CRA Terms of Reference for the Development of CRA-endorsed Clinical Guidance Documents

This document is a guide to developing documents containing clinical guidance for the Canadian Rheumatology Association (CRA). It outlines the procedures required to receive CRA endorsement and the recommended overall approach for development. It is not meant to be a comprehensive manual covering the entire process of guideline methods.

1. General procedures

1.1 Before you begin

Developing clinical guidance is an important activity of the CRA. If done well, they can help provide evidence-based guidance on important clinical issues for rheumatologists, patients, and other stakeholders. They may help standardize care based on best evidence and ideally lead to improved patient outcomes. Developing clinical guidance however requires numerous resource commitments. Before investing too much time, the purpose, available resources and eventual utility should be considered. Having a cochair who is a methodologist with experience in guideline development is strongly recommended and may impact the strength of the recommendations.[1]

1.2 What are the different types of Clinical Guidance Documents?

The CRA has outlined three types of documents that would fall under a broad heading of clinical guidance documents. These are:

1. **Clinical Practice Guidelines**:

   Clinical practice guidelines are the highest standard of guidance documents. They may be referred to as CRA-endorsed Clinical Practice guidelines or Treatment Recommendations, at the preference of the guideline group. They are meant to provide up-to-date, high-quality recommendations that are relevant to the CRA membership. Clinical Practice Guidelines should be developed using the GRADE approach and must be relevant to the CRA membership (which is typically informed through a needs assessment survey).

2. **Position Statements**:

   A Position Statement is a document that outlines CRA's stance on a topic relevant to its membership. They are generally developed as a quick response to emerging or controversial issues. Although there is usually insufficient time to adopt the same rigorous approach as Clinical Practice Guidelines, the position statements should still refer to appropriate evidence-based literature to support their statements and must be approved by the CRA prior to being published. Sometimes a position statement might precede a formal Clinical Practice Guideline.

3. **Special cases**:

   There are situations that may not fit into either a Clinical Practice Guideline or Position Statement. An example is where a document has already been developed by another organization but requires some adjustments in order to be 'Cast in the Canadian Context'.[2] Recognizing this diversity, the CRA will consider other documents for potential CRA-endorsement on a case-by-case basis. These decisions will be made considering the documents relevance and usefulness to the CRA membership and whether the rigour of its development is appropriate for the purpose of the document.

1.3 Who may develop CRA-endorsed clinical guidance?

Any CRA member can lead the development of a CRA-endorsed clinical guidance document. The team should involve people with the necessary expertise to ensure a successful end product, which will depend on the clinical topic and type of document being developed.

1.4 How the CRA can help

The CRA is committed to helping support the development and dissemination of high-quality and practical clinical guidance for its membership. The CRA encourages guideline leaders to apply for funding to relevant agencies and will provide letters of support for funding applications. The Guidelines Committee will also provide funding support to individual groups up to a maximum amount, which is set yearly by the CRA Board of Directors. The funding may be used to support direct activities related to the guideline and may include: meeting expenses, methodological support, and open access publication fees. The Guidelines Committee will work with the leads to find the appropriate methods experts as needed for each group.

The CRA will also provide in-kind support that may include: methodological advice through the Guidelines Committee; dissemination of needs assessment surveys; support

for guideline group meetings at the CRA Annual Meeting; posting of guidelines or related methodological material on the CRA website; active participation in guideline dissemination to relevant stakeholders. The CRA will also support requests for open-access publication fees, up to a maximum amount that is set yearly by the CRA.

To apply for funding support, the lead of the guideline should contact the chair of the Guidelines Committee and submit a brief proposal to the chair of the Guidelines Committee and the CEO (Appendix A). The requests for funding should be submitted at least 6 weeks prior to the CRA Annual Scientific Meeting (ASM). They will be reviewed by the chair of the Guidelines Committee and CEO for approval, who may seek further input from the Guidelines Committee, additional experts and/or the CRA Board. The CRA will consider the priority of the topic to its membership, and the expertise of the guideline team when reviewing funding requests. The list of ongoing guidelines will be reviewed at each CRA Annual Scientific Meeting (ASM) by the Guidelines Committee to decide which ones need to be updated and when. The Guidelines Committee will make efforts to space out guideline updates, such that all CRA-prioritized guidelines receive sufficient support.

