EUROPEAN COMMISSION
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Directorate F – Health, Consumers and Reference Materials
Unit F1 Health in Society

European Commission Initiative on Breast Cancer (ECIBC)

GDG MEETING: Plenary sessions*

19 – 21 September 2017

Minutes

Document history			
Version	**Date**	**Drafted by**	**Comments**
0	23/10/2017	Colin MACKAY	Initial draft version proposed by MOSTRA
1	25/10/2017	Donata LERDA Zuleika SAZ-PARKINSON	Draft for approval of GDG
2	05/12/2015	GDG and Donata LERDA	Approved version

** Minutes of subgroup meetings (Monitoring & Evaluation, Testing Imaging, Testing Pathology, Training, Communication and Inequalities) are available as separate files*

Presentations are available on the ECIBC web hub and/or on the CIRCABC dedicated space

List of Participants in Annex I

The Agenda is available at http://ecibc.jrc.ec.europa.eu/-/gdg-working-meeting.

Opening session
19 September 2017: 13:30 – 14:15

This session was opened by Ciarán Nicholl (CN – JRC) with a warm welcome to the 9th meeting of the GDG.

Session began with Donata Lerda (DL-JRC) presenting new members of JRC team, Elena Parmelli and Sazan Pakalin, and describing collaborations with other Units of the JRC about ECIBC implementation. She also reported on other ongoing JRC activities and prepared the GDG to receive a questionnaire on guidelines dissemination, a draft proposal on the life-cycle (updating) strategy and the hyperlink to an 'Invitation to express preliminary interest in a future European Breast QA scheme Piloting for Breast Cancer Services and stakeholders'. In particular, DL reported about the starting of ECICC (colorectal cancer initiative); the JRC asked Holger Schünemann (HS) to help develop the methodological framework and, as agreed with the Steering Group, consent of the GDG on his engagement while keeping the role of methodological co-chair was sought. The GDG did not detect any possible conflicting interest between HS contract with the JRC about ECICC and his chairing role for ECIBC, however expressed concerns about his availability in terms of time. HS reassured all on this point by confirming that the majority of his work for ECICC would be carried out during a sabbatical period, hence not impacting on his engagement with ECIBC. The approach followed would be:

- Evaluation of process
- Interview studies
- External validation
- External peer review

DL had also been asked by Steering Group to provide more details to the GDG on two topics:

- Mandate of ECIBC working groups. The aim is to successfully achieve the mandate goals, meaning finishing all PICOs already selected and run the pilot lifecycle updating strategy. The initial mandate was of *at least 30 months* from start of the work, meaning that it was initially foreseen to be able to complete the mandate by March 2018; however, some more meetings would be needed to complete the GDG mandate (and as well QASDG minimum foreseen engagement time would need to be extended). For this reason during November meetings a foreseen deadline and number of meetings will be provided by the JRC, so to facilitate ECIBC contributors' in setting up their future plans.
- Authorship rules are being updated to include contractors. Anyone that contributes meaningfully can be credited as the author, but at least one of the corresponding authors has to be the JRC, to allow sustainable follow-up. DL suggested reading the Authorship rules and informing the JRC in case Prospero registration rules should be included.

Finally DL asked participants to spend ten minutes to complete the questionnaire regarding Guidelines dissemination also detailing the activities they would undertake to disseminate their work, thus informing JRC on possible other tools or displaying features to be developed.

Then Grazia Federico (GF - JRC) presented the Team Event; she noted that the Steering Group was not given the opportunity to approve the event as JRC is used to these events, hence no action for flagging it to the Steering Group and GDG was taken; however JRC apologised for the perceived lack of transparency. The goal was to analyse and improve working styles using external facilitators.

Silvia Deandrea (SD – JRC) gave a presentation (hyperlink to slides) on the 'Invitation to express preliminary interest in a future European Breast QA scheme Piloting for Breast Cancer Services and stakeholders'. It has the scope to provide early warning on piloting and to prepare the breast cancer services also to participate into piloting studies. This open call will be published online and will remain open until the launch of the call for piloting (foreseen for September 2018). ECIBC National contacts will be involved as coordinators of possible actions at country level and to assist in dissemination. SD stressed that GDG and QASDG would have a key role in both dissemination and support to ECIBC National Contacts.

Clinical co-chair election

Ciarán NICHOLL (CN) then proceeded to the nomination and election of the clinical co-chair to replace Chris de Wolf who stepped down during May meetings. A note describing all details of the process had been distributed in May and included the list of 18 eligible candidates.

