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Harmonizing guidelines and other clinical practice documents: A joint comprehensive methodology manual by the American Association for Thoracic Surgery (AATS), European Association for Cardio-Thoracic Surgery (EACTS), European Society of Thoracic Surgeons (ESTS), and Society of Thoracic Surgeons (STS)

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Central Message

A comprehensive pathway for creating multidisciplinary CPGs: encompassing research formulation and synthesis, development of evidence-based recommendations, rigorous validation, publication, and continuous updates to maintain relevance, accuracy, and trustworthiness.

Perspective

Governing bodies of the AATS, EACTS, ESTS, and STS chose a writing panel based on expertise in the development of clinical practice documents to establish uniform methodology for joint societies' projects. This document integrates existing independent methodologies into a singular collaborative methodology, further enriched by adopting the basic standards for development proposed by key stakeholders.

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ABBREVIATIONS AND ACRONYMS

AATS	American Association for Thoracic Surgery
COI	conflict of interest
CPG	clinical practice guideline
EACTS	European Association for Cardio-Thoracic Surgery
ESTS	European Society of Thoracic Surgeons
IOM	Institute of Medicine
PICOT	Population, Intervention, Comparison, Outcome, and Time framework
RCT	randomized controlled trial
STS	Society of Thoracic Surgeons

Clinical practice guidelines (CPGs) are essential documents offering practical recommendations developed to enhance patient care and inform health care. Properly formulated through meticulous assessment of scientific evidence and medical expertise by multidisciplinary teams, CPGs strive to ensure an optimal balance between care benefits and potential risks. Because of the dynamic nature of medicine, health care professionals often balance delicate decisions with significant uncertainties. These professionals rely on scientific literature, personal skills and experience, patient preferences, and guidelines from different organizations. Yet, these sources can suggest different paths derived from the same evidence, as is the case in contemporary guidelines on the management of valvular heart disease. [1]

No universally accepted standards for developing CPGs exist, even though multiple methodologies exist for evaluating and translating research evidence into treatment recommendations. [2–5] The Institute of Medicine (IOM) provides an authoritative and comprehensive guide for CPG development, introducing several pivotal characteristics regarded as essential for producing reliable documents: (1) transparency, (2) diversity in the writing group composition, (3) conflict of interest (COI) management, (4) thorough systematic literature reviews, (5) synthesis of evidence and evidence strength ratings, (6) clear communication in recommendation and supporting text, (7) external validation, and (8) regular updates. Although these criteria may seem straightforward, aligning with them can be challenging. [6] Many organizations have hesitated to embrace the IOM's criteria entirely, emphasizing the increase in expenses and publication delays without substantial added value. [7]

In response to the critical demand for a standardized medical language with the exponential growth of medical knowledge and technology, leading organizations have taken significant steps with specific initiatives to enhance awareness among health care professionals and patients about the vital role of evidence-based practices in improving outcomes. These organizations include the American Association for Thoracic Surgery (AATS), the European Association for Cardio-Thoracic Surgery (EACTS), the European Society of Thoracic Surgeons (ESTS), and the Society of Thoracic Surgeons (STS). The organizations have achieved this awareness by developing, distributing, and extensively discussing clinical guidelines and other pertinent materials that serve to direct clinical decision-making and practices.

A significant portion of guideline recommendations might extend beyond strictly empirical scientific arguments, as indicated by the minimal proportion of recommendations grounded in the most robust level of evidence. [8] In addition, the rapid proliferation of medical knowledge, anticipated to double at least every 73 days, [9] underscores the essential need for reliable practice guidelines in medicine. Moreover, in the light of disparate reported outcomes emerging from recent industry-sponsored versus investigator-initiated studies [10, 11] and growing demands for increased transparency and standardization, [12–14] these 4 cardiothoracic surgery associations are actively working to re-establish trust in CPGs within the medical community. Their objective is to produce guidelines and other practice documents with utmost clarity and rigor, ensuring that physicians, patients, and pertinent stakeholders can access and depend on this information. By adopting this methodology in future endeavors, this medical community aims to foster an environment in which decisions are evidence-based, transparent, unbiased, and focused on the safety and effectiveness of patient care.

Development Methods Used for the Creation of the Present Documents

The governing bodies of the AATS, EACTS, ESTS, and STS chose a writing panel on the basis of their expertise in the development of clinical practice documents to establish a uniform methodology for joint societies' projects. This document integrates existing independent methodologies into a singular collaborative methodology, [15, 16] further enriched by adopting the basic standards for development proposed by the key stakeholders [2, 5] (Table 1). The writing panel collaborated to draft all document sections that were reviewed and discussed during several committee meetings. Consensus was achieved in every phase throughout the development process. In the tables detailing relationships with industry, anonymous voting was applied, and the panel set a 75% approval threshold for finalizing decisions.

This document does not address the cost-effectiveness or cost-benefit of specific patient care recommendations as the result of 2 factors: the substantial variability in economic parameters and the absence of standardized cost-effectiveness and cost-benefit data in Europe and globally. Instead, it concentrates on the processes guiding the development of best practice recommendations to provide the best patient care, which aligns with physicians' primary roles in taking care of patients.

The document received unanimous approval from the writing committee members before its submission for external review. It was then presented to 8 expert reviewers appointed by the involved associations. Once declared suitable for publication, it was sent for final review and approval to the 4 societies' governing bodies. After final approval, it was concurrently published in the *Journal of Thoracic and Cardiovascular Surgery*, the *European Journal of Cardio-Thoracic Surgery*, and the *Annals of Thoracic Surgery*.

Types of Clinical Practice Documents

The writing panel proposes the creation of an array of specialized documents, each designed to meet particular surgical needs within the cardiothoracic community. All clinical practice documents, regardless of their type, must adhere to the fundamental principles of developing clinical practice guidelines. These stages

Table 1 The fundamental principle proposed for the development of joint clinical practice documents

Organizations	Writing committee composition	Standards for initiating a systematic review	Evidence review committee	Evidence appraisal system	Conflict of interest (COI)	Recommendations	Economic consideration
AATS, EACTS, ESTS, and STS	A multidisciplinary team of 10-20 balanced members, including clinicians, various methodologic experts (such as statisticians, epidemiologists, and/or public health specialists), and, if needed, representatives from populations expected to benefit from the guideline.	The patient, intervention, comparison, outcome, and time (PICOT) framework	Experts in clinical content, an expert in systematic review, and an expert in searching for relevant evidence	The Risk Of Bias 2 (ROB2) tool for randomized trials, the Risk of Bias due to Missing Evidence (ROB-ME) in a meta-analysis, and the Risk Of Bias In Non-randomized Studies - of Interventions (ROBINS-I) frameworks	Individuals being considered for the writing committee should comprehensively declare interests and activities that may result in COI or the appearance of COI with development group activities through written disclosure before selection. The Chair or Co-Chairs should not have any relevant COI, and other members should either have no relevant COIs or those deemed manageable only.	Members with potential COI are excluded from related votes. A 75% provisional agreement of present members is required to advance a recommendation. The Delphi Method requires an 80% response rate and at least 75% agreement for approval of an individual recommendation. Voting continues based on anonymous feedback until a consensus is reached.	No economic evaluation for treatment interventions; recommendations for best practice care should be provided.

