EUROPEAN COMMISSION
DIRECTORATE GENERAL
JOINT RESEARCH CENTRE
Directorate F – Health, Consumers and Reference Materials
Unit F1 Health in Society

ECICC - European Commission Initiative on Colorectal Cancer

Mandate of the ECICC Working Group

Purpose of the document: Outline of the principal tasks and duration of the ECICC working group members

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This document describes the mandate for the working group of the European Commission Initiative on Colorectal Cancer (ECICC), called the ECICC working group. The suggestions contained in this document do not prejudge the form and content of any future modification put forward by the European Commission.

BACKGROUND

In 2008, the European Parliament Resolution on combatting cancer called on the Commission for the development of European accreditation/certification programmes in cancer screening, diagnosis and treatment based on evidence-based European guidelines. In order to achieve these goals, several initiatives were launched, one of which is the ECICC as a follow up of the European Commission Initiative on Breast Cancer (ECIBC). Both are covered by an administrative arrangement between the Joint Research Centre (JRC) and the Directorate-General Health and Food Safety under the Commission Implementing Decision of 1 December 2011. The key element of this current initiative is to develop the European colorectal cancer guidelines and the European colorectal cancer quality assurance (QA) scheme.

To recall, the ECIBC guidelines, commenced in 2015, are based on systematic reviews and developed using the GRADE Evidence to Decision (EtD)[1] frameworks. Considering the experience from the ECIBC, where the guidelines and the quality assurance scheme were developed in parallel with limited integration, an overarching and integrated approach for the European colorectal cancer guidelines (the guidelines) and the European colorectal cancer QA scheme (the scheme) will be applied to this new initiative on colorectal cancer (the initiative). In the light of the lessons learned from the ECIBC, one single working group with a reduced number of members will be set up for ECICC, while subgroups will be formed according to specific and changing needs.

[1] Moberg, J., Oxman, A.D., Rosenbaum, S. et al. The GRADE Evidence to Decision (EtD) framework for health system and public health decisions. Health Res Policy Sys 16, 45 (2018). https://doi.org/10.1186/s12961-018-0320-2

THE ECICC WORKING GROUP

The ECICC working group (the working group) will follow the methodological framework for the integrated development of the guidelines and the scheme. Members of the working group will be selected *via* an open call.

The working group will work in close collaboration with subgroups of experts appointed to specific activities and chosen primarily from the ECICC expert pool. If additional scientific or technical expertise is needed for specific aspects, the working group can as well rely on outsourced expertise (external experts) hired from Commission expert pools or other means (e.g. procurement) for a limited time period and for concrete assignments.

To ensure alignments and/or information exchanges, the Joint Research Centre (JRC) will also form a small group with selected representatives of main players in the field of colorectal cancer guideline and QA assurance developments after the establishment of the working group. The working group may collaborate with this stakeholder representatives group as needed.

The mandate of the working group will last for at least 48 months.

The tasks of the working group will include the following:

1. Critically evaluate and summarise the existing evidence to develop patient centred and evidence-based European colorectal cancer guidelines on colorectal cancer prevention, screening and diagnosis.
   The guidelines will provide evidence-based advice to organisations that decide to follow them. These organisations may include screening programme developers, hospitals treating colorectal cancer patients or institutes working in support at national, or more often at regional levels. These organisations may choose to adopt all the guidelines or only some of them.
   The guidelines may be adapted to the national/regional contexts to facilitate implementation.

2. Develop quality & safety requirements and performance measures for colorectal cancer services.
   These indicators and measures will constitute the European colorectal cancer QA scheme, and its uptake will be voluntary. Public or private colorectal cancer services may choose to follow the scheme to ensure, and/or to improve, the quality of care they offer.
   The correct application of the scheme in these cases is envisaged to be audited through an accredited certification process.

3. Assist the JRC in obtaining and/or processing the feedback received on the European colorectal cancer guidelines and the European colorectal cancer QA scheme.
   The ECICC, will collect input on specific scientific/technical aspects of the guidelines and the scheme, from relevant stakeholders through public consultations/surveys or other means. The stakeholders include, but are not limited to, individuals, professional organisations, hospitals, national contact points assigned to this project, as well as other entities active in the topic area.

