research & Evaluation* (AGREE) instrument on the assumption that the variance of professional’s behaviour can be explained by different approaches to CSP considered in the GLs issued by scientific societies to which they refer.

Searching the main databases and websites we identified guidelines on CSP written in Italian or English since 2000. Of the 32 relevant documents identified for breast CSP, 12 could be evaluated with AGREE.

Documents from different countries and health systems differ in terms of the main recommendations given, the quality of the documents and in competing interests of the authors and sponsors. Documents produced by governmental agencies (the majority of them located in Europe) had, in average, higher scores than documents produced by scientific societies (the majority of them located in USA) and clinicians should be made aware of this overall evaluation.

Differences in scores have also been found among the three EU guidelines (for breast, cervical and colorectal cancer screening) because of diversity in methodology applied and in consistency between objective and contents. These aspects were greatly improved in the guidelines more recently issued and a move from quality assurance (QA) of the single procedure to QA of the whole screening process is also observed.

In conclusion, guidelines:

1. should be considered a tool for a more complex way of managing clinical problems and governance issues
2. should ensure stakeholders of good quality and inter-country validity
Output of the first workshop as basis for discussion

(JRC – Nicholas NICHOLSON)

The conclusions from the first workshop, which are also included in ANNEX III of this report, were sent to invitees of the second workshop prior to the event and further presented to the audience in order to inform and provide a starting point for further discussion of the project concept proposed by the JRC to the audience.

Results from the survey on the European Guidelines for Quality Assurance on Breast Cancer Screening and Diagnosis and Example of possible new structure

(JRC – Donata LERDA and Silvia DEANDREA)

During the first workshop a possible structure of a new edition of the European QA Guidelines was proposed but no agreement could be reached. Therefore, two weeks prior to the second workshop, JRC decided to launch a survey among countries delegates on the use of current European QA Guidelines, on the use of other guidelines and on how to make next edition of European QA Guidelines more usable.

Eighty-three per cent of the countries responded, 93% of respondents were aware of the European QA Guidelines, and 71% respondents reported using other guidelines in addition to the European ones (e.g. National ones derived from the 4th edition of the European QA Guidelines). Many respondents preferred having regularly updated and better structured Guidelines, possibly following the care stages. It was also mentioned that the Guidelines should be evidence-based as well as web-based.

Following the suggestions from countries delegates (direct users of Guidelines), a possible multi-layered structure was proposed. The entrance stage, the invitation to screening, was proposed as an example. The word “invitation” was searched in the 4th edition of the European QA Guidelines and 66 hits were found in five different chapters. JRC team proposed to convey the information distributed in those different chapters through questions following the walkthrough stages. For instance, “How should the invitation letter be structured?” could be one of the possible questions to be addressed by screening guidelines. A possible model for the NEW European Guidelines could be characterised by the following points:

1. Input for the respective recommendation would be literature review and experts opinion
2. Output would be the recommendation on invitation letter requirements, an accreditation requirement on information to be included in the letter and a standard template letter
3. The primary structure of the guidelines would be per stage and additional layers can be added (possibly in a web-based architecture): stage layer would be screening, cancer layer would be breast (but also colon and cervical), profile layer would be screening programme manager, general practitioner and women/patients, and, finally, the quality dimension layer would be effectiveness and responsiveness.
DAY 2

The situation of Breast Cancer Services in Europe

CO-CHAIRS:

Szilvia MÁDAI - Public Association for Healthy People

Donata LERDA - JRC

Picture 6 – Open discussion during the presentation of Breast Cancer Services in the participating countries
Presentations of results from a survey on Breast Cancer Services in the participating countries

(JRC – Donata LERDA)

See paragraph 4.1

Presentation of comparison of quality assurance schemes for Breast Cancer Services in Europe

(JRC – Silvia DEANDREA)

See paragraph 4.1

Breast Cancer Services in Ireland

(National Cancer Control Programme – Dr Jerome COFFEY)

Breast Cancer Services in Czech Republic

(Onkologicka klinika - Bohuslav MELICHAR)

Breast Cancer Services in France

(Bureau MC3, maladies chroniques somatiques Ministère des affaires sociales et de la santé - Rosemary ANCELLE-PARK)

Breast Cancer Services in Sweden

(Unilabs AB – Karin LEIFLAND)

Breast Cancer Services in Germany

(Bereichsleiterin Zertifizierung - Deutsche Krebsgesellschaft e.V. - Simone WESSELMANN and Vanessa KAAB SAYNAL)
Future associated elements

CHAIR: Ciarán NICHOLL - JRC

Directive 2011/24/EU on patients’ rights in cross-border healthcare - Implications on patients' safety and quality

(DG SANCO D.2 – Katja NEUBAUER)

The Directive 2011/24/ EU on the application of patients' rights in cross-border health-care seeks to clarify the rights of patients to access care in another EU Member State. It also seeks to ensure that such care is safe and of good quality.

The provisions of the Directive related to patient safety and quality of care include: obligation of EU Member States to inform patients about safety and quality standards and guidelines in place; cooperation of Member States on standards and guidelines on quality and safety; possibility of refusing a prior authorisation if a health-care provider chosen by a patient raises serious concerns about patient safety. To facilitate exchange of information between Member States and to provide information to patients and health professionals on cross-border health-care, the Directive requests Member States to put in place national contact points. The names and contact details of such national contact points should be communicated to the European Commission. The Directive also foresees creation of European reference networks composed of centres of expertise which fulfil specific criteria. These criteria will likely include the ones related with safety and quality of care. The Directive is currently under transposition until 25 October 2013.

Joint Actions on Cancer - EPAAC and Cancer Control - aiming at improving the coherence and the quality of cancer management in the EU

(National Institute of Public Health Slovenia – Tit ALBRECHT)
Conclusions and next steps

CHAIR: JRC team

Organisation of future work and agreement on project fundamentals and next steps

(JRC – Donata LERDA)

The workshop activities were summarised and project next steps were reported. The JRC foresees that the project concept initially proposed to the participants into the two workshops (Project concept) will be modified according to the main comments received during and after the two events, taking into account inputs received from other stakeholders during subsequent bi-lateral meetings and parallel on-going projects, and in agreement with DG SANCO. The planning of activities, and the organisation of working groups, will strongly depend upon the updated version of the project concept, but some general lines were drawn, defining the main goals and their design. In addition, the desired collaboration from countries was defined through the possible roles at different stages of the project.
5 Conclusions from the workshops

5.1. Workshop for experts 21-22 February 2013

Shortly after the workshop (28 February 2013) a draft document with the conclusions of the workshop was sent out to all participants asking to send back their comments and concerns on those conclusions. A revised version of the document, which incorporated participants’ comments, was created and given to Europa Donna for additional input and review. The final version was prepared and sent out to all participants into the first workshop on 8 March 2013; it is still in the draft form until an aggregated conclusions’ document is prepared for both workshops and included in this report (see paragraph 6). The third updated version of the document was also sent to participants of the second workshop, together with the project concept and can be found in ANNEX III.

