



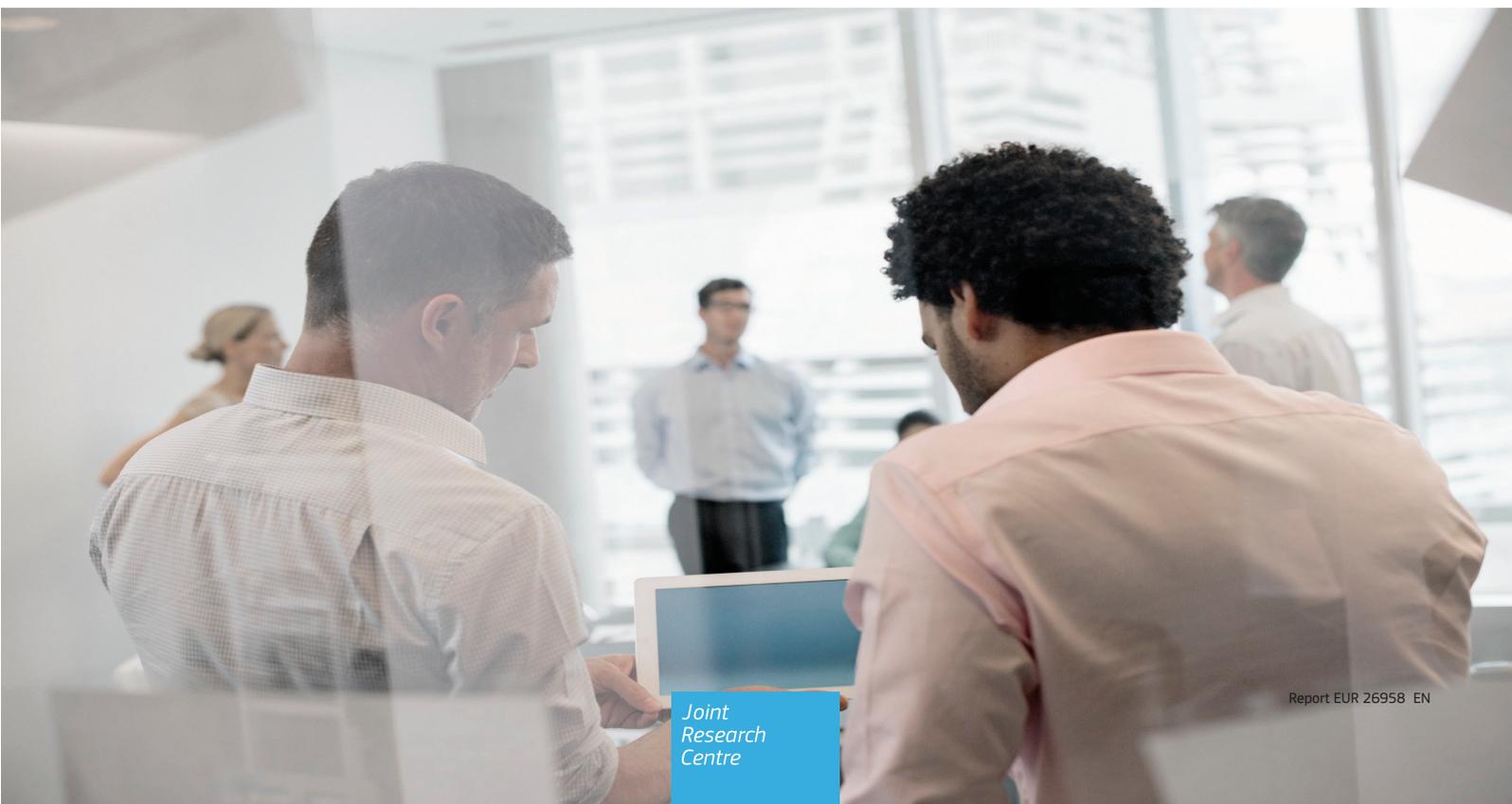
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GRADE workshop: grading the **quality** of evidence and **strength** of recommendations

11-12 December 2013

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Executive summary

In December 2013, the *Public Health Policy Support Unit* at the European Commission's *Joint Research Centre* organised a two-day workshop on developing evidence-based guidelines and healthcare recommendations using GRADE.

