EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection (Ispra)
I.2. Public Health Policy Support

KICK OFF MEETING OF THE QUALITY ASSESSMENT SCHEME DEVELOPMENT GROUP (QASDG)

European Commission Initiative on Breast Cancer (ECIBC)

JRC, Ispra (Varese), ITALY. 9-11 September 2015

Approved Minutes

Chair: JRC

Wednesday, September 9 (12:00 – 17:45)

1. WELCOME AND ADOPTION OF THE AGENDA

Ciarán Nicholl, Head of Unit, Public Health Policy Support (PHPS), Joint Research Centre (JRC), **Michael Hübel**, Head of Unit SANTE C.1, Directorate General for Health & Food Safety (DG SANTE, EC) and **Donata Lerda**, Healthcare Quality Team (HQ) Leader, PHPS, JRC, EC welcomed the participants and introduced them to the JRC, the ECIBC and the Agenda of the meeting to do.

The agenda was adopted.

The list of participants is in the Annex.

All the presentations and documents discussed will be published at CIRCABC (the collaborating platform of the QASDG) and at the ECIBC's website.

2. PROJECT PLAN, COMMITMENT, RULES OF PROCEDURE, DECLARATION OF INTEREST

Silvia Deandrea, Healthcare Quality Team, PHPS, JRC, EC introduced the general project plan, milestones and timelines. Interaction of the QASDG with other working groups is foreseen, in particular with the Guideline Development Group (GDG). Further the development of the *European Quality Assurance scheme for breast cancer services* (henceforth *European QA scheme*) is supported by two contractors to the project: the Iberoamerican Cochrane Centre provides support in respect to systematic literature review; the European Cooperation for Accreditation (EA) provides support for framing the *European QA scheme* within the European legislation for accreditation (Regulation (EC) No 765/2008) in view of its piloting and implementation.

The participants read and signed the Declaration of Commitment.

The draft Rules of Procedure were discussed and the following changes proposed:

- **Point 1:** observers will not be accepted to the QASDG meetings. The bias that could be induced by external observers and their possible influence on decision making within the group was felt to be not controllable. However, persons, organisations and countries that are interested in the progress of the project will have the opportunity to participate in the ECIBC plenary meetings.
- **Point 2:** A "qualified majority" was defined as including at least two thirds of all votes. This definition is in line with the definition of a qualified majority that is usually used in the EC.
- **Point 3:** In general the Rules of Procedure of the GDG and the QASDG should be alike; in particular the same terminology should be used.
- **Point 4:** GDG members shall be allowed to contribute to QASDG subgroups upon need and with to be agreed modalities.

The document describing the Quality Assurance Team was sent to participants but there was no time to discuss it during the meeting due to other topics engaging more time than foreseen. The agreement on that document will be reached via email or by using the CIRCABC working space allocated to the QASDG.

Jesús López, Healthcare Quality Team, PHPS, JRC, EC presented the Declaration of Interest. The Declarations of Interest of each working group member will be published on the project homepage. In addition to paid positions (such as memberships in advisory boards of pharmaceutical companies etc.) also unpaid positions should be declared, such as memberships to boards of non-profit organisations. It was agreed that also 'intellectual interests' should be declared. This relates to all areas relevant to the work of the QASDG where participants have expressed a 'strong view' in the past. Reasoning for declaring also 'intellectual interests' is based on the potential of 'intellectual interests' declaration to help interpreting and understanding better decisions of the QASDG. The ECIBC Coordination Team will review the Declarations of Interest and will decide on possible measures to be taken. The Declarations of Interest may need to be updated during the process of the development of the scheme according to changing tasks of its members or upcoming subjects in the development process.

The meeting was closed at 17.45.

Thursday, September 10 (8:45 – 17:45)

3. JRC SURVEYS ON THE STATE OF PLAY OF QUALITY ASSURANCE FOR BREAST CANCER CARE IN EUROPEAN COUNTRIES

Silvia Deandrea, Healthcare Quality Team, PHPS, JRC, EC, presented a survey on external quality assessment schemes for breast cancer services (BCSs), which are available in European countries: http://publications.jrc.ec.europa.eu/repository/handle/JRC89731.
A search of external quality assessment schemes for breast cancer care already in place in Europe was carried out using different strategies in: MEDLINE, website of relevant scientific societies, and EC Reports. Seventeen schemes specifically addressing breast cancer were identified in Europe and thirteen countries have at least one scheme in place. The number of BCSs implementing such schemes goes from three to 277 with a median of 23. In some countries, more than one scheme is present, with a maximum of 4 schemes present in one country.