AATS, American Association for Thoracic Surgery; *EACTS*, European Association for Cardio-Thoracic Surgery; *ESTS*, European Society of Thoracic Surgeons; *STS*, Society of Thoracic Surgeons.

include (1) systematic literature review, (2) careful synthesis of evidence, and (3) strict compliance with prescribed process and transparency. The documents are methodically categorized into 3 primary categories, each representing unique characteristics as detailed in Table 2, with slight variations possible depending on the project's scope.

Clinical Practice Guidelines

CPGs are documents that comprehensively address a broad topic of interest. IOM defines these guidelines as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." [2] The guidelines must offer structured recommendations that are clearly articulated, with the primary aim of improving patient care. Such recommendations should be derived on the basis of a thorough evaluation of current evidence, with accumulated clinical experience serving to complement and contextualize the evidence, balancing various treatment options' potential benefits and risks. The formulation of clinical guidelines requires a joint effort from a specialized, multidisciplinary writing committee of experts.

This committee is characterized by its diversity in caregiving perspectives and its members' specialization in various medical fields. Under the leadership of clinical content experts, the committee includes evidence review experts, comprising clinical methodologists and biostatisticians with proficient knowledge in the development of clinical practice documents. In addition, the writing committee may include research fellows/early-career academic physicians, and support from a medical informatics expert. Each member contributes to a more rigorous and thorough evidence-appraisal process, ensuring that the guidelines are well-rounded, catering to a wide range of patient needs, and incorporating the latest advancements in medical science.

The key aspects of guidelines primarily depend on findings from rigorous, well-conducted, randomized controlled trials (RCTs) and large patient registries ensuring a robust evidence base. Whether the primary data come from randomized or observational studies, the writing committee must meticulously assess the quality of the evidence, focusing on relevance and methodologic rigor of each relevant study. However, RCTs may not always be feasible for various reasons, such as long-standing procedures where further research could present ethical issues, including the absence of equipoise between 2 treatment options.

Addressing these challenges, observational and case studies with the accumulated clinical experience play a crucial role in tackling prevalent clinical questions. These insights form the basis for low-level evidence-driven recommendations, followed by expert opinion, aiming to enhance patient outcomes. The writing committee harnesses its collective expertise to develop guidelines that mitigate nonevidence-based decision-making, thus elevating the standard of patient care. This consensus is especially critical in fields with scarce comparative data and widely varied treatment practices. The committee also highlights areas needing further research, thereby paving the way for continuous improvement in health care delivery and research efforts.

Before its official release, each guideline undergoes a thorough review process involving relevant experts, coordinated by the editorial offices of the affiliated societies and guideline committees. The guideline should be made available online for public commentary concurrently, enabling the writing committee to meticulously review and consider all feedback. This review phase concludes only after the authors have satisfactorily addressed feedback from anonymous reviewers and secured final approval from the lead reviewers and editors-in-chief. Once the governing bodies, including editors-in-chief of the target journals, offer

Table 2 Types of clinical practice documents

	Clinical practice guidelines	Expert consensus statements	Clinical statements/white papers
Definition	Evidence-based documents containing systematically developed recommendations with an explicit clinical scope and explicit consideration of benefits, harms, values, and preferences.	Expert position on a controversial or specific clinical topic, formulated as a statement of facts based on available evidence and expert consensus in situations where high-level evidence is unavailable.	Extensive reports outlining positions on critical clinical issues while highlighting areas of ongoing uncertainty or concern for patient safety.
Source of evidence	Randomized controlled trials (RCTs) are available and serve as the primary source of information; observational data are used if considered robust.	Robust observational data are available and serve as the primary source of information in conjunction with a limited number of RCTs.	Any research and health care regulations
Number of writing committee members	Up to 20	Up to 20	Up to 10
Review	Following the writing committee's established composition principles, a lead reviewer and up to 5 anonymous reviewers from each participating entity in collaboration with the governing bodies	Following the writing committee's established composition principles, a lead reviewer and up to 5 anonymous reviewers from each participating entity in collaboration with the governing bodies	Following the writing committee's established composition principles, up to 3 anonymous reviewers from each participating entity
Length	Up to 30,000 words and a total of 500 references	Up to 15,000 words and a total of 300 references	Up to 5000 words and a total of 50 references
Time frame	24 months	12 months	6 months

approval and endorsement, the guideline is officially finalized and prepared for publication.

Expert Consensus Statements

Expert consensus documents cover areas characterized by significant variations in practice patterns and where the absence of sufficiently rigorous comparative studies precludes the development of a more definitive guideline document. Instead of delivering firm recommendations, they provide clinical suggestions through statements not supported by a designated level of evidence or class of recommendation and are explicitly identified as such. The process starts with identifying the central clinical issues and associated questions. An expert writing committee conducts an extensive literature review and synthesizes the evidence. This committee is selected following the same principles as those used for the CPG committee, ensuring diversity and balance to represent a wide range of perspectives and expertise. These documents typically begin with the following:

- a comprehensive introduction that sets the context for the issue at hand;
- establishment of the rationale for addressing the specific area of practice variation;
- a critical appraisal of the evidence obtained; and
- expert statements while highlighting the respective knowledge gaps to encourage further research.

Before consideration for publication, the documents undergo a comprehensive review and approval process similar to the CPGs. The only notable exception is that, unlike guidelines, these documents are not mandated to be posted for public comment, streamlining their path to publication.

Clinical Statements/White Papers

A clinical statement or white paper is a comprehensive guide or report on specific medical, clinical, or health-related issues, carefully prepared by leading experts or authoritative figures within medical associations. It tackles subjects such as novel procedures and technologies, recent research, or newly proposed health policy documents in which conclusive findings may be limited, deemed inappropriate, and subject to interpretation. These papers aim to assess the existing literature thoroughly, highlight divergent opinions, and explore potential treatment implications, offering direction for further clinical practice and research. The main objective is to clarify societies' positions on critical clinical issues and emphasize areas of ongoing uncertainty or concern for patient safety.

Development Process for CPGs

The formulation of CPGs is a comprehensive process organized into 3 critical interconnected phases. The initiation or preparatory phase lays the foundation by establishing goals, delineating the scope, and selecting the writing committee to ensure the soundness of the document and preserve scientific integrity. The second, or writing phase, includes the meticulous gathering and synthesis of evidence, which is formulated into preliminary recommendations. The last phase, validation, involves thorough peer review, public comment when appropriate, and adjustments to ensure accuracy, relevance, and consensus before the guidelines are finalized and disseminated to the health care community. Each crucial phase builds on the previous one to develop authoritative and practical guidelines.

The collaboration of multiple societies is fundamental in developing better CPGs. Pooling knowledge and expertise from diverse fields ensures these collaborative efforts develop guidelines that are comprehensive, evidence-based, and reflective of the latest advancements in medical science. Such multidisciplinary collaboration promotes a well-rounded approach to patient care, enabling the creation of clinically sound guidelines that are also adaptable to various health care settings.