5.2. Workshop for Countries delegates 13–14 March 2013

As with the first workshop, an initial version of workshop’s draft conclusions was sent to participants shortly after the conclusion of the second workshop (25 March 2013). A second version was prepared and circulated for final comments (see ANNEX III) before merging the two sets of recommendations and conclusions into this report (see chapter 6).
6 Merged conclusions and impact on the initiative

The main points of agreement for the two main activities of the project - the development of a voluntary European quality assurance scheme for breast cancer services and the updating / integration of the 4th edition of the European QA Guidelines - can be summarised as follows:

a. The European QA Guidelines were functional to the development of screening programmes and they should be maintained as reference document for the whole of Europe. Therefore the updating of the 4th edition of those guidelines is urgent and has to be given priority.

b. Both the process of guidelines updating / integration and of development of the European scheme should cover all breast cancer care stages (screening, diagnosis, treatment, survivorship – support – palliative care, and management of recurrence).

c. The two processes should be undertaken in parallel, as guidelines will constitute the reference base for the quality assurance requirements, and be modular, in order to accommodate different organisational settings (in particular as regards screening and the rest of the process being in many cases under different entities).

d. Women / patients should be at the centre of the initiative and of its outcomes.

e. It is essential for the initiative to involve all concerned stakeholders: clinical experts, policy makers, general practitioners, screening programme managers, patients’ associations, cancer leagues, experts in accreditation, methodologists, etc.

f. The QA scheme should take into due account the relevant Council conclusions\(^2\), \(^3\) and fulfil requirements from the European legal framework regarding both accreditation\(^1\) and patient safety\(^9\).

g. The uniqueness of benchmarking across different countries, which should grant that requirements essential to improvement of outcomes are fulfilled across Europe by those Breast Cancer Services obtaining the certificate, will be ensured by the framework of accreditation bodies foreseen by the European Regulation on Accreditation\(^1\).

h. The QA scheme should be owned by an EU Institution as this would highlight its independence and make it more reliable.

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i. The QA scheme should consider existing schemes; in particular, where key performance indicators (and corresponding data collection) are similar in different schemes their inclusion in the European scheme should be considered. Furthermore, it should not overlap with or endanger existing national schemes (e.g. proposing a lower level of quality requirements)

j. The QA scheme should be sustainable, not expensive and not imposing heavy bureaucratic burden. High level professionals should be involved in the auditing in order to make the scheme, which is voluntary, attractive enough also for those services already certified by other entities

k. The QA scheme should not require the concentration of all stages of care in a unique centre, but focus more on quality requirements and checks between collaborating structures in order to grant that all patients' data and information are made available and that patients are transparently informed on the meaning and impact of the QA scheme for their own survival and quality of life

l. Guidelines can be supranational as the recommendations are obtained via a common evidence/consensus grading process, but their implementation at National- / local-level is governed by National-, and local health policies and set-ups. Therefore the translation of recommendations into requirements for the quality assurance scheme has to be agreed with concerned countries and take into account boundary conditions. This aspect has to be considered in particular for the treatment stage

m. Guidelines should be developed involving experts' (e.g. for the Screening guidelines, the team involved in the 4th edition of the European QA Guidelines should be involved for updating them). The JRC should provide guidance and coordination, in particular as regards the service provision aspects and the linkage between recommendations in the guidelines and quality requirements in the scheme

n. The monitoring process is functional to the implementation of the guidelines and of the QA scheme. It is therefore essential to identify key-performance indicators and to explore the possible interface with cancer registries and the need of clinical databases

o. Further information is needed on the functioning of accreditation under the EU legal frame (and is included into the updated concept of the EC initiative on breast cancer where a section is dedicated to accreditation aspects; the updated concept document will be soon made available to all project stakeholders)

The updated project concept and respective planning of activities for this European Commission initiative take into account the conclusions above, further internal discussions and information received during bi-lateral meetings taking place after the workshops.
In particular as regards the updating of existing European QA Guidelines, experts involved in the development of the previous editions will be invited to participate into the working groups. Concerning other stages and aspects of care than screening, The JRC will operate for the creation of a common platform for those guidelines which can be used as reference documents for the QA scheme; criteria for acceptance of guidelines will be decided by a specific working group. The AGREE\textsuperscript{4} approach might be applied as concerns some of the domains to be considered and the scoring method can be agreed upon by open consultation. As regards the European QA scheme, it will be developed in collaboration with European cooperation for Accreditation and several stakeholders will be involved, in particular for the definition of the list of specific requirements.

The first draft version of the project concept is available at the following link:

**Draft project concept**

*(DRAFT version presented to workshops' participants)*

The updated concept of the project taking into account inputs from stakeholders, inclusive of a draft planning of activities, is at the following link:

**Project concept**

*(Third version upon workshops' participants comments and internal approval)*

### 7 Workshop evaluation

The purpose of collecting and evaluating the participants’ feedback was to determine if the workshop objectives were successfully met and to highlight areas for improvement—resulting in better organisation of similar events.

Participants were asked to anonymously comment on the general content, specific content related to breakout sessions and/or plenary sessions, the workshop design and the organisation and logistics. For reasons of comparison, Likert scale items *(below expectations, met expectations, above expectations, not applicable)* are reported as percentages and open-ended comments have been organized under the general categories of ‘positive or most useful

\textsuperscript{4} http://www.agreetrust.org/resource-centre/agree-ii/
aspects’ and ‘least useful aspects and ways of improving’. Thematically similar comments have been grouped together into one representative comment, for both experts and delegates. However, a full list of participants’ comments is available upon request.

A feedback form (ANNEX V) was included in each registration kit and participants were asked to complete the feedback form on the final day of each workshop.

For the first workshop, only 18 out of 41 experts completed the feedback form, representing a response rate of 44%. Due to low response rate, the results could not be considered representative of all participants. However, those who did respond provided valuable information on how to improve the organisation of future events and therefore their feedback was taken into account.

Based on the low response for the first workshop, to increase the number of participants who provided feedback from the second workshop, a specific time during the meeting was allocated for completion of the feedback form. Using this method, 31 out of 35 delegates completed the feedback form, representing a response rate of 89%. A second measure based on participants’ feedback from the first workshop, was to provide more time for discussion. This suggestion was echoed by participants of the second workshop as well. This request was considered by the organisers not only as an indication of extending discussion time for future events, but also as a sign of interest in actively contributing to the project.

In general, participants’ feedback was more positive for the second workshop than for the first and it can be attributed, in part, to the implementation of participants’ suggestions from the first workshop.