Aslı Ulutürk, Healthcare Quality Team, PHPS, JRC, EC, presented a survey on the use of accreditation and conformity assessment in BCSs http://publications.jrc.ec.europa.eu/repository/handle/JRC92204 .
The objective of this survey was to collect information from the National Accreditation Bodies (NABs) in collaboration with EA on the accreditation status of the countries. Twenty-five out of 35 contacted countries responded, corresponding to a response rate of 71%. The most applied standard resulted to be ISO 15189 and the most covered stage of care diagnosis.

4. TRAINING ON PICO QUESTIONS

Jesús López, Healthcare Quality Team, PHPS, JRC, EC provided training on the formulation of PICO questions (PICO: Population-Intervention-Comparison-Outcome). PICO questions are used in developing evidence-based recommendations. If evidence for requirements that is considered relevant for the quality of care is lacking or unclear, the QASDG has the opportunity to challenges this evidence through a PICO-question guided process. The QASDG will be assisted in that by the Iberoamerican Cochrane Centre. As the GDG will use PICO-Questions more extensively, close collaboration with the GDG should be sought to prevent doubling of PICOs.

5. TRAINING ON ACCREDITING SERVICES ACCORDING TO THE FRAMEWORK OF THE EUROPEAN COOPERATION FOR ACCREDITATION

The *European QA scheme* will be developed within the broader framework of accreditation procedures established by EA on the basis of the European regulation on accreditation (Regulation (EC) No 765/2008). In particular two ISO-Standards are relevant for the *European QA scheme*:

1. ISO/IEC 17065 will be used by NABs for the accreditation of local bodies/organisations that will in fact assess BCSs. The contents and assessment methods of this accreditation have to be defined within the *European QA scheme* (scheme owner's requirements) and will be developed with the support of the QASDG. The aim is to ensure that the accreditation process is performed consistently across countries.

2. ISO 15189 will be used for the accreditation of testing activities within the *European QA scheme*.

Franco Gattafoni, EA provided training on the working modalities of EA and the meaning of ISO-Standards 17065 and 15189.

6. DRAFT *EUROPEAN QA SCHEME* AND FRAMEWORK/SCOPE

Silvia Deandrea and **Anke Bramesfeld**, Healthcare Quality Team, PHPS, JRC, EC, presented the framework for the *European QA scheme*. In particular they highlighted the concept of Quality Domains and the concept of a Treatment Pathway, by which Quality Potentials are defined. Domains, treatment pathways and quality potentials will be used to focus and prioritise requirements for the *European QA scheme*.

The QASDG provided several inputs (*e.g.* to replace digital mammography with the broader breast imaging process) that will be included in the new version of the Treatment Pathway.

The meeting was closed at 17.45.

Friday, September 11 (09:00 – 12:00)

7. CONTINUATION - DRAFT *EUROPEAN QA SCHEME* AND FRAMEWORK/SCOPE

The draft scheme (EA deliverable 1.2) was discussed and the QASDG requested some changes that will be implemented by EA in the next version of the document (e.g. the deletion of part of chapter five, where the list of processes will be replaced by a reference to a separated document, the *Draft framework for the European Quality Assurance Scheme for breast cancer services*, where those processes are detailed).