Initiation Phase

The initiation phase for clinical guidelines is the foundational step that involves selecting a relevant topic, establishing clear objectives, and assembling a dedicated writing committee of experts while managing practical considerations such as timelines, budgets, and COIs.

Topic selection. A successful CPG document begins with an explicit and well-defined purpose focused on the diagnosis, treatment, or follow-up of a disease or condition. The selected topic and associated clinical question(s) must be both timely and relevant to contemporary medical practice, typically addressing areas with significant variation in clinical approaches and associated outcomes and indicating a clear need for standardized guidance. Crucially, the development of such a document is warranted only when a substantial body of evidence exists to support its creation, thus ensuring that the guidance is scientifically valid and clinically applicable.

In this context, the working groups led by societal guideline committees carefully select topics, craft critical clinical questions, and propose them to the society's governing bodies for approval. Recognizing the constraints of finite resources and the duty of care to patients and clinicians to provide robust and defensible recommendations, the associations make strategic decisions, including provisional publication timelines. To enhance transparency and ensure that the voices and advice of all members are heard and considered, members from each association are encouraged to suggest topics and submit proposals for consideration in the guideline-development process. The guideline committee of the member's primary association conducted an initial evaluation of these proposals. On the basis of the proposal's merits, the guideline committee makes a decision about whether to proceed to the next steps. Proposals passing this initial vetting phase are forwarded with preliminary acceptance to the other associations' guideline committees for further appraisal. These committees collectively decide whether a proposal should be developed into a CPG, expert consensus document, or clinical statement while determining urgency and priority. They share conclusions with the proposer whether the project is declined, deferred due to insufficient priority or lack of immediate resources, recommended as a CPG, an expert consensus statement, or a white paper. If recommended, the project advances to the governing bodies of all associations for final ratification. The process is finalized with the agreement of all involved parties and the execution of a memorandum of understanding, which

outlines the practical responsibilities of each side involved in the project, including budget, timelines, and other process details.

Determining scope and objectives. Defining the scope and objectives is pivotal in developing CPGs. Although surgical management is a central theme, the guidelines often cover critical associated aspects of care, such as diagnosis and treatment selection through multidisciplinary decision-making, as well as the necessary postintervention care to ensure adherence to guideline-proposed therapies and clinical follow-up. The purpose of any guideline is to provide direct, evidence-supported guidance rather than an all-encompassing, textbook-style overview. To ensure comprehensiveness, focus, and practical application for clinicians, the guidelines should have a maximum of 30,000 words and 500 references and provide an executive summary, regardless of the subject matter, thus providing a concise and clinically relevant set of recommendations.

Selection of co-chairs and writing committee members. The next step in creating a CPG requires assembling a writing committee composed of published experts in the relevant clinical field and (depending on the type of document) professionals proficient in various aspects of guideline development, such as systematic reviews, research methodologies, statistics, epidemiology, and quality improvement initiatives. To ensure a comprehensive perspective, the committee's composition must reflect the membership of participating associations, encompassing a wide range of specialties, practice settings, and geographic, generational, and gender distributions. Its composition must represent the field and allow for true representation of alternative viewpoints. Mere nominal representation of key stakeholders that could enable an overrepresented majority to override competing views is not appropriate. In addition, involving patient representatives from relevant organizations is encouraged to enrich the dialogue and decision-making process.

The number of writing committee members should not exceed 20, including co-chairs, content experts, methodologists, and research fellows/early-career academic physicians, to ensure an efficient workflow. [2] All members are obligated to provide substantial input into document development, including the following:

- formulating clinical questions;
- synthesizing and evaluating evidence rigorously;
- drafting guideline sections, revising drafts;
- engaging actively in group discussions and document revisions; and
- participating in compulsory in-person meetings and voting, ensuring that all members contribute meaningfully to the process.

A signed agreement outlining roles and responsibilities of writing committee members will be completed before members are officially appointed.

Typically, each association involved in the guideline production process appoints its co-chair. In the complex guideline production process, co-chairs play a pivotal role, leading the committee's efforts and functioning as a dedicated facilitator available to the writing committee, project manager, and governing bodies of the involved associations. The co-chairs have several critical tasks:

1. They assist in the selection of writing committee members in conjunction with the guideline committees.
2. They prepare the initial table of contents according to the assigned scope of the project.
3. They delegate research and writing assignments.
4. They manage potential COIs.
5. They schedule and lead writing committee meetings and oversee the document's drafting.
6. They meticulously review and revise the document drafts before submitting the final version for external validation.

In addition, the co-chairs supervise the review process, liaise between reviewers and the writing committee, and coordinate the creation of executive summaries when needed. The co-chairs are responsible for defining the clinical guidelines' work plan, establishing a completion timeline, maintaining integrity of the review and voting process, and consistently updating the guideline committee on progress.

When selecting other writing committee members, it is critical to prioritize candidates recognized for their expertise, substantial contributions to the field, and proven substantive involvement in relevant research work. It is also important to manage, as much as possible, industry influence, COI, and research or specialty bias. The ideal members should be esteemed for their academic achievements, positive team dynamics, and productive work habits, which are essential for collaborative success. To uphold the integrity of the selection process, the associations shall implement an open call for applications, ensuring that all interested parties have an opportunity to participate. This call shall be widely disseminated through relevant channels to reach a diverse pool of potential candidates. Subsequently, applications should be evaluated carefully by the societies' selected committees in partnership with the co-chairs, who will oversee the assessment process per the previously established criteria. This process guarantees transparency and promotes diversity, reflecting a commitment to inclusive excellence. At the project's conclusion, the CPG committees will assess the committee members' work and engagement in the review and vetting of evidence to ensure that those who have maximally contributed to the project's development are recognized and given consideration given for participating in future endeavors. This evaluation will reinforce the merit-based selection of contributors and encourage ongoing dedication to the highest standards of collaborative academic work.

The structured approach ensures that the CPGs are developed by experts and carefully managed to produce a clinically relevant, evidence-based document that will stand the test of practical application in diverse health care settings.

Dealing with COIs. Transparency in declaring and managing potential COI is critical for developing trustworthy guidelines. A COI refers to any relationship that could introduce bias or appear to influence an individual's opinion or work, including financial relationships, career advancement, intellectual biases, and institutional benefits. Financial COIs include any relationship for which one receives remuneration or in kind. These include holdings in individual investments (eg, stocks, stock options, bonds, or any direct investment of pharmaceutical or device companies) and patents associated with licensing and/or financial or in-kind benefits. This applies to guideline participants,

their spouses, domestic or life partners, dependents, and children. Intellectual COIs include any roles or activities that would promote one's own research or could influence an individual's position, opinion, and judgment.

Before appointment, candidates must submit declaration of interest forms that the selected members of the guidelines committee will review to determine eligibility, resulting in one of the following decisions (Figure 1):

1. appointment;
2. appointment with management conditions; or
3. disqualification.

Individuals appointed with management conditions will receive clear instructions regarding the limitations imposed on their participation. These limitations may restrict their involvement in discussions, drafting sections of the text or recommendations, or voting on content related to specific conflicts.

Occasionally, a candidate may be considered for approval after divesting from COI, provided substantial confidence exists that no further impact on the candidate's objectivity remains.