GRADE stands for *Grading of Recommendations Assessment, Development and Evaluation*. It is a method for grading the quality of evidence and going from this evidence to the corresponding healthcare recommendation.

The aims of the workshop were:

- To explain how to develop evidence-based guidelines and health recommendations using the GRADE approach.
- To build a template for future trainings organised by the JRC on the guideline development process.

Twenty participants, without experience using GRADE, attended the workshop—including 14 JRC staff, as well as representatives from the Directorate General for Health and Consumers (DG SANCO), the European Centre for Disease Prevention and Control (ECDC) and various external institutions. The workshop consisted of lectures on the theory behind guidelines development, group work and computer-based exercises.

Organisers and participants deemed the training a success and the Public Health Policy Support Unit is planning additional GRADE-oriented workshops in the future.

List of acronyms and abbreviations

DECIDE	Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence
DG RTD	Directorate-General Research and Innovation
DG SANCO	Directorate-General for Health and Consumers
EC	European Commission
ECDC	European Centre of Disease Prevention and Control
ECIBC	European Commission's Initiative on Breast Cancer
EFSA	European Food Safety Authority
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IHCP	Institute for Health and Consumer Protection
IOM	Institute of Medicine
JRC	Joint Research Centre
PHPS	Public Health Policy Support
RCT	Randomised Controlled Trial

1. Context of the workshop

The European Commission (EC) will develop the new *European Guidelines for Breast Cancer Screening and Diagnosis* (hereinafter referred to as the *New European Guidelines*) within the *European Commission's Initiative on Breast Cancer* (ECIBC). The ECIBC is coordinated by the EC's JRC, in particular by the Public Health Policy Support (PHPS) Unit¹ within the Institute for Health and Consumer Protection (IHCP).²

The JRC is building the methodological framework for developing the *New European Guidelines*. Consequently, there is a need to choose the most appropriate approach to

grading evidence that could be potentially applied at all EC institutions involved in developing guidelines.

Although there are a number of systems for grading evidence, GRADE, which stands for 'Grading of Recommendations Assessment, Development and Evaluation'^[1], was the system chosen by the ECIBC for the development of the *New European Guidelines* and the system which was proposed to the ECIBC stakeholders. This report summarises a two-day workshop on GRADE held at JRC-Ispra on 11 and 12 December 2013.

2. Aims of the workshop

The aims of the workshop were:

- To explain how to develop evidence-based guidelines and health recommendations using the GRADE approach.
- To build a template for future trainings organised by the JRC on the guideline development process.

1. http://ihcp.jrc.ec.europa.eu/our_activities/public-health.

2. <http://ihcp.jrc.ec.europa.eu/>.

3. Workshop methods

Group work and computer-based exercises were held after theoretical sessions. Meeting facilitators were available to give practical advice. For most of the exercises, adapted versions of the templates provided by the *GRADE Working Group* were used. For the

Risk of Bias exercise, the standard materials provided by *Cochrane Training*³ were used and a randomised controlled trial (RCT) was simulated, which allowed participants to discuss issues of study design and identify methods to minimise bias.

4. Organisation of the workshop

Invitations and selection of participants

This workshop was initially conceived as an internal training for the JRC PHPS Unit. However, workshop organisers considered that other colleagues and stakeholders could also benefit from the training. Therefore, invitations were sent to:

- JRC PHPS Unit staff
- Staff from other EC institutions:
 - DG Health and Consumers (DG SANCO)
 - DG Research & Innovation (DG RTD)

- Staff from European Union Agencies:
 - The European Food Safety Authority (EFSA)
 - The European Centre of Disease Prevention and Control (ECDC)
- Individuals experts.

Participants

20 participants attended the workshop, none of whom had experience with GRADE. Fourteen participants worked at the JRC, three at DG SANCO, one at the ECDC, and two participants were from other non-EC institutions.

