

American College of Rheumatology Guidance Subcommittee and Endorsement of Guidance Documents

Background

In early 2020, the American College of Rheumatology (ACR) identified the need for a new subcommittee to review and evaluate projects seeking ACR endorsement or collaboration that do not fit into existing ACR publication pathways.

The ACR currently develops and approves several types of guidance documents, including clinical practice guidelines, position papers and white papers. **Guidelines** are overseen by the Quality of Care Committee (QOC) and are developed using rigorous methods and established processes, including a systematic literature review, GRADE methodology, conflict of interest (COI) vetting and thresholds, and a formal peer review process before journal publication. **Position papers** are usually overseen by the Committee on Rheumatologic Care (CORC), are more consensus-driven with some references to published data, and are used mainly in advocacy activities (e.g., payors, government). **White papers** generally convey the current state of a particular topic, with few or no actionable recommendations; these are sometimes done in the years before a guideline is developed, but white papers are not in the sole purview of the QOC.

In 2019, the ACR received increased numbers of requests for involvement in projects that would result in future products that don't fit into any of the currently available ACR document types. There was a need for another type of ACR mechanism and guidance document that could be developed when the ACR wanted to be nimbler than a 2-year guideline development process would allow, and/or when the full rigor of a guideline was not needed, in areas where clinical guidance was desired by the community but was not yet available. For example, a guideline group may be unwilling to make a recommendation because a topic is too narrow or does not have high enough priority for ACR guideline work, in the context of other priorities, or if a topic requires more multispecialty input than exists in the guideline group.

Given these discussions, in February 2020 the ACR Board of Directors approved a new QOC subcommittee to oversee the development of these alternate guidance documents.

The Guidance Subcommittee

The Guidance Subcommittee includes representation from the practice community, the ACR journal(s) and other appropriate stakeholders, including Association of Rheumatology Professionals (ARP) members, as warranted by topics or papers under consideration. The subcommittee is charged with vetting guidance-related topics and proposals that are brought to the ACR. The subcommittee is also charged with generating unique ideas for ACR guidance projects / publications that may not cleanly fit into another ACR publication pathway and proposing them via QOC to the ACR Board for concept and budget approval.

Responsibilities of oversight include review of submitted proposals or internal ideas for importance, methodology, and budget (where appropriate), as well as review of drafted guidance documents for

ACR endorsement and dissemination. The subcommittee decides on a case-by-case basis, from the inception of each topic/proposal that it proposes, approves, or oversees:

- if a certain topic/product should be set up from the start for possible future ACR endorsement, or if it should intentionally be more of a facilitated debate between experts, in which case it may not bear the ACR name;
- if other organizations or ACR committees should be involved, how (e.g., formally, at organization/committee and/or individual level, or informally), and implications for project management, approvals, and publication;
- what COI rules/thresholds will apply, if any, and how they will be monitored;
- who would ideally lead the project, who might work with that person, and how and when these people will be confirmed;
- what the format and general length of the final publication should be, e.g., case-based or other format;
- where the final product will ideally be published (subject to journal and/or other approvals, as needed) and how else it will be disseminated; and
- a detailed project timeline and budget.

Project Team Composition

The proposed project process should describe iterative steps and list participants. Community input should be sought, which could include input from community providers, patients, relevant rheumatology professionals, and other specialists. Membership of the group that is assembled to develop the guidance document should be managed to include diverse opinions that include senior and junior personnel; it is important to include varied expert viewpoints that adequately represent the breadth of views in the field. Geographic, gender, racial and ethnic diversity enhances the value of the project and should be addressed. The Guidance Subcommittee may appoint a liaison to the project to provide methodologic guidance and ensure ACR requirements are met, to increase the likelihood of an eventual positive ACR review for endorsement.

Projects

Projects to be considered by the Guidance Subcommittee and considered for ACR endorsement should be timely and of high interest to ACR members and other stakeholders.

Endorsed Methodologies

Ideally, a guidance document should be developed using a balance of expert-based and data-driven methodologies. The methodology used for gathering and evaluating the summary of the evidence should be clearly explained in the document. Illustrative examples would include a systematic or scoping review, or something more focused. Depending on the data, meta-analysis may be presented. Alternatively, a qualitative review may be presented. For some diseases, case reports and observational data are all that may be available. In other cases, the quality of the literature may be variable. In this case, evaluation of the quality of the literature may be reported using standardized frameworks such as GRADE or the Center for Evidence Based Medicine (CEBM) framework.

Regardless of the method used to summarize the evidence, an explanation should be provided in the guidance document about the breadth and quality of available literature, and why it justifies the conclusions and recommendations made. The guidance should clearly distinguish which parts are based on evidence and which are based on expert opinion. Putting the recommendations into this context is important, as it may justify more reliance on expert opinion, or a patient preference-based approach when applying the recommendation at an individual level. Authors are encouraged to include in the guidance document an explanation about areas of evidence that were sought but not found (i.e., a research agenda for the topic).

The final document should include a clear description of how experts were selected and the consensus building process. Delphi methods; the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach; UCLA/RAND appropriateness methods; multicriteria decision analysis (e.g., using 1000 Minds software); and nominal group technique are examples of consensus methods. These examples are provided as illustration and not intended to be a complete list or required.

Conflict of Interest

All relationships, including but not limited to conflicts of interest, must be disclosed at the beginning and throughout the project process. A list of participant disclosures should be provided to all participants during the project, so relationships are transparent, and to the ACR when it is being asked to review a guidance document for possible endorsement. Unless an exception is granted, the group leader and, if applicable, the leader of any literature review that is done, must have no COI relevant to the topic of the project/guidance, and no more than 49% of the members of the project group may have relevant conflict of interest.

ACR Endorsement

ACR endorsement of a document is considered on a case by case basis. Criteria necessary for endorsement include favorable review by the Guidance Subcommittee, Committee on Quality of Care, and ACR Board of Directors, as well as successful peer and/or editorial review from an ACR publication (e.g., Arthritis & Rheumatology, Arthritis Care & Research, ACR Open Rheumatology, The Rheumatologist) or the ACR web page (rheumatology.org).

Once a product is drafted, the subcommittee considers whether it should be recommended to the QOC and ACR Board for ACR endorsement. The recommendations in the guidance document should be consistent with the values of the ACR. The ACR journals receive the right of first refusal for peer-reviewed publication, unless it is deemed that an alternative dissemination mechanism is a better option in a particular case (e.g., because the guidance is not well suited for a peer-reviewed journal format).

The ACR will consider shared naming with another professional or disease-specific organization, if appropriate. Any desire for this should be disclosed when the project is being proposed to or by the Guidance Subcommittee.

Example

Although it was initially developed by another ACR group as the ACR Guidance Subcommittee was being formed, a good example of the type of guidance document the ACR would favor endorsing is the <u>ACR</u>

<u>Guidance for the Management of Rheumatic Disease in Adult Patients During the COVID-19 Pandemic</u> (<u>https://onlinelibrary.wiley.com/doi/10.1002/art.41301</u>), which models many of the principles described above.

Table 1. Guidance Project/Document Evaluation Checklist

Criteria	Check
Project is timely and of high interest to stakeholders	
Project includes some sort of evidence review and synthesis	
Project includes some sort of expert-based consensus methods	
Project outlines how disclosure was/will be done and conflicts of interest	
were/will be managed	
Recommendations are consistent with the values of the ACR	