1.5 When and how to involve the CRA

With any clinical guidance document, the CRA should be involved at the earliest possible time. Ideally, this is at the start of the planning process. The project should be registered by submitting a proposal (template in Appendix A). The CRA can then assist in ensuring the necessary processes are followed to ensure the document receives CRA endorsement. If the CRA is not informed prior to development, it may not be possible to receive CRA endorsement.

. The following milestones should be used to communicate with the CRA:

1. Registration: At the earliest possible stage, the project should be registered by submitting a registration form (Appendix A). The purpose is to make the CRA aware of the project so the CRA can provide support for its development.
2. Funding requests: Any requests for funding or letters of support should be submitted to the chair of the Guidelines Committee and CEO using the form provided (Appendix A). Letters of support for funding applications should be submitted ideally 4 weeks in advance of the funding deadline. The CRA will provide letters of support outlining the in-kind support and resources that it can provide (see role of the CRA above). All projects requesting letters of support should be registered first. Note: the Journal of Rheumatology charges a publication fee, so it is important to submit funding requests to the Guidelines Committee at the earliest stage, to ensure the publication costs are added to the annual Guidelines Committee budget and reimbursed by the CRA.
3. Needs assessment survey (if needed): Any needs assessment survey requires CRA approval. Once approved, the CRA will distribute to its membership.

4. Development: It is recommended to communicate frequently with the CRA for updates on the status of the project. The Guideline Committee can serve as a resource to help address challenges that may arise during development.
5. Completion of the draft manuscript: The draft manuscript (ready for publication) must be circulated confidentially to the chair of the Guideline Committee, who will circulate it confidentially to members of the guideline committee for comments and approval. Once approved by the Guidelines Committee, it must be submitted to the CEO for approval. Once approved by the CEO, and before submitting the manuscript for publication, it must be approved by the CRA Board of Directors. Once approved, the primary author may then submit the manuscript to Journal of Rheumatology.
6. Publication of the manuscript: The CRA should be informed when the publication is approved. If appropriate to do so, the support from the CRA, including funding and/or in kind support should be acknowledged in an acknowledgement section of the manuscript. When the manuscript is approved for publication, the lead author must notify the Guidelines Coordinator, and forward the final version of the manuscript to them. If not already on MAGICapp, the Guidelines committee will assist with adding it. At this time, the Guidelines Committee Coordinator will assist with translation of (at minimum) the recommendations and any key remarks. It is CRA policy that all Guidelines must be published in both English and French. The Guidelines Coordinator will assist with coordinating the timing of publication, so it is published in JRheum, on MAGICapp and on the CRA website (in English and French) simultaneously.
7. Dissemination: The CRA can assist in the dissemination plan and guideline developers should consult the CRA for advice.

1. 6 Funding and conflicts of interest

To receive CRA endorsement, the clinical practice document should be developed free of funding from a source with a vested interest in the content of the guidelines. All real or perceived conflicts of interest from guideline committee members should be disclosed to the CRA at the time of Registration and of course in the in the submission of the manuscript for publication according to the guidelines of the journal the article is submitted to. As per the CRA Guidelines COI Policy, Guideline Panel Members (defined as those directly involved in developing guidelines under the direction of a Guideline Lead) should disclose any potential COIs three years retrospectively from the start and throughout the development process (should their COI declaration change). See the CRA Guidelines COI Policy for specific reporting requirements.

1.7 Intellectual property:

The intellectual property of any CRA-endorsed clinical guidance document lies with the CRA, or jointly with another society if the document has co-developed. The CRA will assist in disseminating the guidelines (in conjunction with Optimal Care and Education committees) and has the right to do so. The CRA will not disseminate the guideline prior to its publication, so as not to interfere with publication.

