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Position Paper

Background to Eusoma guidelines and statements

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ABSTRACT

The European Society of Mastology (Eusoma) is committed in writing and diffusing guidelines on Breast Cancer, aiming at harmonising the quality of Breast Cancer care throughout Europe.

To achieve this Eusoma organises scientific meetings, "workshops" or "Consensus meeting", inviting European experts from the different disciplines involved in the multidisciplinary management of Breast Cancer patients, to give their contribution in drafting "guidelines" or "consensus statements".

In this regard Eusoma Executive Committee members found it appropriate to define the rules to organise its scientific meetings and to write the documents resulting from these meetings, i.e guidelines or statements.

This will guarantee an homogeneity in the meeting organisations and in drawing up the scientific documents.

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1. Introduction

One of the main objectives of the European Society of Mastology is to harmonise the quality of patient care in Europe and with regard to this the Society draws up and diffuses referring guidelines on the management of breast cancer.

These referring guidelines are intended for clinical practice, to increase the quality of patient care and to suggest the methods to perform quality control.

Up to now Eusoma has published eight guidelines as position papers in the European Journal of Cancer.

For the future Eusoma will continue to prepare documents on different issues related to breast cancer and for this reason Eusoma Executive Committee members found it appropriate to write these 'Background to Eusoma guidelines and statements'.

They have to be considered as the know how and the methodology Eusoma has identified to carry out its scientific meetings and to write the conclusions reached by the experts, taking into account not only the structure and the contents of the Eusoma documents — 'guidelines' if they result from workshops and 'statements' if they result from consensus meetings — but also the details regarding the organisation of the scientific meetings.

The aims of this document are to optimise the organisation within the Society and to give a better visibility of Eusoma's way of working.

2. General rules

2.1. Subject

Upon request of the President, Eusoma Executive Committee members suggest the topics (normally after each EBCC) for the organisation of workshops and consensus meetings. Topics may include when appropriate, the update of existing EU-SOMA documents.

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Following circulation of a list of topics, the Executive Committee members will indicate their preferences and priorities. Topics selected should be described in detail also by means of a list of questions that should be answered.

Once the list for the yearly meetings has been decided, Executive Committee members will appoint the Chairpersons, based on their professional and scientific experience on the specific issues.

2.2. Chairpersons

The Chairpersons will receive an invitation from the Eusoma President to chair the meeting and to prepare the list of experts to invite.

2.3. Date and venue

The Chairpersons, together with the Eusoma Secretariat, decide upon the date and venue for the meetings (if possible preferably during the weekend to reduce travel costs). The meetings should last a maximum of 2 days depending on the topic to be discussed.

2.4. Meeting organisation

The Chairpersons communicate to the Eusoma Secretariat full contact details of the experts to invite.

The panellists will receive an invitation letter signed by the President and the Chairpersons.

Hotel reservation and meeting facilities will be arranged by the Eusoma Secretariat, while travel arrangements will be made directly by the participants and travel expenses will be reimbursed (for flight tickets Eusoma will reimburse the lowest tariff applicable for the days of the meeting).

3. Eusoma workshops

- 1. Definition and aims
- 2. Chairman
- 3. Panellists
- 4. Preliminary document
- 5. The Writing Committee
- 6. The workshop
- 7. The final document: a) contents, b) structure.

3.1. Definition and aims

The 'Eusoma workshop' is made up of a group of experts, usually medical professionals, who meet to discuss specific issues with some controversial aspects within the domain of breast cancer prevention or management.

The aim of the workshop is the assessment of the evidence on different management options and the definition of recommendations and quality assurance objectives for clinical practice.

3.2. Chairman

The Chairman will receive an invitation from the Eusoma President to chair the meeting and to prepare the list of experts to

invite (a maximum of about 20 experts). The Chairman chooses the panellists from among the major experts in the issue according to his/her personal experience and, following the results of a medline search, whether they have published papers on the specific issue in peer reviewed journals.

3.3. Panellists

The panellists should be experts in the specific topic and should create a well balanced group both from a geographical (representing several European countries) and a scientific point of view, i.e. experts from all relevant disciplines should be part of the group. Even when the topic is very specific, some experts from disciplines different from those most directly involved should be included in the group. Panellists will be invited at least 3 months prior to the date fixed for the meeting.

Executive Committee members may participate in all meetings.

Eusoma Officers will verify that the list prepared will meet the requirements mentioned above.

3.4. Preliminary document

The Chairman, with the assistance of the Eusoma Secretariat, will perform a systematic search in the literature for relevant papers. The Chairman will then prepare the agenda of the meeting and a draft document which will include short introductions on the different points to be discussed and the description of the available evidence, or he/she can prepare an index of the different chapters and assign to some participants the task of writing paragraphs on specific aspects. Once the Chairman has received all the paragraphs, he/she will edit them and prepare the draft document.

If the Chairman considers it appropriate, he/she can prepare an overview of the issue.

References will be included in the draft document as well as the description of the criteria used for conducting the systematic search in the literature.

