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# Clinical practice guidelines: ensuring quality through international collaboration

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Over the last 2 decades, the development of clinical practice guidelines (CPGs) has seen a significant stepwise increase, reflecting their growing importance within global healthcare systems. In 2023 alone, more than 1700 articles with 'guideline' in the title were listed on PubMed, compared to 188 in 2000. These guidelines have become essential tools in healthcare systems for enhancing patient management across various health conditions [1–3]. They are appreciated by healthcare professionals, government bodies and policy-makers not only as vital tools for delivering effective and efficient care but also as increasingly valuable in their ability to translate the rapid influx of research findings into practical clinical applications. This capability is crucial, given the astonishing pace at which medical knowledge has expanded: the doubling time of medical knowledge was estimated to be 50 years in 1950, reduced to 7 years by 1980, to 3.5 years by 2010, and is projected to be a mere 73 days by 2020 [4], and with artificial intelligence, a matter of days. However, to ensure these guidelines are both clinically applicable and effective, they must meet rigorous quality standards, making them reproducible as in any other research. Users must trust that any potential biases in the development of these guidelines are carefully addressed, guaranteeing that the recommendations are both valid in theory and practice and realistically implementable in different environments [5, 6].

Nonetheless, numerous studies have indicated that the methodological quality of many guidelines varies and often does not meet expected standards [7, 8]. While clinical guidelines hold the potential to address critical issues in patient care, significant challenges must be overcome to improve their quality and trustworthiness to maximize their effectiveness.

## CHALLENGES IN CLINICAL PRACTICE GUIDELINES

### Inconsistencies and quality concerns

Healthcare professionals more frequently find themselves overwhelmed with numerous guidelines on the same subject, offering conflicting recommendations [9–11]. Unfortunately, many of these guidelines are developed without employing rigorous methodologies, often fail to utilize the best available evidence and lack transparency in their development processes. Additionally, some may represent the interests of specific parties, including the healthcare industry. This issue is particularly evident in recommendations developed based on clinical trials at high risk of bias, where biases cannot be adequately addressed by standard 'Risk of Bias' tools [12]. Such trials often involve funding and authorship from sponsors who also provide data analysis, leading to conclusions favouring these sponsors [13].

Furthermore, a study analysing a random sample revealed that most CPGs archived in the AHRQ National Guideline Clearinghouse fail to meet basic academic standards, resulting in multiple FDA alerts over the years following their publication [14]. The consistent issues with these guidelines highlight the need for development by reputable national and international organizations using well-recognized, transparent methodologies that detail every process step and incorporate multiple checks. This approach could improve the trustworthiness and credibility of the guidelines.

### Dealing with gaps in evidence

Despite thorough research and analysis, only a minimal portion of the recommendations in many widely used guidelines is

supported by clear and applicable evidence, classified under the highest level of evidence (LoE) A [15, 16]. The formulation of recommendations often depends more on expert opinions (LoE), preferences of physicians and societal values than on robust research findings [17]. Where evidence is lacking, there is a critical need for reliable methods to integrate these diverse inputs into guideline development. However, many existing methodologies for creating guidelines do not include such mechanisms [18].

## Translating evidence into practice

Translating evidence into practical recommendations remains a formidable challenge. Guidelines are expected to serve a diverse patient population and adapt to complex healthcare processes not considered in the original studies. For example, clinical trials comparing conservative, percutaneous and surgical procedures often focus on specific selection criteria within a select group of patients [19–21]. In contrast, actual care typically involves intricate, multidisciplinary processes across varied patient demographics and risk profiles [22–24]. Research on the optimal management of these comprehensive care pathways and decision-making processes across different healthcare providers is scarce. This challenge is compounded by the lack of nationwide registry studies, which should be published regularly, typically yearly, to ensure the safety and effectiveness of newly introduced treatment modalities. Moreover, guidelines often struggle to capture all the necessary clinical details for individual patient care, frequently missing these critical nuances. Most policies do not adequately address these complexities, which leads to challenges in applying them effectively in real-world settings.

## Interpretation of evidence

The development of guidelines is inherently human-driven and susceptible to errors and subjective interpretations. The composition of the Writing Committee and geographical backgrounds significantly influence how evidence is understood and applied. For instance, guideline developers from diverse geographic or professional backgrounds often interpret the same evidence differently [8]. A notable example is the management of the most common valvular disorder in developed countries: severe secondary mitral regurgitation [25]. The European Society of Cardiology (ESC)/European Association for Cardio-Thoracic Surgery (EACTS) guidelines recommend transcatheter edge-to-edge repair for patients deemed inappropriate for surgery by the multidisciplinary team [26]. In contrast, the ACC/AHA guidelines recommend transcatheter edge-to-edge repair for patients with appropriate anatomy, irrespective of surgical risk [27], based on the same 2 clinical trials that yield conflicting results [28, 29]. These differences suggest that even evidence-based guidelines can reflect underlying cultural beliefs, impacting their acceptance and application.