3. *Cochrane Training* (<http://training.cochrane.org/>) is an initiative of *The Cochrane Collaboration* that covers all aspects of training related to the preparation and production of Cochrane reviews.

Facilitators

<p>Jesús LÓPEZ ALCALDE <i>Scientific/Technical project officer</i> European Commission Joint Research Centre IHCP PHPS Unit – Healthcare Quality Team +39 0332 78 3719 Jesus.Lopez-Alcalde@ec.europa.eu</p>	<ul style="list-style-type: none"> • M.D. • Specialist in preventive medicine, epidemiology and public health • Master of public health • Experienced in systematic reviews, guidelines and conducting literature searches
<p>Carlos MARTÍN SABORIDO <i>Scientific/Technical project officer</i> European Commission Joint Research Centre IHCP PHPS Unit – Nutrition and Health team</p>	<ul style="list-style-type: none"> • BA in physiotherapy • MSc in health economics • MSc in health law • MSc in health policy • Ph.D. in biomedical sciences • Experienced in health technology assessment (HTA) and economic evaluation
<p>Juan Antonio BLASCO AMARO <i>Scientific/Technical project officer</i> European Commission Joint Research Centre IHCP PHPS Unit – Medical Devices Task Force +39 0332 78 9210 juan-antonio.blasco-amaro@ec.europa.eu</p>	<ul style="list-style-type: none"> • M.D. • Specialist in preventive medicine, epidemiology and public health • Master of public health, health economics and health services management • Experienced in HTA, guidelines and patients decision aids
<p>Theodora MOURATIDOU <i>Scientific/Technical project officer</i> European Commission Joint Research Centre IHCP PHPS Unit – Nutrition and Health team +39 0332 78 5343 Theodora.Mouratidou@ec.europa.eu</p>	<ul style="list-style-type: none"> • Nutritionist • Specialist in dietary assessment, epidemiology and public health • MSc in human nutrition • Ph.D. in dietary assessment • Experienced in childhood and adolescent obesity, dietary assessment methodology and energy balance-related behaviors

5. Content of the workshop

The facilitators explained how to develop evidence-based guidelines and health recommendations using GRADE. The participants were guided through the following processes:

- overview of the general process to develop evidence-based guidelines
- formulation of the questions to be answered in the guideline
- identification of patient relevant outcomes
- evaluation of the quality of evidence
- moving from the evidence to the recommendation
- using the *Guideline Development Tool*.⁴

The contents of the workshop are summarised below.⁵

Introduction: Guideline development process and the GRADE approach

Facilitator: Jesús López Alcalde – JRC

A **guideline** is a document that focuses on a disease or condition and includes recommendations for appropriate management of patients with this disease or condition. The guideline should be based on the best available evidence and should help healthcare providers by supplementing their knowledge and skills. Guidelines can be tailored

to clinical settings, health policy, health systems or public health [2, 3].

The workshop covered the criteria suggested by the Institute of Medicine (IOM) for considering a guideline as trustworthy [4]. According to the IOM, a guideline should:

- be based on a systematic review of existing evidence
- be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups
- consider important patient subgroups and patient preferences
- be based on an explicit and transparent process that minimises biases and conflicts of interest
- provide a clear explanation of the relationships between alternative care options and health outcomes
- be reconsidered and revised as appropriate.

The full guideline development process, from the recruiting of the guideline panel (the team developing the guideline) to implementation and updating was explained and some relevant organisations involved in developing guidelines, such as *Guidelines International Network (GIN)*,⁶ *AGREE Trust*⁷ and *GRADE Working Group*⁸ were mentioned.

4. <http://www.guidelinedevelopment.org/>.

5. The agenda, presentations, and bibliography of the workshop are available at JRC-IHCP-Cancer Policy Support webpage: http://ihcp.jrc.ec.europa.eu/our_activities/public-health/cancer_policy_support/presentations-from-the-grade-workshop-are-now-available.

6. <http://www.g-i-n.net/>.