Among those eligible, Mireille Broeders and Axel Gräwingholt were the only nominees. Both were viewed as excellent candidates by the GDG and a proposal was put forward by some GDG members to have two co-chairs.

It was requested to know whether this election affected Cecily Quinn's role as vice-chair and whether she was eligible for election. DL confirmed that she is formally the back-up of the clinical co-chair, so election does not directly impact her current role and that she is eligible as clinical co-chair but it would require election of a vice-chair to replace her.. Cecily Quinn said that being radiology the most relevant competence, it would be important to have a radiologist on the Steering Group (as consequence of a radiologist being nominated clinical co-chair).

DL requested that if in the future there should be questions about proposed procedures, they should be raised on time (in this case the procedure was proposed in May and it seemed late to discuss having two clinical co-chairs, which was in contradiction with current GDG rules). In particular, the importance of differentiating between questions over procedure and proposed candidatures, as the latter should not influence the rules.

A GDG member stated that it was a matter of credibility to have the multidisciplinary nature of screening represented at co-chair level, not leave it to chance, hence to change the rules before the election to make it possible to have two clinical co-chairs.

Another GDG member express his discomfort with changing rules 'on the fly' in particular in relation to a key role in the GDG. CN agreed that changing the rule 'on the fly' was not correct.

There was a request to change the role name from 'clinical co-chair' as candidates appeared not to be practicing clinicians. The point was clarified and role name stayed unchanged.

Following brief presentations from Mireille Broeders and Axel Gräwingholt, the group voted 13 to 9 in favour of Axel Gräwingholt, with two abstentions. CN congratulated Axel and thanked everyone for their work.

19 September 2017: 14:15 – 14:45

Nancy Santesso and patients' versioning of recommendations

Nancy Santesso from Mc. Master University presented her experience regarding her work on developing patient versions of recommendations. The completed Evidence to Decision Frameworks (EtDs) are the basis of what is used to produce patient versions, which are then made available on the EC website.

She explained that there is ongoing work in order to find the best way to present EtDs.

This work is based:

a. on research she has carried out with patients to find out what they think of guidelines,
b. scoping the literature to find out what was already available and collecting other useful information from other groups producing patient versions, both big and small organisations.

In addition, her work in the DECIDE project has also involved focus groups including patients to determine what they want to see in a patient version. This has been used to develop different formats that are tested in focus groups which revealed that people want:

- education on what they can do for themselves;
- reassurance their doctor is doing the right thing according to guidelines;
- information to make informed decisions; and
- empowerment to be able to discuss effectively with their doctor.

Etd is not only about harms and benefits, it has many other criteria, accessibility, feasibility, values and preferences and costs to be presented in a fit-for-purpose manner, and patients expressed interest in having access to those criteria too. They concluded that patients prefer information that they clearly see as relating to them which is why the patient version in the section of "who is this for" uses the second person "you". Patients like the headings of "who is this for" and they also like to see numbers, instead of long narrative text. Patients understand differences between strong and conditional recommendations but they want to know when it is conditional why this is so, so this part is included in patient version.

Basic principles, tested outside a GDG e.g. with focus groups, are: use same terms consistently, do not use medical terms, use short sentences, prefer active voice to passive.

The actual process to produce this information for the website is as follow:

a. the EtD is sent to Nancy Santesso, who performs a first patient version draft including values and preferences, burden and costs if GDG identified them as important
b. This is sent back to Zuleika Saz-Parkinson from JRC (ZSP), who
c. shares this with Individuals GDG members (profile patients/individuals) and a few other GDG members for their input.
d. It is then adapted and uploaded on the web.

However, ZSP clarifies that after May meeting it was agreed that the first draft goes to the PICO responsible Unit (PRU) and then once a version is agreed with them it goes to the entire GDG for their approval before it goes on the website (under a tab that is named patient/individual).

It was asked whether the patient versions are checked with lay people outside the GDG as the patients in GDG may be too expert. It was also added that the target population of screening recommendations are not patients, and therefore it is essential that these versions are passed by focus groups of lay people that don't have a breast cancer diagnosis. Nancy Santesso clarified that in the focus group testing, public members who are not diagnosed were included, but in the future perhaps it would be necessary to add this external group in the revision, hence to formalise this new process. Another GDG member wanted to know what efforts were being made to reach culturally deprived or isolated audiences, such as refugees that find it difficult to be part of screening programmes and are in general far from the healthcare system. It was also pointed out that beside the amazing progress that has been done so far, there are concerns about language and computer literacy barriers for deprived groups. Giulia Bocchi from JRC (GB) clarified that translations are also going on as soon as patient/individual versioning are finalised; however it should be considered that social policies are under Member States' responsibility and hence we can only improve communication tools but cannot enter into social policies.