The document will circulate among the panellists at least 20 days before the meeting.

If necessary they will send suggestions/amendments to the Eusoma Secretariat in due time, so that the new draft version can be prepared for the meeting.

3.5. The writing committee

The Chairman has to set up the writing committee which is made up of a few panellists.

Together with the Chairman, the writing committee has the task of drawing up the final document following the conclusions reached by the panellists during the meeting.

The writing committee will prepare the final document within 2 months after the meeting.

3.6. The workshop

Prior to the meeting the Chairman can nominate some section leaders who will introduce the different topics to facilitate the discussion.

The section leaders should prepare a short introduction (a maximum of 10 minutes) which can be supported by slides/ overheads. The Chairman will lead the discussion, making sure to follow the agenda in order to be able to discuss all points in due time.

The aim of the discussion is to agree on the contents of the final document.

3.7. The final document: contents and structure

a) contents: Eusoma documents will be evidence based. In absence of other evidence the documents will be based on the most relevant experience and opinion collected and agreed by the panellists. The level of evidence for each recommendation will be graded according to the enclosed table (Tables 1 and 2). The document will also, when appropriate, point out priority areas for research.

Eusoma documents should contain indications for breast cancer care (prevention, diagnosis, treatment, ...) according to the best standards available, which should become applicable by professionals throughout Europe, without any purpose of clinical research.

The need of the guidelines and the questions posed should be described. Recommendations should be clearly stated and highlighted in the final document. Target users should be specified. The main potential organisational barriers and cost implications should be briefly addressed, if relevant.

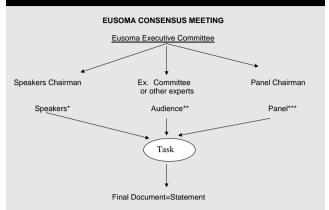
The document will point out 'Quality Assurance Methods', which could be applicable in all European countries. The text should include a 2-box system: Quality Objective and Outcome Measure. Each box contains short explanations of the rationale and cites the evidence. The box system is also aimed at simplifying the establishment of an audit system.

Any conflicts of interest of panellists should be stated.

The format of the references should be that of the Vancouver guidelines (i.e. European Journal of Cancer (EJC)-like) and should be listed on a new page at the end of the document.

Once the writing committee, together with the Chairman, has prepared the final document, it will be sent to the Eusoma Secretariat and it will be circulated among the panellists for their final approval.

Table 3 - EUSOMA CONSENSUS MEETING



*Speakers: Each speaker has to present evidence based data, pointing out the areas for which it is possible to reach a consensus and those for which the consensus can't be reached.

**Audience: The audience has to be active, listen to the speakers presentations, ask

**Audience: The audience has to be active, listen to the speakers presentations, ask provocative questions and comment on each presentation. The discussion will follow each presentation.

each presentation.

***Panel: Panel members have to listen to the speakers presentations and to the discussion which will take place the first day. On the second day of the meeting they will discuss and prepare the preliminary answers to the questions.

The Chairman then sends the final document to the Eusoma President for his/her approval.

b) structure: the final document will be submitted to EJC as a position paper.

The Eusoma Secretariat will submit the final document to EJC for publication. The Chairman will be the corresponding author.

Panellists will be listed only if they attended the meeting or gave relevant written contribution. All panellists listed are considered authors.

The final document should be ready for submission within 6 months from the workshop. See Tables 2 and 3.

4. Eusoma consensus meeting

- 1. Definition and aims
- 2. Composition
- 3. Identification of the issue
- 4. List of questions related to the issue
- 5. Setting up of the different groups

Table 1 - Levels of evidence

- Level I: Evidence obtained from a systematic review of all relevant randomised controlled trials (meta-analysis)
- Level II: Evidence obtained from at least one randomised controlled trial
- Level III: Evidence from non-randomized controlled trials, from cohort or case control studies, or multiple time series with and without the intervention
- Level IV: Opinions of respected authorities and expert committees¹

Table 2 - Level I evidence includes systematic reviews with

- The search should have been carried out with a comprehensive and explicit strategy
- The included studies should have been assessed for quality
- Characteristics and results of the studies should have been appropriately summarised
- Source of heterogeneity should have been explained²

- 6. Tasks definition
- 7. Timing
- 8. Drawing up of the document: 'The Statement'

4.1. Definition and objectives

The 'Consensus Meeting' is made up of experts in different medical and non medical disciplines. It aims at answering clearly different specific questions on clinical, scientific, technical issues, which could also take into consideration economic and social aspects.

The consensus meeting involves not only the scientific community, but also health administrators, organisations and other professionals related to the specific issue, and representatives of the general public.

The final aim of the consensus meeting is the correct transfer of a technology to the clinical practice indicating the precise definition of its aims and limits. The answers formulated in the final statement have to become precise recommendations for daily practice.

The conclusions reached by the panel should refer to evidence based medicine. In absence of clinical trials and evidence based medicine, consensus reached on the basis of individual experience, common sense or relevant opinion should be clearly specified.