7. <http://www.agreetrust.org/>.

8. <http://www.gradeworkinggroup.org/>.

Framing a clinical question with the PICO format

Facilitator: Jesús LÓPEZ ALCALDE–JRC

A guideline attempts to answer relevant questions related to the guideline topic. The facilitator described the different types of questions that a guideline developer may face and explained how to formulate questions in terms of:

- population (**P**),
- alternative options (an intervention (**I**) and a comparator (**C**)), and
- all outcomes that are important to patients and relevant stakeholders (**O**).

Choosing outcomes: the relative importance of outcomes

Facilitator: Jesús LÓPEZ ALCALDE–JRC

Participants were informed about how to select outcomes and how to classify them as ‘critical’, ‘important but not critical’ or ‘not important’ as regards the citizen, patient or other relevant stakeholder that will be affected by the recommendation. Moreover, the participants were guided through an exercise to formulate the question ‘Should parenteral anticoagulants versus placebo or no intervention be used in patients with cancer with no indication for anticoagulation?’ (see exercise here: [JRC-IHCP-Cancer Policy Support web-page](#)).

Study designs

Facilitator: Theodora MOURATIDOU–JRC

Guideline developers should consider study designs that are likely to provide reliable data for each guideline question. The facilitator explained what a study design is, the differences between experimental and observational designs, and the study designs of choice for each research question. Because the workshop focused on guidelines about the effects of healthcare interventions, the study design of choice was the RCT, as randomisation is the only way to prevent systematic differences between baseline characteristics of participants in different intervention groups in terms of both known and unknown (or unmeasured) confounders [5].

Finally, the facilitator ran an exercise to ensure that participants had a good understanding of each type of study design.

Search of the literature

Facilitators: Theodora MOURATIDOU and Carlos MARTÍN SABORIDO–JRC

Participants learned that evidence-based recommendations must be based on exhaustive search strategies that allow the identification of relevant evidence related to each critical or important outcome [6]. The facilitator provided information on where to search for evidence (*e.g.* MEDLINE and other sources) and how to create search strategies with Boolean

operators,⁹ truncations,¹⁰ controlled vocabulary and free terms, etc. In addition, a number of *PubMed* functionalities, such as *My NCBI*¹¹ were demonstrated. Finally, the participants carried out a practical exercise.

Determinants of QoE (I): risk of bias

Facilitator: Jesús López Alcalde – JRC

The GRADE Working Group interprets the word evidence as ‘confidence in the estimates of the effect as provided by research’ and suggests a two-step process for rating its quality (or certainty):

1st step: rate the overall quality of the evidence (QoE) for each outcome across studies

2nd step: rate the overall QoE for the recommendation across all outcomes.

GRADE acknowledges that QoE may differ across outcomes and explicitly addresses this issue [7]. The workshop participants were trained on how to rate the QoE as defined by GRADE.

Then, the session focused on the *risk of bias*, one of the factors to downgrade the QoE for a given outcome [5]. In order to clarify the concept of *risk of bias*, participants were invited to participate to an interactive exercise designed by *Cochrane Training*¹². During the exercise a randomised controlled trial (RCT) was simulated, which allowed discussion of issues related to study design and identify methods to minimise the risk of bias.

Table 1. Levels of certainty of the evidence.¹³

Levels of certainty of the evidence	Definitions
High 	This research provides a very good indication of the likely effect. The likelihood that the real effect will be substantially different from the effect provided by research is low.
Moderate 	This research provides a good indication of the likely effect. The likelihood that the real effect will be substantially different from the effect provided by research is moderate.
Low 	This research provides some indication of the likely effect. However, the likelihood that the real effect will be substantially different from the effect provided by research is high.
Very Low 	This research does not provide a reliable indication of the likely effect. The likelihood that the real effect will be substantially different from the effect provided by research is very high.

9. Boolean operators (AND, OR, NOT) link concepts and are used to broaden or narrow the search strategy.

10. Truncation can be used when you want the search engine to find all terms that begin with a given text string. Truncation is represented by the asterisk (*), sometimes referred to as a ‘wildcard’ in PubMed (<http://goo.gl/1GARoe>).