The *Draft framework for the European Quality Assurance Scheme for breast cancer services*, including the methods and scope proposed, was presented and the following subjects were raised:

- **Point 5 – Pilot.** The *European QA scheme* will be first piloted before released for implementation. It is to be expected that after piloting changes will need to be made to the *QA scheme*. Piloting on BCSs in different healthcare services scenarios is envisaged to ensure that the piloting serves the scope of verifying the scheme applicability in all concerned/interested countries.
- **Point 6 – Palliative care:** The expert group stressed unanimously that all phases of breast cancer care, including end-of-life treatment and palliative care, need to be included. Palliative care should be mentioned explicitly as a cross-cutting issue in all documents referring to processes of care. The potential for palliative care to be reported as an additional care process (beyond those already defined) has been discussed.
- **Point 7 – Psychosocial care:** Also psychosocial care should be understood as a cross-cutting topic.
- **Point 8 – Evidence reference for requirements**: For the quality assurance of screening and diagnosis processes the reference guidelines are those currently developed by the GDG as a parallel process. For all the other processes in breast cancer care the evidence needs to be found in other pre-existing guidelines. The JRC is about to establish a platform for evidence based guidelines on breast cancer care. Close collaboration between the QASDG, the GDG, and the guidelines platform is foreseen. For the *European QA scheme*'s requirements that are likely to be not fully covered by clinical guidelines (*e.g.* good clinical practices, quality management, etc.) evidence can be sought through literature searches done by the Iberoamerican Cochrane Centre or by other indirect means.
- **Point 9 – Continuity of care:** Ideally all breast cancer processes should be provided by the same service to facilitate continuity of the care. However, in most countries breast cancer care processes are provided by several independent services that may be linked to each other by network/collaboration frameworks that can be differently binding and functioning. Continuity of care thus becomes a quality potential of major importance.
- **Point 10 – Certifying the whole care pathway vs. modular *European QA scheme***: Referring to the fact, that breast cancer care is often provided by a multitude of services, the *European QA scheme* needs to be flexible and offer also partial, or modular certification to services, which may not serve the whole treatment pathway. Most QASDG members were in favor of identifying at least a list of core modules that shall not be certified separately while foreseeing a way forward to include all

processes. In addition, the importance of having strict 'interface' requirements among services, independently from their allocation in the same entity or not, was highlighted.

- **Point 11 – Essential requirements:** Among the requirements to be developed, essential requirements need to be defined. They relate to the possibility of setting a starting point/entrance gate for being certified.
- **Point 12 – Male breast cancer:** Most QASDG members were in favour of not excluding male breast cancer treatment from the *European QA scheme,* as most of the quality requirements for BCS would also apply to the treatment of breast cancer in man. Further most experts recommend that male breast cancer is treated in BCS, since that is where the expertise is concentrated. On the other hand, male breast cancer is included in the list of rare cancer by RARECARENet ('epithelial tumor of male breast') and male breast cancer + high risk women have been excluded by the scope of the new *European Guidelines for Breast Cancer Screening and Diagnosis* upon agreement of the GDG. JRC will check whether male breast cancer is already addressed within one of the European Reference Networks foreseen for rare diseases. Depending on that and on an estimate of the resources needed for retrieving the evidence for male breast cancer treatment (guidelines for the platform, PICO questions, etc.), male breast cancer would be also addressed by the *European QA scheme*.

8. COMMUNICATION AND INFORMATION RESOURCE CENTRE FOR ADMINISTRATIONS, BUSINESSES AND CITIZENS (CIRCABC)

Luciana Neamtiu, Healthcare Quality Team, PHPS, JRC, EC presented the CIRCABC application, used to create collaborative workspaces that is made available for the exchange of documents among QASDG members during the development of the *European QA scheme*. On CIRCABC working group members can download, revise, upload and share documents. The platform will be the major tool for exchanging and drafting documents. A guide on how to use the platform will be provided to the group members.

9. NOMINATIONS OF CHAIRS

Chairs were elected in one ballot. As chair was elected Robert Mansell and Francesco Sardanelli as vice-chair.

10. FORMATION OF SUBGROUPS

Subgroups were created for the following subjects: Testing (Imaging, Pathology, Medical Physics, Molecular/Genetic Testing); Competence; Glossary; Organisation, Scope and Modules (incl. essential requirements); Certification Processes; Indicators.

The QASDG members assigned themselves to the subgroups/tasks forces and domains and appointed coordinators. Details can be found in a separate document that will be made available in CIRCABC, but a summary is provided below.

- **Point 13.** A subgroup for indicators will be a joint group with both QASDG and GDG members.

- **Point 14.** A task force for glossary will work in coordination with the corresponding one in the GDG.

- **Point 15.** Research has been proposed as a key process and a coordinator was appointed.