4. Promote the European colorectal cancer guidelines and the European colorectal cancer QA scheme.
   Outputs of the ECICC will be accessible via the JRC public website as the reference site (https://healthcare-quality.jrc.ec.europa.eu/. A mailing list will be established to regularly update subscribers about the progress made or important milestones reached. The members of the working group will be expected to help enhance the awareness about the existence, values and different potential applications or information tools of ECICC. This will include presentations at scientific conferences, scientific papers and/or interactions with related working groups.

5. Moreover, the ECICC outputs will be distributed to national contacts assigned to this initiative. Their feedback will be reviewed during working group meetings to incorporate flexibility and considering heterogeneity of settings across Europe, which will facilitate future applications of the initiative.

6. Assist the JRC during feasibility testing of the European colorectal cancer QA scheme in colorectal cancer services that volunteered to participate and during subsequent potential modifications.

7. Participate in subgroups.
   The working group will principally rely on the work performed in subgroups, established to work on specific healthcare questions (e.g. questions generated for the development of the guidelines). A subgroup will be formed for each healthcare question/cluster of healthcare questions under discussion and dissolved once the respective work is completed. A subgroup will comprise approximately five to eight members (with a maximum of 10, in exceptional cases only), consisting of one or two working group members, two to four members taken from the ECICC expert pool, (or if no adequate expert is found in the ECICC expert pool, hired on demand through expert contracts or

procurement), one or two JRC staff members and the experts in charge of the systematic reviews of the literature to support the work. The number of involved subgroup members is dependent on the expertise needed to discuss the specific question(s).
Each working group member is expected to participate in subgroups relevant to her/his specific area of competence, as the workload permits.

8. Provide methodological, scientific and technical input to the JRC in conducting studies underpinning the ECICC's main tasks, as defined in points 1-7.

9. Provide input to scientific publications including articles to be published in peer reviewed journals, presentations in conferences or other scientific reports, JRC publications, etc.

The working group will meet physically on a regular basis and upon need, which is foreseen to be not more than twice a year, each lasting two full days and another two-three virtual meetings which might be organised over half working days. However schedule and means for meetings will be dependent on the work progress and/or public health situation. In case of impediments, or meetings organised online only, the working group members shall be in the position to join meetings virtually by means of web based tools.

The working group may also be requested to participate in ad-hoc video- or tele-conferences and use the online tools provided for the work (e.g. GRADEPro, CIRCABC). Appropriate training will be provided.

Regarding the in time limited subgroup activities, the work will be done predominantly by using online means, which can be estimated to be two to three days monthly depending on the subject area. The working group members will selectively participate in those meetings (see before).

The JRC will organise training for the working group members to improve their engagement to the initiative and to help them fulfilling their tasks better. The training will cover mainly the methodologies and working tools, including topics such as systematic reviews and quality assurance, GRADE methodology and guideline development, and the ECICC work flow.

The JRC will provide both the scientific secretariat (e.g. planning and coordinating with the support of the chairs the overall ECICC activities, participating in and steering the subgroup activities together with the respective subgroup coordinator, overseeing the systematic review groups, make provisions for the minutes, organising surveys, conducting studies, publication of the outputs on the institutions' website) as well as logistic services to the working group.

The outputs of the ECICC, the guidelines and the scheme will be provided for voluntary uptake by international, national or regional organisations active in the colorectal cancer care area (e.g. screening programme organisers, hospitals treating colorectal cancer patients, individual cancer services). All the outputs may be implemented through modular and/or adaptable processes with the support of specific tools provided by JRC. The scheme is foreseen to be applied through an accredited certification process.

GLOSSARY OF TERMS AND ABBREVIATIONS

CIRCABC: the service used to create collaborative workspaces, provided by the European Commission.

ECIBC: European Commission Initiative on Breast Cancer

ECICC: European Commission Initiative on Colorectal Cancer

European colorectal cancer guidelines: evidence based health guidelines for colorectal cancer prevention, screening and diagnosis developed by the ECICC

European colorectal cancer QA scheme: quality assurance scheme covering prevention and all processes of care of colorectal cancer developed by the ECICC

GRADE: Grading of Recommendations Assessment, Development and Evaluation

GRADEpro: a web application to create, manage and share summaries of research evidence.

