CCMG Document Guidance Framework: Guidance document for development of CCMG Guidelines, Position statements and other documents

Overview:

This document provides guidance to CCMG committees and working groups in the development of a variety of Practice guidelines, Practice resources, Position statements and other projects. It includes the process and guidance for peer review publication (where applicable). See **"CCMG Proposal form"** to make a project request to the BOD.

Refer to the **"Document Review and Approval process"** on CCMG website for guidance on required documents and responsibilities for document approval.

Document control: all CCMG documents posted to the website require periodic review. Documents are assigned to a responsible committee to manage periodic updates and if required, archiving.

Whether a Clinical practice guideline or a position statement is undertaken, an evidence-based approach is followed using best available evidence; even when evidence quality is low or limited. Ultimately turning evidence into recommendations requires a process of reaching consensus.

Definitions

Type of document	**Definition**	**Level of Peer review**
Practice Guideline (Clinical practice guideline or Laboratory practice guideline)	A systematic approach to evidence-based review in the development of recommendations to inform clinical best practices.	Specific committee, BOD, CCMG membership +/- external organizations
Practice resource (Clinical practice resource or Laboratory practice resource)	These documents are written by experts in the field and rely on published data and experience. It is expected to have a transparent, reproducible methodology, make justifiable recommendations, and discuss its limitations, including the potential for bias given the non-systematic approach.	Specific committee, BOD, lab-discipline specific CCMG membership
Position Statement	A detailed policy report that makes recommendations or advocates for a certain course of action based on best available evidence. It is a statement about a timely issue	Specific committee, BOD, CCMG membership

	that represents the opinions, beliefs, and/or best professional judgments of the College.	+/- external organizations
Points to consider	Brief communication designed as an educational resource to provide quality clinical care; structured explanatory check list regarding relevant points to consider	Specific committee, BOD
Consensus statements	Developed on a collective opinion or consensus of the CCMG membership. Curated and written by an expert panel; should be evidence based, often when a smaller body of evidence is available (ie. emerging technologies clinical practices) and developed around a topic that is narrowly focused.	Specific committee, BOD, CCMG membership +/- external organizations
Information for members	Information for members or trainees that may need periodic updates	Specific committee, BOD

<u>Points to Consider in Document Creation/Revision:</u>

1. Topic selection and type of document to be created/revised

I. Topics may be proposed by CCMG committees, the BOD or membership at large.
II. Determine the most appropriate document that needs to be created/revised (see above)
III. Topics should have the following considerations:
    a. Importance: ie. disease burden, new diagnostic intervention, areas of clinical uncertainty
    b. Potential impacts: potential to affect change in practice, is there risk of inaction?
    c. Potential to resolve important dilemmas, potential to improve quality of care / reduce cost of care
    d. Appropriateness: does not duplicate existing guideline
    e. Feasibility: is there sufficient evidence in literature to inform a guideline?
IV. Topic submission to the BOD are considered in consultation with relevant committee(s).
V. If the document is to be published, ensure instructions to authors are reviewed for requirements before proceeding and design methodology to meet publication requirements (discussed further below).

2. Composition of document development group

I. If the document is being created by an existing committee, the chair of the committee is responsible for reviewing the COI forms for all members involved to ensure all conflicts are addressed
II. If a new working group is formed, a terms of reference for the group is required.
    a. If a working group is required depending on scope (ie. multiple committee membership required) size should be sufficient to represent relevant disciplines and other specialties relevant to interventions and outcomes of interest (CCMG +/- non-CCMG members)

Recommend to include a methodologist or at least one experienced evidence reviewer as well as topic expert(s)

3. Systematic Evidence Review and Guideline Development

I. Review published guideline development checklists. There are 2 frequently used checklists for Guideline development: AGREE and RIGHT checklists. The **AGREE** checklist is provided in Appendix 1 (www.agreetrust.org).

II. Once the aim(s) of the guideline and specific objectives have been defined, a search strategy should be defined and it is recommended to develop this strategy in consultation with a methodologist or group member with experience in guideline development.

III. Define inclusion and exclusion criteria for content

IV. It is recommended the authors use the **GRADE** system to evaluate the quality of evidence https://www.gradeworkinggroup.org/. Members are encouraged to participate in an **online training** module on the GRADE approach.

   a. A table should be created to capture the results (evidence) of each relevant study or reference which is reviewed (ideally) by two individuals. Evidence is summarized and organized by the hierarchy of evidence (ie systematic reviews, RCTs, observational studies, case studies, and narrative reviews). Guidelines from professional societies and other relevant stakeholders should also be summarized.

V. After review of the literature, a consensus process is necessary to formulate recommendations and should seek equal participation from all members and encourage constructive debate

   a. The nominal group technique (NGT) is a structured interaction based on silently and individually generated ideas that are discussed and ranked in a group session in which all the consensus panel participants voice their opinions.

   b. Basecamp can be used to collect and collate ideas, comments and opinions which are then discussed as a group.