- **Point 16.** Also coordinators for the quality domains 'Resources, workforce, facilities', 'Person Experience' and 'Safety' were appointed.

11. NEXT STEPS

- The list of subgroups, task forces and corresponding members will be circulated. QASDG members not present in the meeting can sign up and also provide their inputs on proposed coordinators.

- Contact details of the members of the GDG will be shared with contacts of members of QASDG (and vice versa).

- QASDG members will be asked to provide a short profile and a picture. The QASDG members list and their professional profiles will be made available after the kick-off to the ECIBC working groups and to the public (without emails or phone no's).

- Amended documents will be uploaded in CIRCABC, including the amended version of EA document (EA deliverable 1.2 – draft scheme).

- The Treatment Pathway will be sent around for commenting.

- Next meetings: The ECIBC Plenary Meeting will be held December 9-11, 2015. In the morning of the 9th there will be sessions for the working groups. This will include at least a half hour were members of QASDG and GDG can meet and exchange.

- As time for meetings in the first half of 2016 mid-March and mid-June are proposed. A doodle for fixing the dates more precisely will be sent around.

12. CLOSURE OF THE MEETING

Ciarán Nicholl and **Donata Lerda** expressed their sincere thanks to the working group members. They also emphasised that the project is very important and could serve as a 'blue print' model for other cancer sites and diseases.

The meeting was closed at 12:00 pm.

ANNEX I – LIST OF PARTICIPANTS

Karen BENN

Bettina BORISCH

Hilde BOSMANS

Anke BRAMESFELD (EC)

Augusto CARACENI

Luigi CATALIOTTI

Saskia CLAASSEN

Silvia DEANDREA (EC)

Nadia DIMITROVA

Alexandru ENIU

Franco GATTAFONI (EA)

Andre GRIVEGNEE

Cristiano GUSMEROLI (EC)

Michael HÜBEL (EC)

Cary KAUFMAN

Donata LERDA (EC)

Jesus LOPEZ ALCALDE (EC)

Robert MANSEL

Luciana NEAMTIU (EC)

Ruben ORDA

Piera POLETTI

Antonio PONTI

Liisa PYLKKANEN (EC)

David RITCHIE

Vitor RODRIGUES

Elio Giovanni ROSSI

Francesco SARDANELLI

Zuleika SAZ PARKINSON (EC)

Charles SHAW

Sabine SIESLING

Giorgio STANTA

Aliki STATHOPOULOU

Luzia TRAVADO

Aslı ULUTURK (EC)

Jan VAN DER POEL (EA)

Cary VAN LANDSVELD-VERHOEVEN

Chantal VAN ONGEVAL

Simone WESSELMANN

Margaret WILCOX

ANNEX II – DOCUMENTS DISCUSSED AT THE KICK-OFF MEETING - ACTIONS PLANNED

Document	File	Decision	Future actions
Quality Assurance Team	20150825-DRAFT-Quality assurance team-v0	Not discussed during the meeting	New version including points 13 to 16 circulated by e-mail on 5 October 2015
Rules of procedure	DRAFT_Rules of procedure_QASDG_v0	Amended according to points 1-4 and approved.	A new version of the Rules of Procedure including the assessment of independence will be circulated before 25 October 2015
Draft scheme's framework	Draft framework for the QA Scheme_v0	To be amended according to points 5-12	A new version for subgroups contribution will be available on CIRCABC by 31 October 2015
Draft *European QA scheme*	D1 2 Final Draft Proposal EA WG Final Approved Clean Version 2015-08-21_Rev1_approved	To be amended according to points 5-12	A new version will be provided by EA
Guidance to declare interests	To be provided by ECIBC coordination team	ECIBC coordination team will provide guidance	Provide the guidance
Process to assess interests and to manage COI	To be provided by ECIBC coordination team	ECIBC coordination team will define the process to assess interests and to manage COIs	Assess interests according to this process
Subgroups and task forces	To be provided by ECIBC coordination team	ECIBC coordination team will distribute a document detailing the subgroups/tasks forces and the QASDG members will express their interests to participate (points 13-16). Work will continue by means of electronic exchanges.	Finalise the document by 25 Oct 2015