JRC: Joint Research Centre

QA: Quality assurance

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Rules of Procedure of the ECICC Working Group

Purpose of the document: Outline of organisational and procedural aspects of the ECICC working group activities

Author: Joint Research Centre's Healthcare Quality Group

Last update and version: 18 July 2022, version 1

Contents

1. RULES OF PROCEDURE OF THE ECICC WORKING GROUP

The European Commission Initiative on Colorectal Cancer (ECICC) working group ('the working group'),

HAS ADOPTED THE FOLLOWING RULES OF PROCEDURE:

Article 1. **Operation of the group**

The ECICC working group and its subgroups shall act at the request of the JRC (European Commission's Joint Research Center).

Article 2. **Chair and Vice-chair**

JRC selects one chair and one vice-chair from among the working group members ('the members').

Article 3. **Replacement of members**

The members who resign, who are no longer capable of contributing effectively to the working group's deliberations[1], or who, in the opinion of the JRC, do not comply with the confidentiality condition set out in Article 339 of the Treaty on the Functioning of the European Union[2] may be replaced for the remainder of their term of office. The JRC, in agreement with the chair, appoints an expert from the ECICC expert pool, taking into account the relevant field of competence that needs to be covered. In case the ECICC expert pool does not adequately cover the competence, an external expert can be nominated.

[1] See article 14.
[2] The members of the institutions of the Union, the members of committees, and the officials and other servants of the Union shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components.

Article 4. **Convening a meeting**

1. Meetings of the working group either are convened by the JRC, on its own initiative, or at the request of the members after the JRC has given its agreement.
2. Meetings of the working group will preferably be held at the JRC Ispra (IT) premises (or close to it) or virtually if and as needed. In case of impediments to travel or meetings are organised online, the members shall be in the position to join meetings virtually by means of web-based tools. In case of physical meetings, the JRC will decide the location.
3. Attendance of at least two thirds of the members is required to convene a meeting.

Article 5. **Agenda**

1. The JRC will draft the agenda in consultation with the chairs and send it to the members.
2. The members shall adopt the agenda at the start of each meeting.

Article 6. **Documentation to be sent to group members**

1. The JRC shall send the meeting invitation and the draft agenda to the members no later than thirty calendar days before meeting date.
2. The JRC shall send documents on which the working group is consulted to the members no later than fourteen calendar days before the meeting date.
3. In urgent or exceptional cases, the time limits for sending the documentation mentioned in points one and two may be reduced to five calendar days before the meeting date.

Article 7. **Opinions of the group**

1. As far as possible, the working group and the subgroups shall adopt its opinions, recommendations, requirements/indicators or reports by consensus, based on provided latest evidence. In case the working group or the subgroup does not reach consensus, the position will be adopted *via* voting.
2. In the event of a vote, the outcome will be decided either by simple majority or qualified majority.

3. For the direction of the recommendation (i.e., to recommend for or against an option), decision will be taken by simple majority. For the strength of the recommendation (strong or weak recommendation), a qualified majority of 80% will be needed.

4. To issue a requirement or a set of requirements, including criteria and indicator measurements, a qualified majority of 80% will be needed.

5. For the remaining decisions of the working group or the subgroup, the threshold will be decided on a case-by-case basis.

6. In principle, the chair will not vote. In cases of a tie where simple majority is required to take a decision, the chair may vote.

7. The members that have abstained or voted against shall have the right to document the reasons for their minority opinion.

Article 8. **Sub-groups**

1. The subgroups will work on specific healthcare questions in preparation of the voting by the working group memebers. The JRC, on its own initiative, or the working group, in agreement with the JRC will set up the subgroups. Generally, each subgroup will comprise approximately five to eight members, consisting of one or two JRC members, one or two working group members and subgroup members either taken from the ECICC expert pool or hired on demand (through expert contracts or procurement). The number of involved subgroup members depend on the expertise needed to discuss the specific question.

2. Each subgroup will have two co-leads, one coming from the ECICC working group and one coming from the ECICC expert pool. They will be responsible of leading the subgroup's work and the meetings' activities.

3. Each working group member is expected to participate in subgroups relevant to her/his specific area of competence, as the workload permits.