11. <http://www.ncbi.nlm.nih.gov/myncbi/>.

12. Cochrane Training (<http://training.cochrane.org/>) is an initiative of *The Cochrane Collaboration* that covers all aspects of training related to the preparation and production of Cochrane reviews.

13. Adapted from the DECIDE Project: <http://www.decide-collaboration.eu/WP5/Strategies/Framework>.

Determinants of QoE (II): indirectness

Facilitator: Jesús LÓPEZ ALCALDE – JRC

Another factor to downgrade the QoE for a given outcome is indirectness [8]. GRADE considers that indirectness is due to:

- the presence of substantial differences between the population, intervention, or outcomes measured in the studies and those under consideration in the guideline being developed; or
- the absence of data for direct comparisons of the interventions addressed by the guideline (*e.g.* a recommendation aims to compare *drug A* versus *drug B*; however, data from RCTs directly comparing these two drugs are lacking, and the only available data are from RCTs comparing drug A to placebo and drug B to placebo). According to GRADE, such evidence would be downgraded due to indirectness.

Determinants of QoE (III): imprecision, inconsistency and publication bias

Facilitator: Juan Antonio BLASCO AMARO – JRC

The facilitator explained that imprecision, inconsistency and publication bias are additional factors for downgrading the QoE for a given outcome. The facilitator explained how to interpret meta-analyses, forest plots, funnel plots and heterogeneity as well as highlighted that a meta-analysis should only be done under certain circumstances.

Determinants of QoE (IV): factors to upgrade the QoE

Facilitator: Carlos MARTÍN SABORIDO – JRC

The facilitator explained that GRADE considers certain criteria for upgrading the QoE for a given outcome including:

- a large magnitude of effect
- the presence of a dose-response relationship
- issues related to confounding (*e.g.* all plausible confounders or biases would decrease an apparent treatment effect, or would create a spurious effect when results suggest no effect).

GRADE offers the possibility of upgrading the QoE initially assigned according to the study design.¹⁴ This approach may be especially useful in areas where RCTs are scarce and observational studies frequent, such as public health or healthcare quality and safety, as it allows considering the evidence provided by observational studies.

Going from the evidence to the recommendation

Facilitators: Jesús LÓPEZ ALCALDE and Carlos MARTÍN SABORIDO – JRC

Participants learned how GRADE separates the rating of the QoE from the rating of the strength of the recommendation and how the GRADE framework helps a guideline panel move from the evidence to the clinical

¹⁴. Traditional systems to grade the evidence considered the quality of evidence arising from RCTs always as 'high' and evidence from observational studies as 'low'.

cal recommendation. In addition, the participants were guided through two primary aspects of this process:

- defining the *direction of the recommendation* ('recommend for' or 'recommend against' an option)
- grading the *strength of the recommendation* ('strong recommendation' or 'weak recommendation').

The *strength of the recommendation* reflects the extent to which a guideline panel is confident that the desirable effects of following a recommendation outweigh the potential undesirable effects. Its interpretation varies depending on who will use the recommendation or guideline [9]:

Table 2. *Meaning of the strength of the recommendation.*

Strength of the recommendation	Meaning for clinicians or patients	Meaning for policy makers
Strong	The panel believes that all or almost all informed people would choose the recommended choice of action.	The panel believes that the recommendation can be adopted as a policy in most situations.
Weak (conditional)	The panel believes that most informed people would choose the recommended choice of action, but a substantial number would not.	The panel believes that policy making will require substantial debate and involvement of many stakeholders.

According to GRADE, a panel must consider factors besides the QoE when developing a recommendation. Therefore, high QoE will not always imply a strong recommendation while low QoE could imply a strong recommendation (if a number of factors are fulfilled). Again, this approach can be especially useful in areas where RCTs are scarce and observational studies frequent, such as public health.