It was commented that, as currently many patients get a lot of information from social media such as YouTube and twitter, there should be plans to disseminate guidelines not only in written format but also in a dynamic way and Nancy Santesso clarified that interactive tables are being included in the patient versions. In addition, GB suggested that some GDG members could help in this effort that may also help circumvent language barriers.

19 September 2017: 14:45 – 15:30

Update on marker states

Tejan Baldeh gave an update of the feedback received since last May meeting, along with HS, on Clinical Marker States and clarified their use for recommendations: Marker States (MS), as standardised definition of health outcomes, have two roles, the primary being to consolidate understanding of health outcomes and the secondary to provide context for the end user.

Tejan Baldeh pointed out that diversely from the first utility survey carried out by GDG , for the second an effort was made to focus on physical health and to reduce the amount of information provided and make it clearer. The survey results from the second round are more precise, as the standard deviation has decreased from the first and second survey. Results of the second utility survey would be circulated soon, but it appeared that panel members had difficulties with breast cancer stage and a few of the communication MS.

He clarified that MS should be used as a reference during panel discussion to resolve disagreement and that GDG members should be open to using MS that may not completely match their views. Minor changes to a few of the MS are necessary and he will continue with the final interviews scheduled throughout this meeting, to address in particular their general content and format of MS tool. In addition the MS are undergoing patient testing, with women who are not patients but intend to participate in screening, and he is waiting for the prior ethic approval by Mc. Master University.

HS stressed that this MS work should have ideally been undertaken earlier, in order to reduce variations in how outcomes were being interpreted. It was suggested forming a PRU of 5-7 people to systematically check the documents for factual errors and some GDG members volunteered to check the MS by 01/11/2017 (Axel Gräwingholt., Mireille Broeders, Lydia Ioannidou-Mouzaka, Solveig Hofvind; Cecily Quinn and Stephen Duffy volunteered to edit and finalise the MS)

Tejan was thanked for his work and for the iterative process that allowed 'learning by doing' and highlighting inconsistencies, however somehow shadowing the need to fulfil a deadline.

19 September 2017: 16:00 – 18:30

Presentation of the workflow

ZSP presented the updates to the Workflow as discussed in May, showing (i) inclusion of the outcome prioritisation step to be carried out by entire GDG after the question is framed, and (ii) as requested by the GDG and agreed, that patient version, after PRU revision, has to be approved by the entire GDG.

She also gave an update of the recommendations published so far, the development stage of all PICOs in progress and she announced that the Steering Group had agreed a maximum discussion time for each EtD of two hours. If a specific question requires more time, it is necessary for the chair to point this out to JRC so this can be agreed.

It was requested that the PRUs would introduce the PICOs to be presented to the group at the meeting and ZSP clarified that this had already been agreed in February and carried out in this way during the May meeting.

GDG meeting recommendations (PICO 10)

The recommendations started being discussed. The first question to be discussed was PICO 10. The evidence for this question was presented by Miranda Langendam. After the presentation of the evidence, discussion of the EtD for this question, that initially had three EtDs, followed.

20 September 2017: 08:30 – 13:00

GDG Meeting Recommendations (PICO 10 finish and PICO 36&37 first 3 EtDs)

Discussion of PICO 10 recommendation continued and Sue Warman expressed a minority opinion (that will be also reported in the published recommendation): she does not support the PICO 10 recommendation on targeted vs. general communication.

Initially 3 EtDs were programmed but the GDG agreed to include in the evidence profile of one of the EtDs (targeted vs. general) the evidence for another of the questions (tailored vs. targeted) as they didn't think this EtD could be presented as a separate recommendation.

Paolo Giorgio Rossi presented the evidence of PICO 36&37. The GDG was warned about the fact that PICO numbers changed from the initial ones as now they refer to how they are coded in the Literature Review contract with CCIb. Then the GDG started the discussion on the first three EtDs. It was mentioned that 'stage' of the patient can't be defined before staging interventions and suggested changing 'stage' to 'tumor size'. In addition it was specified that this PICO included staging done without pathological diagnosis, done based on clinical state of the patient, as already done in other studies. It is decided that the definition of the term 'staging' should be added to the EtDs.