Once approved, each candidate must sign a formal writing committee member agreement acknowledging the COI policies and, if applicable, the specific terms of their management.

To prevent perception of bias, the initiation of new or additional relationships potentially constituting a COI is discouraged from document development through publication. Any writing committee member considering a new relationship must obtain written permission from the chairs before engaging in the activity.

The final composition of the writing group should include co-chairs who have no relevant COIs and other members who have either no relevant COIs or are deemed manageable, as detailed in Figure 2, which outlines a proposed disclosure process on the basis of the refined standards of the American College of Chest Physicians. [17] Along with the publication, the disclosure of interest forms for each member should be made available online as a Online Data Supplement.

Confidentiality agreement. Every member of the writing committee must sign a confidentiality agreement before the project starts, prohibiting any communication of details related to the guideline's content and development before its official release. Until the document is published online, only the names of the co-chairs shall be disclosed to the public; the identities of other writing committee members and reviewers shall remain confidential until the official publication to diminish the potential influence of their decision during the development process. Any writing committee member who violates confidentiality through unauthorized dissemination of information to external parties may be immediately excluded from all current and future activities pertaining to this area of work.

Timelines and milestones. Adhering to strict timelines is also critical because delayed publications may yield outdated aspects of this review. From the inception of the first meeting, the timing toward the publication of the document must not span beyond 24 months, ensuring timely delivery while maintaining the integrity and relevance of the information. The countdown begins with the systematic literature review. The writing phase, which includes creation of the submission draft, figures, and evidence tables, is allocated a strict 1-year timeline to ensure meticulousness and efficiency in generating a robust draft. Upon completion of the draft, the focus shifts to the validation and publication phase, for which a maximum of 12 months is allotted. This final year ensures that the document undergoes rigorous scrutiny and adjustment to reflect the latest point of view and expert insight in the field before it reaches its readers.

Support and resource allocation for clinical guidelines development. A single organization will be responsible for providing and funding the project manager and required technology and will manage each guideline project. A project manager is essential for providing guidance and support to the writing committee and logistical support by organizing online and in-person meetings and delivering timely progress reports. This approach encompasses the initiation and writing phases, leading external validation through the participating organizations' journals, and facilitating regular communication to update the governing bodies of the involved associations about significant developments throughout the project.

The participating associations exclusively fund the development costs without permitting sponsorships or grants to contribute to the individual project. To ensure transparency and agreement, the leading association outlines the financial framework and budget for guideline development and shares this for approval with all involved parties. Typically, the budget will include expenses for one in-person meeting, such as travel and venue arrangements. The in-person meeting should take place during the final phase of the document's development when recommendations are being finalized; previous phases can leverage online meetings to maximize resource efficiency and minimize the carbon footprint. The budget will cover the expenses for engaging an informatics medical specialist and a graphic designer, publication costs, including copyediting services, and other expenditures that may arise during the project's development.

Writing Phase

After completing all steps of the initiation phase, the writing phase of CPGs begins. This crucial stage entails the comprehensive drafting of the guidelines: creating submission drafts of the document and its supplementary material, detailed figures, and evidence tables. It is a period characterized by intensive research, systematic information organization, extensive group discussions, and the meticulous articulation of recommendations. This approach ensures that the guidelines are both evidence-based and applicable in contemporary clinical settings. The phase commences with a mandatory introductory kick-off writing committee meeting and concludes with submitting the document for external validation.

Table of contents. The table of contents delineates a structured framework for the document's composition, detailing the primary sections and their subdivisions following the defined project scope. It lays the groundwork for formulating specific research questions and practice recommendations. The content encompasses the main text, central illustration and highlights, and applied methodology. It addresses critical knowledge gaps needing immediate medical community response and distills key take-home messages with profound implications for clinical practice enhancements. The co-chairs prepare the preliminary

Type of Relationship	Committee Role: Chair	Committee Role: Other member
Research and Scholarly Activity		
Authorship in scientific peer-reviewed publications and book chapters.	A	A
Authorship of peer-reviewed publications in support of a commercial entity*:		
• With no product in the topic area	A	A
• With a product in the topic area	U	M
Investigator in grant-funded research on government-related topics, with funds directed to the institution.	A	A
Investigator in grant-funded research on unrelated or related topics funded by a commercial entity* with no product lines related to the topic:		
• With funds directed to the institution	A	A
• With funds directed to individual	M	M
Investigator in grant-funded research topics funded by commercial entity* with product lines related to the topic:		
• With funds directed to the institution	U	M
• With funds directed to individual	U	M
Educational Activities		
Faculty in CME/MOC accredited activity.	A	A
Faculty in a commercially sponsored, nonaccredited activity where a not-for-profit organization fully controls speaker selection and content (e.g. AATS-run commercially sponsored symposia).	A	A
Faculty in commercially sponsored nonaccredited activity in an unrelated area to the guideline topic:		
• With no product lines related to the topic	A	A
• With product lines related to the topic	M	M
Advisory/Consultancy		
Participation in a data safety monitoring board.	A	A
Advisor/consultant to industry or industry-sponsored entity on study design, education, or focus group on an unrelated topic:		
• With no product lines related to the topic	A	A
• With product lines related to the topic	M	M
Advisor/consultant to industry or industry-sponsored entity on study design, education, or focus group on a related topic.	U	M

