European Respiratory Society clinical practice guidelines: methodological guidance

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Shareable abstract (@ERSpublications)
ERS has published official methodological guidance for clinical practice guidelines. ERS recommends this to ensure that state-of-the-art guidelines are developed. https://bit.ly/3xP5SSr

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As one of the leading respiratory organisations, the European Respiratory Society (ERS) brings together physicians, healthcare professionals, scientists and other experts working in respiratory medicine. One of their roles is to provide guidance on clinical practice by developing high-quality clinical practice guidelines (CPGs). This is achieved by establishing specific task forces through an annual call for applications (except for short documents, for which applications can be submitted at any time [1]), and a rigorous selection and peer review process. Once approved, task force members, supported by ERS methodologists, work together for 2 years to develop CPGs using rigorous methodology, which, on satisfactory completion, are then adopted by ERS as official documents.

CPGs are documents that contain recommendations for clinical practice, aiming to provide physicians, healthcare practitioners and patients with information and strategies for making decisions on important areas for specific clinical conditions [2]. Having in mind the indispensable role that they play in clinical practice and their potential impact on patients' health, it is of outmost importance that they contain evidence-based recommendations and are developed using state-of-the art methodology. Furthermore, task forces involved in guideline development should encompass all required areas of expertise by including clinical experts, allied healthcare professionals, early career investigators and patient representatives, and they should mirror the diversity of the society by being international, and age- and gender-balanced.

To facilitate this, ERS has developed the "ERS Handbook for Clinical Practice Guidelines", which is the society's methodological guidance for developing evidence-based CPGs. It specifies in detail the roles and duties of all task force members, as well as all the steps that need to be followed during the development of the guideline, including management of any potential conflicts of interest. In this editorial, we give an overview of this guidance, highlighting the main methodological steps described therein.

Methodology of ERS CPGs

ERS CPGs are based on systematic literature reviews, assessment of the quality of the evidence using Grading of Recommendations, Assessment, Development and Evaluations (GRADE) and a transparent process of decision making using the Evidence to Decision (EtD) frameworks. The methodology for developing ERS CPGs is divided into 12 methodological steps, which should be followed carefully by the task forces.

Defining the research questions

Defining the research questions represents one of the most important steps of CPG development. The questions should be clinically important and phrased clearly, using the Population, Intervention, Comparator and Outcomes (PICO) format, as required by GRADE [3]. PICO questions can be supplemented by narrative questions, which are not answered using the GRADE approach, but are based on systematic literature searches and EtDs, and can lead to recommendations [4].

Rating the importance of patient-relevant outcomes

As part of the GRADE process, panellists (task force members with voting rights) should decide on the importance of patient-relevant outcomes for each PICO question. There are three levels of importance: "critical", "important but not critical" and "of limited importance" [3], and only outcomes rated as critical or important will be considered in the CPG for clinical decision making.

Defining the inclusion criteria

For each research question, inclusion and exclusion criteria for the studies to be included should be defined in detail. This will help the information specialist design the search strategies, determine which studies to include in the review, and keep the process transparent and consistent for any possible replication of results or CPG update in the future.

Literature search

The literature search is a systematic and organised search for published and unpublished studies in electronic databases, which should be well documented and updated yearly. ERS requires, as a minimum, that MEDLINE should be systematically searched, with additional databases to be decided depending on the topic.

Screening and selection of studies

Screening and selection is a two-phase process (title/abstract and full-text screening) for selection of relevant studies [5] with clear documentation of the procedure using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram for increased transparency and consistency [6]. This can be performed with online screening tools. The two main bodies of evidence (BoE) to be considered in the CPG are randomised clinical trials (RCTs) and nonrandomised studies of intervention [5]. Depending on the topic and type of questions, one would be considered as the main BoE for making recommendations (preferably RCTs) while the other will have a supplementary role. Real-life evidence could also be considered as supplementary evidence [7].