4. These subgroups shall be disbanded as soon as their mandate is fulfilled.

5. The subgroups shall report to the working group.

Article 9. **Admission of third parties**

The JRC may invite on an *ad hoc* basis experts from outside the working group (or the subgroup) with specific competence in a subject on the agenda to participate in the work. In

addition, the JRC may give an 'observer' status to individuals, organisations as defined in Rule 7(2) of the horizontal rules on expert groups[3], and candidate countries.

Article 10. **Written procedure**

1. If necessary, the working group's (or the subgroup's) opinion or recommendation/requirements/indicators on a specific question may be delivered via a written procedure. In such a case, the JRC sends to the members the document(s) on which the working group (or the subgroup) is being consulted.
2. The outcome of the written procedure is adopted by consensus based on the latest evidence available. If consensus is not reached, simple majority of the concerned members would adopt the outcome.
3. If a simple majority of the working group (or the subgroup) members asks for the question to be examined at a meeting, the written procedure shall be terminated without result and the JRC shall convene a meeting as soon as possible.

Article 11. **Secretariat**

The JRC will provide the scientific secretariat (e.g. planning and coordinating with the support of the chairs the overall ECICC activities, overseeing the systematic review groups, make provisions for the minutes, organising surveys, conducting studies, publication of the outputs on the institutions' website), as well as logistics services to the working group and the subgroups.

Article 12. **Minutes of the meetings**

1. The JRC shall make provisions to make available the draft of the meeting minutes. With the exception of the minority opinions, the minutes shall not mention the individual position of the members during deliberations.
2. The draft minutes shall be circulated among the members. Disagreements shall be notified to the JRC.
3. The final minutes shall be approved by the members. The final approved minutes will be made publicly available.

[3] C(2016)3301

Article 13. **Attendance**

At each meeting, the JRC shall draw up and record an attendance list of the participants including the working group members and if applicable, the subgroup members, external experts, as well as the observers.

Article 14. **Participation criteria**

1. In each calendar year, members are expected to attend at least 75% of the working group meetings.
2. The members are expected to be in a position to contribute actively to the discussion and deliberations on subjects within their field of competence during meetings of the working group and, when requested, with written comments.
3. JRC will record/assess on a yearly basis the extent to which members have been in a position to participate in the work of the working group. After consultation with the chair, the JRC shall examine the situation with the members who have not been in a position to comply with the participation criteria[4].

Article 15. **Conflict of interests**

1. At the beginning of each calendar year, each member shall complete an annual declaration of interest form and provide it to the JRC for the assessment of potential conflict of interests.
2. The JRC and the chair of the working group shall, at the first meeting of each calendar year remind all members of their obligation to promptly inform the JRC of any relevant change in the information previously provided, as regards upcoming activities, in which case they must immediately submit a newly completed declaration of interests describing the change, in order to enable the JRC to assess it in due course, in compliance with the horizontal rules.
3. Before each meeting, each member shall complete a specific request for the declaration of interests related to the specific topics under discussion.
4. At the start of each meeting, any member whose participation in the working group's work would raise a conflict of interests shall inform the JRC and the chair.

[4] See article 3

5. Should a conflict of interests in relation to a member arise, the JRC may exclude this member from the working group, or a particular meeting thereof or may decide that the member in question shall abstain from discussing the items on the agenda concerned and from any vote on these items.

6. Conflict of interests shall be recorded in the meeting minutes.

7. Point 5 shall also apply to deliberations taken by the working group (or the subgroups) in written procedure.

Article 16. ***Meeting expenses***

1. Participants in the activities of the working group and subgroups will in principle not be remunerated for the services they offer. However, the JRC may decide to pay for extraordinary activities via the signature of an expert contract with concrete working group members. This would amount to a maximum of 12 days/year/expert (450 EUR/day as of June 2022).

2. Details/conditions for payments will be provided later during the process. However, the members must have responded to at least 75% of the inquiries sent by the JRC related to the working group tasks to be able to receive a remuneration. To be noted, fulfilling this criterion does not necessarily mean that the member will receive a remuneration.

3. The amount of the possible remuneration will be determined individually for each member, taking into consideration the meeting attendance within the last 12 months.

4. Travel and subsistence expenses (€192 per meeting day as of June 2022), incurred by participants in the activities of the working group and its subgroups will be reimbursed in accordance with the provisions in force within the Commission and within the limits of the available appropriations allocated to the Commission departments under the annual procedure for the allocation of resources. .