Continued

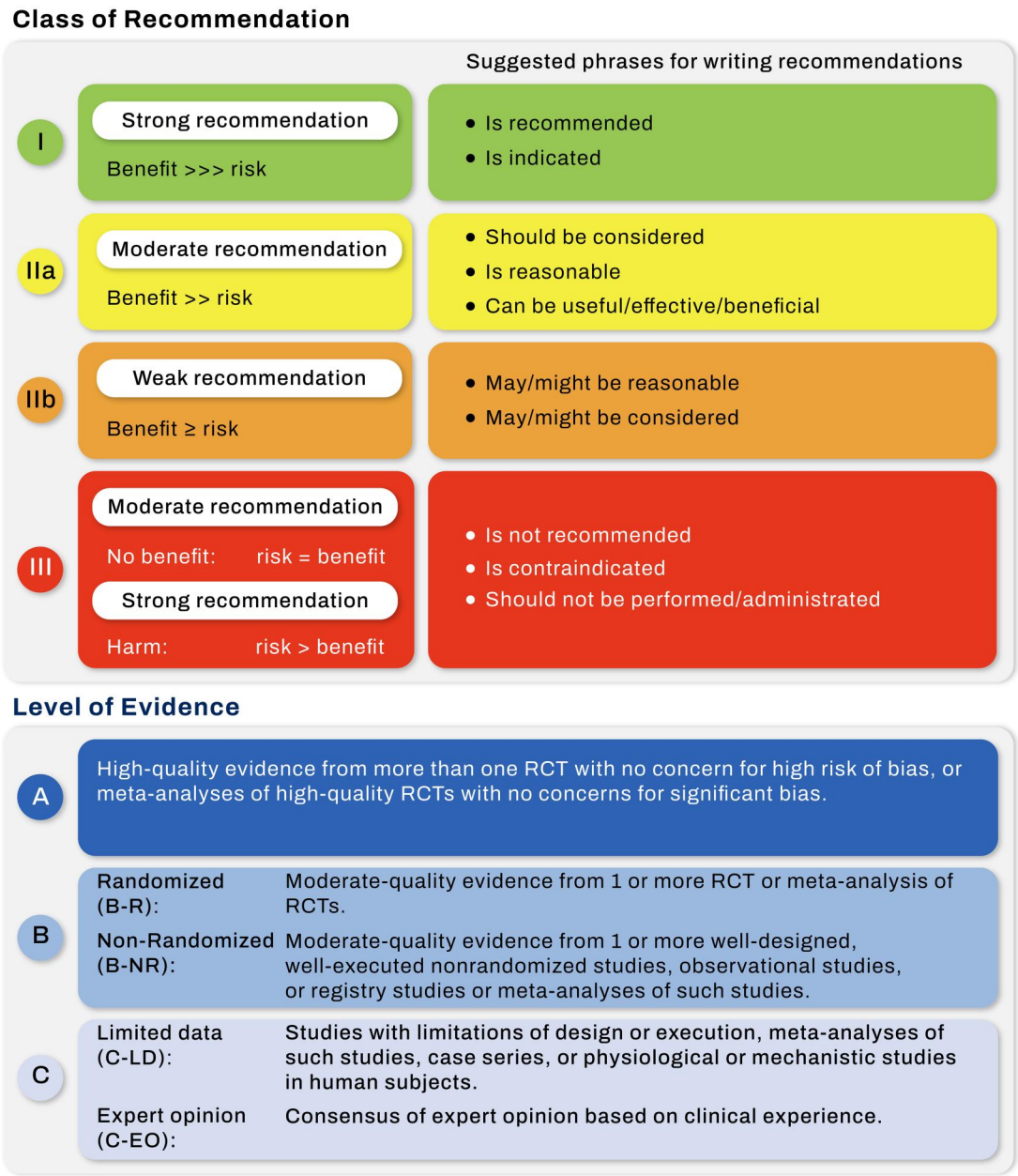
Figure 1 Type of relationship/activity, committee role, and decision about participation in the writing committee. *CME*, Continuing medical education; *MOC*, maintenance of certification; *AATS*, American Association for Thoracic Surgery.

Participation in a speaker's bureau on any topic for a commercial entity, where the company controls the content:		
• With no product lines related to the topic	U	M
• With product lines related to the topic	U	M
Public Statements		
Issuing statements on an unrelated topic on behalf of a commercial entity:		
• With no product lines related to the topic	U	M
• With product lines related to the topic	U	U
Issuing statements on a related topic on behalf of a commercial entity.	U	U
Providing paid expert testimony on an unrelated topic on behalf of a commercial entity:		
• With no product lines related to the topic	U	M
• With product lines related to the topic	U	U
Providing paid expert testimony on a related topic on behalf of a commercial entity.	U	U
Providing paid expert testimony on a related or unrelated topic privately for a non-commercial entity (e.g. patient, private sector).	M	A
Intellectual Property and Investments		
Patent holder or applicant:		
• Patent unrelated to the topic	A	A
• Patent related to the topic	U	M
Investments (e.g. stock holdings, stock options, warrants, shares, bonds, or any other form of direct investment (not as part of mutual fund) in pharmaceutical companies or any other commercial entities (e.g. device manufacturers) that manufacture or sell products related to management of an individual with disorders addressed by cardiothoracic surgery:		
• With no product lines related to the topic	A	A
• With product lines in the topic area	U	M
Employment		
Full-time/part-time employment arrangement with a commercial entity:		
• With no product lines related to the topic	U	M
• With product lines related to the topic	U	U

Keys: A Acceptable - M Manageable - U Unacceptable

*Definitions of Commercial Entity: Accreditation Council for Continuing Medical Education's definition of a commercial entity is any entity producing, marketing, reselling, or distributing health care goods or services. The ACCME does not consider clinical service providers directly to patients as commercial interests - unless the provider of clinical service is owned or controlled by an ACCME-defined commercial entity.
CME, Continuing Medical Education; MOC, Maintenance of Certification.

Figure 1 Continued.



AATS, American Association for Thoracic Surgery; **EACTS**, European Association for Cardio-Thoracic Surgery; **ESTS**, European Society of Thoracic Surgeons; **STS**, Society of Thoracic Surgeons: RCT, randomized controlled trial.

Figure 2 Adopted definitions of classes of recommendation and levels of evidence.

outline, which is then refined on the basis of the group's consensus during the initial meeting. Once discussed and ratified, the table of contents is generally considered final; however, it may undergo modifications after external validation, with possible additions, adjustments, or cuts on the basis of authoritative feedback from the lead reviewers. As an essential organizational tool, it facilitates a productive start by delegating topics to chapter leaders for the initiation of literature review and chapter drafting. This approach also provides straightforward manuscript navigation postpublication, enabling scholars and practitioners to locate and consult relevant segments swiftly.

Standards for systematic literature review. A scoping literature review offers a swift and efficient alternative to systematic literature reviews for synthesizing research findings. [18] This approach is necessary for developing recommendations or clinical statements in practice documents and balances rigor with the need for rapid results. Making strategic trade-offs between scope and detail provides experts with an immediate grasp of the evidence's rigor, facilitating quicker decision-making in clinical guideline development. The writing committee members conduct scoping reviews for each section containing recommendations and must adhere to the PICOT (Population, Intervention, Comparison, Outcome, and Time) questions framework:

- Population: Identifies the specific group of patients under consideration, typically those affected by the disease or condition of interest. The definition of the patient population should be precise.
- Intervention: Defines the treatment or diagnostic test and determines whether its application is beneficial. In the case of diagnostic assessments, the document's focus may be on the implications of positive versus negative test results.
- Comparison: Presents an alternative to the proposed intervention, often the current standard of care or control, which could include no treatment, a placebo, or an alternative therapeutic approach. For screening questions, the comparison might be opting not to screen.
- Outcomes: Involves selecting outcomes most relevant to the patient population, with a focus on direct measures significantly impacting patient care and indirect measures supporting the proposed recommendation. Therapeutic queries prioritize treatment effectiveness and safety, whereas diagnostic or prognostic inquiries concentrate on improving disease detection or forecasting outcomes.
- Time: Relates to the time frame necessary for an intervention to show results or the duration of participant recruitment and monitoring.

Using the developed set of PICOTs, medical informatics specialists can conduct focused searches for the established clinical questions. The teams, composed of chapter leaders and a research fellow or junior career academic physician with the assistance of evidence review experts, receive a narrowed literature review without publication duplicates, ready for subsequent title-abstract screening. Assigned chapter leaders oversee the development and content of individual chapters, ensuring the selection of articles for detailed review aligns with the guideline's overall objectives.

Guidelines should be based on peer-reviewed studies published in English, with the understanding that the writing committee guides the evidence synthesis without additional analyses beyond those peer-reviewed and reported in the literature.