## Challenges of implementation

The feasibility of implementing guidelines, which includes considering clinician and patient acceptance as well as the necessary resources, staff, skills and equipment, is frequently overlooked during their development. For instance, a study assessing patient-reported statin use in almost 5700 patients with indications for lipid-lowering therapy revealed that 60% of the participants did not follow the evidence-based recommendation, primarily due to fear of side effects and lack of informed decisions [30]. Another example involves the implementation of transcatheter aortic valve implantation procedures, which resulted in a significant increase in the total number of aortic valve procedures due to the possibility of treating a much broader patient population [31], raising concerns about resource allocation and the inequitable adoption inversely correlated with the gross national income of a country [32, 33]. These instances underscore that the financial implications of medical innovations are often overlooked during guideline formulation despite playing a significant role in their implementation.

Finally, it has been presumed that well-structured, evidence-based recommendations naturally lead to improved clinical practice and patient outcomes. However, while some efforts may significantly improve care processes [34], the aspiration to develop guidelines that are even geographically applicable often falls short [35]. This discrepancy arises because the challenges of effectively applying guidelines in diverse healthcare settings, along with the lack of targeted implementation strategies, are seldom addressed during the guideline development process [36, 37]. Thus, although guidelines are designed to enhance patient care, these implementation gaps limit their real-world impact.

# THE PECTUS CARE GUIDELINES

In this journal issue, Dunning *et al.* [38] published guidelines for the treatment of patients with pectus abnormalities. They aimed to create this document using a significantly modified version of the EACTS methodology manual for clinical guidelines, which their leading author also co-authored. Additionally, they attempted to incorporate the 2018 ESC methodological standards for grading the strength of recommendations and assessing the levels of evidence, which closelely aligns with the EACTS standards framework.

After establishing a writing group composed of members from the Society for Cardiothoracic Surgery in Great Britain and Ireland, the Marfan Trust, the Chest Wall International Group, the British Orthopaedic Association and the British Association of Paediatric Surgeons, the authors outlined a clear project scope. They conducted a systematic literature search based on specific search terms and employed the Delphi process. Consensus thresholds of 80% or more were reached for all recommendations except for the single issue of the number of cases required to determine the competence of a surgeon, for which a simple majority was accepted. Non-published guidelines were discussed at an open forum at the Royal College of Surgeons of England to gain additional input from healthcare professionals before submission to European Journal of Cardio-Thoracic Surgery.

The authors provide a broad review of pectus excavatum, from the investigation, physiological symptoms to surgical management, including perioperative analgesia and follow-up. This includes a summary of findings tables with the most essential evidence for each topic. They provided a total of 38 recommendations in specific recommendation boxes: 15 strong recommendations (13 Class I and 2 Class III), 20 moderate recommendations (Class IIa) and 3 weak conditional-only recommendations (Class IIb). None of these recommendations hold an LoE A; 22 are classified as LoE B, and 16 as LoE C, expert-based

recommendations. Finally, the authors identified gaps in knowledge and provided guidance for future research.