Extracting the data from the primary studies

Data should be extracted in systematic way, using piloted data sheets, in order to avoid loss of information, and make sure that the studies are comparable and that results are presented consistently throughout the document.

Risk of bias assessment

An assessment of the risk of bias should be performed for included studies belonging to the main BoE. For different types of studies, different tools can be used to assess the risk of bias; for example, the Cochrane Risk-of-Bias Tool for Randomized Trials or its revised version [8, 9], the Newcastle–Ottawa Scale [10], ROBINS-I [11], QUADAS-2 [12], or the QUIPS tool [13].

Data analysis/synthesis

Data synthesis is the process of analysing the data from all included studies in order to reach valid conclusions and make clinical practice recommendations. This can be performed using the quantitative approach (with meta-analyses, if appropriate) or with the narrative/descriptive approach (without meta-analyses). When interpreting results from primary studies or from conducted meta-analyses, task forces should take into account not only the point estimates or p-values but all aspects of the results, including effect measures and their confidence intervals, statistical significance, clinical significance, and the quality of evidence.

Rating the quality of evidence

ERS mandates using the GRADE approach for rating the evidence in order to determine the extent to which our confidence in an estimate of the effect is adequate to support a particular recommendation [14]. The quality of evidence for the main BoE is rated for each outcome, followed by rating of the overall quality of evidence across all outcomes (*e.g.* ranked as very low, low, moderate or high). This should be stated for each recommendation made.

Making recommendations using GRADE EtD frameworks

The purpose of EtD is to structure the discussion and the decision making process in order for task forces to consider important aspects and contexts of the interventions, and to provide a summary of the evidence and the rationale of recommendations to the readers [15, 16]. One EtD should be compiled for each research question (PICO or narrative). Task forces can make recommendations for or against an intervention, or in some cases, a recommendation will not be possible. The decision for or against a certain intervention should take into consideration the balance between desirable and undesirable outcomes, quality of evidence, values, balance of effects, resources required, impact on health equity, acceptability, and feasibility. Recommendations must be actionable, stated concisely using an active voice, and should contain the population, the intervention, the recommendation strength and the quality of evidence [14].

Writing the manuscript

The main document of an ERS CPG should not contain more than 8000 words (excluding tables, figures and references) but supplementary material can be added without any word limit [17]. The manuscript should contain a brief introduction focusing on positioning the questions addressed in the context of clinical care, and a methods section containing all relevant information such as the scope and purpose, panel information, conflict of interest management, literature searches, main inclusion criteria, data analyses, *etc*. The results should be presented for each question separately using a pre-defined format, which can be found in the handbook. The discussion should be kept short, and used for presenting a summary of results, similarities and differences with other CPGs, and strengths and limitations of the CPG.

Manuscript finalisation and submission

After the manuscript has been drafted, it needs to be reviewed in detail by the appointed ERS in-house methodologist (from a methodological point of view) and by all co-authors (from a clinical point of view). After finalisation, the manuscript should be sent to ERS for an overall preliminary check. Only then it can be submitted for publication to the *European Respiratory Journal* (*ERJ*), which is the first journal to be considered. The manuscript will undergo an external peer-review process and the (possible) publication is an editorial decision of the *ERJ*. Once approved for publication, the ERS staff submits the final version to the ERS Executive Committee for endorsement, which is required in order for the CPG to be published as an official ERS document. The manuscript and all deliberations of the task force must remain confidential until acceptance for publication.

Conclusions

ERS Handbook for Clinical Practice Guidelines is the society's official methodological guidance for developing CPGs. It integrates ERS values for diversity in task force composition, and determines roles and duties of each task force member. It empowers patients by making sure their voice is actively heard in every step of the process. ERS recommends this handbook to all its members when drawing up proposals for new ERS CPGs and throughout the entire CPG development process, to ensure that state-of-the-art documents are developed.

ERS Handbook for Clinical Practice Guidelines is freely available at www.ersnet.org/science-and-research/development-programme/ers-clinical-practice-guidelines-statements-and-technical-standards/.

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