

Consensus Conference Standard Operating Procedures

ESMO Guidelines Committee, latest revision January 2017

CONSENSUS CONFERENCE MEMBERSHIP:

- Proposal and rationale for CC by Subject Editor (SE) to ESMO Guidelines Committee (GLC).
- One CC Chair nominated by SE, the SE being the CC Co-chair. Validation by GLC.
- Up to 40 members providing pan-European and global representation, priority to ESMO Faculty members.
- Acknowledged, multidisciplinary experts in the field. Maximum of 4 non-Europeans if they bring scientific expertise.
- In case of joint CC with other societies, Memorandum of Understanding (MoU) in place.
- Declarations of conflict of interest (COI) are obtained from all invited contributors.
- The CC Chairs break the CC into several topics, and each topic is assigned to a Working Group (WG, 3-10 members of the CC).
- The CC Chairs will appoint a WG Chair to coordinate the activities of each WG.
- Each WG will identify specific questions within each topic to be addressed. The target audience is physicians practicing in the field of oncology.

PREPARATION MEETING:

- A pre-meeting (1 day) must be organised between CC Chairs and the WG Chairs to work on defining the topics and potential questions for each topic. This meeting must take place preferably 6 months prior to and at least 3 months prior to the CC.
- During the preparation meeting, CC Chairs and WG Chairs will select the participants to be invited to the CC.

WG PREPARATION:

- Following the preparation meeting, participants will be invited to join a specific WG and contribute to the preparatory work of the CC.
- WG Chairs will decide how the group will work and will assign specific tasks to each WG member.
- WG members will work on the topics assigned and develop questions via exchange of emails, teleconferences, MyESMO, Skype, etc. Remote work through a modified Delphi method may also be used (See Appendix, Instruction 1)⁽¹⁾. No funding for formal physical meetings is foreseen.

- WG members are each responsible for conducting a study of relevant evidence for the assigned questions including a narrative review of the evidence and a list of important references.
- In cases where the CC Chairs consider necessary a systematic review of the evidence, this should be done in house.
- WG Chairs should prepare a summary report for the CC Chairs to review prior to the CC.

CONSENSUS MEETING:

- The CC Chairs are responsible for and have authority over the conference.
- Suggested general outline (2-3 day conference):

➤ **INTRODUCTION**

Introduction with all participants to discuss the aims, structure and process of the conference.

➤ **WG DISCUSSION PHASE: No voting, Parallel break-out sessions**

A summary report with Questions, Evidence and Recommendation options is made available to all WG members before the CC. Each WG discusses topics/questions, with a view to finalising specific recommendations with evidence levels. Diverging opinion in Questions/Recommendations should be recorded for presentation to the Plenary Session.

➤ **JOINT PRESENTATION PHASE: Plenary Session with Discussion and Voting**

WG Chairs present the Questions and Recommendations (with all diverging opinions) from their group for discussion. Discussion takes place for each Question and Recommendation. The plenum concludes to a Recommendation statement. Voting for each recommendation takes place and should be stated as percentages of Agree, Disagree, Abstain.

➤ **CONCLUSION PHASE: Final plenary session**

CC Chairs and WG Chairs provide a summary of discussions. This should include the Questions, Recommendations and percentages of agreement for each recommendation. The CC Chairs review with the Member Panel the next steps for manuscript preparation and the timeline for publication.

➤ **SUMMARY MEETING:**

The CC Chairs and WG Chairs may spend some additional time at the end of the conference to discuss decisions and next steps.

POST-CONSENSUS RESOLUTION OF DISAGREEMENTS:

- For each recommendation on a clinical problem, the result of voting with percentage of agreement, disagreement and abstention should be stated during the meeting and reported in the final paper.
- If the results of voting are not stated or <75% agreement on a recommendation or >20% of disagreement is achieved during the meeting, a post-meeting consensus should be achieved by filling a GRADE grid (See Appendix, Instruction 2)⁽²⁾.

- The statement of recommendation on a specific intervention for a clinical problem is sent to each participant with a GRADE grid to be filled and sent to ESMO staff within 72 hours.
- Results are polled; if <75% consensus is achieved, statements are recirculated by asking for voting again on the same or modified statements.

FINALISATION OF MANUSCRIPT:

- The CC Chairs and WG Chairs finalise the Recommendations with Levels of Evidence (LOE), Grades of Recommendation and Magnitude of Clinical Benefit (MCBS) scores where applicable. For each recommendation, Voting is shown as percentages of Agree, Disagree, Abstain.
- Following the CC, all WGs should send their draft topic manuscripts with Questions, Recommendations and LOE/GOR/MCBS scores to the CC Chairs within one month.
- CC Chairs incorporate all topic manuscripts in a pre-final manuscript.
- Areas of controversy and dissent are included and acknowledged in the final text.
- LOE/GOR/MCBS scores and references are provided for every formulated recommendation throughout the document. The grading system must be consistent across guidelines and form the basis for the class of recommendation and LOE/GOR/MCBS scores documented.
- The pre-final manuscript is circulated to all members of the CC for a final check and comments/suggestions. The Chairs finalise the document and forward it to the GLC for approval.
- Authorship includes all members of the CC. Only those participating at the CC can be included as authors, although the CC Chairs have the final decision.
- All participants will be listed as authors on the manuscript, either as named authors following the manuscript title or in the Member Panel included as an Appendix. Lead authors are normally listed in this order: CC Chair, WG Chairs (alphabetical) and SE (Co-chair, last). In the event of multiple manuscripts per WG, the WG members are listed by name for their respective WG manuscripts.