Evidence review. The literature search should be systematic, documented, and follow a reproducible methodology in line with Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) reporting standards, [19] enabling replication by readers. In collaboration with the research fellow, chapter leaders will develop an evidence table containing comprehensive information on study design, population, interventions, and specific outcome data on the basis of the formulated PICOT questions. The chapter leaders will create additional tables to evaluate the individual quality of clinically relevant papers and its risk of bias. The writing committee is responsible for preparing a final literature report. This report should encapsulate the search strategy, PRISMA flow diagram, evidence tables, risk of bias assessments, and a reference list, all of which will be included as supplementary material.

Evidence quality assessment tools. The thorough assessment of methodologic quality is indispensable in appraising clinical research that informs practice guidelines. Every study selected for inclusion in recommendation tables requires a meticulous evaluation of potential biases and methodological robustness. The Risk Of Bias 2 (ROB2) tool shall be used for RCTs to identify biases that might systematically influence outcomes. [20] Observational studies shall be examined through the Risk Of Bias In Nonrandomized Studies - of Interventions (ROBINS-I) framework to gauge the likelihood of bias in the absence of randomization. [21] When appraising bias from missing evidence (outcomes) in systematic reviews with meta-analysis, the Cochrane Collaboration tool (ROB-ME) serves as a guideline to ascertain the synthesis's robustness and reliability. [22] In addition, other validated tools may be used as the science of evidence appraisal evolves. Each tool contributes to a scrupulous analysis. However, they should be used as aids, and not simple checklists, as their application alone may not reveal instances of research misconduct, such as incomplete reporting. [23] This underscores the importance of diligently reviewing source materials, including trial protocols and statistical analysis plans, to account for all relevant and significant results.

Formulation of recommendations. Recommendations are the foundational elements of guidelines, serving as focal points that must stand alone and be understandable without reading the supporting text. Using clear, unambiguous language and precisely defined terms is crucial for accurately describing the patient group, specific medical indication, and target audience for the recommendation. The language used should vary only according to the "Class of Recommendation" and must include the appropriate verb, as detailed in Figure 3. The main text provides context, clarification, and a detailed explanation documenting how these elements contribute to the formation of the recommendations.

A fundamental principle of evidence-based medicine is the hierarchical system of classifying evidence, known as the levels of evidence. Although adequately designed and conducted RCTs are usually assigned the highest level of evidence, not all RCTs are designed and executed equally, and their results must be scrutinized carefully. The grading system providing the strength of evidence-based recommendations has evolved to prevent the automatic assignment of the highest level of evidence where an increased risk of bias in the cited RCTs or conflicting evidence between them exists. In such instances, the level of evidence shall be downgraded from A to B, which is only on par with observational data. The same principle applies to meta-analyses of RCTs when an observed high risk of bias or significant heterogeneity exists. Finally, the universally accepted grading system indicates whether recommendations are based solely on consensus or supported by substantial evidence to improve academic rigor and stimulate further research.

Consensus achievement (discussion, voting, and dealing with COI). The writing committee's role in developing clinical guidelines is a dynamic and iterative process occurring through all phases of guideline formulation. This process includes continuous dialogue and consensus-building through online and in-person meetings and e-mail correspondence.

Drafting potential recommendations begins with the chapter leaders' evaluations of available evidence. Chapter leaders are primarily responsible for presenting draft recommendations, which are then subject to collective deliberation and refinement during full group meetings. The co-chairs play a critical role in facilitating discussions among authors, resolving any differences

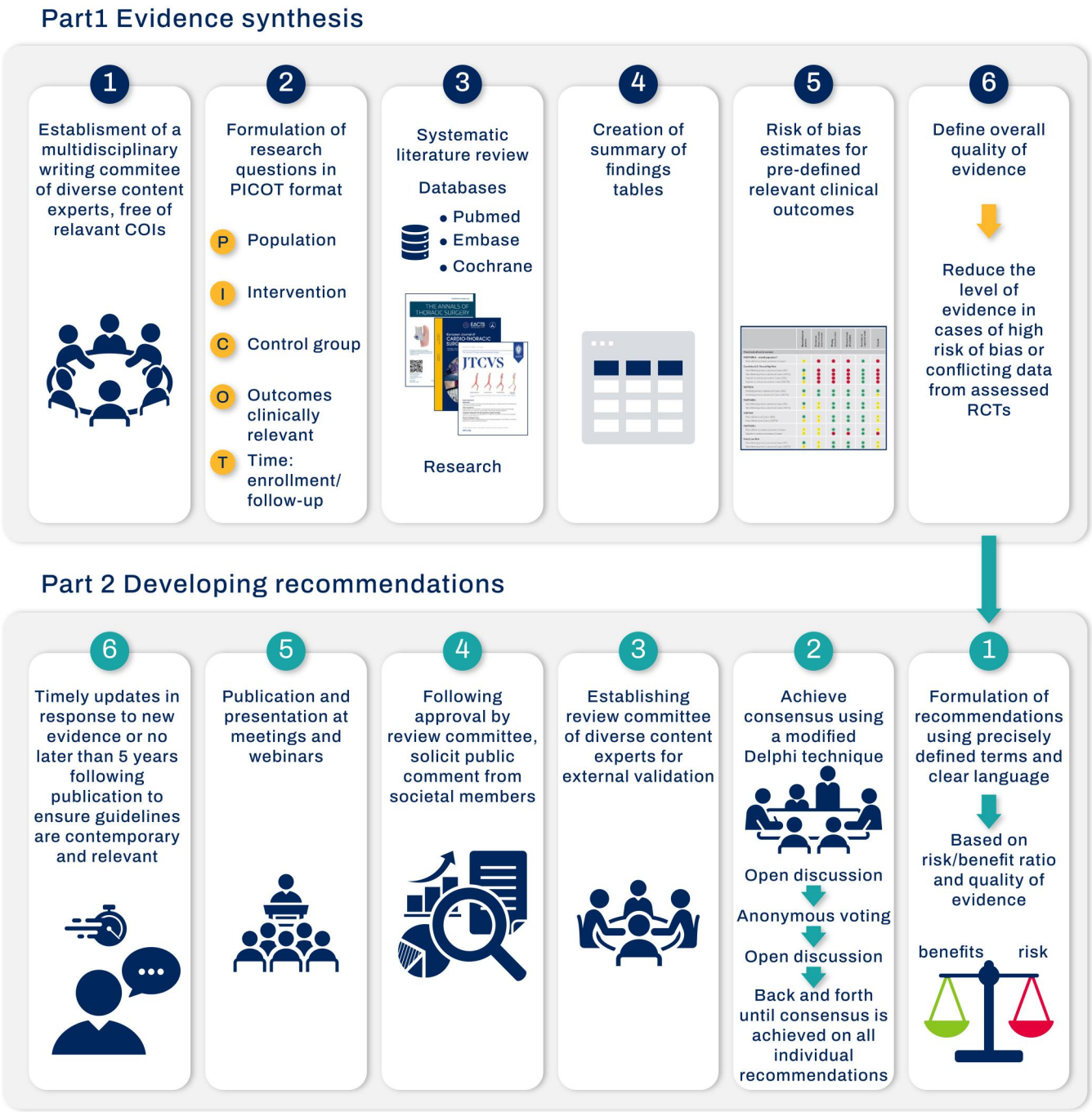


Figure 3 A comprehensive pathway for creating multidisciplinary clinical practice guidelines: encompassing research formulation and synthesis, development of evidence-based recommendations, rigorous validation, publication, and continuous updates to maintain relevance and accuracy. *COI*, Conflict of interest; *PICOT*, population, intervention, comparison, outcome, and time; *RCT*, randomized controlled trial.

in evidence classification, and refining the precise wording of each recommendation. The writing committee members with relevant COI must recuse themselves from discussing and voting on any recommendations their interests could potentially influence. Members vote using an anonymous electronic survey with 3 multiple-choice options (agree, disagree, abstain) for each recommendation, accompanied by a corresponding class of recommendation and level of evidence. An 80%+ response rate and minimum 75% agreement among those voting "agree" reaches consensus.