1.8 Industry and Media Questions regarding Guidelines

CRA members should not answer questions about CRA guidelines with members of Industry or the Media directly. Similarly, it is CRA policy that members of Industry are not permitted to contact authors of guidelines/statements directly to ask questions about guidelines or statements. Any questions from Industry or Media should be directed to the CRA, vie email to **info@rheum.ca** whereupon it will go through the proper CRA response channels.

2. Methodology for Developing Clinical Practice Guidelines

The following sections outline the recommended steps that should be taken when developing a Clinical Practice Guideline. They are also relevant for other clinical guidance documents, although not all steps may be necessary. The following is not meant to cover the process of guideline development in general but is meant to provide a brief overview of the steps to consider.

2.1 Setting up a team for guidelines

The target audience of the guideline should be considered when choosing which stakeholder groups should be included. It is important that patient/consumer groups have input into the guidelines, by incorporating representatives (a minimum of 2) into the guidelines team and by ensuring that they can provide input through the process. Additionally, it is recommended as part of the GRADE process to search for literature on patient's preferences and values around the disease and intervention to use this to inform the recommendations.

The availability of the team and resources will also frame the amount of work that can be done. When deciding on the depth of coverage of the guideline, one needs to take into account what is feasible with the team and available resources.

2.2 Scope of the guideline and defining the questions

In order to proceed with a guideline for CRA, a needs assessment survey of the CRA membership is required. The assessment does not need to be new: if previous needs assessments on the same topic are available, one can consider whether the survey needs to be updated.

2.3 Setting up the questions

From the needs assessment and the input from the guideline group, a list of topics and clinical questions should be defined, based on their clinical importance. After generating this list, the questions should then be framed in the PICO format (Patient – Intervention- Comparison- Outcome), as this will help focus the evidence retrieval process and the guideline panel process. The questions must be sufficiently focused that they can be answered with a yes or no vote. When all questions have been defined in the PICO format, the guideline group may want to re-prioritize the list of key questions, considering the resources available and workload required. Some questions may be left for future updates on the guidelines and can stimulate further research in the area by other groups.

2.4 Identifying the appropriate evidence

The first step is to locate other guidelines on the same topic. Ideally, these other guidelines will have used GRADE approach. Even if the guideline did not use the GRADE approach, it might reduce the burden of screening. Additionally, it might help to re-think the priorities if some questions are adequately addressed in another guideline. If a GRADE guideline is available, the guideline panel can use the GRADE evidence tables available that summarize the benefits and risks of the evidence used to support the recommendation. These evidence tables can be reviewed to see if they adequately address the clinical question of interest and whether they are deemed as rigorous, complete and up to date. If so, the guideline group should then review the recommendation of the other guideline, considering any contextual differences that may exist. This includes differences in patients' preferences, cost/resource considerations, and feasibility of implementation that may differ between the Canadian context and the parent guideline. GRADE provides guidance on this process, which they refer to as 'adolopment'.[3]

If there are no available GRADE guidelines, or the GRADE evidence tables available do not match the clinical questions, then the guideline group will need to develop their own evidence tables. It is recommended to first look for available systematic reviews that address the clinical question. From these, GRADE evidence tables can be developed. If no adequate systematic reviews are available, then guideline groups will need to conduct their own systematic review of the appropriate literature. **Throughout this process, it is highly recommended to involve someone with experience using the GRADE process**.

2.5 Evidence appraisal

Once the evidence is identified, it is important to appraise the quality of evidence and the adequacy of the evidence to address the clinical question. The AGREE-II instrument can be used to assess the quality of an existing clinical practice guideline, although this tool is not designed to assess whether the guideline followed the GRADE process.[4 5]

GRADE evidence tables should be checked to ensure that process was done in a consistent way with current GRADE recommendations. GRADE provides explicit criteria for rating the quality of evidence that include study limitations, imprecision, inconsistency, indirectness, and publication bias.[6] GRADE provides a structure to summarize the evidence in succinct, transparent, and informative evidence tables that provide detailed information about the reason for the quality of evidence rating.