Using the Guideline Development Tool (GDT) software

Facilitator: Jesús LÓPEZ ALCALDE – JRC

The facilitators guided the participants in using the GRADE-DECIDE guideline development tool (GDT) which allows the management of the whole guideline development process. The tool is freely available at: <http://www.guidelinedevelopment.org/>.

According to its developers, the GDT is an easy to use, all-in-one web solution for summarising and presenting information for healthcare decision-making. It supports creating concise summary tables for systematic reviews and health technology assessments as well as facilitates the development of clinical practice guidelines and recommendations in public health or health policy decisions.¹⁵

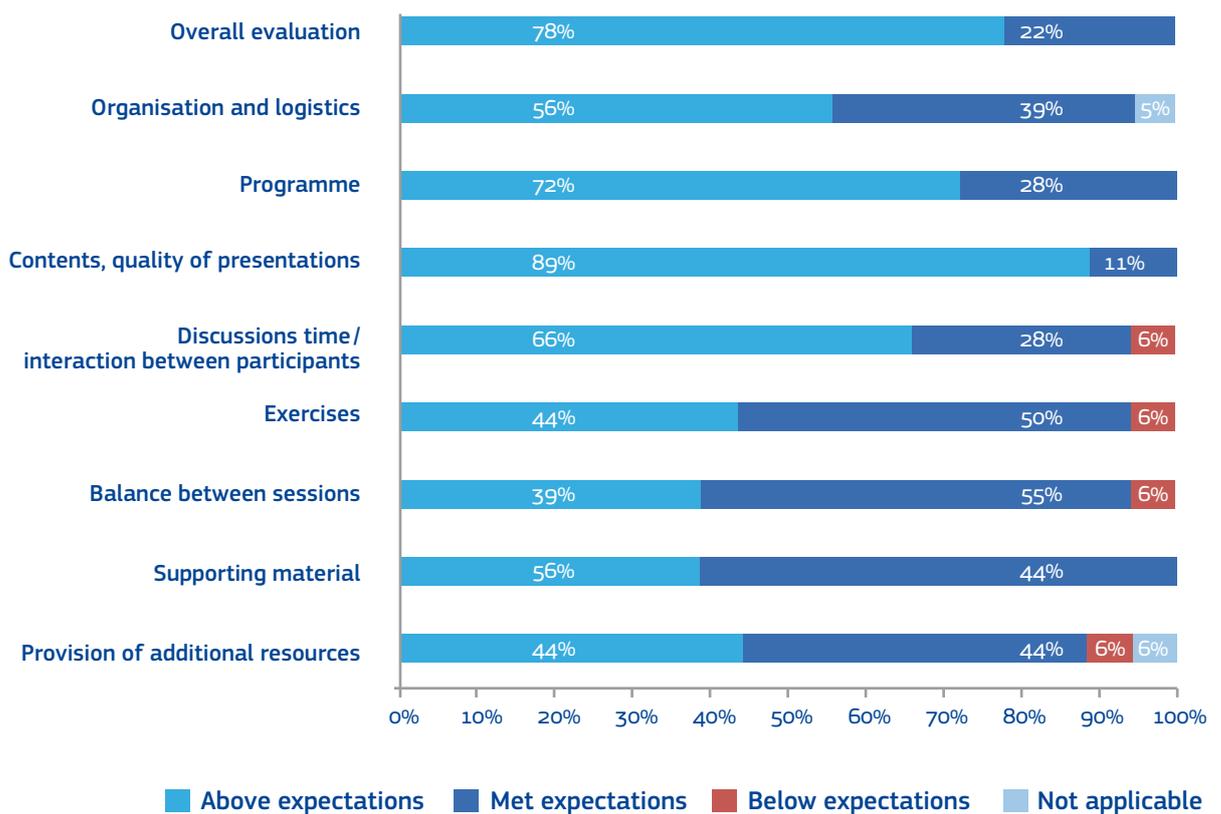
15. <http://www.guidelinedevelopment.org/>.