Authors who disagree with a recommendation or who abstain from voting must provide a rationale for their responses that will lay the groundwork for further discussion and refinement of the recommendation in preparation for another round of voting, if necessary. This iterative process is repeated until all recommendations receive a positive endorsement. The same applies to all proposed treatment algorithms, other illustrations, or any table that provides different forms of clinical guidance.

Finally, the writing committee should refrain from finalizing recommendations when there is a significant divergence in

expert opinion or when recommendations consistently fail to receive positive affirmation by members of the committee despite numerous attempts. Such scenarios raise the risk of disseminating flawed guidance. Under these circumstances, describing the different inferences and proposing areas for future research to bridge the gaps in evidence and clinical experience is recommended. Instances of nonconsensus among the writing committee shall be transparently indicated in the accompanying commentary of the voted recommendations. In addition, even when consensus is achieved regarding a given recommendation, members of the writing committee who voted in disagreement have an opportunity to explain the rationale for their dissent. The supplementary material should include these opinions.

Final draft document. After securing affirmative votes on the recommendations, illustrations, and tables, the associated text is revised to align with these decisions and the master copy finalized for additional commentary. The recommendations that have achieved consensus are now fixed; however, all authors are expected to review the draft text critically and collaborate to achieve enhanced clarity and consistency throughout the document. The co-chairs are responsible for preparing the final draft, which is then circulated among the authors for their conclusive feedback and endorsement. Only after it receives support by unanimous collective responsibility and the supplementary material, including the voting summary, is completed is the document ready for external validation.

Validation Phase

A robust validation phase is essential in practice guideline development. During this phase, the preliminary document draft is finalized after the content undergoes a rigorous examination to ensure it aligns with established clinical standards and goals. The process involves a thorough review to establish the quality and trustworthiness of the guidelines, culminating in their publication. Central to this process are the subject matter experts, whose impartial evaluations and thoughtful assessments are critical to the guidelines' integrity. This review requires meticulous attention to detail and stringent observance of established evaluation benchmarks to create a uniform and comprehensive inspection of the guidelines' facets.

The validation phase enhances the reliability and authority of the CPGs, thereby increasing their value for practitioners and patients. The primary goal of this phase is to refine the guidelines into their most practical and relevant form, ensuring they are ready for distribution and application within clinical environments.

Selection and role of lead reviewers and other reviewers. At the outset of the writing process, the governing bodies, in collaboration with the respective journals' editors in chief, assign a lead review and appoint up to 5 anonymous reviewers from each participating entity to contribute to the external validation process. In addition to providing content feedback, the lead reviewers play a pivotal role in ensuring the quality and integrity of the review process. They are responsible for coordinating the efforts of the review team, synthesizing their feedback, and ensuring that all comments are addressed comprehensively by the writing committee. The lead reviewers also have the authority to request an extension of the review period until all issues are satisfactorily resolved, ensuring that the review process is thorough, unhurried, and of high quality.

Typically, there are 2 review rounds: an initial review is conducted as individual chapters are completed and a second review once the entire document is completed. Each round of review takes 1 month at most, matching the writing committee's time frame for responding to comments. The lead reviewer may request an extension of the review period to ensure all issues are addressed. Changes in recommendations and algorithms necessitate a formal vote before resubmission. The process concludes when the lead reviewers are satisfied with the responses to their critique and the writing committee members formally endorse the revised document. Finally, the document is posted online for 2 weeks of public comment. The co-chairs and the lead reviewers should evaluate any feedback to determine whether any significant changes to the document are warranted. The latter would entail an additional cycle of approvals by the reviewers and the writing committee.

Reviewers' efforts are recognized by listing their names as contributors in the final document, although they can remain anonymous in the publication, if request.

When persistent disagreements arise between the writing committee and the reviewers, the societies activate a de-escalation process. This process involves proposing up to 3? impartial experts with the requisite expertise to mediate the conflict. These experts work closely with the co-chairs and lead reviewers to bridge gaps in understanding and interpretation, fostering a collaborative environment. Their goal is to steer both parties toward a mutually agreeable resolution, ensuring that the clinical guidelines are both evidence-based and consensually validated.

Governing approval process. Once the reviewer coordinators have given their final approval, the document is next sent to the language editor for final copyediting and then to the co-chairs for proofreading. Participating associations' executive committees/boards, and the editors-in-chief of the target journals receive the document next for final approval. These bodies serve as the ultimate tier of review. The writing committee should address these final concerns with the same rigor as they would for earlier reviewers. The document is deemed acceptable for publication only when it has received the collective agreement of all involved parties, including the writing committee.

Publication process. The publication process signifies the completion of the clinical guidelines' development and often aligns with a scientific conference. This strategic timing ensures the guidelines are presented to a diverse audience and allows authors to address questions and concerns directly in real time. Once published, the guidelines should be freely accessible online to foster engagement from the broader medical community. In the case of joint publications across various journals, efforts are made to synchronize their release and ensure uniformity, including word count and other formatting elements. Such coordination guarantees widespread and uniform distribution of the guidelines, facilitating a unified understanding and adoption of the recommendations within the medical community.

In the interest of transparency, all proceedings should be archived and recoverable on request, subject to joint leadership review and approval, until the release of the next updated publication. These proceedings include.

- agendas;
- minutes;
- reviews;
- written comments; and
- correspondence relating to the document development process.

Update process. As medical practices evolve, the regular reassessment and updating of clinical guidelines to include new therapeutic and diagnostic developments are crucial. [24] A methodical process must ensure CPG revision at least every 5 years or when the evidence base has significant advances. This regular review keeps CPGs aligned with current research and its effects on established advice and practices. Updates should be executed promptly when new critical evidence, especially from robust clinical trials, arises. These updates may entail precise modifications or comprehensive evaluations. The scope of these updates and the necessity for a writing committee are determined by the extent of the changes required, as decided by the governing bodies. Notably, health care professionals should regard the current version as contemporary until an updated or revised guideline or clinical statement prompting specific clinical action is published.

Distinguishing Features in the Development and Content of Clinical Guidelines Versus Other Clinical Practice Documents

The development of clinical guidelines is distinct from other clinical practice documents in several vital aspects: scope, evidence strength, nature of recommendations, review thoroughness, and updated schedules, as presented in Table 2. Clinical guidelines offer a broad and thorough perspective on patient care underpinned by robust evidence from many prospective, well-designed, and conducted studies ensuring a solid foundation for recommendations. Other clinical documents with a narrower focus address specific patient care issues or clinical questions marked by variable practices typically relying on observational studies. However, distinguishing document types solely on evidence strength can be complex.