In Figure 1 (and in the graphs included in ANNEX IV), the feedback obtained is reported by comparing the per cent of responses between the two groups of participants and, to take into account the lower statistical significance of the feedback from the first workshop, corresponding bars were filled in with partially transparent colours.

The feedback provided and the comments added in the free text boxes will be carefully considered when planning and organising future events but also entered in the quality system of the Institute for Health and Consumer Protection.

For further details on the evaluation and comments/suggestions provided by participants for the two events, please refer to ANNEX IV)
Figure 1 – Overall evaluation of the two events

Delegates (N=29)
- Below expectations: 3%
- Met Expectations: 52%
- Above expectations: 45%
- Not Applicable: 0%

Experts (N=18)
- Below expectations: 11%
- Met Expectations: 61%
- Above expectations: 28%
- Not Applicable: 0%
8 Acknowledgements

The authors would like to acknowledge the fundamental support of Brigitte WESTRITSCHNIG and Elisa REGENT for the organization of both events and the essential contribution of all participants to the outcomes of the workshops. In particular, we wish to thank the sessions' chairs, the break-out sessions' leaders and all the speakers for facilitating and stimulating a lively and fruitful discussion on the main project pillars and for providing essential information to the audience during both workshops.

The authors would also like to acknowledge European co-operation for Accreditation for providing much needed support for the accreditation terminology and terms of reference.
9 ANNEXES

9.1 ANNEX I – Additional useful links

Links to JRC webpages

Public Health webpage

Cancer Policy Support webpage

Breast cancer care initiatives webpage

Workshops webpage

Links on accreditation

Brochure of European co-operation for Accreditation

Accreditation page of DG ENTR
## 9.2 ANNEX II – Participants lists

### Table 1 – List of participants for Experts Workshop

<table>
<thead>
<tr>
<th>Name Surname</th>
<th>Affiliation</th>
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<td>WP 6 (Screening and early diagnosis) Leader</td>
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<td>Name Surname</td>
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| Sara BRUCKER      | Tübingen University  
German Society of Senology (DGS) |
| Augusto Tommaso CARACENI | European Association of Palliative Care (EAPC)  
Institute for Health Research - Lancaster University  
Istituto Tumori - Milano |
| Fatima CARDOSO    | Champalimaud Cancer Center, Lisbon  
European School of Oncology (ESO) |
| Luigi CATALIOTTI  | European Cancer Care Certification (ECCC) (President) |
| Marina DAVOLI     | Department of Epidemiology - Lazio Regional Health Authority  
Developing and Evaluating Communication Strategies to  
Support Informed Decisions and Practice Based on Evidence |
| Roberto D'AMICO   | Italian Cochrane Centre  
Università Modena e Reggio Emilia |
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</table>
| Rolf STRAUB   | Swiss Accreditation Service (SAS)  
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| Corrado TINTERI | Istituto Clinico Humanitas – Rozzano  
|               | Breast Centres Network                                                                                                                       |
| Sven TÖRNBerg | Editor of 4th edition of Guidelines  
|               | Karolinska Institute                                                                                                                          |
| Luzia TRAVADO | International Psycho-oncology Society (IPOS)  
|               | Champalimaud Cancer Center, Lisbon                                                                                                              |
| Dominika TRZASKA | European Commission - Directorate General Research & Innovation (DG RTD)                                                                       |
| Wim H. VAN HARTEN | The Netherlands Cancer Institute  
|               | Organisation of European Cancer Institutes (OECI) (President)                                                                               |
| Lawrence VON KARSA | Editor of 4th edition of Guidelines  
|               | International Agency for Research on Cancer (IARC)                                                                                            |
| Clive WELLS   | Contributor to 4th edition of Guidelines (§ 6.a & 6.b)  
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</tbody>
</table>
Table 2 – List of participants for Countries Delegates Workshop

* Country is reported only for those participants who were present as officially nominated delegates for their own country

<table>
<thead>
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<tr>
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<td>Accompanying person</td>
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<td>Karin LEIFLAND</td>
<td>Chef Mammografi Sverige - Unilabs AB</td>
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<td>Fakultní nemocnice Olomouc</td>
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<td>Katja</td>
<td>NEUBAUER</td>
<td>European Commission - Directorate General Health and Consumers (DG SANCO)</td>
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<td>Inés</td>
<td>PALANCA</td>
<td>Ministero de Sanidad y Política Social</td>
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<td>Ana Cristina</td>
<td>PORTUGAL</td>
<td>Direção-Geral da Saúde</td>
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<td>Name SURNAME</td>
<td>Affiliation</td>
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<td>Constanta TIMCHEVA</td>
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CONCLUSIONS FROM THE FIRST WORKSHOP

(version 3 – including participants' inputs)

Introduction

The main aim of the workshop was to discuss and seek agreement on the underlying concepts and processes towards developing an European scheme (underpinned by accreditation) for quality assurance of breast cancer services, and update and revision of the 4th edition of the European guidelines for quality assurance in breast cancer screening and diagnosis (hereafter referred to simply as the European QA Guidelines).

The two-day workshop was by invitation to participants active in breast cancer health-care from a range of different but relevant backgrounds and disciplines and provided a unique occasion in terms of bringing together such a diverse range of experts to work towards improving breast cancer care in Europe.

The workshop was organised according to plenary sessions, followed by a series of discussion/question time slots. In addition, four parallel break-out sessions tackled relevant questions, addressing: accreditation; research & guidelines; patients; and cancer registries. The groups were asked to provide some high-level guiding recommendations to be discussed with all other participants on the second day of the workshop. Further information on the event may be found from the JRC's cancer policy support webpage.

This document summarises the broad conclusions reached during the workshop.

Conclusions

1. Overall considerations

1.1. There is a critical need to improve the general situation of breast cancer care in Europe.

1.2. The European QA Guidelines (now in its 4th edition) has been instrumental in promoting good practices. The current edition was however published in 2006 and there is an urgent need for updating it so that it does not become out-dated.

1.3. An European scheme, underpinned by accreditation, to ensure quality of breast-cancer services, is considered a critical tool allowing women – regardless of the country in which they reside – the confidence afforded by a high standard of care recognised across the whole of the EU and associated countries.

1.4. The two processes of updating the European QA Guidelines and developing the European scheme should be undertaken in parallel. The European QA Guidelines updating process is at least as equal in importance as the development of the European scheme.

1.5. The individual (in terms of the screening stage) and the patient (once diagnosed with breast cancer) should be at the heart of both processes.

1.6. Both processes should ideally cover the whole breast-care chain (including screening, diagnosis, treatment, and survivorship, supportive and palliative care). A number of participants highlighted the potential need to focus initial priority on the screening and diagnosis stages which account for 80% of women involved (but without losing sight of the whole chain in order to avoid fragmentation). Some of the services in the later parts of the chain are not specific just to breast cancer patients but are more generic in nature and could therefore constitute more generic guidelines. Nevertheless all aspects of care must be coordinated at all stages (the multidisciplinary aspects being vital).