4. Review Process and Finalization of Document

I. The committee/working group should familiarize the committee/working group in the approval process (see **CCMG Document Review and Approval Process**) to understand the requirements and who is responsible for each step of the process.

II. Each stage of review and revisions should aim for a 14 day turn around and should include clear documentations of recommendation, revised document with track changes and separate document outlining how each recommendation was addressed and where in the revised document it is detailed.

III. All revisions to an existing document are to be submitted to the BOD for review and approval

5**. Guidance on Publication**

I. Authors should review Instructions to Authors of your Journal of choice early on to ascertain guidance on:

a. type of document and length guidelines,
b. GRADE requirements,
c. reference formatting and any other requirements

II. In selecting the journal, consider the intended audience and consider journals that the majority of CCMG members would likely have access to through their institution.
III. Discussions on granting authorship and order of authorship should be done early in the document process.

Appendix 1:

AGREE Reporting Checklist

2016

AGREE REPORTING CHECKLIST

This checklist is intended to guide the reporting of clinical practice guidelines.

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
DOMAIN 1: SCOPE AND PURPOSE		
1. OBJECTIVES *Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.*	☐☐ Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) ☐☐ Expected benefit(s) or outcome(s) ☐☐ Target(s) (e.g., patient population, society)	
2. QUESTIONS *Report the health question(s) covered by the guideline, particularly for the key recommendations.*	☐☐ Target population ☐☐ Intervention(s) or exposure(s) ☐☐ Comparisons (if appropriate) ☐☐ Outcome(s) ☐☐ Health care setting or context	
3. POPULATION *Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.*	☐☐ Target population, sex and age ☐☐ Clinical condition (if relevant) ☐☐ Severity/stage of disease (if relevant) ☐☐ Comorbidities (if relevant) ☐☐ Excluded populations (if relevant)	
DOMAIN 2: STAKEHOLDER INVOLVEMENT		
4. GROUP MEMBERSHIP *Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations.*	☐☐ Name of participant ☐☐ Discipline/content expertise (e.g., neurosurgeon, methodologist) ☐☐ Institution (e.g., St. Peter's hospital) ☐☐ Geographical location (e.g., Seattle, WA) ☐☐ A description of the member's role in the guideline development group	

5. TARGET POPULATION PREFERENCES AND VIEWS *Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.*	☐☐ Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) ☐☐ Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) ☐☐ Outcomes/information gathered on patient/public information ☐☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
6. TARGET USERS *Report the target (or intended) users of the guideline.*	☐☐ The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators) ☐☐ How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)	

DOMAIN 3: RIGOUR OF DEVELOPMENT		
7. SEARCH METHODS *Report details of the strategy used to search for evidence.*	☐☐ Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL) ☐☐ Time periods searched (e.g., January 1, 2004 to March 31, 2008) ☐☐ Search terms used (e.g., text words, indexing terms, subheadings) ☐☐ Full search strategy included (e.g., possibly located in appendix)	
8. EVIDENCE SELECTION CRITERIA *Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.*	☐☐ Target population (patient, public, etc.) characteristics ☐☐ Study design ☐☐ Comparisons (if relevant) ☐☐ Outcomes ☐☐ Language (if relevant) ☐☐ Context (if relevant)	

9. STRENGTHS & LIMITATIONS OF THE EVIDENCE *Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.*	☐☐ Study design(s) included in body of evidence ☐☐ Study methodology limitations (sampling, blinding, allocation concealment, analytical methods) ☐☐ Appropriateness/relevance of primary and secondary outcomes considered ☐☐ Consistency of results across studies ☐☐ Direction of results across studies ☐☐ Magnitude of benefit versus magnitude of harm ☐☐ Applicability to practice context	
10. FORMULATION OF RECOMMENDATIONS *Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.*	☐☐ Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered) ☐☐ Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures) ☐☐ How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)	
11. CONSIDERATION OF BENEFITS AND HARMS *Report the health benefits, side effects, and risks that were considered when formulating the recommendations.*	☐☐ Supporting data and report of benefits ☐☐ Supporting data and report of harms/side effects/risks ☐☐ Reporting of the balance/trade-off between benefits and harms/side effects/risks ☐☐ Recommendations reflect considerations of both benefits and harms/side effects/risks	
12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE *Describe the explicit link between the recommendations and the evidence on which they are based.*	☐☐ How the guideline development group linked and used the evidence to inform recommendations ☐☐ Link between each recommendation and key evidence (text description and/or reference list) ☐☐ Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline	

13. EXTERNAL REVIEW *Report the methodology used to conduct the external review.*	☐☐ Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) ☐☐ Methods taken to undertake the external review (e.g., rating scale, open-ended questions) ☐☐ Description of the external reviewers (e.g., number, type of reviewers, affiliations) ☐☐ Outcomes/information gathered from the external review (e.g., summary of key findings) ☐☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)	
14. UPDATING PROCEDURE *Describe the procedure for updating the guideline.*	☐☐ A statement that the guideline will be updated ☐☐ Explicit time interval or explicit criteria to guide decisions about when an update will occur ☐☐ Methodology for the updating procedure	
DOMAIN 4: CLARITY OF PRESENTATION		
15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS *Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.*	☐☐ A statement of the recommended action ☐☐ Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects) ☐☐ Relevant population (e.g., patients, public) ☐☐ Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply) ☐☐ If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline	
16. MANAGEMENT OPTIONS *Describe the different options for managing the condition or health issue.*	☐☐ Description of management options ☐☐ Population or clinical situation most appropriate to each option	
17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	☐☐ Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms ☐☐ Specific recommendations grouped together in one section	
DOMAIN 5: APPLICABILITY		