Like many CPGs, several weaknesses in the development process and general project limitations merit consideration. Although the authors opted to follow EACTS and ESC methodological standards for guidelines development, the process had several significant differences. First, the EACTS guidelines strongly advocate for including a multidisciplinary group, including methodologists and biostatisticians, to ensure methodological rigour, especially when interpreting evidence and formulating recommendations. Moreover, EACTS methodology strongly recommends geographical and gender diversity to ensure different perspectives and widespread geographical distribution of recommendations and avoid providing local perspectives. This is especially critical in projects that lack robust evidence. Second, a basic standard for initiating a systematic review includes the clinical questions the writing committee develops before formulating recommendations to avoid any information bias. To ensure comprehensive evidence appraisal, this should be done using the patient, intervention, comparison, outcome and time (PICOT) framework and specifically developing search strings for multiple databases (PubMed, Embase, Cochrane) rather than seldom defined search terms. Third, although the authors have provided an evidence appraisal table, they have no provided robust assessment using any risk of bias tool. Fourth, individuals being considered for the writing committee should comprehensively declare interests and activities that may result in conflicts of interest (COIs) or the appearance of COI with development group activities through written disclosure before selection. This was not the case here, as no information on how COI was handled is available. Fifth, writing, voting and presenting the recommendations are crucial steps in the development of a clinical guideline. Since many readers focus solely on the recommendations, it is essential that the wording is clear, precise and easily applicable in clinical settings. Each recommendation, or individual bullet point, should articulate a single primary action and must be fully interpretable without referring to the text. In this case, although the authors generally declared that they followed ESC standards for their formulation, this was not consistently applied; the suggested wording depicting different classes of recommendation must be strictly used without exception. Every recommendation with designated LoE B or A must be supported with references directly inside the recommendation table and critically appraised in the main text to justify the proposed recommendation further. Visual signalling, a 'semaphore-like' system described in ESC and EACTS Methodologies but unfortunately lacking here, successfully guides attention of readers to relevant information, primarily using red and green to indicate actions to take or avoid. Sixth, the Writing Committee should avoid finalizing recommendations if there is considerable disagreement among experts or if the recommendations repeatedly fail to gain approval from at least 75% of the committee members despite multiple efforts. Such circumstances increase the risk of issuing unreliable guidance, as may be the case with the recommendation on a number of cases required to determine the competence of a surgeon. Seventh, the review process must be rigorous, involving multiple levels of scrutiny. This includes the involvement of committee members, at least 10 anonymous reviewers, including methodological experts, journal editors, and a final review and approval by the governing bodies before it is officially released for publication. Unfortunately, this was not the case in this process, as the review was conducted in a manner similar to that of any other article type.

Finally, and most importantly, the critical aspects of guidelines should be grounded in findings from rigorous, well-conducted randomized controlled trials and extensive patient registries to ensure a robust evidence foundation. Based on these issues, this document does not qualify as a CPG according to EACTS methodology. When there is insufficient evidence, particularly in the absence of any clinical trials as in the present document, EACTS develops Expert Consensus Documents, not Guidelines. These Expert Consensus Documents provide clinical suggestions through statements not supported by a designated LoE or class of recommendation and are explicitly identified as such rather than as recommendations. This distinction is essential due to the implications recommendations may have in patient care and healthcare policy-making, quality assurance, reimbursement and medicolegal aspects [39, 40].

Nevertheless, the authors are to be congratulated on their impressive work and dedication to sharing their extensive expertise in improving patient care. Although there are several shortcomings with the applied methodology, they made an excellent effort to address a clinically relevant question, offer advice for daily practice and acknowledge gaps in knowledge to stimulate research activities in the field.

## ADVANCING GUIDELINES DEVELOPMENT: THE POWER OF INTERNATIONAL COLLABORATION

The effectiveness of CPGs fundamentally relies on strict adherence to established quality criteria that emphasize minimizing biases and maximizing transparency. Recognizing persistent challenges such as transparency issues, the scarcity of multidisciplinary input and inherent biases [41], many organizations have formed strong international collaborations to advance guideline development standards. A prime example is the recent collaboration between the EACTS, the American Association for Thoracic Surgery (AATS), the Society of Thoracic Surgeons (STS) and the European Society of Thoracic Surgeons (ESTS). This initiative aligns with the Institute of Medicine essential principles [42], implementing a structured methodology through 3 interconnected phases: initiation, writing and validation.

Each phase plays a pivotal role:

- The initiation phase sets clear objectives and scope, assembling a global Writing Committee of experts without relevant COIs to ensure scientific integrity.
- The writing phase involves meticulously gathering and synthesizing the best available evidence into draft recommendations.
- The validation phase subjects the guidelines to a rigorous, multi-step peer review process to confirm their accuracy, relevance and broad consensus before finalization.

This collaborative approach to guideline development sets a new standard for advancing patient care, highlighting the profound impact of coordinated international efforts on global health standards through harmonizing methodologies and guidelines within the medical community. By leveraging the expertise of diverse international entities, a collaborative approach ensures that the resulting guidelines are comprehensive, grounded in the latest medical evidence and adaptable across various healthcare settings.

Guideline developers are encouraged to follow these collaborative principles. By pooling resources, expertise and perspectives from around the world through joint efforts, the medical community can overcome existing challenges and drive substantial progress in developing and implementing evidence-based medicine. Prioritizing international collaborations is essential, as they have immense potential to create guidelines that are methodologically robust, equitable and free of biases, thereby fostering trust and confidence among healthcare providers and patients alike.

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## DATA AVAILABILITY

The data will be shared on reasonable request to the corresponding author.

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Editorial