1.7. Patient representation organisations should be involved in each stage of the process.

2. **European quality assurance scheme underpinned by accreditation**

2.1. The European scheme should neither be expensive nor disruptive to implement, it should not impose a heavy bureaucratic burden and should seek out the crucial clinical skills and working practices vital to satisfactory health-care outcomes. ISO standards are sufficient for laboratory practices but where skill and competence of professionals is concerned, other criteria are needed.

2.2. The scheme should not define mediocre standards but state-of-art standards that can be used to set ambitious targets and optimise breast cancer care.

2.3. The choice of indicators is critical, especially given the constraints of not having too many of them which could otherwise make the whole process infeasible.
2.4. Data collection, monitoring, and evaluation are extremely important. Agreement even of minimal core data sets is a difficult and lengthy process. An essential element to the scheme will be the setting up of a database to capture the relevant and agreed information and indices. Another critical component concerns the associated interface to population-based cancer registries (necessary, for example, to evaluate the impact of the organisation of breast cancer care in the entire population).

2.5. The development of the European scheme should not be delayed until the next edition of the European QA Guidelines is available. However, the identification of those requirements agreed as essential to the scheme need not be delayed until the publication of the 5th ed. of the European QA Guidelines, and moreover can help drive the updating process itself.

2.6. The scheme should allow for certification of the whole process as well as for a more modular approach for centres that together offer the breast cancer care services. Moreover the scheme will include parts that can be directly accredited (e.g. testing activities). Regardless of the particular set-up of breast cancer services, the importance of integrated care pathways (including accessibility of psychological support, symptom management, and palliative care) cannot be underestimated and requires a strong focus in the European scheme on the multidisciplinary and multi-professional processes with corresponding input from all associated stakeholders (oncologists, palliative care specialists, physicians, nurses, patients, etc.).

2.7. If the accreditation frame is used, there is no discussion on the choice of standards. The respective testing activities, conformity assessment bodies, inspection and certification bodies will be accredited according to the harmonised international standards (and any additional requirements). EU accreditation operates under Regulation (EC) No 765/2008.
2.8. As regards the meaning of accreditation, certification, and inspection processes, reference needs to be made to the European legislative framework for accreditation. It is extremely important that terminology of the accreditation framework is used correctly and meticulously to avoid confusion. Accreditation checks testing activities and the technical capacity of a conformity assessment body but it will not set the requirements. The schema presented in the ANNEX of the draft concept document on the workshop website illustrates the complex but encompassing structure of accreditation and accredited certification. Given the European scheme (ISO standards plus requirements derived from guidelines plus other possible requirements), different entities may submit to National Accreditation Bodies their request to be accredited (for being authorised to audit and certify the Breast Cancer Services under that scheme.

2.9. The pathways to be included in the accreditation can be identified as follows:
- Screening
- Diagnosis
- Treatment (including adjuvant treatments, and treatment for advanced diseases)
- Survivorship, Supportive and Palliative Care (the area advanced disease may overlap with palliative care and the critical need to address quality of life and symptom control).

3. Revision of European QA Guidelines

3.1. Guidelines should be evidence-based (which also includes expert opinion). Organisational aspects included in the requirements of the scheme should also be evidence-based.

3.2. Despite the tool used for grading evidence, it is vital to involve experts who can formulate the important questions to search for evidence. This is not a trivial process or one that can be undertaken by generalists.

3.3. If the revision is to include the other patient walk-through stages, distinction should be made between guidelines concerning service provision and guidelines concerning clinical practice. The European QA Guidelines are directed more to service-provision elements. Competent clinical experts could identify appropriate clinical practice guidelines (e.g. the ESMO breast cancer guidelines) that are applicable to the European scheme.

6 “General scope and design of the proposal for a voluntary European scheme for breast cancer services underpinned by accreditation and the further development of the European Breast Cancer Guidelines.”
3.4. The updating process should be undertaken by an editorial team of top experts (as has happened in the past). The editorial board of the 4th edition of the European QA Guidelines has moreover highlighted aspects that need updating.

4. Aspects which require further development, clarification and/or consensus

4.1. As for the terminology for accreditation, agreement on the meaning and use of guidelines terminology is important (e.g. guidelines are very often intended as lists of recommendations).

4.2. The process for updating the European QA Guidelines has three elements – revision of existing parts; inclusion of new subjects; and an element related to format and structure. The first two elements were agreed by all participants, but there was a divergence of opinion concerning the structure itself. Some participants considered that the guidelines were too focused on the disease aspects rather than holistic patient needs and guidelines could be grouped according to the different needs of a patient. It was also conceded that the structure could be more optimal (references were made to the particular structure of the European colorectal cancer guidelines). Further discussion is needed on whether recommendations should be separated from technical specifications and quality assurance aspects (e.g. quality control and maintenance planning of medical equipment).

4.3. Agreement on the tools and methods to use for determining, where relevant, the evidence base of guidelines and associated indicators.

4.4. Agreement on the tools, requirements and sources for selecting guidelines covering stages of breast cancer care other than screening and diagnosis.

4.5. Specialist breast centres were considered as a fundamental issue in the drive towards quality outcomes. Given the wide diversity of health service infrastructures in Europe, it has to be more clearly understood if different parts of breast cancer services separated in different centres could, under the requirements of the European scheme, provide the same level of quality as a dedicated and localised specialist breast unit.
4.6. The creation of working groups dedicated to different aspects of the work was widely supported. The nature, scope, focus, tasks, and expert constituents of the working groups have however to be formalised and agreed. Working groups for both the vertical (e.g. patient walk-through stages) and horizontal aspects (e.g. quality management, multidisciplinary approach, patient trackability over time, and stage of care as well as over geographical location - including selection of data for monitoring and evaluation, etc.) will be necessary. Related to this issue is the task of drawing up a specific organisational structure and work plan (including time-lines) for the two projects.

4.7. An advisory board with correct representation was considered important by many participants to ensure the project maintains a strategic focus. The remit and tasks of the Board need to be defined and agreed.

**Next Steps**

The JRC will carefully consider the recommendations received during the workshop. Following the workshop involving Member State representatives, it will synthesise the conclusions of both workshops and will map out the project lines for both the development of the scheme and the updating of the European QA Guidelines. These project plans will be sent to the participants involved for consultation. In this regard, the JRC will also further investigate the best means of proceeding in the areas of divergence, taking into account the following guiding criteria:

- The approach chosen should provide a scalable model for adoption into other fields of health-care (e.g. modular approach for both guidelines and the scheme underpinned by accreditation);

- The need to involve Countries' nominated delegates/representatives in cancer/health policy. The European scheme is voluntary and buy-in from those who have influence to promote it (and the guidelines) within their own countries is important, as too the aspect of full transparency.