20 September 2017: 14:00 – 16:30

GDG Meeting Recommendations (PICO 36&37 first 3 EtDs finish and PICO 38)

Before the starting of the discussion on the recommendations, Grazia FEDERICO from the JRC gave a brief presentation on the definition of reference documents, their use within the ECIBC to support implementation, and the activities planned in the process of their development.

DL reminded the contributors to complete the questionnaire on guidelines dissemination distributed by the JRC.

Discussion of 3 EtDs of PICO 36&37 continued after this presentation and was finalised.

The GDG started to discuss PICO 38. Annette Lebeau presented the evidence for this PICO.

21 September 2017: 08:30 – 13:00

GDG Meeting Recommendations (PICO 38 finalise and PICO 39)

DL mentioned that JRC and the GDG co-chairs discussed the possible actions to improve the GDG work process after the Team Event. As first action, co-chairs suggested that the GDG contributors turn off the screens of their personal PCs (unless they are used to follow the EtDs) during the discussions and to add a dedicated email breaks to the agenda of the future meetings.

The GDG continued and finalised the discussion on PICO 38.

Cecily Quinn presented the evidence for PICO 39 and the GDG started to discuss EtDs of the PICO.

21 September 2017: 14:00 – 16:30

GDG Meeting Recommendations (PICO 39 finalised, PICO 36&37 last 3 EtDs)

The GDG continued and finalised the discussion on PICO 39.

Paolo Giorgi Rossi presented the background for the remaining 3 EtDs of PICO 36&37. It is decided that the online voting will be started once the evidence is ready.

JRC presented the results of the Team Building Event. The actions' proposals from the Event were put into six streams. Each GDG contributor and each JRC member were asked to choose a stream to work on with the others choosing the same category as a team and produce solutions by next meeting (20-23 November 2017).

It was agreed that JRC will send the GDG the list of new PICO numbers, starting from diagnostic PICOs to be discussed in November.

Finally, the importance of making ECIBC known and disseminating information on the initiative was highlighted and JRC confirmed that actions are being taken in this direction, for instance the pre-call for piloting (hyperlink to pre-call) to which GDG and QASDG members will be asked to contribute.

Action points

Task	Who is responsible	Deadline
Formalise external review of patients versions	JRC	15 November 2017
Send results of utility survey	Tejan Baldeh	1st November 2017
MS PRU to agree on final version of MS	As reported in the minutes (Axel Gräwingholt., Mireille Broeders, Lydia Ioannidou-Mouzaka, Solveig Hofvind; Cecily Quinn and Stephen Duffy)	1st November 2017
Send the list of future diagnostic PICOs along with the number of the PICOs.	JRC	asap
Add email breaks to future agendas	JRC	By next meeting

ANNEX I:

Participating GDG-QASDG contributors (members, associated members and external experts)

Mariangela AUTELITANO,
Bettina BORISCH,
Mireille BROEDERS,
Xavier CASTELLS,
Jan DANEŠ,
Stephen DUFFY,
Patricia FITZPATRICK,
Markus FOLLMANN,
Livia GIORDANO,
Paolo GIORGI ROSSI,
Axel GRAEWINGHOLT,
Solveig HOFVIND,
Lydia IOANNIDOU-MOUZAKA,
Susan KNOX,
Miranda LANGENDAM,
Annette LEBEAU,
Helen MCGARRIGLE,
Lennarth NYSTRÖM,
Elsa PEREZ,
Cecily QUINN,
Peter RABE,
Holger SCHUNEMANN,

Alberto TORRESIN,
Ruben VAN ENGEN,
Sue WARMAN,
Ken YOUNG

Absent GDG-QASDG contributors (members, associated members and external experts)

Edoardo COLZANI,
Cary VAN LANDSVELD-VERHOEVEN

Participating ECIBC contractors and JRC staff

Pablo ALONSO,
Tejan BALDEH,
Carlos CANELO,
Colin MACKAY,
Thomas PIGGOTT,
David RIGAU,
Nancy SANTESSO,
Massimo AMBROSIO
Asli ULUTURK
Grazia FEDERICO

ANNEX II: List of abstentions due to conflicting interests

Co-Chair election: Miranda LANGENDAM excluded from voting as external expert, Livia GIORDANO was absent at the moment of voting.

PICO 36 and 37: Miranda LANGENDAM excluded from voting as external expert, Axel GRAEWINGHOLT excluded from voting for declared interests.

PICO 38: Miranda LANGENDAM excluded from voting as external expert.

PICO 39: Miranda LANGENDAM excluded from voting as external expert, Xavier CASTELLS excluded from voting for declared interests.