ORGANISATION/FUNDING/UPDATE OF CC:

- No funding should originate from the industry in order to safeguard the integrity of the guidelines (only ESMO or professional networks).
- No involvement of industry representatives in CC. Participation of patient representatives/advocacy groups optional.
- eUpdates may be performed by CC Chairs, GLC-Steering Committee (GLC-SC) on a case by case basis, these will be included in the ESMO Guideline section of the ESMO website.

APPENDIX

Instruction 1: Modified Delphi method for Remote Work of WGs before the CC

It is a method used to gather opinion from large numbers of participants working independently who answer questionnaires in two or more rounds. After each round a facilitator provides in a short period of time, an anonymous summary of the contributions and ask the participants to revise their answer(s) in light of the summary results within 48 hours. The process terminates after a predefined stop criteria (number of rounds, achievements of consensus, stability of results).

Delphi Questionnaires in each WG:

- After the questions are finalised, the WG Chairs produce a Delphi Questionnaire comprising the questions, each with Alternative Options/Answers or “Do You Agree” sections.
- The Delphi Questionnaire is circulated to all WG members.
- The answers are anonymised and collated in a summary report prepared by ESMO staff and forwarded to all WG members.
- The Delphi Questionnaire is sent to all WG members for a second round.
- The final round questions and answers are collated to a Summary with Questions and Recommendation options.

Instruction 2: Use of GRADE grid for post-CC dissents

For each recommendation, the participant fills a GRADE grid Module 1 by defining his opinion on quality of evidence (based on available data)⁽³⁾ and the balance between desirable (beneficial health outcomes, cost savings, less burden for patients and staff) and undesirable effects. Quality of evidence and balance between desirable/undesirable effects influences the strength of recommendations (the higher the quality of evidence or the larger the difference between the desirable and the undesirable effects, the more likely a strong recommendation is warranted). The questionnaire is sent to ESMO staff within 72 hours, who then circulate a polling summary which reflects the collective judgement on strong recommendation in favour of an intervention (desirable outweigh undesirable effects), weak or no recommendation at all.

The GRADE grid:

- Participants are provided with guidance on factors to be taken into account in formulating the recommendation.

	Grade score				
	1	2	0	-2	-1
<p>Superiority of intervention</p> <p>Balance between desirable and undesirable consequences of intervention</p>	<p>Definitely superior AND Desirable clearly outweigh undesirable</p>	<p>Probably superior AND Desirable probably outweigh undesirable</p>	<p>Equal to other option OR Trade-offs equally balanced or uncertain</p>	<p>Probably inferior OR Undesirable probably outweigh desirable</p>	<p>Definitely inferior OR Undesirable clearly outweigh desirable</p>
<p>Recommendation</p>	<p>Strong: definitely do it</p>	<p>Weak: probably do it</p>	<p>No specific recommendation</p>	<p>Weak: probably don't do it</p>	<p>Strong: definitely don't do it</p>
<p>For each proposition below, please mark with a "X" the cell which best corresponds to your assessment</p>					
<p>Example: Chemotherapy + Drug A should be the preferable option over Chemotherapy + Drug B for X-type Y cancer patients with Z as the aim</p>		<p>X</p>			

LEVEL OF EVIDENCE (LOE) SCALE AND GRADE OF RECOMMENDATION (GOR) SCALES

LOE

I	Evidence from at least one large randomised, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well-conducted randomised trials without heterogeneity
II	Small randomised trials or large randomised trials with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity
III	Prospective cohort studies
IV	Retrospective cohort studies or case–control studies
V	Studies without control group, case reports, experts opinions

GOR

A	Strong evidence for efficacy with a substantial clinical benefit, strongly recommended
B	Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended
C	Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (adverse events, costs, ...), optional
D	Moderate evidence against efficacy or for adverse outcome, generally not recommended
E	Strong evidence against efficacy or for adverse outcome, never recommended

Dykewicz CA. Summary of the guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. Clin Infect Dis 2001; 33: 139–144. By permission of the Infectious Diseases Society of America.

MCBS Grading

The CC chairs construct an MCBS Table with all drugs referred to in the CC manuscript and approved post Jan 2016 with an MCBS Score. The GLC and MCBS WG review and approve the MCBS Table within 2 weeks. The MCBS score is inserted next to the LOE and GOR in every recommendation referring to the new drug.

References

1. Jones Y and Hunter D. Qualitative research: consensus methods for medical and health services research. *BMJ* 1995; 311: 376–388.
2. Jaeschke R, Guyatt GH, Dellinger P et al. Use of GRADE grid to reach decision on clinical practice guidelines when consensus is elusive. *BMJ* 2008; 337: a744.
3. Guyatt GH, Oxman AD, Kunz R et al. What is quality of evidence and why is it important to clinicians? *BMJ* 2008; 336: 995–998.