- The need to ensure that benchmarking will be patient-centred and serve to bring about a reduction of inequalities;

- Evidence-based recommendations in guidelines will constitute a general basis for requirements of the accreditation / certification scheme;

- Requirements to be included in the scheme will be selected based on their level of criticality and strength of impact on the outcomes of breast cancer care, including quality-of-life aspects. Additional requirements may be incorporated at a later time;
For stages other than those covered by the European QA Guidelines (screening and diagnosis) a framework should be established in consultation with experts for the selection and use of evidence-based existing guidelines to be included as reference points in the European scheme underpinned by accreditation.\textsuperscript{7}

\textsuperscript{7} Possible criteria for selection of existing guidelines could be, e.g., last update, evidence grading, patient-centric aspects, expert opinion, etc.
CONCLUSIONS FROM THE SECOND WORKSHOP

(version 2 - including participants' inputs)

Introduction

The main aim of the workshop was to discuss the underlying concepts and processes towards developing an European scheme (underpinned by accreditation) for quality assurance of breast cancer services, and update and revision of the 4th edition of the European guidelines for quality assurance in breast cancer screening and diagnosis (hereafter referred to as the European QA Guidelines) into a 5th edition (hereinafter referred to as NEW European Guidelines).

The workshop was by invitation to participants identified through the network of National Contacts of the Joint Action European Partnership for Action Against Cancer (EPAAC). The network was initially contacted to help coordinate the launch in 2012 of a survey on the set-up of breast cancer services in Europe.

The workshop was organised along a number of plenary sessions, followed by a series of discussion slots. Further information on the event may be found from the JRC's Cancer policy support webpage.

This document summarises the broad conclusions reached at the workshop.

Information provided and received

Prior to the workshop, participants had access to:

- The conclusions of the previous workshop organised for experts
- A document proposing a project concept for developing an European quality assurance scheme, underpinned by accreditation, for Breast Cancer Services (hereinafter referred to as European QA scheme) and for updating the European QA Guidelines
- Background information (European legislative framework, priority activities) available on the web page of the Cancer Policy Support group (Cancer policy support webpage)

Following the workshop, all presentations were posted on the webpage associated with the event.
As most of the countries' delegates participating in the workshop were primarily direct or indirect users of the European QA Guidelines, prior to the workshop they were asked to answer to few questions regarding:

- How they refer and use the European QA Guidelines
- Other Guidelines to which they refer
- Proposals for the NEW European Guidelines

The aggregated results obtained from the questionnaire were presented during the workshop and the respective slides, together with a presentation on a possible example of a web-based structure for the NEW European Guidelines, are also posted on the webpage mentioned above.

Conclusions

1. Overall considerations

Economic and sustainability aspects should be considered at all stages of the project in order to make it possible for all countries to implement the NEW European Guidelines, and other possible correlated recommendations, and to adhere to the European QA scheme.

It was considered essential to involve in the project the first contacts with women and patients (e.g. general practitioners - GPs, gynaecologists, depending on countries' organisational settings) both for granting the correct information to patients and their trackability and to include in their needs (e.g. for training of GPs, for using decision aids, etc.).

Treatment is much more difficult to agree upon than screening and diagnosis. There are huge variations in practice across Europe (e.g. treatment of metastatic cancer). Such variability presents a large challenge to the project, impacting both the establishment of a stable and sustainable life-cycle for the NEW European Guidelines and the accreditation scheme itself. This requires an agreed modality for identifying accreditation requirements, taking into account the diverse organisational and economical boundary conditions in different countries, still keeping a patient-centric focus throughout the whole process of care.

As the involvement of countries is fundamental at all stages of the project, the identification of nominated delegates/representatives in cancer/health policy (one phone number per country) will be essential. At different stages and for the various working groups such National contact will be invited to indicate experts for the different stages and working groups of the project.
2. European quality assurance scheme underpinned by accreditation

2.1. The European QA scheme should provide the overall framework which allows the relevant national bodies to implement it according to national set-ups and national laws. Moreover the European framework should allow the integration/promotion of good national schemes. More specifically, the European QA scheme should not undermine existing high quality national schemes. With this aim, the possibility of assessing the European scheme requirements and the existing requirements in parallel will be explored together with other possible solutions.

2.2. The owner of the European QA scheme should be identified. This could be the European Commission.

2.3. The accreditation frame foreseen by Regulation (EC) No 765/2008 will be used; therefore international harmonised standards will be applied.

2.4. Notwithstanding the clear European legal framework regarding accreditation, a definition is required of what is implied by the envisaged scheme concerning accreditation and certification\(^8\). Participants are also referred to their respective national accreditation bodies which are aware of the discussions concerning the scheme.

2.5. The pathways to be included in the European QA scheme can be identified as follows:
   - Screening
   - Diagnosis
   - Treatment
   - Survivorship - Support - Palliative Care and Management of Recurrence.

2.6. The scheme underpinned by accreditation should allow for coverage of the whole process (all pathways) but keep a modular structure in order to be adaptable to different organisation settings.

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\(^8\) Concerning this point, reference is made to the conclusions of the experts’ workshop where it was concluded: "As regards the meaning of accreditation, certification, and inspection processes, reference needs to be made to the European legislative framework for accreditation. It is extremely important that terminology of the accreditation framework is used correctly and meticulously to avoid confusion. Accreditation checks testing activities and the technical capacity of a conformity assessment body but it will not set the requirements. The schema presented in Annex I of the draft concept document on the workshop website illustrates the complex but encompassing structure of accreditation and accredited certification. Given the European scheme (ISO standards plus requirements derived from guidelines plus other possible requirements), different entities may submit to National Accreditation Bodies their request to be accredited (for being authorised to audit and certify the Breast Cancer Services under that scheme). For those countries where an advanced certification system is already in place, the integration with the European QA scheme may be proposed through the provision that only Breast Cancer Services already certified with the advanced certification system may apply to NABs for the European scheme. The agreement on such provision and its legal feasibility will be discussed within the working groups which will be set up for this initiative."
2.7. It is important to focus on the real core/priority issues. These may then be expanded/improved as required. The basis is sound enough to make a start.

2.8. Key performance indicators should be given priority in the process of defining quality requirements.

2.9. The European QA scheme should be balanced between those countries having already a well-developed quality assurance system in place and those which have yet to define quality requirements.

2.10. The entity responsible for the screening stage is in general different from the entities responsible for the other stages of care. Moreover, different entities may also be responsible for any of the other patient walk-through stages. These aspects need careful consideration in the development of the European QA scheme underpinned by accreditation.

2.11. It is critical that participating services see the benefit of the audits. This can be assured by inclusion of professionals in the audit of services (e.g. medical oncologists if the audit is regarding that stage). In any case, the competences required of auditors need to be defined.