Guidelines offer well-defined recommendations for health care providers and policymakers detailed with classes of recommendations and levels of evidence. In contrast, other documents show clinical statements or suggestions to serve as consultative guidance. The scrutiny for guidelines is more comprehensive, demanding input from a broad array of reviewers and confirmation by prominent authoritative bodies. Other clinical documents are subject to a simplified review process, needing only the consensus of a select review panel and the approval of the journal's editorial board. Finally, the timing for updating guidelines is more rigorous, ensuring they consistently reflect the latest evidence. In contrast, revising other clinical practice documents is more flexible, with timing that adjusts to new evidence and allows for deferral without significant findings.

Irrespective of the document type, a systematic process including comprehensive literature reviews, meticulous statement development, and consensus achieved via voting—with strict adherence to these procedures and transparency about the process—is needed to develop all clinical practice documents.

Dissemination and Implementation of CPGs

The dissemination and implementation phase of CPGs is critical and can result in low adoption rates if not rigorously approached. [25] Effective circulation ensures the guidelines reach the intended audiences, including health care providers, policymakers, and patients. Multiple channels, including publication in scientific journals using layperson's terms, distribution via professional networks, social media, conference presentations, and incorporation into educational materials and clinical decision support systems can ensure all intended audiences see these guidelines.

Implementation refers to the practical application of the guidelines in clinical settings. Factors identified as major barriers to guideline adherence include the complexity of guideline documents and the high number of weak or conditional recommendations. [26] Implementation often requires a strategy to encourage adoption by health care professionals in the clinical setting. Strategies include national society endorsement and the integration of guidelines into electronic health records. Monitoring guideline implementation to provide feedback on the extent to which the guidelines are being followed and their impact on clinical practice is critical during this phase. Data derived from regional and national databases and membership surveys can inform the guidelines' extent and variation of penetration and identify hurdles and opportunities for enhanced adoption. Moreover, the implementation process considers the various barriers that may impede the integration of guidelines into routine practice, such as resistance to change, lack of resources, or contradictory guidelines. Addressing these challenges often involves tailored interventions to support health care providers and organizations in making the necessary changes to align with the guidelines' recommended best practices.

Ultimately, dissemination and implementation aim to ensure that CPGs lead to improved health outcomes, enhanced quality of care, and greater patient safety by translating the best available evidence into everyday clinical practice.

Gaps in Knowledge and Future Perspectives

Identifying and addressing knowledge gaps is a dynamic and ongoing process in clinical practice documents. As medicine evolves with emerging research and new technologies, guidelines must be responsive, assimilating new findings and addressing current gaps. Future directions in guideline development will increasingly focus on personalized medicine, shaping recommendations to fit individual patient's unique genetic, environmental, and lifestyle contexts.

The development of clinical guidelines requires embracing a multidisciplinary approach. Engaging patient organizations, clinical methodologists, and consumer representatives will help develop comprehensive, inclusive, and patient-oriented guidelines. Efforts are underway to embed patient preferences and values into the heart of guideline development, fostering evidence-based, patient-centered care. Leveraging artificial intelligence

and big data analytics offers exciting prospects for enhancing the precision of guidelines and more effectively tailoring interventions to specific patient groups.

As guidelines become more sophisticated, the need for improved dissemination and implementation methods increases, ensuring seamless integration into clinical practice. Adherence to guidelines is not well studied and might be another topic of future perspectives. Overall, it makes sense to implement and integrate solid guidelines into health care plans. This approach could include innovative educational resources, decision support systems, and policy measures that embed recommendations and quality metrics into daily practice.

Continuous learning and flexibility will continue to characterize CPGs, enabling them to maintain their pivotal role in informing clinical decisions and elevating patient care outcomes.

Conclusions

The credibility of CPGs has come under scrutiny as the result of transparency issues, lack of multidisciplinary input, potential biases, and COIs, all of which have led health care practitioners and patients to doubt their utility. In response, the AATS, EACTS, ESTS, and STS have thoroughly reviewed and discussed the critical methods for creating clinical practice documents. This collaborative evaluation has resulted in a detailed methodologic manual outlining procedures for formulating joint guidelines with precise, stringent adherence to established principles. Meeting high standards requires the following integral steps:

- emphasizing fundamental development principles;
- conducting systematic literature reviews;
- conducting comprehensive evidence synthesis;
- leveraging precise evidence grading; and
- championing transparency.

This document establishes methodologic norms for equitable, achievable, and unbiased guidelines and gains physicians' trust? for crucial health care decisions. This collaborative effort enhances the methodologic rigor and transparency in guideline creation, strengthens physicians' confidence in their recommendations, and sets the stage for future projects that will continue to advance patient care.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Supplementary Data

Online Data Supplement

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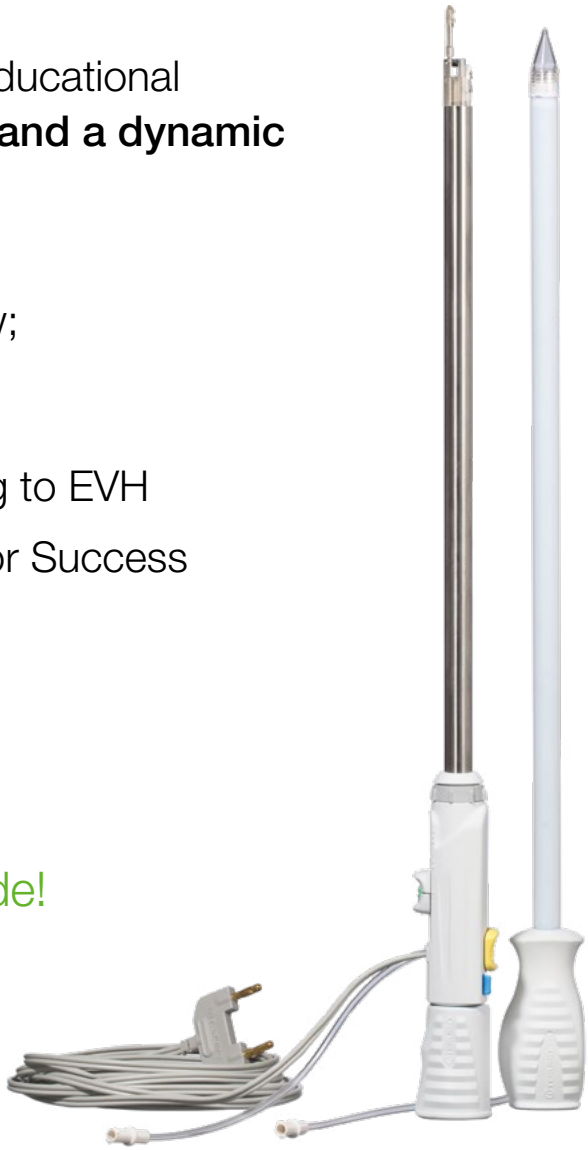

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