6. Workshop evaluation

Participants' feedback was collected and evaluated in order to determine satisfaction with the event and to identify areas for improvement. The feedback form covered the event's preparation, delivery, organisation, logistics as well as an overall evaluation of the workshop. The results of this evaluation will be carefully considered by the JRC in the planning and organisation of future workshops.

In order to increase the response rate, a specific time on the final day of the workshop was allocated for completion of the feedback form. Eighteen out of the 20 participants completed the form (corresponding to 90% response rate). Likert scale items ('below expectations', 'met expectations', 'above expectations', 'not applicable') are reported below as aggregate percentages. A full list of the participants' comments is available upon request.

Summary of the workshop evaluation



7. Conclusions

The JRC organised a workshop on the guideline development process. It aimed to explain how to develop evidence-based guidelines and health recommendations using the GRADE approach, and to build a template for possible future trainings.

The training was deemed a success as suggested by participant feedback.

The JRC will organise workshops with the same format dedicated to stakeholders involved in developing guidelines, such as the working group that will develop the new *European Guidelines for breast cancer screening and diagnosis*.

The workshop materials are available for download in PDF format on the JRC-IHCP website:

- [Agenda](#)
- [Presentations, bibliography and exercises.](#)

8. Acknowledgements

The *Public Health Policy Support Unit* would like to thank the *GRADE Working Group* for the materials provided, in particular the generous support provided by Professor Holger SCHÜNEMANN, and the technical team of the *Guideline Development Tool (GDT)*.

We are also grateful to *Cochrane Training*, an initiative of *The Cochrane Collaboration* that covers all aspects of training related to the preparation and production of Cochrane reviews, for their assistance and supply of materials for the *Risk of Bias* exercise.

The authors would like to acknowledge the fundamental support of Brigitte WESTRITSCHNIG, Chiara MARGAGLIANO, Elena MONETA

and Marie OSKARSSON for the organisation of the workshop.

In addition, we are grateful to Sabrina GIORIA and Pablo MENDOZA for reviewing this report.

And finally, but not least, the authors are grateful to the participants for their questions and comments.

For further information about this workshop or future events, please contact:

jrc-cancer-policy-support@ec.europa.eu

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Annex: Participant feedback form

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

Event:	GRADE Workshop			
Date(s):	11-12 December 2013			
Location:	JRC-Ispra			
Organiser:	Public Health Policy Support			
Participant's name (optional):				
Event's preparation	Below expectations	Met expectations	Above expectations	N/A
Programme	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objectives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Event's delivery	Below expectations	Met expectations	Above expectations	N/A
Contents, quality of presentations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discussion time/interaction between participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Balance between sessions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Speakers performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Jesús López Alcalde</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Theodora Mouratidou</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Juan Antonio Blasco Amaro</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Carlos Martín Saborido</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Supporting material	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Provision of additional resources (useful links, downloads, contacts)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Organisation and Logistics	Below expectations	Met expectations	Above expectations	N/A
Organisation, location, communication with the participants, side events	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
General Comments	Below expectations	Met expectations	Above expectations	N/A
Overall evaluation of the event	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any additional comment (especially for explaining the reasons for "below expectations")				

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Abstract

The European Commission's Joint Research Centre (JRC) organised a workshop on evidence-based guidelines development with GRADE ('Grading of Recommendations Assessment, Development and Evaluation'). GRADE is a method of grading the quality of the evidence and going from this evidence to the corresponding recommendation.

Twenty participants attended the workshop, none of whom had experience with GRADE. Fourteen participants worked at the JRC, three at the Directorate General for Health and Consumers (DG SANCO), one at the European Centre of Disease Prevention and Control (ECDC), and two participants were from other non-European Commission institutions.

The workshop consisted of group work and computer-based exercises held after theoretical sessions. Meeting facilitators were available to give practical advice.

The training was deemed a success as suggested by participants' feedback. The JRC will organise workshops with the same format dedicated to stakeholders involved in developing guidelines, such as the team of the new European Guidelines for breast cancer screening and diagnosis.

For further information about this workshop or future events, please contact: jrc-cancer-policy-support@ec.europa.eu

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