2.12. Some countries will need help with the auditing process (e.g. external experts).

2.13. The need to evaluate the likely costs of implementing the European QA scheme and to identify any possible means of support to those countries experiencing limitations in health budgets was mentioned by many participants.

2.14. The collection of data and transmission to population-based cancer registries is important but data protection laws in some countries makes this very difficult to do in practice. Moreover registries are organised differently and governed by different legal frames in different countries.

2.15. The European QA scheme should take into account the requirements set in Council Recommendations of 9 June 2009 on patient safety, including the prevention and control of health-care associated infections (2009/C 151/01).

2.16. The cross-border health-care Directive\(^9\) lays down requirements relating to patient safety and information/communication to patients and the European QA scheme for quality assurance of breast cancer services should be aligned with such requirements.


\(^9\) DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients’ rights in cross-border healthcare
3. Revision of the European QA Guidelines

3.1. The European QA Guidelines have had a very positive input at the national level.

3.2. There is an urgent need to update the European QA Guidelines. The process for maintaining them thereafter should be addressed.

3.3. Many guideline documents exist for breast cancer health-care (32 identified in the presentation given by Antonio Federici, Ministero della Salute Italiano), with several areas of disagreement in critical areas. The context of a guideline is extremely important and raises the need for an appropriate level of knowledge management.

3.4. The NEW European Guidelines should cover, or include in a guidelines’ framework of structure and methodologies, all stages of breast cancer care, as for the accreditation scheme.

3.5. The provision of NEW European Guidelines and National Guidelines are not necessarily exclusive processes. Often International Guidelines require National Guidelines for their practical implementation (adaptation process). Moreover, depending on the system used for grading of guidelines, the grading may also be subject to national differences (an evidence grade A in one country may equate to evidence grade B in another country and vice versa). This however does not pose a problem if an international grading system is used (e.g. GRADE).

3.6. National Guidelines on screening and diagnosis exist in many countries and in many cases they are based on European QA Guidelines. For this reason the task of updating the European QA Guidelines should be given priority.

3.7. It is very important to make a clear distinction between guidelines for service provision and clinical guidelines (e.g. for treatment). At this stage, except for the Screening and Diagnosis sections that will be directly updated, the NEW European Guidelines should make reference to existing guidelines on treatment and other aspects of the pattern of care establishing a set of acceptance criteria for referring to them (e.g. grading of evidence, last edition update, etc.).

3.8. In particular, as regards the stage of screening, Guidelines content may differ depending on the meaning assigned to the word "screening"; sensitivity and specificity might be the main points addressed or many other aspects, like empowerment, disease management, and quality improvement should be included depending on the conceptual frame of screening proposed.
3.9. The need of looking at the NEW European Guidelines as a tool in the hands of policy makers and of the wide range of different stakeholders was expressed. The structure and the content should take into account all these needs (as well as aspects relating to versioning, language translations, ease of tagging and indexing information, etc.)

3.10. Comparison of existing Screening Guidelines by application of the tool AGREE was presented and showed that often National Guidelines reach a very good quality level and in some cases even higher than that of guidelines developed by professional bodies. This is particularly important when the clarity and applicability are evaluated as these aspects have an impact on the implementation rate and imply that both medical professionals as well as programme implementers are involved in the following stages of the project, depending on the area of interest.

3.11. The recommendations provided in the NEW European Guidelines should be contextualised in the respective health systems. In the long term it may be possible to have European Guidelines, developed in a co-ordinated way, instead of National Guidelines. However, for the next years to have a unique set of European Guidelines for the whole Europe might not be feasible. In view of national differences, the NEW European Guidelines have to be adapted to the national set-ups. For the past in some cases the National version of the European QA Guidelines are even referred to directly within the national legislation.

4. Aspects which require further development, clarification and/or consensus

4.1. Further information regarding the functioning of accreditation is required, in particular regarding the interface with National Authorities own licensing / quality policies and the role of different players. It was clarified that National Accreditation Bodies were already informed about the project, however they would not take any further step (e.g. hiring of experts) until the accreditation scheme is more explicitly defined.

4.2. As for the terminology for accreditation, agreement on the meaning and use of guidelines terminology is important (e.g. guidelines are very often intended as lists of recommendations). The proposals for the structuring of the NEW European Guidelines should take into account how guidelines are more frequently intended and used.
4.3. Due to the divergence from the previous workshop's participants on the proposal for a new structure for the NEW European Guidelines, this point was specifically addressed in a pre-workshop questionnaire and an example was presented during this workshop. The need for having a structure allowing a quick and targeted retrieval of the information sought by different user profiles (e.g. clinicians, general practitioners, hospital administrators, policy makers, patients, etc.) was expressed clearly by many participants. However, a more detailed proposal should be prepared for further discussion.

4.4. Specialist breast centres were considered as a fundamental issue in the drive towards quality outcomes. Given the wide diversity of health-service infrastructures in Europe, it has to be more clearly understood if different parts of breast cancer services separated in different centres could, under the requirements of the European QA scheme, provide the same level of quality as a dedicated and localised specialist breast unit. A close check with demanding requirements in the European QA scheme for the interfaces between entities dealing with different stages of care (e.g. addressing trackability of patients across entities, countries and for long time) was proposed, but needs further evaluation to verify if it can govern the quality of the whole pattern of care in those countries were no centralisation of care is in place or foreseen.

4.5. As for the previous workshop, participants expressed their concerns on the timeline and content of the project: they agree on the need to speed up in particular the issuing of the NEW European Guidelines (and therefore on the need of drawing up a specific organisational structure and work plan including time-lines) and for some of them the co-existence and link of guidelines and quality assurance scheme was not clear. However they also indicated the need of not wasting the resources and called DG SANCO, JRC and the new Joint Action (European Guide on Quality Improvement in Comprehensive Cancer Control) to strongly collaborate and coordinate their activities.

4.6. The ideal situation for a straightforward development of the project was considered to be one in which the entities responsible: (a) for the cancer registries, (b) for the development of guidelines, and (c) for monitoring the European QA scheme for breast cancer services, could all work together in a coordinated way in all countries. The project may encourage this level of cooperation, however, in many cases this cooperation does not exist. The fact that these three aspects are all needed for the development of the European scheme and also for the revision of the European QA Guidelines could pose a risk for the optimal running of the project if not well coordinated.
4.7. Some of the participants both during the workshop and in their feed-back to the first version of this document expressed their concern on the JRC not being the right place to develop Guidelines, in particular with reference to clinical guidelines and on the need to use what already developed / updated from the European QA Guidelines in order to save time and resources. Therefore, further investigation is needed on how to set-up the process for having a synchronised process for clinical and service provision guidelines life-cycle and implementation of a European QA scheme.

4.8. Another area of concern expressed by some participants, and therefore to be proposed for further clarification and agreement, is the necessity of link between evidence-based guidelines and the European QA scheme requirements.