When generating the evidence tables, it is essential to consider both benefits and harms. These tables should be accompanied by documentation on the presence/absence of GRADE criteria to upgrade or downgrade the evidence, as well as the values, preferences and context elements that inform the question(s) and help understand the balance of benefits, harms and implementation. GRADE provides a free tool (http://gradepro.org/) to develop the evidence tables under these principles.

2.6 Developing treatment recommendations

Once the evidence tables that will support each question have been developed, the treatment recommendations can be developed. Again, the GRADE process is recommended, and the evidence tables should be the basis for the recommendations. When writing the recommendations, it helps to adhere to standard wording to improve consistency. It is important to clearly state the strength of the recommendation for each statement, as well as special considerations for the implementation of each recommendation. It is also important to set out the recommendations clearly within the guidelines.

2.7 Dissemination

It is key to identify who is the target audience for each recommendation, and to design a plan to reach each of the audiences. This helps to facilitate materials for the dissemination of the guidelines for different stakeholders, targeting the message as required. To improve the uptake, one should identify champions for each target audience to disseminate the results. The CRA can assist with dissemination. Open access publications can be posted directly to the CRA website. Alternatively, a link to the published guideline can be posted. It may be useful to have a set of short slides / statements prepared that can be used by others for dissemination purposes. Finally, the support and assistance from the Guidelines Committee of the CRA should be acknowledged in the published guideline, as appropriate. Publications and statements endorsed by the CRA should have recognized potential COIs listed.

2.8 Knowledge Translation

Key to the dissemination of all guidelines is knowledge translation (KT), and all guideline panels should consider developing appropriate KT to accompany the guideline. KT may take the form of an infographic or a Patient Decision Aid. The CRA is able to provide funding to assist with the development of KT (for graphic designers etc). All funding requests should follow the same steps as outline in Section 1.5.

As part of the guideline publication process, all panel leads (or others, as applicable) will be required to host a 1 hour long accredited zoom webinar on the new guideline, and participate in a 1 hour long *Around the Rheum* podcast session. This only applies to new guidelines, and not to updates of living guidelines.

2.9 Updating

There is no strict time-frame for deciding when to update a guideline. A simple rule of thumb is to review every two to three years; however, guidelines may need to be reviewed sooner if new evidence arises. It may not also be necessary to update every recommendation within a guideline. In order to decide whether a guideline should be updated or not we should consider:

- Any new evidence that might change the recommendations
- Other guidelines with conflicting information
- New agents/interventions that were not considered in previous reviews
- Whether the guideline incorporates new approaches to interpret the recommendations (e.g., patient values and preferences)

- For CRA Board approval of new recommendations to be added to living guidelines, the Board should be sent the shortened version of the new recommendations (just the recommendations and the key remarks), as well as a preamble indicating that "If approved, the update will be added to the living guideline on MagicApp, and will also be published as a Letter to the Editor in the Journal of Rheumatology." The Board does not need to approve the text for the Letter to the Editor.

About this document

This draft document was co-written by the chair of the Guidelines Committee (Glen Hazlewood), Jordi Pardo and Peter Tugwell. It was reviewed, edited and approved by all members of the Guidelines Committee. The CRA thanks Holger Schunemann for his assistance and advice in developing the document. The document may be revised by the Guidelines Committee on an ongoing basis.

APPENDIX A – Proposal for a clinical guidance document

Name of project lead:

Type of clinical guidance document proposed (see CRA handbook):

Brief description of project (max 250 words):

Methods proposed (may be point form):

List of authors and conflicts of interest: (Note: As per the CRA Guidelines COI policy, at the start of their involvement, guideline panel members should submit a Conflict of Interest form from the International Committee of Medical Journal Editors (ICJME) to their Guideline Lead, to be reviewed and then forwarded to the Guidelines Committee Chair. The form is available at http://www.icmje.org/conflicts-of-interest/.

Funding for project (secured/applied for/planned applications):

Has funding been secured outside of the CRA?

When were the last guidelines updated?

Are there recent systematic reviews of the literature that can be used (please list)?

Support requested from CRA:

Note: This process is for determining priorities for financial support exclusively, endorsement of

guidelines will go through usual process of review by the Guidelines Committee.

REFERENCES

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