Article 17. **Correspondence**

1. Correspondence relating to the working group or the subgroups shall be addressed to the JRC as indicated hereafter at one of the following addresses:

Email:

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

Postal address:

European Commission - Joint Research Centre

Directorate F – Health, Consumers and Reference Materials

Health in Society Unit - JRC Healthcare Quality Group

Via E. Fermi, 2749. TP 127

I-21027 Ispra (VA)/Italy

2. Correspondence to the members shall be sent to the e-mail address, which they provide for that purpose.

Article 18. **Transparency**

1. As concerns the composition of the working group and the subgroups, the following data will be published on the JRC Healthcare Quality website:

   a) the name of individuals appointed as working group members and their brief CVs;

   b) the name and affiliation of individuals appointed as subgroup members;

   c) the name and affiliation of external experts;

   d) the name and affiliation of observers;

   e) the name of stakeholder representatives.

2. Individuals who do not wish to have their names disclosed may submit a request to the JRC for a derogation from this rule. A derogation shall be granted where justified on compelling legitimate grounds in relation to the specific situation of the individual, in particular where disclosure of the individual's name could endanger their security or integrity, which should however be the exception.

3. The following documents will be published on the JRC Healthcare Quality website (see link in footnote 2), respecting the confidentiality requirements as

well as protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, such as:

a) Draft agendas and/or agendas of meetings;

b) Minutes of meetings;

c) Declarations by working group members, subgroup members and external experts who participate in ongoing work of their commitment to act independently of any external influence;

d) Annual declaration of interests;

e) Declaration of interests in relation to specific topics under discussion;

f) Rules of procedures;

g) Eventual stakeholder dialogue activities (e.g. consultations, calls for information, calls for experts, calls for hearings, public consultations, etc.).

4. Access to the JRC Healthcare Quality website will not be subject to user registration or any other restriction. In particular, the agenda and other relevant background documents will be published in due time ahead of the meeting, followed by a timely publication of minutes. Exceptions to publication will only be foreseen where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001[5].

Article 19. **Access to documents**

Applications for access to documents held by the working group (and the subgroups) shall be handled in accordance with Regulation (EC) No 1049/2001[6].

5 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

6 See footnote 4

Article 20. **Deliberations**

1. The working group's (and the subgroup's) deliberations shall be confidential.
2. In agreement with the JRC, the working group (or the subgroups) may decide to open its deliberations to the public by a simple majority of its members.

Article 21. **Protection of personal data**

All processing of personal data for the purposes of these rules of procedure shall be in accordance with Regulation (EU) 2018/1725[7].

7 OJ L 295, 21.11.2018, p. 39–98

2. ANNEX: Glossary of terms and abbreviations

ECICC: The European Commission Initiative on Colorectal Cancer

ECICC expert pool: Experts selected as a result of the ECICC open call and who accepted to be included in the ECICC expert pool. Those allocated to this pool were not appointed as a member to the working group. This pool will serve to choose subgroup members, or to nominate new members of the working group if and as needed.

ECICC working group: The working group of the ECICC, nominated as an outcome of the ECICC open call. It represents the decision body for guideline recommendations and requirements/indicators for quality assurance.

ECICC working group member: A member of the ECICC working group appointed by JRC in her/his individual capacity following the ECICC open call.

External expert: Experts contributing temporarily to the ECICC working group or a subgroup activities. They are not a member of the ECICC working group or a subgroup. They are chosen from the ECICC Expert Pool or hired through expert contracts or specific procurement. Their mandate ends once the required tasks are completed. They typically don't vote.

JRC: Joint Research Center

Minority opinions: Declared objections to the opinion adopted.

Qualified majority: A majority in a vote that reaches a pre-set minimum of the votes according to specific rules.

Simple majority: A single vote more than half of the number of the members who voted (abstentions and absent are not counted).

Subgroup: A small working group that is formed in agreement with the JRC and the ECICC working group members to work on specific healthcare questions/requirements covering the entire care pathway, including experts from the ECICC expert pool as well as from the ECICC working group or experts taken via specific contracts if needed. Subgroups are dissolved once their mandate is completed.

Subgroup member: A member of an ECICC subgroup.