4.2. Composition

The consensus meeting is made up of three groups³:

- speakers
- audience
- panel

4.3. Identification of the issue

The Eusoma Executive Committee will identify the issues suitable to become the topic of a consensus meeting. These issues have to be related not only to clinical practice but should involve more general aspects.

4.4. List of questions related to the issue

The Eusoma Executive Committee will identify the questions or appoint other experts for this task. The questions have to be: few in number (a maximum of 3–4), clear (simply formulated and understandable to non-experts) and representative (covering the major aspects of the issue).

4.5. Setting up of the different groups

The Consensus Meeting is made up of three different groups: the speakers, the audience and the panel.

• speakers: they are experts (a maximum of ten speakers) with data to present in the specific issue. This group is led by a Chairman.

- audience: is composed by the Eusoma Executive Committee members or by other experts appointed by them.
- panel: members of the panel must be non-advocate on the specific issue and they cannot have published research on the issue.

4.6. Tasks definition (see Table 3)

- speakers Chairman: The Eusoma Executive Committee will appoint the speakers Chairman, who will identify the different speakers (a maximum of ten). He will assign the topic to each speaker and collect the questions that the audience can submit. He has to chair the speakers presentations and lead the discussion. The Chairman will also identify the areas for which the consensus can't be reached, or further investigation is needed.
- speakers: Upon the Chairman's indication each speaker has
 to present evidence based data, pointing out the areas for
 which it is possible to reach a consensus and those for
 which the consensus can't be reached.
- audience: The audience is made up of Eusoma Executive
 Committee members or by other experts appointed by
 them. The audience has to be active, listen to the speakers
 presentations, ask provocative questions and comment on
 each presentation. The discussion will follow each presentation. Prior to the meeting members of the audience can
 submit questions to the speakers Chairman on specific
 aspects to be discussed.
- panel Chairman: The Eusoma Executive Committee will appoint the panel Chairman, who will identify the panel members (a maximum of 12). The panel has to be neutral, representative and comprehensive.
- panel: Panel members do not have to be personally involved in the issue or have specific interests in it. They have to listen to the speakers presentations and to the discussion which will take place the first day.

On the second day of the meeting they will discuss and prepare the preliminary answers to the questions.

Within 2 weeks from the meeting the panel Chairman will prepare the final version of the document, i.e. 'the Statement'.

The final version of the Statement will be sent to Eusoma Executive Committee members for their approval. If something is not clear enough they can ask for clarification from the panel. Then the Eusoma Executive Committee will endorse the final document.

4.7. Timing

The Consensus meeting lasts 2 days (see Table 4).

- first day: all three groups are involved in the first meeting day. The speakers presentations will be followed by the discussion with the audience.
- second day: the only group working on the second meeting day is the panel to discuss and identify the answers to the questions.

Table 4 – EUSOMA CONSENSUS MEETING Timing 1.st DAY: Speakers Audience Panel presentations and answer audience questions questions 2.nd DAY: / draw up the final document

Table 5	
Eusoma Workshop	Eusoma Consensus Meeting
Subject: selected by the Executive Committee members. Definition and aims: Experts meet to discuss specific issues with some controversial aspects within the domain of breast cancer prevention or management. The workshop aims at assessing the evidence on different management options and defining evidence based recommendations and quality assurance objectives for clinical practice.	Subject: selected by the Executive Committee members. Definition and aims: health professionals and other experts meet to answer clearly to different specific questions on clinical, scientific, technical issues, which could take into consideration economic and social aspects. The meeting is composed of:
Chairpersons: appointed by the Executive Committee members.	Chairpersons: speakers and panel chairpersons are appointed by Eusoma Executive Committee members. Speakers: experts with data to present. Audience: members of the audience have to ask questions and comment on each presentation.
Panellists: experts representing the different European Countries.	Panellists: they don't have to be personally involved in the issue or have specific interest in it. They will prepare the preliminary answers to the questions.
Document: 'guidelines': evidence based recommendations.	Document: 'Statement': the answers formulated in the document

4.8. Drawing up of the final document: 'The Statement'

The answers prepared by the panel have to be short, clear and comprehensive, expressing certainty when resulting in strong recommendations for practical use. The evidence supporting the recommendations should be clearly summarised.

The Statement written by the panel Chairman will be submitted to the Eusoma President.

The Eusoma President or his delegate together with the speakers Chairman will write an introduction to it.

The Statement will be submitted to EJC for publication within a maximum of 2 months from the meeting.

The names of the members of the three groups involved (speakers, audience, panel) in the meeting will be listed at the end of the document. Any conflict of interest will be stated. The Statement format is as follows:

4.8.1. Statement format:

- Eusoma consensus meeting title.
- Introduction by Eusoma President (or his/her delegate) name and affilitation.
- Speakers chairman name and affiliation.

- Text of the Statement.
- Names of the members of the three groups:speakers, audience, panel.

have to become precise recommendations for daily practice.

4.8.2. Text of the statement

Names of the members of the three groups: speakers, audience, panel see Tables 4 and 5.

Conflict of interest statement

None declared.

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