**Next Steps** (partially in common with the previous workshop Conclusions document)

As for the previous workshop, the JRC carefully considered the recommendations received from participants and incorporated them into this document. Then the JRC will synthesise the conclusions of both workshops and will map out the project lines for both the development of the scheme and the issuing of the NEW European Guidelines. These project plans will be sent to the participants involved for consultation. In this regard, the JRC will also further investigate the best means of proceeding in the areas of divergence, taking into account the following guiding criteria:

- The approach chosen should provide a scalable model for adoption into other fields of health-care (e.g. modular approach for both guidelines and the scheme underpinned by accreditation);

- The European QA scheme is voluntary and buy-in from those who have influence to promote it (and the NEW European Guidelines) within their own countries is important, as too the aspect of full transparency;

- The need to ensure that benchmarking will be patient-centred and serve to bring about a reduction of inequalities through the establishment of essential quality requirements; identification of general, high-level goals is one of the priorities for the project;

- Evidence-based recommendations in the NEW European Guidelines (and in the framework of guidelines for other stages of care) will constitute a general basis for requirements of the European QA scheme;
Quality requirements and key performance indicators to be included in the scheme will be selected based on their level of criticality and strength of impact on the outcomes of breast cancer care, including quality-of-life aspects. Additional requirements may be incorporated at a later time;

For stages other than those covered by the NEW European Guidelines (still to be defined) a framework should be established in consultation with experts for the selection and use of evidence-based existing guidelines (mentioned above as correlated recommendations) to be included as reference points in the European QA scheme underpinned by accreditation.
9.4 ANNEX IV – Evaluation of the two events

The feedback obtained is reported by comparing the per cent of responses between the two groups of participants; to take into account the lower statistical significance of the feedback from the first workshop, corresponding bars were made partly transparent.

Summary of the feedback – General and logistics

The general evaluation of the workshops was very positive: 61% of experts and 52% of delegates declared that the workshop 'met expectations' and for 28% and 45% it was 'above expectations' respectively.

As regards organisational and logistic aspects, feedback was required on administrative organisation, information received, location and logistics, material provided, and additional documents available. Detailed results for each question are available upon request, but in general the feedback was very positive and is summarised in Figure 1 below.

Comments on possible areas for improvement can be summarised as follows:
Some felt that the session rooms were too small and that the meeting venue was not ideal as it was necessary to take the bus to go to and from the hotel and the airport. It was also noted that participants should be informed prior to the start of the meeting that the meeting would be recorded and that meeting documents should be sent to participants more in advance before the meeting; this last comment may be addressed by a longer period of planning for events and for a prolongation of the time interval between the two.
Summary of the feed-back – Content

The workshops’ content was evaluated positively by participants. Figures summarising average response for the various groups of questions are included in this report, but detailed information is available upon request.

As regards the general evaluation, covering the capacity of the event to meet the envisaged objectives, the relevance to own work and the quality of presentations, the average response is summarised in Figure 2 below.

Comments received highlighted the need for more background on the different types of accreditation which have already been implemented (e.g. EUSOMA) and on how the current project intends to build on / or differs from those systems. Additionally, as mentioned already in chapter 8, the need of additional time for discussion was also expressed by participants to both events. As regards in particular participants at the second workshop, their comments showed that some were expecting a workshop focussed more on guidelines than on the QA scheme (and accreditation terminology needs clarification – see links in ANNEX I).
As regards specific sessions, the two events differed mainly for the break-out sessions (first workshop for experts only), for the presentation of "The situation of Breast Cancer Services in Europe" with presentations from several countries (second workshop for countries delegates only), and for the session "Future associated elements" dedicated to other initiatives which may impact on the project, like the new Joint Action on Cancer, the Council Recommendations for patients' safety and the Cross-Border Healthcare Directive (second workshop only).

For those workshop-specific sessions' contents, average evaluations are presented in Figures 3 and 4 respectively.

Comments received on suggested improvements in relation to break-out sessions mostly converged on the need to dedicate more time to discussion; some experts felt that a longer discussion and an anticipated provision of informative documents could bring to a more shared and solid outcome from break-out sessions.

Concerning presentations from countries, one participant suggested reducing the number of countries presenting for future workshops.
Figure 3 – Average response for the break-out sessions (BOS) [Experts’ workshop]

<table>
<thead>
<tr>
<th>Reportage of BOS</th>
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<th>Met Expectations</th>
<th>Above expectations</th>
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<tbody>
<tr>
<td></td>
<td>7%</td>
<td>87%</td>
<td>7%</td>
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<tr>
<td>BOS 4 - Cancer data</td>
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<td>BOS 3 - Patients</td>
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<td>22%</td>
<td>13%</td>
</tr>
<tr>
<td>BOS 2 - Guidelines</td>
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<td>57%</td>
<td>0%</td>
</tr>
<tr>
<td>BOS 1 - Accreditation</td>
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<td>43%</td>
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Percent of participants (%)

Figure 4 – Average response for the sessions "The situation of Breast Cancer Services in Europe" and for the session "Future associated elements" [Countries delegates workshop]

<table>
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<th>Met Expectations</th>
<th>Above expectations</th>
</tr>
</thead>
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<td>73%</td>
<td>18%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Future associated elements (N=22)</th>
<th>Below expectations</th>
<th>Met Expectations</th>
<th>Above expectations</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0%</td>
<td>63%</td>
<td>35%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Percent of participants (%)
As regards the sessions which were common to the two workshops, results from feedback showed that the content of the workshop was considered as informative and appropriate by participants; they are summarised as averages for all common sessions and in parallel for the two events in the Figure 5. The feedback questionnaire section included the events’ sessions dedicated to the background of the project, to the accreditation-certification European frame, to the updating of European QA Guidelines and guidelines in general and to the concluding session on the agreement points.

Figure 5 – Average response on the content of the sessions common to the two workshops
Summary of the feed-back – Workshop design

Several aspects were covered in the feed-back questionnaire concerning the general design of the workshop: balance between participation and presentations, the degree of involvement of participants, the sessions design and the balance between general and targeted information. The outcome was mostly positive (as summarised in Figure 6) but in particular participants to experts’ workshop, from 4 to 6 participants over a total of 41 (from 1/4 to 1/3 of the respondents), depending on the specific aspect addressed, highlighted that the workshop design can be certainly improved. As the second workshop participants' feed-back appears to be more positive also regarding the design of the event, it can be deducted that possible shortcomings were already addressed for the workshop for countries delegates.