18. FACILITATORS AND BARRIERS TO APPLICATION *Describe the facilitators and barriers to the guideline's application.*	☐☐ Types of facilitators and barriers that were considered ☐☐ Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) ☐☐ Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the	
	population receive mammography) ☐☐ How the information influenced the guideline development process and/or formation of the recommendations	
19. IMPLEMENTATION ADVICE/TOOLS *Provide advice and/or tools on how the recommendations can be applied in practice.*	☐☐ Additional materials to support the implementation of the guideline in practice. For example: ○ Guideline summary documents ○ Links to check lists, algorithms ○ Links to how-to manuals ○ Solutions linked to barrier analysis (see Item 18) ○ Tools to capitalize on guideline facilitators (see Item 18) ○ Outcome of pilot test and lessons learned	
20. RESOURCE IMPLICATIONS *Describe any potential resource implications of applying the recommendations.*	☐☐ Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) ☐☐ Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) ☐☐ Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) ☐☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	

21. MONITORING/ AUDITING CRITERIA *Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.*	☐☐ Criteria to assess guideline implementation or adherence to recommendations ☐☐ Criteria for assessing impact of implementing the recommendations ☐☐ Advice on the frequency and interval of measurement ☐☐ Operational definitions of how the criteria should be measured	
DOMAIN 6: EDITORIAL INDEPENDENCE		
22. FUNDING BODY *Report the funding body's influence on the content of the guideline.*	☐☐ The name of the funding body or source of funding (or explicit statement of no funding) ☐☐ A statement that the funding body did not influence the content of the guideline	
23. COMPETING INTERESTS *Provide an explicit statement that all group members have declared whether they have any competing interests.*	☐☐ Types of competing interests considered ☐☐ Methods by which potential competing interests were sought ☐☐ A description of the competing interests ☐☐ How the competing interests influenced the guideline process and development of recommendations	

From:
Brouwers MC, Kerkvliet K, Spithoff K, on behalf of the AGREE Next Steps Consortium. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. *BMJ* 2016;352:i1152. doi: 10.1136/bmj.i1152.

For more information about the AGREE Reporting Checklist, please visit the AGREE Enterprise website at www.agreetrust.org

Appendix 2: Grading of Recommendations assessment, Development and Evaluation (GRADE)

The GRADE working group began in 2000 as an informal collaboration of academics with an interest in addressing the shortcoming of grading evidence to inform health care decisions.

The GRADE approach considers factors that collectively determine how confident we are in the results and ensures a systematic and transparent process

Grades for strength (of overall quality) of evidence using the GRADE process are high, moderate, low, very low (or high, moderate, low).

GRADE provides detailed methods and table templates for reviewing strength of evidence and some publications are focused on clinical lab testing (4,5).

Domains

- Risk of bias – limitations of study design and execution
- Applicability – consideration of setting with respect to target population of guideline
- Inconsistency – consistency of results across studies or heterogeneity of results within a publication
- Imprecision – certainty of evidence (CI)
- Indirectness – for example - test accuracy as a surrogate for clinical outcomes
- Reporting bias – publication bias (may be flaws in presentation of results or conclusions drawn from results)

There are numerous GRADE publications. The following are links and references specifically for evaluating test accuracy and the patient-important outcomes (in the context of clinical care) and people- important outcomes (in the context of population or public health).

These resources may be helpful in designing the table to summarize evidence

https://guidelines.gradepro.org/profile/yGIrrlHxuTI

REFERENCES:

1. ACMG Protocol Manual for Evidence-based Guideline development 2014
2. European Reference network: Clinical Practice Guidelines and Clinical Decision support tools 2020 https://health.ec.europa.eu/document/download/92d12de1-aae6-4dd5-b9d9-9afce9042ba3_en (europa.eu)
3. Clinical Consensus methodology ACOG
4. Schunemann HJ et al GRADE guidelines: 21 Part 1: Study design, risk of bias, and indirectness in rating the certainty across a body of evidence for test accuracy. J of Clin Epid;2020;122:129-141
5. Schunemann HJ et al GRADE guidelines 21 Part 2: test accuracy: inconsistency, imprecision, publication bias, and other domains for rating the certainty of evidence and presenting it in evidence profiles and summary of findings tables. J of Clin Epid 2020;122:142-152
6. www. right-statement.org
7. www.agreetrust.org
8. Djulbegovic B et al Evidence vs Consensus in Clinical Practice Guidelines. MAMA 2019;322(8);725-26

CCMG Board of Directors Use Only

Document Revision History

Date	**Process**
Dec 2024	Created
	Board Approval