Figure 6 – Average response for the questions on the design of the two workshop
9.5  ANNEX V – Forms

Feed-back form for Experts’ workshop

---

**Content – specifics**

<table>
<thead>
<tr>
<th>Expectations</th>
<th>Below expectations</th>
<th>Net expectations</th>
<th>Above expectations</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>How did the plenary session “Introduction and background” meet your expectations?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did the plenary session “Framework for an accreditation scheme for cancer registries and for a capacity of public health services” meet your expectations?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did the plenary session “Revision of the European Breast Cancer Guidelines – a suitable approach” meet your expectations?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did the plenary session “New initiatives” meet your expectations?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did the Break-out session (BOS) 1 (Accreditation) tackle the relevant issues?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did the Break-out session (BOS) 2 (Research and Guidance) tackle the relevant issues?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did the Break-out session (BOS) 3 (Tertiary) tackle the relevant issues?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did the Break-out session (BOS) 4 (Database and Cancer Registry) tackle the relevant issues?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did the plenary session on “Vagaries of Break-out sessions” meet your expectations?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did the plenary session on “Final agreement” meet your expectations?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

In case you would like to report additional comments / ideas for the future on the context of the workshop, please enter them in the following box:

---

Institute for Health and Consumer Protection

EXPERTS WORKSHOP

[Event Details]
In case you would like to report additional comments/proposals on the methodology applied for the workshop, please enter them in the following field:

---

**OVERALL EVALUATION**

<table>
<thead>
<tr>
<th>Your global opinion</th>
<th>Below expectations</th>
<th>Met expectations</th>
<th>Above expectations</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

How do you.platform the event?  

**THANKS FOR YOUR PARTICIPATION AND CONTRIBUTION AT THE EVENT**
Feed-back form for Countries Delegates’ workshop

**IHCP events – participant’s feedback**

A voluntary accreditation scheme for Breast Cancer Services & the further development of European Breast Cancer Guidelines

**MEMBER STATES DELEGATES WORKSHOP**

Ispra (VA) – 13 and 14 March 2013

Dear participant, please take a few moments to fill out this feedback form. It will help us to assess how well this workshop met your expectations and will contribute to the improvement of future events. Many thanks for your contribution.

<table>
<thead>
<tr>
<th>Content – Specific</th>
<th>Below expectations</th>
<th>Net expectations</th>
<th>Above expectations</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>how did plenary session “Introduction and background” meet your expectations</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>how did plenary session “Accreditation and certification” meet your expectations</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>how did plenary session “Guidelines within the accreditation scheme” meet your expectations</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>how did the plenary session on “The situation of Breast Cancer Services in Europe” meet your expectations</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>how did the plenary session on “Future associated elements” meet your expectations</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>how did the plenary session on “Conclusions and next steps” meet your expectations</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

In case you would like to report additional comments / ideas for the future on the content of the workshop, please enter them in the following field:

---

76
In case you would like to report additional comments / proposals on the methodology applied for this workshop, please enter them in the following field.

OVERALL EVALUATION

THANKS FOR YOUR PARTICIPATION AND CONTRIBUTION AT THE EVENT
BCSs organisation survey form

As it is a very long form (34 pages) it is not included here but will be made available into the report on the survey which will be issued soon.
Guidelines evaluation survey form

A voluntary accreditation scheme for Breast Cancer Services & the further development of European Breast Cancer Guidelines

MEMBER STATES DELEGATES WORKSHOP
Ispra (VA) - 13 and 14 March 2013

QUESTIONNAIRE on Screening and screening Guidelines

Dear participant to the Workshop, thank you for dedicating some of your time to complete this questionnaire.

In order to appropriately plan and organise the activities related to the project, in particular the tasks associated with the updating of Guidelines, it would be very important to receive from you some information on the impact of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis in your daily work. As we consider that most of the participants are within the National Authorities, we count on you to map out the general application and opinions on those existing Guidelines.

This questionnaire is not intended to produce a formal implementation report, but to provide updated and general information on the use and application of the above mentioned Guidelines.

We would like to remind you that our only interest is to optimise the situation of Breast Cancer Care and that we are free of intellectual and affiliation interests, and therefore we would really appreciate if you can provide direct and sincere replies.

For any information or help concerning the questionnaire, please contact:

Name | Telephone
---|---
Donata LEFDA | 0039-0331-786201
Silvia DEANDREA | 0039-0331-785532

E-mail: jrc-bccp-cancer-policy@ec.europa.eu

>> Read carefully before filling-in the FORM <<

1. This FORM has to be filled in using Adobe Acrobat Reader and submitted electronically. Data entered in the fields can be saved to disc and retrieved later or forwarded to others to complete.

2. Once you have completed the form, please send it back to us: you will find at the end of the questionnaire a button for sending the created FORM Submit by Email.

The fields marked with a * are mandatory; you will not be able to send the FORM if you have not filled in all the mandatory fields.

PLEASE SEND BACK THIS FORM BEFORE THE 08/03/2013

CONTACT DETAILS

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Name*</td>
<td></td>
</tr>
<tr>
<td>Surname*</td>
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<tr>
<td>Affiliation*</td>
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<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>E-mail*</td>
<td></td>
</tr>
</tbody>
</table>
QUESTIONS

1. Please select the profile which better describes your role

<table>
<thead>
<tr>
<th>A breast cancer screening policy maker</th>
<th>A breast cancer screening programme manager</th>
<th>Both</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

If you choose Other, please provide a more detailed description

2. Are you aware of the existence of the European guidelines for quality assurance in breast cancer screening and diagnosis?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

If yes, do you make reference to them?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

If you DO make reference to them:

1. You make general reference to the Guidelines
2. You make reference to specific parts (chapters or sessions)

If you choose option 2, please specify for which chapters you make reference (and which parts of chapters, if relevant)

If you DO make reference to them, then you do it:

1. Directly
2. Indirectly (e.g. via a quality assurance scheme such as EUSOMA or EURIF)

[1 e.g. citing them in regulations or plans]
If you do NOT make reference to those guidelines, could you please shortly report in the following field the reasons for not applying them at all:

3. Do you reference any other sets of guidelines?*

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Abstract

Two Workshops were organised in order to inform and involve stakeholders about the task the JRC has been given of updating existing European Guidelines on Quality Assurance in Breast Cancer Screening and Diagnosis and, in parallel, to develop a quality assurance scheme for breast cancer services. Participants at both workshops, coming from different areas of competence and of interest (e.g. clinical experts, patients’ associations, guidelines methodologists, policy makers, screening programme managers, etc), were asked to contribute with their own experience and knowledge and to provide input on project pillars and modalities to coordinated and optimise the direction of the project. This report not only includes the narration of the events, but also the main conclusions derived from a thorough discussion on the main aspects of the project and their impact on the planning of activities for meeting the requirements of the two tasks.
As the Commission’s in-house science service, the Joint Research Centre’s mission is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle.

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

Key policy areas include: environment and climate change; energy and transport; agriculture and food security; health and consumer protection; information society and digital agenda; safety and security including nuclear; all supported through a cross-cutting and multi-disciplinary approach.